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THE LIMINALITY OF NHS RESEARCH ETHICS COMMITTEES

Navigating Participant Protection and Research Promotion Across Regulatory Spaces

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PhD in Law

The University of Edinburgh

2017

Declaration

As per Regulation 23 of the Postgraduate Assessment Regulations for Research Degrees, I acknowledge that portions of this thesis have appeared, or will appear, in published form in the following peer-reviewed publications. My contribution and those of the other authors to this work have been explicitly indicated below. I confirm that appropriate credit has been given within this thesis where reference has been made to the work of others.

- Samuel Taylor-Alexander, Edward Dove, Isabel Fletcher, Agomoni Ganguli-Mitra, Catriona McMillan, and Graeme Laurie, 'Confronting the Liminal Spaces of Health Research Regulation: Beyond Regulatory Compression' (2016) 8(2) *Law, Innovation and Technology* 149–176 [equal contribution to article];
- Agomoni Ganguli-Mitra, Edward Dove, Graeme Laurie, and Samuel Taylor-Alexander, 'Reconfiguring Social Value in Health Research Through the Lens of Liminality' (2017) 31(2) *Bioethics* 87–96 [equal contribution to article];
- Graeme Laurie, Edward Dove, Agomoni Ganguli-Mitra, Isabel Fletcher, Catriona McMillan, Nayha Sethi, and Annie Sorbie, 'Charting Regulatory Stewardship in Health Research: Making the Invisible Visible?' *Cambridge Quarterly of Healthcare Ethics* (in press) [equal contribution to article]; and
- David Townend and Edward Dove, 'Approaching Ethics Review Equivalency Through Natural Justice and a "Sounding Board" Model for Research Ethics Committees' (2017) 36(1) *Medicine and Law* 61–86 [equal contribution to article].

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- been composed entirely by myself;
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- not been submitted for any other degree or professional qualification.

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Acknowledgements

This research was conducted with the funding support of the Wellcome Trust. I held a PhD studentship connected with a five-year (2014-19) Wellcome Senior Investigator Award entitled 'Confronting the Liminal Spaces of Health Research Regulation' (Award No: WT103360MA): http://www.liminalspaces.ed.ac.uk/. I am grateful to Wellcome for their generosity and enthusiasm in supporting both my research and the research of the Liminal Spaces Project team.

This research would not have been possible without the cooperation and gracious hospitality of the people whom I interviewed and observed over the course of a year. I thank each of them for their patience and forthrightness in sharing their insights and experiences with me. Undoubtedly, not all of the participants in my research will share the interpretation I place on my findings. Nonetheless, I trust that they are defensible and contribute to the debate about what RECs do in practice, and how to improve the regulatory framework for health research involving human participants.

I owe my gratitude to the authorities and individuals who helped assist in bringing my empirical investigation to fruition. This includes the Health Research Authority; Jo-Anne Robertson at the Research Governance & QA Office of the University of Edinburgh; the staff at the Wellcome Library; the staff at the Archive and Museum Services of the Royal College of Physicians of London; and the transcription team at 1st Class Secretarial Services. Thanks is also given to the organisers of the Postgraduate Bioethics Conference and Socio-Legal Studies Association (SLSA) annual meetings, who permitted me to present initial findings of my research in 2016 and 2017.

Heartfelt thanks goes to former Mason Institute colleague Leslie Stevens and to my fellow Liminal Spaces Project team members (Agomoni Ganguli-Mitra, Catriona McMillan, Annie Sorbie, Isabel Fletcher, Emily Postan), and especially Nayha Sethi, for her committed friendship and endless academic support, including a willingness

to read several draft chapters. There are many mentors who have guided me before and during this PhD. In particular, I am deeply grateful for the mentorship and friendship of Bartha Knoppers, David Townend, Mark Taylor, and Barbara Prainsack. I would also like to thank Shawn Harmon for supervising me and offering thoughtful advice about the nuances of risk, regulation, and empirical research.

My principal supervisor and 'academic steward', Graeme Laurie, deserves special thanks. A paragon among supervisors, his dedication, guidance, patience, and good cheer sustained me throughout this journey. Truly, I could not have asked for a better mentor, nor can I ask for a better friend.

Finally, and most importantly, I thank my sister, Sarah, and my parents for their abiding love and invaluable support. As always, they helped me at every turn. It is to them that this thesis is dedicated.

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Abstract

NHS research ethics committees (RECs) serve as the gatekeepers of health research involving human participants. They have the power to decide, through a regulatory 'event licensing' system, whether or not any given proposed research study is ethical and therefore appropriate to undertake.

RECs have several regulatory functions. Their primary function has been to protect the interests of research participants and minimise risk of harm to them. Yet RECs, and other actors connected to them, also provide stewardship for the promotion of ethical and socially valuable research. While this latter function traditionally has been seen as secondary, the 'function hierarchy' is increasingly blurred in regulation. Regulatory bodies charged with managing RECs now emphasise that the functions of RECs are to both protect the interests of research participants, and also promote ethical research that is of potential benefit to participants, science, and society. Though the UK has held in some of its previous regulations (broadly defined) that RECs equally function to facilitate (ethical) health research, I argue that the 'research promotionist' ideology has moved 'up the ladder' in the regulation of RECs and in the regulation of health research, all the way to implementation in law, specifically in the Care Act 2014, and in the regulatory bodies charged with overseeing health research, namely the Health Research Authority.

This thesis therefore asks: what impact does this ostensibly twinned regulatory objective then have on the substantive and procedural workings of RECs? I invoke a novel 'anthropology of regulation' as an original methodological contribution, which enables me to study empirically the nature of regulation and the experiences of actors within a regulatory space (or spaces), and the ways in which they themselves are affected by regulation. Anthropology of regulation structures my overall empirical inquiry to query how RECs, with a classic primary mandate to

protect research participants, now interact with regulatory bodies charged with promoting health research and reducing perceived regulatory barriers.

I further query what this changing environment might do to the bond of research and ethics as seen through REC processes of ethical deliberation and decision-making, by invoking the original concept of 'regulatory stewardship'. I argue that regulatory stewardship is a critical, but hitherto invisible, component of health research regulation, and requires fuller recognition and better integration into the effective functioning of regulatory oversight of research involving human participants.

Lay summary

NHS research ethics committees (RECs) decide whether a proposed research study involving human research participants is ethical. The purpose of RECs is to protect the interests of participants and minimise risk of harm to them. RECs also seek to promote ethical and socially valuable research. Though this latter function traditionally has been seen as secondary, recently, regulatory bodies that manage RECs now emphasise that these two functions are of equal value. What impact does this twinned regulatory objective of protection *and* promotion have on RECs? Through a novel 'anthropology of regulation' approach, I explore how RECs work in practice to both protect research participants and also promote ethical research. I claim that RECs and other actors seek to fulfil these two functions, which they acknowledge and appreciate, through a 'regulatory stewardship' role in guiding researchers through stages of research. I argue that regulatory stewardship is a critical component of health research regulation and requires fuller recognition and better integration into current regulatory regimes.

Chapter 1
Introduction

1.1 Aims of the thesis

Research ethics committees (RECs) occupy a critical position in health research governance. In the UK, 86 National Health Service (NHS) RECs review approximately 6,000 research applications each year that seek to involve potential research participants who are in the NHS system. One of the tasks of NHS RECs is to ensure 'that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society'.[1] Through their discretionary power to modify an applicant's research design, RECs can impact what knowledge is produced and can significantly affect the relationship between researchers and research participants. They make for a fascinating object of investigation, particularly in light of recent regulatory changes. Having held a personal and academic interest in ethics committees for a number of years, this PhD affords me a unique opportunity to uncover their workings and relationships within a network of connected actors, both regulators and regulatees, state and non-state-affiliated.

This socio-legal-driven PhD project is part of a larger, interdisciplinary, five-year, Wellcome-funded project researching the 'liminal spaces' of health research regulation. I am interested in the roles and practices of RECs in light of recently implemented health research regulation that explicitly seeks to promote health research in the country, in part by streamlining regulation itself. It is unclear how these recent regulatory changes, stressing efficiency and maximisation of UK competitiveness for health research and maximisation of return from investment in the UK, may affect the substantive and procedural workings of RECs. It is also

[1] Department of Health, *Governance Arrangements for Research Ethics Committees: A Harmonised Edition* (Department of Health 2011, updated April 2012) para 1.2.2 [colloquially known as and cited hereinafter as GAfREC].

unknown whether the modification of research regulation at the level of legal architecture to promote research—seen, for example, in the Care Act 2014 and in the mandate of the Health Research Authority (HRA)—'trickles down' to the day-to-day practices of RECs, which the HRA is responsible for managing directly in England and partially across the UK.

More granularly, we lack good understanding about how and why RECs make the decisions they do, and how the dynamics of RECs and central 'managing' regulators play into decisions in this emerging regulatory backdrop. This research project fills this lacuna by: 1) going inside RECs to ask and examine how they, as individual members and as a collective body, see themselves in a changing regulatory environment; and 2) going inside a managing regulator (the HRA) to gather perspectives on the roles of RECs and the relationship between the HRA and RECs, which in turn provides deeper understanding of the meta-level contributions of these entities as regulatory agents, both in their own right and in an interconnected way.

Thus, this project involves an original, empirical investigation of health research regulation and RECs, examining how these entities, designed to essentially give an ethical 'licence' to researchers, undertake ethics deliberation and work under the umbrella of regulation that is becoming more streamlined and research-promoting. As this research constitutes a doctoral dissertation in the School of Law, my primary aim is to provide both an original, critical understanding of what RECs and regulators actually do (and see themselves doing), and also to explain and understand the nature of health research regulation. The objective is to provide my intended audience of academics, lawyers, regulators, and policymakers, as well as the Wellcome Trust, a crucial contribution to understanding the roles RECs and members within them (and connected to them) play in regulating health research.

The research findings, as I suggest in Chapters 7 and 8, could further offer normative assessments of RECs and health research regulation, thereby informing policy decisions. Indeed, a secondary aim is to encourage a reimagining of

'regulatory spaces' if they are seen to be under-delivering in what they set out to achieve. Ultimately, then, this PhD may show how the success of the REC system directly reflects on the effectiveness of the overall regulatory and governance structures in place. Through theoretical insight and empirical investigation, this research will suggest what regulation and regulators can do to stimulate meaningful research oversight.

1.2 Research questions

The primary research question that this study addresses is:

> How do RECs act among themselves and interact with other actors within the context of 'next-generation' regulation that aspires to both protect research participants from harm *and also* promote health research through streamlining perceived regulatory barriers—and what might this mean for the bond of research and ethics as seen through the ostensible REC processes of ethical deliberation and decision-making?

The overarching research question engenders two specific subsidiary questions to guide my investigation:

1. What is the precise nature of the interaction between central regulators and RECs? and
2. What are the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion?

The main purpose of this study is to empirically investigate whether, and if so how, regulatory changes emphasising efficiency and research promotion have impacted the everyday practices of RECs, who historically have been charged primarily with protecting participants.

1.3 Anthropology of regulation as methodology

In exploring these research questions, I undertake a modified socio-legal analysis, drawing on an 'anthropology of regulation' methodology that I have developed and which is influenced by regulatory theory and the anthropological concept of liminality. Liminality refers to a threshold phase in social transitions characterised by processual (temporal and spatial) dynamics.[2] Harnessing liminality as a sensitising concept in an anthropology of health research regulation enables one to examine the ways in which practices, people, and entities are structured in and by regulation, and vice versa.

As argued principally in Chapter 4, anthropology escapes the trap of a purely law-based approach that examines and often reifies bounded spaces by instead focusing on what happens *within* the regulatory spaces and *under* the layers of regulation across time. This thesis transcends the relatively narrow confines of law as an object of investigation (particularly with its positivist connotations about state organisation, rules, rule-making bodies, and judiciary and enforcement agencies) and the logic of boundaries. Through a focus on both time and space(s), it also goes beyond the relatively broad range of social patterns of interaction and forms of internal normative orderings within various communities that characterise much sociological and regulatory studies research (e.g. institutionalism approaches). The research questions aim to explore and explain—through documentary research comprised of historical tracing and present-day regulatory analysis that explicates the internal constitution of regulation, as well as through observation and interviews—the experiences and behaviours of specific individual actors in the health research regulatory space who govern the ethics of health research involving participants, namely RECs and their managing regulators. Anthropology of regulation allows me to investigate both the nature of regulation as a social form (an ontological concern), as well as what regulation does to actors and what actors do to

[2] Samuel Taylor-Alexander and others, 'Beyond Regulatory Compression: Confronting the Liminal Spaces of Health Research Regulation' (2016) 8 Law, Innovation and Technology 149, 150.

regulation (a functional and experiential concern). Regulatory theory is necessary to help provide potential explanatory background; empirical research is equally necessary to help provide understanding of everyday practice. In essence, anthropology of regulation allows the researcher to bring theory and practice meaningfully together by focusing on capturing the experiences of regulators in their multiple contexts.

1.4 Structure of the thesis

In order to answer the three research questions outlined above, this thesis contains eight chapters divided into three main parts:

Part I – Conceptual Framework and Historical Regulatory Tracing

Following this introductory Chapter 1, Part I (consisting of Chapters 2 and 3) provides a conceptual framework and historical regulatory tracing of RECs. Chapter 2 offers an overview of the UK REC system. It raises the question of whether the roles and practices of RECs are shifting in response to 'next-generation' regulation (particularly regarding research promotion), and whether modifications to the health research regulatory space at the levels of statutory law and central regulatory authorities (i.e. central administrators) 'trickle down' to the day-to-day practices of RECs. At the end of the chapter, I pose several questions that drive the empirical investigation.

Chapter 3 traces the regulatory development of RECs and health research regulation within the UK, with a view to demonstrating both the growth of health research regulation and the increasingly central role that RECs play in regulating health research. The central claim I make is that while to a certain degree, research promotion has always been embedded in the regulatory techniques of RECs, it has not until now been instantiated in law with the creation of the HRA and rules promulgated under the Care Act 2014. The subsequent and fundamental research question to explore is whether this instantiation of research promotion in law has a (hitherto absent) trickle-down effect that impacts the day-to-day practices of RECs,

and if so, how, or indeed, whether the law is only now coming to reflect an everyday practice that has long existed.

Part II – Methodology and Methods

Part II (consisting of Chapters 4 and 5) describes the methodology and methods. In Chapter 4, I explain the research approach, theoretical underpinnings, and analytical concepts that drive my thesis. I show how regulatory theory provides a solid but ultimately insufficient foundation on its own for the empirical investigation that informs this thesis. I argue that there is a need for an empirically-grounded discussion of regulatory practice. I propose an anthropology of regulation that contributes to extant socio-legal studies by blending the theoretical with the empirical, which affords critical methodological improvements to common research approaches. As anthropology of regulation draws explicit attention to processes, passages, and change, I further draw on the anthropological concept of liminality, which serves as a sensitising concept in addition to concepts provided by regulatory theory. Together with regulatory theory, liminality helps us to better understand the *nature* of transformations of actors within the regulatory space, the *form* of regulation in this space, as well as the *behaviours* and *experiences* of actors as they go through processes of change.

In Chapter 5, I describe the research methods undertaken for my empirical work and which define an anthropology of regulation, including the justification for undertaking a 'research trinity' of document analysis, semi-structured interviews, and naturalistic observation. I explain how my research methods serve as the most robust platform for answering my research questions and making sense of the empirical data.

Part III – Empirical Research Findings: Engaging with RECs and Regulators in Practice

Building on the examination of protection and promotion from an historical basis in Chapter 3, Part III (consisting of Chapters 6 and 7) then provides an empirical evaluation of the research questions and, based on the findings, proposes several modifications to the regulatory framework of ethics review.

In Chapter 6, I engage with the empirical data collected from the interviews and observations and, coupled with the findings from the document analysis, make sense of them through an anthropology of regulation approach. Through investigation of three main themes (the 'black boxes' of ethics review; regulatory connectivity; and regulators as facilitators and stewards), I explore what happens in REC meetings, consider the operationalisation of 'next-generation' health research regulation (particularly in light of the twin aims of protection and promotion), and investigate the procedures and substance behind risk-based regulation. I do this by querying whether risk-based regulation is being practised by RECs and the HRA, and more fundamentally, by querying the nature and function of the interactions among RECs, researchers, and the HRA. Throughout, I draw on the implications of space and time in ethics review, signifying the importance of liminality to this thesis and its contribution to the normative discussion to come in Chapter 7.

Chapter 7 then further unpacks the significance of liminality of RECs and the ability of actors within the health research regulatory space to serve as 'regulatory stewards'. I do so by suggesting a normative model of what a new regulatory framework for health research oversight ought to look like if it were to explicitly endorse regulatory stewardship. I also chart how protection and promotion can and should work together. I conclude that a reformulated regulatory framework could work to improve regulatory conversations between actors, provide ongoing opportunities for 'regulatory play' to emerge, and shift the burden and emphasis away from more procedural work and towards flexibility and experimentation in

ethics review. What I suggest, in other words, is a refinement of the extant regulatory framework, not wholesale change.

The final chapter (Chapter 8) reflects on the data, discussion, and regulatory framework presented, and proposes future directions for research.

Having laid out my research questions, introduced anthropology of regulation as a methodology, and mapped the structure of the thesis, I now turn to provide a conceptual framework of RECs, setting the scene for 'protection' and 'promotion'.

PART I—

CONCEPTUAL FRAMEWORK AND HISTORICAL REGULATORY TRACING

Chapter 2
Conceptual framework—setting the scene for 'protection' and 'promotion'

2.1 Introduction

Health research[3] is a highly formalised, institutionalised, and regulated activity, replete with actors, rules, tools, policies, and diffuse sets of social constraints. Researchers who wish to gather data, investigate questions, test hypotheses, and build new generalisable knowledge in areas that involve human participants confront at the earliest stages of their study design the application of abstract ethical principles such as respect for persons, social value, beneficence, and justice, not to mention ethical rules and norms such as informed consent and confidentiality. Additionally, researchers confront a panoply of law and regulation.[4] When it comes

[3] The Care Act 2014, s 110(3), defines health research as 'research into matters relating to people's physical or mental health'. I define 'health research' as research involving human participants, their data, or their tissue, which seeks to understand the biology of disease and health and to prevent ill health. This closely track the terms 'biomedical research' and 'clinical research', and would include, for example, genetic research, clinical trials, and research into medical records. Such studies may be non-intrusive—with no direct contact with human participants (e.g. epidemiological research) or intrusive—and either invasive (e.g. administering drugs) or non-invasive (e.g. psychological inquiries). 'Health research' as I use it in this thesis would exclude, however, social science-driven research that seeks to understand e.g. patients' experiences with a health service. The latter could be termed health-*related* research. Health-related research may still involve the same rules and actors that govern health research (e.g. NHS research ethics committees, NHS R&D offices).

[4] Both law and regulation are notoriously tricky to define, not the least because of cultural variation in ascribing meaning to phenomena that are 'legal' or 'regulatory'. In this thesis, law (at least in its positivistic sense) is taken to mean a system of rules, codes, and pronouncements promulgated by state or state-like actors within a particular community (e.g. sub-national, national, international) with the aim of regulating the actions of its members and which it may enforce by the imposition of penalties. Examples of law include a statute and statutory instrument (i.e. an Act or Statutory Instrument approved by Parliament) or a case judgement from a law court. By contrast, '[r]egulation is a broader category and includes much more flexible and innovative forms of social control.' See Neil Gunningham and Cameron Holley, 'Next-Generation Environmental Regulation: Law, Regulation, and Governance' (2016) 12 Annual Review of Law and Social Science 273, 274. I define regulation as a set of rules, principles, mechanisms, strategies, or activities

to health research involving humans, determination of its ethical acceptability has taken a particularly regulated, technocratic, and structured form, with specific groups of individuals wielding power to decide whether a research study may proceed on ethical grounds. This group is known as a REC.[5]

This thesis will explore the mandate and operation of one particular type of REC in the UK, the NHS REC, drawing on both governance instruments and policies and original empirical research.[6] This chapter begins the process by querying whether the practices of these RECs align with their recently established regulatory mandate—as set out in instruments promulgated by the UK government, devolved administrations, and regulatory bodies—which has modified the 'regulatory space'[7] applicable to health research involving humans. In particular, it explores a shift

promulgated by state or non-state actors that either affect behaviour as an incidental effect or are designed to steer behaviour in a socially, politically, and/or economically desirable way. It may involve self-regulation, persuasion, and co-regulation. Thus, regulation is broader than law and can encompass anything from codes of practice of professional bodies to traffic lights and signs in a neighbourhood. My definition of regulation does *not* privilege the state; the state is simply one node among many actors sharing control of resources. Law and regulation are components of governance. Governance refers to the constellation of actors and mechanisms that promulgate, implement, or enforce norms across sites of authority; it is the managerial version of politics.

[5] Different jurisdictions use different names for these committees (or 'boards'), though the underlying regulatory structure and functions ('regimes') are often similar. For example, in the US, RECs are referred to as Institutional Review Boards (IRBs). In Canada, they are referred to as Research Ethics Boards (REBs). In Australia, they are referred to as Human Research Ethics Committees (HRECs). Often the biggest distinction between these committees is whether they are a) governed by law or policy; and b) institution-based (as is the case for IRBs, REBs, and HRECs)—implying greater private ordering – or region-based (as is the case for NHS RECs)—implying greater public ordering.

[6] 'NHS RECs' is a shorthand way for describing those RECs tasked by regulation with 'reviewing research that relates to areas of responsibility of the UK Health Departments'. This refers to the fact that the NHS is one service, albeit a critically important one, offered by each of the four nations' health departments. Each of the UK Health Departments has a Research Ethics Service that manages RECs within their health system. See GAfREC (n 1). As discussed below, NHS RECs may also review research studies that fall into areas outside the responsibility of the UK Health Departments.

[7] The concept of 'regulatory space' can be defined as an analytical construct for determining the range of regulatory issues subject to public decision by a variety of actors. See Leigh Hancher and Michael Moran, 'Organizing Regulatory Space' in Leigh Hancher and Michael Moran (eds) *Capitalism, Culture and Economic Regulation* (OUP 1989).

from a protectionist model that has been seen by some as paternalistic, with regulators disproportionately focusing on research risks in comparison to research benefits and inexplicably road-blocking otherwise ethical research, to a more broadly facilitative model, undergirded by law, that could be called 'next-generation' in that it seeks to foster an environment that both protects research participants *and also facilitates* responsible health research through proportionate risk-based regulation and coordinated alignment of ethics review and other regulatory processes. Seemingly invigorating a public interest aim of health research oversight—to promote valuable research that advances human health for the benefit of the public—this next-generation regulation has emerged most clearly in the last decade (through policies and guidelines) and is reflected most overtly in the statutory Care Act 2014 and in the body that exemplifies this new way of regulating health research—the HRA. This work is the first of its kind to conduct qualitative research that reveals a critical understanding of what RECs actually do and the nature of health research regulation involving RECs in the UK. This research thus offers a crucial contribution to understanding the roles actors play in health research and how these roles transform over time.

This chapter raises the question of whether the roles and practices of RECs are shifting in compliance with this next-generation regulation, which was driven foremost by persistent criticism from research communities (e.g. academic, industry) regarding the perceived clogged regulatory space of 'human subjects research'. As such, I query whether modifications to the health research regulatory space (composed of public and private actors with 'cross connections between domains of authority'[8]) at the levels of statutory law and central regulatory authorities (i.e. central administrators) 'trickle down' to the day-to-day practices of RECs. In other words, I explore the following overarching question:

[8] Frank Vibert, *The New Regulatory Space: Reframing Democratic Governance* (Edward Elgar 2014) 18.

> How do RECs act among themselves and interact with other actors within the context of 'next-generation' regulation that aspires to both protect research participants from harm *and also* promote health research through streamlining perceived regulatory barriers—and what might this mean for the bond of research and ethics as seen through the ostensible REC processes of ethical deliberation and decision-making?

In exploring this overarching question, I undertake a modified socio-legal analysis, drawing on an 'anthropology of regulation' methodology that I have developed and which is influenced by regulatory theory and the anthropological concept of liminality. Liminality refers to a threshold phase in social transitions characterised by processual (temporal and spatial) dynamics.[9] Harnessing liminality as a sensitising concept in an anthropology of health research regulation enables one to examine the ways in which practices, people, and entities are structured in and by regulation, and vice versa. The overarching research question engenders two specific subsidiary questions to guide my investigation:

1. What is the precise nature of the interaction between central regulators and RECs? and
2. What are the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion?

To begin this exploration, I first provide an overview of the UK REC system.

[9] Taylor-Alexander and others, 'Beyond Regulatory Compression' (n 2) 150.

2.2 An overview of the UK REC system

RECs serve as gatekeepers of research involving humans. While the characterisation of RECs as 'gatekeepers' is not uncontroversial,[10] I contend that they are gatekeepers in that they serve to control access to the potentiality of research involving humans, and as such occupy a central position in research governance.[11] Governments around the world have delegated to RECs the power to decide, through a regulatory 'event licensing'[12] system and in some cases on the pain of sanction,[13] whether or not any given proposed research study involving humans (or their data or tissue) is ethical and therefore appropriate to undertake or to continue. RECs are, therefore, 'discretionary bodies with the power to apply the principles of research ethics, and the rules relating to particular fields of experimentation on human subjects, to research proposals and research in progress'.[14] Largely self-regulatory creations that first arose in the US in the mid-20th century in response to both research scandals and concerns about institutional liability,[15] RECs have evolved from *ad hoc*, unstructured committees of peer reviewers in a few hospitals—fellow physicians or biomedical researchers assessing the ethical acceptability of a proposed study—to institutionalised, regulated bodies of diverse members existing worldwide, prospectively reviewing, deciding upon, and, to a limited degree, monitoring the 'ethical acceptability'[16] of all types of research involving humans, from

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[10] See e.g. Nathan Emmerich, 'When is a REC not a REC? When it is a Gatekeeper' (2016) 12 Research Ethics 234.

[11] Research governance can be defined as the system of 'administration and supervision through which research is managed, participants and staff are protected, and accountability is assured'. See Sara Shaw, Petra Boynton and Trisha Greenhalgh, 'Research Governance: Where Did it Come From, What Does it Mean?' (2005) 98 Journal of the Royal Society of Medicine 496, 497.

[12] Carl Schneider, *The Censor's Hand: The Misregulation of Human-Subject Research* (MIT Press 2015) 33.

[13] Brazier and Cave write that, '…outside the remit of the UK Clinical Trials Regulations a researcher contravenes no law in carrying out research without ethical approval. However, other sanctions and ethical guidance deter any such practice.' See Margaret Brazier and Emma Cave, *Medicine, Patients and the Law* (6th edn, Manchester University Press 2016) 478. See also The Medicines for Human Use (Clinical Trials) Regulations 2004, regs 49, 52.

[14] Paul McNeill, *The Ethics and Politics of Human Experimentation* (CUP 1993) 205.

[15] The regulatory development of RECs is charted in Chapter 3.

[16] See Council for International Organizations of Medical Sciences, *International Ethical*

epidemiological or observational studies to clinical trials. As the leading international guideline on health research, the *Declaration of Helsinki*, states: 'The research protocol *must* be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins.'[17] RECs regulate not just the ethical acceptability of health research, then. Because of their gatekeeping and monitoring role, they regulate very much the production and use of health research knowledge itself through *ex ante* control of which research is approved, which research questions can be asked, and how they may be answered.

The UK has a hybrid, and one might say uncoordinated, system of RECs. Some are institution-based. Others are location or region-based; some are centralised, covering the whole country. Several different types of RECs exist. They can be split into two main categories of non-NHS RECs (e.g. institution-based higher education RECs[18]) and NHS RECs.[19] Here, I discuss only the latter.

Guidelines for Health-related Research Involving Humans, Guideline 23: 'All proposals to conduct health-related research involving humans must be submitted to a research ethics committee to determine whether they qualify for ethical review and to assess their ethical acceptability...' <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> [hereinafter CIOMS Guidelines].

[17] World Medical Association, *Declaration of Helsinki* (World Medical Association 2013) para 23 (emphasis added). The *Declaration of Helsinki* was first published in 1964 and is updated (and expanded) every few years. Illustrating the growth in research and complexity of regulation, the first edition contained four paragraphs (with several containing subparagraphs) and 713 words. The latest edition from 2013 contains 37 paragraphs and 2124 words.

[18] See e.g. Anthea Tinker and Vera Coomber, *University Research Ethics Committees: Their Role, Remit and Conduct* (King's College London 2004).

[19] Health Research Authority, 'Determine Which Review Body Approvals Are Required' <http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/>. In this thesis, when using the term 'RECs', I intend it to mean NHS RECs only, unless otherwise specified.

2.2.1 NHS RECs

NHS RECs, also known more formally as 'RECs within the UK Health Departments' Research Ethics Service' (RES),[20] are region-based committees. Officially overseeing a local health area within the NHS system,[21] in practice they operate within a centrally administered system that enables them to review research applications and provide an ethics opinion[22] on health research involving humans in the NHS taking place anywhere in the UK. The Care Act 2014 defines a NHS REC as:

> *a group of persons which assesses the ethics of research involving individuals*; and the ways in which health or social care research might involve individuals include, for example—(a) by obtaining information from them; (b) by obtaining bodily tissue or fluid from them; (c) by using information, tissue or fluid obtained from them on a previous occasion; (d) by requiring them to undergo a test or other process (including xenotransplantation).[23]

Across the UK, the 86 currently existing NHS RECs review approximately 6,000 research applications each year that seek to involve potential research participants (including patients) who are in the NHS system.[24] Formally existing since 1991,[25]

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[20] See n 6 above.

[21] This means NHS Trusts or NHS Foundation Trusts for England, Health Boards for Scotland and Wales, or the whole of Northern Ireland.

[22] There are five categories of opinions a REC can make: (1) 'favourable with standard conditions', which means that the study has ethical approval to proceed, as long as HRA Approval/local R&D is in place prior to the study starting; (2) 'favourable with additional conditions', which means that the study has ethical approval in principle but there are certain issues which need to be addressed prior to the study starting; (3) 'provisional opinion', which means that there are more substantial changes which need to be made and re-reviewed by certain members of the REC (usually the Chair and one or two other members) before the study starts, or that a final opinion cannot be issued until further advice has been sought from a referee; (4) 'unfavourable opinion', which means that the study does not have ethical approval to proceed and a further application would need to be submitted should the applicant choose to proceed with the study; and (5) 'no opinion', which applies to Proportionate Review only, and means that the Proportionate Review sub-committee (generally consisting of three REC members) has deemed that the proposed study contains 'material ethical issues' and will therefore need to be reviewed by the full committee.

[23] Care Act 2014, s 112(2) (emphasis added).

[24] Health Research Authority, 'Research Ethics Committees (RECs)' <http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/>. There are two RECs in Northern Ireland; seven RECs in Wales; 11 RECs in Scotland; and 66 RECs in England (including the National Social Care REC in London).

[25] Prior to 1991, some RECs were constituted to serve a NHS health district rather than a single institution (e.g. hospital), but this was not a formal policy. This changed with

they are committees of between seven and 18 individuals[26] (one-third of whom must be 'lay'[27]) who are independent of research sponsors,[28] funders, and investigators, and serve to opine on the ethical acceptability of research involving NHS staff, or patients and/or their tissue and data, among other kinds of health-related research.[29] Currently, there are over 150 staff members (e.g. REC Managers/Co-ordinators, HRA Regional Managers, etc.) and over 1000 volunteer members of NHS RECs across the UK.

REC members are appointed by the HRA in England, the Health & Social Care Business Service Organisation through the Office for Research Ethics Committees Northern Ireland (ORECNI) in Northern Ireland,[30] and the local Health Boards in Scotland and Wales.[31] Each REC has a Chair, a Vice Chair and an Alternate Vice

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Department of Health, HSG(91)5, *Local Research Ethics Committees*, which through formal 'guidance' (a type of policy circular) created local research ethics committees (LRECs) for each NHS health district. Scotland and Wales also published similar guidance to establish LRECs: 1992(GEN)3 for Scotland and WHC(91)75 for Wales.

[26] An operational change from a maximum of 18 members to 15 members was formalised by the HRA in December 2014; however, the policy is such that RECs may still have up to 18 members, though 'the HRA optimum is 15'. See Health Research Authority, 'Annual Report Summary for RECs in England - April 2015 to March 2016' <http://www.hra.nhs.uk/documents/2016/11/annual-report-summary-recs-england.pdf>.

[27] The UK classifies REC members as either 'expert' or 'lay', the latter category meaning 'a mixture of people who reflect the currency of public opinion', and the former category meaning people who 'have relevant formal qualifications or professional experience that can help the REC understand particular aspects of research proposals' (i.e. physicians and other health care professionals). Lay members 'are people who are independent of care services, either as employees or in a non-executive role.' See GAfREC (n 1) paras 4.2.3, 4.2.7. The HRA has decreed that half of the lay members must be 'lay plus' members, who are people who have never been care professionals, researchers in a care field, or chairs, members, or directors of care service bodies or organisations providing care.

[28] Research sponsors are the organisations responsible for the management and conduct of the research.

[29] GAfREC (n 1) para 2.3.

[30] Office for Research Ethics Committees Northern Ireland <http://www.hscbusiness.hscni.net/orecni.htm>.

[31] Health Research Authority, 'REC Membership: HRA Policy and Applying to Join a REC' <http://www.hra.nhs.uk/research-ethics-committee-members/rec-membership/>. Even though RECs in Scotland and Wales may cover more than one Health Board, or so-called 'regions', (e.g. the two RECs based in Edinburgh, known as South East Scotland REC 1 and 2, officially cover both NHS Lothian and NHS Borders, together known as the South East Scotland region), generally the bigger Health Board (in terms of resources) will make the

Chair, and is coordinated by a Manager (as well as an Assistant, who, along with REC Managers in England, may cover several RECs).[32] Unlike in other countries, there is no requirement that a REC include a lawyer, theologian, ethicist, patient advocate, or 'community member'. Instead, the GAfREC state: 'The membership of a REC should allow for a sufficiently broad range of experience and expertise so that the rationale, aims, objectives and design of the research proposals that it reviews can be effectively reconciled with the dignity, rights, safety and well-being of the people who are likely to take part.'[33] RECs also 'should reflect the diversity of the adult population of society'.[34] Further, so-called lay members are expected to 'reflect the currency of public opinion', while so-called expert members are expected to 'have relevant formal qualifications or professional experience that can help the REC understand particular aspects of research proposals'.[35]

Though only some kinds of health research must obtain prior REC approval *under the law*,[36] convention dictates through institutional or regulatory policies that few health research studies may proceed in the UK without an NHS REC receiving and reviewing the research protocol and attendant documents, and providing a positive (i.e. favourable) opinion. Indeed, the standard operating procedures (SOPs) for NHS RECs apply to a variety of health research: 'The policy of the UK Health Departments is that the operating procedures required by the EU Directive and the Clinical Trials Regulations should also apply in general to the review by RECs in the

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appointment. As the GAfREC states, 'Where an NHSScotland Health Board is not a REC appointing authority, they must contribute proportionately to the running costs of their NHS Research Scotland nodal research ethics service.' GAfREC (n 1) at 41.

[32] GAfREC (n 1) para 4.2.13. In Scotland, REC Managers are termed REC Co-ordinators, and unlike in England, the practice is that REC Co-ordinators are responsible for only one REC.

[33] ibid para 4.2.1.

[34] ibid para 4.2.4.

[35] ibid para 4.2.3.

[36] NHS REC review for research within and outwith the NHS may be required by law. This would include clinical trials as per the Medicines for Human Use (Clinical Trials) Regulations 2004, and research involving adults with incapacity as per the Adults with Incapacity (Scotland) Act 2000 and Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002, as amended 2007 (which requires ethics review by specific REC known as Scotland A REC). See also GAfREC (n 1) Annex A.

UK of all other health and social care research reviewed under GAfREC.'[37] As noted by the HRA and the GAfREC, there are 'requirements' for ethics review of research under *statutory instruments* (i.e. legal requirements) applying to the UK as a whole or particular countries of the UK, and 'requirements' for ethics review under the *policy* of the UK Health Departments, where research relates to the services for which they are responsible.[38] A 2011 Academy of Medical Sciences report also notes the wide reach of these RECs: 'Because positive opinion from a REC is required for all studies that take place in the NHS, this review forms a core component of the regulation and governance pathway'.[39]

In addition to research involving participants identified from, or because of, their past or present use of the NHS, common categories of NHS REC review include:[40]

- Clinical Trial of an Investigational Medicinal Product (CTIMP), including NHS Phase 1 CTIMPs in healthy volunteers;
- research involving medical devices;
- social care research;
- research involving children;
- health-related research involving prisoners;
- research involving adults lacking capacity;
- the establishment of research tissue banks/biobanks; and

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[37] Health Research Authority, *Standard Operating Procedures for Research Ethics Committees* (Version 7.2, Health Research Authority 2017), Introduction [hereinafter REC SOPs].
[38] Health Research Authority, 'Is NHS REC Review Required?' <http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/>. As noted above, sanctions for failure to obtain REC approval prior to conducting research vary. See also GAfREC (n 1) s 2.3.
[39] Academy of Medical Sciences, *A New Pathway for the Regulation and Governance of Health Research* (Academy of Medical Sciences 2011) 76 [hereinafter AMS, *A New Pathway*]. The Academy does not explain in its report why a positive opinion from a REC is 'required' for *all* NHS-involved research. While perhaps true according to custom or other regulation regimes, under the law, as explained above, this is only the case for some types of health research. See also Health Research Authority, 'Legal Requirements for Research Ethics Review' <http://www.hra.nhs.uk/resources/research-legislation-and-governance/legal-requirements-for-research-ethics-review/>.
[40] Health Research Authority, 'Research Ethics Committees (RECs)' (n 24).

- the establishment of research databases.

The research applicants who must submit a REC application[41] would therefore include pharmaceutical and medical device companies; health care professionals in the NHS; academic researchers, including students; and prison health researchers.[42] Thus, whether a researcher is conducting clinical, epidemiological, or even law and social science-driven health research, if the proposed study involves NHS patients or service users as participants, staff, property or records, the researcher must apply for NHS ethical approval through application to a REC.[43] A favourable opinion from a REC is *not* a licence to immediately begin research. Researchers must also obtain research governance (i.e. Research and Development or 'R&D') permission from each relevant NHS management authority—or since 2016, in lieu of NHS management authority approval, approval from the HRA ('HRA Approval') for all health research led from England and that involves the NHS in England.[44] Through their 'consideration, comment, guidance and approval'[45] of research applications, RECs play a critical role in regulating health research, and therefore can themselves be seen as regulatory bodies. I expand this claim in later chapters.

As noted, a centralised attitude is taken to managing RECs in the UK, compared to a more 'devolved' institution-based approach seen in other jurisdictions such as

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[41] An application to a REC would typically include the standard REC form available from the Integrated Research Application System (IRAS), often called the 'IRAS application form'; the research protocol; insurance forms; the participant information sheet and consent form; and copies of questionnaires and advertisements (if the project involves such methods and recruitment strategy).

[42] Health Research Authority, 'Research Ethics Committees (RECs)' (n 24).

[43] This is not the case, however, if the proposed research is limited to involvement of NHS staff as participants, and thus there is no involvement of NHS patients or service users as participants.

[44] HRA Approval replaces the need for R&D checks of legal compliance and related matters by each participating organisation in England. See Health Research Authority, 'HRA Approval' <http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/>. Depending on the type of research study, other regulatory approvals may be necessary. For example, if the research involves a CTIMP to be conducted in the UK, the sponsor(s) must also seek to obtain a Clinical Trial Authorisation from the Medicines and Health products Regulatory Agency (MHRA).

[45] *Declaration of Helsinki* (n 17) para 23.

Canada or the US. NHS RECs are overseen by central regulators, including the United Kingdom Ethics Committee Authority (UKECA) for those RECs 'recognised' to give an ethical opinion on a CTIMP. In England, RECs are overseen by the RES, an office under the auspices of the HRA, which itself is an arm's-length body situated in England's Department of Health. The HRA's RES operates five offices across England (London, Bristol, Nottingham, Manchester, and Jarrow), which in turn manage RECs more or less within their region. Each office is led by a RES Regional Manager, though currently there are two Managers who manage more than one office.[46] There are equivalent Research Ethics Services in each of the devolved nations. In Scotland, the Health Boards function as the HRA equivalent, while four Scientific Officers and a Chief Scientist Office (CSO) ethics 'point person' function as the equivalent for the RES for RECs within NHSScotland.[47] There are equivalent bodies in Northern Ireland (ORECNI) and Wales (Division for Social Care and Health Research), but as will be seen, in law and practice, the HRA through its RES has taken a leading (and coordinating) role for managing RECs throughout the UK, albeit to varying degrees and with varying degrees of success. Assisting the HRA's RES is the National Research and Ethics Advisors' Panel (NREAP), which is an independent, multidisciplinary expert panel appointed by the HRA that provides ethical guidance and training to RECs and the wider research community. The HRA's RES also delivers a managed structure to support RECs, a quality assurance (QA) framework,[48] and a training programme.

[46] Health Research Authority, 'Annual Report Summary for RECs in England - April 2015 to March 2016' (n 26).

[47] Scientific Officers are part of the Research Ethics Service within Scotland, itself a wing within the Chief Scientist Office (CSO), situated within the Scottish Government Health Directorates. However, the four Scientific Officers are hired and paid by the relevant Health Boards in their region, which currently are: NHS Lothian (South East Scotland), NHS Greater Glasgow and Clyde (West of Scotland), NHS Tayside (East of Scotland), and NHS Grampian (North of Scotland). Traditionally, the CSO also has had an ethics 'point person' to coordinate the Scientific Officers and liaise with the HRA.

[48] NHS RECs are audited every three years and there is a quality assurance 'check' every six months conducted by the HRA's quality assurance department.

NHS RECs tend to convene once per month (up to 10 or 11 times per year) for a 'full committee' meeting that can run anywhere from two-and-a-half to five hours. The majority of the meeting time is spent reviewing new applications, which generally are capped at six per meeting (the norm is between four and six per meeting). In-between the monthly meetings, a smaller group of REC members discuss up to four new applications submitted for 'Proportionate Review' (i.e. applications submitted for a quicker review because they are said to raise 'no material ethical issues'). These discussions usually take place electronically (i.e. emails) or via teleconference. A smaller group of REC members (usually led by the Chair) also meet each month outside the formal monthly meeting to discuss 'substantial amendments' submitted by researchers concerning their applications already approved by the REC. For full review, RECs are required to provide a final opinion within sixty calendar days of receipt of a valid application, and a provisional opinion within ten working days of the application's review at the meeting.[49] RECs are required to provide an opinion on a Proportionate Review application within 21 calendar days of receipt of a valid application. Summaries of research and the REC opinion are available on the HRA website approximately 90 days after the REC opinion.[50]

While NHS RECs handle a range of health research studies, there are in fact two broad categories of committees. First, some of these RECs are 'recognised' (i.e. legally recognised by UKECA) to give an ethical opinion on a CTIMP to be undertaken anywhere in the UK. These UKECA-recognised RECs may review CTIMPs of either 'Type 1' (healthy volunteers anywhere in the UK) or 'Type 3' (patients anywhere in the UK), or both.[51] The second category of RECs are

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[49] GAfREC (n 1) para 3.2.9. The actual average review time is much less—in Scotland, on average, it is around 28 days for a full committee review (personal communication with Scientific Officer, 5 December 2015). If the REC renders a 'provisional' opinion requesting further information, the 60 day (for non-proportionate review application) or 21 day (for a proportionate review application) clock is suspended until the information is received.

[50] Health Research Authority, 'Research Summaries' <http://www.hra.nhs.uk/news/research-summaries/>.

[51] These Types were created by UKECA, a regulatory authority created in 2004 by the Medicines for Human Use (Clinical Trials) Regulations 2004. Type 2 (patients in a single

'authorised', which means that they are established under the GAfREC, but are not recognised by UKECA, and therefore cannot review applications relating to a CTIMP. Since 2007, all NHS RECs are subject to an accreditation scheme now managed by the HRA (under its RES). Some RECs also have specialist expertise (known as 'committee flags') in areas such as research involving children, research involving prisoners, the establishment of research tissue banks, qualitative research, or research involving adults lacking mental capacity. Proposed research falling within these areas is steered towards RECs that are 'flagged' to review such research.

Having provided a brief overview of NHS RECs, I now turn to explore their role.

2.3 The roles of RECs

As will be further explained in Chapter 3, RECs are not, by and large, creatures of statute. Rather, they were created informally by the UK health research community in the late 1960s to ensure British researchers could continue to receive funding from the US federal government following that country's newly enacted policy of institutionalised IRB review.[52] RECs were also created, however, in response to private and public concerns about participants' safety in health research, and in response to general guidance from both the Royal College of Physicians of London and the Ministry (later Department) of Health encouraging their formation in every hospital.[53] Thus, RECs have developed through varying forms of non-statutory

region of the UK) is currently in abeyance after the disbandment of the LREC/MREC system in 2004, which is discussed in Chapter 2. The HRA has established a 'Phase 1 Advisory Group' to discuss issues relating to the ethical review of Phase 1 trials in the UK, including 'initiatives to improve the efficiency and effectiveness of ethical review.' The Advisory Group meets twice per year and comprises representatives from the HRA, MHRA, industry, phase 1 trial units, and RECs with Type 1 recognition to review phase 1 trials. See Health Research Authority, 'Phase 1 Trials' <http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/phase-i-trials/>.

[52] Adam Hedgecoe, '"A Form of Practical Machinery": The Origins of Research Ethics Committees in the UK, 1967-1972' (2009) 53 Medical History 331.

[53] McNeill, *Ethics and Politics of Human Experimentation* (n 14) 66-67. See also Julia Neuberger, *Ethics and Health Care: The Role of Research Ethics Committees in the United Kingdom* (King's Fund Institute 1992) 9.

regulation, namely policy, guidelines, and custom. Still, today, no UK law clearly defines the role of RECs (other than a high-level statement found in, for example, the Clinical Trials Regulations 2004 or the Care Act 2014), nor their procedural and substantive aspects, nor their legal status (a situation that, as argued in Chapter 7, can be seen as beneficial). Instead, the role of RECs must be inferred through statutes (and their regulatory components) such as the Human Tissue Act 2004, Medicines for Human Use (Clinical Trials) Regulations 2004[54] and the Care Act 2014, as well as through interpretation of policies and guidelines. Before unpacking these roles, however, it is worth pausing to query what is meant by RECs ostensibly undertaking, according to the *Declaration of Helsinki*, 'consideration, comment, guidance and approval'[55] of research applications.

2.3.1 Ethics deliberation?

As their name indicates, RECs are expected to consider and comment on the *ethical* aspects of a research application. The HRA considers that REC members will 'have opportunities to debate challenging issues'.[56] But what exactly constitutes ethics review, or deliberation of an ethical nature, and whether RECs actually engage in this as they become more institutionalised through procedures and forms, is unclear. What is clear is that RECs must operate according to their mandated SOPs,[57] but these SOPs speak to procedural standards rather than substantive standards. RECs may consider a variety of national and international ethics standards, policies, exemplars, and guidelines, as well as to a certain degree, laws and regulations, such as the Data Protection Act 1998, Human Tissue Act 2004, and the Mental Capacity Act 2005 (or, where they exist, their equivalent across the devolved nations). These instruments provide a range of rules or broad principles

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[54] See e.g. The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, reg 15(5), which sets out what a REC should consider in its opinion for a clinical trial application.

[55] *Declaration of Helsinki* (n 17) para 23.

[56] Health Research Authority, 'Information for Potential Research Ethics Service Committee Members' <http://www.hra.nhs.uk/documents/2015/12/standard-application-pack-rec-members.pdf>.

[57] REC SOPs (n 37).

about aspects of health research. For example, the Council for International Organizations of Medical Sciences (CIOMS) has published several editions of its *International Ethical Guidelines for Health-related Research Involving Humans* since 1982 (CIOMS Guidelines),[58] which are intended to establish or improve ethical justification of research and review mechanisms. The latest edition, published in 2016, establishes 25 Guidelines that cover a variety of areas, including community engagement, research involving children and adolescents, and use of stored biological materials and related data.

But the CIOMS Guidelines and other well-established ethics guidance documents do not provide clarity as to *how* RECs are to evaluate ethical principles such as 'social value' or how to ensure that 'risks to participants are minimised and appropriately *balanced* in relation to the prospect of individual benefit or the social value of the research'.[59] Nor do the documents clarify what an ethics evaluation must include, and how ethics can provide an answer as to whether a particular research study should be undertaken. Indeed, we might ask whether RECs engage in ethics deliberation at all—and just as critically, whether this matters to fulfilling their putative *regulatory* role. Can a regulator that is faced with limited resources (i.e. a tight budget from the NHS and a strictly volunteer effort by REC members) and is pressed for time (as regards, for instance, the turnaround time for opining on research applications, and the three or four hours dedicated to a full committee meeting once per month) really be expected to engage in deep ethics deliberation? This further begs the question as to what would constitute ethics deliberation in any case. Would we know it when we see it? Arguably, ethics deliberation suggests less a focus on formulaic, bureaucratic (arguably synonymous with 'regulatory') answers to questions (e.g. 'is there informed consent?', 'Have they used our template?') and more of a focus on seeking deeper, more philosophically-engaged answers to penetrating questions, such as: 'Do we really need informed consent

[58] The CIOMS Guidelines were first published in 1982, and were revised in 1993, 2002, and 2016.
[59] CIOMS Guidelines (n 16) (emphasis added).

here?'; 'What sort of alternative safeguards might there be and why?'; 'What ethical stance are we taking to say that consent is not needed here?' 'Is this research in the public interest?'; and 'What public good might come from this research and is the financial and social cost commensurate?'

At this stage, and to set the scene for the empirical research discussion to come in Part III, it will be helpful to further unpack the meaning of ethics deliberation. Ethics 'is a generic term covering several different ways of understanding and examining the moral life.'[60] Ethics can be normative, exploring the identification and justification of moral norms, or non-normative, investigating moral beliefs and conduct or methods of reasoning in normative ethics. For the purposes of evaluating research protocols, ethics can be seen as 'a system of principles or values that assist in decision-making'.[61] Ethics should enable REC members individually, and the REC in aggregate, to reach an 'opinion' and justify that opinion by referencing, explicitly or implicitly, wider, socially-accepted norms or values. Levine opines that ethics reasoning may be conducted at various levels of systemisation: from the highest level of abstraction—theories—and from there to principles (e.g. respect for persons, beneficence, non-maleficence, justice), to rules or norms (e.g. good research design, competent investigator, favourable balance of harm and benefit, informed consent), which in turn yield ethics judgements.[62] In theory, each REC member, and the REC's collective opinion, may appeal to and apply a spectrum of theories, such as

[60] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics* (7th edn, OUP 2013) 1.
[61] Graeme Laurie, Shawn Harmon, and Gerald Porter, *Mason and McCall Smith's Law and Medical Ethics* (10th edn, OUP 2016) 2.
[62] Robert Levine, *Ethics and Regulation of Clinical Research* (2nd edn, Yale University Press 1988) 14.

principlism,[63] casuistry,[64] deontology[65] or utilitarianism,[66] not to mention pragmatism,[67] each of which may consist of a systematic corpus of principles and rules. REC members are expected to have face-to-face training in 'research ethics' through initial induction within six months of appointment, 'Equality and Diversity' training within the first 12 months of their appointment, and the equivalent of one-day (five hours) training annually.[68] This training may provide a survey of different theories and regulations (i.e. rules) that reflect (perhaps implicitly) a particular approach to ethics deliberation.

A REC gives a favourable opinion only 'if it is assured about the ethical issues presented by the proposed research'.[69] As the ethical issues may vary, depending on the research in question, REC members receive training and guidance about the issues they should consider, both in general and in particular cases. According to

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[63] Principlism, one of the better known ethical approaches, is associated with Beauchamp and Childress' 'canon' of bioethics that espouses four foundational principles: autonomy, non-maleficence, beneficence, and justice. See e.g. Beauchamp and Childress (n 60).
[64] Casuistry is case-based reasoning used to resolve moral problems by extracting or extending theoretical rules from particular instances and applying these rules to new instances. See e.g. Stephen Toulmin, 'How Medicine Saved the Life of Ethics' (1982) 25 Perspectives in Biology and Medicine 736.
[65] Deontology (from the Greek, δέον or *deon*, meaning duty) is a normative ethical position that judges the morality of an action based on the action's adherence to a rule or rules. It is commonly viewed as a rights-, rules-, or duty-based ethical framework. Thus, an action itself is evaluated apart from its expected consequences. A strict deontologist might argue that if an action is deemed morally wrong, then it cannot be justified on any grounds. See e.g. Immanuel Kant, *Groundwork of the Metaphysic of Morals* (2nd edn, CUP 2012).
[66] Utilitarianism evaluates the moral rightness of human actions in terms of their expected consequences. An action is morally right if it is likely to contribute to the development of 'goods', such happiness or pleasure. In traditional utilitarianism, an action is not evaluated on its own for its moral rightness or wrongness; rather, consequences play a strong role in evaluating an action. See e.g. R.M. Hare, 'A Utilitarian Approach' in Helga Kuhse and Peter Singer (eds), *A Companion to Bioethics* (2nd edn, Wiley-Blackwell 2009); Jonathan Baron, *Against Bioethics* (MIT Press 2006).
[67] Pragmatism is an American-born approach that believes philosophical topics such as ethics are best viewed in terms of their practical uses and successes. Pragmatism embraces scepticism, empiricism, and experimentation. See e.g. Glenn McGee (ed), *Pragmatic Bioethics* (2nd edn, MIT Press 2003).
[68] GAfREC (n 1) para 1.1.3 ('All the committee members are given training to understand research ethics').
[69] ibid para 5.3.1.

the GAfREC: 'The training and guidance reflect recognised standards for ethical research, such as the *Declaration of Helsinki*, and take account of applicable legal requirements.'[70] Yet even if REC members learn about what 'research ethics' is supposed to entail, according to 'recognised standards' and 'applicable legal requirements', are the REC meetings themselves reflections of a kind of instantiated deliberative ethics—ethics as input, process, and outcome—where members individually and collectively evaluate and come to decide on the ethical acceptability of research proposals by invoking and deliberating on rules, norms, or principles?

There is room for scepticism when we shift our gaze from theory to practice. As Dixon-Woods and colleagues have found in their empirical investigation of REC opinion letters to researchers:

> Though clearly RECs are making firm recommendations to researchers in these [previously discussed] examples of both inconsistent and consistent advice, the source of ethical authority for the REC in coming to their conclusions is rarely explicit in the letters. GAfREC—which provides the framework within which RECs are expected to work—is not referred to in any of the letters in our sample. Specific ethical principles or even guidelines are rarely invoked explicitly, and when they are, it is to authenticate or legitimise the decisions of the committee […].[71]

If the REC opinion letter is a reflection of the contents of a REC meeting's discussion, there is some doubt as to whether ethical rules, norms, or principles are openly discussed at all. Other empirical research has affirmed this finding.[72] As Chapter 3 stresses, a common past criticism of RECs has been that they engage in a 'tick-box' bureaucratic ethics rather than a deliberative ethics. The former channels otherwise deep analytical and philosophical evaluation of a research application's

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[70] ibid.
[71] Mary Dixon-Woods and others, 'Written Work: The Social Functions of Research Ethics Committee Letters' (2007) 65 Social Science & Medicine 792, 796.
[72] Maureen Fitzgerald, Paul Phillips and Elisa Yule, 'The Research Ethics Review Process and Ethics Review Narratives' (2006) 16 Ethics & Behavior 377.

ethical issues into a formulaic assessment of items that rests on the REC's self-created legitimacy. Again quoting Dixon-Woods and colleagues:

> The absence of external referents in these letters reinforces the implication that the source of the REC's authoritativeness is the REC itself. The authority of the REC letter derives from its organisational and institutional location and status, the processing of the application within the remit and procedures granted to the REC, and the REC's exercise of its role as a moral authority.[73]

As this thesis will argue, the name bestowed upon these bodies ('ethics committees'), and the related expectation that they should engage (only) in ethics deliberation (and related criticism that they do not do enough of this) may in fact be misplaced. I suggest through my empirical research that as RECs become institutionalised and professionalised, acting as multi-faceted and multidisciplinary micro-*regulators* of health research (concerned with minimising risks, ensuring scientific value and social value, and so on), and as more national and international regulations come into force that impact health research, RECs might be expected to act more as risk-assessing 'health research regulatory committees' writ large. Yet even if RECs do not engage in something approaching substantive ethics deliberation, and this is accepted as an outcome of changing socio-political circumstances, might they still be able to fulfil their aim of targeting areas of health research that pose moral concern, and might they still be able to mitigate the manifestation of those concerns?[74] This leads to a query of what exactly the roles of RECs are.

2.3.2 Primary role: protection

RECs, and arguably some of their individual members as well, have several regulatory roles. The *primary role* of a REC has been to *protect* the health, welfare, and dignity of research participants. They do this by issuing a single, independent opinion of a research application, set within a regulatory framework and, more

[73] Dixon-Woods and others (n 71) 796.
[74] The normative recommendations in Chapter 7 may help to address this issue, too.

broadly, a legal architecture.[75] To quote the GAfREC, RECs aim to ensure 'that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society'.[76] As the GAfREC further state emphatically: 'Whatever the research context, the interests of participants come first. Their dignity, rights, safety, and well-being must be the primary consideration in any research proposal, as well as in REC review.'[77] In other words, the primary obligation of a REC is to safeguard participants and minimise risk of harm. RECs, then, may be seen to operate to a great extent as *risk-based regulators*.[78] They exist to protect participants from possible harm in research by means of anticipatory avoidance—serving as independent *ex ante* watchdogs and gatekeepers of ethical conduct in research.

This primary 'risk minimising' or 'participant safeguarding' role is crucial to understanding the linkages between RECs, other health research regulators, researchers, participants, science, and society. RECs ostensibly engage in a variety of prospective inquiries, tests, and decision-making processes to determine whether a research study is 'ethical' and whether potential research participants are sufficiently *protected*. This role has been constant, to varying degrees, in RECs since their creation and serves to assuage society that science will proceed in a responsible manner.[79] This, then, can be seen as a variation of a public interest aim, vis-à-vis the

[75] This is distinct from providing a legal opinion, which RECs are neither qualified nor authorised to do.
[76] GAfREC (n 1) para 1.2.2.
[77] ibid para 3.2.1.
[78] Annette Rid, 'How Should We Regulate Risk in Biomedical Research? An Ethical Analysis of Recent Policy Proposals and Initiatives' (2014) 117 Health Policy 409; Michelle Meyer, 'Three Challenges for Risk-Based (Research) Regulation: Heterogeneity among Regulated Activities, Regulator Bias, and Stakeholder Heterogeneity' in I. Glenn Cohen and Holly Fernandez Lynch (eds), *Human Subjects Research Regulation: Perspectives on the Future* (MIT Press 2014).
[79] See e.g. Robert Levine, 'Institutional Review Boards' (1989) 298 British Medical Journal 1268 (The 'principal function of these committees is to review proposals to conduct research in humans to assure conformity with ethical standards'); Robert Veatch, 'Human Experimentation Committees: Professional or Representative?' (1975) 5 Hastings Center Report 31, 35 ('At the most general level the purposes of the [REC] are fairly clear. The task is to protect human subjects from possible harms and wrongs which they might suffer

public having an interest in seeing its individual members (specifically research participants, be they volunteering healthy individuals or patients) sufficiently safeguarded against harm. Undertaking this primary role also suggests that the process effectively results in an 'ethical covenant' whereby the REC must trust that the researchers will proceed as they have promised to do; beyond the expectation of a filing of an annual progress report and any substantial amendments to the study,[80] there is limited power to monitor or police later.[81] This suggests an unmet need to survey or even steward research protocols as they move past the approval stage; I address the theoretical, practical, and normative implications of this in Part III.

2.3.3 Secondary role(s): promotion

Protection of research participants may be RECs' primary role, but crucially, they have also always performed secondary roles. One such role is a variation of the public interest aim: RECs have an obligation to society to provide stewardship for the *promotion of ethical and socially valuable research*.[82] Similarly, RECs also have an obligation to researchers, namely through treating researchers' proposals with

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during the course of biomedical […] research'); Will van den Hoonaard, *The Seduction of Ethics: Transforming the Social Sciences* (University of Toronto Press 2011) 56 ('Protecting "subjects" is the claimed central purpose in all international and national research-ethics codes.').

[80] GAfREC (n 1) paras 3.2.17, 5.2.1.

[81] According to the GAfREC:

> Although RECs must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research, *they are not responsible for enforcement if the research turns out to be unsafe or is not carried out as agreed*. This responsibility rests with the relevant regulators or comparable bodies, as well as with the researchers' employer and sponsor and with the care organisations where the research takes place (or through which the researchers have access to participants, or their tissue or information) or where the researchers have contracts.

See GAfREC (n 1) para 3.2.15 (emphasis added). The GAfREC encourages RECs to notify relevant bodies responsible for enforcement if they have grounds to suspect that enforcement action is warranted (para 3.2.16), and to reconsider its favourable opinion in light of pertinent information that comes to its attention, in the form of annual progress reports or otherwise (para 3.2.17).

[82] See GAfREC (n 1) para 3.2.2.

respect and due consideration and enabling their ethical research.[83] If research is seen as a public good (and most would accept that it is) and a morally valuable activity through the pursuit of knowledge, RECs serve not just to protect research participants from being exploited, exposed to excessive risks, or injured; they also serve to evaluate research for its societal benefit and reconcile this with the value of participant protection. So, in some sense (and as will be explored empirically in later chapters), RECs engage in a value weighting system of protection and promotion. This said, the GAfREC indicate that these roles are not equal, but rather secondary, even placing 'science and society' under a separate heading and below the heading 'protection of research participants':

> **Science and society**
>
> The interests of researchers and research *are always secondary* to the dignity, rights, safety and well-being of people taking part in research. RECs also take into account the interests and safety of the researchers, as well as the public interest in reliable evidence affecting health and social care, and enables [sic] ethical and worthwhile research of benefit to participants or to science and society.[84]

Such a 'role hierarchy' or 'principle hierarchy', as it were, aligns with international statements on research ethics, including the EU's Good Practice Directive,[85] the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being*,[86] and previous editions of the *Declaration of Helsinki*. For example, the 2000 edition of the *Declaration of Helsinki* stated at Paragraph 5: 'In medical research

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[83] Gerry Kent, 'The Views of Members of Local Research Ethics Committees, Researchers and Members of the Public Towards the Roles and Functions of LRECs' (1997) 23 Journal of Medical Ethics 186.

[84] GafREC (n 1) para 3.2.2 (emphasis added).

[85] See Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products [2005] OJ L91/13, ch 2, s 1, art 2 ('The rights, safety and well being of the trial subjects shall prevail over the interests of society').

[86] Council of Europe, *Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, ETS No 164 (1997), art 2 [hereinafter Oviedo Convention].

on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.' This was slightly modified in the 2008 edition, which stated at Paragraph 6: 'In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.' The latest edition of the *Declaration of Helsinki*, from 2013, states at Paragraph 8: 'While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.'[87] At Paragraph 5, it states: 'Medical progress is based on research that ultimately must include studies involving human subjects.'[88] These statements on their own do not suggest any kind of 'balancing' between personal harms or benefits and societal benefits, as some claim is the role of RECs;[89] one clearly trumps the other. The sentiment appears to be that 'in order for science to progress, good research must be facilitated'.[90] This does not foreclose a proportionate or other kind of approach to account for the value of participant protection and the value of research. Indeed, no guidelines or regulations for RECs exhort them to have regard *solely* for the rights, interests, and welfare of participants. What it does mean, though, as Cave and Nichols note, is that '…the goals of research and researcher, while important, should always be secondary to the dignity, rights and wellbeing of the research participant'.[91]

[87] *Declaration of Helsinki* (n 17) para 8.
[88] ibid para 5.
[89] Simon Whitney, *Balanced Ethics Review: A Guide for Institutional Review Board Members* (Springer 2016). See also Emma Cave and Christopher Nichols, 'Reforming the Ethical Review System: Balancing the Rights and Interests of Research Participants with the Duty to Facilitate Good Research' (2007) 2 Clinical Ethics 74 ('The balancing of the imperatives […] is the key to ethical research.').
[90] Cave and Nichols (n 89) 74.
[91] ibid.

2.3.4 Ambiguity in the role hierarchy

Despite the GAfREC's text, the role hierarchy of RECs in the UK has long been ambiguous.[92] In 1984, for example, the Royal College of Physicians of London issued a highly-cited document, *Guidelines on the Practice of Ethics Committees in Medical Research* (RCP Guidelines), which served as a much-needed source of information and opinion on a range of matters concerning the procedures of RECs, with the aim of standardising them. The RCP Guidelines viewed RECs as not just protecting participants from possible harm. The objectives of RECs, according to the Guidelines, were 'to facilitate medical research in the interest of society, to protect subjects of research from possible harm, to preserve their rights, and to provide reassurance to the public that this is being done. Committees also protect research workers from unjustified attack.'[93] Elsewhere, the RCP Guidelines stated that 'it is important [for RECs] to be continuously aware of the need to avoid impeding good medical research. The Committee should indeed seek to facilitate good research'.[94] This statement was retained in future editions and arguably strengthened, no longer suggesting ambiguity but rather clarity: the latest edition of the RCP Guidelines from 2007 states emphatically that 'RECs have a *duty* to encourage important ethical research'.[95]

Similarly, informal guidance for REC members stresses a dual role that involves some kind of balancing. For example, the sixth edition of the *Manual for Research Ethics Committees*, last published in 2003, states that:

> Members of Research Ethics Committees have the responsibility of ensuring that medical research on humans is conducted in an ethical manner. In order

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[92] McNeill, *Ethics and Politics of Human Experimentation* (n 14) 5 ('In both Britain and New Zealand the purposes for research ethics committees include: (1) the protection of the human subjects of research; (2) promoting research; and (3) reassurance of the public.'). McNeill found these multiple roles unusual compared to the other jurisdictions he researched.
[93] Royal College of Physicians, *Guidelines on the Practice of Ethics Committees in Medical Research* (1st edn, Royal College of Physicians 1984) 1.
[94] ibid 2.
[95] Royal College of Physicians, *Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants* (4th edn, Royal College of Physicians 2007) 4 (emphasis added).

> to fulfil this function, Research Ethics Committees must engage in reasonable discussion and consideration of the ethical issues in each of the research proposals they have to review. This is demanding and time-consuming work, and the responsibilities entailed are considerable. *On the one hand* there is the need to contribute to the evidence base upon which modern medicine is based, *on the other* is the need to protect those who participate in the research process.[96]

As discussed more fully in Chapter 3, the language of 'protection and promotion' has been instantiated in statutory regulation such as the Care Act 2014, and operationalised in the mandates of the HRA and its RES branch, as well as the mandates of RES offices in the devolved nations. For instance, HRA guidance for potential REC members states: 'The key duty of a REC is to protect the interests of research participants whilst at the same time facilitating ethical research.'[97] NHSScotland's CSO also states this dual role, without specifying a role hierarchy: '[The National Research Ethics Service] has a duel [sic] mission: to protect the rights, safety, dignity and well-being of researcher [sic] participants and to facilitate ethical research which is of potential benefit to participants, science and society.'[98] The mission of Northern Ireland's ORECNI is stated as: 'To maintain a Research Ethics Service to protect the rights, dignity and welfare of research participants within the HSC System/NHS, and to protect the rights of researchers to perform ethical research and legitimate investigation'.[99] In its recent annual report, ORECNI's mission is stated somewhat similarly: 'To protect the rights, safety, dignity and well-being of research participants; and to facilitate and promote ethical research that is of potential benefit to participants, science and society'.[100]

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[96] Sue Eckstein (ed), *Manual for Research Ethics Committees* (6th edn, CUP 2003) xvii.
[97] Health Research Authority, 'Information for Potential Research Ethics Service Committee Members' (n 56).
[98] Chief Scientist Office, 'Research Ethics Structure in Scotland' <http://www.nhsresearchscotland.org.uk/services/research-ethics>.
[99] ORECNI, 'Mission Statement' <http://www.hscbusiness.hscni.net/services/orecni.htm>.
[100] ORECNI, 'HSC REC A & HSC REC B Executive Summary Annual Report 2015-2016' <http://www.hscbusiness.hscni.net/images/HSC_REC_A_and_HSC_REC_B_Executive_Summary_Annual_Report_2015-2016.doc>.

The claim that RECs equally serve to facilitate 'good medical research' or 'important ethical research'—perhaps even as a moral duty if we interpret the 2007 RCP Guidelines suggesting such—establishes a notably different message regarding the regulatory role of RECs in health research, as seen in both the literature and in documents such as the GAfREC, and arguably a message that is more pronounced than in other countries.

2.4 To protect *and* (equally) promote?

It could be said that regulation is by its nature designed to *affect* behaviour of some kind (whether to restrict or to enable it),[101] and therefore in some sense RECs have always, even if indirectly, been implicated in the *facilitation* of ethical health research. By considering, commenting on, guiding, and approving research studies that are well-designed scientifically and in accordance with law and established rules and principles of ethical conduct, RECs do promote a certain desired kind of behaviour, and this is what makes them regulators.[102] Yet, even if regulation is, at its essence, about steering and therefore affecting social behaviour,[103] critical questions still remain regarding: 1) how twinning the roles of 'protection and promotion' might influence REC performance and decision-making, and 2) whether there might be regulatory misalignment between some of the instruments specifically for RECs—emphasising participant protection—and regulatory instruments governing central regulators of health research and RECs themselves—imposing research

[101] See e.g. Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (2nd edn, OUP 2012) 3.

[102] Sheelagh McGuinness, 'Research Ethics Committees: The Role of Ethics in a Regulatory Authority' (2008) 34 Journal of Medical Ethics 695; Linus Johnsson and others, 'Making Researchers Moral: Why Trustworthiness Requires More Than Ethics Guidelines and Review' (2014) 10 Research Ethics 29. Similarly, Montgomery argues that RECs can be seen as a consolidation of bioethical practices into an advisory and regulatory structure. See Jonathan Montgomery, 'Bioethics as a Governance Practice' (2016) 24 Health Care Analysis 3.

[103] Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (CUP 2007) xiv ('We understand 'regulation' scholarship as a broad and open-ended category that can readily apply to many forms of intellectual inquiry concerning the purposive shaping of social behaviour, particularly state and non-state standard-setting, monitoring and behaviour-modification processes').

promotion—that impacts the overall quality and effectiveness of health research regulation.

As briefly noted above, and as will be detailed in Chapter 3, that the UK emphasises protection and promotion simultaneously is not new *per se*.[104] For years, the country has held in some of its regulations and policies that RECs aim to facilitate (ethical) health research. The guidelines for RECs first emanated from the health research-favourable Royal College of Physicians in 1984. Then, as now, there was scholarly concern that 'the British guidelines have tipped the balance too far in the direction of the interests of researchers and have not given sufficient emphasis to the protection of subjects'.[105] Then, as now, there was a concern that 'committee members are confused by a perceived conflict between the requirement to facilitate research and their need to be critical of research'.[106]

So, what is different? In short: the regulatory embeddedness of research promotion. In my thesis, I demonstrate through an anthropology of regulation—qualitative research guided by anthropological and regulatory theory—that the 'promotionist'

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[104] A parallel may be drawn to data protection law, specifically the EU's Data Protection Directive 95/46/EC and General Data Protection Regulation (GDPR) (EU) 2016/679, which also speak of protection and promotion as twin aims (see e.g. Recital 10, which speaks of the GDPR seeking '…to ensure a consistent and high level of protection of natural persons and to remove the obstacles to flows of personal data within the Union'). Yet, what this means in practice for data controllers or data protection authorities has never been spelled out, nor is it clear that the promotion aim of the GDPR, and its predecessor EU Data Protection Directive 95/46/EC, has ever been achieved. Commentary suggests that the Data Protection Directive has been successful in protecting Europeans' personal data, but less so in facilitating data transfers from one member state to another, much less outside the EU. Arguably, the Directive's twenty-year history would suggest that the twin aims of protection and promotion have been more rhetorical aspiration than workable success.

[105] Paul McNeill, 'Research Ethics Review in Australia, Europe, and North America' (1989) 11 IRB: Ethics and Human Research 4, 5.

[106] McNeill, *Ethics and Politics of Human Experimentation* (n 14) 67, citing the study of REC members conducted by Julia Neuberger. See Neuberger (n 53) 44 ('There is ambivalence arising from the sense that REC members should be supporting and facilitating research rather than criticising it, and from the knowledge that RECs have inadequate powers, and often insufficient status, within their [District Health Authorities].'). Yet Neuberger herself also stresses the dual role of RECs, stating that 'their role is both to act as public watchdog and to encourage good quality research'. ibid 45.

ideology has moved 'up the ladder' in the regulation of RECs and in the regulation of health research, all the way to implementation in law, most pointedly in the Health and Social Care Act 2012 and Care Act 2014. What was once custom or guidance has now become legal rule. Relatedly, the thesis queries whether this ideological movement is unidirectional (top-down), or whether recent legal developments reflect already-existing REC practices. To date, we do not really know the practical impact (if any) of this explicit *legal* regulatory shift, especially on RECs. Empirically, we remain largely uninformed of how RECs in the UK make decisions under the penumbra of ethics, law, and other forms of regulation, and how they engage with regulatory bodies such as the HRA in the course of doing their work, particularly in this regulatory environment of protection and promotion. As I will argue in my thesis, an anthropological approach that draws attention to process, time, and space can reveal new understandings of regulatory theory and the nature of health research regulation, and what it means to experience being in or in charge of a REC. Such an approach will also provide an opportunity to explore the relationship between regulation and ethics in operation. At this preliminary, scene-setting stage, however, we can speculate that several different processes are at play.

2.4.1 Ethical, political, and regulatory processes

As McNeill observes, and as will be discussed in Part III, determining the ethical acceptability of research is not just a complex and amorphous ethical process; it is also a political process.[107] REC members may employ discursive strategies to convince other members of their position on an issue; power dynamics may arise between 'expert' and 'lay' members, not to mention between the REC Chair and the other members. The REC Manager and Scientific Officer themselves may play a

[107] McNeill, *Ethics and Politics of Human Experimentation* (n 14) 1 ('It is about balancing one set of interests in the community against another set of interests: the interests of science and scientists (principally) on the one hand and the interests of human subjects of experimentation on the other.'). McNeill clearly states that the primary mechanism undertaken by RECs is balance, a claim that I question in my thesis. Without question, determining the ethical acceptability of research is also a psychological process within each member and in aggregate in a group dynamic.

crucial gatekeeping and intermediary role. As a committee, RECs may be drawn further into power dynamics with their 'managing' regulatory authorities. As this thesis will explain, in the current regulatory environment, hortatory guidelines and self-regulation have given way to legal regulation and centralised regulatory bodies to coordinate and manage RECs. RECs must navigate the complexities of modern health research and the challenging cross-cutting demands from their managing regulators that encourage both protection of research participant interests and also promotion of health research. This entails a working through of the interests of researchers and research participants, and of science and society as well—which suggests that the process of determining whether research is ethically acceptable is also a regulatory process.

Curran observed many years ago that '[t]he use of review committees is a common law approach. These committees will be building the law as they go along.'[108] Curran's comment was more aspiration than observation; nevertheless, the regulatory process is observed both in statutory regulations that RECs follow or apply to research proposals (e.g. research involving adults lacking capacity), as well as in the regulatory techniques they employ to govern research. Indeed, as health research regulators themselves, RECs can look not only to what statutory or other types of regulations may (or may not) say about a proposal, they can also issue researchers many self-generated regulatory commands in their opinion letter, concerning, for example, whether a research design is flawed; whether a researcher may use human tissue on ethical grounds; whether a participant has mental capacity to consent; whether different groups of participants should be included; and not uncommonly, whether the information sheet says too little about burdens or risks or misrepresents what may happen. Such commands, it seems, reflect a

[108] William Curran, 'Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies' (1969) 98 Daedalus 542, 585. Curran used 'law' as a metaphor here, suggesting that ethics review committees would be building a corpus of rules, principles, and well-reasoned precedents for their own consistent and robust decision-making.

hybrid blend of legal and ethical reflection that *in toto* signify a power to say 'yes', 'maybe', or 'no'. RECs are said to provide an 'opinion' on research proposals, but this is understated euphemism. The power of a REC opinion is profound. In effect, the opinion is a regulatory event licence: without a positive opinion, research simply cannot proceed, either by way of law (in the case of clinical trials, for instance), policy, or practice (in most other instances of health research, where it likely could not be published in any journal or otherwise gain the respect of the research community).

Since the new millennium, and especially as RECs (in England) are now under the management of the HRA through the Care Act 2014,[109] the role hierarchy of participant protection and research promotion has flattened acutely, to the concern of some. Previewing discussion in Chapter 3, shortly after the dawn of the new millennium, Cave and Holm expressed concern that the EU Clinical Trials Directive 2001/20/EC 'led to a subtle change of emphasis from the protection of research participants to the facilitation of research'.[110] In the same time period, Beyleveld, a legal scholar, expressed concerned about a conflict of interest the dual roles could create:

> The root of the problem is that, despite the World Medical Association Declaration of Helsinki, the management of the REC system believes that the role of RECs is not just to protect the rights of research subjects, but also to facilitate good quality research. […] [T]his just highlights a conflict of interest. A dog cannot serve two masters, and the role of RECs, in fact, is solely to try to prevent unethical research. The facilitation of research is the role of other bodies.[111]

Beyleveld expressed particular concern that the operation of multi-site RECs (MRECs), created in 1997 (and later disbanded in 2004 after he wrote the words

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[109] The relationship of the HRA to RECs in light of the Care Act 2014 is discussed further in Chapter 3.

[110] Emma Cave and Soren Holm, 'New Governance Arrangements for Research Ethics Committees: Is Facilitating Research Achieved at the Cost of Participants' Interest' (2002) 28 Journal of Medical Ethics 318.

[111] Deryck Beyleveld, 'Law, Ethics and Research Ethics Committees' (2002) 21 Medicine and Law 57, 72-3.

above), was in the hands of the NHS R&D Directorate, whose role, in part, was to promote research. In light of the recent regulatory reform, I believe his message still holds force even after the dissolution of local RECs (LRECs) and MRECs. The ethical, political, and regulatory processes by which RECs render an opinion may well manifest quite differently under the research-transformative HRA. Such a change may resolve some or most of the problems that critics (mainly health researchers) have levelled against RECs for years, but it may also lead to collateral, even unintended changes in how RECs review research studies, such as making determinations about balance of harms and benefits, and interpreting the form and function of consent. If changes will have emerged in this next-generation regulatory environment, it is an as-yet unknown answer what impact it may have on participants, researchers, and society. Phrased both empirically and normatively, can and should RECs *both* protect *and* promote? And if this is a new approach, what kind of regulator do RECs become?

Likely, many in the health research community would respond positively to this more explicitly twinned role, claiming that RECs do not just act as a safeguard against unethical research, they also encourage ethical research to improve health and health care, as outlined above.[112] McNeill, a legal scholar, also thinks there is a place for research promotion:

> In my view, systems of review by committee in most countries […] are systems for allowing research on human subjects with a minimum of interference. […] In practice, committees are composed as if the priority is the creation of optimal conditions for research on human subjects with a minimum of interference. In a sense, the British Royal College of Physicians guidelines are more open about the actual function of ethics committees. […] [T]he principle purpose of research ethics committee review is not protection of subjects but reassurance of the public so that the research enterprise can continue relatively unhindered.[113]

[112] George Alberti, 'Multicentre Research Ethics Committees: Has the Cure Been Worse than the Disease?' (2000) 320 British Medical Journal 1157.
[113] McNeill, *Ethics and Politics of Human Experimentation* (n 14) 198.

Similarly, Miller, a bioethicist, argues that research ethics as a whole 'inherently' suffers from a 'tension' between these two 'ethical' objectives that must be 'balanced', and seems to suggest that RECs (among other actors) should be charged with undertaking this inquiry and 'balancing' assessment:

> Research ethics inherently involves tension between two ethical objectives: 1) promoting socially valuable knowledge aimed at improving medical care and public health and 2) protecting research subjects from exploitation and harm. Accordingly, the research enterprise and research ethics can err in two ways: by excessive restrictions on valuable research and by failure to provide adequate protection of research subjects. […] Striking justifiable balances between these two ethical objectives is the fundamental task of research ethics, which calls for searching inquiry and honest debate.[114]

This view may contrast with those held by some within the REC community. For instance, a former member of three RECs in two countries found that his fellow members do *not* actively seek to facilitate research, but rather focus on the ethical acceptability of a given research study by asking four basic, *risk-avoiding*, participant-safeguarding questions: (1) What hazards are raised by the research protocol? (2) Can the protocol be redesigned to reduce these hazards without compromising its ability to answer the research question? (3) Have the investigators taken reasonable steps to minimise the chances that the (remaining) hazards result in harm? (4) Are either the hazards or the risk of their resulting in harm disproportionately great in relation to the apparent importance of the knowledge to be gained?[115]

This is not to discount or disfavour the (wider) public interest aim of RECs that stresses a view beyond a possibly overly cautious and conservative one focused

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[114] Franklin Miller, 'Does Research Ethics Rest on a Mistake?' (2005) 5 The American Journal of Bioethics 34, 35.

[115] Konrad Jamrozik, 'Research Ethics Paperwork: What is the Plot We Seem to Have Lost?' (2004) 329 British Medical Journal 286. See also George Masterton, 'Two Decades on an Ethics Committee' (2006) 332 British Medical Journal 615 ('Our main rewards [as REC members] were intangible: protecting patients from bad research and contributing to the greater good. Altruism wasn't the only motivation, however: the work promised stimulating intellectual challenges and the ability to keep abreast of medical developments as they unfolded').

solely on research participants. Indeed, some qualitative research supports the view that RECs are reflexive of their position in health research governance; they do consider how their work could impact research and society. Hedgecoe's ethnographic study of three RECs, for example, found that 'REC members see their role as one of supporting or encouraging research, in addition to the *more obvious duties* of protecting patients and ensuring informed consent'.[116] What Hedgecoe's empirical research suggests is that RECs act as the GAfREC encourages them to: foremost, to safeguard participants; but also, somehow—and perhaps secondarily, but perhaps not—to facilitate research.

Even if this is the case, though, how does this arguably secondary but important reflexive role align with the 'primary' role of participant protection? Undoubtedly, the roles work together, but they are not necessarily balanced, nor might 'balance' be the appropriate mechanism. 'Balance' is a stalwart in the legal and regulatory literature (not to mention case law), but, as is too often ignored, can serve as a rhetorical ploy in regulation to mask other techniques to render judgement.[117] In health research, Veatch has observed that IRBs in the US may employ different techniques to interpret and apply the 'fundamental' ethical principles of respect for persons, beneficence, and justice. These include: 1) a 'single principle view', where one principle takes precedence; 2) a 'simultaneity view', where all principles must be satisfied simultaneously for a protocol to be deemed acceptable; 3) a 'balancing view', where the principles taken together must be satisfied on balance; and 4) a 'ranking view', where principles can be rank-ordered such that the highest ranking principle must be fully satisfied before the next rank is considered. Veatch further observes that US health research regulation fails to offer a theory of what should

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[116] Adam Hedgecoe, 'Research Ethics Review and the Sociological Research Relationship' (2008) 42 Sociology 873, 878 (emphasis added).

[117] Scholars in other fields have deconstructed the term. See e.g. Robert Patterson and Ronald Lee, 'The Environmental Rhetoric of "Balance": A Case Study of Regulatory Discourse and the Colonization of the Public' (1997) 6 Technical Communication Quarterly 25; Derek Ross, 'Ambiguous Weighting and Nonsensical Sense: The Problems of "Balance" and "Common Sense" as Commonplace Concepts and Decision-making Heuristics in Environmental Rhetoric' (2012) 26 Social Epistemology: A Journal of Knowledge, Culture and Policy 115.

happen when a proposed research project involves a conflict of principles.[118] In this thesis, I take up Veatch's important observation, arguing that it may apply to the twin objectives of 'protection and promotion', and that, in the absence of an expressed theory of how these two objectives should be achieved, a theory (or decision framework) should be crafted that may not invariably hinge on balance.

If we question the rhetorical use of or under-theorised reference to 'balance', we may further wonder if instead, RECs evaluate research studies implicitly in *stages* and act as gatekeepers or stewards at several *thresholds*, including a 'tolerable (risk of) harm' (i.e. protection) threshold and a subsequent 'social value' or public benefit (i.e. research promotion) threshold.[119] That is, once a REC has deemed an application *prima facie* ethically acceptable because the risks to participants are minimised and weighed against any possible benefits to them (and often there are few if any individual direct benefits), might the REC *then* move to consider research promotion, whereby the prospect of societal benefit or the social value of the research is evaluated and considered against the risks to participants? If so, what happens in these stages of dual commitment—of accommodating potential harms to participants as well as potential benefits to society, not to mention other considerations? In this realm of possibility, might a REC take a lead in maximising outcomes such as suggesting 'improvements' to the research questions, methods, proposed uses of findings, and so on? If so, this would suggest less a concern with 'balance' and more a concern with research *optimisation*. Thus, while 'balance' seeks to achieve a suitable equilibrium bewteen two at-times competing values at all stages of research (along the lines of Veatch's simulteneity view), optimisation seeks to achieve a stage-based satisfaction of ranked, but similarly appreciated, values.

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[118] Robert Veatch, 'Ranking, Balancing, or Simultaneity: Resolving Conflicts among the Belmont Principles' in James Childress, Eric Meslin and Harold Shapiro (eds), *Belmont Revisited: Ethical Principles for Research with Human Subjects* (Georgetown University Press 2005).

[119] Taylor-Alexander and others, 'Beyond Regulatory Compression' (n 2).

This critical question of balance versus optimisation (or something else) regarding protection and promotion remains open. It also raises several additional questions about the impact this next-generation regulatory environment may have on RECs—whether RECs encounter this twin, potentially competing role of protection and promotion in their work today (or long before), and if so, how it is operationalised in their practices.

2.4.2 Empirical questions raised by the structure and roles of RECs

In light of the above discussion, several questions arise under three broad headings that will be addressed in the course of this thesis:

<u>Changing REC characteristics?</u>

- What is the role today of a REC? Do RECs act as risk-based regulators, and how would we recognise this approach in practice?
- What does 'good' ethics review look like for REC members—and what supports this, and what gets in the way of it? Do REC members do things they should not do according to regulations, and equally, are there things they do not do that they think they should do?
- What are the perceived practical changes in RECs, if any, with next-generation regulatory reform such as the Care Act 2014 and establishment of the HRA?

<u>Balance, ranking, optimisation—or something else?</u>

- Do REC members perceive a 'push' to both protect research participants and also facilitate responsible health research through proportionate or streamlined regulation and alignment of REC processes? Are there proxies or symbols that suggest mechanisms for aligning (or reconciling) protection and promotion?
- How do regulators (particularly the HRA) and REC members think a suitable alignment of research participant protection and research promotion

can be achieved in practice (e.g. would proportionality of ethics review processes be a manifestation of research promotion)?

- If RECs are indeed seen to operate in a new regulatory environment, what strains might these demands of protection and promotion put on RECs as a regulatory body? Could RECs or the devolved nations' Research Ethics Services run into political conflict with the HRA?

<u>The liminality[120] of ethics review?</u>

- Do REC members and regulators think that health research is adequately guided throughout the research lifecycle? Should RECs and/or other bodies (e.g. HRA, CSO), or specific actors within these bodies, do more to guide researchers and research participants across the research lifecycle, and not just at the preliminary stage of ethics review?
- Do RECs evaluate research studies in stages and act as gatekeepers, or stewards, at several thresholds? If so, what happens in this liminal space of accommodating risks and potential benefits such as social value, as well as other considerations?
- If the law is creating a regulatory space within which there is more room to protect and promote, has it created a space for more epistemic latitude—a realm of possibility—for RECs to roam in along with, or together with, other actors? If so, what is the relationship of the REC to the 'space': do they occupy it as one of many actors; do they mould and shape the space, or do they create the space—or spaces within spaces?

[120] Arnold van Gennep, *The Rites of Passage* (University of Chicago Press 1960 [1909]). Liminality refers to 'the experience of finding oneself at a boundary or in an in-between position, either spatially or temporally'. It involves 'the experience of inbetweenness itself, as well as how exactly that experience is shaped and structured anew as subjects and collectivities move through the in-between, try to overcome it, and leave it behind – with a difference'. See Bjorn Thomassen, 'Thinking with Liminality: To the Boundaries of an Anthropological Concept' in Agnes Horvath, Bjorn Thomassen, and Harald Wydra (eds), *Breaking Boundaries: Varieties of Liminality* (Berghahn Books 2015) 40.

2.5 Conclusion

RECs have been a backbone in regulating the ethical acceptability of health research—and by extension, much of health research's very existence—since the late 1960s. They serve as gatekeepers that determine whether a proposed research study is ethically acceptable and therefore may proceed. RECs not only play a central role in the health research regulatory space, they also hold tremendous power over what knowledge is produced, and from knowledge production across the translational divide, what medico-scientific applications are created. While many support the underlying idea of *ex ante* ethics review by a committee as a means of protecting and promoting the rights, interests, and welfare of participants, many also have expressed dissatisfaction with the structure of the ethics review system and the individual processes of RECs. As this thesis will explain, multiple regulatory techniques and instruments have been employed over the years in the hopes of remedying the many problems attributed to RECs, foremost the concerns of inefficiency and ineffectiveness. Many researchers found the regulatory techniques and instruments of yore, particularly through the 1990s and in the form of 'guidance', to offer a weak remedy.

Recent changes may bode differently. Since its formation in late 2011, the HRA has been tasked with both protecting research participants from harm *and* also facilitating a productive research environment by streamlining health research regulation. The HRA is a central regulatory body that is seen to help make the UK once again an attractive place to conduct health research such as clinical trials. Money, jobs, and international pharmaceutical and regulatory competition are all at stake. One pathway to make the country more attractive for conducting health research, and to provide national economic benefit, is to remove perceived regulatory thickets. Ethics review has been viewed as part of this thicket.

The HRA, particularly through its RES, and equivalent bodies such as the CSO and ORECNI, are working to make REC processes more effective and efficient. As the HRA's RES website states: 'We have a duty to provide an efficient and robust ethics

review service that maximises UK competitiveness for health research and maximises the return from investment in the UK, whilst protecting participants and researchers.'[121] What is unclear, however, is how this stress on *duties* of efficiency and maximisation of 'UK competitiveness for health research' and maximisation of 'return from investment in the UK' may affect the substantive and procedural workings of RECs. Can or should efficiency, as well as competition and investment maximisation, be accomplished while simultaneously protecting participants? The UK is seen by many as a leader in health research regulation, and many have taken an interest in its recent reforms. As one author notes in a review of health research regulation across four countries: 'The current regulatory complexity appear[s] to be largely irrational, probably arising from piecemeal reactions to specific problems and scandals in the past. Thus, the new […] HRA is of great interest in terms of future developments. If successful, it may have an impact outside [the UK].'[122]

Rich, empirical evidence is needed to investigate these questions. There have been relatively few in-depth qualitative studies of RECs, much less from a regulatory perspective.[123] This undermines effective regulation, as policymakers and regulators (through state actors or otherwise) increasingly seek to develop regulation through intricately documented evidence of problems and the effects of regulation on

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[121] Health Research Authority, 'Research Ethics Service (RES)' <http://www.hra.nhs.uk/about-the-hra/our-committees/res/>.

[122] Elina Hemminki, 'Research Ethics Committees in the Regulation of Clinical Research: Comparison of Finland to England, Canada, and the United States' (2016) 14 Health Research Policy and Systems 5, 9.

[123] There have been several empirical studies of IRBs (US) and REBs (Canada). See e.g. van den Hoonaard, *The Seduction of Ethics* (n 79); Laura Stark, *Behind Closed Doors: IRBs and the Making of Ethical Research* (University of Chicago Press 2012); Robert Klitzman, *The Ethics Police? The Struggle to Make Human Research Safe* (OUP 2015); Jan Federici Jaeger, 'An Ethnographic Analysis of Institutional Review Board Decision-Making' (PhD thesis, University of Pennsylvania 2006); Raymond De Vries and Carl Forsberg, 'What Do IRBs Look Like? What Kind of Support Do They Receive?' (2002) 9 Accountability in Research 199. There have been a few qualitative research studies of RECs in the UK. See e.g. Fitzgerald, Phillips, and Yule (n 72); Sarah Dyer, 'Rationalising Public Participation in the Health Service: The Case of Research Ethics Committees' (2004) 10 Health & Place 339; Adam Hedgecoe and others, 'Research Ethics Committees in Europe: Implementing the Directive, Respecting Diversity' (2006) 32 Journal of Medical Ethics 483; Hedgecoe, 'Research Ethics Review' (n 116).

society—what is termed 'evidence-based policy'.[124] Through document analysis, in-depth interviews, and observation—and guided by anthropological and regulatory theory—we should endeavour to build a knowledge base from which we can investigate the nature of health research regulation, pinpoint weaknesses, and recommend improvements—in other words, we should embark on an anthropology of regulation and build an evidence-based regulatory framework. There is a need for qualitative research, asking how and why RECs make the decisions they do, and how the nested dynamics of RECs and central 'managing' regulators play into decisions.

Documented problems of RECs have largely relied on evidence and anecdote proffered by health researchers and physicians. Little evidence has been proffered by social scientists or legal scholars who have gone *inside* RECs to ask and examine how they, as individual members and as a body, see themselves and their committee in a changing regulatory environment, and *inside* regulatory bodies to gather the regulators' perspective on the roles of a REC within the health research regulatory space. Just what is the power of a word like 'promotion'? By gaining a critical understanding of what RECs actually do and exploring the nature of health research regulation, such research could offer a crucial contribution to understanding the roles actors play in health research and how these roles transform over time and across stages in research.

The next chapter traces the regulatory development of RECs and health research regulation within the UK, with a view to demonstrating both the growth of health research regulation and the increasingly central role that RECs play in regulating health research. As with all bodies that become institutionalised and gain prominence, RECs have faced more external scrutiny. For many years, there were repeated calls for structural reform, particularly from the research community—a

[124] Nancy Cartwright and Jeremy Hardie, *Evidence-Based Policy: A Practical Guide to Doing it Better* (OUP 2012); Sandra Nutley, Isabel Walter, and Huw Davies, *Using Evidence: How Research Can Inform Public Services* (Policy Press 2007).

community, of course, that since the beginning has participated in and been directly affected by RECs. The REC system in the UK has indeed now undergone structural reform, partly due to ongoing macro-regulatory changes occurring at the European Union level that impact on member states' national regulations. Overall, recent reforms appear to have been to the satisfaction of the research community. The central claim I wish to make is that while to a certain degree, research promotion has always been embedded in the regulatory techniques of RECs, it has not until now been instantiated in law with the creation of the HRA and rules promulgated under the Care Act 2014. The subsequent and fundamental research question to explore is whether this instantiation of research promotion in law has a (hitherto absent) trickle-down effect that impacts the day-to-day practices of RECs, and if so, how, or indeed, whether the law is only now coming to reflect an everyday practice that has long existed. This question, and the methodology and methods that drive it, are unpacked in Parts II and III of the thesis.

Chapter 3
The historical development of RECs as health research regulators

3.1 Introduction

The previous chapter provided a conceptual framework of RECs and their roles in regulating health research. I claimed that while research promotion—acting to advance knowledge and discovery in the interests of science and society—has been a longstanding role of RECs in the UK, that role traditionally has been situated as secondary in key regulatory instruments and, somewhat less clearly, in practice. I claimed further that research promotion is now embedded as a *twinned* objective of health research regulators *in law*, which is hitherto unseen, and signals a 'flattening' of the role hierarchy of participant protection and research promotion in RECs. I use the term 'signals' because ultimately this is a claim that warrants empirical investigation. Part I of this thesis provides a space to query, based on regulatory and historical analysis rather than empirical investigation, the 'trickle-down' effect this next-generation, streamline-emphasising regulatory environment has on RECs—that is, whether RECs can be expected to encounter this twin role of protection and promotion in their work today (or before), and if so, how it is felt and operationalised in their practices. Through conceptual overview and deep historical tracing, Part I serves to make the original claim about the uneasy tension between protection and promotion, which consequently demands certain further, empirical-based research, as covered in Parts II and III, which, reciprocally, also helps better make sense of the historical context provided here.

Thus, this third chapter steps back in time to better understand the present context, and to further set the stage for the empirical investigation and analysis presented in Parts II and III. Here, I present a historical tracing of the development of RECs as health research regulators within the UK. The aim in this chapter is not to provide

simply more background to the current environment, but rather to argue that there has been growth in the volume and complexity of health research regulation since the mid-20th century, with a consequent backlash against negative repercussions for research, health, and the economy. I further argue that RECs are a critical node in the health research regulatory space, a space comprised of a variety of actors who may at times hold cross-cutting resources and motives. To properly examine the development of RECs and the responses by various actors to mitigate their many perceived problems (most significantly, as a bureaucratic bulwark against otherwise ethical research), we would be better served to examine the health research regulatory space itself. If there are problems with RECs, to a large degree it is likely a reflection of the regulatory space in which they are situated. This chapter claims that through significant reforms, RECs and their managing regulators have come to serve as a focal point for not only the protection of research participants, but also the sustainability *and promotion* of health research.

Tracing history over the past half-century, we will see that as health research gained prominence in the UK as both a driver of scientific knowledge *and* economic development, self-regulation of health research—*ad hoc* peer review by fellow scientists based on professional norms and local customs—gradually gave way to stricter, stronger, more centralised forms of regulation, particularly through policies and guidelines set by the UK's constituent governments. This was done in an effort to steer health research in an ethical manner and provide coordination and coherence for researchers, research sponsors, and the general public. In the course of this regulatory evolution, RECs became institutionalised within the NHS system (albeit haphazardly) and proliferated in number. Pressure was placed on RECs by different stakeholders to review research applications for 'consideration, comment, guidance and approval'[125] as this was seen as conforming to emerging good international practice. But this pressure led to RECs facing increased scrutiny and opprobrium from members of the research community, many of whom argued that

[125] *Declaration of Helsinki* (n 17) para 23.

RECs were performing the reviews poorly. The accusation was that they were too numerous in number, duplicative in their reviews of the same application for a multi-site study, and overly complex, opaque, and inconsistent in their functions. By the late 1990s, the picture painted by some was one of regulatory chaos rather than order. Despite a degree of reforms in the early 2000s, there remained concern about the future of health research in the UK due to ostensibly obstructive, economically destructive regulation. Stakeholders made repeated calls for substantial reform at the level of regulatory architecture of health research, i.e. the regulatory pathways for designing and conducting health research, rather than at the structural level of the regulatory nodes, such as abolishing RECs altogether.

Largely, these calls appear to have been answered. RECs and their overlaying, nested regulatory architecture have undergone substantial reform in the past decade. Partly this is due to ongoing macro-regulatory and macro-political changes occurring at the European Union level that impact member states' national regulations (e.g. the EU's Clinical Trials Regulation that is expected to take effect in the UK in 2019,[126] and the still-uncertain outcome of the 'Brexit' EU referendum result in June 2016). This next-generation health research regulatory reform is designed to be 'streamlined'-attuned and proportionate, calibrated to the 'scale and complexity of the research proposed'.[127]

The tone of the current regulatory era is reflected in the HRA's RES, which states on its website: 'We have a duty to provide an efficient and robust ethics review service that maximises UK competitiveness for health research and maximises the return from investment in the UK, whilst protecting participants and researchers.'[128] This appeal to efficiency and a 'duty' to maximise UK competitiveness for health research and maximise the return from investment in the UK reflects an increasingly neoliberal discourse in government policy grounded in regulatory speed and,

[126] Regulation EU No 536/2014.
[127] GAfREC (n 1) para 3.2.4.
[128] Health Research Authority, 'Research Ethics Service (RES)' (n 121).

which, as Flear writes, 'fuses governmentality with technical reason and means-end, or instrumental, market rationality' and considers economic optimisation the central aim of governance.[129] Unquestionably, researchers and the pharmaceutical industry seem satisfied with the most recent reforms. The number of academic articles lamenting the state of ethics review in the UK has dwindled and transformed into praise; many look at the UK's ethics review system today with envy, viewing it as comparatively highly coordinated, efficient, and robust.[130] But what do these regulatory reforms tell us about the nature of next-generation health research regulation and what its impact might be on RECs (to say nothing of its impact on research participants and publics)? With the creation of the HRA in late 2011, the statutory rules promulgated under the Care Act 2014, and ensuing changes in regulatory instruments governing RECs, a key question arises: does instantiation of research promotion in law and at the governmental level of health research regulatory bodies have a trickle-down effect that impacts the day-to-day practices of individual, 'independent' RECs? Or, is law now merely reflecting a long-standing everyday practice of RECs? More broadly, has anything *really* changed in how ethics 'is done' by RECs, or have the changes only been at a higher, more overtly political level of legal and regulatory architecture?

I begin to answer these questions through a historical tracing from the 1960s, with the development of RECs in the UK in the late 1960s and their scattered, at-times haphazard entrenchment as health research regulators in the 1970s and 1980s. Following this, I explore the formal establishment of LRECs in 1991, MRECs in 1997, and the earlier incarnation of the central regulatory bodies (COREC and NRES) that sought to manage them, particularly in England. I then discuss the creation of three important regulatory instruments in the early 2000s—the *Research Governance*

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[129] Mark Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Hart Publishing 2015) 26, 141.

[130] See e.g. Hemminki (n 122) 11 ('Certain features of REC work in individual countries could serve as a model for others. Streamlining of the ethics committee system in England […] [is an example].').

Frameworks from the four nations, the *Governance Arrangements for Research Ethics Committees* (GAfREC) originally issued separately in England and Scotland, and the uniform *Standard Operating Procedures for Research Ethics Committees*—all set within the backdrop of the controversial 2001 EU Clinical Trials Directive[131] and the UK's national transposition of the Directive in The Medicines for Human Use (Clinical Trials) Regulations 2004,[132] which ended the bifurcated and much-maligned LREC/MREC system and brought RECs, for the first time, within a legislative framework with imposed statutory duties. Throughout this deep historical tracing of regulatory reform in the UK across the decades (which has not been done previously), I weave in critical commentary proffered by the research community that lobbied repeatedly for regulatory reform, particularly in the 1990s and through the first decade of the 2000s. I then discuss more recent regulatory reforms such as the introduction of the online, centralised Integrated Research Application System (IRAS) in 2004; the regulatory streamlining-orientated HRA in 2011; the Health and Social Care Act 2012; the Care Act 2014; the Central Booking Service and the online HRA Assessment Review Portal (HARP) in May 2014; the harmonised *UK Policy Framework for Health and Social Care Research* that replaces the four nations' *Research Governance Frameworks*; and recent government white papers and policy papers encouraging further streamlined health research regulation. I reflect on the sometimes-troubled interaction between different stakeholders and RECs, which in turn, enables me to conclude with a reflection on the potential changing regulatory nature of RECs.

My central contention in this chapter is that while research promotion has emerged as a recent *statutory* phenomenon in health research regulation, it has existed, somewhat ambiguously, as a critical value throughout the history of RECs, appearing in various disguises. Similarly, participant protection has always been a driving value of, and role for, RECs; however, this has never been the sole, as

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[131] EU Clinical Trials Directive 2001/20/EC.
[132] The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, SI 2006/1928.

opposed to primary, concern of RECs. Indeed, RECs were created as much out of pragmatic response and political necessity, driven by concerns of organisational liability and financial harm, as they were out of concern for participant protection. Participant protection and research promotion have had an uneasy, unequal, but sustained marriage across the RECs' lifespan. And along the way, REC members have faced the challenging task of working in regulatory spaces that demand that they work with various regulatory actors and that they not only operate within the (shifting) regulatory spaces' confines, but also help shape their contours.

3.2 REC development in the UK

The notion of *ethical evaluation* of a *proposed* research study by a *committee* of people qualified in some way to assess either or both the study's methodology and ethics has long been viewed by many scholars as necessary, but not necessarily sufficient, for the successful functioning of, and public trust in, health research. RECs, it is said, reflect a well-designed if not pragmatic system of 'social control' by researchers' peers and others. As May opined in 1975: 'The primary guarantee of protection of subjects against needless risk and abuse is in the review *before* the work is undertaken. […] [I]t is the only stage at which the subject can be protected against needless risk of injury, discomfort, or inconvenience.'[133] Robertson similarly concluded in 1979: 'The [REC] is an important structural innovation in the *social control of science*, and similar forms are likely to be developed for other such controversial areas.'[134] By regulating research in an event licensing capacity—that is, by offering opinion on and ethical approval of a research study *before* it commences—RECs are seen to mitigate risks to researchers, participants, and society.

At the same, with sustained stakeholder support and growing institutionalisation through stricter forms of regulation, RECs have come to hold tremendous power

[133] William May, 'The Composition and Function of Ethical Committees' (1975) 1 Journal of Medical Ethics 23, 24 (emphasis added).
[134] John Robertson, 'Ten Ways to Improve IRBs' (1979) 9 Hastings Center Report 29 (emphasis added).

over how research is shaped—and thus, what knowledge is produced—and how the relationship between a researcher and a research participant is circumscribed. As Stark observes, ethics committees 'are empowered to turn a hypothetical situation (this study *may be* acceptable) into shared reality (this study *is* acceptable). […] [T]hey change what is knowable.'[135]

How did RECs come to hold such power? And, for the purpose of this thesis, what were the regulatory roles envisioned for RECs when they were created?

3.2.1 Pragmatic creation in the 1960s and medical profession self-regulation

Some of the first RECs in the UK were constituted following recommendations in the 'Responsibility in Investigations on Human Subjects' policy statement, published in the Report of the Medical Research Council (MRC) for 1962-63,[136] which was presented to Parliament in July 1964. However, in his ground-breaking historical study of RECs, Hedgecoe carefully details how, as a whole, they were born not out of any research scandal, but rather out of the *practical* and economic-driven necessity of British researchers to maintain funding from the US Public Health Service. Hence, many RECs arose only after the US Surgeon General's policy from 8 February 1966, announcing that all research institutions in the US *and overseas* receiving Public Health Service funds for health research would have to receive prior approval from an ethics committee—a committee of the principal investigator's 'institutional associates'—based at each institution, and with each

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[135] Stark (n 123) 5.

[136] Medical Research Council, 'Responsibility in Investigations on Human Subjects' in Medical Research Council, *MRC Annual Report, 1962-63*. Cmnd 2382 (HSMO 1963) ('In the opinion of the Council, the head of a department where investigations on human subjects take place has an inescapable responsibility for ensuring that practice by those under his direction is irreproachable. […] In regard to any particular type of investigation, only a small group of experienced men who have specialized in this branch of knowledge are likely to be competent to pass an opinion on the justification for undertaking any particular procedure. But in every branch of medicine specialized scientific societies exist. It is upon these that the profession in general must mainly rely for the creation and maintenance of that body of precedents which shall guide individual investigators in case of doubt, and for the critical discussion of the communications presented to them on which, the formation of the necessary climate of opinion depends').

committee determining what would constitute ethical research.[137] RECs were thus created as a pragmatic compromise to events unfolding in different locales and to concerns by different actors about the smooth operation of medical research and maintaining (or increasing) funding for it. The Thalidomide scandal of 1962 and Maurice Pappworth's exposés (to be discussed) had little impact on regulatory development.[138] As will be seen, the defining feature of REC creation in the UK was the maintenance of the medical profession's self-regulation.

Many more RECs were created after a July 1967 report from a committee of the Royal College of Physicians of London (RCP), which recommended that each competent authority (e.g. Board of Governors, Medical School Council, Hospital Management Authority) in medical institutions should ensure 'that all projects involving experimentation on humans' be approved by 'a group of doctors including those experienced in clinical investigation'.[139] The RCP report was careful to warn that:

> [I]t is of great importance that clinical investigation should be free to *proceed without unnecessary interference and delay*. Imposition of rigid or central bureaucratic controls would be likely to deter doctors from undertaking investigations, and if this were to happen, the rate of growth of medical

[137] US Public Health Service, 'Memo to the Heads of Institutions Conducting Research with Public Health Service Grants from the Surgeon General', 8 February 1966 (Department of Health, Education and Welfare 1966); Hedgecoe, '"A Form of Practical Machinery"' (n 52); Adam Hedgecoe, 'Scandals, Ethics, and Regulatory Change in Biomedical Research' (2017) 42 Science, Technology, & Human Values 577. See also Jenny Hazelgrove, 'British Research Ethics after the Second World War: The Controversy at the British Postgraduate Medical School, Hammersmith Hospital' in Volker Roelcke and Giovanni Maio (eds), *Twentieth Century Ethics of Human Subjects Research: Historical Perspectives on Values, Practices, and Regulations* (Franz Steiner Verglag 2004) (arguing that RECs in the UK were first born out of reaction to external criticism from Maurice Pappworth and the Patients Association, among others, and had the chief motivations of protecting the reputation of the medical profession and maintaining medical control of research).

[138] Duncan Wilson, *The Making of British Bioethics* (University of Manchester Press 2014) 44-51.

[139] Max Rosenheim, 'Supervision of the Ethics of Clinical Investigations in Institutions: Report of the Committee Appointed by the Royal College of Physicians of London' (1967) 3 British Medical Journal 429, 430.

> knowledge would inevitably diminish with resultant delay in advances in medical care.[140]

At the same time, the RCP recognised that 'it has now become necessary for a procedure to be available for the ethical guidance of clinical investigators. The provision of such guidance would not only serve to allay understandable anxiety in the public, but would be appreciated by clinical investigators, themselves, when faced with ethical problems.'[141] The then Ministry of Health widely circulated the RCP report, providing it a form of regulatory approbation, albeit from some distance. These early RECs were constituted only to give guidance to staff in hospitals or similar institutions. The RCP report 'deliberately' did not give specific guidance on the structure or functioning of such committees since it considered that what might be appropriate in one institution might be inappropriate elsewhere:[142] according to the RCP committee, 'the way in which this could best be organised must vary with different institutions'.[143] A green light was given in regulatory instruments for local ways of operating RECs, as determined by the medical profession.

Pappworth's book, *Human Guinea Pigs*, was published in 1967, which, similar to Henry Beecher's article a year prior,[144] laid out damning evidence of unethical research carried out in the UK and other jurisdictions.[145] Pappworth, an English physician, undoubtedly put his finger to the wind and sensed policy changes afoot in his country and the US. Pappworth advocated that clinical research studies

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[140] Royal College of Physicians of London, *Committee on the Supervision of the Ethics of Clinical Investigation in Institutions* (Royal College of Physicians of London 1967) 3 (emphasis added) [hereinafter 1967 RCP Report].
[141] ibid 3-4.
[142] Michael Denham, Ann Foster, and David Tyrrell, 'Work of a District Ethical Committee' (1979) 2 British Medical Journal 1042.
[143] 1967 RCP Report (n 140) 4.
[144] Henry Beecher, 'Ethics and Clinical Research' (1966) 274 New England Journal of Medicine 1354.
[145] Maurice Pappworth, *Human Guinea Pigs: Experimentation on Man* (Routledge & Kegan Paul 1967). Pappworth had earlier published a damning article on the same subject. See Maurice Pappworth, 'Human Guinea Pigs: A Warning' (1962) 171 Twentieth Century 66.

undergo prospective ethics committee review by physician-researchers' peers, with committees at each hospital board being responsible to the General Medical Council, which in turn would be answerable to Parliament. His book meant to ensure those policy recommendations were robust and implemented, but few in government listened. While his work 'alerted the public to the ethical issues associated with clinical experiments, and contributed to a broader critique of professional expertise, it had little impact on the governance of medical research or treatment'.[146] Changes were soon to come, but only when the self-regulating medical profession deemed it necessary in light of political and economic interest. The value of Pappworth's and Beecher's exposés is that they augmented the general public malaise with research oversight on both sides of the Atlantic. As the US and UK were both undergoing rapid economic expansion in the post-war era, health research and science were seen as key drivers of progress and prosperity. But progress and prosperity could only be sustained by a robust regulatory system that garnered public trust and avoided scandal. In response—and when the profession felt it had to act to retain its power—the era between the late 1960s and early 1970s was marked by revolutionary regulatory enactments.

The Ministry of Health issued its first circular on RECs—HM(68)33: 'Supervision of the Ethics of Clinical Investigations'—in May 1968 to Regional Hospital Boards, Hospital Management Committees, and Boards of Governors, and referred to the earlier reports of the MRC and RCP. HM(68)33 recommended that hospitals should establish ethics committees, tellingly termed 'informal advisory bodies'. As Gilbert and colleagues observe of this development, hospital 'authorities were not legally required to establish ethics committees, and the committees were offered no formal legal status. No specific guidelines on practices and methods were given because it was thought that strict rules of conduct would not be adaptable to local needs.'[147] And as Hedgecoe observes, the Ministry of Health seemed content to rely on the

[146] Wilson (n 138) 50.
[147] Claire Gilbert, Kenneth Fulford, and Chris Parker, 'Diversity in the Practice of District Ethics Committees' (1989) 299 British Medical Journal 1437.

RCP as a form of 'proxy' to ensure the spread of RECs, but the RCP's powers were limited, not least in compelling REC creation at each hospital and ensuring that hospitals (and hence the NHS and its Ministers) took legal responsibility for RECs' decisions:

> It is not that RECs were not a form of self-regulation, but rather that this informal status was less the result of *laissez-faire* "drift" on the part of the policy makers than a deliberate, *active* decision to dissociate these committees from NHS bodies and thus help preserve the idea of clinical autonomy.[148]

Following the request of the Chief Medical Officer in 1971 for analysis of the supervision of the ethics of clinical research in hospitals and other institutions,[149] in July 1973, a further report was published by the RCP that provided details of the recommended composition and scope of ethics committees,[150] including a call for 'experienced clinicians with a knowledge of clinical research investigation' and a recommendation that 'there should be a lay member'.[151] The report stated that 'supervision' of research ethics in an advisory role should normally be the sole function of the committee rather than as a police watchdog, and that applications should be made to an ethics committee for *all proposed* clinical research investigations, including trials of drugs approved under the Medicines Act 1968 and teaching demonstrations on students.[152] The report stated that the object of ethics committees was 'to safeguard patients, healthy volunteers and the reputation of the profession and its institutions in matters of clinical research investigation'.[153] Further, it recommended that ethics committees 'be small and they must not be so

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[148] Hedgecoe, '"A Form of Practical Machinery"' (n 52) 350.
[149] Apparently, the Chief Medical Officer, Sir George Godber, was responding to external pressure, foremost from the Patients Association, to inquire into allegations of unethical research practices in teaching practices. See Hazelgrove (n 137) 193.
[150] Royal College of Physicians of London, *Committee on the Supervision of the Ethics of Clinical Research Investigations in Institutions* (Royal College of Physicians of London, 1973) [hereinafter 1973 RCP Report]. As with the RCP's 1967 report, the text of the report itself also runs two pages. See also Editorial, 'Guardians of Ethics' (1973) 4 British Medical Journal 502.
[151] Editorial, 'Guardians of Ethics' (n 150).
[152] Editorial, 'Local Ethical Committees: Council Approves Revised Report' (1981) 282 British Medical Journal 1010.
[153] 1973 RCP Report (n 150) 3.

constituted as to cause an unreasonable hindrance to the advancement of medical knowledge'.[154]

This was the first clear regulatory statement in the UK of the role of RECs in protecting participants, but one notices immediately that the aim of protecting participants and 'public safety' is considered *as important* as that of protecting researchers and institutions and 'improving rather than blocking' research. What is unclear is how exactly these two concerns of protecting participants and not unduly hindering the advancement of medical knowledge were to be reconciled by committees. Regardless, this view towards safeguarding the medical profession's reputation and improving research while protecting participants seems to have aligned well with what REC members considered their aims to be: protecting participants but not stifling research. In a 1979 article, members of one REC stated:

> The ethical committee decided it had three main aims: firstly, to ensure that the highest ethical standards are maintained during research investigation on man *while ensuring that, at the same time, research is not stifled*; secondly, to ensure the protection, safety, and well being of the patient or volunteer, whether or not the procedure is to be of benefit to him; and, thirdly, to ensure that subjects are fully informed about any research that affects them and also that consent is properly obtained.[155]

The RCP's 1973 report was evidently endorsed and promoted by the government. In June 1975, HM(68)33 was replaced by HSC(IS)153: 'Supervision of the Ethics of Clinical Research Investigations and Fetal Research', which emphasised that 'all proposed clinical investigations should be referred to an ethical committee'.[156] That same year, a new version of the *Declaration of Helsinki* was released and for the first time mentioned RECs: 'The design and performance of each experimental procedure involving human subjects should be clearly formulated in an

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[154] ibid.

[155] Denham, Foster, and Tyrrell (n 142) 1043 (emphasis added).

[156] Department of Health and Social Security, 'Supervision of the Ethics of Clinical Research Investigations and Fetal Research', HSC(IS)153 (DHHS 1975).

experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.'[157]

By the late 1970s, RECs were a well-established feature at hospitals, but it became apparent that their remit should expand to cover much of the health research occurring outside of hospitals as well, given the growth of research in universities and stand-alone research sites. As early as 1974, the NHS was reorganised such that area health authorities[158] became responsible for clinical research conducted in all premises under their control, so many RECs began to consider research projects in the wider community and not just in a hospital. Some changed their name to reflect the larger district area and independence from any hospital.[159] As a 1981 editorial in the British Medical Journal (BMJ) reported: 'It is now apparent that the ethical committees, which were set up to review hospital-based research, should have a wider composition and cover research in all fields of medical practice.'[160] Taking a cue from these regulatory developments, funders such as the MRC began to make it a condition of funding that researchers have local ethics committee approval for research involving clinical trials and for investigations involving human subjects, whether conducted within or outwith a hospital.[161] These local RECs that sprang up across the country continued to have wide latitude to interpret whether a research project was ethically acceptable. The meta-regulatory question that would soon arise was whether development of RECs should be spearheaded by the government or by the medical profession. Should self-regulation by the medical profession continue relatively unabated under the guise of clinical autonomy, or should the

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[157] World Medical Association, *Declaration of Helsinki* (WMA 1975) Principle I.2.
[158] Health authorities are bodies established by the NHS to oversee health matters for the population of a defined area.
[159] Denham, Foster, and Tyrrell (n 142) 1043. Some scholars in the 1970s advocated the institutional independence and wider geographic scope of RECs. See e.g. JC Garnham, 'Some Observations on Informed Consent in Non-Therapeutic Research' (1975) 1 Journal of Medical Ethics 138, 144.
[160] Editorial, 'Local Ethical Committees' (n 152) 1010.
[161] Ian Thompson and others, 'Research Ethical Committees in Scotland' (1981) 282 British Medical Journal 718.

government begin to enact stronger forms of regulatory control? As we will see, the response in the 1980s reflected the same tone as the previous decades, if not more so: strong self-regulation by the medical profession and the absence of centralising, state-led regulatory control.

3.2.2 Limited regulation through the 1980s

By the early 1980s, RECs were established as 'satellite regulators' of health research in multiple countries, as recommended by international guidance such as the *Declaration of Helsinki* and the 1982 *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, published by CIOMS in collaboration with the World Health Organization (WHO). The RCP's report from 1973 was superseded in 1984 with its now well-known *Guidelines on the Practice of Ethics Committees in Medical Research* (RCP Guidelines).[162] As already noted in Chapter 2, the RCP Guidelines stated that RECs were 'to facilitate medical research in the interest of society' and 'to protect subjects of research from possible harm'.[163] No mention was made of the value of participant protection ranking above the value of facilitating medical research. The RCP Guidelines were seen as the best 'effective standard for RECs in the UK,[164] and, apparently, they were needed. As early the late 1970s—little more than ten years after many RECs were created—the research community maligned both the rapid growth and complexity of RECs, as well as the inconsistency in their operations in part due to reorganisations of the NHS.[165] One commentator lamented:

> Decentralisation of the management of the NHS locally organised research scheme was intended to enable regional health authorities to develop arrangements best suited to their local circumstances [but] [t]he variations in

[162] Royal College of Physicians, *Guidelines on the Practice of Ethics Committees* (n 93).
[163] ibid 1.
[164] McNeill, *Ethics and Politics of Human Experimentation* (n 14) 67.
[165] Denham, Foster, and Tyrrell (n 142); Thompson and others (n 161); BT Williams, 'NHS Locally Organised Research Scheme: Regional Research Committees and the Way They Work' (1978) 1 British Medical Journal 85; Ethical Committee, University College Hospital, 'Experience at a Clinical Research Ethical Review Committee' (1981) 283 British Medical Journal 1312; Pauline Allen, W Estlin Walters, and AM McGreen, 'Research Ethical Committees in 1981' (1982) 17 Journal of the Royal College of Physicians 96.

> the structure and practice of regional research committees suggest […] that differing standards of adjudication and review may also have resulted.'[166]

Similarly, Thompson and colleagues' survey of 34 RECs in Scotland in 1980 found that:

> In their present form research ethical committees do not satisfy fully the interests of the public or the research worker. There is inadequate representation of lay interests at all levels, and with most committees maintaining strict confidentiality over their proceedings there is little other scope for public accountability. The limited use of expert assessors and capricious monitoring leave the research worker in a state of uncertainty. […] The committees provide only limited safeguards for patients and research workers, and more effective, standardised procedures are [needed].[167]

In 1982, Lewis remarked that while the establishment of RECs was 'in many ways […] an excellent thing' because it 'restrains the over-enthusiastic researcher and provides protection to those who take part in research both as subjects and investigators', there were a 'number of negative aspects of the present system'.[168] Among his system-level concerns was the 'institutionalisation of ethics' in medical research whereby in approving a study the REC agrees 'to shoulder a portion of the investigator's responsibility', meaning the researcher 'has a measure of responsibility lifted from him and begins to act as if his actions were directed by a higher authority': 'In the state of devolved responsibility between the committee and the investigator, each can push its ethical responsibilities off onto the other.'[169] Lewis also voiced concern about the procedural nature of RECs, commenting that they were 'by nature bureaucratic and process applications using guidelines which tend to become stereotyped'.[170] Most troubling about this bureaucracy was that 'most, although not all' RECs 'insist that every subject taking part in research

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[166] Williams (n 165) 87.
[167] Thompson and others (n 161) 718, 720.
[168] Peter Lewis, 'The Drawbacks of Research Ethics Committees' (1982) 8 Journal of Medical Ethics 61.
[169] ibid 61-62.
[170] ibid 62.

projects gives informed consent to the research in writing'.[171] For Lewis, there were some circumstances (namely trials comparing two accepted therapies for patients with a fatal disease) where written consent could 'be distressing to the subjects and hence […] the antithesis of "ethical".'[172] As Lewis rhetorically asked: 'Why should the research ethics committee, *which is there primarily to protect subjects*, insist on a procedure which cannot benefit a patient but which can only cause harm? The answer is really administrative convenience, rigidity of procedure.'[173]

Concerns were also raised about the inconsistency and randomness of RECs, in part a symptom of the self-regulatory, clinical autonomy paradigm long-espoused by the government. By the late 1980s, Gilbert and colleagues noted that RECs seemed to spring up haphazardly and idiosyncratically across the country: some within hospitals, others independently but with responsibility to a district health authority or management team that appointed them, and others within pharmaceutical companies for phase 1 clinical trial studies.[174] RECs were, in other words, operating in a hybrid regulatory space where they were seen as under-regulated regulators but themselves over-regulating health research. In part, this was due to the government's explicit position of deferring regulatory authority to the medical profession and removing regulation where they could. Hedgecoe and others have noted that in the early 1980s (and until the Clinical Trials Regulations 2004), the government deregulated areas of biomedical research such as phase 1 clinical trials to encourage more clinical trials in the country, all but removing regulatory oversight from the Medicines Division of the Department of Health and Social Security and later the Medicines Control Agency (the predecessors of the Medicines and Healthcare products Regulatory Agency, or MHRA), and placing both ethics

[171] ibid.
[172] ibid.
[173] ibid (emphasis added).
[174] Gilbert, Fulford, and Parker (n 147).

and scientific review within RECs alone.[175] While RECs could be a thorn in the sides of researchers, RECs typically were less stringent than drug regulators and certainly one less regulator from which researchers would need to secure approval.

But all the same, many commentators found the REC system Byzantine. RECs were public, private, institutional, and regional. Even though some felt confident in averring that '[e]thics committees exist to protect patients and to ensure that uninformed opinion does not hinder good clinical research',[176] the prevailing opinion was that the only common approach of RECs was to bewilder researchers and stifle research. Few were clear as to the remit and scope of their review, much less the standards by which they undertook evaluation of a research proposal. The RCP Guidelines were revised in 1990, but it had become apparent to many in the research community that under-regulated, inconsistent RECs were too damaging to research, despite the fact that most REC members were researchers or clinicians themselves, and guidance from the RCP encouraged them to facilitate research. Guidelines were not enough, many felt; it was time for the government to step in and attempt to achieve some marked level consistency in how these committees were structured and how they functioned. As an editorial in the BMJ in 1990 opined, citing articles recently published by researchers in its own journal and a report published by the Institute of Medical Ethics in 1986[177]: 'evidence suggests that the ethical control of medical research remains inconsistent and ineffective', 'sensible suggestions about the structure and process of ethics committees have been widely ignored', and '[t]hirty years should have been adequate for ethics committees to get

[175] Adam Hedgecoe, 'A Deviation from Standard Design? Clinical Trials, Research Ethics Committees, and the Regulatory Co-Construction of Organizational Deviance' (2014) 44 Social Studies of Science 59, 63.
[176] David Weatherall, 'Commentary' (1982) 8 Journal of Medical Ethics 64.
[177] Institute of Medical Ethics, *Research Ethics Committees in England and Wales: The Institute's Survey* (Institute of Medical Ethics 1986, Supplement No 2).

their act together, yet there are still wide discrepancies in their constitution and working'.[178]

The problem was that no regulatory network nor central health research regulatory authority existed for distributing guidelines and standards to achieve procedural and substantive consistency,[179] and many RECs seemed to ignore the RCP Guidelines and operate as they pleased, revelling in what was little more than self-regulation and local control within a health district. Julia Neuberger's in-depth empirical investigation of RECs across the UK in the early 1990s found that it was lack of statutory regulation for RECs that caused problems, including researchers not taking RECs seriously. RECs were fundamentally disempowered regulators of research. 'RECs have not hitherto followed guidelines particularly closely', she reported, 'lack power, being advisory to [district health authorities] and other appointing authorities, and have no policing or monitoring role'.[180] Neuberger therefore concluded starkly that RECs were neutered regulators:

> However hard they work, however thorough their examination of research protocols on a case-by-case basis, however much better constituted and trained, and however well supported they may be administratively, *unless they have the power to ensure that all research is submitted to them and to stop research that they regard as unethical, they will not be taken sufficiently seriously*. For these reasons and others, this report, whilst making detailed recommendations for improvements to present practice, recommends that *there should be proper legislation*.[181]

3.2.3 Formal LREC/MREC establishment and further criticism: 1990s

On the heels of Neuberger's investigation, a degree of regulatory clarity and robustness came in August 1991 when the Department of Health issued Health Service Guideline (91)5: 'Local Research Ethics Committees', which replaced HSC(IS)153 from 1975 and formally introduced LRECs in England. (Wales and

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[178] Stephen Lock, 'Monitoring Research Ethical Committees' (1990) 300 British Medical Journal 61.
[179] Michael Gelder, 'A National Committee for the Ethics of Research' (1990) 16 Journal of Medical Ethics 146.
[180] Neuberger (n 53) 8.
[181] ibid (emphasis added).

Scotland passed their own guidelines to establish LRECs in 1991 and 1992, respectively.[182]) Hedgecoe observes that this 'marked the point where power over the shape of ethics review shifted from the medical profession (in the form of the RCP) to central government.'[183] The Health Service Guideline, colloquially referred to as 'the Red Book', stated that 'every [NHS] health district should have a local research ethics committee to advise NHS bodies on the ethical acceptability of research proposals involving human subjects'.[184] LRECs would scrutinise research projects involving patients from within the specific health authority. Thus, each LREC acted on behalf of and for the local health authority in an advisory capacity, so it was ultimately the NHS body (e.g. NHS Trust, Special Health Authority) that would decide whether a project should go ahead. However, no sanctions for non-compliance were mentioned in the Red Book and thus NHS institutions were not compelled to adopt the guidelines and institute LRECs.

This regulatory guidance and the Department of Health taking responsibility for RECs failed to quell the research community's criticism of RECs. And, arguably because the guidance was not statutory regulation as advocated by commentators such as Neuberger, RECs were still not taken 'sufficiently seriously' by many researchers.[185] Neuberger's report was written just after the Red Book's release; analysing the new guidance, she concluded that 'whilst their tone is tougher than that of previous versions, they lack the detailed discussion of the RCP guidelines'.[186] Neuberger also observed that the Red Book differed somewhat in substance from the 1990 RCP Guidelines (having superseded the original 1984 version). The Red Book suggested that multi-centre research could be approved by a single LREC, whose decision would then be accepted by other committees, but the details were

[182] See Welsh Government, Welsh Health Circular WHC(91)75; Scottish Office, Department of Health, NHS Circular 1992(GEN)3.
[183] Hedgecoe, 'Scandals' (n 137) 585.
[184] Department of Health, 'Local Research Ethics Committees', HSG (91)5.
[185] See also Hedgecoe, 'Scandals' (n 137), who argues that the Red Book was a reflection of two strands of thinking common in the 1980s: the need to standardise to protect the interests of researchers and to reduce the influence of the medical profession.
[186] Neuberger (n 53) 13.

not specified and so unsurprisingly, this never happened. Each LREC sought to approve research conducted in its health district, regardless of the outcome of reviews conducted by LRECs elsewhere. Though some RECs voluntarily entered into local arrangements to recognise other local REC decisions, this was by no means universal and rarely extended beyond a single health authority boundary.[187] The light-touch regulatory approach from the Department of Health only served to exacerbate REC differentiation across the country. By this time, there were over 200 RECs across the UK. Studies from the mid-1990s indicated that large variations in application requirements, review procedures, and opinions occurred in practice among different LRECs.[188] The level of support and accountability to their appointing authorities were equally variable.[189] Calls for a common, standardised research application form were common in medical and science journals. Despite the introduction of standard operating procedures for LRECs in 1994,[190] members of the research community continued to express discontentment with stifled health research.

The REC structure was partially modified in 1997 when new Department of Health guidelines sought to simplify the procedure for ethical review of multi-centre studies. HSG(97)23[191] required research studies conducted in the UK that involved

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[187] Clive Collett, 'Setting the Strategic Landscape for the HRA – Ethics Governance' (2013) (unpublished internal HRA paper provided to the author).

[188] George Alberti, 'Local Research Ethics Committees: Time to Grab Several Bulls by the Horns' (1995) 311 British Medical Journal 639; Paul Garfield, 'Cross District Comparison of Applications to Research Ethics Committees' (1995) 311 British Medical Journal 660; Claire Middle and others, 'Ethics Approval for a National Postal Survey: Recent Experience' (1995) 311 British Medical Journal 659; Alison While, 'Ethics Committees: Impediment to Research or Guardian of Ethical Standards?' (1995) 311 British Medical Journal 661.

[189] Collett (n 187).

[190] See Christine Bendall, *Standard Operating Procedures for Local Research Ethics Committees: Comments and Examples* (McKenna and Company 1994); Christine Bendall and J. Riddell, *Using Standards for Local Research Ethics Committees: A Guide to Using the Framework of Standards and the Standard Operating Procedures* (NHS Training Division 1994); Leigh and Baron Consulting Limited and Christie Associates, *Standards for Local Research Ethics Committees: A Framework for Ethical Review* (Department of Health 1994).

[191] Equivalent guidance was published in Wales and Scotland: DGM 98/25 and MEL 97/8, respectively. According to the original GAfREC, MRECs 'undertake the review of the ethics of the research protocol, including the content of the patient information sheet and consent

four or more LREC geographic localities (i.e. four or more health authority boundaries) to have approval from *both* a single 'MREC' in the country (out of 13 that eventually existed), and the LREC for each participating site. As a Department of Health document, the rationale for the MREC creation was to *streamline* research governance processes to improve the environment for clinical trials:

> …[the] reasons for streamlining the system for LREC review of multi centre trials [...] [are] [….] To contribute to improved clinical outcomes by approving potentially beneficial research more efficiently [….] To reduce delays to good research […] [and] [….] To avoid a large number of LRECs all devoting time to the same aspects of identical protocols.[192]

The MREC system was overseen by the NHS Research and Development Directorate (and was directly accountable to the Department of Health), whereas LRECs were overseen by regional health authorities. Research could not proceed until each LREC informed the approving MREC of its lack of objection with respect to 'locality issues', which were later specified in the first edition of the GAfREC released in September 2001. This meant that LRECs could provide advice about the local acceptability of a protocol and could reject the research protocol for 'locality issues', but could not amend the study protocol or the study instruments. One MREC approval would be valid throughout the UK; if the MREC declined to give a favourable opinion on the application, any existing approval by LRECs still stood, but those LRECs had to be informed of the MREC's decision.

Despite this regulatory change that was intended to smooth approvals for multi-site research, many researchers found that in practice, MREC approval did not

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form. No further ethical review of these items shall be undertaken by other RECs (except in the process of a "second review" […])*.*' See Department of Health, *Governance Arrangements for NHS Research Ethics Committees* (Department of Health 2001) para 8.7. Locality issues undertaken by LRECs were 'limited to': 'the suitability of the local researcher; the appropriateness of the local research environment and facilities; specific issues relating to the local community, including the need for provision of information in languages other than English'. ibid para 8.8.

[192] Department of Health, 'Review of Ethics of Multi-centre Trials', February 1995, CMO's Consultative Group on Research Ethics, RE/95/1, NPA, as quoted in Hedgecoe, 'Scandals' (n 137) 586.

necessarily lead to more efficient and cost-effective LREC approval.[193] As Collett notes:

> Many local RECs did not trust these newly-formed MRECs and were unhappy to relinquish their perceived responsibility for the *ethical* review of research projects taking place within their patch. This often resulted in lengthy delays whilst LRECs and the MREC disagreed over *ethical* issues occasionally resulting in the local REC refusing to approve the study for their local site.[194]

In summary, though RECs in the NHS system have existed sporadically and informally since the late 1960s, they had no formal standing until guidance was put forth by the Department of Health in 1991, and it must be emphasised that this was only *guidance*. Through the 20th century, then, RECs in the UK were simply ungoverned by statutory regulation. Until the 21st century, when statutory regulations were introduced that legally required REC review and approval for certain types of health research, there was no legal requirement for health researchers to obtain prior REC approval, and there was no statutory regulation that governed the practices of RECs. This is not to say that the impact of REC practices were unfelt by researchers. On the contrary, as we have seen, their impact on controlling research was profound. As Kennedy and Bates would write as late as 2003, before the national transposition of the EU Clinical Trials Directive:

> Research Ethics Committees do not have the legal status of a statutory body, with clearly defined legal powers and duties. Thus, any authority that an Ethics Committee wields is informal and extra-legal. Such authority should not, however, be underestimated. […] [A]lthough there is no clear legal obligation on a potential researcher to submit a protocol to an Ethics Committee for approval, researchers within the NHS will be denied access to patients and data without such approval. Furthermore, those who fund research ordinarily stipulate that research must be approved by a Research Ethics Committee if it is to be funded. In relation to the publication of

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[193] Rustam Al-Shahi and Charles Warlow, 'Ethical Review of a Multicentre Study in Scotland: A Weighty Problem' (1999) 33 Journal of the Royal College of Physicians of London 549; Isobel Larcombe and Martin Mott, 'Multicentre Research Ethics Committees: Have They Helped?' (1999) 92 Journal of the Royal Society of Medicine 500; Nicholas Dunn, Ann Arscott, and Ronald Mann, 'Costs of Seeking Ethics Approval Before and After the Introduction of Multicentre Research Ethics Committees' (2000) 93 Journal of the Royal Society of Medicine 511.

[194] Collett (n 187) 4 (emphasis in original).

> research, it is standard practice, at least in English journals, for editors not to publish research results if proper approval was not sought or given.[195]

RECs' informal and extra-legal authority was acute, and for many researchers, deeply troubling. Clinical autonomy and self-regulation would have to be reined in.

3.3 Centralisation and legislation in the new millennium

By the late 1990s, RECs had become an established if maligned feature in the health research regulatory space. In response to 1) criticisms that the functions and standards of RECs were imprecise and harmful to valuable research; 2) the coming into force of the EU Clinical Trials Directive; and 3) the North Staffordshire research scandal that erupted in the 1990s,[196] RECs underwent significant changes in the new millennium. They became governed by a variety of governance mechanisms—including top-down, state-led commands and controls—that sought to make them work efficiently and harmoniously, and in so doing, impacted more directly how they worked. Every few years, new guidance from the UK's Health Departments emerged to 'update' RECs to make the process smoother for researchers and more robust for the public interest, including: the establishment of the Central Office for Research Ethics Committees (COREC) in 2000; a *Research Governance Framework* in 2001; governance arrangements for RECs in 2001; the requirement for a single UK-wide REC opinion in 2004 that replaced the LREC/MREC system; standard operating procedures for RECs in 2004; an online Research Ethics Database (RED) to enable REC administrators to import application data and documentation and to process and control research applications through to the approvals stage and to record and track post-approval activity; and the creation of an online portal to submit research applications (today known as IRAS) in 2004.

Despite these many reforms, the growth of health research regulation through guidelines and frameworks that sought to make RECs more efficient, consistent, and

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[195] Ian Kennedy and Phil Bates, 'Research Ethics Committees and the Law' in Eckstein (ed), *Manual* (n 96) 15.

[196] See subsection 3.3.1 below.

robust in their processes—coupled with the passage of three major Parliamentary statutory instruments on clinical trials, human tissue, and mental capacity—led to a perception that research was just getting buried in paperwork and bureaucratic acronyms, and that RECs were getting papered over but not fundamentally reformed. As RECs were created before there was any national legal requirement for their use or adherence to a governing framework, consistency, effectiveness, and cooperation were long-standing challenges. Regulatory add-ons did not remedy the problems identified by many, or if they managed to plug the hole on one issue, others would appear. Deeper regulatory solutions were called for to solve the problems created in part by misaligned, siloed regulation itself.

Researchers were frustrated with the growing amount of bureaucracy in the system.[197] Some felt that the process of acquiring ethics approval was 'so onerous that it is compromising clinical research',[198] and that the system had become a 'rather prescriptive, bureaucratic and rigid process', with 'a fairly standardised review procedure and application form, leading to standardised research procedures.'[199] Researchers were particularly unhappy with having to obtain both REC approval and 'R&D permission' (i.e. research governance permission) from

[197] Hilary Hearnshaw, 'Comparison of Requirements of Research Ethics Committees in Eleven European Countries for a Non-Invasive, Interventional Study' (2004) 328 British Medical Journal 140; Glyn Elwyn and others, 'Ethics and Research Governance in a Multicentre Study: Add 150 Days to Your Study Protocol' (2005) 330 British Medical Journal 847; Nina Fudge and others, 'Streamlined Research Governance: Are We There Yet?' (2010) 341 British Medical Journal c4625; Andrew Thompson and Emma France, 'One Stop or Full Stop? The Continuing Challenges for Researchers Despite the New Streamlined NHS Research Governance Process' (2010) 10 BMC Health Services Research 124; Helen Snooks and others, 'Bureaucracy Stifles Medical Research in Britain: A Tale of Three Trials' (2012) 12 BMC Medical Research Methodology 122; John Barry, 'Improvements to the Ethical Review Process are Good News for Psychologists and Health Researchers in Europe, Especially in the UK' (2012) 8 Europe's Journal of Psychology 1.

[198] Louise Robinson, Deborah Murdoch-Eaton, and Yvonne Carter, 'NHS Research Ethics Committees' (2007) 335 British Medical Journal 6.

[199] Sue Richardson and Miriam McMullan, 'Research Ethics in the UK: What Can Sociology Learn from Health?' (2007) 41 Sociology 1115, 1119.

each of the NHS service providers (e.g. NHS trusts) involved in their research study, as established in the second editions of the *Research Governance Framework*.

Over-regulation and a disproportionate approach to research presenting low risk were seen as the main problems. As one group of researchers intoned: 'In a risk-benefit arena that is now heavily stacked towards perceived risk, the instigators of over-regulation must bear responsibility for the real and emerging risks of a failure to deliver the potential lifesaving benefits of clinical research promptly.'[200]

Coupled with their criticisms, clinicians and researchers invoked the rhetoric of research 'promotion'. For example, in a BMJ editorial in 2000, the then-President of the RCP insisted the REC system needed to be improved as it was obstructing 'research that will in the long run improve health care and health'—which was one of the 'two major functions' of a REC, along with protecting participants and the public from possible harm.[201] This positioning was strategically important, as continuing to frame RECs as carrying *two equally important* roles would enable the research community, including the powerful and politically connected RCP and AMS (Academy of Medical Sciences), to lobby the UK government for favourable changes to the research regulatory and governance structure.

In the following sections, I trace the steps of deep regulatory reform in the new millennium with a view to demonstrating that the reform was in direct response to criticisms made by the research community (and its representative bodies), and that the reform was to be led by the central government, which instantiated the dual roles of participant promotion and research promotion at the level of legal architecture.

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[200] Paul Stewart and others, 'Regulation—The Real Threat to Clinical Research' (2008) 337 British Medical Journal a1732.
[201] Alberti, 'Multicentre Research Ethics Committees' (n 112) 1158.

3.3.1 2000-2010: A series of fundamental reforms

To address the continuing concerns about the processes around ethics review, and to help RECs prepare for future implementation (in May 2004) of the EU's Clinical Trials Directive,[202] England's Department of Health established COREC in 2000. COREC's mission was to improve the system of operation of RECs and to advise the Department of Health on necessary policy requirements concerning their operation.[203] COREC took on the administrative functions for MRECs and provided management support for LRECs, including through local Offices of Research Ethics Committees (ORECs) situated across ten sites in England, with each led by a OREC Manager. The local health authorities (Health Boards and Strategic Health Authorities) remained the appointing authorities for the LRECs. While COREC acted for the Department of Health in England, it 'also provided a focus for discussion and collaboration with the relevant bodies and individuals in Wales, Scotland and Northern Ireland. It undertook most of the development work to create a common UK system' for RECs.[204] Among the procedural changes instituted by COREC early in the new millennium was the creation of a Central Allocation System in 2004, a common UK-wide ethics application form, and standard opinion letters issued by RECs. Even so, some researchers criticised the application form for being too long and cumbersome.[205]

In March 2001, the Department of Health published the first edition of the *Research Governance Framework for Health and Social Care* (RGF), which set forth a quality and accountability framework within which research was to be undertaken in the

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[202] Directive 2001/20/EC. The Clinical Trials Directive, under Article 6 in particular, required member states to establish RECs and have RECs approve clinical trial protocols. According to Article 7, for multi-centre clinical trials limited to the territory of a single member state, member states had to establish a procedure providing, notwithstanding the number of RECs in its territory, for the adoption of a *single opinion* for that member state. In the case of multi-centre clinical trials carried out in more than one member state simultaneously, a single opinion would be required for each member state concerned by the clinical trial.

[203] Collett (n 187).

[204] ibid 4.

[205] Jamrozik, 'Research Ethics Paperwork' (n 115).

NHS.[206] Both the RGF and GAfREC were created partly in response to a report published in May 2000 that looked into the North Staffordshire scandal, where from 1990 until 1993, it was alleged that premature infants in North Staffordshire Hospital had been put into a controlled trial of an alternative type of ventilator without their parent's knowledge or consent.[207] Allegations of lack of consent were first raised by a group of parents in the late 1990s, when apparently they first became aware that their infants had been enrolled in the controlled trial. The controversial inquiry set up in February 1999 and the subsequent report, led by Professor Rod Griffiths, recommended a major overhaul of the way in which all clinical research was conducted in the NHS, including establishing 'formal guidance on research governance within the NHS' in the form of a *national* research governance framework,[208] as well as clear governance arrangements for RECs. The government accepted the key recommendation, and began crafting a research governance framework in 2000.[209]

Notably, the RGF reinforced the language from previous guidance documents in the UK (most notably the RCP Guidelines) that emphasised RECs should also facilitate research. But, it declared that participant protection nonetheless was '*primary*', thus ranking roles (or 'responsibilities') previously treated equally under the RCP Guidelines:

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[206] Scotland and Wales published a similar RGF that same year. Northern Ireland did not publish its first RGF until 2006.

[207] The RGF also built on several documents published to support the government's modernisation agenda of the NHS. See e.g. Department of Health, *The New NHS: Modern; Dependable* (Department of Health 1997).

[208] NHS Executive West Midlands Regional Office, *Report of the Review into the Research Framework in North Staffordshire Hospital NHS Trust* (NHS Executive 2000) para 4.1.2.

[209] Hedgecoe observes, however, that: 'The [Griffiths] panel's recommendation for the revision of research governance in the NHS was *not* an original consequence of the [North Staffordshire scandal] scandal, but rather fed into changes that were already underway, and indeed were in part shaped by broader regulatory changes at a European level […], rather than a national research scandal.' See Hedgecoe, 'Scandals' (n 137) 589. In other words, the Department of Health was already beginning to develop a research governance framework; the Griffiths report simply provided further impetus for regulatory reform.

> Their primary responsibility is to ensure that the research respects the dignity, rights, safety and well-being of individual research participants. They should also work efficiently to facilitate the good conduct of high quality research that offers benefits to participants, services and society at large. Unjustified delay to such research is itself unethical.[210]

Elsewhere, the RGF also identified RECs as holding two 'key responsibilities', namely: 'ensuring that the proposed research is ethical and respects the dignity, rights, safety and well-being of participants'; and 'assuring the scientific quality of proposed research'.[211]

Working with COREC, the Department of Health also released in July 2001 its *Governance Arrangements for NHS Research Ethics Committees* (GAfREC), which replaced the previous guidance issued under cover of HSG(91)5 (which established LRECs) and HSG(97)23 (which established MRECs). Scotland published an equivalent GAfREC in October that same year.[212] Sensing that MRECs and LRECs were not operating efficiently, the GAfREC were drafted as guidance to provide 'a standards framework for the process of review of the ethics of all proposals for research in the NHS and Social Care which is efficient, effective and timely, and which will command public confidence.'[213] Meant to be read in conjunction with the RGF, the 34-page GAfREC (and its subsequently longer version published in 2011) set out 'general standards and principles for an accountable system of RECs'.[214] Seeking to create a comprehensive national system of RECs, the GAfREC stated that RECs provide 'independent *advice* to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for research studies comply with recognised ethical standards',[215] 'offer an opinion

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[210] Department of Health, *Research Governance Framework for Health and Social Care* (Department of Health 2001) para 3.12.2.
[211] ibid 20.
[212] Scottish Government Health and Wellbeing Directorate, *Governance Arrangements for NHS Research Ethics Committees in Scotland* (Scottish Government Health and Wellbeing Directorate 2001).
[213] GAfREC (n 1) Preface.
[214] ibid.
[215] ibid para 2.1 (emphasis added).

on research within the NHS',[216] and, ever-careful to preserve their independence, 'are advisory committees to, not subcommittees of, NHS organisations'.[217] While the GAfREC did not require RECs to undertake scientific review and consideration of the potential relevance of applicable laws and regulations, it expected RECs to be 'adequately reassured' about the 'scientific design and conduct of the study'[218] and have 'due regard for the requirements of relevant regulatory agencies and of applicable laws.'[219] Moreover, in line with prevailing international ethics guidelines such as the *Declaration of Helsinki* and the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being*,[220] and more clearly stated than in the RGF, the GAfREC declared RECs as having 'primary' and 'secondary' responsibilities:

> RECs are responsible for acting *primarily* in the interest of potential research participants and concerned communities, but they should also take into account the interests, needs and safety of researchers who are trying to undertake research of good quality. *However, the goals of research and researchers, while important, should always be secondary* to the dignity, rights, safety, and well-being of the research participants.[221]

Together, both the RGF and the GAfREC signalled a subtle shift in the evolutionary development that was emerging in the UK. These regulatory instruments certainly did not jettison research promotion as a responsibility of RECs; rather, they clarified that the UK's RECs would be mandated with a primary role shared with RECs in other countries, and which heeded the message of international ethics guidelines, namely that in assessing the ethical acceptability of research, participant protection must always take precedence over the interests of research and researchers.

To comply with and give domestic effect to the EU Clinical Trials Directive (2001/20/EC), the UK passed The Medicines for Human Use (Clinical Trials)

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[216] ibid para 4.1.
[217] ibid para 4.6.
[218] ibid para 9.12.
[219] ibid para 2.6.
[220] Oviedo Convention (n 86) art 2.
[221] GAfREC (n 1) para 2.3 (emphasis added).

Regulations 2004,[222] operative from 1 May 2004. Ushering in 'root and branch reform' and arguably marking 'the end of the self-regulation of research ethics',[223] the Regulations established NHS RECs on a *legal* basis for the first time, providing detailed provisions on their composition and what RECs *must*, as a statutory duty, consider in preparing their ethics opinion.[224] The Regulations provided for a single UK-wide opinion for multi-centre studies. They also set a defined time period (60 days) for issuing an ethics opinion. To avoid the confusion that would result from having parallel but different operating ethics review systems, the four UK Health Departments agreed to make it a policy to apply this approach also to *all* health research within the NHS involving individuals, their organs, tissue, or data—not just clinical trials. The Regulations also established the UKECA as a legal entity, consisting of the health ministers of the four UK constituent countries. The UKECA remains the authority through which the UK government discharges its responsibilities for providing an ethics review system under the EU Clinical Trials Directive. Thus, its remit extends beyond the NHS. As mentioned in Chapter 2, the UKECA 'recognises' certain RECs to review CTIMPs.

Also in 2004, version 1.0 of the UK-wide *Standard Operating Procedures for Research Ethics Committees* (REC SOPs) was produced to meet the obligations of the EU Clinical Trials Directive for the operation of ethics committees in relation to CTIMPs. As previously mentioned, the SOPs included provision for a single UK-wide ethics opinion on all types of health research, thus reducing if not eliminating

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[222] The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) Amendment 2006, SI 2006/1928. The amended Regulations were intended to give domestic effect to the EU's Good Practice Directive (2005/28/EC).

[223] Susan Kerrison and Allyson Pollock, 'The Reform of UK Research Ethics Committees: Throwing the Baby Out with the Bath Water?' (2005) 31 Journal of Medical Ethics 487.

[224] See e.g. The Medicines for Human Use (Clinical Trials) Regulations 2004 reg 15(5). This said, the first statutory regulation to establish a REC was The Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002 (2002 No 190), which established a REC as per section 51 of The Adults with Incapacity (Scotland) Act 2000. This REC is today referred to as the Scotland A REC. Uniquely to NHS RECs, members of the Scotland A REC are appointed by the Scottish Ministers rather than a local Health Board or the HRA.

the duplication and inconsistency in opinions rendered by RECs for multi-site studies. The SOPs obligated RECs to render a decision on any individual application within 60 days, unless the REC asked for more information (in which the case the clock stopped until that information was received).

New statutory and regulatory developments required RECs to consider the implications of research ethics in areas previously not considered or minimally considered. The Human Tissue Act 2004 was passed to govern the collection and use of human tissue (or 'relevant material' as the Act states), including for research purposes, in England, Wales, and Northern Ireland.[225] The Mental Capacity Act 2005 followed thereafter, again imposing greater responsibilities for RECs, this time for research involving adults lacking mental capacity. Organisational changes also occurred; following the Department of Health's Arm's Length Body Review,[226] the National Patient Safety Agency (NPSA) took over responsibility for COREC in April 2005.[227]

Also in April 2005, largely in response to the EU Clinical Trials Directive, the second edition of the RGF was published by the Department of Health; the three other UK nations also published their own shortly thereafter.[228] As noted by the Scottish RGF (and in language used verbatim in the Welsh and Northern Irish RGFs), and in contradistinction to the first edition of the RGF and the GAfREC, the goal of the document was to set out a 'balance' between participant protection and research promotion:

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[225] Scotland passed its own Human Tissue (Scotland) Act 2006, with different governance arrangements. The UK's Human Tissue Authority performs certain tasks on behalf of the Scottish Government, however. All NHS RECs in Scotland are recognised by the other three UK Health Departments for the purposes of the Human Tissue Act 2004, which means that a Scottish REC can give UK-wide approval for research involving human tissue.
[226] Department of Health, *Reconfiguring the Department of Health's Arm's Length Bodies* (Department of Health 2004).
[227] Existing since July 2001, the NPSA was a special health authority covering England and Wales and coordinated system-wide NHS patient safety functions. It was abolished in 2012.
[228] Scotland published the second edition of its *Research Governance Framework* in 2006; Wales followed suit in 2009 (Northern Ireland published its first edition in 2006).

> The change in the law stimulated wide debate on good practice and regulatory process in collaborative trials. The lessons drawn are visible throughout this edition [of the RGF] and recognise the need to achieve *a proper balance by safeguarding the rights of patients involved in clinical trials while avoiding a disproportionate impact on those who carry them out*.[229]

The English RGF, however, phrased its preface to the second edition differently, emphasising a risk-based regulatory approach and the need to still *primarily* protect participants:

> Regulations on clinical trials involving medicines took effect in 2004. The change in the law stimulated wide debate on good practice and *risk-based regulatory process*. We have drawn lessons throughout this edition. […] There has been new legislation on human tissue and on mental capacity, with provisions to protect those who participate in research. *Whatever the context, the interests of research participants come first*. Those responsible must be satisfied they have taken all reasonable steps to protect the dignity, rights, safety and wellbeing of participants. We have to be frank about risks, and businesslike about managing them.[230]

As clinical researchers continued to express publicly concerns that RECs were burdensome and 'impeded, delayed, and sometimes distorted research',[231] in late 2004, the UK government appointed an advisory group led by then health minister Lord (Norman) Warner to review the operation of RECs regulating research in the NHS in England. The review had explicit economic and regulation-streamlining aims. It was to consider 'regulatory blocks impeding research';[232] 'developments and trends affecting the remit, administration, operation and workload of NHS RECs in England';[233] and 'options for investment and measures to contain recurrent costs.'[234] The review was to recommend, among other things, 'how to reduce the time

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[229] Scottish Executive Health Department, *Research Governance Framework for Health and Community Care* (Scottish Executive Health Department 2006) Preface (emphasis added).
[230] Department of Health, *Research Governance Framework for Health and Social Care* (Department of Health 2005) Foreword (emphasis added).
[231] Susan Mayor, 'Advisory Group to Review NHS Research Ethics Committees' (2004) 329 British Medical Journal 1258.
[232] Department of Health, *Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees* (Department of Health 2004) 17 [hereinafter Lord Warner Report].
[233] ibid. This said, observers included representatives from Scotland, Northern Ireland, and Wales in recognition of the UK Health Departments' aim to maintain a UK-wide system for ethics review.
[234] ibid.

required of researchers starting high quality research; provide for a single point of entry, consistent process, and single decision appropriate for all the types of research requiring a NHS REC's opinion'; and 'strengthen the systems, structures and processes supporting NHS RECs to make their business process as efficient as possible and improve users' and committee members' experience of it'. The ad hoc advisory group published their report in June 2005.

Critically, this Lord Warner Report at times stressed a dual role of RECs to protect and promote: 'the role of Research Ethics Committees is *both* to protect the interests of human participants in research and to promote research that is of real value.'[235] Yet elsewhere, the report suggested that the roles were not twinned, but rather, as stated in the GAfREC, primary and secondary:

> It should remain the role of research ethical review to safeguard the rights, dignity, safety and welfare of potential human research participants by providing an independent opinion on the ethical implications of a research proposal. […] Research of relevance and good quality is essential to underpin further developments in health and social care. This gives Research Ethics Committees *a secondary role* – to facilitate ethical research.[236]

The report imposed ethical obligations on both regulators (within COREC and RECs) *and* researchers:

> Just as the process of research ethics appraisal needs to be better focused and more efficiently carried out, so too researchers, and the research community more broadly, have a responsibility to work towards being better informed about ethical issues – including the importance of good quality medical research and the need to protect potential participants, and the relevant legal and governance responsibilities.[237]

The Lord Warner Report noted that 'many of the criticisms' they heard from researchers 'reflect pent-up frustration with the operation of the REC system over a number of years, and do not always take account of improvements that COREC has introduced more recently.'[238] Thus, 'major improvement in the efficiency of the

[235] Lord Warner Report (n 232) para 2.6 (emphasis added).
[236] ibid, Conclusions, paras 1-2 (emphasis added).
[237] ibid para 2.5.
[238] ibid para 2.5.

process of ethical review in the very recent past […] has not yet been fully appreciated'.[239] Nonetheless, the report acknowledged that some criticisms were valid, including unexplainable inconsistencies among RECs and overcapacity of RECs (i.e. too many RECs 'with very small workloads'[240]). Systemic reform was urged: 'The achievements of the ethical review system attained so far, whilst impressive, have been largely incremental. The time has now come for a step change in the system of RECs, to address perceived weaknesses in the system, and provide better support for Chairs, members and administrative staff.'[241] Among the report's nine recommendations were further rationalisations of the number of RECs in England, 'with more intense operation for the smaller number resulting';[242] the creation of 'Scientific Officers' in COREC to support the work of RECs;[243] improvements to the national application form and application process; improvements to quality assurance and training; substantial improvement to local R&D procedures and their interaction with REC review; and a more proportionate review process, i.e. excluding from REC review 'surveys or other non-research activity if they present no material ethical issues for human participants'.[244]

Following the Lord Warner Report, in August 2006 COREC release its response publication, *Building on Improvement*, based on consultation with stakeholders. COREC highlighted its role both to facilitate research and help RECs protect participants.[245] The report supported pilot screening studies through early provision of advice, reviews proportionate to the level of risk presented by a study, the establishment of REC centres within certain geographic areas of England, and a reduction in the number of RECs in England to 120 by 2006, with further

[239] ibid, Conclusions, para 4.
[240] ibid para 3.6.
[241] ibid 15.
[242] ibid para 11.
[243] Crucially, this recommendation was implemented in Scotland only.
[244] ibid, Recommendation, para 1.
[245] Central Office for Research Ethics Committees, *Building on Improvement: Implementing the Recommendations of the Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees* (National Patient Safety Agency 2006) [hereinafter COREC Report].

rationalisation thereafter.[246] The COREC report also recommended removing the nominal distinction between MRECs and LRECs, and that MREC appointing authorities be transferred to be in line with those for LRECs.[247] Though the COREC report did not take up the Lord Warner Report's recommendation to establish Scientific Officers, it did recommend the creation of a 'new independent group of national research ethics advisers' who would:

> […] ensure that full committees consider only those studies needing intensive scrutiny. They will be able rapidly to review studies with minimal ethical dimensions as an executive research ethics sub-committee. In England, one or more of these sub-committees will specialise in streamlined review. National research ethics advisers will also be able to support the development of the service by providing training, advice and feedback to RECs and applicants.[248]

The COREC report, like the Lord Warner Report and the Cooksey Review from December 2006 on UK health research funding,[249] signalled an explicit governmental effort to streamline extant regulations and make the regulatory approvals and governance process smoother for researchers to promote high-quality research and national economic benefit.

Several substantial operational and procedural developments occurred within and outwith RECs following COREC's 2006 report to improve the research landscape and ethics review service, and respond to concerns outlined above that RECs were under-regulated but, ironically, also burdensome from a regulatory perspective.

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[246] 'The number of RECs in England has reduced from 195 in April 2003, to 175 in April 2004 and 155 in April 2005. The proposed changes would result in 120 RECs operating from 17 REC centres by December 2006.' COREC Report (n 245) para 2.7.2.
[247] In practice, the distinction between MRECs and LRECs ended in 2004, but many RECs still maintained the nominal titles for a number of years thereafter.
[248] COREC Report (n 245) 8. This recommendation was never implemented. In 2012, the HRA ran an HRA Ethics Officer Pilot, but, as discussed in Chapter 6 of this thesis, it was never rolled out due to internal concerns about how it was structured. More recently, the HRA has contemplated rolling out a 'REC Application Review and Advice Service', but this appears to be on hold. Currently, the HRA provides online decisional 'toolkits' and the possibility for email queries to HRA staff. See Health Research Authority, 'Seek Advice and Support' <http://www.hra.nhs.uk/research-community/before-you-apply/seek-advice-and-support/>.
[249] Sir David Cooksey, *A Review of UK Health Research Funding* (HMSO 2006).

First, in April 2006, the UK government established the National Institute for Health Research (NIHR) to better fund and support clinical and applied health and social care research, as well as research infrastructure in the NHS. While not directly impactful on RECs, the creation of NIHR signalled the government's intention to position health research as a key driver of the UK's economy. This, in turn, necessitated reforming other elements in the research regulatory space to ensure the successful realisation of research into innovations. Second, in April 2007, the National Research Ethics Service (NRES) was established, incorporating both COREC and NHS RECs in England as a means of maintaining a UK-wide regulatory framework for ethical review of research within the NHS. Third, that same year, the Shared Ethical Debate (ShED)[250] scheme was piloted, and became operational in 2008. ShED's main aim over the years has been to address consistency among RECs and develop standards in ethics review.[251] Other aims are to identify and build consensus on an ethics issue (and the need for possible guidance to applicants and REC members); identify issues in REC processes (i.e. problems regarding minutes); and identify training needs for REC Chairs and members.[252] Fourth, and along the same lines, NRES established in 2007 a three-year rolling accreditation programme to audit RECs against agreed standards as detailed in the

[250] Health Research Authority, 'Quality Assurance' <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

[251] Hugh Davies, 'Standards for Research Ethics Committees: Purpose, Problems and Possibilities' (2008) 4 Research Ethics Review 152; Peter Heasman, Alain Gregoire, and Hugh Davies, 'Helping Research Ethics Committees Share their Experience, Learn from Review and Develop Consensus: An Observational Study of the UK Shared Ethical Debate' (2011) 7 Research Ethics 13.

[252] Collett (n 187) 6. The scheme works whereby selected RECs are provided with a real research application (for which consent has been given for its use in the scheme by the investigator) to review as part of their full REC meeting. These RECs review the application as a normal application, recording the discussion and decision in the minutes. The resultant minutes are analysed and the results fed back to the participating RECs, HRA operational teams, the National Research Ethics and Advisors' Panel (NREAP), and the HRA training department in order to develop HRA policies and guidance. The Shared Ethical Debate has more recently been supplemented with a 'Single Issue Debate', whereby individual RECs are given a short series of questions to respond to concerning a topic (e.g. consent in observational studies), and the responses from the REC are sent back to the HRA for evaluation.

SOPs and GAfREC. Still ongoing as with ShED, RECs are issued with an audit decision (now by the HRA) that is either full accreditation, accreditation with conditions (low risk non-compliance identified requiring an action plan), or provisional accreditation (high and low risk issues requiring an action plan). More recently, this has been coupled with 'quality control' checks by HRA Operational Managers, who undertake six-monthly quality control checks on RECs against agreed standards. This includes an annual observation of a REC meeting. Opinions on the value of these reforms, as will be discussed, have been mixed.

Fifth, in 2009, the National Research Ethics and Advisors' Panel (NREAP) was established. NRES was originally asked by the four UK Health Departments, through the UKECA, to establish a central advisory panel to help with the strategy, quality assurance, and service development of RECs and improve the research environment in the UK.[253] NREAP remains an independent body, but is hosted within the HRA (previously NRES). It serves as a resource to provide advice and support to all RECs funded by the UK Health Departments,[254] as well as appointing authorities in exercising their responsibilities under the GAfREC and SOPs.[255]

Sixth, in 2010, following the earlier pilot study from 2009 based on the recommendation from the Lord Warner Report, the Proportionate Review Service was introduced across the UK. This 'PR' service, as it is called, allows researchers

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[253] Collett (n 187) 6.
[254] Health Research Authority, 'The National Research and Ethics Advisors' Panel (NREAP)' <http://www.hra.nhs.uk/about-the-hra/our-committees/panels-and-advisory-groups/>.
[255] Until February 2017, NREAP was comprised of eight members and was named the National Research Ethics Advisors' Panel; in March that year, NREAP was renamed and reformed to become the National Research and Ethics Advisors' Panel. Instead of being composed of eight ethicists, it now consists of nearly 50 people with expertise in a number of specialist areas so as to provide the HRA 'more timely and tailored input to the broad range of activities the panel will be involved in'. See Health Research Authority, 'New National Research and Ethics Advisors' Panel Starts Work' <http://www.hra.nhs.uk/news/2017/03/29/new-national-research-ethics-advisors-panel-starts-work/>.

whose studies present 'no material ethical issues'[256]—previously determined initially by the researcher (who requested to book their application for Proportionate Review), now determined by RES staff,[257] followed by REC members via a Proportionate Review sub-committee rather than at a full meeting of a REC—to not have to wait as long for a REC opinion as researchers with more 'ethically complex' studies. Indeed, the aim of PR is to deliver the final opinion letter to the applicant within 21 calendar days of receipt of a valid application.

Finally, a key infrastructural change in the first decade of the millennium was the move in 2008 of the NRES online form to the Integrated Research Application System (IRAS),[258] the online application system used to apply for most permissions and approvals for research in health and social care in the UK. In May 2014, IRAS was further modified to interact with the newly established REC Central Booking System and, for the first time, to allow for electronic submission of applications.[259] IRAS is seen as providing multiple benefits for researchers, not the least of which is streamlining the research application process by enabling researchers to enter information about their study once instead of duplicating information in separate application forms. Other benefits include using filters to ensure that the data collected and collated are appropriate to the type of study, and consequently the permissions and approvals required; and helping researchers meet regulatory and governance requirements. IRAS allows researchers to use a 'Project Filter' to select the type of research and enable other sections and forms relevant to their project

[256] The HRA defines 'no material ethical issues' as having 'minimal risk, burden or intrusion for research participants'. See Health Research Authority, 'Proportionate Review - Information and Guidance for Applicants' <http://www.hra.nhs.uk/documents/2017/01/proportionate-review-information-guidance-document.pdf>. Evaluation of Proportionate Review suitability is done by Central Booking Service, REC Managers, and the REC Proportionate Review sub-committee.

[257] Health Research Authority, 'Proportionate Review - Information and Guidance for Applicants' (n 256).

[258] IRAS <https://www.myresearchproject.org.uk/>.

[259] Previously, researchers would have to book a meeting with a REC by calling into one of three telephone services depending on the type of research study (Local Allocation System, Central Allocation System and Proportionate Review Allocation System), and then mailing their application to the REC.

(e.g. ionising radiation, new/existing tissue samples, adults unable to consent) to appear. The IRAS NHS REC application form, and especially the questions it poses to researchers, has become central to the work of RECs, as will be seen in Part III.

3.3.2 Ongoing criticisms and the critical AMS 2011 report

At this point in the historical tracing, it would be beneficial to step back and situate the criticisms of and reforms to RECs in a broader context. If many in society support the concept of prospective ethics review of a research study by a committee of qualified people, many others have not supported the past practices of RECs. For as long as they have existed, RECs have been the source of opprobrium by the research community and other commentators, mainly because they are seen as under-, over- or simply mis-regulated bureaucratic bulwarks against otherwise ethical, minimally risky, or non-risky research. Empirical research has indicated a high level of variation of decision-making processes in RECs[260] and dissatisfaction from various stakeholders.[261]

Many of the problems encountered in RECs have been due paradoxically to accusations of both weak regulation and de-centralisation (leading to duplicative review, procedural inconsistency, and substantive inconsistency of decision-making), and also over-regulation and centralisation (leading to cumbersome rules and complex thickets of disproportionate regulation for minimal risk research). Yet unlike the US and other jurisdictions, RECs in the UK remain governed relatively lightly through statutory regulation.[262] RECs hold a long tradition of independence

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[260] See e.g. Bernard Barber and others, *Research on Human Subjects: Problems of Social Control in Medical Experimentation* (Russell Sage Foundation 1973). See also Dixon-Woods and others, 'Written Work' (n 71) 796 (noting that, in their review of REC letters to researchers, RECs 'showed significant diversity in their approaches to some issues.').

[261] See e.g. Alberti, 'Local Research Ethics Committees' (n 188); Paul Benson, 'The Social Control of Human Biomedical Research: An Overview and Review of the Literature' (1989) 29 Social Science & Medicine 1; Konrad Jamrozik, 'The Case for a New System for Oversight of Research on Human Subjects' (2000) 26 Journal of Medical Ethics 334; Richardson and McMullan (n 199); Robertson (n 134); Charles Warlow, 'Clinical Research Under the Cosh Again' (2004) 329 British Medical Journal 241.

[262] Until the Care Act 2014, The Medicines for Human Use (Clinical Trials) Regulations 2004 was the only British regulation that directly regulated RECs through law and gave them

from central or institutional control.[263] Indeed, that NHS RECs are not formally associated with any specific research institution is what distinguishes them most from US IRBs and Canadian REBs that also evaluate research involving patients in hospitals and healthy volunteers. Though RECs in the NHS system have existed sporadically and informally since the late 1960s, as discussed, they had no formal standing until guidance was put forth by the Department of Health in 1991,[264] and it must be emphasised that this was merely *guidance*, backed with no legal enforceability. Effectively, these guidelines were the standards governing their practice, though RECs had the discretion to exercise their judgement as to what their primary function should be—and indeed some did not abide by or accept the guidelines.[265] As a consequence, RECs were permitted to thrive and self-regulate independently. Across the UK, local RECs created separate fiefdoms of customs, standards, and rules that caused, it is said, administrative nightmares for researchers embarking on multi-site and even single-site studies.

A major criticism of RECs centred (and continues to centre) on their ostensibly over-bearing emphasis on information sheets and consent forms, and minute wordsmithing of both. This can lead to the inevitable elongating of the documents and increased risk of non- or miscomprehension by participants, which ironically may lead to stigmatisation of or lack of respect for participants and a failure in fact to obtain valid consent. Commentators since at least the 1960s[266] have argued that

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statutory authority (other than the Scotland A REC as per The Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002). In other words, prior to 2004 outside of the specific context in Scotland, there was simply no *legal* requirement for researchers to obtain prior REC approval. Not surprisingly, some scholars view the Clinical Trials Regulations 2004 as a watershed moment where '[t]he era of self-regulation ended'. See Kerrison and Pollock (n 223).

[263] Andrew George and others, 'Research Governance at the Crossroads' (2002) 8 Nature Medicine 99. See also Editorial, 'Local Ethical Committees' (n 152).

[264] Department of Health, HSG(91)5, *Local Research Ethics Committees*. See also 1992(GEN)3 for Scotland and WHC(91)75 for Wales.

[265] Neuberger (n 53).

[266] See e.g. Beecher (n 144) 1355 ('Consent in any fully informed sense may not be obtainable. […] A far more dependable safeguard than consent is the presence of a truly *responsible* investigator').

consent cannot and should not act as a stand-alone bulwark against unethical research. Some commentators argue, however, that RECs continue to fixate on consent and information sheets as a locus for determining and setting researchers' ethical behaviour, demonstrating 'the acme of self-defeating ritual compliance'.[267] Perhaps it is because 'these documents constitute one of the few aspects of researcher interactions with subjects – a very downstream process – that committees feel they can control'.[268] Garnett argues that a 'Standard Model' of consent thus permeates RECs, whereby through focusing on the participant's subjective state of mind, they evaluate the potential for a participant to gather sufficient information about a research study, even though this is a flawed approach: 'the informed consent "requirement" is viewed as a chore and a ritual, an impersonal incantation, a hurried signing of papers. We know this is true, yet we cherish the myth of informed consent, skating over its lack of real content or impact.'[269]

As RECs arguably have become institutionalised in the health research regulatory space and classic bureaucracies in the Weberian sense, they may be seen to increasingly focus on measureable procedures demonstrating consistency and objective, rational outcomes rather than incalculable substantive matters such as the myriad ethical issues at play in a given research study. A bureaucratic preference for procedures, rules, and standards, coupled with an uptick in legal (albeit siloed) regulation of health research—most significantly the transposing of the EU Clinical Trials Directive through The Medicines for Human Use (Clinical Trials) Regulations 2004, which was widely seen as regulatory overreach and reducing the attractiveness of the EU (and therefore the UK) for conducting clinical trials on medicines[270]—led to complaints about the legalisation in the workings of RECs,

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[267] Scott Burris and Jen Welsh, 'Regulatory Paradox in the Protection of Human Research Subjects: A Review of Enforcement Letters Issued by the Office for Human Research Protection' (2007) 101 Northwestern University Law Review 643, 678.
[268] Klitzman (n 123) 139.
[269] Richard Garnett, 'Why Informed Consent? Human Experimentation and the Ethics of Autonomy' (1996) 36 Catholic Lawyer 455, 476.
[270] The UK government remarked that it would seek 'to influence the Commission to bring forward soundly based proposals to reduce regulatory burdens in the European Clinical

which is to say: a fetishisation for more and longer forms and standards and procedures set within a positivist paradigm. This is not the 'good kind' of REC legalisation Curran envisioned in 1969, replete with a common law-like generalisable body of precedents and principles of procedure and substance that allow the process of deliberation to flourish.[271] Instead, to many it is viewed as a troubling kind—rigid and standardised, treating ethics as a tick-box, form-ridden technological and structured one-off event.

The criticism levelled against RECs can be reframed as scepticism about the primary role of participant safeguarding.[272] Some claim that the otherwise admirable protectionist function has become reduced to a formulaic exercise to ensure compliance with a plethora of regulatory requirements. Others claim that the protectionist function of RECs is inherently paternalistic and fails to represent the full interests of participants, not to mention the public interest.[273] Here, some challenge that *the other primary* role of RECs should be consensus-driven and public interest-focused, such that the scales of balance between assessing welfare and risk and scientific advance should be recalibrated to see beyond just potential risks to

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Trials Directive'. See HM Treasury, Department for Business Innovation & Skills, *Plan for Growth* (HM Treasury 2011) 54. The European Commission, clearly worried about economic repercussions and global competitiveness, has noted that the number of clinical trials conducted in the European Union fell by 25 per cent between 2007 and 2011. The European Commission remarked that 'The Clinical Trials Directive has been criticised by patients, researchers and industry alike for its disproportionate regulatory requirements. High costs and a lack of harmonisation of the applicable rules necessary for multinational clinical trials are a few examples.' The driving purpose of the EU Clinical Trials Regulation in 2012 was 'to cut red-tape and bring patient-oriented research back to Europe. The objective is to restore European Union's competitiveness in clinical research and the development of new and innovative treatments and medicines for the ultimate benefit of patients.' See European Commission, 'Proposal for a Clinical Trials Regulation - Questions and Answers' (European Commission, Memo/12/566, 17 July 2012) 1-2.

[271] At their formation in the 1960s, Harvard Law Professor William Curran held high hope that ethics committees, acting like common law courts, would achieve consistency within and between each other. See Curran (n 108) 585.

[272] cf Schneider (n 12), who argues that, at least in the US, there is no evidence IRBs have prevented harms from occurring.

[273] See e.g. Franklin Miller and Alan Wertheimer, 'Facing Up to Paternalism in Research Ethics' (2007) 37 Hastings Center Report 24.

individual participants and more towards the greater range of actors' interests at play and the societal benefit that could accrue from research. In other words, the role of RECs should be to balance or otherwise reconcile the at-times cross-competing interests of individual participants, science, and society (even if society can be viewed as an abstracted aggregate of individuals). And yet still others, invoking Goffman's dramaturgical model,[274] suggest the protectionist role may be more form than function, such that RECs inevitably serve other hidden but more realistic roles, 'the most obvious of which is *to appear* [to an outside audience] *to meet the official goal*', thereby keeping the REC above criticism and serving 'to add legitimization to the conduct of clinical research'.[275] In other words, RECs may strive to appear in the front stage to be protecting research participants, but their 'real' back stage function is to legitimatise the research enterprise—a perhaps not too-unsurprising claim if we consider that the majority of REC members are or have been researchers themselves.

There has been a mismatch between REC concept (or Platonic essence) and REC practice, and a mismatch between what we seem to have long acknowledged—for instance, that consent cannot protect against ethical lapses in health research, that it can work against protecting the dignity of participants, and that more paper does not equate to better protection[276]—and what RECs do. The response by the UK government in the last decade to the criticism against RECs and health research regulation more broadly has been to *streamline* the regulation of health research, and

[274] Erving Goffman, *The Presentation of Self In Everyday Life* (Doubleday 1959).
[275] Bradford Gray, *Human Subjects in Medical Experimentation* (Wiley 1975) 46, 53.
[276] See e.g. Adam Nishimura and others, 'Improving Understanding in the Research Informed Consent Process: A Systematic Review of 54 Interventions Tested in Randomized Control Trials' (2013) 14 BMC Medical Ethics 28; Alan Meisel and Loren Roth, 'Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies' (1983) 25 Arizona Law Review 265.

to make the regulation more *proportionate*, so as to facilitate more research and greater economic prosperity.[277]

The persistent criticism levelled against the clogged regulatory space of 'human subjects research'— i.e. not within RECs alone—was evidently (and some would add, eventually) heard by the UK government. In March 2010, the still-ruling Labour government (through the Secretary of State for Health Andy Burnham) asked the AMS, an independent body in the UK founded in 1998 that represents medical science,[278] to undertake a 'rapid independent review' of health research amid concern that strict regulation was driving research abroad.[279] The Academy convened a work group of senior doctors and scientists; only three of the nineteen members were drawn from outside the NHS or the biomedical research sector. Its now well-cited report, *A New Pathway for the Regulation and Governance of Health Research*,[280] published only several months later in January 2011, found much to criticise and sounded alarm bells: 'UK health research activities are being seriously

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[277] Jean McHale, 'Reforming the Regulation of Health Research in England and Wales: New Challenges: New Pitfalls' (2013) 1 Journal of Medical Law and Ethics 23.

[278] The London-based AMS is comprised of over 1200 elected Fellows. One of the UK's five National Academies, the AMS's mission is to 'advance biomedical and health research and its translation into benefits for society'. See Academy of Medical Sciences, 'About' <http://www.acmedsci.ac.uk/about/>.

[279] Donald Asprey, 'UK Government Asks Academy to Review Regulation of Research' (2010) 340 British Medical Journal c1770.

[280] AMS, *A New Pathway* (n 39). The report's Working group membership was chaired by Professor Sir Michael Rawlins (currently chair of the MHRA), and comprised academics, NHS Trust managers, and representatives from industry. The AMS report built on two earlier AMS reports that also called for streamlined regulation and governance procedures. A report from 2010 called for a 'proportionate, risk-based regulatory framework for medical research involving patients, which is fit for the purpose and informed by an independent review of existing regulations'. See Academy of Medical Sciences, *Reaping the Rewards: A Vision for UK Medical Science* (Academy of Medical Sciences 2010) 6. A report from 2006 called for 'more streamlined and effective procedures for research governance' involving the use of personal data, and advocated that '[i]dentifiable data can be used for medical research without consent, provided that such use is proportionate with respect to privacy and public interest benefits.' See Academy of Medical Sciences, *Personal Data for Public Good: Using Health Information in Medical Research* (Academy of Medical Sciences 2006) 21, 42.

undermined by an overly complex regulatory and governance environment',[281] it intoned, without any evidence of improved participant or patient safety.

The AMS report recommended that the UK's regulation and governance framework around health research be underpinned by four *principles*, the first two of which were 'to safeguard the well-being of research participants', and 'to facilitate high-quality health research to the public benefit'.[282] Crucially, similar to the RCP Guidelines but dissimilar to the GAfREC and first edition of the RGF, when it came to discussing recommendations for RECs, the report pinned them with two *equal* responsibilities: 'Research proposals are reviewed [by RECs] to consider whether they provide sufficient protection for the interests and safety of research participants *and* to enable ethical research that is of benefit to society.'[283]

Though RECs came away relatively unscathed in the AMS report,[284] the health research regulatory and governance environment as a whole was seen by the AMS in need of substantial pruning, including the need for 'a proportionate approach to ethics review' in line with US and Canadian approaches.[285] With respect to ethics review, the AMS report found that:

> High ethical standards in research can only be *partially achieved through regulation and governance* and researchers need support to identify and address the ethical issues arising in their research, outside of applying for an

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[281] AMS, *A New Pathway* (n 39) 5.

[282] ibid 6. The other two principles were: '3. To be proportionate, efficient and coordinated. 4. To maintain and build confidence in the conduct and value of health research through independence, transparency, accountability and consistency.' ibid.

[283] ibid 73 (emphasis added).

[284] In recognition of the changes by COREC and NRES (which undoubtedly included the introduction of Proportionate Review a year earlier in 2010), and as was acknowledged in the Lord Warner Report a few years prior, the AMS report observed:

> NRES and its predecessor, the Central Office for Research Ethics Committees (COREC), have made substantial improvements to the process of ethics review. The development of a single UK-wide opinion has been an important success in streamlining regulatory and governance processes in the UK. […] The balance of evidence submitted to this review highlights that ethics review is rarely a rate-limiting step.

ibid 73, 76.

[285] ibid 76.

> ethics opinion. In addition to the need to embed a proportionate approach within the ethics system, including implementation of 'proportionate review' following the NRES pilot, we recommend that […] NRES should lead *on improving support and advice for researchers by providing centralised, coordinated guidance and training on ethical issues for health researchers*. Institutions engaged in health research should also improve the local availability of ethics advice and the training of local support staff.[286]

Significantly, the AMS report recommended the establishment of an independent, central 'Health Research Agency' 'to rationalise the regulation and governance of all health research'.[287] It also recommended the establishment of a National Research Governance Service within the proposed HRA to perform all study-wide NHS governance (i.e. R&D) checks and recommend research projects as suitable for undertaking within the NHS. In the AMS' view, the HRA would be capable of providing 'the necessary oversight and impetus' to oversee the regulation and governance of health research, as well as 'removing complexity and streamlining the pathway as a whole'.[288] It would also provide a 'home for some aspects of regulation and governance that urgently require better coordination and clearer governance'.[289] Other recommendations included providing greater access to patient data for research while protecting individuals' interests and embedding a culture that would value research within the NHS.

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[286] ibid 79 (emphasis added).

[287] ibid 7. The AMS report acknowledged that the proposal for a 'Health Research Agency' was a development of the Department of Health's recommendation in its July 2010 report to create a single regulator of health research. The Department of Health's report noted the twin mandate of NRES to protect and promote:

> The National Research Ethics Service helps protect the interests of patients and research participants in clinical trials and facilitates and promotes ethical research. It includes recognising and authorising Research Ethics Committees, which approve individual research applications. We propose that the future of the National Research Ethics Service is considered as part of the wider Academy of Medical Science's review of research regulation with a view to moving this function into a single research regulatory body.

See Department of Health, *Liberating the NHS: Report of the Arm's-Length Bodies Review* (Department of Health 2010) para 3.63.

[288] AMS, *A New Pathway* (n 39) 100.

[289] ibid.

3.3.3 Government response: 2011 – present

The coalition Conservative-Liberal Democrat government quickly took up the AMS report's recommendation as announced that same year in its March 2011 budget statement,[290] agreeing with the report's findings and clearly emphasising the economic gains to be reaped through streamlining of regulation: 'The complexity of health research regulation and governance has increased over the last twenty years through successive legislative changes. National complexity was then compounded by diverse local approval systems, inconsistent, sometimes risk-averse, local interpretations, and confusion about the standards for compliance that apply to different types of research.' The government announced that it would:

> […] set up a new health research regulatory agency *to streamline regulation and improve the cost effectiveness of clinical trials*. […] At national level [sic], the Government will create a health research regulatory agency *to combine and streamline the approvals for health research* which are at present scattered across many organisations. *This will reduce the regulatory burden on firms, improve the timeliness of decisions about clinical trials and hence the cost-effectiveness of their delivery in the UK*, and has clear support from the Academy of Medical Sciences Review of health research regulation and governance. As a first step, the Government will establish this year a Special Health Authority with the National Research Ethics Service as its core. The new agency will work closely with the Medicines and Healthcare products Regulatory Agency to create *a unified approval process and promote proportionate standards for compliance and inspection* within a consistent national system of research governance.[291]

Thus, the HRA was established by the UK government as a central health research regulator for the UK and a one-stop-shop for approvals and accompanying guidance.[292] As recommended by the AMS, and which was presumably already in

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[290] See *Plan for Growth* (n 270) 91.

[291] ibid 92.

[292] The UK government created the HRA in part, though, because the National Patient Safety Agency had recently been abolished. See HL Deb 15 November 2011, vol 732, col GC219. This said, the HRA was expected to act more boldly than NRES and the NPSA. Baroness Thornton confirmed that:

> As noble Lords know, this order establishes the Health Research Authority to *facilitate and promote research related to the health service through the research ethics committee* that will check that research proposals meet ethical standards and will establish and appoint members to those committees. I think everybody would agree that the provenance of this initiative is the

line with the government's wishes, the HRA was created rapidly—on 1st December that same year—as an interim Special Health Authority.[293] The creating order made clear the HRA's role in promoting research:

> **Functions of the Authority**
>
> 3.—(1) The Authority is to exercise—
>
> (a) such functions in connection with—
>
> (i) the facilitation and promotion of research;
>
> (ii) the establishment of Research Ethics Committees, and the appointment and indemnification of members of Research Ethics Committees; and
>
> (b) such other functions;
>
> as the Secretary of State may direct.[294]

In May that year, the GAfREC was revised, replacing the first editions of the policy previously issued separately in England and Scotland in 2001, and also applying in Wales and Northern Ireland (indeed, this still-current edition is referred to as a 'harmonised edition').[295] Taking up the AMS report's call for a more proportionate ethics review, the revised GAfREC introduced several streamlining moves, including the removal of required REC review for certain types of research (e.g. research involving NHS staff recruited by virtue of their professional role; research

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> Academy of Medical Sciences's review, which was published in January, and that the urgency arises from the abolition of the National Patient Safety Agency. ibid col GC225 (emphasis added).

[293] The Health Research Authority (Establishment and Constitution) Order 2011, 2011 No 2323. See also The Health Research Authority Regulations 2011, 2011 No 2341. The HRA was abolished as a 'Special Health Authority' in the Care Act 2014, s 109(3), when it became a statutory body corporate (i.e. Non Departmental Public Body) as of 1st January 2015. See The Care Act 2014 (Health Education England and the Health Research Authority) (Consequential Amendments and Revocations) Order 2015, SI 2015/137 and see also SI 2014/3090. It is important to note that The Health Research Authority (Establishment and Constitution) Order 2011 applied in relation to England only. The HRA's legal remit covers England only; however, it works closely with the devolved administrations in Scotland, Wales, and Northern Ireland to support UK-wide compatibility. The Health Research Authority (Establishment and Constitution) Order 2011 defines a REC at s 1(3) as 'a group of people appointed to assess whether research proposals relating to the health service conform to recognised ethical standards'.

[294] The Health Research Authority (Establishment and Constitution) Order 2011, s 3(1).

[295] GAfREC (n 1).

limited to use of or access to a care organisation's premises or facilities). At the same time, however, the current edition of the GAfREC retains the language about primary and secondary responsibilities of RECs.

Since its formation in December 2011, the HRA's mission has been: 'to promote and protect the interests of patients, streamline regulation and promote transparency in health and social care research'.[296] Proportionate regulation[297] and streamlined research processes are a driving aim of the HRA. Through its RES and other arms, the HRA aims to 'improve and *transform* the health research process'.[298] According to its website, participant protection and research promotion are inextricably linked:

> It is already clear that there is a fundamental link between promoting the public's interests in health and social research and protecting it, and that these are complementary. Patients, participants and the public share an interest with researchers and sponsors in ensuring good, ethical research is carried out, subject to proportionate regulation. Our role in streamlining the research processes will not only increase opportunities for patients and the public to take part in research, but will also make this country a more attractive place for companies to do research. This investment will, in turn, benefit patients and the public.[299]

Emphasis on research promotion was reflected explicitly in statutory regulation for the first time in the Health and Social Care Act 2012, which imposed new duties on the Secretary of State and Clinical Commissioning Groups to promote research relevant to the NHS and to use the evidence obtained from such research.[300] Emphasis on research promotion is further reflected most pronouncedly in the most recent change in the regulatory apparatus of RECs (at least in England)—the Care Act 2014, which is a watershed piece of statutory regulation of health research.[301] It

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[296] Health Research Authority, 'Who We Are' <http://www.hra.nhs.uk/about-the-hra/who-we-are/>.
[297] The nature of 'proportionate' regulation will be discussed in Chapter 4.
[298] Heath Research Authority, 'Our Plans and Projects' <http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/> (emphasis added).
[299] Health Research Authority, 'Who We Are' (n 296).
[300] NHS Act 2006, ss 1E, 14Y.
[301] Most of the provisions in the Care Act 2014 extend only to England, save where specified otherwise. But see Care Act 2014, Explanatory Notes, Territorial Extent and Application (paras 34-54).

establishes the HRA as a non-departmental statutory body corporate (otherwise known as a Non-Departmental Public Body) to foster the HRA's UK-wide responsibility for health and social care research governance.[302] The main objective of the HRA in exercising its functions is stated in the Care Act 2014 as two-fold:

> (a) *to protect* participants and potential participants in health or social care research and the general public *by encouraging research* that is safe and ethical, and
>
> (b) *to promote* the interests of those participants and potential participants and the general public *by facilitating the conduct of research* that is safe and ethical (including by promoting transparency in research).[303]

In exercising its functions, the HRA—under the law—'must promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and it must, in doing so, *seek to ensure that such regulation is proportionate*'.[304] Elsewhere, the Act states that '[a] reference to research that is ethical is a reference to research that conforms to generally accepted ethical standards',[305] though it is unclear what 'generally accepted ethical standards' might constitute.[306] The Care Act 2014 requires the HRA and eight key regulators and government bodies to 'co-operate with each other in the exercise of their respective functions relating to health or social care research, with a view to co-

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[302] Care Act 2014, s 109. The HRA became a statutory body corporate on 1st January 2015. As Explanatory Notes for s 109 state:

> The HRA is to replace the Special Health Authority (SpHA) also known as the Health Research Authority and take on its functions, which include those relating to reviewing the ethics of research proposals in England. Like the SpHA, the HRA will have the objective of protecting and promoting the interests of actual and potential participants in health and social care research and the general public by facilitating and promoting high quality research that is safe and ethical.

[303] ibid s 110(2) (emphasis added).

[304] ibid s 111(3) (emphasis added).

[305] ibid s 110(6).

[306] One may surmise these constitute standards deriving from the ethical principles from the principlist ethical theory approach: autonomy, beneficence, non-maleficence, and justice, but this is not a certainty, and the standards from these principles are not necessarily generally accepted.

ordinating and standardising practice relating to the regulation of such research',[307] while having regard for the need (mimicking the same language in the previous section of the Act):

> (a) *to protect* participants and potential participants in health or social care research and the general public *by encouraging research* that is safe and ethical, and
>
> (b) *to promote* the interests of those participants and potential participants and the general public *by facilitating the conduct of such research*.[308]

Similarly, the Act states that the 'HRA and each devolved authority must co-operate with each other in the exercise of their respective functions relating to the regulation of assessments of the ethics of health and social care research, with a view to co-ordinating and standardising practice in the United Kingdom relating to such regulation'.[309]

The Act also speaks directly to RECs, covered under sections 112-115. The HRA is authorised by the Act to recognise, establish, and abolish RECs in England[310] and 'must ensure' that these RECs 'provide an efficient and effective means of assessing the ethics of health and social care research'.[311] In other words, the HRA now has statutory power to directly manage RECs, including for example, the power 'to require RECs to impose conditions on approvals for clinical trials'.[312] The HRA must publish a 'REC policy document' (currently the GAfREC[313]) that 'specifies the

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[307] Care Act 2014, s 111(1). These regulators or bodies are: the Secretary of State; the licensing authority for the purposes of the Medicines Act 1968; the Health and Social Care Information Centre (HSCIC, now known as NHS Digital); the Chief Medical Officer of the Department of Health; the Human Fertilisation and Embryology Authority (HFEA); the Human Tissue Authority (HTA); the Care Quality Commission; the Administration of Radioactive Substances Advisory Committee; as well as 'such person, or a person of such description, as regulations may specify'.
[308] ibid s 111(2) (emphasis added).
[309] ibid s 111(4).
[310] ibid s 115.
[311] ibid s 112(1). See also s 110(1)(b) ('The main functions of the HRA are – […] functions relating to research ethics committees.').
[312] *R (on the application of Richmond Pharmacology Ltd) v The Health Research Authority* [2015] EWHC 2238 (Admin), para 4.
[313] As the Explanatory Notes to the Care Act 2014 state at para 108:

requirements which it expects research ethics committees it recognises or establishes […] to comply with' and 'must monitor their compliance with those requirements'.[314] The HRA is also empowered to 'do such other things in relation to research ethics committees it recognises or establishes […] as it considers appropriate'.[315] Explicitly mentioned examples include: 'co-ordinate their work; allocate work to them; develop and maintain training programmes designed to ensure that their members and staff can carry out their work effectively;' and 'provide them with advice and help (including help in the form of financial assistance)'.[316]

In sum, the Care Act 2014 has explicitly imported the twinned language of participant protection and research promotion[317]—language that has graduated from RCP Guidelines, literature from the research and academic community, commissioned reports, and governmental policy—to statutory regulation governing a central regulatory body that has direct managerial oversight of RECs. It is clear that the Care Act 2014 seeks to promote the collective value of health research through the streamlining of its regulation. Certainly, this reflects a broader push by the UK government, which through its statutory and thus binding *Regulators' Code*, requires regulators to 'avoid imposing unnecessary regulatory burdens through their regulatory activities', to 'choose proportionate approaches to those they

> *Subsection (3)* [of Section 112] requires the HRA to publish a REC policy document to set out the requirements that RECs recognised or established by the HRA would be expected to comply with and must monitor their compliance. These requirements are currently set out in the Governance arrangements for RECs (GAfREC) document published by the Department of Health.

[314] Care Act 2014, s 112(3).
[315] ibid s 112(4).
[316] ibid.
[317] Albeit in language that wraps 'promotion' around the presumed 'interests' of participants and potential participants.

regulate', and to consider, among other things, 'how they might support or enable economic growth for compliant businesses and other regulated entities'.[318]

What remains unclear, however, and what must be uncovered, is how the HRA intends to 'streamline' regulation and deliver 'proportionate' regulation vis-à-vis those regulators it governs, namely RECs. The AMS report recommended that the HRA 'should lead on the development of proportionate approaches to regulation and governance that take into account the benefits and risks of a research study, rather than applying a "one-size-fits-all" model. This should be embedded through a new edition of the Research Governance Framework.'[319] As the four nations' *Research Governance Frameworks* have now been transformed into a harmonised *UK Policy Framework for Health and Social Care Research*,[320] through what mechanisms will the HRA manage RECs? In turn, will RECs heed the HRA's steering (i.e. catalysing) or rowing (i.e. controlling) role[321]—and what will be the response in the devolved nations?

Based on recent white papers and policy papers from the Scottish and English governments, there seems to be a strong degree of consistent approach in principle. The Department of Health has published several policy papers advocating further system efficiencies, such as a governmental commitment 'to simplify how research is regulated as part of our plans to increase innovation in medical science';[322] and

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[318] Department for Business, Innovation and Skills, *Regulators' Code* <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf>. The *Regulators' Code* came into statutory effect on 6 April 2014 under the Legislative and Regulatory Reform Act 2006, replacing the *Regulators' Compliance Code* issued in 2008.

[319] AMS, *A New Pathway* (n 39) 89.

[320] See Health Research Authority, 'UK Policy Framework for Health and Social Care Research' <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>. The drafting of the *UK Policy Framework* began in 2015 and was completed in late 2017.

[321] David Osborne and Ted Gaebler, *Reinventing Government: How the Entrepreneurial Spirit Is Transforming the Public Sector* (Addison-Wesley 1992).

[322] Department of Health, *Policy Paper: 2010 to 2015 Government Policy: NHS Efficiency* <https://www.gov.uk/government/publications/2010-to-2015-government-policy-nhs-efficiency/2010-to-2015-government-policy-nhs-efficiency>.

giving 'the NHS a duty to encourage medical research, so more patients have the chance to take part in clinical studies'.[323] The most recent NHS Constitution for England now reflects this, stating: 'The NHS aspires to the highest standards of excellence and professionalism […] through its commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population', and that the NHS 'pledges […] to inform you of research studies in which you may be eligible to participate'.[324]

Likewise, but even more resoundingly, the Scottish Government announced in October 2015 that while it was pleased with its nation's ethics review system, further efficiencies could be gained:

> …it is imperative that Scotland continues to lead the agenda on streamlining the approvals process and reducing bureaucracy; and there is scope for further improvement.
>
> A high percentage of ethics submissions across the UK receive a provisional opinion, requiring the submission of additional information and further ethics consideration before a full opinion is forthcoming. Many of these resubmissions could be avoided by the provision of advice to researchers prior to their submission of documents. Similarly in R&D permission early contact with, and support for, researchers can significantly reduce delay later on in the process. However much activity is focused currently on gatekeeping rather than assisting researchers, driven by the Research Governance Framework which focuses on responsibilities rather than outcomes. CSO believes that through the provision of early advice supported by a revised Research Governance Framework that recognises the importance of facilitating good research, greater efficiencies will be forthcoming in the handling of applications.[325]

To that end, the Scottish Government announced that the CSO would seek to combine the Scottish Research Ethics Service and NHS Research Scotland (NRS) R&D Offices into a 'single integrated service for researchers while retaining the independence of the REC decision making function'; that CSO would arrange for

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[323] ibid.

[324] Department of Health, *The NHS Constitution for England* <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>.

[325] Scottish Government, *Delivering Innovation through Research - Scottish Government Health and Social Care Research Strategy* (Scottish Government 2015) 11, 16.

'shared access to study data for ethics and R&D staff through the HRA's HARP database, streamlining access to electronic documents for R&D staff throughout Scotland'; that CSO would 'work with the HRA to revise the Research Governance Framework and implement an efficient ethics and R&D permission system across the UK that both builds on the efficiencies already delivered through [NHS Research Scotland] and operates seamlessly for sponsors and researchers across the UK'; and that CSO would 'refocus the early contact of ethics and NHS R&D staff with researchers on facilitating study approvals, with named R&D contacts being given to support the researcher in obtaining those approvals'.[326]

As Hedgecoe reminds us, even as the REC SOPs have allowed for some regulatory control over REC processes by the state, 'the content of REC decisions remains largely outside Department of Health control'.[327] The HRA and CSO do not have the legitimacy or statutory authority to *directly* amend statutory regulation, and the independence of NHS RECs is a highly cherished value, as reflected in the Scottish white paper mentioned above. What the HRA and CSO can do, though, is 'transform the health research process'[328] by amending regulatory instruments affecting RECs, and acting itself, or helping RECs and the actors therein act, as a steward for researchers to guide them through the *process* (i.e. the multiple stages) of embarking upon a health research study.[329] The HRA is working closely with its equivalent regulatory bodies in the devolved nations to foster education and training for REC members, staff, and the research community,[330] and harmonisation

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[326] ibid 16-17.
[327] Hedgecoe, 'A Deviation from Standard Design?' (n 175) 74.
[328] Heath Research Authority, 'Our Plans and Projects' (n 298).
[329] See AMS, *A New Pathway* (n 39) 101 (Recommendation 16: 'The Health Research Agency should support researchers and raise research standards by providing consistent advice and interpretation of legislation and a single point of contact to ensure better communication in navigating the regulation and governance pathway.'). See also Care Act 2014, s 111(3) ('The HRA must promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and it must, in doing so, seek to ensure that such regulation is proportionate.').
[330] See e.g. Health Research Authority, 'HRA Training' <http://www.hra.nhs.uk/hra-training/>.

of ethics review processes through its publishing of multiple policies and guidance documents, and (in England) with HRA Approval, which is largely an instantiation of the recommendation in the 2011 AMS report to create a National Research Governance Service with the HRA.[331] Indeed, greater harmonisation and simplification of forms is most recently manifest in the HRA's announcement in June 2017 that a combined IRAS form that merges the REC and R&D forms, previously only in place for projects where the lead NHS R&D office is based in England, is now available for use across the UK, which will save time and effort for applicants and sponsors and help build UK-wide consistency.[332] Almost certainly these arrangements will further assuage many of the concerns levelled against RECs over the years. Indeed, as this Chapter 3 has emphasised, very few criticisms are levelled against ethics review and RECs today, especially compared in the recent past to the NHS trust R&D approvals process.[333]

Consequently, the long-standing criticisms of RECs mostly have been quelled, first through influential reports authored by the research community itself in the past decade that were directly taken up by the government, and more recently, through

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[331] AMS, *A New Pathway* (n 39) 83 (advocating the creation of a 'Health Research Agency' with authority 'to include a new National Research Governance Service' for England […], which would perform all study-wide NHS governance checks and recommend research projects as suitable for undertaking within the NHS').

[332] Health Research Authority, 'Four Nations NHS/HSC Compatibility Programme: Questions & Answers on Release of IRAS Form UK Wide' <http://www.hra.nhs.uk/documents/2017/06/single-iras-form-qa.pdf>. Applications for Research Tissue Banks, Research Databases and for research projects not taking place in the NHS will continue to use the REC form.

[333] In the House of Lords debates on the Care Act 2014, the bioeconomic imaginary and regulatory competition mind-set was reflected in the comments expressed by Lord Hunt of Kings Heath:

> As regards research, again, the provisions are very welcome but there is real concern that *this country is losing out* in terms of the number of multi-centre trials that take place here. Does the noble Earl thinks that the HRA should be given more authority over both the local research ethics committees and NHS trusts in terms of R&D approval? We cannot just leave it to these different bodies when *the whole prosperity of our country is in many ways based on this kind of investment*.

HL Deb 21 May 2013, vol 745, col 823 (emphasis added).

the alignment of the research community, industry (particularly as sponsors or funders of research), and government in designing a regulatory regime that optimises competition (through efficiency and accelerated review pathways) and economic gain. This does cause one to wonder, though: how, if at all, does this next-generation regulatory reform impact the independence and primary function of RECs, which must, under the stewardship of the HRA and its mandate to streamline regulation, work to 'provide an efficient and effective means of assessing the ethics of health and social care research'?[334] As Kerrison and Pollock remarked a decade ago following the passage of the Clinical Trials Regulations 2004 and the creation of the UKECA, '…by taking control of the ethics review, a government intent on seeing biomedical research as an economic driver will be in a good position to ensure that [ethics] committees do not raise difficult ethical barriers to such research'.[335] Increased regulatory speed, coded as 'efficiency' and embedded in the regulatory documents governing RECs and in the practices of RECs, certainly begs questions about the role of industry promoting competitive edges and in the wider implications of such a regulatory feature in health research.

3.4 Conclusion

In this chapter, I have argued that while the value and REC role (or responsibility) of research promotion has emerged as a recent statutory phenomenon in health research regulation, perhaps as a kind of beacon to encourage a more proportionate or streamlined approach to regulating health research, promotion has nevertheless existed throughout the history of RECs, appearing in various disguises alongside the role of participant protection. I have also argued that having become entrenched in the regulation of health research for more than half a century, and through 'steady, incremental institutional change',[336] RECs are now governed by the government and by central regulatory agencies, administrative staff and offices,

[334] Care Act 2014, s 112(1).
[335] Kerrison and Pollock (n 223) 488.
[336] Hedgecoe, 'Scandals' (n 137) 590.

standardised forms and communications, lengthy governance arrangements[337] and SOPs—the latest version of which stands at a daunting 325 pages—up 63 pages from the previous version released one year prior.[338]

As advisory but fundamentally research gatekeeping bodies, RECs are a key node situated at the centre of the health research regulatory space, working, perhaps increasingly, with potentially competing values of participant protection and research promotion. The criticisms have been intense, historically marked by concerns of both under-regulation of RECs and over-regulation by RECs of research studies. As one REC member observed after twenty years of service:

> In the 1980s the research ethics world seemed much simpler. The Declaration of Helsinki informed our discussions and decisions, and we supplemented this when the need arose from those few guidelines that existed. We weren't hamstrung by 'Europe,' acts of parliament, regulations, and a clock obsessed set of standard operating procedures; nor were we working in a climate of constant criticism. I feel increasingly caught between a rock and a hard place as we try to protect patients from silly research and researchers from silly regulations.[339]

What we have seen in the UK is a march, aided by health research interest groups such as the AMS, towards significant regulatory reform underpinned by a neoliberal discourse stressing market rationality and economic optimisation. Hedgecoe suggests that ethics review is a form of 'professional self-regulation without a profession', where 'the overall aim of such review centers on the needs of researchers and research funders, as opposed to the idea that ethics review is driven by the need to increase protection for research subjects'.[340] This thesis will test that claim. Undoubtedly, the march towards reform has culminated recently in a turn towards the law for a facilitative remedy—as indeed law is often seen as the ultimate guide for bringing order to rough regulatory terrain. Law, seen in the Care

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[337] See GAfREC (n 1).
[338] See REC SOPs (n 37). By comparison, version 1.0, released in March 2004, stood at 182 pages.
[339] Masterton (n 115).
[340] Hedgecoe, 'Scandals' (n 137) 591-92.

Act 2014, is viewed as a beacon of clarity and power, providing the HRA a firm legal footing and a legal mandate, albeit set within a flexible framework, for streamlining health research regulation and facilitating research.

But law alone cannot provide a complete remedy to the concerns expressed by so many for so many years. Ethical judgements and the workings of these committees of diverse individuals must occupy the liminal spaces in the regulatory gap that exists between documented law and everyday practice, and in the space between protection and promotion. The Care Act 2014, GafREC, SOPs, and the *UK Policy Framework* alone cannot dictate the behaviour and everyday practices of RECs. Ethical behaviour and regulatory stewardship practised by regulatory actors must be co-produced with regulation, and regulation and ethical judgement are co-dependent. What remains unknown, though, is if these next-generation regulatory reforms signal a fundamental shift away from the instrumental, techno-rational compliance, and indeed, *gatekeeping function* that has characterised health research regulation and RECs for years, or, given their neoliberal underpinning, remain entrenched in a regime of technical solutions.

Thus, the critical questions that arise from the historically-grounded argument laid out in this Chapter 3 are as follows:

(1) What is the precise nature of the regulation that now governs RECs?
(2) In turn, what is the nature of the regulation that RECs exhibit toward research studies, and what do these everyday practices and ethical judgements by individual RECs and actors therein look like in the backdrop of recent regulatory reform at the national and international level that seeks to promote a more proportionate and streamlined approach?
(3) More broadly, what is the methodology for realising the objective—or reconciliation—of protection and promotion in practice?

In the next chapter, which opens Part II, I explain how these questions will be addressed in my empirical research guided by qualitative research methods and a

methodology informed by regulatory theory and anthropology—what I term an anthropology of regulation.

PART II—
METHODOLOGY AND METHODS

Chapter 4
Methodology—research approach, theoretical underpinnings, and analytic concepts

4.1 Introduction

Part I provided a conceptual framework and historical regulatory tracing of RECs, arguing that the roles and practices of RECs may be shifting in response to next-generation health research regulation. I showed how the previous generation of regulatory design, which was notably marked by self-regulation of health research involving participants—that is, *ad hoc* ethical peer review by fellow scientists based on local customs and guidance from the medical profession (and the RCP especially)—gradually gave way to stricter, stronger, more centralised forms of regulation, particularly through statutes, policies, and guidelines set by the government. This was done to provide better coordination and coherence for researchers, research sponsors, and publics, in large part as a response to years of criticism that generated a crisis of reputational risk to RECs, threatening their legitimacy. This was also done in response to developments in EU regulation, such as the Clinical Trials Directive. Part II situates the thesis's conceptual framework of protection and promotion and the historical tracing in the present context by sketching the possible regulatory techniques and behaviours employed by RECs and their managing regulators. Part III will consider the empirical question of whether and if so, how, these regulatory techniques and behaviours appear in practice.

This Chapter 4 introduces Part II by explaining the research approach, theoretical underpinnings, and analytical concepts that drive my thesis. Together, this is commonly known as the *research methodology*: the overall approach to a research project that is linked to a paradigm or theoretical framework. I have made a

conscious decision to separate in this Part II the chapters covering methodology and methods. As Caelli and colleagues write:

> When engaging in any qualitative research, methodology must be clearly distinguished from method. Methodology reflects the beliefs about knowledge and existence that arise from the values in the philosophic framework that is to be employed. Methodology also represents theoretical frameworks that guide how the research should proceed, and implies a concern for constructing a particular type of knowledge. […] Methods, on the other hand, refer to the tools, techniques, or procedures used to gather the evidence.[341]

Applying this insight and desire to obtain greater clarity in my own qualitative research, in Chapter 4 I discuss the methodology for the empirical investigation—my philosophical and theoretical underpinnings and analytic lenses. To make sense of my empirical data, I employ the method of thematic analysis (explained in Section 2 below), which is informed by 'sensitising concepts'[342] drawn from regulatory theory and anthropology. Specifically, I explore regulatory theory, design, and strategy, focusing on the concepts of 'regulatory space', 'decentred regulation', 'proportionate regulation', and 'risk-based regulatory approach'. These sensitising concepts add further analytic weight to the historical tracing undertaken in Part I. They also allow us to better understand the precise regulatory form *and* functions of RECs, as well as the regulatory strategies employed by RECs and other regulators of health research, which will be presented in Part III.

Part I suggested that RECs are risk-based regulators. Foremost it seems that they exercise a role of participant protection (i.e. protecting participants from harms that might manifest from a research study) largely informed by assessment of risk—and through this role they operate as key actors in the health research regulatory space,

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[341] Kate Caelli, Lynne Ray, and Judy Mill, '"Clear as Mud": Toward Greater Clarity in Generic Qualitative Research"' (2003) 2 International Journal of Qualitative Methods 6.
[342] A sensitising concept is an interpretive device and starting point for a qualitative study that draws attention to important features of social interaction and provides guidelines for research in specific settings. It serves as a background idea that informs the overall research problem. See Glenn Bowen, 'Grounded Theory and Sensitizing Concepts' (2006) 5 International Journal of Qualitative Methods 1.

controlling what research may be approved, and thus what knowledge may be produced. We discovered that since its formation in December 2011, the HRA's mission has been not only to promote and protect the interests of participants in health research, but also to 'streamline regulation'[343] of health research.

Now, we unpack these concepts in Chapter 4. The central question that will emerge from the theoretical discussion in this chapter is: what do the empirical research findings tell us about the nature of the interaction between central regulators and RECs in the health research regulatory space, and the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion? Another central question that will emerge is: do the empirical research findings reflect and validate the suggestions supplied in Parts I and II that RECs engage in risk-based regulation, and that health research regulation is increasingly streamlined and proportionate? In other words, are RECs *really* risk-based, proportionality-attuned regulators, or is something else going on, and if so, what? What might proportionate and 'streamlined' regulation mean? Is 'decentred' regulation at play in health research, whereby an array of state and non-state actors is influencing behaviours? Or, is something else occurring, such as increasingly 'centred' regulation where the state is exercising growing influence and control?

I will argue in this chapter that there are limits to what regulatory theory can tell us about 'what is going on' based on the research questions posed, and that extant research approaches (e.g. legal anthropology, socio-legal studies) do not sufficiently answer my research questions as they are commonly designed to understand law and legal practice rather than regulation and regulatory practice—fields that I have endeavoured to show are ontologically distinct. I explain the justification for going beyond regulatory theory and harnessing a novel methodological approach that I call an 'anthropology of regulation', which structures my overall empirical inquiry. I

[343] Health Research Authority, 'Who We Are' (n 296).

claim that this is both an (inter)disciplinary and a methodological development of existing anthropological and socio-legal research approaches that are currently insufficient to answer the kinds of research questions that this thesis poses. As anthropology of regulation draws explicit attention to processes, passages, and change, I further draw on the anthropological concept of liminality. Liminality thus also serves as a sensitising concept, in addition to those concepts provided by regulatory theory. Together with regulatory theory, liminality helps us to better understand the *nature* of transformations of actors within the regulatory space, the *form* of regulation in this space, as well as the *behaviours* and *experiences* of actors as they go through processes of change. In short, anthropology of regulation as an approach and field of enquiry adds explanatory power to my empirical data and to the kinds of contributions that socio-legal work might also make.

Thus, the key aim of this Chapter 4 is to explain and justify the strength of my research approach. I do this in several steps. First, I show how regulatory theory provides a solid but ultimately insufficient foundation on its own for the empirical investigation that informs this thesis. Second, I explain that there is a need for an empirically-grounded discussion of regulatory practice, but that extant socio-legal and legal anthropology approaches are also insufficient to address fully the questions raised in this thesis. Therefore, I propose an anthropology of regulation that blends the theoretical with the empirical, and which affords a methodological contribution to the fields of socio-legal studies and legal anthropology, in part by drawing attention to (regulatory) processes and change, which was illustrated in the conceptual framework and historical tracing in Part I. Together with the conceptual framework and historical tracing, and methods described in the subsequent Chapter 5 that are constructed from an anthropology of regulation, I argue that this approach, underpinned by regulatory theory and liminality, serves as a robust platform for making sense of the empirical data, as well as setting those data in a more meaningful context relative to the historical account. It offers a rich account of the steady, incremental transitions in health research regulatory practice across

time, as well as new ways of imagining the regulatory framework for ethics review of health research and of understanding how liminality provides a powerful, unique, and useful heuristic for making sense of how RECs navigate participant protection and research promotion in an era of next-generation health research regulation.

4.2 Research approach

My empirical investigation is guided by an (inter)discipline and methodological approach that I term 'anthropology of regulation'. I elucidate this (inter)discipline and approach below. Anthropology of regulation draws on specific theoretical underpinnings in regulatory theory and anthropology, which are explained later in this chapter, and specific research methods, which are detailed in Chapter 5. However, I highlight at this point that the empirical data are interpreted through *thematic analysis*, an analytical approach that is most appropriate for answering my research questions (compared to, for example, phenomenology or grounded theory). Thematic analysis is a popular qualitative analytic *method* for 'identifying, analysing and reporting patterns (themes) within data. It minimally organises and describes [the] data set in (rich) detail. However, frequently it goes further than this, and interprets various aspects of the research topic.'[344] Several scholars describe thematic analysis as a *process for encoding qualitative data*, rather than a theoretically informed model for research and analysis.[345] Indeed, thematic analysis is an analytic tool for making sense of the data, whereas anthropology of regulation is underpinned by sensitising concepts that are brought to bear in the encoding process. The encoding requires explicit 'codes', which are 'a form of shorthand that researchers repeatedly use to identify conceptual reoccurrences and similarities in the patterns in the data',[346] and which are usually situated in a 'codebook', which is

[344] Virgina Braun and Victoria Clarke, 'Using Thematic Analysis in Psychology' (2006) 3 Qualitative Research in Psychology 79.
[345] Richard Boyatzis, *Transforming Qualitative Information: Thematic Analysis and Code Development* (SAGE 1998); Greg Guest, Kathleen MacQueen, and Emily Namey, *Applied Thematic Analysis* (SAGE 2012).
[346] Melanie Birks and Jane Mills, *Grounded Theory: A Practical Guide* (2nd edn, SAGE 2015) 89.

the compilation of the codes in a study. A theme is 'a pattern found in the information that at the minimum describes and organizes the possible observations or at the maximum interprets aspects of the phenomenon';[347] it 'captures something important about the data in relation to the research question and represents some level of patterned response or meaning within the data set.'[348]

Thematic analysis is distinct from grounded theory. Unlike grounded theory, which contains an arguably rigid list of 'essential methods'[349] and calls for a continual interplay between data collection and analysis to produce a theory during the research process,[350] thematic analysis allows for flexibility in data analysis to produce conceptually-informed interpretations of the data. Examples of this flexibility include choices between rich, thematic characterisations of a data set or an account of just one particular theme (or group of themes) within the data, a 'bottom-up' or 'top-down' analytic process, and themes identified at a semantic or a latent level. Further, unlike grounded theory, thematic analysis does not demand that the researcher develop a substantive theory as the research output; though theoretical models can be devised, the key purpose is to ascribe meaning to the data by developing concepts and themes and an understanding of the relationship between the various themes.[351] While both thematic analysis and grounded theory involve coding, generation, and interpretation of broader patterns in data, *grounded theory fundamentally is a methodology*, containing an inbuilt theoretical framework with epistemological positions and a set of analytic procedures, whereas *thematic analysis is a (pragmatic) method*, independent of theory and can, therefore, be applied across a

[347] Boyatzis (n 345) 161.
[348] Braun and Clarke (n 344) 82.
[349] Birks and Mills (n 346). The 'essential' grounded theory methods Birks and Mills identify are: initial coding and categorisation of data; concurrent data generation or collection and analysis; writing memos; theoretical sampling; constant comparative analysis; theoretical sensitivity; intermediate coding; identifying a core category; and advanced coding and theoretical integration.
[350] Bowen (n 342).
[351] Ji Young Cho and Eun-Hee Lee, 'Reducing Confusion about Grounded Theory and Qualitative Content Analysis: Similarities and Differences' (2014) 19 The Qualitative Report 1.

range of theoretical and epistemological approaches. This is why thematic analysis is an approach that is well-suited for an anthropology of regulation. As anthropology of regulation is itself a methodology that contains a theoretical framework and epistemological and ontological positions, as well as a set of analytic procedures, grounded theory can unduly constrain the interpretive flexibility and theoretical underpinnings needed to answer the research questions. To be clear, thematic analysis as an analytic process serves as a component of an anthropology of regulation, whereas grounded theory serves as a complete approach on its own.

To facilitate coding and the generation (and interpretation) of themes in the data, the empirical investigation has been theoretically informed by two key strands of literature that form the theoretical backbone of anthropology of regulation: regulatory theory and liminality.[352] I begin with a discussion of regulatory space, decentred regulation, risk-based, and proportionate regulation. I then move to discuss anthropology of regulation, and end with discussion of why liminality serves as a crucial sensitising concept that unifies the elements of my approach overall.

4.3 Regulatory theory

4.3.1 Regulatory space(s)

Regulatory theory is defined as 'a set of propositions or hypotheses about *why* regulation emerges, *which actors* contribute to that emergence and typical *patterns of interaction* between regulatory actors'.[353] To be clear, my research project is not hypothesis-driven, but regulatory theory nonetheless serves as an important underpinning because it helps provide explanation for what is going on. The discussion in Part I argued that RECs are regulatory actors situated within a

[352] It should be noted that some proponents of grounded theory, especially one of its 'founders', Barney Glaser, advocate *not* engaging with the relevant literature prior to beginning data analysis, to avoid the analysis being shaped by preconceptions from existing research. I disagree with this approach, which is another reason I have eschewed grounded theory.

[353] Morgan and Yeung (n 103) 16.

hierarchical and nested regulatory structure within at least a part of the health research regulatory space, as depicted in Figures 4.1 and 4.2.

Figure 4.1. Hierarchical representation of RECs within (part of) the health research regulatory space.

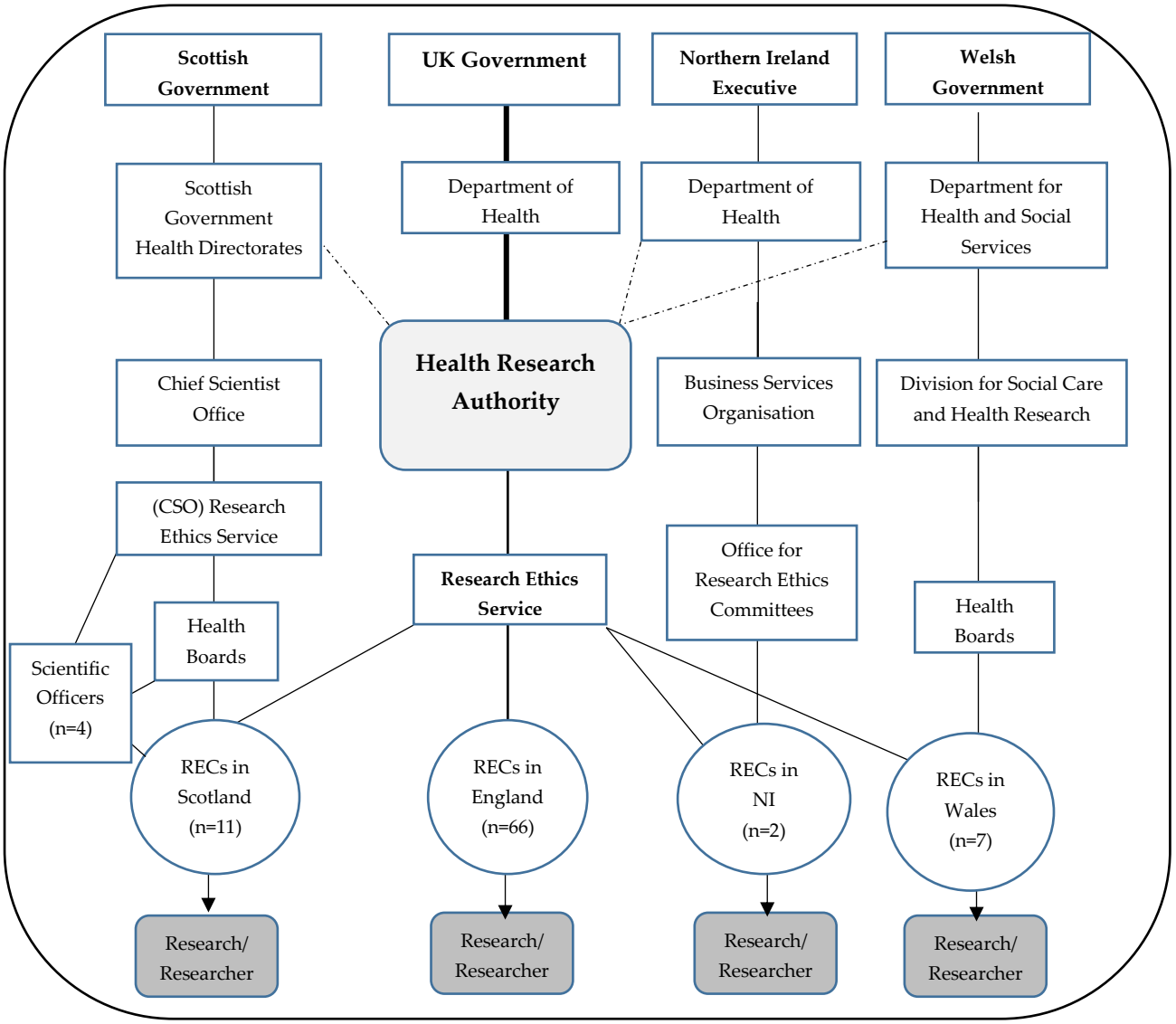
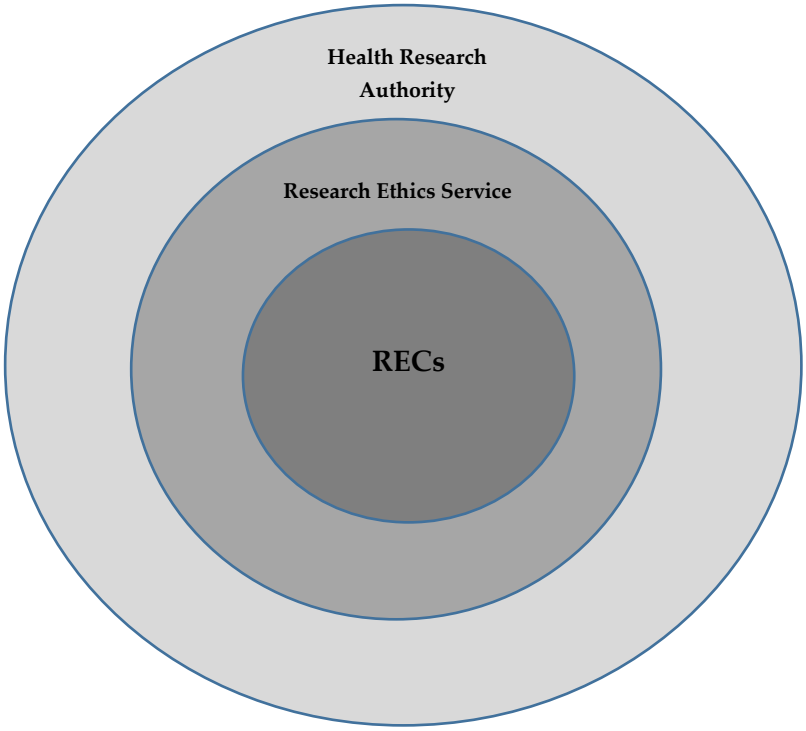


Figure 4.2. Nested regulatory structure of RECs within (part of) the health research regulatory space (representation of English RECs only).



RECs are regulators of health research in that they quite clearly serve as social controls of science. They are 'independent' bodies charged with assessing the ethical acceptability of health research proposals through application of ethical standards and analysis of social and scientific value and risk-benefit assessment, and thereby determine whether the study *should* be undertaken. Since their establishment, RECs have been delegated authority from the government and regulatory agencies to determine, often through norms of practice set by the medical and science professions, the ethical acceptability of a research study. On a case-by-case basis, RECs set the conditions around how a given study should be conducted. Always, their independence from both managing regulatory authorities and other organisations (be it NHS Trusts or Health Boards, universities, or otherwise) is emphasised.

While RECs regulate the activities of researchers, above them sits a Research Ethics Service (not always named such) in each of the four nations that regulate the RECs'

activities. Each Research Ethics Service is itself situated within a regulatory authority (e.g. CSO in Scotland, HRA in England) that issues sets of commands to be applied by the Research Ethics Service, and through them, RECs, within their respective but coordinated jurisdictions. The HRA is the primary authority for RECs in England but cooperates with equivalent authorities in the three other nations in the exercise of their respective functions relating to the regulation of assessments of the ethics of health and social care research, with a view to co-ordinating and standardising practice in the United Kingdom relating to such regulation.[354] Thus, in many ways, the HRA is the UK's primary health research authority with regulatory command of RECs (*primes inter pares*) as seen through its control of regulatory instruments such as the REC SOPs, GAfREC, and the *UK Policy Framework*.[355]

The ethnographic work of Stephens and colleagues at the UK Stem Cell Bank[356] suggests, however, that even if a (meta- or managing) regulator has ultimate legal authority, it may not necessarily have day-to-day authority. Stephens and colleagues found that despite what formal regulations mandate regarding the quality and origins of the stem cell lines received from depositors, scientists engage in a kind of *interpretive flexibility* when it comes to interpreting and operationalising the regulations. Scientists at the UK Stem Cell Bank engage in 'bridging strategies' to reconcile the written demands of regulators and the social demands of scientific practice. Efforts to resolve tensions in the practical implementation of regulatory guidance are done through '*instantiated regulation*', which describes the processes of translating written regulatory guidance into practical action ('making the

[354] Care Act 2014, s 111(4).
[355] See e.g. Health Research Authority, 'UK Policy Framework for Health and Social Care Research' (n 320) s 2.2 (noting that the UK Policy Framework 'will be supported by operational arrangements and guidance provided by the HRA and the Devolved Administrations, working in collaboration to ensure a consistent approach to co-ordinating and standardising regulatory practice. This will achieve compatibility across the UK for the management and conduct of health and social care research.').
[356] Neil Stephens, Paul Atkinson, and Peter Glasner, 'Documenting the Doable and Doing the Documented: Bridging Strategies at the UK Stem Cell Bank' (2011) 41 Social Studies of Science 791.

documented doable'), and serves as 'a response to the interpretative flexibility of regulatory texts'.[357] For Stephens and colleagues, regulatory instantiation demonstrates the inherent interpretive and procedural flexibility of regulatory scripts (i.e. law) and that regulation is always distributed and locally managed by the actors on the ground:

> In these different settings, members have to find organizationally and situationally specific ways to implement rules, regulations and equivalent normative frameworks. In principle, no 'rule' (which for our purposes also includes ethical and regulatory protocols) can specify precisely how it shall be applied in specific cases. In practice, this does not result in an endless regress of rules-about-rules or rules-of-application, because social actors routinely find and collectively negotiate practical, doable solution. Everyday solutions depend on finding formulations that can be held to justify actions that (arguably) reflect the 'spirit' of the regulation, or that can be found to be 'good enough' for the purpose at-hand: a property of rule use termed the 'et cetera clause' of background expectancies by Garfinkel (1967).[358]

In the case of the UK Stem Cell Bank, regulatory instantiation was demonstrated in the 1) iterative modification of the Cell Line Information Form by the UK Stem Cell Bank working together with laboratories; 2) visits to the laboratories by the UK Stem Cell Bank, which built trust through networks; and 3) the shaping of both laboratory and UK Stem Cell Bank practices as a result of these interactions.

The insight from Stephens and colleagues ties in with the discussion of the interstitial nature of many regulatory spaces within the formal regulated space. Their insight suggests that as both regulators and regulatees, RECs, too, must navigate situationally-specific ways to implement risk-calibrated regulations (from the SOPs, GAfREC, and so on) that govern their practice in determining the ethical acceptability of research applications. It also further suggests that RECs may have more regulatory flexibility than we may think and that part of this flexibility is based on 'interpersonal trust in instantiating and maintaining system trust'.[359] In Part III of the thesis, the insights from Stephens and colleagues will be invoked in

[357] ibid 794.
[358] ibid.
[359] ibid 808.

discussions surrounding the key theme of 'regulatory stewardship' and its connection with liminality.

Describing the nested regulatory structure of RECs and opportunities for instantiated regulation is distinct from exploring *why* ethics review regulation emerged in the first place, *which actors* contributed to that emergence, and the *patterns of interaction* between RECs, the Research Ethics Service, and other regulatory actors, to say nothing of what the day-to-day regulatory practice of RECs looks like. What constitutes ethics review in the practices of RECs, particularly as they become more institutionalised and this 'next-generation' regulation is brought to bear on them?

Regulatory theory helps frame these questions. RECs first emerged because of historical contingency and political manoeuvring by lawyers, policymakers, and legislators in Washington, DC in the mid-1960s.[360] Out of concern for ongoing research scandals, potential legal liability, and governmental regulation, NIH policymakers enacted a delegated 'satellite regulator' model as an adaption of the 'group consideration' structure from the NIH Clinical Center's Clinical Research Committee. In this model, committees of self-regulating medico-scientific peers at local institutions would review protocols submitted by fellow physician-researchers at their institutions and give 'due consideration' to 'pertinent ethical issues'.[361] Some American commentators take issue with the regulatory choices made or rationales for the creation of ethics committees. Schneider, for example, finds that the IRB system in the US 'has proved a poor tool because it is compounded of ill-judged regulatory choices. It was born of scandal, not study of the extent and nature of

[360] Stark (n 123). Stark's monograph provides a thorough history of IRB creation in the US.
[361] US Public Health Service, 'Revised Procedure on Clinical Research and Investigation Involving Human Subjects', 1 July 1966 (Department of Health, Education and Welfare 1966).

ethical problems and of possible solutions to them. Its framers were too inexpert in regulation to appreciate the costs of event licensing.'[362]

In the UK, we saw a follow-on effect from this American creation, with hospitals establishing RECs beginning in the late 1960s as a pragmatic response from the US Surgeon General's policy.[363] But growth and development of RECs were incremental and patchy; they were distinctly *not* in response to research scandals.[364] Contrary to the US, it was not until the new millennium that statutory regulation was enacted that set legally binding requirements on RECs' form and function—and technically, this was only for CTIMPs. Thus, for much of their history, RECs were unique products of actively designed *decentred regulation*,[365] whereby the government shifted authority to and trust in the medical and scientific professions as well as independent regulatory authorities to set the principles and standards for their operation. However, as we will see, RECs exhibit a unique kind of regulatory design as compared to common understandings of decentred regulation in that the locus of the activity of regulating RECs has been gradually shifting *towards* the state.

Surveying the history, three rationales appear to have been at play in the aim of creating health research ethics regulation beginning in the 1960s, both voluntarily from within the profession and top-down from state actors. These were: 1) to protect research participants from potential harm by minimising the risks exposed to them by the proposed research; 2) to address information deficits between the researcher and participant in terms of the proposed study by requiring researchers to explain clearly (e.g. through information sheets) what would be involved in the study, including the potential risks and benefits, to allow (healthy) volunteers and patients

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[362] Schneider, *The Censor's Hand* (n 12) xxx (Introduction) .
[363] US Public Health Service, 'Memo' (n 137).
[364] Hedgecoe, 'Scandals' (n 137).
[365] Decentred regulation can be defined as 'a shift (and recognition of such a shift) in the locus of the activity of "regulating" from the state to other, multiple, locations, and the adoption on the part of the state of particular strategies of regulation'. See Julia Black, 'Decentring Regulation: Understanding the Role of Regulation and Self Regulation in a "Post-Regulatory" World' (2001) 54 Current Legal Problems 103, 112.

to make an informed decision about whether to participate in the study; and 3) to broker a compromise between public welfare-attuned politicians and regulators concerned with safety and public trust (not to mention being perceived to act in the public interest), and professional physician-researchers who were concerned with maintaining freedom of science and minimising the impact of external regulation that might hinder their research (the argument for 'clinical autonomy'). In the early age of RECs' creation, a mixture of public and private interests drove regulation in this nascent regulatory space.

However, the historical tracing in Chapter 3 also suggests that regulatory developments in this area have never purely been a matter of 'public' *or* 'private' interests (or some hybrid mix thereof), though certainly both exist, and the recent legal instantiation of research promotion may signal a surge of private interests, particularly from the research community (including industry). More is occurring in health research regulation than a prolonged war between public welfare and research autonomy punctuated by battles or scandals. Instead, even from the nascent stage of the REC system's creation and the emergence of regulatory controls on science, there has been an emphasis on social processes and how they shape health research ethics regulation. The historical tracing in Chapter 3 demonstrates that the progression of regulatory controls, both *on* RECs and *of* research involving participants, is symptomatic of incremental *process* rather than action:reaction punctuated by nodal points in regulatory history. Through an anthropology of regulation, this thesis thus bridges the historical tracing with present understanding and with future outlook: we cannot understand where we are and where are going with health research regulation unless we understand where we have been. The past, present, and future are inextricably linked in time and place and bonded by processes of gradual change reflected in the actions of various actors.

The analytic concept and metaphor of 'regulatory space', first described by Hancher and Moran,[366] and already referred to above, provides useful spatial-temporal framing of the processes here. Regulatory space proponents argue that local context and historical configuration (i.e. time and space), as well as institutional dynamics, affect the relevant regulation and influence the practices that happen within the space.[367] As to the metaphor itself, regulatory space focuses on *networks* of regulation and mixing of regulators and strategies:

> The 'space' here is conceived of as a cluster of regulatory issues, decisions, or policies (a 'regulatory arena') that involves the interplay and competition between various interests. Regulatory authority is widely shared between private and public actors (therefore making the distinction largely meaningless), and regulatory approaches are shaped by location, timing, and history. […] In the world of regulatory space, as in the world of regulatory networks, the idea of 'capture' makes only limited sense; regulatory authority is inherently shared, and private interests are driven to, or accept, playing legitimate roles in the regulation of themselves, of industry sectors (through associations), and of wider society.[368]

According to Scott, the regulatory space concept posits that the 'resources relevant to holding of regulatory power and exercising of capacities are dispersed or fragmented'; the resources 'are not restricted to formal, state authority derived from legislation or contracts, but also include information, wealth and organisational capacities.'[369] Moreover, 'the possession of these resources is fragmented among state bodies, and between state and non-state bodies'.[370] Scott elaborates:

> Put another way, *capacities derived from possession of key resources are not necessarily exercised hierarchically within the regulatory space, regulator over regulatee*. We recognise the presence within the space not just of regulators and regulatees, but of other interested organisations, state and non-state, possessing resources to a variable degree. *Relations can be characterised as complex, dynamic and horizontal, involving negotiated interdependence*. This re-conceptualisation of regulatory processes is important in understanding the limits of law within regulation. The dispersed nature of resources between

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[366] Hancher and Moran, 'Organizing Regulatory Space' (n 7).
[367] See e.g. Colin Scott, 'Analysing Regulatory Space: Fragmented Resources and Institutional Design' (2001) Public Law 329.
[368] Hancher and Moran, 'Organizing Regulatory Space' (n 7) 64-65.
[369] Scott, 'Analysing Regulatory Space' (n 367) 330.
[370] ibid.

> organisations in the same regulatory space means regulators lack a monopoly both over formal and informal authority. This observation draws our attention to the need to conceive of strategies of regulation as consisting of a wide range of negotiated processes, of which rule formation and enforcement are but two.[371]

Further elucidation of the regulatory space is provided by Black, who suggests that three principal regulatory functions can be mapped across a range of actual or potential regulators—standard setting, monitoring, and enforcement—and a wide variety of institutional actors can be 'enrolled' to carry out, alone or in collaboration, one or more of these regulatory functions.[372] Burris and colleagues extend this concept with discussion of polycentric, or 'nodal' character of, contemporary governance, which 'is an elaboration of contemporary network theory that explains how a variety of actors operating within social systems interact along networks to govern the systems they inhabit'.[373] They posit that institutions (which I would broaden to 'actors') are substantially comprised in *nodes*, having a set of technologies, mentalities, and resources that mobilise the knowledge and capacity of members to manage the course of events: 'Networks are a prime means through which nodes exert influence.'[374] Burris finds that there are a number of nodes that do or could help regulators (including ethics committees) regulate how researchers treat research participants. This can range from medical journals to professional organisations to courts to ethicists, all of whom can act as 'norm entrepreneurs' in formulating and disseminating new standards.[375]

The concept of regulatory space, along with insights from polycentric contemporary governance, helps us understand *why* the current regulation of health research

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[371] ibid (emphasis added).
[372] Julia Black, 'Enrolling Actors in Regulatory Systems: Examples from UK Financial Services' (2003) Public Law 63. As I argue below, however, the enforcement function has limited application to RECs.
[373] Scott Burris, Peter Drahos, and Clifford Shearing, 'Nodal Governance' (2005) 30 Australian Journal of Legal Philosophy 30, 33.
[374] ibid.
[375] Scott Burris, 'Regulatory Innovation in the Governance of Human Subjects Research: A Cautionary Tale and Some Modest Proposals' (2008) 2 Regulation & Governance 65, 71.

involving human participants is less a matter of public authorities *versus* private interests. Indeed, the underlying institutionalist framework of research ethics review by dispersed expert ethics committees and pluralist organisational involvement was established already by the 1970s, and this was in large part due to a conscious effort by the state to delegate much of the decision-making authority to private interests in the form of the RCP and other non-state actors.

Interestingly, then, what appears to exist in the UK is *not* the 'decentred' regulation of health research that scholars like Black emphasise is a *modern* characteristic of the regulatory world,[376] where the state is increasingly joined by other (non-state) institutional actors precisely because the state is shifting the locus of the activity of regulating to these non-state actors. Rather, the health research regulatory space, or at least in the particular space of health research ethics as it pertains to RECs, reflects an increasingly pronounced positioning by the state. What we see today is a shifting of the locus of regulating *towards the state*, with more 'centred' or truly *poly*centric regulation. State actors such as the NHS (via Trusts, Foundation Trusts, and Health Boards and the R&D offices within them), Department of Health (and their equivalents in the devolved administrations), and the HRA assert much firmer control with rules- and principles-driven regulation (e.g. Care Act 2014, *UK Policy Framework*, GAfREC, The Medicines for Human Use (Clinical Trials) Regulations 2004, REC SOPs) that both seek to streamline ethics review processes and also remove a degree of autonomy from RECs.[377]

But the state is not alone, of course. It is situated next to the long-standing and previously dominant presence of non-state regulatory actors and sources of authority such as researchers and physicians, industry (e.g. pharmaceutical

[376] Black, 'Decentring Regulation' (n 365).
[377] Cave and Nichols (n 89) 74, 78 ('Following the introduction of the Clinical Trials Directive and the ongoing reform of the UK NHS-REC system, a rigorous and bureaucratic process that gave substantial freedom to ethics committees has given way to a more streamlined process with curtailed freedom to ethics committees.'). See also Richard Nicholson, 'Another Threat to Research in the United Kingdom' (2004) 328 British Medical Journal 1212.

companies), organisations within the medical and scientific profession (e.g. RCP), and new(er) organisations explicitly promoting a pro-research agenda (e.g. AMS). Unlike standard accounts of decentred regulation, then, here we see that the state has only recently asserted itself into the mix of regulatory actors. Not unusually, each of these actors can exert cross-competing demands and the polycentric nature of the space exhibits potentially cacophonous forms of standard setting, monitoring, and enforcement. In sum, while the state has recently asserted itself and the HRA has emerged as a central regulatory actor, the latter is not a 'one-stop shop' for the regulation of health research as marketed. One can today delineate multiple actors (or 'nodes') that populate the health research regulatory space in the area of research ethics, including:

- RECs;
- sponsors and institutions (i.e. research employers);
- NHS (e.g. (Health Boards, Trusts, Foundation Trusts);
- Department of Health / devolved administration equivalents;
- Health Research Authority / devolved administration equivalents (including the Research Ethics Service);
- UKECA;
- MHRA;
- regulatory licensing authorities (e.g. HFEA, HTA);
- regulatory advisory committees (Confidentiality Advisory Group, Administration of Radioactive Substances Advisory Committee, Public Benefit and Privacy Panel for Health and Social Care);
- industry (e.g. commercial firms);
- Data Monitoring Committees;
- funders (e.g. Wellcome Trust; MRC);
- courts;
- professional organisations (e.g. Royal College of Physicians; British Medical Association; World Medical Association);

- interest groups (e.g. Academy of Medical Sciences);
- research colleagues;
- ethicists;
- journals;
- news media;
- research participants; and
- publics.

Clearly, many actors (or 'nodes') populate this regulatory space, which, it must be stressed, merely covers one discrete area: regulation of the ethics of health research involving human participants. Indeed, some argue that in health research, the regulatory space is not unitary but in fact comprised of 'a multiplicity of spaces ostensibly engaged in the same endeavour but with little means to learn lessons between them'.[378] How, then, can we put these nodes under the analytic microscope and make sense of this space or these spaces? Vibert recommends that one helpful approach to thinking about the regulatory space is not an overarching account of system behaviour, but rather a bottom-up account of the individual units that regulate or are subject to regulation. Certainly, this approach plays better with anthropology of regulation and my research design, which focuses on RECs as individual units (or more accurately, as individual nodes, with supra-units and sub-units or supra/sub-nodes within or connected to them, such as the HRA, Research Ethics Service, Chairs, Managers, and Scientific Officers). As Vibert says: '[t]his involves selecting a technique of analysis, relevant to regulation, that provides a point of entry into the more general logic and workings of the regulatory system and serves to open up wider issues.'[379]

Law is important to consider here, and it is worth highlighting that in the institutionalist and polycentric theory of regulation, *law is facilitative* rather than

[378] Graeme Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-Between?' (2017) 25 Medical Law Review 47, 50.
[379] Vibert, *The New Regulatory Space* (n 8) 33.

prohibitive, 'emphasising non-legal organisational and systemic dynamics as crucial to regulatory objectives', and helping 'to structure the interactions between regulatory participants rather than directly to shape the substance of the regulatory issue'.[380] Yet law also polices the boundaries of the regulatory space where actors interact, and is limited in what it can achieve, or holds itself out to achieve. As Scott observes:

> [L]aw is more marginal to actions within the regulatory space than lawyers might assume. That political systems seek to use law instrumentally for regulatory purposes does not give law the pre-eminence in ordering society which some argue it had when adjudication was a central form of governance in an earlier period. Indeed, the argument that law is increasingly used to co-ordinate 'pre-existing relationships of power' is at odds with the dominant, but symbolic conception of law as being exercised hierarchically.[381]

So, even if we find, for example, that the Care Act 2014 has bestowed formal legal authority on the HRA to regulate RECs (directly in England and indirectly in the devolved nations) and a duty to promote the co-ordination and standardisation of practice in the UK relating to the regulation of health and social care research, as well as a duty to co-operate with each devolved authority in the exercise of their respective functions relating to the regulation of assessments of the ethics of health and social care research, this does *not* mean that the HRA necessarily possesses *actual* regulatory authority over health research. What it means is that the HRA has ultimate (legal) authority, but this is not equivalent to saying that it can or does dictate what happens on the ground or *within* the regulatory space(s). Things might 'work well', but not in ways that the HRA foresees or would necessarily sanction. The insight from Scott about the limits of law tells us that 'authority' can take many forms, legal and extra-legal, depending on how it is defined, who wields it, when, and in what ways, and who in return is impacted by it. Scott's insight thus draws attention to the problems inherent in a law-centric approach. We must be open to the possibility that authority may be wielded in myriad ways and at different times

[380] Morgan and Yeung (n 103) 76.
[381] Scott, 'Analysing Regulatory Space' (n 367) 334.

by RECs and other regulatory actors, such as R&D offices, researchers, and sponsors, who possess key resources of information and organisation even if not sanctioned with these resources by law.

Thus, we see that the value of regulatory space as an analytic concept is its usefulness in demarking the range of actors and processes in health research, and for 'drawing in perspectives which question the capacities of instrumental law and regulation, and envisage greater reflexivity or responsiveness in systems characterised variously as post-bureaucratic or post-interventionist'.[382] As Scott writes, '[b]efore we conclude that all key resources are possessed by a single regulatory agency, we ask first whether those resources are in fact dispersed through a more fragmented pattern.'[383] Lastly, an openness to surprise is warranted when applying a nodal analysis of the regulatory space in this context. For Burris:

> The positive potential of a nodal [analytic] view is clear: when the available regulators are identified and their capacities assessed, 'unregulated' activities can be revealed as highly regulated, or potentially so. In the case of human subjects regulation, a diversity of regulators may be creating problems of over-regulation, over-punishment, and over-deterrence.[384]

Ongoing or further recourse to the law as a means of achieving a robust health research regime, it seems, may not be appropriate.

It bears noting that some commentators consider a drawback to the regulatory space metaphor to be its difficulties in 'accounting for the boundaries of regulatory spaces and in explaining the different dimensions that characterize the "topology" of the space—notably: the relative power of the different actors; the distribution of resource dependence relevant to the space; and the nature of the communication flows between actors.'[385] As will be argued, this, in fact, is where liminality adds key support to the metaphor, especially in making sense of the spaces in-between

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[382] ibid 352.
[383] ibid.
[384] Burris, 'Regulatory Innovation' (n 375) 71.
[385] Baldwin, Cave, and Lodge (n 101) 65.

boundaries. Additionally, an anthropology of regulation rounds out the call for richer characterisation of the 'topology' of the space by paying close attention, through empirical research, to the dynamics of interaction between actors and how resources are distributed. It complements socio-legal research approaches by investigating the *extra*-legal elements of social practices from the inside out and paying attention to the *processual* nature of regulation. Engaging in anthropological investigation of regulation accounts for a deeply contextual understanding of the behaviours and experiences of actors who intentionally intervene in the activities of a target population (i.e. regulators), as well as those actors whose activities have been regulated (i.e. regulatees).[386]

4.3.2 Regulatory design: risk-based and proportionate regulation

If regulatory space serves as a useful frame to make sense of the range of nodes that share regulatory authority of a given activity, what can be said of regulatory design—the structures, techniques, and strategies deployed by regulatory actors to accomplish their tasks? Risk assessment and management is a classic *modus operandi* of regulators. Baldwin and colleagues observe that 'regulation can be seen as being inherently about the control of risks',[387] while Lodge argues that we live in 'the age of risk-based regulation'.[388] Recent changes in health research regulation described in Part I of this thesis suggest a pronounced move towards this risk-focused approach, which also accords with the UK's Hampton Review in 2005 that recommended all UK regulators operate a risk-based system,[389] and the statutory

[386] Christel Koop and Martin Lodge, 'What is Regulation? An Interdisciplinary Concept Analysis' (2017) 11 Regulation & Governance 95, 105.
[387] Baldwin, Cave, and Lodge (n 101) 83.
[388] Martin Lodge, 'Risk, Regulation and Crisis: Comparing National Responses in Food Safety Regulation' (2011) 31 Journal of Public Policy 30.
[389] Philip Hampton, *Reducing Administrative Burdens: Effective Inspection and Enforcement* (HM Treasury 2005).

Regulators' Code, which requires regulators to 'base their regulatory activities on risk' and 'choose proportionate approaches to those they regulate'.[390]

Risk, a key theme in contemporary societies,[391] can be defined simply as an 'adverse event that may occur in the future'.[392] The CIOMS Guidelines define risk more thoroughly as 'an estimate of two factors: first, how likely it is that a participant will experience a physical, psychological, social or other harm; and second, the magnitude or significance of the harm'.[393]

Risk-based regulation is defined as 'the prioritizing of regulatory actions in accordance with an assessment of the risks that parties will present to the regulatory body's achieving its objectives'.[394] Surveying the literature, one finds that it generally contains the following key elements (Box 4.1):[395]

Box 4.1. Elements of risk-based regulation.

1. There are three sequential phases: 1) assessment (framing and forecasting the probability and consequences of identified hazards); 2) management (designing and implementing actions and remedies to address risks through a consideration of potential risk treatments and selection of the most appropriate); and 3) review (decision-making processes are transparent and open to revision in light of new information);
2. The regulator's aim is to control relevant risks rather (or more) than compliance with sets of rules;

[390] Department for Business, Innovation and Skills, *Regulators' Code* <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf>.
[391] Iain Wilkinson, *Risk, Vulnerability and Everyday Life* (Routledge 2010).
[392] Robert Baldwin and Julia Black, 'Driving Priorities in Risk-based Regulation: What's the Problem?' (2016) 43 Journal of Law and Society 565, 566.
[393] CIOMS Guidelines (n 16) Guideline 4, Commentary.
[394] Baldwin, Cave, and Lodge (n 101) 281.
[395] Adapted from Baldwin, Cave, and Lodge (n 101) 281-90 and Gregory Bounds, 'Challenges to Designing Regulatory Policy Frameworks to Manage Risks' in OECD (ed), *Risk and Regulatory Policy: Improving the Governance of Risk* (OECD 2010).

3. Once assessed, a range of responses can be applied to manage the risks, such as risk avoidance, risk reduction, risk retention, and risk transfer;
4. There is clear identification of risks that the regulated organisations (i.e. researchers and their studies) may present to the achieving of the regulator's objectives;
5. There is a comprehensive system for assessing such risks and scoring these in either a quantitative or qualitative manner, underpinned by scientific evidence and a robust decision methodology;
6. There is a linkage of risk scoring mechanism/risk evaluation with resource allocation (e.g. more resources to regulate the higher risk organisation or activity);
7. There is recognition that risk tolerance and use of a risk-based framework is more political art than pure technical application; and
8. The risks that the regulator is concerned with may not align with the risks on which regulatees are focused.

Throughout their history, RECs have been designed to focus much of their attention on assessing risks and expected benefits. They are charged with assessing, or weighing a favourable 'balancing' of, the harms (i.e. the adverse events) and benefits of a given research study, or phrased another way, risks against the probability of benefit. As the GAfREC state: 'The committee has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society.'[396] Elsewhere, it states that 'RECs must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research',[397] and that 'research can sometimes involve an element of risk, because research can involve trying something new. It is important that any risks are

[396] GAfREC (n 1) para 1.2.2.
[397] ibid para 3.2.15.

minimised and do not compromise the dignity, rights, safety and well-being of the people who take part.'[398] At least on paper, there would appear to be two general levels of risk in the assessments undertaken by RECs: minimal risk, and greater than minimal risk.[399] For their part, investigators are expected to prepare descriptions of risks and intended benefits for REC members, potentially other regulators (such as the MHRA), as well as research participants. Together, the risk-benefit calculus is said to operationalise all three of the 'classic' (principlist) ethical principles of beneficence, respect for persons, and justice.[400] It is also said to reflect a consequentialist approach, where the 'right choices are those with the best overall consequences'—the potential benefits of a research study must be proportionate to the risks borne by participants.[401]

Assessing the elements outlined in Box 4.1 and turning our attention to the context of ethics review, we can speculate that RECs most often engage in risk management techniques of risk reduction (e.g. setting conditions on the research study for it to be ethically acceptable) and risk avoidance (e.g. prohibiting certain research studies or activities within them by not granting a favourable opinion).

Further and relatedly, we can surmise that risk-based regulation is linked with notions of 'proportionate' regulation. In law and regulation, proportionality connects 'the exercise of legal power with doctrines and ideas of reason, fairness, fittingness, and order circulating within broader political and indeed cultural

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[398] ibid para 2.2.1.

[399] As Rid explains, referencing common ethical guidelines, '…when participants cannot give their own informed consent (e.g. children, psychiatric patients), or they do not give informed consent for reasons of feasibility (e.g. waivers of consent for secondary uses of existing data) or for methodological reasons (e.g. research involving deception), any net risks to participants should be minimal'. In all other instances, the risk is seen as greater than minimal. See Annette Rid, 'Rethinking Risk–Benefit Evaluations in Biomedical Research' in Daniel Strech and Marcel Mertz (eds), *Ethics and Governance of Biomedical Research* (Springer 2016) 154.

[400] Levine, *Ethics and Regulation of Clinical Research* (n 62) 38.

[401] Marilyn Morris and Jason Morris, 'The Importance of Virtue Ethics in the IRB' (2016) 12 Research Ethics 201, 205.

discourse'.[402] As Meyer notes, there has been 'a global trend toward "risk-proportionate" regulation of [human subjects research]' […] It aims for two politically unassailable goals—the safety and welfare of research participants and the efficient use of scarce resources—and wraps these goals in the seemingly unobjectionable language of "proportionality"'.[403] An OECD report from 2010 observes that '[a] risk-based approach to regulation explicitly acknowledges that the government cannot regulate all risks and that regulatory action, when taken, should be proportionate, targeted and based on an assessment of the nature and magnitude of the risks and of the likelihood that regulation will be successful in achieving its aims.'[404] It finds that for central regulators (in this case, the HRA for example): 'A significant objective of incorporating a better treatment of risk in regulatory management is to improve regulatory design and administration, to reduce the fiscal costs of administering regulation and minimise the burden that regulation imposes on business and the community.'[405] This language accords with the UK's *Regulators' Code*, which states that: 'Regulators should carry out their activities in a way that supports those they regulate to comply and grow', which means that, among other things, they 'should avoid imposing unnecessary regulatory burdens through their regulatory activities' and 'should consider how they might support or enable economic growth for compliant businesses and other regulated entities […]'.[406]

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[402] Nicola Lacey, 'The Metaphor of Proportionality' (2016) 43 Journal of Law and Society 27, 35.

[403] Michelle Meyer, 'Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem' (2013) 65 Administrative Law Review 237, 294-95. See also Scott Kim, Peter Ubel and Raymond De Vries, 'Pruning the Regulatory Tree' (2009) 457 Nature 534, who argue for greater risk-proportionate regulation of human subjects research.

[404] Bounds (n 395) 16.

[405] ibid 26.

[406] Department for Business, Innovation and Skills, *Regulators' Code* <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf> paras 1-1.2.

For RECs specifically, an early shift towards risk-*proportionate* regulation can be traced to the Lord Warner Report from 2005, which recommended proportionate ethics review such that '[t]he remit of NHS RECs should not include surveys or other non-research activity if they present no material ethical issues for human participants.'[407] COREC's response publication in 2006, *Building on Improvement*, acknowledged that the Lord Warner Report sought 'proportionality of review' as a means to *streamline* the extant regulation, and in response, COREC recommended introducing 'a research ethics service incorporating RECs working in structured networks, where decisions are made as a result of review proportionate to the level of risk provided by the study.'[408] As noted in Chapter 3, in 2010, following the earlier pilot study from 2009 based on the recommendation from the Lord Warner Report, the Proportionate Review Service was introduced across the UK to operationalise a proportionate regulatory approach based on the level of risk a study proposed.

Similarly, the AMS emphasised the need for proportionate regulation in its report from 2011, recommending it as a key principle underpinning health research regulation (indeed, it was one of the four principles they advocated): '…the application of regulation should be both proportionate and symmetrical. A "one-size-fits-all" approach to regulation damages us all. Instead, regulation of health research should be proportionate to the risks and benefits to individuals and society.'[409] Throughout its report, the AMS recommended that an 'ideal' health research regulatory system would, among other things, apply regulatory requirements in a way that is proportionate to the potential benefits and harms of the research. Within ethics review, the AMS encouraged NRES (as it then was) to roll out Proportionate Review to all RECs, charging that '[i]t is particularly important to adopt a proportionate approach to ethics review because of the

[407] Lord Warner Report (n 232) 15.
[408] COREC Report (n 245) 9.
[409] AMS, *A New Pathway* (n 39) 5. 'Principle 3' is: 'Be proportionate, efficient and coordinated.'

diversity of research that undergoes this assessment, which includes: questionnaires for staff and patients, minimally interventional studies and clinical trials of new drugs. The benefits of a proportionate approach are recognised in both the US and Canadian ethics review systems…'[410]

Even after the HRA's creation, the research community has continued to advocate for a turn towards streamlined and proportionate regulation in the hopes of 'increasing value and reducing waste in biomedical research regulation and management'.[411] In an influential article published in *The Lancet* in 2014, University of Edinburgh clinical neurologist Rustam Al-Shahi Salman and colleagues (including Janet Wisely, then Chief Executive of the HRA) wrote alarmingly of 'the increasing burden, inconsistency, and complexity of regulation in the past two decades, sometimes out of proportion to the risk of the research'[412] that ultimately had led to a 'threat to public health'.[413] Chief among their concerns was that: 'Although the conceivable risks of research vary, regulatory requirements do not seem to have been designed to be proportionate to the extent to which safety of patients is likely to be jeopardised.'[414] In this context, they cited the example of requiring consent for 'low-risk' epidemiological research and biobanking and the application of the Clinical Trials Directive to non-commercial trials assessing licensed treatments that have already been adopted in practice. Though they noted examples from the UK of solutions to some sources of waste and inefficiency in regulation of clinical research (e.g. the development of COREC to NRES to the HRA and the latter's strategic plan from 2013), they also noted much more could be done to reduce 'wasteful regulation and management of research'.[415] As they wrote: 'The main solution to disproportionality is to limit regulation to whatever is essential,

[410] ibid 76.
[411] Rustam Al-Shahi Salman and others, 'Increasing Value and Reducing Waste in Biomedical Research Regulation and Management' (2014) 383 The Lancet 176.
[412] ibid 177.
[413] ibid 183.
[414] ibid 178-79.
[415] Ibid 183.

both to protect the autonomy and wellbeing of research participants and to be proportionate to the plausible risks posed to them.'[416] The authors did not, however, clearly explain what entails 'essential' regulation.

A final example of proportionate regulation is seen in the Care Act 2014, which mandates the HRA to 'promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and it must, in doing so, *seek to ensure that such regulation is proportionate*'.[417] Operationalising this legal mandate in practice, the *UK Policy Framework for Health and Social Care Research* 'recognise[s] the value of their proportionate application to different types of research'[418] and throughout, emphasises a proportionate approach, including as a principle for regulators: 'The HRA has a specific role to ensure the following. […] a. The regulation of health and social care research is proportionate, so that research that is clearly lower-risk gets processed accordingly.'[419]

Based on the foregoing discussion, a question arises as to whether this next-generation health research regulation implements a risk-based and proportionate approach for RECs that fulfils the elements described in Box 4.1 above. Are RECs' deliberative processes 'informed by an assessment of the probability of harm expected to arise' from a given research study, or if the probability of harm cannot be calculated, do RECs demonstrate 'a rational and transparent consideration of other relevant factors that for want of evidence remain uncertain'?[420] This is a critical and empirical question that will be explored in Part III. At this stage, in setting the methodological foundation for the empirical research, it may be beneficial to look at what the UK regulations state.

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[416] ibid 181.
[417] Care Act 2014, s 111(3) (emphasis added).
[418] Health Research Authority, 'UK Policy Framework for Health and Social Care Research' (n 320) s 5.1.
[419] ibid s 9.19.
[420] Bounds (n 395) 16-17.

In short, what the regulations state about risk assessment by RECs is minimal. The REC SOPs provide no detailed guidance on how risk is to be assessed. Somewhat clearer guidance is provided by international regulatory instruments such as the CIOMS Guidelines,[421] but as Rid points out, 'there is no explicit upper risk limit when informed consent is obtained, provided the net risks to participants are reasonable in relation to the scientific or social value of the research'.[422]

Risk-proportionate assessment also lacks clarity. The REC SOPs state that: 'The Proportionate Review Service (PRS) provides for proportionate review of research studies raising no material ethical issues, including projects involving straightforward issues which can be identified and managed routinely in accordance with standard research practice and existing guidelines.'[423] It then proceeds to discuss procedural guidance on how the PRS is to operate. The GAfREC specify that 'REC review is proportionate to the *scale* and *complexity* of the research proposed',[424] neither of which are attributes that necessarily equate to risk, but nevertheless are seen as linked. A 'No Material Ethical Issues Tool' published by the HRA (though no longer active on its website) lists seven categories (i.e. types of research) considered to present no material ethical issues (e.g. research using prospectively collected data or tissue that is anonymous to the researcher), followed by an eighth category, which is described as 'Studies which do not fit categories 1-7 but do not have any "Material Ethical Issues"'. According to the HRA, these categories *prima facie* raise no material ethical issues because they 'have minimal risk, burden or intrusion for research participants'.[425]

Such is how the ethics review system is currently designed for the purposes of assessing risk. Detailed regulatory guidance is lacking, which can raise conceptual

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[421] See e.g. CIOMS Guidelines (n 16) Guideline 4.
[422] Rid, 'Rethinking Risk–Benefit Evaluations' (n 399) 156.
[423] REC SOPs (n 37) para 4.1.
[424] GAfREC (n 1) para 3.2.4.
[425] Health Research Authority, 'Proportionate Review - Information and Guidance for Applicants' (n 256).

and practical challenges. Few scholars have closely analysed the risk-based regulatory design of RECs to assess its strengths and weaknesses,[426] particularly as seen through the behaviours and experiences of RECs (who experience risk-based regulation imposed from the HRA and other central managing regulators), managing regulators (who seek to design and influence risk-based regulation), and regulatees (i.e. researchers, who must navigate the demands of the regulatory system). Rid, one of the few scholars to research this area outside the US, argues that 'frameworks for risk-benefit evaluations of biomedical research remain surprisingly vague',[427] 'arguably places too much emphasis on informed consent as a condition of acceptable net risk to participants',[428] and that the 'documented variation and inconsistency of risk judgments between RECs'[429] raises concerns about both over- and under-protection of participants from risks, not to mention possible stifling of 'valuable research for overall marginal gains in subject protection'.[430] In Part III of this thesis, the empirical research will shine light on the extent to which RECs engage in risk-based regulation, and examine how RECs (and the HRA) address the conceptual and practical challenges raised by the lack of clarity surrounding risk assessment.

So far in this chapter, I have argued that sensitising concepts from regulatory theory, namely regulatory space and risk-based regulation, along with its related concept of proportionality, help us understand why regulation emerged in this space and the different array of actors who share in regulating health research.

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[426] Several US scholars have critically examined IRB risk assessment. See e.g. Carl Coleman, 'Rationalizing Risk Assessment in Human Subject Research' (2004) 46 Arizona Law Review 4; Lars Noah, 'Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research' (2004) 25 Journal of Legal Medicine 267; Burris, 'Regulatory Innovation' (n 375); Meyer, 'Three Challenges' (n 78); Simon Whitney, 'Institutional Review Boards: A Flawed System of Risk Management' (2016) 12 Research Ethics 182.
[427] Rid, 'Rethinking Risk–Benefit Evaluations' (n 399). See also Annette Rid and David Wendler, 'Risk–Benefit Assessment in Medical Research—Critical Review and Open Questions' (2010) 9 Law, Probability & Risk 151; Rid, 'How Should We Regulate Risk' (n 78).
[428] Rid, 'Rethinking Risk–Benefit Evaluations' (n 399) 160.
[429] ibid 156.
[430] ibid.

However, regulatory theory has its limitations. On its own, it cannot validate whether models (or propositions) hold up in reality; regulatory theory can be highly abstracted and pay too little attention to the 'human' roles in regulatory practice, be they emotions, instincts, and relations, not to mention the connections between regulated objects and the subjects.

The research questions this thesis poses demand an empirically-grounded investigation of regulatory practice. We have learned from an ethnographic study (of the UK Stem Cell Bank) that instantiated regulation brings nuanced insight into how regulation is actually done on the ground, and what it means to be a regulatee who—it turns out—has more of a regulatory role than theory or law might suggest. Other behaviours and experiences of actors may be missing from law and theory that require a fresh perspective and a new lens. In the following sections, first, I introduce anthropology of regulation as a response to the empirical demand and to extant socio-legal and legal anthropology approaches that are insufficient; and then, I argue that liminality is a critical component to anthropology of regulation and a strong response to the need to fill in the knowledge gaps of process and transformation in regulation.

4.4 Anthropology of regulation

This thesis contributes to emerging forms of socio-legal scholarship. Fundamentally, this is a study of the form and function of *regulation* rather than law, and of the behaviours and experiences of those that impact and are impacted by it. Here, I want to make the claim that a novel methodology is required to drive this research forward in a comprehensive way. The rationale behind anthropology of regulation can be summed up by paraphrasing a well-known quote from the socio-legal scholar Lawrence Friedman:[431] Regulation is a massive vital presence in the world; it is too important to be left to regulators—or even to the realm of pure thought. Anthropology of regulation is both an (inter)discipline and a methodology

[431] Lawrence Friedman, 'The Law and Society Movement' (1986) 38 Stanford Law Review 763, 780.

grounded in interdisciplinary dialogue and mixed research methods. It sits neither fully within anthropology nor within law or regulatory studies; it is a mode of enquiry in its own right within the broader social science tradition. It is a study of the nature of regulation and of the behaviours and experiences of actors within a regulatory space (or spaces), and the ways in which they themselves are affected by regulation. It draws on insights provided from law, regulatory studies, socio-legal studies, and anthropology. As a methodology, it draws on empirical qualitative research through methods of document analysis, observation, and interviews.

Anthropology of regulation contributes to the fields of legal anthropology (also known as anthropology of law) and socio-legal studies. Legal anthropology is a similar field, of course, as it aims to understand the nature of law and how it is integral to culture, and culture to law; in other words, it explores how law is a window into the nature of culture itself. Socio-legal studies (and its cousin, legal sociology) employ 'various empirical methods to study what is *legal* about legal processes, legal institutions and legal behaviour'.[432] It draws attention to the interfacing social context within which law exists, and concerns itself with the empirical study of law as a set of social practices or as an aspect of a field of social experience.[433]

The limitation of both approaches is that they tend to take *law* (or legalities) as the primary focus of investigation. As the above discussion of regulatory space elucidates, in making sense of the form and function of regulation, law fundamentally provides boundaries around space(s). Or, as Sarat and colleagues put it: 'In its basic operation, law attempts to create, police, and occasionally transgress social, spatial and temporal boundaries. […] Within law's spatio-

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[432] Reza Banakar and Max Travers, *Theory and Method in Socio-Legal Research* (Hart Publishing 2005) x (Introduction). Some scholars advocate for a broader definition of socio-legal studies, encompassing a shift away from (formal notions of) 'law and' and towards 'legalities' in society. See e.g. David Cowan and Daniel Wincott, 'Exploring the "Legal"' in David Cowan and Daniel Wincott (eds), *Exploring the 'Legal' in Socio-Legal Studies* (Palgrave 2016).
[433] Roger Cotterrell, 'Sociology of Law' in David Clark (ed), *Encyclopedia of Law and Society: American and Global Perspectives* (SAGE 2007).

temporal grid, complex classifications are established, creating boundaries that define individuals, communities, acts and norms…'[434] As discussed above, law's role within the regulatory space is limited; fundamentally, a focus on law alone would not adequately answer my research questions that examine not the logic of boundaries, but rather the logic (or illogic) of processes and regulatory spaces. Moreover, the regulatory spaces with which I am concerned—being those occupied by RECs that are explicitly focused on ethics and *not* law—require an approach to their study that does not put law as the central object of attention. This said, anthropology of regulation does not appear out of thin air; it builds on the work of different strands of methodology from legal anthropology and socio-legal studies, as outlined below.

First, several scholars have undertaken ground-breaking observational studies of human behaviour in the context of regulatory compliance or regulatory enforcement by a public agency or official.[435] To some extent, anthropology of regulation owes its allegiance to these pioneering observational (typically ethnographic) studies. However, to my knowledge, none of these studies have investigated non- or semi-public regulatory bodies such as RECs. Nor have these studies attempted to branch out from compliance and enforcement reflected in command-and-control regulation so as to analyse both the form and function of *non*-rules-based regulation *and* its impact on regulators and regulatees. My research focuses on risk-based approaches and ethical reflection and governance rather than rules-based compliance or enforcement. In the REC world, there is limited 'stick-beating'; at worst, research is

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[434] Austin Sarat and others, 'The Concept of Boundaries in the Practices and Products of Sociolegal Scholarship: An Introduction' in Austin Sarat and others (eds), *Crossing Boundaries: Traditions and Transformations in Law and Society Research* (Northwestern University Press 1998) 3-4.

[435] See e.g. Keith Hawkins, *Environment and Enforcement: Regulation and the Social Definition of Pollution* (OUP 1984); Bridget Hutter, *Compliance: Regulation and Environment* (OUP 1997); Clare Hall, Christopher Hood, and Colin Scott, *Telecommunications Regulation: Culture, Chaos and Interdependence Inside the Regulatory Process* (Routledge 1999); Garry Gray, 'The Regulation of Corporate Violations: Punishment, Compliance, and the Blurring of Responsibility' (2006) 46 British Journal of Criminology 875.

not approved by the REC and thus cannot commence, or the REC revokes its ethics approval following a material ethical breach. Thus, the focus of anthropology of regulation, and specifically my research, is different. As I discuss further below, anthropology of regulation builds on these empirical regulatory studies through its theoretical underpinning of liminality, which draws our attention to the processual nature of regulation and the importance of human experience during periods of uncertainty and transition. Anthropology of regulation also extends this work as it does not seek merely to identify, document, and understand observed regulatory practices. Through its multi-method approach, it also seeks to provide larger theoretical and *normative* insight into regulatory processes within a given space and within a given society. That is, it aims to prescribe and evaluate the desirability of different regulatory strategies and styles. The descriptive and normative arms of anthropology of regulation appear in Chapters 6 and 7, respectively.

Second, Moore's ground-breaking 'sociological study of reglementation', which she defines as 'the study of the way partial orders and partial controls operate in social contexts',[436] provides foundational support to anthropology of regulation. She too desires a qualitative exploration of social processes and order that occur beyond state-based law, considering 'reglementation' as covering both 'government law and non-governmental sites of rule-making and/or rule-enforcing'.[437] Nevertheless, Moore quite clearly bases her approach on *rules*, coded as elements of order and control, which consequently envelops regulation within a narrow paradigm. I have made clear that this thesis concerns itself with regulation, which is much broader than law, even if law is defined as including non-state forms of normative ordering. And, to reiterate, unlike Moore, I believe regulation must include not only rules, but also principles, mechanisms, strategies, or activities promulgated by state or non-state actors that either affect behaviour as an incidental effect or are designed to

[436] Sally Falk Moore, *Law as Process: An Anthropological Approach* (Routledge & Kegan Paul 1978) 30.
[437] ibid 18.

steer behaviour in a socially, politically, and/or economically desirable way.[438] This notion of regulation privileges neither the state nor rules. It does, however, accept and incorporate Moore's message that a researcher should take 'into account that there is a constant struggle between deliberate rule-making and planning, and other more untameable activities and processes at work in the social aggregate, [which] should be inspected together'.[439]

Third, institutionalism (e.g. sociological institutionalism, historical institutionalism, political institutionalism) is an approach that examines, often through empirical methods, how actions and decisions by individual actors may be influenced (or structurally determined) by higher-level institutional factors and contexts.[440] While anthropology of regulation certainly acknowledges that social processes shape regulation (and indeed it is influenced by the institutionalist approach of regulatory space), it does *not* presume that institutions and institutional frameworks influence or constrain decision-making. More importantly, it does not focus its analysis on the structural level of institutions (e.g. laws, the HRA, RECs) to explain processes and outcomes at a lower level (e.g. decision-making by a REC or individual REC members). It does not ask how institutions affect the behaviour of individuals, nor how individual behaviour affects the evolution of institutions. Rather, anthropology of regulation engages in investigation of regulation itself as both an ontological and functional concern. It examines the ways in which regulatory actors affect and are affected by processes of regulation, which in turn sheds light on regulation as a social form. The unique contribution of anthropology of regulation is that it focuses on the behaviours and experiences of regulatory actors within a space (or spaces) and the ways in which they themselves are affected by regulation, but it does so by scaling up of the units of analysis, from the individual-level to the social level and

[438] See discussion in (n 4).
[439] Moore, *Law as Process* (n 436) 29.
[440] Edwin Amenta and Kelly Ramsey, 'Institutional Theory', in Kevin Leicht and J Craig Jenkins (eds), *The Handbook of Politics: State and Civil Society in Global Perspective* (Springer 2010) 15.

drawing insights from empirical research to accomplish what the regulatory space metaphor seeks to do: examine 'how the actions and intentions of regulatory actors are embedded in larger systems and institutional dynamics'.[441] And indeed, the research questions in this thesis aim to explore and explain—through documentary research comprised of historical tracing and present-day regulatory analysis that explicates the internal constitution of regulation, as well as through observation and interviews—the experiences and behaviours of specific individual actors (i.e. units or nodes) in the health research regulatory space governing the *ethics* of health research involving participants, namely RECs and their managing regulators.

In sum, there are limits to law-based or even rules-based methodological approaches. Anthropology as a discipline escapes the trap of a law-based approach that examines and often reifies bounded spaces by instead focusing on what happens *within* the regulatory spaces and *under* the layers of regulation across time. This thesis focuses on regulatory spaces, which are less explored than the classic sites of empirical legal research, though there are signs that legal anthropology is beginning to explore these spaces.[442] This thesis transcends the relatively narrow confines of law as object of investigation (specifically with its positivist connotations about state organisation, rules, rule-making bodies, and judiciary and enforcement agencies) and the logic of boundaries, but it also goes beyond the relatively broad range of social patterns of interaction and forms of internal normative orderings within various communities that characterise much sociological and regulatory studies research.

Thus, anthropology of regulation allows me to investigate both the nature of regulation as a social form (an ontological concern) and what regulation does to

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[441] Morgan and Yeung (n 103) 59.

[442] See e.g. Marie-Andrée Jacob and Annelise Riles, 'The New Bureaucracies of Virtue: Introduction' (2007) 30 PoLAR: Political and Legal Anthropology Review 181; Annelise Riles, *Collateral Knowledge: Legal Reasoning in the Global Financial Markets* (University of Chicago Press 2011); Susan Bibler Coutin and Veronique Fortin, 'Legal Ethnographies and Ethnographic Law', in Austin Sarat and Patricia Ewick (eds) *Handbook of Law and Society* (Wiley 2015).

actors and what actors do to regulation (a functional and experiential concern). In so doing, it permits recognition of the limits of regulation, taking up Moore's apt message (at least through the prism of rules) that we should be cognisant of 'social processes which operate outside the rules, or which cause people to use rules, or abandon them, bend them, reinterpret them, side-step them, or replace them'.[443] Regulatory theory is necessary to help provide potential explanatory background; empirical research is equally necessary to help provide understanding of everyday practice. In essence, anthropology of regulation allows the researcher to bring theory and practice meaningfully together.

Anthropology of regulation consists of theoretical underpinnings drawn from regulatory and anthropological theory and is grounded in a trinity of empirical research methods to provide 'a confluence of evidence that breeds credibility'.[444] The approach is interpretivist rather than positivist: it considers people as products of their environment and as those who construct the environment through their understandings of it. The focus is on subjective understandings: the 'inner worlds' of people and their understanding of the world.[445] It does not seek to produce 'objective' findings about human activities (of which regulation is part) precisely because it rejects that such a position is possible. Documentary research uses interpretive methods to examine sources of regulation to determine how regulation has developed and been applied over time. It asks both what the law is on a particular issue and how an activity is regulated and how that regulation has developed over time. It is, in other words, research into regulation, regulatory concepts, regulatory practices, and the symbioses between them. The result of such interpretation is both descriptive analysis (explaining how a segment of regulation fits within the larger regulatory space) *and* normative evaluation of the processes of

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[443] Moore, *Law as Process* (n 436) 4.
[444] Elliot Eisner, The *Enlightened Eye: Qualitative Inquiry and the Enhancement of Educational Practice* (Collier Macmillan Canada 1991) 110, quoted in Glenn Bowen, 'Document Analysis as a Qualitative Research Method' (2009) 9 Qualitative Research Journal 27.
[445] Lisa Webley, 'Qualitative Approaches to Empirical Legal Research' in Peter Cane and Herbert Kritzer (eds), *The Oxford Handbook of Empirical Legal Research* (OUP 2010).

regulating an activity. The empirical evidence gathered through observation and interviews add to our understanding of human behaviours and experiences, and also are analysed qualitatively. While the specifics of the epistemological and ontological positions, as well as the detailed steps in the empirical research, are described in Chapter 5, the claim I wish to make here is that anthropology of regulation's detailed attention to regulatory sources and human behaviours and experiences allows us to take special notice of context—historical, political, legal, economic, social, cultural, organisational—to explain and understand the nature of regulation as well as the experiences of regulatory actors who both regulate and are regulated. While this might, tangentially, touch on understandings of law, legal concepts, and even legal consciousness of actors,[446] this approach extends socio-legal studies and legal anthropology by fundamentally focusing on the regulatory.

Box 4.2 summarises the key elements of anthropology of regulation.

Box 4.2. Key elements of anthropology of regulation.

1. **Definition**: the study of the nature of regulation and of the behaviours and experiences of actors within a regulatory space (or spaces), and the ways in which they themselves affect and are affected by processes of regulation.
2. **Theoretical underpinnings:** Informed by theoretical underpinnings from regulatory theory (i.e. regulatory space) and anthropology (i.e. liminality) that together draw attention to the human factors that determine the nature of regulation and how regulators actually work, as well as the connections between regulated objects and the subjects (e.g. humans) connected to them.
3. **Methodological approach**: empirical research set within an interpretivist tradition that is constructed around a multimethod approach[447] ('research

[446] For discussion of legal consciousness and the fluidity of legalities as experienced in everyday life, see generally Susan Silbey, 'After Legal Consciousness' (2005) 1 Annual Review of Law and Social Science 323.

[447] I avoid the term 'ethnographic approach' as ethnography implies a particular set of features, whereas anthropology of regulation's features are broader and may be non-ethnographic, e.g. naturalistic observation for a short period of time. Ethnography 'usually

trinity') of document analysis, interviews, and observations to make sense of the form and function of regulation (i.e. what it is and how it is expressed) and its impact on regulators and regulates (i.e. how it is experienced).

- Document analysis: qualitative analysis (e.g. content analysis and thematic analysis) of regulatory sources (e.g. texts) covering a particular area that provides context and historical tracing of how regulations developed and have been applied over time. This includes analyses of the relationship between regulations and regulatory actors. The research is a two-part process that first involves locating regulatory sources (historical and current), and then interpreting and analysing the sources to make sense of processual developments. The outcome of the analysis can be both descriptive and normative.
- Observations and interviews: evidence of the behaviours and experiences of regulatory actors who both regulate and are regulated gathered through direct observation. The gathered evidence is typically analysed qualitatively (i.e. thematic analysis), which, as with document analysis, can be both descriptive and normative. The observation may be naturalistic or participant-based; the interviews may be unstructured or semi-structured.

4. **Goals**: 1) to explain and understand the processual nature of regulation *and* the behaviours and experiences of regulatory actors who both regulate and are regulated (i.e. how they understand their own actions); and 2) to provide larger theoretical and normative insight into regulatory processes within a given space and within a given society.

involves the researcher participating, overtly or covertly, in people's daily lives for an extended period of time, watching what happens, listening to what is said, and/or asking questions through informal and formal interviews, collecting documents and artefacts – in fact, gathering whatever data are available to throw light on issues that are the emerging focus of inquiry'. See Martyn Hammersley and Paul Atkinson, *Ethnography: Principles in Practice* (3rd edn, Routledge 2007) 3.

I have mentioned that anthropology of regulation focuses on the *processual* and is underpinned in part by theory drawn from anthropology. I have not yet discussed the intricacies of anthropological theory and why it serves as a crucial component of the thesis. In the following section, I expand on liminality as a key anthropological concept (and as another 'sensitising concept') that underpins anthropology of regulation and is a crucial component of this thesis's investigation of RECs and next-generation health research regulation. As I will argue, liminality helps us to understand the processual dimensions of regulation—the passages of actors from one stage to another, to document and understand experiential dynamics in regulatory spaces, and to reconceptualise the nature of health research regulation.

4.5 Liminality

4.5.1 Its value to this thesis

As defined by Thomassen, liminality is an anthropological concept that 'refers to moments or periods of transition during which the normal limits to thought, self-understanding and behaviour are relaxed, opening the way to novelty and imagination, construction and destruction.'[448] Thomassen argues that liminality is a universal concept because 'cultures and human lives cannot exist without moments of transition, and those brief and important spaces where we live through the in-between'.[449] In this PhD's context, liminality is central to everyday regulatory practices and mechanisms governing health research involving humans. Given its universality, Thomassen argues liminality should be posited as a central concept in the social sciences, akin to 'structure' and 'practice', for it gives meaning and understanding to how humans *experience and react to change*—and indeed, liminality is foremost based on experience, because to experience something means, etymologically, to *go through* something. Liminality is thus not so much an

[448] Bjorn Thomassen, *Liminality and the Modern: Living Through the In-Between* (Ashgate 2014) 1.
[449] ibid 4.

explanatory concept as it is a state of affairs: it exists, it happens, and humans 'react to liminal experiences in different ways'.[450] It constantly 'emerges in the in-between of a *passage*'[451] and through its constant appearance, it helps us understand transition periods and social processes of change. Liminality can apply to individuals, groups, and even societies, and may occur in a single moment, over a period, or across an epoch. Similarly, liminality has a spatial dimension that can relate to specific places or thresholds (e.g. a doorway in a house), areas (e.g. border areas between countries, airports), and countries or larger regions (e.g. Ancient Palestine).[452] Examples of liminal experiences include marriage, baptism, puberty, graduation ceremonies, New Year, natural disasters, and revolutions.

Liminality serves as an integral component of anthropology of regulation and, as further advantage, accords well with regulatory theory. Both regulatory space and liminality affix themselves to the temporal and spatial dynamics of various actors. However, whereas regulatory space affords a metaphysical mapping of the actors involved in the space (or spaces), liminality affords a processual and experiential understanding of those actors and the ways in which they are affected by regulation, particularly at moments or periods of transition where uncertainty is paramount. The value of liminality is that it serves *as a lens* to make sense of the processual nature of health research regulation and RECs (and individuals therein) as key nodes in the health research regulatory space. It shines analytical light on the kinds of potentially transformative activities RECs both perform and experience. It offers perspective on what it means to be a regulator of health research, and also indirectly through my empirical investigation, draws attention to the experiences of researchers and research participants who, individually and collectively, undergo the transformative experience of becoming these embodied actors.

[450] ibid 7.
[451] ibid 2.
[452] ibid 90-1.

Liminality also supplements the concept of risk-based regulation. Risk-based regulation is about dealing with uncertain futures through the prism of risk identification and management. Liminality often—indeed, usually—occurs when there are moments of change and uncertainty. A lens of liminality therefore helps us both to recognise uncertainties, embrace them to a certain extent, potentially even exploit them, and pay attention to what is required to work through them. Liminality thus has the potential to yield novel insights into the nature of health research and its regulation—and the limits thereof, namely by helping us to uncover alternative paths to governing the behaviour of various actors and enforcing norms across sites of authority in research ethics oversight. It further helps us consider the importance of transition and transformation among critical components of health research.

In what follows, I trace liminality's conceptual evolution.

4.5.2 Conceptual evolution

Liminality as a concept emerged at the beginning of the 20th century. In 1909, the anthropologist Arnold van Gennep wrote that upon analysis of 'detailed descriptions and monographs concerning magico-religious acts' throughout the world, he could 'attempt a classification of these acts, or rites, that would be consistent with the progress of science.'[453] Van Gennep found that all cultures exhibit ritual behaviour (i.e. ceremonies or rites) to mark the passage of an individual or social group from one status to another. However, van Gennep singled out 'rites of passage' in his study as he found them to serve as a critical component of the reproduction of social order: 'The life of an individual in any society is a series of passages from one age to another and from one occupation to another.'[454] 'The underlying arrangement is always the same. Beneath a multiplicity of forms, either consciously expressed or merely implied, a typical pattern always

[453] van Gennep (n 120) xxv.
[454] ibid 2-3.

recurs: *the pattern of the rites of passage*.'[455] In each of these series of passages, ceremonies are invoked by the society in which the individual is situated to enable him or her 'to pass from one defined position to another which is equally well defined',[456] and consequently, these ceremonies share a wide degree of similarity (seen, for instance, in birth, childhood, marriage, and funerals).

Though he did not invoke the noun 'liminality' as such, nor ever define it, van Gennep posited a tripartite conceptual schema of these ceremonial patterns that 'accompany a passage from one situation to another or from one cosmic or social world to another',[457] and selected rites of passage as a special category of transition, which he then subdivided into: (1) the symbolic separation of individuals (or a group) from their existing social position (rites of separation); (2) the transformation of their social status as they pass through an adjacent space (liminal or transition rites); and (3) their spatial and symbolic reincorporation into society (rites of incorporation). Van Gennep clarified that 'although a complete scheme of rites of passage theoretically includes preliminal rites (rites of separation), liminal rites (rites of transition), and postliminal rites (rites of incorporation), in specific instances these types are not always equally important or equally elaborated'.[458] Indeed, van Gennep reiterated several times in his seminal work that the 'liminal' stage often takes on an autonomy of its own.

Often during the transition (liminal) periods in the rites of passage, van Gennep observed that:

> …a special language is employed which in some cases includes an entire vocabulary unknown or unusual in the society as a whole […]. This phenomenon should be considered of the same order as the change of dress, mutilations, and special foods (dietary taboos), i.e. as a perfectly normal differentiating procedure.[459]

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[455] ibid 191.
[456] ibid 3.
[457] ibid 10.
[458] ibid 11.
[459] ibid 169.

Van Gennep further found that the passage from one social position to another is associated with a territorial passage, seen for example in the crossing of streets or entrance into a house or moving from one room to another. 'This identification explains why the passage from one group to another is so often ritually expressed by passage under a portal, or by an "opening of the door".'[460] This focus on territorial passage draws attention to the passages that research protocols go through as they wend their way through the stages of the research lifecycle, an observation that I will return to in Part III.

Building on this interpretation of ritual practices, in the 1960s, the anthropologist Victor Turner 're-discovered' the work of van Gennep, which was largely unknown in the English-speaking world, and extended his analytic framework by turning attention to liminal experiences in non-ritual, Western societies. In so doing, the 'ritual moment' could be less structured, more informal, and lend itself to wider application. Turner expanded the concept in several ways. First, he argued that the liminal state could be distinguished from the 'liminoid' states. Whereas a liminal state is a crucial aspect of the ceremonial process, a liminoid state speaks to the more optional, playful kinds of activities characteristic in the modern world (e.g. music festivals, plays, sporting events). Second, Turner advanced the claim that liminality must be tied to an experientially-based process approach, and he did this by invoking the portmanteau of *communitas*. This refers to moments of transition from one structural status to another where 'a strong sense of "humankindness," a sense of the generic bond between all members of society'[461] comes into being such that pre-existing formal structures disappear and are replaced by an unstructured or loosely structured, spontaneous, ethereal moments of a coming together of individuals on an equal plane.

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[460] ibid 192.

[461] Victor Turner, *The Ritual Process: Structure and Anti-Structure* (Aldine Transaction 2008 [1969]) 116.

In 1971, the sociologists and 'founders' of grounded theory, Glaser and Strauss, also sought to advance van Gennep's work by arguing that 'status passages' (which they considered the modern vocabulary for rites of passage) could be characterised by at least thirteen properties, as outlined in Box 4.3 below.[462] Glaser and Strauss found that by focusing on these properties during analyses of status passages, the more systematic such analyses would be, which in turn would better 'account for the behaviors of, and consequences for, the persons involved in any given status passage'.[463] In their own work, Glaser and Strauss organised the properties of status passage around six principal considerations: reversibility, temporality, shape (i.e. periods, control over the passage), desirability, circumstantiality (i.e. whether the passage is made by one person or in aggregate or collectively), and multiplicity (i.e. multiple status passages experienced by every person).

Box 4.3. Properties of 'status passages', as described by Glaser and Strauss.

1. The passage may be considered in some measure *desirable* or undesirable by the person making the passage or by other relevant parties.
2. The passage may or may not be *inevitable*.
3. The passage may be *reversible* to some degree.
4. A passage may be *repeatable* or non-repeatable.
5. The person who goes through the passage may do so *alone*, *collectively*, or in *aggregate* with any number of other persons.
6. It follows that when people go through a passage collectively, or in aggregate, they may not be *aware* that they are all going through it together or at least not aware of all aspects of their similar passages.
7. Although aware, the person may be unable to *communicate* with the others.
8. The person making the passage may do so *voluntarily* or have no choice in the matter (or perhaps have degrees of choice).

[462] Barney Glaser and Anselm Strauss, *Status Passage* (Routledge & Kegan Paul 1971) 4-5.
[463] ibid 6.

9. There is a degree of *control* which various actors, including persons undergoing the passage, have over various aspects of the passage.
10. The passage may require special *legitimation* by one or more authorised actors.
11. The *clarity* of the signs of passage, for the various actors, may vary from great to negligible clarity.
12. The signs of passage may be *disguised* by relevant actors.
13. There is a *temporality* to the passage, which can be very short or very long or somewhere in-between.

Following Glaser and Strauss's call that 'primary analysis should be organized around those core properties which seem especially relevant to the substantive area under study',[464] attention will be paid to several of these properties in Part III's presentation of the empirical data, particularly the temporality, shape, and multiplicity of passages in the health research regulatory space.

Liminality has been further developed in recent decades by scholars who apply the concept from various disciplinary perspectives to modern social settings and social theorising of modernity, be it political revolutions, earthquakes, gambling, or bungee jumping.[465] Thomassen argues that liminality is omnipresent in modernity, thus completing a circle from what might otherwise seem like a marginal and old-fashioned (if not colonial) anthropological account of status passages in exotic lands to a central conceptual device that helps to capture key features of many moments of modern life.[466] Scholars increasingly also have plumbed the analytic depths of liminality. Diverging from the findings of Glaser and Strauss, who argue that liminality need not be strictly controlled and rigid, Szakolczai contends that any rite of passage 'must follow a strictly prescribed sequence, where everybody knows what to do and how' and that 'everything is done under the authority of a master of

[464] ibid 10.
[465] Thomassen, *Liminality and the Modern* (n 448); Horvath, Thomassen, and Wydra (n 120).
[466] Thomassen, *Liminality and the Modern* (n 448).

ceremonies, the practical equivalency of an absolute ruler […] whose word is Law – though only during a rite, when there is no law.'[467] Other scholars, however, gravitate closer towards Glaser and Strauss; they qualify Szakolczai's observation by suggesting liminal experiences need not always be demarcated with an institutionalised transition 'rite' with identifiable masters of ceremony,[468] such as in moments of 'spontaneous liminality' which is unforeseen and resulting from crisis.[469] Yet Szakolczai's contention that there is often an independent actor serving as a master of ceremonies to guide people through rituals, moments, or periods of transition may have some powerful resonance in health research regulatory encounters; it is one I will return to in Part III.

For this thesis, the key relevant and important features of liminality are its focus on processual change and transformation, and the numerous actors that experience uncertainty and transformations as a result of health research and regulation, both of which in turn cause reflection on how regulatory apparatuses structure process and transformation. Liminality also draws attention to authority figures that may guide actors through status passages. The regulatory theory literature notes that significant coordination challenges can arise in getting actors within regulatory space to operate effectively. Various modes can be devised in response. One such mode is hierarchy, where, often through a legal framework, a top-down arrangement is instituted such that a central control body lays down rules that direct lower-rung institutions within the network. Through the lens of liminality, this is something to consider as existing between the HRA and RECs. For example, the HRA Approval process could be seen as a liminal period in itself. This new procedure has been instituted as of March 2016 for researchers and RECs in England, with direct impact on how they do their work (researchers in putting together the application; REC members in changing which aspects they should be

[467] Árpád Szakolczai, 'Liminality and Experience: Structuring Transitory Situations and Transformative Events' in Horvath, Thomassen, and Wydra (n 120) 18.
[468] Thomassen, 'Thinking with Liminality' (n 120) 50.
[469] Laurie (n 378).

reviewing). The HRA has instituted HRA Approval with the express purpose of smoothing the regulatory approvals process for researchers. Yet the roll-out has been controversial for REC members, many of whom remain unfamiliar with the regulatory changes and feel left in the dark from the HRA about how these changes bear upon them. Not uncommonly, REC members expressed concern to me that the HRA had imposed something top-down on them, perhaps for a good reason, but in a way that also created uncertainty and frustration. A second example of a liminal period includes the HRA's gradual move to a paperless system via HARP—a significant change when one considers the amount of paper that dominates REC operations—which also has caused some controversy among REC members.

Another key feature of liminality is the attention drawn to rituals, which reflect the fundamental values of a group of actors. Additionally, a regulatory network coordination mode itself can be based on rituals. Rituals can serve as 'structured processes that serve to organize not only the actions taken by network members but the meanings that participant individuals or organizations give to events or decisions'.[470] They may be imposed or voluntarily adopted by the network, 'but the essence of ritualistic network coordination is that *embedded processes* drive forward the collaborations that are found within the network'.[471] For many regulators, the central motivation is to employ ritualistic processes 'in a manner that serves their own organizational interests. Their broad attitude will be that interactions with other agencies can best be seen in terms of their impacts on achieving success in rituals. Claims and responses will be processed through embedded procedures and will be structured accordingly.'[472] From within the literature on regulatory theory, Baldwin and colleagues elaborate:

> In *ritualistic cohabitations*, processes can be used to allocate institutional roles and to encourage the development of common aims and approaches by ordering experiences, creating shared meanings, building feelings of community, and encouraging trust. They may be used to facilitate the

[470] Baldwin, Cave, and Lodge (n 101) 161.
[471] ibid (emphasis added).
[472] ibid 162.

> development of discourses that generate bodies of common knowledge, generalized ways of seeing challenges and problems, and authoritative versions of situations and values. The difficulty, however, is that, in the absence of authority, rituals may not suffice to reconcile all interests and perceptions and this may impede the establishing of objectives and an organized regime for delivering on these. Rituals, moreover, can lead to stultification if they are following unthinkingly.[473]

Yet, despite recognition of rituals in regulatory theory, the notion is underexplored both theoretically and empirically. Machado and Burns, some of the few scholars to explore rituals in regulation, explain that 'complex social organisations' (e.g. a state, university, corporation, nuclear system, regulatory agency, large-scale medical system) consist of heterogeneous modes of organising, with each mode containing its own principle, constitutive rules, norms, identity, and so on.[474] These heterogeneous modes can generate benefits, such as creativity, reflectivity, and innovation, but they also can sometimes be drawn into incongruencies, tension, and conflict. To mitigate these problems, organisational spacing, mediators, discourses, and rituals can play a key role. Rituals for Machado and Burns are defined as 'a type of patterned or institutionalized symbolic action, collectively defined and constituted within a group or organization. It consists of words, gestures, and actions and use of objects and artefacts to express a conception, symbolic meaning, feeling or sentiment within a group or collectivity.'[475] They are 'one of the most important devices to define and "re-structure" the experience of situations and events'.[476] Machado and Burns explain that rituals minimise incongruence and tension in non-discursive and non-rationalised ways; this is seen, for example, in hospital rituals that range from rituals of caring (e.g. fixing pillows, touching the patient, taking temperature, writing down information) to rituals of authority and deference such as medical rounds, consultation, case conferences, and mortality and morbidity conferences. These rituals are embedded to a significant degree in the

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[473] ibid 163.
[474] Nora Machado and Tom Burns, 'Complex Social Organization: Multiple Organizing Modes, Structural Incongruence, and Mechanisms of Integration' (1998) 76 Public Administration 355.
[475] ibid 372.
[476] ibid 373.

schedules, procedures, and practices of a hospital: 'Through institutionalized rituals within hospitals, professionals structure their own experiences and the experiences of their clients and avoid or negate considerably incongruent or disequilibrating information and experience.'[477] As they further elaborate:

> Ritual helps to: (a) order the experience in critical situations by creating and re-creating a sense of order in a chaos of experiences, and gives a sense of security through a pattern of predictability (where for example an individual knows what is, has and will be done in such situations); (b) enforce a given meaning in an unclear situation; and (c) strengthen the sense of community that shares knowledge about what is to be done in ambiguous and critical situations. *An important characteristic of ritual (and ritualized behaviour) – that to a large extent accounts for its effectivity and cultural persistence – is that it enables actors to collectively handle ambiguous and incongruent situations in a non-discursive (i.e. non-verbalizable) way*.[478]

We can draw a parallel here to the HRA and the RECs they manage, and in turn, to the interface between RECs and researchers. Though they cite Turner, Machado and Burns do not fully draw attention to the rich linkages between rituals, regulation, and liminality, especially the notions of transition from one stage or threshold to another, nor to the importance of transformation and experience by actors as part of the reproduction of social order. Liminality is particularly helpful in adding value to the analytical framing, which regulatory theory on its own offers only so much. It demonstrates how rituals *and processual developments across time and space* in fact play a crucial role in regulatory coordination when we consider the ways in which an activity (e.g. research) may be regulated by a network of regulators (e.g. RECs, MHRA, HRA) through a variety of rituals (e.g. ritual of consent, ritual of research application construction, ritual of ethics review at REC meetings) that work across numerous thresholds, and which in turn can have a tangible impact on the regulatory actors' behaviour, *particularly when those rituals are disrupted by regulatory change*. Liminality thus supplements regulatory theory by encouraging us to identify and pay attention to symbolically and practically significant stages or thresholds. And, given the processual nature of regulation and the regulatory spaces that exist

[477] ibid.
[478] ibid 373-74 (emphasis in original).

within health research, liminality also buttresses anthropology of regulation by providing a lens for understanding human experiences within health research and the roles of regulation within these spaces.

4.6 Conclusion

In this chapter, I described and justified the strength of my research approach, theoretical underpinnings, and analytical concepts that drive this thesis. Particular attention was drawn to ideas from regulatory theory and anthropology, namely the metaphor of the regulatory space, decentred regulation, risk-based (proportionate) regulation, and liminality. I argued that there are limits to what regulatory theory can tell us about 'what is going on', how and why an anthropology of regulation contributes to and extends common socio-legal research approaches, and how it naturally aligns with liminality. Anthropology of regulation draws attention to experience, time, and space(s) that is otherwise often overlooked in analyses (too narrowly) fixated on law as the object of investigation or (too broadly) fixated on social patterns of interaction. I closed this chapter with discussion of the evolution of liminality and its contribution as a sensitising concept to anthropology of regulation. With the methodological framework now developed, in Chapter 5, I turn attention to research methods by explaining the procedural steps undertaken to embark on this anthropology of regulation. I discuss serendipitous encounters as well as challenges experienced when designing, conducting, and analysing the empirical research.

Chapter 5
Methods—research steps, techniques, and tools

5.1 Introduction

The previous chapter described and justified the research approach, theoretical underpinnings, and analytical concepts that drive my thesis. I argued that regulatory theory provides a solid but ultimately insufficient foundation on its own for the empirical investigation that informs this thesis. I explained that there is a need for an empirically-grounded discussion of regulatory practice, but that extant socio-legal and legal anthropology approaches are also insufficient. I therefore proposed an anthropology of regulation that blends the theoretical with the empirical, and that supplements common research approaches, in part by drawing attention to processes, passages, and transformation.

In this Chapter 5, I build on that methodology discussion by describing the research methods undertaken for my empirical work and which define an anthropology of regulation, including the justification for undertaking a 'research trinity' of document analysis, semi-structured interviews, and naturalistic observation. Research methods can be defined as 'the procedures and activities for selecting, collecting, organizing and analysing data'.[479] Bryman expands on this definition to claim that:

> By 'methods' we typically mean the techniques that researchers employ for practising their craft. 'Methods' might be instruments of data collection like questionnaires, interviews or observation; they might refer to the tools used for analysing data, which might be statistical techniques or extracting themes from unstructured data; or the term might refer to aspects of the research process like sampling.[480]

[479] Norman Blaikie, *Designing Social Research* (2nd end, Polity Press 2010) 8.
[480] Alan Bryman, 'Of Methods and Methodology' (2008) 3 Qualitative Research in Organizations and Management 160.

Bryman contrasts methods with methodology, the latter of which he defines as 'the study of the methods that are employed. It is concerned with uncovering the practices and assumptions of those who use methods of different kinds.'[481]

Applying the definitions above, here I link anthropology of regulation methodology with its methods by discussing procedural aspects such as recruitment strategy, interview topic design, data analysis, ethical considerations, and potential limitations to my methods. This is done on the basis of both description and personal reflection of the challenges and successes experienced. The key aim of this Chapter 5 is to explain how my research methods serve as the most robust platform for answering my research questions and making sense of the empirical data. The aim is also to show how the empirical data presented in Part III will speak for themselves, grounded as they are in an inductive approach, but with recognition that the analysis is drawn explicitly from the anthropology of regulation methodology (including its theoretical underpinnings) described in Chapter 4.

5.2 Research methods

In this section, I describe the choices and steps made in designing the empirical investigation, from the data collection stage through data analysis, as well as the challenges and serendipitous moments experienced.

5.2.1 Research questions and purposes

As noted in Part I, the overarching research question of this thesis is:

> How do RECs act among themselves and interact with other actors within a reformed health research regulatory space that aspires to both protect research participants from harm *and also* promote health research through streamlining perceived regulatory barriers—and what might this mean for the bond of research and ethics as seen

[481] ibid.

through the ostensible REC processes of ethical deliberation and decision-making?

The overarching research question engenders two specific subsidiary questions to guide my investigation:

1. What is the precise nature of the interaction between central regulators and RECs in the health research regulatory space? and

2. What are the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion?

Together, these questions indicate that this study is interested in description and exploration, which are hallmarks of qualitative research,[482] but, taking up a thematic analysis approach,[483] I am equally interested in explaining and understanding the beliefs and practices of regulatory actors, such as RECs and the HRA, and the social and cultural phenomenon of regulatory practice. Thus, these questions are more than description-generating; they are also designed to yield normative insight into health research regulation based on the data, potentially generating a robust evidence-base for regulatory change. To be clear, given its pragmatic orientation, there is nothing that prevents a researcher using thematic analysis from building theoretical models or finding solutions to real-world problems.[484] Though thematic analysis is more commonly applied to locate meaning in the data, it can equally be applied to develop complex and sophisticated conceptual interrogations of the

[482] Qualitative research can be defined as 'any research that uses data that do not indicate ordinal values'. See Guest, MacQueen, and Namey (n 345) 5.
[483] See discussion in Section 2 of Chapter 4.
[484] Guest, MacQueen, and Namey (n 345) 13 (commenting that thematic analysis 'does not preclude theoretical development' but that 'its primary goal is to describe and understand how people feel, think, and behave within a particular context relative to a specific research question').

underlying meaning in data in a systematic way that provides explanation for 'what is going on'.

The empirical research questions address how RECs navigate the regulatory demands of protection and promotion, and set the socio-historical context of RECs within the UK, with a view to demonstrating both the evolution of health research regulation and also the increasingly central role that RECs play in regulating health research. The questions allow me to understand what RECs actually do in assessing the ethical acceptability of research applications. The questions also provide insight into how individual actors within and connected to RECs (such as REC Managers, Chairs, and Scientific Officers) see their roles and practices, and insight into what I perceive their roles and practices to be. REC members and regulators who have served in their role for many years presumably should be able to provide deeper, richer insight into any perceived changes in regulatory practice, but this study is not intended to look exclusively at such perceived changes across time in light of recent regulatory reform. Though historical perspective from these informants is valuable (and, of course, the historical tracing of RECs and health research regulation that was done in Chapter 3 is crucial for understanding regulatory processes), the research questions behind this thesis and situated within an anthropology of regulation focus attention on present practices to understand how and why RECs make the decisions they do, and how the dynamics of RECs and central 'managing' regulators play into regulatory decisions and practices.

Anthropology of regulation, underpinned in part by liminality, draws the researcher's attention to process, time, and place. Health research regulation, and in particular the practice of research protocol approval, is an inherently processual activity. The sensitivity required for an anthropology of regulation encourages the researcher to recognise 'multiple orders' of the social fields within health research regulation; the disparate ways in which regulatory texts are made doable (including through rituals); the processes involved in health research regulation; and the importance of detailing encounters with regulatory actors to illuminate the

interconnected strands within health research. In what follows, I describe my procedural approach to undertaking the empirical investigation and the challenges and successes experienced.

5.2.2 Research strategies and concepts

There is little positive law in the form of judgments and statutes that directly cover RECs, and in any event, I have already explained why analysis of such positive law alone, even through a socio-legal studies prism, would not provide an adequate assessment of the health research regulatory space based on the primary empirical questions I seek to answer. Going beyond the narrow confines of traditional doctrinal and even socio-legal research is necessary as RECs and health research oversight are rooted in multiple disciplines and social contexts, and are situated outside the confines of the juridical field. An anthropology of regulation allows for exploration of not only the regulatory aspects of ethics review of health research, but also the nature, function, and social ramifications of health research and actors within the space, such as RECs and the HRA. For human health research protection *and* promotion to be meaningfully understood, it should be reflected in faithful reporting of the experiences of REC members and regulators who are legally, sociologically, and ethically 'key' informants in the space. As such, my research weaves together elements from the social sciences and regulation, as well as positive law (where this is relevant to the enquiry).

To conduct this anthropology of regulation, I undertook an empirical investigation based on qualitative research methods.[485] Specifically, I employed qualitative research methods of observation and interpretation of conversations, behaviours, and documents to understand human behaviour and the reasons that govern such behaviour. I employed an inductive research strategy: data were collected that could relate to certain pre-identified concepts (namely regulatory space, risk-based

[485] Many of these methods were learnt in two postgraduate courses I enrolled in at the University of Edinburgh in the 2015-16 academic year: PGSP11016 (Data Collection) and PGSP11208 (Research Design).

regulation, liminality) and were analysed to produce generalisations and themes that emerged from the data.[486] Similar to phenomenology, I wanted to 'enter' the social world of the regulatory actors being investigated; I wished to understand how they construct the idea and practice of 'ethics review', and understand their regulatory mandates and the tasks and meanings and motives associated with research ethics oversight. In turn, I wished to *re*-describe these motives and meanings through the theoretical framings of regulatory space and liminality, and situate these within previous empirical research findings regarding RECs, thereby providing more systematic explanatory accounts of what is going on in RECs and health research regulators in our present context. This research strategy, focused on thematic development but also theoretical openness, encouraged me to adopt a 'subtle realist' ontological assumption and a 'constructionist' epistemological assumption.[487] That is, ontologically, I assumed that an independent, knowable reality exists, but also that, epistemologically, knowledge is uncertain and based on cultural assumptions. My aim was to discover why REC members and regulators do what they do based on discovery and description of an 'insider' view.[488] What is presented in this thesis then are not positivist, Baconian 'true' discoveries through empirical observation, but rather, technical and theoretical reflections of my own interpretation of others' everyday knowledge and encounters with the social world.[489]

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[486] Blaikie, *Designing Social Research* (n 479). See also Webley (n 445) 929 (commenting that '[q]ualitative methods often rely heavily on inductive reasoning').
[487] Blaikie, *Designing Social Research* (n 479).
[488] Norman Blaikie, *Approaches to Social Enquiry: Advancing Knowledge* (2nd edn, Polity Press 2007).
[489] Isaac Reed, 'Justifying Sociological Knowledge: From Realism to Interpretation' (2008) 26 Sociological Theory 101.

5.2.3 Data sources, types, and forms

Following the design of my research strategies and concepts, I set out to determine what procedural steps would best answer the research questions. Anthropology of regulation as I have described it is constructed around a multi-method approach ('research trinity') of document analysis, interviews, and observations. Together, these research methods allow for a rich understanding of why RECs are seen as a fundamental part of health research ethics and regulation, and of how RECs operate in practice. It also helps frame the debate about the nature and scope of RECs in the current era. The insights afforded by this multi-method approach also help furnish normative insight into evaluating RECs and health research regulatory oversight. These normative insights form the basis of the recommendations in Chapter 7.

For this chapter, procedurally, the expectation was that the first arm of the trinity—document analysis—would commence in 2015 from my desk, and that the other two arms—the interviews and observations—would commence in January 2016 following regulatory approvals and would last the duration of the calendar year (i.e. largely comprising a data collection year), with 2017 comprising data analysis and writing.

As regards the first arm of the research trinity, I undertook a literature review that centred on qualitative document analysis of legal rules and academic and grey literature from different disciplinary fields—primarily law, anthropology, sociology, and biomedical science—as well as 'human subjects' research regulations. These texts were examined both for substance and context through thematic analysis. Examples of the legal and regulatory sources providing sense of the principles and rules governing RECs include the GAfREC, *Research Governance Frameworks* and the more recent *UK Policy Framework*, REC SOPs, The Medicines for Human Use (Clinical Trials) Regulations 2004, and the Care Act 2014. Examples of academic and grey literature include the many past articles in the BMJ criticising RECs; books on ethics committees, liminality, and regulation; articles from legal and regulatory scholars and sociologists; annual reports and other statements from the HRA; and

governmental and non-governmental reports such as the Lord Warner Report and the AMS's *A New Pathway for the Regulation and Governance of Health Research*.

In the second year of my PhD (2016), this document analysis was coupled with obtaining primary data in word and visual form (through interviews and observations) from individuals and groups in natural and semi-natural settings, as I explain below.[490]

There are several reasons why interviews are a suitable method to answer my research questions, including methodological reasons and more pragmatic reasons such as ease of access and structure compared to focus groups, and suitability for my skillset, unlike questionnaires or surveys, which require knowledge in quantitative research methods and analysis.[491] I viewed the interview method as the most appropriate method in which to gather REC members' and regulators' rich, detailed points of view and to illuminate the meaning of ethics review. It is also a robust method to converse with people to get a sense of their perspective as a stakeholder in research ethics and, together with the interviewee, to produce new knowledge about ethics review and research regulation.[492] Conversing with those directly implicated in the field of ethics review is seen as a beneficial method to draw out insights and perceptions into research ethics oversight, as well as to gather insight on and interpret the challenges of ethics review and uncover potential solutions to those challenges. The goal is not to discover some objective 'truth' about RECs and the regulation of ethics review; rather, it is to understand these individuals' subjective accounts of everyday practice and the issues at stake.[493]

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[490] See in particular the discussion about 'naturalistic observation' at the end of Section 5.2.3.
[491] Alan Bryman, *Social Research Methods* (5th edn, OUP 2016); Jennifer Mason, *Qualitative Researching* (3rd edn, SAGE 2018).
[492] Hilary Arksey and Peter Knight, *Interviewing for Social Scientists: An Introductory Resource with Examples* (SAGE 1999); Svend Brinkmann and Steinar Kvale, *InterViews: Learning the Craft of Qualitative Research Interviewing* (3rd edn, SAGE 2015); Jane Ritchie and Jane Lewis, *Qualitative Research Practice: A Guide for Social Science Students and Researchers* (SAGE 2003).
[493] Reed (n 489).

A limitation of interviews is that the data are restricted to what participants say they do. Observational data reveal what they actually do (at least in the eyes of the observer), strengthening ecological validity.[494] This is especially crucial in a regulated area such as health research, which begs for deep investigation. As Moore observes: 'The more "rational" a society seems in its parts, and its rules, and its rules about rules, the thicker the layer of formalism and ideological self-representation to be penetrated to find out what is really going on.'[495]

Therefore, in the second year I also observed REC meetings to gather data on actual behaviours and practices and develop a detailed description of how RECs operate and make decisions as actors within the health research regulatory space. By observing RECs, I aimed to witness what members of these committees do in their natural settings.[496] This meant that I observed not only REC members, but also a fluctuating array of other actors that form part of the ethics review system, e.g. REC Managers, REC Assistants, investigators, patient advocates, and other Observers. Some of these other actors varied from one meeting to another for different reasons. Individual REC members could be absent for a meeting due to illness or scheduling conflict, investigators and patient advocates would appear only for their specific application, REC Assistants and REC Managers occasionally would be replaced by a substitute, and Observers generally would attend only one meeting. On one occasion, for example, the REC Chair was ill and a Chair from another REC in another city came in to replace him, creating an interesting dynamic with the other REC members. Observations took place at the site where full committee REC meetings occur; usually these are in hotel conference rooms, NHS Health Board buildings, or NHS hospital conference rooms. I took photographs of the meeting rooms (a couple of these photographs appear in Chapter 6). I also collected, with permission, some social artefacts of RECs, such as the agendas of each meeting and,

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[494] Robert Dingwall, 'Accounts, Interviews and Observations' in Gale Miller and Robert Dingwall (eds), *Context and Method in Qualitative Research* (SAGE 1997).
[495] Moore, *Law as Process* (n 436) 30.
[496] Yvonna Lincoln and Egon Guba, *Naturalistic Inquiry* (SAGE 1985).

occasionally, a REC member's review of an application as written in the HRA Ethical Review Form.

A point of clarification: I use the term 'naturalistic observation' in contradistinction to 'participant observation', as the latter implies that the observer becomes part of the group being observed to get a deeper insight into their lives. As an 'Observer' of RECs who was required to remain silent during the meetings, the term 'participant' seems inappropriate, even if I attended multiple REC meetings over one year. Moreover, naturalistic observation describes the technique of observing people in their natural environment, usually episodically rather than continuously (e.g. REC members at their monthly full committee meetings) without any manipulation by the observer, which more accurately describes my research.

5.2.4 Selection of data sources: REC observations

The sample size for interviews and observations was largely dictated by resource and time constraints. I had three years to complete my PhD and had to ensure that the data collected were robust enough to answer my research questions, but not so large to make it impossible to analyse them in the time allotted to me by the University. I determined at the end of the first year of my PhD, in October 2015, that it would be sufficient to select four RECs across both England and Scotland for observation over the period of approximately one year (the majority of which would be in the second year of the PhD in 2016), though as I explain below, this eventually increased to five RECs. Consulting with my supervisors, I identified RECs on both sides of the border. This was not out of an explicit desire for a comparative approach in either a legal or social science methodological sense, but rather, to collect data in different settings. Nonetheless, throughout my research trinity, I intended to account for any perceivable cultural and legal differences between these two nations. RECs were also identified relatively early on in my PhD, just after my First Year Panel and simultaneous to my ethics application to the Edinburgh Law School Research Ethics and Integrity Committee (REIC). This enabled me to leave sufficient time to navigate the necessary regulatory approvals from my own Law

School's REIC, the HRA, and the Health Boards in Scotland (as well as the Scottish Government through the CSO), which could be further subject to tailored arrangements for each REC based on what each REC Chair felt comfortable agreeing to.

One REC was identified through a serendipitous encounter with an academic colleague who is a member of a REC in England. In September 2015, when chatting with her at a biobank conference in London, she suggested that I write to her REC Chair to see if it would be possible to observe it. Accepting her advice and invitation, I did so, and the Chair invited me to observe the REC over the course of the year. The other three RECs I purposively selected through browsing the HRA's online REC directory:[497] I selected one REC in England and two RECs in Scotland. These RECs were deliberately chosen for their geographic differences and for their different 'committee flags', which is the term used by the HRA to denote specific areas of health research that RECs are authorised to review (e.g. gene therapy clinical trials, phase 1 studies in healthy volunteers). The fifth REC also was added serendipitously. I encountered it after an interviewee suggested I speak with the Chair of this REC; I then did so, and he invited me to observe his REC. I also was invited by two interviewees to observe two of the HRA's five offices in England: the Skipton House office in London and the Jarrow office, which is situated outside of Newcastle. A third interviewee (REC Manager) invited me to the NHSScotland Health Board office where her REC meets to get a sense of how her job and the HARP system works.[498] Table 5.1 lists attributes of each of the five RECs observed. Below I explain why the Scotland A REC is explicitly identified.

[497] Health Research Authority, 'Search RECs' <http://www.hra.nhs.uk/news/rec/>.
[498] HRA Assessment Review Portal (HARP) <https://www.harp.org.uk/Account/Login>.

Table 5.1. Attributes of RECs observed in 2016/17.

REC	Location	Committee type	HRA committee flags
REC 1	England	• RECs recognised to review CTIMPs in patients - type iii	• IRB Registered • Research Involving Children
REC 2	England	• RECs recognised to review CTIMPs in patients - type iii	• Establishing Research Databases • Establishing Research Tissue Banks • Phase 1 Studies in Patients • Research Involving Adults Lacking Capacity • Research Involving Children
REC 3	England	• RECs recognised to review CTIMPs in healthy volunteers - type i • RECs recognised to review CTIMPs in patients - type iii	• Gene Therapy or Stem Cell Clinical Trials • IRB Registered • Phase 1 Studies in Healthy Volunteers • Phase 1 Studies in Patients • Research Involving Children
REC 4	Scotland	• Authorised REC	• *No flags*
Scotland A REC	Scotland	• RECs recognised to review CTIMPs in healthy volunteers - type i • RECs recognised to review CTIMPs in patients - type iii	• Gene Therapy or Stem Cell Clinical Trials • IRB Registered • Phase 1 Studies in Healthy Volunteers • Research Involving Adults Lacking Capacity

I agreed with the REC Chairs to not identify the observed RECs in my thesis. However, I obtained explicit consent to identify one of the RECs, the Scotland A REC, which meets monthly in Edinburgh.[499] This was done because of the unique nature of this REC; indeed, it would be impossible to adequately anonymise since it is the only REC in Scotland that is authorised to review 'Phase 1 studies in healthy volunteers' and 'research involving adults lacking capacity', as the HRA parlance

[499] Consent was obtained in the Scotland A REC meeting held on 19 January 2017.

terms it. Even a brief amount of description of the REC and its dynamic likely would enable someone to identify it. The Scotland A REC was specifically constituted by statutory regulation in 2002[500] following the enactment of the Adults with Incapacity (Scotland) Act 2000. Uniquely, members of the Scotland A REC are appointed not by a Health Board, but by the Scottish Ministers. That I can explicitly identify this REC bodes well for the analysis to come in Part III, particularly regarding exploration of the legal constraints of the Scotland A REC. In unpacking what the rules say, this *sui generis*, legally constrained entity can be compared to the other, comparatively less regulated RECs and it may be observed whether this REC feels more constrained in its regulatory behaviour ('room to roam') than others.

5.2.5 Selection of data sources: interviews

As to the third arm of my 'research trinity', I planned to approach targeted RECs and regulatory bodies to interview individuals situated within RECs (as members, Chairs, and Managers) and regulatory bodies (e.g. HRA, NREAP situated within the HRA), or straddling both (Scientific Officers). These were conducted as one-on-one, in-depth, semi-structured interviews. The interviews were conducted in a semi-natural setting, specifically in-person at the individual's office or over Skype, to discuss the activities in which these individuals were engaged in their natural settings: REC(s) or regulatory authorities that oversee RECs.

My strategy for the (managing) regulator-associated interviewees was to accumulate names through snowball sampling. After initially identifying a couple of individuals based on recommendations to me from a Scientific Officer and the HRA's Head of Research Ethics Service (England), I asked interviewees who else they thought would be valuable to speak with, whether they be regulators or REC members. This strategy worked well in accumulating a list of names, including the Chair of the fifth REC I came to observe. My strategy for the REC-associated

[500] Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002, as amended 2007. Originally, two RECs were authorised to review adults with incapacity research in Scotland: MREC A and MREC B. They merged in 2008 to form the Scotland A REC.

interviewees was to approach the Chairs of the two initially identified RECs in England to see if they would be willing to be interviewed. Both obliged. I also asked each Chair if they would be comfortable asking their members and the REC Managers to share their email addresses with me, so that I could then contact those members who responded affirmatively. Again, the REC Chairs obliged with this request, the first one very early on in 2016. A somewhat different strategy was employed in Scotland, where the responsible Scientific Officer requested that I work through him/her and the REC Co-ordinators rather than directly contacting the REC Chairs. This difference signified to me quite early on the crucial gate-keeping role of the Scientific Officer in the Scottish RECs.

Remaining mindful of resource and time constraints, I intended to interview no more than 25 individuals, constituting a mix of REC members and regulators involved in health research ethics and RECs particularly. Ultimately, emails were sent to 30 individuals, some of whom were REC members that contacted me first after my email address and interview request was shared with their REC Chair. In the end, 28 individuals were interviewed after two failed to respond to follow-up emails after expressing initial interest (both of whom were members of a REC in Scotland). Of these 28, seven were affiliated with the HRA (one was a member of the HRA's NREAP), and the rest were REC members or Scientific Officers.[501] This number exceeds what is deemed necessary to achieve both 'code saturation' (i.e. adequate identification of the range of thematic issues) and 'meaning saturation' (i.e. adequate textured understanding of the issues).[502] Eleven of the participants were located in Scotland; the remainder were located in England. The average interview time was 65 minutes (ranging from 27 minutes to 99 minutes). I sought and obtained written consent (via email) and verbal consent (prior to the interview

[501] Several of these participants emphasised to me that they were speaking in their individual capacity and not on behalf of their organisation.
[502] Monique Hennink, Bonnie Kaiser and Vincent Marconi, 'Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough?' (2017) 27 Qualitative Health Research 591. The authors find that code saturation is reached at nine interviews, while 16 to 24 interviews are needed to reach meaning saturation.

commencing) from each interview participant. Table 5.2 below lists attributes of each of the interviews. In the remainder of this thesis, I refer to each interview participant as P1, P2, and so on.

Table 5.2. Attributes of interviews.

Interviewee (participant: 'P#')	Location of interviewee	Date of interview in 2016	Affiliation of interviewee: REC-affiliated, managing regulator-affiliated, or both	Location of interview: In-person or Skype
P1	England	29 January	Regulator (HRA)	In-person
P2	England	29 January	Regulator (HRA)	In-person
P3	England	1 February	REC (Chair)	Skype
P4	England	3 February	Regulator (NREAP)	In-person
P5	England	8 February	REC (member)	Skype
P6	England	9 February	REC (member)	Skype
P7	England	11 February	REC (Vice Chair)	Skype
P8	England	12 February	REC (member)	Skype
P9	England	15 February	REC (Vice Chair)	Skype
P10	England	16 February	REC (Chair)	Skype
P11	England	25 February	REC (Chair)	Skype
P12	Scotland	3 March	REC (member)	In-person

P13	England	3 March	Regulator (HRA)	Skype
P14	England	7 March	REC (member)	Skype
P15	England	11 March	REC (Manager)	Skype
P16	Scotland	14 March	Both (Scientific Officer)	In-person
P17	England	30 March	Regulator (HRA)	Skype
P18	Scotland	19 April	REC (member)	Skype
P19	Scotland	11 May	REC (member)	Skype
P20	Scotland	13 May	REC (member)	Skype
P21	Scotland	17 May	REC (member)	Skype
P22	Scotland	19 May	REC (member)	Skype
P23	Scotland	4 July	Both (Scientific Officer)	Skype
P24	Scotland	4 July	Both (Scientific Officer)	Skype
P25	Scotland	7 July	REC (Manager)	Skype
P26	England	13 July	Regulator (HRA)	Skype
P27	Scotland	13 July	Both (Scientific Officer)	Skype
P28	England	14 July	Regulator (HRA)	Skype

5.2.6 Interview guides

As these interviews were semi-structured, two interview guides were designed, one for REC members (including Chairs and Managers), and another for the regulators at the HRA and Scientific Officers.[503] The interview guides were formulated based on findings from the document analysis conducted in 2015 and were influenced by an anthropology of regulation methodology: many of the questions were crafted to draw out the experiences of REC members and regulators, and to understand the ways in which they themselves affect and are affected by processes of regulation. Though the structure of questioning was consistent in the interviewees (beginning with biographical background and ending with questions about overall satisfaction with the ethics review system), many of the specific questions were modified as the study progressed to iteratively explore themes that appeared to emerge in prior interviews. After making a brief introductory statement about my research project and emphasising confidentiality and confirming consent with participants to audio-record and transcribe the interview, the interview then proceeded to explore several broad topics as follows.

Regarding the REC member interview guide, I first asked for the participant's background information, including their involvement in ethics review and a summary of their current activities, with the expectation that their life experiences (within and outwith research ethics) might shape their views as a REC member. I then asked about their REC characteristics (e.g. the 'usual procedure' in their REC for reviewing and monitoring, if one existed; the ethical standards of research applications), to see whether REC members might have widely varying ideas as to what constitutes a 'good' REC and a 'good' ethics review, and how (if at all) ethics is instantiated in reviewing and monitoring a research project. I then discussed with them the 'next-generation' regulatory environment of health research regulation so

[503] Both interview guides are available in the Appendices (Appendix 1 and 2).

as to gather perspectives on whether participant protection and research promotion were perceived as regulatory objectives in their work as members. I also asked for their views on whether the REC system was operating well and whether any improvements could be made. Finally, I closed the interview by asking whether the participant had any points to discuss, and any questions they may have. I thanked the participant for their time, reminded them of my duty to respect confidentiality, and, in some instances, asked if they had suggestions for other individuals I could interview. The interview guide for regulators and Scientific Officers was similar; the only difference was that some questions were either focused more on health research regulatory dimensions or were tailored to be broader to cover the state of RECs across the UK, England, or Scotland. Though the interviews were semi-structured, they were also open-ended, leaving participants free to form and express multiple associations with the concepts of 'protection' and 'promotion' and how these twin regulatory demands were seen to be operationalised in everyday practice of RECs, again, if at all.

5.2.7 Navigating regulatory approvals

Following identification of the RECs I wished to observe and drawing up an initial list of interviewees, in September 2015, I made inquiries with the Research Governance & QA Office at the University of Edinburgh concerning the regulatory approvals I may need for my empirical research. The Office suggested that I contact one of the Scientific Officers responsible for the RECs in the South East Scotland area (which covers Edinburgh), who could advise on the regulatory approvals needed. I did so in late September 2015. The Scientific Officer very quickly replied, stating that Edinburgh Law School's REIC would be appropriate and sufficient for ethics approval, and that NHS ethics approval (via a NHS REC) was unnecessary for my project as there was no policy requirement as per the REC SOPs (e.g. research involving NHS patients, data, or tissue) and no legal requirement (e.g. ionising radiation, adults lacking capacity). The Scientific Officer also informed me that I would need to obtain 'management' approval from each of the HRA and the relevant Health Boards in Scotland, as well as the CSO since Scotland A REC

members are appointed directly by the Scottish Ministers and the CSO runs the Research Ethics Service in Scotland. This necessitated completing the electronic IRAS Application Form (Parts A-D),[504] along with other documents, for review and approval by both the HRA and the Health Boards and CSO in Scotland.

Following the Scientific Officer's confirmation, in late September 2015, and with the assistance of the Scientific Officer, I was put in contact with the HRA's Head of Research Ethics Service (England) to begin the process of obtaining HRA management approval to observe the RECs in England and interview individuals. She informed me that she could arrange my observation of REC meetings and interviewing of REC members in England if I let her know which RECs I was interested in; she also suggested that I approach REC members via the REC Chair or Manager, which she also could arrange, and that ultimately it would be up to the individual REC members to decide whether to participate.

Late September through November 2015 was dominated by preparatory regulatory approvals work. I submitted a 'Level 2' ethics application form (and related documents, such as consent forms and interview topic guides) to Edinburgh Law School's REIC on 7 October 2015; approval was received on 25 November 2015.[505] In October and November, I drafted the IRAS application in consultation with the point person in the Research Governance & QA Office at the University of Edinburgh, who kindly commented on draft versions of the 29-page IRAS NHS R&D application form, and informed me of the relevant materials I would need to include with my submission, including a 'study protocol', interview topic guides, and consent forms. On 10 November, the Research Governance & QA Office 'signed

[504] Integrated Research Application System <https://www.myresearchproject.org.uk/>.
[505] Edinburgh Law School's REIC does not compose written approval letters, nor keep a numbering system for applications received and reviewed. However, I have retained the email communicating ethics approval of my project, which serves as the 'official' correspondence.

off' on my IRAS form,[506] which enabled me to submit it for review by the HRA and Health Boards. That same day (much to my surprise), I received approval from the HRA's Head of Research Ethics Service (England) and the following day, received R&D acknowledgement from NHS Lothian Health Board in Scotland.[507] On 9 December, I received confirmation from the CSO that they had no objection to my approaching NHS RECs in Scotland for the purpose of my project.[508]

Thus, by the end of 2015 and much to my delight, I had achieved the target of securing all necessary regulatory approvals to commence my empirical research in England and Scotland, and following these approvals, secured the first several interviews to commence in late January 2016, coincidental with observations of the two initially identified RECs in England. The first REC observation in Scotland took place in February 2016, following the Scientific Officer speaking with the two identified Scottish RECs and securing approval from each of the REC's Chairs.

5.2.8 Data collection and timing

The research questions call, in part, for a historical tracing of RECs and health research regulation to make connections between the milieu of REC members and regulators and the wider social and historical forces in which they are enmeshed. This is a classic approach in social sciences and socio-legal research.[509] For the most part, however, this was a cross-sectional project aiming to explain and understand REC members' and regulators' motives and meanings in the current regulatory era, which necessitates an anthropology of regulation that draws on empirical research that bridges theory and practice. Data from the interviews were collected at one

[506] IRAS ID 194243; Study title: 'The changing health research regulatory environment and NHS RECs'. The University of Edinburgh is my project Sponsor. This approval letter is available in Appendix 3.
[507] An R&D letter from NHS Lothian (covering the Edinburgh area) waiving approval is available in Appendix 3.
[508] A copy of the confirmation email from the CSO is available in Appendix 3.
[509] See e.g. C Wright Mills, *The Sociological Imagination* (OUP 2000 [1959]).

point in time in 2016, while data from the REC meeting observations were collected at multiple points in 2016 and early 2017.

As noted in Chapter 2, RECs meet monthly at full committee meetings up to 11 times per year. Knowing that two of the identified RECs had overlapping meeting dates and that I had cross-competing academic commitments in my diary, I aimed to observe at least four meetings for each REC over 2016, though this would come to depend not only on my own schedule, but in the case of Scotland, unforeseen situations such as one of the RECs cancelling a meeting when no new applications were received. This would also depend on the ongoing need of approval from the REC Chairs via the Scientific Officer and REC Co-ordinators, which seemed to turn on whether other Observers were already scheduled to attend a meeting (a reoccurring issue for the Scotland A REC), and thus eliminating my ability to do so. The concern was that that REC Chairs did not want too many Observers attending a meeting, which might distract the REC members and/or the investigators attending in person. In total, I attended 24 REC meetings. The REC observation schedule in 2016/17 is reflected in Table 5.3.

Table 5.3. Schedule of REC observations in 2016/17.

REC	Times observed
REC 1	5 (2016: January, March, July, September, October)
REC 2	6 (2016: March, April, May, August, October, November)
REC 3	5 (2016: April, June, August, November, December)
REC 4	5 (2016: February, June, July, November, December)
Scotland A REC	3 (2016: February; 2017: January, February)

Before each REC meeting commenced, I would greet the REC Chair and Manager/Co-ordinator, the latter of whom would sometimes hand me a standard HRA confidentiality agreement form (tailored only to state which REC it applied to), which I was asked to sign and date. (Other times, the REC Manager/Co-ordinator would email the form for me to sign and return email in advance of the meeting.) The confidentiality agreement required me, as an Observer (a term discussed in the GAfREC and SOPs[510]) to agree to treat in complete confidence all information disclosed to me either in the meeting documentation or matters discussed at the meeting.[511] In addition, some of the Chairs would verbally inform each investigator who attended the meeting that I was an Observer conducting PhD research on RECs, and give the investigator an opportunity to object to my presence (if there was an objection, I would have been asked to leave the meeting room for the REC's face-to-face discussion with the investigator). No investigator ever objected to my presence; indeed, the most common reaction was one of casual indifference, focused as they were on soon being interrogated by the REC members. This action by the Chairs is recommended (phrased as a 'should') in the SOPs,[512] and indeed, it was not always followed. Some Chairs would never inform investigators of my presence as an Observer; others would sometimes inform the first few that

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[510] The GAfREC state that 'REC meetings are not public meetings. External observers may attend following a written invitation which states the terms and conditions of their attendance. Attendance will be agreed by the REC and minuted accordingly.' They also state that 'Observers play no part in the deliberations of the REC.' See GAfREC (n 1) paras 4.2.22, 4.2.23. Similar language is in the SOPs, with the added proviso that:

> External observers may be invited to attend REC meetings, subject to written invitation setting out the terms under which observer status is permitted, the signature of a confidentiality agreement, and the agreement of the REC at the meeting to be attended.

See REC SOPs (n 37) para 2.68.

[511] An anonymised version of this confidentiality agreement is available in Appendix 4. To adhere to this agreement signed at each REC meeting observed, Part III discusses matters observed at these meetings in a general sense; I do not disclose any information specific to individuals, institutions, or research projects.

[512] REC SOPs (n 37) para 2.72.

would appear at the meeting but then apparently forget my presence as the hours of the meeting progressed.

To ensure that the data were accurate and comprehensive, I audio-recorded the interviews with the permission of each participant. To record behaviours, actions, and settings of the REC meetings, I wrote fieldnotes on a tablet computer.[513] This was not an extraordinary sight; at each of the REC meetings, at least one member would operate from a tablet or laptop.

5.2.9 Data analysis

Digital files of the audio-recorded interviews were immediately uploaded securely and transcribed in intelligent verbatim by a digital audio transcription typing specialist company based in Midlothian, Scotland (1st Class Secretarial). Via written agreement, the company agreed to treat all transcribed interviews in confidence. Once the transcribed interviews were completed by the professional transcribers, I would compare the transcription with the audio recording to ensure accuracy. The transcripts and fieldnotes were then anonymised by removing all identifying information that enabled indirect or inferential identification. The audio file of the interviews would then be deleted both from my computer and the company's server within three months from the recording. Once both the interview transcripts and the majority of the fieldnotes were completed in late 2016, I printed out hard copies of both and put them into binders. Coding was done manually and in multiple stages, with Microsoft Office Spreadsheet and Microsoft Word used as electronic aids (e.g. keeping tabs of codes, development of a systematic and iterative codebook), as I felt I could obtain a deeper connection with the data and see patterns more clearly than I could with qualitative research software such as NVivo, which, though a powerful tool to assist in data analysis, is more prone to overwhelm than enlighten me. Several scholars have noted that simple word processing and spreadsheet

[513] Knowledge of how to write ethnographic fieldnotes, as well as how to analyse them, was gained through reading Robert Emerson, Rachel Fretz, and Linda Shaw, *Writing Ethnographic Fieldnotes* (2nd edn, University of Chicago Press 2011) and Hammersley and Atkinson (n 447).

applications can be used effectively with qualitative data.[514] During the coding process, I took notes in a memo-style format by writing down words and thoughts I considered could be of use during the data analysis and serve as a reference for potential coding ideas.

The analysis was inductive (i.e. data-driven) in that I coded the data without attempting to fit them into a pre-existing coding frame or analytic pre-conceptions. This is not to say that I coded the data absent any theoretical and epistemological commitments, as anthropology of regulation is underpinned by theoretical concepts drawn from regulatory theory and anthropology (such as regulatory space, risk-based regulation, and liminality). However, I made a conscious effort to strongly link the identified themes discussed in Part III of this thesis *to the data themselves*, rather than casually map or force the data onto any of my theoretical underpinnings or analytic interests in the area.

As mentioned in Chapter 4, the data from both the interviews (transcripts) and observations (fieldnotes) were coded using qualitative thematic analysis, which is the most commonly used method of analysis in qualitative research, though it is much less well discussed in the research methods literature compared to approaches such as grounded theory. Thematic analysis offers theoretical freedom and flexibility to yield rich and detailed, yet complex, accounts of data, providing an understanding of the 'big picture'.[515] Thematic analysis can be divided into six phases: 1) becoming familiar with the data (i.e. creating a 'start list' of potential codes in a journal or in memos prior to reading the transcripts or fieldnotes); 2) generating initial codes in a cyclical process; 3) searching for categories and themes (i.e. examining how codes combine to form over-reaching themes in the data); 4)

[514] Daniel Meyer and Leanne Avery, 'Excel as a Qualitative Data Analysis Tool' (2009) 21 Field Methods 91; Johnny Saldaña, *The Coding Manual for Qualitative Researchers* (3rd edn, SAGE 2016).
[515] Braun and Clarke (n 344).

refining and reviewing categories, subthemes, and themes; 5) defining and naming subthemes and themes; and 6) producing the report.[516]

The process was such that I generated initial codes by comparing each of the transcripts and fieldnotes. I started 'open coding' by reading each transcript and the fieldnotes (collated into five bundles for each observed REC) word-by-word and line-by-line. After completion of the open coding, I constructed initial codes that emerged from the text and then coded the remaining transcripts and fieldnotes with those codes. When I encountered data that did not fit into an existing code, I added new codes (the total number of codes exceeded 250). I then grouped the similar codes and placed them into categories. These categories were reorganised into broader, higher order categories, then grouped, revised, and refined, and finally checked to determine whether the categories were mutually exclusive. At this point I formed final categories, identifying subthemes both within and across the categories, which were then organised into main themes.[517] This process of coding using qualitative thematic analysis enabled me to fulfil the goal of anthropology of regulation: to explain and understand the processual nature of regulation and the experiences of regulatory actors who both regulate and are regulated (i.e. how they understand their own actions), thereby providing larger theoretical insight into regulatory processes within a given space and within a given society. The results of this analysis comprise Part III.

5.2.10 Research method limitations, challenges and successes, and ethical issues

There are some limitations with my research design. Regarding the research strategy, analysis revealed from an inductive approach is limited in time and space—in my case, broad generalisations from research regarding RECs, the nature of ethics review, or health research regulation are not possible. I can only present themes and concepts that emerged from the data as situated in the locations under

[516] ibid.
[517] This inductive approach is taken from Cho and Lee (n 351).

study and in the time period in which the data were collected. But, as Moore says, 'life in society should always be conceived in a time-conscious frame, as in process, as in motion, and as a conglomeration of diverse activities noted at a particular time'.[518] For anthropology of regulation to have methodological integrity and resonance with liminality, attention to time-conscious frames and processes are a sign of strength rather than weakness. Semi-structured interviews are also necessarily limited to capturing a moment in time. This does not mean, however, that the themes and normative findings to be described in Part III cannot be abstracted beyond the RECs observed and individuals interviewed, nor that the findings cannot be situated in their larger political, social, and regulatory contexts (which themselves contain past and present stories).

There are limitations to the naturalistic observations. First, I observed only a snippet of what happens in ethics review processes. The full REC meetings that occur monthly are but one of the many activities that RECs perform; for example, previous chapters have noted that there is sub-committee work (e.g. Proportionate Review, substantial amendments) conducted 'by correspondence' (i.e. email), and there are multiple documents that circulate among the REC members that I never had access to, the most important of which were the research applications and attendant documents themselves. This limited my ability to understand the intricate details of the discussions during REC meetings; I could only surmise what REC members were talking about for a given research application as I never could see the documents themselves. Second, the observations do not constitute a representative sample of RECs across the UK and may not be reliable as variables cannot be controlled, which also means cause and effect relationships cannot be established (e.g. that the Care Act 2014 and the HRA's regulations *cause* RECs to instantiate research promotion in their practices). I did not perceive any pronounced observer effects, however. This was likely due to the fact that Observers are a regular

[518] Sally Falk Moore, 'An Unusual Career: Considering Political/Legal Orders and Unofficial Parallel Realities' (2015) 11 Annual Review of Law and Social Science 1, 2.

presence at REC meetings and I sat quietly either at a corner of the conference table, or in a chair in the corner of the room, taking notes by hand or on my tablet computer. Occasionally, REC members would make a joking remark to the effect of, 'Are you recording that, Edward?', but my impression was that my presence did not impact the style and substance of meeting dynamics.

Reliability with thematic analysis causes some concern as a limitation (particularly for those within a positivist tradition) because of the wide variety of subjective interpretations that arise from the themes, as well as applying themes to large amounts of data (in my case, a daunting corpus of approximately 1000 pages of transcripts and fieldnotes). To increase reliability as much as possible, I monitored themes and code tables throughout the data analysis process through memos and detailed progress tracking.[519] Regarding limitations to the sampling strategy, it may both under- and over-represent particular groups (e.g. RECs and individuals) within the sample. For instance, many of the REC member interviewees were members of the same REC in England; also, I interviewed only two REC Managers and three REC Chairs, which consequently may not provide a comprehensive portrait of these roles. Since the sample of interviewees and RECs was not chosen at random, there is an inherent selection bias such that the samples are unlikely to be representative of the target population of RECs, REC members, and regulators. Again, this can undermine my ability to make generalisations from my sample to RECs and health research regulation at large.[520] Nonetheless, purposive and snowball sampling afforded me relatively easy access in a short amount of time and yielded significant data that, in my firm belief, addressed my research questions.

One of the challenges anticipated was access to meetings. RECs (and REC members) are notoriously difficult to access for those wishing to make them the object of

[519] Guest, MacQueen, and Namey (n 345).
[520] One example of this was my observation that the demographics of RECs do not match that of Scotland or England. There was noticeable gender balance among REC members, but all members in the five observed RECs were white (save for one) and well-educated, and appeared to be of a relatively high socio-economic status.

investigation.[521] Similarly, regulators can be difficult to access and may not speak forthrightly about their views. Yet few access difficulties were encountered. Though I was expecting the HRA, the CSO, or a specific REC Chair to decline my requests, none did, and on the contrary, all were quite accommodating. I was particularly surprised at how accommodating the HRA was in both allowing me to speak with employees within the Authority, and also expressing interest in my project. This is not to say that no challenges were encountered during the course of the empirical studies. Gaining ongoing access to RECs and REC members in Scotland, particularly the Scotland A REC, proved more challenging than I had expected. This was due to the Scientific Officer and REC Chairs acting as first-order gate-keepers, something I had not appreciated until I had largely completed the data collection in 2016. It was not unusual for the Scientific Officer or REC Manager to inform me that I could not attend a REC meeting, even if previously agreed, because other Observers (including from the Scottish Government) had requested to attend the meeting and they took priority. Though this was a frustrating experience in terms of slightly delaying the period of data collection, overall, it did not impact my research findings. I was able to attend each REC several times and gain access to the individual members with whom I wanted to speak.

Regarding ethical issues, in the course of drafting the 'Level 2' ethics application form (i.e. application for research involving humans) for Edinburgh Law School's REIC and drafting the R&D application form for the HRA and Health Boards, I reflected on the subject matter of the empirical studies and the ethical issues they might present. There were no physical risks involved in participating in this project. I expected that the personal or emotional risks involved would be small, basically equivalent to the possible stress faced by participants who discuss their professional experiences with friends, family, or workplace colleagues. Should participants feel

[521] Such access challenges for empirical investigations of ethics committees were noted, for example, by van den Hoonaard, *The Seduction of Ethics* (n 79) 10, 39 and Klitzman (n 123) 360-61. See also Raymond de Vries, 'How Can We Help? From "Sociology in" to "Sociology of" Bioethics' (2004) 32 The Journal of Law, Medicine & Ethics 279.

uncomfortable sharing their opinion or experience at any time during the interview, I informed them that they could refuse to answer any question at any time. While the subject matter in the interviews was not deemed sensitive, nor were the interviewees deemed vulnerable, I endeavoured to protect the confidentiality of both interviewees and the RECs. All data collected from the interviews and fieldnotes have been kept strictly confidential. All personally identifying information was removed from the transcripts and coded with a number. Only three individuals had access to the raw data in identifiable form, namely myself and my two PhD supervisors.

5.3 Conclusion

In this chapter, I described the research design for my empirical research, including the procedural steps undertaken. This comprised discussion of data sources (and justification for my 'research trinity' of document analysis, semi-structured interviews, and naturalistic observations), data collection and analysis, and the ethical issues encountered. I also highlighted both difficulties and successes in the course of undertaking the empirical research, such as gaining access to RECs and securing the necessary regulatory approvals. Overall, there was great satisfaction in how the data collection and analysis stages developed; the collection was more or less within the projected timeframe, and the data analysis has yielded rich findings. The limitations of this research have been acknowledged, though they do not undermine the integrity and strength of my findings.

Both Chapters 4 and 5 covered how I conducted my research about health research regulation, regulatory processes, and RECs from the distinct methodological standpoint of anthropology of regulation. Anthropology of regulation was constructed because there was no pre-existing and prescribed method that enabled me to investigate regulation and regulatory actors in the ways I desired, while remaining mindful of the importance of presenting an original, systematic, reliable, and rigorous contribution to the interdisciplinary field of health research regulation. I desired a more creative approach to this investigation that would draw on

theoretical diversity and innovation, particularly inspiration from Hancher and Moran's concept of regulatory space and van Gennep's notion of liminality, to provide understanding about the nature of transformations of actors within the health research regulatory space, the form of regulation in this space, as well as the experiences of actors as they go through processes of change. The anthropology of regulation methodological approach enabled me to craft both the research questions and specific research methods, as well as to methodically analyse the empirical data so as to draw out themes concerning the processual nature of regulation and the experiences of regulatory actors who both regulate and are regulated. This thesis is interdisciplinary; anthropology of regulation integrates aspects of regulation, anthropology, and law into one single, coherent approach that transcends the theoretical and methodological limitations of each of the disciplines in question. The result is the formulation of a new form of analysis and the creation of a new interdisciplinary space. To reiterate, the methodology, its theory, and the methods are inextricably linked: the methods are a direct output from the methodological approach and employed in deference to the theoretical perspective, and in turn, the chapters that follow in Part III present the empirical research findings based on my anthropology of regulation-grounded research questions. This means that the findings are presented in a way that is sensitive to anthropology of regulation. They will be tethered to sensitising concepts drawn from regulatory theory and anthropology, which add further analytic weight to the historical tracing undertaken in Part I, and deeper explanation and understanding of the precise regulatory form and functions of RECs, as well as the regulatory strategies employed by the various actors in health research regulation today.

Having described the methodological approach and its connected methods, I now turn to present what the empirical research findings tell us about the nature of the interaction between central regulators and RECs in the health research regulatory space, and the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion. We

will see whether the empirical research findings reflect and validate the suggestions supplied in Parts I and II—that RECs engage in risk-based regulation, that health research regulation is increasingly streamlined and proportionate, and that health research regulation is increasingly 'centred' such that the state is exercising growing influence and control.

PART III—

EMPIRICAL RESEARCH FINDINGS: ENGAGING WITH RECS AND REGULATORS IN PRACTICE

Chapter 6
Operationalising 'next-generation' regulation—what is happening in practice?

6.1 Introduction

The principal aim of this final Part III is to engage with the empirical data collected from the interviews and observations and, coupled with the findings from the document analysis, make sense of them through an anthropology of regulation approach, as outlined in Chapter 4. In this chapter, I explore what happens in REC meetings, consider the operationalisation of 'next-generation' health research regulation (particularly in light of the twin aims of protection and promotion), and investigate the procedures and substance behind risk-based regulation. I do this by querying whether risk-based regulation—as discussed in Chapter 4—is actually being practised by RECs and the HRA, and more fundamentally, by querying the nature and function of the interactions among RECs, researchers, and the HRA. Throughout, I draw on the implications of space and time in ethics review, signifying the importance of liminality to this thesis and its contribution to the normative discussion to come in Chapter 7.

Inevitably, difficult decisions had to be made in constructing Chapter 6. A number of other themes emerged from the data, such as the struggle for RECs to maintain 'consistency' internally and across other RECs; materiality in ethics review documents and a 'liminality of things'; the contentious transition from paper-based to digital documentation on HARP;[522] and the value of the REC Chair in preserving committee harmony and promoting efficient review and respectful dialogue with researchers. As these themes are not, in my opinion, directly related to the research

[522] HRA Assessment Review Portal (HARP) <https://www.harp.org.uk/Account/Login>.

questions driving this thesis, and I am limited in the amount of space in this thesis, I do not address them. I do intend to address them in future publications.

So, in what follows, I present three themes (subdivided into categories) that: 1) emerge from the data; 2) speak directly to the research questions; and 3) focus on key actors (i.e. RECs, REC Chairs and Managers, Scientific Officers, the HRA) and their interactions. As Chapter 5 indicates, my findings consist of evaluative statements based on an overall assessment of the raw data informed by an anthropology of regulation. Where direct quotes or extracts of fieldnotes specifically enrich the analysis, I rely on them. Given the wealth of data in my notes, however, I cannot do this everywhere. A significant category within the third theme—regulatory stewardship and its connection with liminality—will serve as a bridge to Chapter 7 in Part III, which further unpacks the significance of liminality and, taking up the normative dimension of anthropology of regulation, provides recommendations for refining the health research regulatory framework.

6.2 Themes to emerge from an anthropology of regulation

Each of the three themes focuses on different aspects of regulation and transition. Combined, they paint a picture of a health research regulatory system that both REC members and regulators support, but do not always praise. For both REC members and regulators, the current system demonstrates vast improvement in the last decade. To this end, most members are supportive of the HRA's efforts to further centralise research ethics and create common standards that aim to improve quality and consistency, as well as efficiency. At the same time, however, many REC members are also critical of certain aspects within the system, including the at-times fraught relationship between the HRA and its equivalent bodies in the devolved administrations, and—perhaps surprisingly—between the HRA and RECs themselves.

Most importantly for this thesis, my findings suggest that research promotion is *not* a 'new' twinned role for RECs—some additional primary responsibility only

recently foisted upon members—but, the findings reveal that the practices of REC members vary greatly in how this role is both conceptualised and instantiated. In enacting their regulatory roles, whether for risk/burden-benefit analysis, assessment of the consent process, or legal and scientific checks (itself a questionable role), REC members and regulators demonstrate the symbolic value of leadership and stewardship—most notably expressed through the work of REC Managers, REC Chairs, and Scientific Officers—to set an example for others to follow, and guide REC members and researchers alike *across the stages* of the research application process. Within this latter observation, we uncover key insights into the liminal spaces RECs occupy and the potential role they may play across various thresholds of the research lifecycle, including those beyond the current *ex ante*-dominant positioning of ethics review.

In light of the methods described in Chapter 5, the following subsections investigate three themes, namely: 1) the 'black boxes' of ethics review; 2) regulatory connectivity; and 3) regulators as facilitators and stewards. And, in light of the methodology described in Chapter 4, we will find that elements of anthropology of regulation appear in each of the three themes identified.

1. Regarding the first theme of 'black boxes' of ethics review, anthropology of regulation helps frame the regulatory behaviour of RECs as an instance of internal flexibility, where individual and group behaviour impacts and indeed helps shape a liminal regulatory space wherein RECs and researchers alike explore and deliberate the 'ethics'. Liminality, in turn, draws our attention to rituals and how they play a crucial role in regulatory coordination. The rituals in ethics review serve to organise the REC's actions and reinforce its authority, but they also drive collaboration and coordination with other actors, particularly researchers.
2. Regarding the theme of regulatory connectivity, anthropology of regulation invites us to consider the influence of law, science, and ethics in REC work. Rather than viewing each of these as disciplinary and regulatory

'boundaries', we are better placed to view them as connected regulatory spaces that call for guidance to work through and across each of them. Law, science, and ethics are all wrapped up together in the making of an ethics opinion.

3. Finally, regarding the theme of regulators as facilitators and stewards, anthropology of regulation suggests that particular actors can serve as 'masters of ceremony' in guiding other actors (often regulatees) through stages and thresholds of regulatory processes, where uncertainty often is paramount. This last theme therefore teases out the finding that actors within and connected to RECs serve as 'stewards' who help guide researchers, and their applications, across stages of the research lifecycle, and that the HRA can taking a leading role here.

I now proceed to explore each of the three themes, commencing with the 'black boxes' of ethics review.

6.2.1 The 'black boxes' of ethics review

Learning by observation

As Part I of this thesis underscores, much is unknown academically about how REC members learn to 'do' ethics reviews and what actually happens in the course of their work both before, during, and after a committee meeting. As anthropology of regulation aims to investigate the nature of regulation and the behaviours and experiences of actors within a regulatory space (or spaces), and the ways in which they themselves are affected by regulation, I was interested in understanding how people learn to become REC members and perform the regulatory task of assessing the ethics of research. I was interested in knowing whether REC members felt their knowledge—or indeed expertise—was formed primarily by formal training sessions and regulatory documents, or by the experience itself—learning by doing, in other words.

By and large, REC members felt that they learned how to 'do' ethics reviews simply by observing other REC members in action. They watch, listen, and learn, but what

REC members pick up is not necessarily carbon copied into their own particular ways of doing committee work. Their observations are individually interpreted and subsequently manifest themselves in unique ways based on their own values, experiences, and expertise. Training, such as the mandatory induction for new members, provides a cursory overview of research ethics and points them in the right direction for additional resources if they are uncertain about specific areas, but the actual practice of ethics review—the process of working through applications; adopting the rituals, mannerisms, jargon, and ways of speaking during meetings; evaluating forms; questionning researchers face-to-face; writing up reports; and contributing to the discussions in meetings—is learned by observing other members who have this experience. It is through learning by observation and individual interpretation that members come to contribute 'effectively' and produce a culture of ethics review. As one REC member explained:

> I wasn't expected to contribute for the first few meetings – so if I wanted to I could have done – but it was mostly, 'you're here to learn about how things operate and what sorts of things we're going to be discussing', and then just picking it up from those meetings. […] The best way to learn is by listening to what the other members come up with. (P6)

If REC members learn by observing other members and also individually interpret applications based on their own values and experiences, what might the process of an ethics review look like? How might one describe it? In a surprisingly frank moment, an HRA regulator described ethics review as a 'black box' where the process of review itself constitutes the outcome:

> To some extent you just have to sometimes, I think, look at the RECs as a black box and you just say, 'well, that's how we have decided in this country and across the world to deal with that ethical decision making'. That's it, that's the black box – it's up to 18 people around a table discussing it and out pops the opinion. And it's a bit of a difficult one to get into that black box and mess around with it. It's almost that the process is the ethical decision. We've just decided that's the process and what pops out and we'll live with it. You know, you can train the people who are inside the black box and do everything you can, but I think to some extent this is probably as

> good as it gets when you get [86] committees with up to 18 people sitting around a table making ethical decisions. (P1)

It was the reference to RECs as a black box and the *process* of deliberation as constituting the ethics opinion in this first interview that propelled me to look more closely inside RECs. Does the practice of ethics review align with what the regulations would suggest happens, or should happen? Do REC members have any sense of what other RECs do, any curiosity about it, or any desire to know if they are being 'consistent'? As opposed to a singular black box, could there be a multiplicity of unconnected black *boxes* operating in fairly splendid isolation—and yet with still a fair degree of homogeneity in culture? How exactly does the process of ethics review itself constitute an opinion—not input and then output, but input *as* output, and arguably process as product?

Ethics review—peering inside the black boxes

The HRA's guidance document, 'Information for potential Research Ethics Service Committee members', outlines a process of ethics review in RECs that focuses on the utilitarian calculus of risk-benefit, a robust consent process, and adherence to the REC SOPs and relevant guidance and legislation.[523] The evidence from my research suggests that RECs follow this guidance. They dedicate a great deal of effort and time to three areas: 1) ensuring that consent 'is done properly' whereby participants are fully informed in a Participant Information Sheet (PIS) and are able to make a voluntary decision; 2) ensuring that the burdens or risks to participants are minimised as far as possible, and risks to the researchers are minimised; and 3) ensuring that 'the science is right' (this focus on scientific quality is discussed further below).

Within these three areas of focus, all five RECs approached research studies with a strong degree of liberalism. As one REC Chair explained: 'I think sometimes we have to remind ourselves that if the risks to the participants are minimised as far as

[523] Health Research Authority, 'Information for Potential Research Ethics Service Committee Members' (n 56).

possible then that research should probably be allowed to happen' (P3). The prevalent view that I observed from the meetings is that provided risks are outweighed by potential benefits (or there is a 'fair balance' between risk or burden and potential benefits), and participants are provided all material information during the consent process, then the choice to participate should be theirs to make, not the REC's. A member elucidated this liberal approach as follows:

> …sometimes you have to be careful not to be paternalistic in that actually…well, so long as people have a choice, they don't have to do the study, and if they don't like the fact that they're not going to get paid or they're not going to get travel expenses, we might suggest, 'Well, it would be nice if you could pay them, but if you're not going to pay them then the person won't do the study.' There's a fine balance between thinking a participant hasn't got the brains to work things out for themselves and they have to be mollycoddled every step of the way. It's really hard to think of things that you just want to go: 'No, you can't do that.' (P8)

In REC meetings, ethical issues within the three areas mentioned above are transformed into questions of refinement, or what might be called technical questions (e.g. inconsistencies between the protocol, PIS, or IRAS form; missing information in the PIS; clarification on the recruitment process; whether there will be continuation of a drug after the study ends). *Fundamental* questions demanding deep ethical reflection (e.g. the ethics of gene therapy; the ethics of 'me-too' drug applications) rarely manifested themselves in REC meetings. Instead, there was a cumulative gathering of information: members tended to reinforce other members' comments and add their own. This may be a pragmatic matter driven by time and resource constraints. Or, this may be a matter where REC members do not think it appropriate or think themselves capable of engaging in deep ethical reflection or debate. RECs do not function as a national bioethics council where there are resources and an explicit mandate to deep dive into matters of concern. Rather, they function more as regulatory event-licensing bodies that individually evaluate and collectively deliberate on submitted documents and render a decision underpinned by standards and intuition. This reinforces Schneider's claim that the REC system 'is

not an engine for abstract ethical thought. It is an agency *regulating* research',[524] and Montgomery's claim that a REC 'rarely engages directly in ethical reflection, but is concerned with ensuring compliance with established standards'.[525]

As such, to the extent that there is an underlying ethic guiding these RECs, I would claim it is liberalism and pragmatism. Each member is tasked with interpreting and applying abstract ethical standards (and to some degree, laws and regulations) to concrete research plans. How ethical standards and regulation are instantiated vary among individual members and, to some extent, among RECs. But, while the individual interpretations can vary, they are not limitless.

In her empirical work on IRBs in the US, Stark invokes an 'ethics of place'[526] to denote the peer review model of IRBs—*institutional* review boards—that attaches ethics to a specific physical place—a particular building—rather than a classic code of ethics that attaches to an individual physician or researcher. Peering further into the 'black box' of ethics review in the UK, several key findings emerge that suggest RECs, unlike their institutional counterparts in the US, symbolise an *ethics of space*. Ethics is attached to the REC within their meeting space at an NHS trust hospital, Health Board, or hotel conference room, yet as a node within a network, theirs is also an ethics informed by a larger regulatory framework such that moral authority for a decision rests not just in the REC itself, but also in the institutional apparatus of the Research Ethics Service(s). As bodies that have become centralised and tack closer to the state, their 'room to roam' is wide, but it is not infinite. Ethically appropriate research must fit within the personal sensibilities of REC members, as well as institutional sensibilities set by the HRA and equivalent bodies that prescribe boundaries of ethical acceptability. Invoking an anthropologically informed view of regulatory practice by RECs, we find that the 'ethics' within research *ethics* committees is a proving ground of debate, deliberation, and

[524] Schneider, *The Censor's Hand* (n 12) 107 (emphasis added).
[525] Montgomery (n 102) 11.
[526] Stark (n 123) 83.

negotiation, and a liminal regulatory space that accommodates diversity, disagreement, and dissent across applications and across time.

Within this ethics of space, I discovered that a common behaviour exists across RECs. Intriguingly, *relative to each other, RECs are black boxes, existing in multiple spaces*. Several REC members I spoke with perceive a top-down command from the HRA (while HRA regulators told me they perceive a collaborative ethics co-produced with RECs); several REC members also perceive that they have little interaction with other RECs. Beyond the regional REC Chair meetings held twice a year (across regions in England), 'ordinary' REC members do not have common opportunities to engage with other RECs, and they do not seem to have much desire to do so. Yet, despite these black boxes existing between black boxes, there exists a *surprising degree of group homogeneity in terms of approach and rituals*. What drives this homogenous REC group culture across the different black boxes may be in part HRA standards driving consistency, but this can only be a partial explanation. Many of the rituals and routine performed by REC members are not simple instantiations of HRA standards. RECs have a wide latitude in which to roam, but they appear to roam in similar ways and in similar spaces. Even more intriguingly, elements of REC culture—interpretive flexibility, self-policing behaviour, sensitivities with regard to relationships with researchers—would ordinarily suggest heterogeneity and militate *against* homogeneity. And yet, a strong degree of group cultural and regulatory homogeneity exists. What is going on here?

The ethics of space illustrates the symbolic importance of inviting various actors into the black box, such as researchers, and how the physical dimensions of space impact on the processes therein. The space that is created is on the REC's terms, even if it may be part of the physical space of the health research community. For instance, a clinical researcher may be on her 'home turf', residing in the same NHS trust hospital as where the REC meets, but she must still face the black box by entering the conference room, presenting her research before the members, and submitting to their judgement as the REC casts its opinion on whether her

application is ethically acceptable. One might think that this is a recipe for controversy, where a clash of spaces could emerge. On the contrary, researchers invariably seem to 'submit' to the REC and work together *alongside them* in moving the research application along towards acceptance. There is no evidence from my data that the individual black boxes of RECs set up a confrontational dynamic between them and researchers. Indeed, only once did I observe an overtly hostile situation where a researcher was unwilling to participate in the REC's ethics of space. The REC Manager later told me that this researcher had been to the REC before and had a bit of a 'reputation'. Even so, this hostile situation did not seem to have any bearing on the REC's view towards the research application. The outcome recommended by the Lead Reviewer and agreed by the REC as a whole was 'favourable with conditions'.

In sum, an ethics of space constitutes a *connected* regulatory space of RECs across the UK where homogeneity reigns. A researcher can submit an application in Southampton or Aberdeen and experience a startlingly similar ethics review (and a REC whose members are rather similar in composition). RECs themselves may not be aware of how similar they are. More than once REC members asked me how their REC 'compared' to the others I was observing, and whether I found any differences. As I responded to them, the differences are few and far between. Despite, or perhaps because of this homogeneity, there is a strong desire by RECs, including REC Managers, to preserve the sanctity of *their* black box and ethics of space. As will soon be shown, initiatives by the HRA that try to improve the regulatory pathways for researchers can backfire if there is improper consultation with RECs. Specifically, the 'Ethics Officer' pilot, discussed later in this chapter, can be interpreted as an invasion of this ethics of space. Researchers who enter this space do not create tension, yet other regulators who enter into it can. The irony, then, is that in the present context, regulatory tension or failures exist between regulators, not between regulators and regulatees.

i) A liberal approach to risk and potential benefit

The GAfREC state: 'The [REC] has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society.'[527] Elsewhere, the GAfREC state that 'research can sometimes involve an element of risk, because research can involve trying something new. It is important that any risks are minimised and do not compromise the dignity, rights, safety and well-being of the people who take part.'[528] Specific guidance is not provided as to how this evaluation of anticipated risks and benefits is to be conducted, and how risk minimisation may be done. As we saw in Chapter 4, this concerns scholars such as Rid, who argues that 'frameworks for risk-benefit evaluations of biomedical research remain surprisingly vague'.[529]

Compared to Jaeger's ethnographic study of IRBs in the US, which found that '[m]ost of the time that an IRB spends on a proposal review is focused on identifying and deliberating about risk',[530] my findings suggest that RECs do spend *some* time per application discussing risk, but it does not comprise anywhere near a majority of the REC's meeting time. Surprisingly, to the extent that the risk-benefit or burden-benefit calculus is invoked in decision-making, I observed a number of REC members who tended to focus their discussion more on the prospective evaluation of *burdens* to participants (usually framed as 'mere inconveniences', typically of a temporal or financial variety) than risks of a physical, psychological, or emotional variety. The CIOMS Guidelines define burdens as 'harms of a very small magnitude that are almost certain to occur'.[531] Only on occasion were potential benefits discussed.

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[527] GAfREC (n 1) para 1.2.2.
[528] ibid para 2.2.1.
[529] Rid, 'Rethinking Risk–Benefit Evaluations' (n 399) 153.
[530] Jaeger (n 123) 94.
[531] CIOMS Guidelines (n 16) Guideline 4, Commentary.

One Scotland A REC member agreed that, at least as far as her REC is concerned, the members look at 'the burden probably more than the risk actually. We do occasionally get quite risky looking things, but they're usually in people who are really not well, I mean, really end of life' (P12). This may be because many REC members feel that risks in most studies are in fact relatively minimal (even though they are not non-material as compared to Proportionate Review applications); that there is a high level of unambiguity and certainty in the risks present in most research studies (and thus they do not need to be assessed in any systematic way); or that the scientific aspect of risk assessment is outwith their scope (unlike, say, the MHRA).

Risk discussions in REC deliberations were often limited to identification of risks or burdens, the majority of the time by the Lead Reviewer. Some risks and burdens are explicitly identified before they reach the REC; others may be implied, theoretical, or unknown. Explicit risks, burdens, and benefits may be gathered from the IRAS form: question A22 of the form asks the Chief Investigator to list 'potential risks and burdens'; question A24 asks for a list of potential benefits; and question A26 asks for potential risks for researchers. Non-explicit forms of risk, burden, and benefit may be drawn out in the HRA Ethical Review Form's question 3, which asks REC members to consider whether the risks to the research participant are proportionate to the benefits to the research participant and society. Thus, some risks and burdens are explicitly identified already; others may be implied (i.e. drawn out by REC members in their review and discussion), theoretical (i.e. remote), or unknown (i.e. risks or burdens that the REC cannot identify due to missing or inaccurate information).

Chapter 4 explored risk-based regulation, which can be defined as 'the prioritizing of regulatory actions in accordance with an assessment of the risks that parties will present to the regulatory body's achieving its objectives'.[532] Looking back at the

[532] Baldwin, Cave, and Lodge (n 101) 281.

elements listed in Box 4.1 in Chapter 4, risk-based regulation tends to encompass a broad sweep of risk assessment (or appraisal), risk management, and review, including scoping the various dimensions of a risk, considerations of framing (i.e. how different stakeholders may have conflicting views concerning a risk), scientific risk assessment, and the broader social, institutional, political, and economic contexts that must be taken into account in risk-related decision-making.[533] RECs do provide written opinions and allow for appeals and at times engage in analogical reasoning, but they do not seem to follow specific rules governing particular aspects of the risk assessment process. As Noah argues, risk assessment is a separate endeavour than burden or risk-benefit assessment;[534] the latter may not necessitate 'objective', scientific measurement so much as an intuitive balancing and effort to minimise (that is, manage) risks that may manifest.

And indeed, in the full committee meetings I observed, RECs, and in particular REC Chairs, strived to enact a liberal policy in ethics review while avoiding a paternalistic stance towards risk. No member seemed wantonly unconcerned about risk; none would allow unfettered risks and burdens to be placed on participants. At the same time, though, the REC meeting discussions did not give me the impression that risk was a central focus. Members did not frame their approach to ethics review as a calculus such that their level of scrutiny of a research project was definitively determined by the level of risk it posed to participants. Risk was discussed as but one part of a much larger whole of ethics evaluation. Commonly, risk was a matter to be made clear and explicit in a PIS, and for a potential participant to weigh. As a Scottish REC member explained: 'Nobody wants to stop research being done; we just want it to be done so the person being studied is fully aware of everything that's going to happen to them and to make an informed choice about whether they want to participate or not' (P18).

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[533] International Risk Governance Council, *An Introduction to the IRGC Risk Governance Framework* (IRGC, 2012) 8-10.
[534] Noah (n 426).

An example of this liberal stance can be drawn from my fieldnotes. As I was leaving at the end of a REC meeting, I stopped to chat with the REC Chair. I explained that I was interested in how issues such as risk are conceptualised and assessed by RECs. The Chair thought for a moment and said, 'I don't think this is really a philosophical issue; it's a practical issue. Most research is not at all risky. Where's the evidence that research is risky, beyond a Phase 1?' he asked. 'Who's died from research? Some people have, but more people have died from un-researched care. Actually, if you look at the meta-analyses, taking part in phase 3, phase 4 research is neither good for you nor bad for you.' Pausing a moment for further reflection, he then added, 'I wonder what health research regulation would look like if we considered research to be good for you'.

This prevalent liberal stance towards risk, burden, and potential benefit may work at some level to address the 'heterogeneity problem' raised by Meyer.[535] While I argue that RECs *as a group* exhibit homogenous cultural and regulatory behaviour, scholars such as Meyer argue that individual research participants are heterogeneous in their preferences and other circumstances; thus the same research protocol will offer a different risk-benefit profile for different participants. Likewise, individual members of ethics committees assess risks and benefits based on their individual interpretation of their regulatory mandate to do so. Thus, REC members can engage in *interpretive flexibility*[536] when it comes to interpreting and operationalising the regulations regarding risk-benefit assessment. As Stephens and colleagues demonstrate, interpretive flexibility can be a positive outcome in regulation. To overcome this heterogeneity problem, Meyer advocates greater private ordering whereby individual prospective research participants, rather than the ethics committee, decide whether it is reasonable for them to accept the risks of participating in a particular research study. In the REC meetings I observed, the liberal approach enacted a form of private ordering. RECs fulfilled their regulatory

[535] Meyer, 'Regulating' (n 403); Meyer, 'Three Challenges' (n 78).
[536] Stephens, Atkinson, and Glasner (n 356).

mandate to assess burdens, risks, and potential benefits, yet the most common occurrence for the REC was to insist on clear provision of risks (and honest portrayal of potential benefit) in a PIS. RECs preferred to allow for individual prospective participants to decide whether it was reasonable for them to accept the risks of taking part in a given research study.

In my view, then, it cannot be said that RECs operate *strictly* as risk-based regulators. Were they acting as such, we would expect to see, among other things (recalling Box 4.1), more objective forms of risk assessment (e.g. a system for assessing risks and scoring them, beyond Proportionate Review applications), management, and review; systematic improvement of decision-making processes based on new evidence and insights into potential risk; and allocation of resources where risk is greatest.[537] Instead, RECs' regulatory positioning towards research applications encompass *elements* of risk assessment and risk management (such as communicating risks to participants), although the regulatory positioning extends beyond this. RECs regulate not on the basis of risk alone; value and benefit also factor into their deliberative processes. That is, the social and scientific value of a research study and its likely risks, burdens, and benefits are weighed by RECs; RECs decide whether burdens and risks to participants are ethically justified in light of, and reasonable in relation to, the potential benefits and scientific and social value of a study.[538] Thus, just as critical to RECs' operative deliberation is the *facilitation* of a context in which a *fair choice* is offered to participants whereby they can decide whether to participate in a study that presents ethically acceptable risks and burdens (as determined by the REC) and is likely to answer, or at least contribute to, the research question it purports to address. Moreover, the facilitation is directed

[537] See e.g. OECD (ed), *Risk and Regulatory Policy: Improving the Governance of Risk* (OECD 2010).

[538] See also Jeffrey Cooper and Lindsay McNair, 'Assessing Research Benefits: Practical Ethicist' (2017) 12 Journal of Empirical Research on Human Research Ethics 191.

not just to research participants, but also to researchers themselves, as I discuss further below.

Interestingly, this focus on facilitating participant choice aligns with the Nuffield Council on Bioethics' report on children and clinical research, which suggests that:

> …the fundamental role of ethical review is to ensure that an invitation to participate in research would constitute a '*fair offer*' to children, young people and their parents, where the value of the research and its likely risks, burdens and benefits have been carefully weighed up.
>
> In focusing on the role of the REC in ensuring that research involving children constitutes a fair offer to children and parents, it is also important to recognise *the REC's second and equally important function: its facilitative role*, which arises in recognition of the essential social good of well-designed and well-conducted research. It is not an ethically neutral act to say 'no' to a research proposal that might potentially lead to better outcomes for children's and young people's healthcare.[539]

To preview the discussion to follow, here we begin to see one element of (ethical) research promotion. To the extent risk is assessed, managed, and communicated, RECs concern themselves with risk vis-à-vis its identification and mitigation (as set forth in the HRA Ethical Review Form) in a personalised (read: subjective) and socialised way (i.e. in the course of REC deliberation), but the scope of risk assessment and management is mitigated by a liberal, facilitative approach.

A final key finding within this theme is that different moral considerations apply to different types of research studies, in a twist to the risk-proportionate approach advocated by the HRA, which focuses on reducing the regulatory burden for research that presents 'no material ethical issues' for human participants. RECs approve research studies involving high-risk treatments for late-stage cancer patients (e.g. phase II and III CTIMPs), even though this means there might be known (quantifiable) risks associated with the treatment, or even unknown risks. They approve such studies on the basis that participants could accept the treatment

[539] Nuffield Council on Bioethics, *Children and Clinical Research: Ethical Issues* (Nuffield Council on Bioethics 2015) xxvii (emphasis added).

with the full knowledge of the risks, and that *without* taking the treatment, they could well die rapidly. One reason for this is that, unlike a phase I healthy volunteer study, at least some of the risk-bearers may well also stand to benefit from the risks taken. As Ross and Athanassoulis write, 'while we normally tend to think of risks as something we want to avoid, research risks can be very attractive, especially for those whose last hopes for a treatment lie with the potential research benefits'.[540] In these situations, RECs do make ethical decisions knowing that there are associated high risks. For them, the emphasis is placed on making that knowledge explicit and clear to the participants. It is about making sure potential participants have *adequate* information to make an informed decision. The REC cannot speak on behalf of potential participants, but it can ensure that potential participants have accurate, up-to-date, and understandable information. From there, liberal autonomy seems to dictate: the choice is theirs to make.

This was evident in a REC review of a gene therapy CTIMP that I observed. The REC's main concern was the balancing of safety and efficacy of the therapy. Following the initial discussion, three researchers were invited into the committee room, where the REC Chair began by asking them to describe their study. In a calm, cool, and well-spoken manner, the Chief Investigator described the proposed study. When the REC Chair then asked him about weighing safety and efficacy, the Chief Investigator, in a powerful show of rhetorical flourish, narrated a story about how participants understand risk better than we think. Apparently, a potential participant once asked the Chief Investigator to sign his will before participating in a clinical trial, in case death occurred. The Chief Investigator, speaking deliberately at this point, said to the REC: 'And I didn't sign that will. And you know, I was glad not to because the man had planned to give everything to his girlfriend, and they then broke up six months later!' This drew laughter from the REC. 'He knew he was putting his life on the line', the Chief Investigator continued. His point, of course, is

[540] Allison Ross and Nafsika Athanassoulis, 'The Role of Research Ethics Committees in Making Decisions About Risk' (2014) 26 HEC Forum 203, 205.

that RECs should not assume participants cannot understand risks in research, much less substitute their judgement for a competent adult participant. If the information provided to them is honest and complete, the research should proceed. Following the face-to-face discussion, when the researchers got up to leave, the REC Chair beamed. 'Thank you very much, that was fascinating!' After they left, the REC Chair looked up at his committee members and said: 'What do you want me to do, team? He's quite persuasive, isn't he?' All agreed, and the outcome of this application was a 'happy provisional' opinion.

ii) Pragmatic ethics

REC members explained to me that there is rarely a conscious thought process behind an ethics review. The HRA disseminates guidance and policies driven by procedures; they do not offer guidance on ethical principles or how to conduct an ethics review by reference to substantive ethics. It is, as I discovered, up to REC members and key 'stewards' such as REC Chairs and Scientific Officers to help guide the REC members towards an ethically-informed decision. REC members were hard-pressed to pinpoint the ethical deliberative content in a committee decision; when asked to explain the process, they provided a procedural description that focused on the steps involved in working through the contents of the application form and attendant documents. Members reach an ethically-informed decision of some type, but the decision-making process appears to be performed intuitively or pragmatically. Just as researchers rarely frame ethical scenarios in the moral philosophical language of deontology, consequentialism, and virtue ethics,[541] hardly ever is an ethical principle, be it a Kantian invocation of categorical imperative, autonomy, justice, or otherwise, relied upon to justify an opinion or articulate a reason. Members might have taken utilitarian perspectives or objective dignitarian perspectives when considering risk-benefit analysis (i.e. weighing risks against benefits, as the regulation largely dictates, or suggesting a particular risk of harm could never be justified, regardless of any consideration of benefits), but none

[541] David Johnson and Elaine Howard Ecklund, 'Ethical Ambiguity in Science' (2016) 22 Science and Engineering Ethics 989.

articulated them as such. Foremost, educated (or experiential) gut reactions and feelings drive ethical decision-making processes to render an opinion that seems suitable to and workable in the context at hand.

This finding accords with Mary Warnock's argument that 'morality cannot be divorced from sentiment'[542] and '[e]thical decisions cannot be taken without the examination of ethical feelings'.[543] Each member brings their own culture of moral reasoning to bear on applications, which is then negotiated contextually and situationally in the circumstances that arise for a given application before the committee. This moral intuition, built up from a lifetime of cultural experience, manifests in an ethics assessment undergirded as much by reason as it is by feeling:

> I think in ethics committees, as in life, we make very quick decisions, 'oh, that's right', or 'that's wrong', and most of the time we're okay. And if there's very little contention, if there are no particular problems, it's a very efficient way to make decisions. (P10)

This is not to say RECs and individual members were incapable of justifying their reasoning; rather, it is that the moral reasoning could manifest *ex post* rather than *a priori*, or as one REC Chair put it: 'The actual ethical review process is almost tick box' (P3).

Part of this can be explained both by the growth in volume of forms provided by the HRA to REC members, and by the lack most REC members have in formal ethics training. As noted already, REC members receive basic training in research ethics issues and are encouraged to engage in self-directed learning,[544] but no one thought such training would transform them into philosophers or bioethicists. Few members were interested in academic ethics articles or debating abstract ethical issues. In this

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[542] Mary Warnock, 'Moral Thinking and Government Policy: The Warnock Committee on Human Embryology' (1985) 63 The Milbank Memorial Fund Quarterly. Health and Society 504, 518.
[543] ibid 520.
[544] Health Research Authority, 'REC Members' Training' <http://www.hra.nhs.uk/research-ethics-committee-members/rec-members-training/>.

sense, pragmatism drives the decision-making process: members apply rules, standards, and at times, principles that are practically useful for rendering a decision and that work best for the situation at hand. As a regulator told me, 'there's a disconnect between where ethics is going as an academic discipline and where it talks about research ethics, and the knowledge of RECs about that and that sort of coming together to discuss, so that one informs the other' (P1). This seems to bother neither the HRA, nor RECs, nor, from what I saw in my observations, researchers and sponsors. The important point that regulators and REC members equally stressed is that a REC must be able to justify an outcome that has a grounding in reason: provided an opinion is grounded in reason, it will be seen as valid, legitimate, and ethical. As a REC Chair elaborated:

> I can't tell you how to think, and that actually what I want to try and do is to get people to think: 'How am I deciding? What are the reasons for my decision? How am I reflecting on this? Where can I turn? What questions should I ask myself?' I think if one can provide that sort of framework, then it has to be down to the individual to look back to see, what are my own values? When you come to an ethics committee, when you come to induction training at say whatever age you are, 30, 40, 50, 60, there's so much in your life that you bring to that, that this meeting for one day is going to barely touch. So I try to help people and say: 'Look, if you're going to make decisions, just work out what your reasons are because those are the crucial…why have you made that decision?' By and large, if people think about reasons and think through their reasons, I think they usually come to the right decision. (P10)

As I continued to peer into these black boxes, I also discovered that in bringing their life experiences to bear in the ethics review process, REC members engaged in rituals that helped coordinate relationships, overcome potential disagreement, and achieve a consensus opinion.

iii) Rituals

Ritual patterns are often present in highly 'rationalised' settings such as hospitals, and are embedded to a significant degree in the schedules, procedures, and practices of the setting.[545] RECs and the spaces in which they meet *and* constitute form a highly rationalised setting. In creating and reinforcing their ethics of space, REC members adopt rituals (that is, a type of patterned or institutionalised symbolic action[546]) that manifest throughout the process of ethics review. These include:

- the refrain of phrases expressed by a REC Chair to the REC and attending researchers (a REC Chair might say to the attending researcher: 'Thanks very much for attending today. We've had a *really* good discussion of your application, and as you might expect, have a few questions for you.'; following a face-to-face meeting with a researcher, a REC Chair might jokingly say to the researcher, 'Right, now run for the hills!', or always begin the group deliberation following the face-to-face researcher meeting with, 'What do we think, team?');
- the ordering of questions gathered by the REC Chair (i.e. distilling the REC's discussion of an application into three or four key questions for the attending researchers so as to keep the meeting on time and also not overwhelm researchers);
- rituals of placement, such as the seating arrangement of REC members, researchers, and staff (e.g. the Chair and Manager always sitting side-by-side, researchers sitting at a right angle to the REC Chair and Manager, as opposed to directly across from them, which minimises a sense of confrontation and encourages a more research 'promotionist' approach);
- the shuffling of the bundles of papers, which perpetually swathe the conference tables during meetings;

[545] Machado and Burns (n 474) 372.
[546] ibid.

- the presentation by Lead and Second Reviewers to the REC by reading from their filled-in HRA Ethical Review Form;
- the meeting structure (e.g. on-time starts and a strong collective desire to stick to time); and
- the working through of an application (the structure of Lead and Second Reviewer presentations followed by structured discussion by other REC members).

Rituals play a crucial role in how members formulate comments on an application and approach their ethical decision-making. Similar *group* rituals were present across all five RECs, and within each, members had *individual* rituals vis-à-vis their review process. Thus, how rituals of ethics review played out varied across members. REC members bring their own idiosyncrasies and predilections to their reviews; they have 'certain bugbears' that can make them sound like 'a bit of a broken record' (P12), but this, members explained, helps ensure a well-rounded and consistent review. As a Scientific Officer told me: 'You also have to find your own way [as a REC member], because if everybody reviews an application the same way, you're going to miss something' (P23). Indeed, subjectivity and idiosyncrasy of individual members is a natural outcome of most independent committee structures. The committee structure allows for a more thorough review than if only one reviewer is to pour over an application. Yet, it was rarely the case that subjectivity among individual members led to diametrically opposing viewpoints on the ethical acceptability of an application. Consensus forms the backbone of ethical deliberation, which is reached in large part through rituals:

> …if there wasn't at least an element of opinion and subjectivity in the review process you wouldn't need committees. You could do the entire review with checkboxes on a computer. […] But I also think it's true to say that if you canvassed the committee members about what the decision for this month's applications would be before the meeting started, there would be almost complete unanimity on every application. (P14)

Some members review applications from only a narrow perspective, such as through their niche area of expertise (e.g. statistics, pharmacology). Others, particularly lay members, invoke a process of projection: they read applications from the perspective of a potential participant, reminding themselves to 'think like a patient' and raise issues that may concern even only a few patients. In 'thinking like a patient', the lens may not be ethical *per se*; instead, it may be grounded in relationality with participants, tied in with an ethic of care:

> …I take a step to the side and I think from the patients' or the participants' perspective; not that I sit and think I'm here because I'm a professional with a background in certain things. I would definitely highlight if I thought that the scientific integrity of a protocol wasn't robust, but really because I'm there as not a specialist or not an expert person; I give my opinion from the more personable side, patients' side. (P22)

Some members think it inappropriate, however, to substitute their opinion on whether to participate in a given study with that of an adequately informed potential participant. For these members, relationality with participants is risky; avoidance of paternalism should predominate. An ethical research project for them is one that discloses all material information to participants:

> I remember commenting on a particularly onerous…I think it was pancreatic cancer study. Even if I had the cancer and was as sick as I needed to be to enter the study, I personally would not be prepared to enrol in the study because of the demands it would place on me. It was too onerous. Having said that, was it ethical? Yes, absolutely, because you're telling the patients precisely what's going to be required of them. And whilst I wouldn't agree to it, that doesn't mean to say that other people can't. And that's actually potentially a difficult distinction to make. […] It was an interesting one for me because I wouldn't volunteer for the study, but I wouldn't say it's wrong for other people to do it. (P14)

As noted, one of the key rituals is the meeting and agenda structure for RECs. Established by the HRA in a template form, the meeting agenda was consistent across all five RECs I observed, namely in the order of: Apologies for Absence; Minutes of the Meeting Last Held; Matters Arising; Items for Information and Discussion; REC Manager's Report; Declarations of Interest; New Applications for

Ethical Review led by the Lead Reviewer and then Second Reviewer; Any Other Business; Date of Next Meeting. Within this structure, the timing was constant, too. Items 1-6 rarely extended beyond five minutes discussion in total. The vast majority of each meeting was dedicated to Item 7: New Applications for Ethical Review. Following the presentation by the Lead Reviewer (typically ranging from seven to 15 minutes), the Second Reviewer added a few comments (typically ranging from three to seven minutes) in a gap-filling manner, raising further queries to be posed to the researcher or areas of concern within an application. Then, the REC Chair would invite other REC members to comment on the application. Following this open discussion, the REC Chair would write down the 'main issues' to discuss with the researcher, assuming the researcher was attending in-person. (REC Managers were always taking minutes of the meetings, portions of which are then transformed into opinion letters that are sent to the researchers). Once the list of questions was formulated to all members' satisfaction, the REC Chair or Manager would retrieve the researchers (along with, on occasion, a representative from the sponsor or a student's supervisor) waiting outside (assuming they were attending in person), invite them inside, and ask questions regarding the application. Following this back-and-forth dialogue, the researcher would leave, and the REC Chair would invite members to deliberate further on the application, culminating in a decision.

Rituals of expertise manifested themselves often in meetings. For REC members with a particular niche area of expertise, such as statistics, quite often the REC Chair would turn to a specific member and ask, 'Are the statistics okay?' The member would reply, and then the REC Chair would move on. This indicated that the power of the member's expertise was such that other members did not feel able to adequately comment on the specific matter of concern (though often other REC members would ask general questions about a niche area to the expert member, such as a pharmacist, prefacing their question with self-effacing and self-professed ignorance of the area).

Routine in the ethics reviews undertaken by individual members and routine in the meetings themselves does not necessarily mean there is a predictable outcome in any given application, even though the vast majority of applications (71 per cent from the meetings I observed) are deemed 'provisional'.[547] Interestingly, a provisional opinion is a *forward-focused* step in ethics review. The application moves from the pre-review threshold at submission to the threshold of approval during the REC meeting. A provisional opinion rendered by a REC almost always leads to a favourable opinion once the researcher has addressed the REC's concerns, which are expressed in the opinion letter. (Indeed, members in all five RECs sometimes would use the phrase 'provisional favourable' in announcing their verdict on an application, which symbolically differs from HRA's term of 'provisional opinion', which signals no pre-determined final outcome.) Upon receiving a provisional opinion, a researcher likely will amend the relevant documentation, which is then reviewed by the REC Chair and sometimes one or two other members, and then this 'sub-committee' will render a final decision.

REC Chairs and others often have a sense of where an application is heading in the course of discussion at a meeting, but how the discussion unfolds is not always foreseeable. A Scientific Officer believes the outcome for any given application is unpredictable:

> …the thing is, with committees, you can't predict what they're going to pick up on. Even after all this time, the things that I think they're going to pick up on, they don't, and the things I think are going to sail through, they have huge problems with. They're really difficult to predict. And it depends on their mood, as well. It depends on the weather, I think! I would love to do a study, you know, when you do a committee meeting and the sun's shining, and, you know, the lambs are skipping in the field, the applications always

[547] Out of the 24 meetings I attended, I observed deliberation of a total of 119 new applications: six were approved outright as favourable, 22 were granted favourable with conditions, 85 were deemed provisional, and six were rejected as unfavourable. This compares well to the HRA statistics for RECs in England, which find that of applications reviewed at full committee meetings, over 70 per cent are deemed provisional. See Health Research Authority, 'Annual Report Summary for RECs in England April 2015 to March 2016' (n 26).

> get an easier run, than if it's, you know, pouring down with rain, and there's gales blowing. (P23)

With an array of rituals, idiosyncrasies, moral intuitions, and at times impressionistic judgements, even if ethics is 'situated'—constrained by the limits of the committee structure, the predominance of scientific experts, or the desire for consensus and efficiency—any given REC's output, as with the input, is uncertain. For example, certain cues in the course of ethics review (e.g. the type of research under review, a REC's trust in the researcher, the quality—i.e. lack of errors and comprehensiveness—of the IRAS form and attendant documents) can help make an outcome more predictable, but not necessarily certain. As the Scientific Officer above alludes to, there is always an element of uncertainty in the outcome of an application after REC review. As well, intra-REC precedent (i.e. comparing current applications to past applications and decisions) occasionally was invoked in deliberations to serve as a reference and maintain consistency, but this was not done systematically—which puts my findings in contradistinction to Stark's and Jaeger's findings in the US. One member told me he could only recall two instances in over 20 years of serving on a REC where precedent was invoked. The norm seemed to be that each application was reviewed on its own merits. Instead, group experience, or a 'memory within the group' (P19), predominated the aiding of a decision. As one REC Chair phrased it, 'group moral maxims that we all generally share' (P10) helped determine if the past opinions were relevant to the current application. Collective memory and experience, along with these 'group moral maxims', maintained order and propelled the REC towards a decision that they believed would be consistent within their REC and, ideally, across others.

Figure 6.1 and Figure 6.2. Photographs of REC meeting rooms in an NHS Health Board and hotel, respectively. Attending researchers sit at a right angle to the REC Chair and Manager so that they can feel 'at ease', as one REC Manager told me. REC members usually sit in the same seats or area of the room at the monthly full committee meetings. REC Chairs tend to sit at the front end of a table, symbolically asserting their authority over the REC.

Figure 6.3. Photograph of one of the HRA's five Regional Offices in England (Jarrow).

This Regional Office contains an open floor plan and currently has approximately 20 employees. White boards along the wall help HRA staff manage the flow of information and maintain order in RECs. A REC Manager explained their use to me: 'We use whiteboards in our centre. I don't think all centres use them, but we find it invaluable for the REC Manager, for the REC Assistants […] What we do on our whiteboards, we have a record of the current REC meeting, and I think there's enough space for the next meeting, and then a PR meeting, which is once a month, and then sub-committee meetings for amendments and things we have twice a month. So the REC Assistant would look after the sub-committee, and the REC Manager would usually look after the main committee and PR, and that PR can vary around the country. So as soon as we receive it we accept it on the database and then we try and write everything down on the white marker boards' (P15).

Liminality draws our attention to rituals and how they play a crucial role in regulatory coordination. The rituals in ethics review serve to organise the REC's actions, reinforce their authority, but also drive collaboration and coordination with other actors, particularly researchers (and less frequently or successfully, with their managing regulators). Rituals constitute embedded processes of ethics review that work to create shared meanings, establish order, build feelings of community, and encourage trust in the process and outcome. At the same time, in considering the ways in which an activity (e.g. research) may be regulated by a network of regulators (e.g. RECs, MHRA, HRA) through a variety of rituals (e.g. rituals of consent, rituals of placement at meetings, rituals of words and phrases), we see that

rituals have a tangible impact on the regulatory actors' behaviour, particularly when those rituals are disrupted by regulatory changes, or impositions 'from above', such as the HRA's ShED exercise or Proportionate Review. Liminality invites us to identify and pay attention to symbolically and practically significant rituals and how they organise REC's regulatory behaviour and structure their relations with other actors.

iv) Ethics as an act of faith

As a final key finding discovered when peering inside the 'black boxes' of RECs, ethics review can be an act of faith shared between the REC and researchers. This finding aligns with Hedgecoe's observation that RECs and researchers can interact as 'work groups' and co-construct 'organisational deviance' through 'cultures of production' that contain various features, including trust that RECs place in research applicants' abilities and openness.[548] REC members receive 'marvellous bits of paper' in research applications, some of which may be 'meaningless' (P12), and yet they must make a definitive judgement on what they see and hear. For applications from commercial sponsors especially, REC members feel they must act on faith to trust the researcher or research team to act ethically. For them, there is a risk—but an acceptable one—in approving an application based on their assessment of 'bits of paper' and perhaps a 15-minute discussion with the Chief Investigator or another member of the research team.

A vital component that makes this act of faith acceptable to the REC, researchers, the HRA, and others is the face-to-face meeting with the researcher. This meeting follows the presentation of the application by the Lead and Second Reviewers and the general discussions around the conference table. As we have seen, REC members place a tremendous degree of value on meeting the researcher (or research team) in person, and likewise, though I did not interview them, researchers seemed to value the face-to-face meetings as well.

[548] Hedgecoe, 'A Deviation from Standard Design?' (n 175).

There are two purposes behind asking a researcher to attend a REC meeting. The first is to discuss key issues in the application that may be resolved in the meeting, thus saving time and perhaps even turning an application from a provisional to a favourable opinion. Efficiency and research promotion drive this purpose. As one REC member told me, '…because we can ask them questions straightaway and sometimes they can give answers very quickly, it just resolves the problem in a way' (P20). The second purpose is to get a sense of whether researchers seem trustworthy—something that cannot be investigated nearly as thoroughly through a document review alone. RECs want to get a sense of the researcher's character and probity. A good presentation by a researcher is almost as valuable as a well put-together application. If the REC is comfortable that a Chief Investigator has participants' welfare at heart—and some members believe this is 'easy to convey in an interpersonal interaction' (P14)—then it will go a long way towards delivering a favourable opinion. Given that a number of researchers choose to apply to the same REC, either because the REC is in their local area or because they think highly of the particular committee, the rapport and trust established between REC and researcher can lead to more efficient—but potentially also shortcutted—reviews:

> So [this researcher had] done all that she'd needed to do to use [the medical device]; she just hadn't explained it particularly well in the IRAS [form]. And she put us completely at ease [in the face-to-face meeting] that the safety wasn't going to be an issue. So along comes the second application [from the same researcher a couple months later]. It has essentially the same defect in terms of explaining the safety. But because we knew it was her, we knew it wasn't an issue and we didn't need to spend any time on it, because it was the same piece of kit. The same researcher, and she'd convinced us beforehand. So that was very helpful. (P14)

At the same time, the inability for the REC to observe the researcher *in action*, to monitor what is actually occurring, given its *ex ante* positioning in the research lifecycle, troubles some members. Even if they have a good 'feeling' based on the face-to-face meeting, how sure can they be that the researcher will conduct the study ethically? Again, faith must be placed in the researcher to act ethically: 'All we're approving is the paperwork in effect, and we have no control about what

actually goes on' (P8). To sustain this faith, RECs must work together with other actors to share responsibilities, approve studies that are designed to be ethical throughout, and inculcate virtuous behaviour in researchers. And, in working with other actors, RECs must connect across regulatory spaces. I unpack this as the second theme.

6.2.2 Regulatory connectivity

Law and science occupy an uncertain relationship with RECs as there is an apparent misalignment between what the HRA and other managing regulators expect of RECs on paper and what occurs in practice. The GAfREC indicate that RECs are *not* responsible for assessing the scientific quality and legality of an application; they are neither a scientific review nor legal advisory body. In regard to science, the GAfREC state that: 'A REC need not reconsider the quality of the science, as this is the responsibility of the sponsor and will have been subject to review by one or more experts in the field (known as 'peer review').'[549] In regard to law, the GAfREC state: 'It is not the role of the REC to offer a legal opinion on research proposals, but it may advise the researcher, sponsor or host organisation whenever it considers that legal advice might be helpful to them.'[550] In regard to regulatory responsibilities, interestingly, the GAfREC encourages RECs to *defer* to other bodies where responsibilities may overlap: 'Where others have a regulatory responsibility, a REC can expect to rely on them to fulfil it. If the law gives another body duties that are normally responsibilities of a REC according to this document, RECs do not duplicate them.'[551]

Even if RECs 'need not reconsider' scientific quality, need not offer a 'legal opinion' on research proposals, and should not 'duplicate' other bodies that have regulatory responsibilities (e.g. MHRA, HTA), it still remains the case that often they perform all three roles.

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[549] GAfREC (n 1), para 5.4.2(a).
[550] ibid para 3.2.11.
[551] ibid para 5.4.2(c).

Ethics and science

REC members find it to be a 'constant struggle to try and separate out the idea' that RECs *already* should be assured that the science is 'good' and that the application has had appropriate peer review. As a body partially comprised of past or current researchers, it is a challenge for many to disentangle science and ethics, as even HRA regulators recognise:

> …you have a certain number of experts 'round there who are all jobbing scientists and jobbing researchers, or much of them are, or at least acquainted with research at that level, you know, who can't help but pick over the carcass and the bones of the methodology… It's really difficult…where does ethics stop? Where do you stop thinking it's an ethics issue? But I think they do predominantly, a lot of committees do focus on the methodology, talk about the methodology. (P1)

Indeed, the HRA seems to implicitly acknowledge this potential for a connected ethics/science regulatory space in its push for committees to include a statistician among their membership. The GAfREC too provide ambiguous guidance, stating: 'The REC will be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.'[552] How does a REC satisfy itself with such credible assurances? A good deal of discretion is given to them. Not surprisingly, even REC members who are not 'jobbing scientists' also think it vital to ensure the science 'is right'. Three different members repeated to me a well-worn line in research ethics: Bad Science is Bad Ethics. But they also acknowledged that they cannot simply mimic scientific review committees. In consequence, RECs engage in a secondary form of *self-policed* science review. There were times that I observed RECs expressing uncertainty with the scope of their scientific review, particularly in their communications with researchers.

For example, when a statistician expressed serious concern about the stated scientific accuracy of a CTIMP application, the Vice Chair remarked, 'this is a

[552] ibid para 5.4.2(a).

MHRA issue, though'. The statistician countered that the MHRA advises on research design, but not accuracy. Self-policing itself, the REC as a whole discussed how best to express this to the applicants, deciding that they could *not* say in the opinion letter that they disagreed with the scientific design, but instead they would ask the researchers to more clearly explain their rationale for the study design, given 'concerns' the REC had. In other instances where I observed that RECs felt the science of a proposed research project was not up to par, they policed themselves in terms of not having it colour their overall assessment of the application; their concerns would be expressed in the opinion letter, but the opinion was to be based on a constricted view of the 'ethics'. There was an ongoing challenge in teasing out the ethics from the science. Invariably, the resulting opinion was not a favourable one—not surprising in itself when we see that only six applications were granted 'favourable' outright (which equates to five per cent of the total new applications I observed).[553] The evidence suggests that RECs constrain themselves within their own linguistic and operational paradigm or 'space', implicitly recognising there is another space (i.e. science) that they ought not to enter explicitly. Through these constraints or work-arounds, RECs can satisfy themselves that the ethics of an application has been fully reviewed to their satisfaction, and in a way that does not penetrate too deeply or too explicitly the scientific space.

Is this an instance of 'double jeopardy'[554] or 'ethics creep'[555]? I do not believe so. The ethics/science divide is, I submit, an artificial boundary incapable of being rationally adhered to in this process of review.[556] RECs do not seek to expand their

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[553] This practice endorses Hunter's argument that bad science is poor ethics, but not necessarily bad ethics, and thus not grounds for rejection alone. See David Hunter, 'Bad Science Equals Poor Not Necessarily Bad Ethics' in Jennifer Gunning and Soren Holm (eds), *Ethics, Law and Society: Volume III* (Ashgate Publishing 2007).

[554] Stephen Humphreys, Hilary Thomas and Robyn Martin, 'Science Review in Research Ethics Committees: Double Jeopardy?' (2015) 10 Research Ethics 227.

[555] Kevin Haggerty, 'Ethics Creep: Governing Social Science Research in the Name of Ethics' (2004) 27 Qualitative Sociology 391.

[556] See also Angus Dawson and Steve Yentis, 'Contesting the Science/Ethics Distinction in the Review of Clinical Research' (2007) 33 Journal of Medical Ethics 165 (arguing that the

jurisdictional control[557] over science; if anything, REC members admit hesitancy in assessing scientific quality. The process of ethics review necessarily entails a verification of the scientific quality.[558] The CIOMS Guidelines endorse this position in their latest version, which states: 'Although in some instances scientific review precedes ethical review, research ethics committees must always have the opportunity to combine scientific and ethical review in order to ensure the social value of the research.'[559] And, my empirical findings accord with those of other researchers who found that scientific issues (e.g. sampling; choice of methods; the research question; the measuring instrument; analysis; bias; feasibility; equipoise) are frequently raised in opinion letters to researchers and are often considered a quality problem by RECs.[560] One REC Chair explained the connectivity thusly:

> [An application] might have the best question in the world, it might have the best hypothesis, but if the way the research is designed has not been able to answer that question, then there is a danger that time, effort, and money are all going to be wasted. Participants' time could be wasted and for me that is unethical and shouldn't be allowed to happen. (P3)

RECs want to be satisfied the science is sound, and unverified reliance on the scientific review alone will not suffice.[561] If ethics review is partly an act of faith,

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science/ethics distinction is incoherent and that RECs have an 'obligation' to consider a study's science).

[557] The phrase 'jurisdictional control' can be traced earlier to an analysis of the sociology of professions. See Andrew Abbott, *The System of Professions: An Essay on the Division of Expert Labor* (University of Chicago Press 1988).

[558] This runs against the logic circulating in the EU Clinical Trials Regulation No 536/2014, which separates ethics review from the review of the science. Controversially, the latter review explicitly includes assessment of the risk-benefit ratio. Unsurprisingly, research ethics scholars are critical of the effects the Regulation will have on REC operations and the protection of research participants. See e.g. Eugenijus Gefenas and others, 'Application Challenges of the New EU Clinical Trials Regulation' (2017) 73 European Journal of Clinical Pharmacology 795; Carlo Petrini, 'What is the Role of Ethics Committees after Regulation (EU) 536/2014?' (2016) 42 Journal of Medical Ethics 186.

[559] CIOMS Guidelines (n 16), Guideline 23, Commentary.

[560] Emma Angell and others, 'An Analysis of Decision Letters by Research Ethics Committees: The Ethics/Scientific Quality Boundary Examined' (2008) 17 BMJ Quality & Safety 131.

[561] See also Sarah Edwards, 'The Role, Remit and Function of the Research Ethics Committee – 2. Science and Society: The Scope of Ethics Review' (2010) 6 Research Ethics Review 58.

faith must be undergirded by some reference to reality: science is a significant element of that reality. To the extent there is a 'problem' of overlap, it is not one of ethics creep by RECs or colonisation of other fields, but rather one of a science paradigm that is prevalent within RECs (unsurprising when we consider that so many members are current or former medics or scientists) and of a failure in regulatory frameworks to acknowledge the *necessary* overlap in review as between ethics, science, and law. If RECs are constituted to review, among other things, risk to participants, they necessarily must have due regard to the scientific design that generates such risk, and not merely regard to the value of the science alone.

Previewing discussion to come, some REC members suggest that they could focus less on the science in their reviews if there was better support for a research design service at the nascent stage when researchers are planning their studies. Stewards such as Scientific Officers in the Scottish RECs cannot perform this role alone:

> It's great having Scientific Officers, but it's, like, how far can we go in to the science of the application? And there isn't an obvious other person to send [researchers] to, you know, 'cause you're thinking, oh I should…the science of this…this hasn't been designed very well, this study. …they're overlapping, aren't they, science and the ethics. But you, kind of, feel that you can only go so far down a certain line. So it is a great service up here, but, you know…there's always something missing, isn't there. (P27)

Ethics and law

Similarly, many REC members think it necessary to have due regard for relevant laws. An ethics opinion is not a legal opinion, but it is certainly informed by the law. And for some RECs, such as the Scotland A REC, they *must* have due regard for legislation in their functions.[562] Statutory regulations now ascribe very specific functions to ethics committees (e.g. the Clinical Trials Regulations 2004, Mental

[562] For the Scotland A REC, this includes the Adults with Incapacity (Scotland) Act 2000 and the Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002/190, as amended. Notably, again evidencing the regulatory connection between ethics and science, section 6 of the Regulations makes clear that the Scotland A REC 'must take into account' in its review 'the objectives, design, methodology, statistical considerations and organisation of the research'.

Capacity Act 2005). REC members are aware of the importance of law in undertaking their reviews, as a REC Chair told me:

> When I joined my committee back in 2003…when I first applied I was turned down, and the reason I was turned down was because one of the questions I was asked was whether the ethics committee should consider the law or not. And my response was, 'yes, we should consider the law'. And that was the reason I was turned down. It was the wrong answer! At the time, the view was ethics committees consider ethics and the law to lawyers. Nowadays, that would be the right answer. You cannot undertake an ethical review without considering the law, and very many bits of it. But whether we reference it an awful lot, I don't think we do. Other than the Data Protection Act… (P3)

Yet unlike scientific quality, which most REC members feel is important to consider and discuss regularly, as the REC Chair above indicated, rarely did RECs explicitly consider the law when discussing an application at a meeting, and members did not suggest to me that they consulted the law when conducting an ethics review. Rather, I observed that RECs encouraged researchers to see it as their (and their sponsor's) responsibility to assure compliance with the law, both when designing their study and when conducting the research. REC members agreed that their opinion is not a 'legal opinion', but they strive to ensure their opinion is *intra vires*—providing an ethics opinion that sits within the bounds of legality. Most of my interlocutors did not a feel a lawyer was needed on a committee. As a member of NREAP told me:

> …the ethics committee is not making a legal judgement – what they're doing is providing advice that's consistent with the legal framework that they're having to operate within. That's how I see it. Now, is that operating according to a legal framework or not? I think it is. And it's daft to say the law doesn't have a grip on ethics committees. It does. But it's not on everything. Again, you might say, well practice is around consent, or data management, being engaged with the common law as well as statute. I don't think you can escape from it, but you don't have to be a lawyer to be on an ethics committee. (P4)

The HRA does provide training on relevant areas of the law, such as patient confidentiality; data protection; research involving children; the Mental Capacity

Act 2005; and the Human Tissue Act 2004. For REC members, that is seen as sufficient. After all, they are charged with only having 'regard to statutory provisions for ethical review of particular types of research'.[563] Much of the assurances about legality provided previously from the R&D (i.e. research governance) directorate or R&D offices in England are now from the HRA Approval team. REC members do not want to render an opinion that is blatantly illegal, but nor do they want to carry the weight of expectations that their opinion is *as much legal* as it is ethical. As with science, the ethics opinion necessarily incorporates consideration of the law. The spaces are connected, but not necessarily blended. As one member of the Scotland A REC told me, again in liberal overtones:

> I think there is a bit of a tension between training people in, say, the Data Protection Act, that you are sort of handing them a mantel, in a sense, and empowering them to believe they understand the law and, therefore, are making legal decisions around data protection. I think that's a mistake; that it ought to be around the sort of ethical issues involved in handling data and whether it's appropriate, and whether it's clear and open, and people understand what the deal is and it's a fair choice that's being offered. (P12)

The liberal approach manifests itself most clearly when RECs confront grey areas of the law. RECs must make a good judgement that is consistent with the law, even if they may be unsure of whether their opinion is suitably legal. For example, when a REC reviews an application where adults with incapacity might be enrolled in the study, a specific checklist is consulted so that members ensure that all relevant elements of the Mental Capacity Act 2005 or Adults with Incapacity (Scotland) Act 2000 are observed. The HRA assures RECs the checklist is not meant to be seen as rigid; rather, it serves as an *aide memoire* (for the Lead Reviewer in particular) to consider when reviewing an application.

Other times, RECs are genuinely uncertain of the legal effects of a research study. One REC in England I observed, for instance, was uncertain whether researchers looking to start a UK-wide Research Database required a separate REC approval in

[563] GAfREC (n 1) para 3.2.10.

Scotland. In another REC meeting I observed, a REC member queried other members what would happen if participants lost capacity during a Phase 1b CTIMP. The REC Chair recalled that under The Medicines for Human Use (Clinical Trials) Regulations 2004, if a patient has capacity to consent at the beginning of the trial, that consent continues through for the duration of the trial, unlike for research studies under the Mental Capacity Act 2005. But he also expressed some doubt. He then looked at me and said, 'Edward?' I pointed to my 'Observer' name plate, reminded the REC of my duty to not speak, and everyone laughed. 'Oh, twist his arm!', the Chair joked. 'Okay, I'll look this up and get back to everyone on what the rules are', he added.

Members of the Scotland A REC have particular expertise with the Adults with Incapacity (Scotland) Act 2000 (AWI Act), and those who have served for a long time on the committee are critical of the Act's provisions relating to research. Indeed, this REC's special focus on the Act seemingly enables them to be more flexible in their interpretation of the Act than other RECs I observed, who are mindful in obeying research-related provisions of legislation such as the Human Tissue Act 2004 (only one section of which applies in Scotland). The AWI Act's provisions state that research on an incapacitated adult is forbidden unless: (1) research of a similar nature cannot be carried out on an adult who is capable in relation to such a decision; and (2) the purpose of the research is to obtain knowledge of the causes, diagnosis, treatment, or care of the adult's incapacity; or the effect of any treatment or care given during the adult's incapacity which relates to that incapacity. One of the conditions of such research is that consent *must* be obtained from any guardian or welfare attorney who has power to consent to the adult's participation in research or, where there is no such guardian or welfare attorney, from the adult's nearest relative.[564] What does this mean for research studies on emergency treatment? A strict interpretation would suggest that it can hardly ever be performed. However, Scotland A REC members find that both ethics

[564] Adults with Incapacity (Scotland) Act 2000, s 51.

and law have shades of grey in interpretation, and part of their role is to craft an ethics opinion that respects the spirit of the law without taking an overly conservative approach:

> People often say, well, of course, ethics is very grey but the law is very black and white. And you go, well, no, actually it really isn't. And I think there is…yeah, and I think that's the problem actually with the AWI thing and this absolute requirement for consent. It's never been tested in court, got no idea if there is actually an absolute requirement. No one has ever challenged it and said, well, hang on a minute, I wouldn't normally ask people [for consent] who are capable. There is no other way of doing it, this is a really important question, it's an emergency situation, for example. It's just a complete nonsense. I think you could well find that actually a judge might say, yeah, you're right, it's complete nonsense and start to refine it, but there's never been that. So there's this belief that it's against the law but actually as you know, laws don't really work like that. (P12)

For Scotland A REC members, there is a desire to work beyond a literal interpretation of the AWI Act's research provisions so as to acknowledge situations where consent is not an absolute requirement; they take a *flexible approach* in their interpretation.[565]

In sum, the connections between ethics, law, and science cross-cut across spaces. RECs and other actors such as the HRA Assessment Team (who assess governance and legal compliance as part of HRA Approval) can receive the same pile (or digital file) of documentation, but approach them with differing perspectives. A REC strives to focus its assessment on ethical issues, but inevitably there is some duplication in the process, as RECs and other bodies move across fluid spaces of ethics, law, and science. The research application and its attendant documents involve a network of regulatory actors and resources embedded in several interconnected and overlapping jurisdictional spaces. These documents form a

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[565] Such an approach accords not only with the work of Stephens, Atkinson, and Glasner (n 356), but also with those who plead for RECs to work by ethical principles and pragmatism when laws work against public interest and individual patient interest by thwarting otherwise ethical research. See e.g. Charles Warlow, 'Should Research Ethics Committees be Observing the Law or Working by Ethical Principles?' (2005) 1 Research Ethics Review 23.

dynamic nexus or focal point that circulate throughout the network. The HRA wants its guidance for REC members on relevant legislation (e.g. Mental Capacity Act 2005) reflected in the REC opinion letters, but this is more of a quality control check than anything else. Adding reference to the law changes the force of an ethics opinion letter. As one REC Manager (P15) told me, 'they're not just ordinary letters that we do. I think of them as legal documents'. If a researcher appeals a REC decision, the HRA and another REC can always look at the initial REC and trace what has happened, including whether there was inappropriate information or opinion given about relevant legislation. In this sense, then, a REC must not only always be aware of the legal implications, but also strive to provide adequate assurance that a participant's legal rights are being protected.[566] This is a shared task; other actors involved in health research regulation also must play a part in reaching an outcome that is ethical, scientifically robust, and legal. Despite what the GAfREC state, and despite what some critics label a fundamental problem, RECs do engage in scientific and, to a lesser degree, legal review. This is seen as a responsibility that may be shared with, but not delegated to, other bodies.

To conclude this theme, RECs are embedded in multiple overlapping, interconnecting regulatory spaces. The liminal space of a REC floats within and between these spaces. The evidence suggests that in regards to science and the law, the REC space is the connecting bridge between these other spaces. In this sense, the REC is truly liminal. Rather than viewing these overlapping regulatory spaces as a problem, we would be better served to view them as evidence that regulators can act as facilitators and stewards—that is, they can help researchers and others navigate the various spaces.

[566] Christopher Roy-Toole, 'Research Ethics Committees and the Legality of the Protocol: A Rejoinder and a Challenge to the Department of Health' (2009) 5 Research Ethics Review 33.

2.3 Regulators as facilitators and stewards

A final theme to emerge from the empirical investigation concerns the nature of the interactions between RECs and their managing regulators, the variation in mechanisms to work through the (ostensibly) twin roles of participant protection and research promotion, and the value of regulatory stewardship in guiding researchers across the stages of the research lifecycle. It is within this last subcategory that liminality once again appears, through the guise of leaders shepherding others across thresholds. My findings reinforce Szakolczai's contention that in liminal moments, there is often an independent actor serving as a 'master of ceremonies' to guide people (and things) through rituals, moments, or periods of transition.[567] It is here where I wish to bridge to Chapter 7 in drawing out implications for health research regulation as it concerns embedding 'processual regulation' and regulatory stewardship more visibly into regulatory frameworks.

Aligned interests, complicated interests, and shared responsibilities

The REC members I interviewed viewed themselves relationally, as key nodes in a network of regulatory spaces that, together with other actors, perform tasks that aim to mediate between science and society and between the spaces themselves. Vis-à-vis researchers, members found that only in rare instances would researchers fail to appreciate the value of an ethics review, dismissing it as a bureaucratic step that they should not have to face.[568] Quite often, REC members reported that researchers view RECs as a helpful body that can improve their research and ensure risks towards participants are minimised. In turn, REC members viewed their committees as stewards that could *encourage* researchers and *support* them in conducting robust and ethical research.

Members expressed to me that the interests of RECs, researchers, and managing regulators are aligned, and the common bond is in facilitating meaningful research.

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[567] Szakolczai (n 467).

[568] REC members tend to dismiss these researchers as 'older researchers who don't fill in our IRAS application forms, don't know how to, because they get their juniors to do it'. They are viewed as unchangeable; RECs simply must wait 'until they retire' (P23).

We should recall that a good number of REC members are or have been researchers themselves; they do not sit in a silo, viewing research from only one side. As a REC Chair explained it, 'it's all tied up' (P3), and as another Chair added, REC members, researchers, and other stakeholders form a common community: 'I don't see it as two different communities. I see it as one community trying to learn together. We all have common aims—researchers, research ethics committees, the public—and that's relevant, meaningful, and valid research. And promoting that I think is a shared task' (P10). Linking this to the above discussion about scientific quality and the discussion to follow about research promotion, I found that RECs are confident in suggesting changes to applications to support researchers, not just in terms of ethics, but also in terms of scientific quality. This is something that the HRA recognises and encourages:

> [REC members are] strongly encouraging in terms of what different parts of the application could be changed or how things could be done slightly better. They're just good at giving advice to researchers. Often we receive feedback from the researchers saying it was really helpful to attend the meeting and encouraging. And one thing—we have used the satisfaction reports and we added a question to it to say, 'do you think the REC review enhanced your study?'. And we felt that that was quite a brave question for us to put on. We weren't sure what sort of feedback we'd get, but I think about 75 per cent are saying, yes, they do feel the REC review enhanced their study. So that's been really good to see as well. (P26)

While the relationship between RECs and researchers may be seen as healthily aligned, as already noted above, the relationship between RECs and the HRA is more complicated. As we saw from Chapter 3, for years, RECs, and especially LRECs, operated as local fiefdoms. The move towards centralisation with COREC and the NRES caused entrenched positions to be taken. One regulator told me that a running joke among RECs was that every time NRES put out guidance to RECs, it was dismissed as yet 'another missive from central bunker' (P1).

None of the members I interviewed took such a negative view of the HRA, but their assessments were certainly mixed. A REC Chair described the relationship today as

'collaborative' and 'a team effort' (P3) with regard to sharing aims. A few other REC members I spoke with were generally supportive of the HRA, finding there is a 'reasonable open channel' (P7) of communication with them. However, others I spoke with felt that they were 'completely unaware of what goes on at the HRA' and that constant regulatory changes serve as a distraction. A REC member expressed her frustration to me as such: 'Who do they [the HRA] think they're collaborative with? To me, they send an email to the REC Managers and then the REC Managers forward that on. That's as collaborative as it gets.' She explained that she and other members adopt a cynical approach to dealing with the HRA:

> So I think at the last meeting that you were at, somebody said, 'what's this for, what's HRA Approval mean?' […] And honestly, as a REC member, we don't really get told anything in a way that is digestible, understandable. And, to be honest, it wouldn't actually change how we reviewed the documentation anyway. A study is a study regardless. With my researcher's hat on, my real world job, we have to be very aware of what's going on, and, to be honest, it's not communicated brilliantly. Because all my colleagues, our mantra is don't bother to learn the system because the next time you come to put in an application it will be completely different. So let's go with the flow. If we do it wrong they'll tell us. (P8)

Similarly, members offered mixed assessments about the ShED exercise and Proportionate Review. Focusing on the former, members felt that ShED provides the HRA some idea of whether and where RECs are broadly consistent or inconsistent. One member described it as 'very helpful' for training purposes and improving 'everybody's education' in terms of what to 'look for' in an application (P7). Similarly, an HRA regulator explained that they find ShED adds a lot of value in highlighting where the differences are across RECs and how they can 'be addressed through further training' (P17). The same REC member who adopts a cynical approach to dealing with the HRA, however, described ShED as 'absolute dross':

> Oh God, when we used to get them at [XXX] we used to go, 'oh, not another one, what is the point?' So we'd do it, and I will tell you this, I always realised that I was always leading on it, and then the REC Manager admitted to me, 'oh yes, because I know it will get done properly […], we need to make sure it's done properly so we look good.' Okay. Honestly, everybody's heart sank every time we got one. So you'd review it, and you

> would do it properly, and then several months later you'd get this consolidated report of, well, so many committees said this and so many committees said that. …And the point of that is? So what is the actual answer? […] What is that actually teaching us? I've no idea. […] …utter nonsense. There must be a better way of doing it. I mean, it's to ensure consistency. […] Maybe it's useful for them because they can tick a box. That's me being cynical again. But I can't say I've ever learnt anything from doing it. (P8)

The HRA seems to have heard some of these criticisms. A Scientific Officer told me that the HRA acknowledges members are 'quite unenthusiastic about' the exercise (P26), and are working to improve the individual feedback to RECs. The HRA believes that individual feedback will provide RECs an 'incentive to review [the ShED application] well and show how good they are, in a way' (P26). Yet even with these improvements, in my chats with members over lunch or coffee breaks at the meetings, scepticism seemed to predominate. Two members told me the last time their REC received a ShED application, they were assigned as Lead and Second Reviewers. Yet they were not told it was a ShED application, much to their frustration, and so they 'wasted three hours on it', complete with typed up notes. 'ShED is about the principles, not the practice. And they never told us! Needless to say, the HRA got some choice words from us', one of the members told me. Laughingly, he then added that their REC had not received another ShED application since.

Beyond the coffee chats, I also observed ongoing frustration with the HRA when a ShED application appeared before one of the RECs. The Lead Reviewer began her presentation by stating, 'I've put at the top of my paper, "Many queries"'. The members laughed and nodded in agreement. The Lead Reviewer then added that she only realised *after the fact* that it was not a real application. Reading from her typed up HRA Ethical Review Form, which included sections highlighted in yellow that warranted particular discussion, she read out a litany of problems. 'Well done so far!' the REC Manager said as she was copying down each 'problem' noted by the Lead Reviewer. 'Are there any other ones?' she asked. 'As if that wasn't enough', a

member retorted. Nevertheless, other members then chipped in to add several more concerns. It became quickly evident to me that as part of this 'game', the more 'ethical problems' spotted by a REC, the more favourably the HRA would view them. A long-standing member, visibly frustrated, stated that previous ShED exercises had 'somewhat normal applications. But I gave up halfway through this one because I found it an insult, with a bunch of doctored information'. Other members verbally voiced their agreement. In response, the REC Manager explained the background to this particular ShED application. Apparently, a private clinical trials unit sent this 'case' to the HRA's Director of Operations with a list of all the issues to spot. The REC Manager, sympathising with the committee, added that she had already explained to the HRA her problems with this kind of 'spot the error' game, including how it is a poor use of the REC's meeting time. All REC members agreed with this assessment. The long-standing member added: 'I think the Shared thing is a good idea. But this…', she trailed off, waving her hand over the application. The consensus from the members was that the application contained too many small issues and not enough 'meaty ethical issues'. A member opined that a lot of the issues in the ShED application had been seen in *real* applications, but they were points more for researchers to pick up and learn from than for REC members. The discussion closed with the REC Manager asking the REC if there were 'main ethical issues to flag'. The REC members listed what they considered to be the main issues, with the REC Manager taking careful notes.

For some, then, the HRA is seen as being an active central regulator that is serving the interests of the research community, but not always those of the REC community. And indeed, the evidence suggests that there is more of an alignment between RECs and researchers than between the RECs and their managing regulators. Some REC Chairs are unclear who to contact when they have broad ethical questions or concerns. REC Managers and Regional Managers are seen as 'so overworked and busy just managing the day job of running committees' that they lack 'any kind of mental space' (P11) for addressing broader concerns or issues.

Members indicated that they would appreciate more interaction with the HRA to understand the context of the next-generation regulations—but only to a certain degree. Just as they would appreciate more value for the work they do, members also want to retain their independence. A growth in procedural regulation and centralisation causes some to worry that they are 'being told how to think' (P10); achieving a balance between quality ethics review (through consistency and standards set by managing regulators) and independent ethics review (freedom for an individual and a group to engage in ethics deliberation) is a constant struggle.

In sum, RECs view themselves as having aligned interests with other actors in regulatory spaces. Specifically, they perceive a close bond with researchers, sharing the same goal of facilitating meaningful and ethical research. RECs and HRA also share this goal, but the relationship is more strained. The HRA is not always perceived as working collaboratively with RECs and at times interjects itself into their ethics of space, causing tension and political controversy. What it suggests is that there is a plurality of regulatory spaces and a relationship between regulatory actors that constitutes a space at times filled with tension. But it also suggests that there are spaces between spaces. As we will see, there is a stewardship role *within* these spaces that works for Scotland and could work for others. If RECs perceive aligned interests, the question remains how they work to operationalise those interests. Specifically, how do they work through protection and promotion?

Working through protection and promotion

I now return to the driving question of this thesis—that of how RECs act among themselves and interact with other actors within the context of 'next-generation' regulation that aspires to both protect research participants from harm *and also* promote health research through streamlining perceived regulatory barriers. To the extent any hypothesis had been formed going into the empirical research, I was expecting a number of REC members to express concern on two levels: first, that they had noticed a recent change in the regulatory architecture governing their practice as ethics reviewers; and second, that this change—an imposition of research

promotion—was having detrimental effects on their ability to protect research participants.

As I quickly discovered, REC members expressed a different viewpoint. For them, protection and promotion can be a challenge to work through (and may even be seen as in 'tension'), but it is a twin role they recognise *and support*. Protection and promotion is therefore viewed not as a recent development or challenge in light of the Care Act 2014 or other statutory regulation, nor is it necessarily 'felt' by REC members. Rather, statutory regulation instantiating research promotion is a form of next-generation regulation that embeds in law what has been occurring in practice for a number of years. That it is now embedded in law does not translate into a shift in the relationship between RECs and the managing regulators, nor with researchers themselves. No member I spoke with was aware of explicit instructions issued by the HRA or other managing regulators encouraging or mandating them to look towards facilitating research while protecting participants. There is no explicit change in approach, and none felt that protection has been or is being sacrificed on the altar of a research promotionist agenda. Some even think RECs have become *more* protectionist in certain areas, such as no longer permitting researchers to look through patient notes without consent.

Many view research facilitation as an example of their REC's independence and a key role for them to play, particularly for research that is independent (i.e. not funded by major pharmaceutical companies) or may otherwise be neglected (e.g. rare disease research). And, the aligned interests between RECs and researchers is such that the latter come to appreciate the assistance RECs provide in tweaking their application, be it on research design or a more standard 'ethical' component such as the consent process. The RECs I observed and members I spoke with want researchers to come to them with enquiries; they see part of their role as being educational for researchers. They want researchers to regard ethics review as a favourable experience where RECs offer guidance and suggestions to improve their research study, foremost ethically but also scientifically. In this way, if researchers

apply to the same REC, the REC would hope researchers take on board the issues they raised with them in a previous 'round' so that there is a general improvement of standards.

This said, some recognise that the twinned protection and promotion role has become more pronounced compared to the previous generation before COREC and subsequent efforts to centralise and standardise the Research Ethics Services in the UK. If protection was the 'be-all and end-all' of RECs in the prior generation, next-generation regulation encourages all to view research as a civic good that requires promotion; part of the HRA's role is to 'help facilitate the setup' of research (P2) and provide confidence to the public that good research is being conducted. Research promotion is intertwined with a bioeconomic imaginary that sees the UK as a favourable jurisdiction in which to conduct research and bring economic benefit to the country.[569] As an HRA regulator explained:

> I think there's been a wholesale change if we just focus, say, on ethics committees, a change of emphasis… Before when I joined 20 years ago, running ethics committees, it was all about protection of the individual participant and that was pretty much it. That was the be-all and end-all, that's what we were there to do, protecting the individual participant. […] I think over time that's changed that now we see *research as a kind of civic good*, something that people should have access to. You know, we need to break down barriers so that everyone can get access to research, so I think there's a shift between being protected from research and now being given access to it because it's a good thing. Also, our dual mission now is this sort of protection of the individual but facilitating ethical research and the whole making the UK a good place to do research, so that it comes in a UK PLC business kind of focus to what we're doing, that it's not about just protecting individuals, *it's about making sure that the UK attracts research and money*, and so that's the change, and people will have their views about that. I remain neutral on that. […] I think I just observe that that's been that shift, *that things have become, well, commoditised, I suppose, in a way that research is part of UK PLC, attracting research here, doing research, making research easier, less bureaucratic*, everything else, is all good for the, as I say, UK PLC. So there's

[569] Salman and others (n 411).

> been a shift there, I think, for ethics committees. Now whether that has been reflected in the people who sit on ethics committees… (P1)

RECs, however, are not consciously aware of any political pressure to realise this bioeconomic imaginary. As many are themselves researchers (or former researchers), they are cognisant of drivers that exert a strong influence on research promotion through streamlining initiatives, such as HRA Approval, the IRAS application, and changes in regulations that build the UK's research capacity and seek to harness patient records from the NHS. But they view their role, and the HRA's role in this drive, as but a 'small piece of a much larger jigsaw' (P5). Their independence is well-preserved and they do not fear a present or future context in which they are pressured to 'skim' through application materials. 'I'll be honest with you', a Scottish REC member confided in me, 'sometimes I think the UK wants to be seen as a biomedical hub and it is becoming a biomedical hub and it's good that it becomes a biomedical hub, but it should never be at the expense of ethics and of protecting patients, never' (P20). This member was adamant that RECs would not allow this to happen.

If the HRA regulator I interviewed above is uncertain whether REC members embody this dual mission of protection and promotion, accepting that it is indeed present in REC practice, there is also widespread variation regarding how this dual mission is to be worked through. As I came to discover, in the absence of specific guidance on how to reconcile protection and promotion, members approach this twin role through various heuristics. The HRA regulator speculated that protection and promotion is an *irreconcilable tension*, or as one REC member labelled it, 'an inherent contradiction' (P14), which simply must be acknowledged:

> I think we just acknowledge that tension [between protection and promotion]. Well, some people say there's no tension, other people say that's clearly a tension between those two things and you can't do both and there's a conflict of interest in doing both. I would love to tell you there was some practical way in which we sort of tell people how you balance that…like this is how you balance these two competing…but *in practice, there is no guidance*. We don't have a position on how you do that, *we just hold*

> *these truths to be self-evident. You've got to protect but also you have to promote*. (P1)

Yet later, when I pushed for clarification on how the HRA expects to foster an environment of protection and promotion if they do not offer practical guidance for their 'satellite' REC regulators on how to work through this dual role, several interlocutors came to view protection and promotion not as twin aims to be balanced, but rather, as aims to be treated *sequentially*, working from protection as a primary question that establishes a track record of trust, and only after to address a secondary question of research promotion:

> I suppose it's resolved by you treat[ing] them sequentially. The first one is you have to make sure that it's safe, risk-free and protected, and ethical, and if it is, well, you do everything you can to promote and facilitate that. So maybe it's resolved by that sort of sequential looking at it. *You're not holding them at the same time*, you're focusing first of all on the protection. Once you're assured of that protection, then we need to make sure that we don't then hang around on giving a decision for six months or something, that our processes are…that we can give that full due consideration to the protection in the time that we need to do that, but also make sure we deliver those opinions sort of rapidly so that that facilitates the research and it can go ahead. (P1)

> …the protection is almost *you have to get in the right order*. We can't promote until we have something to promote and in order to promote it we need to make sure that everything is safe, is protected, because otherwise there's no point promoting something that no one has any trust in. […] In order to build up trust you need a track record. You can't just say, trust us, we're the NHS. It doesn't work. People don't work like that. I would say track record is more important. (P2)

Some REC members reiterated to me that 'participant safety and the ethics are always going to come first':

> Standing back and looking in, definitely it's most important to promote research. Absolutely. But as a REC member, when that 12-inch thick pile of paperwork lands on my desk, my job is, as I see it, to read and evaluate those documents to make sure that those studies are scientifically sound or ethically sound and, on balance, no harm is being done to any participant. That's the bottom line. Whatever goes on from a management, HRA point of view, at that point I don't actually care. I care about that cancer patient or

> that healthy volunteer, that's what's important and that's what I'm assessing, as I see it, for me. (P8)

In contrast, on the ground, facing research applications, other REC members saw protection and promotion *as working together*, as 'all tied up in one' (P3), with RECs and researchers both aiming for high quality research. But how exactly do they work together? RECs will not often 'stop research from happening' (P3). The vast majority of research still goes ahead; indeed, the RECs I observed were extremely hesitant in rendering an unfavourable opinion and spent a significant amount of meeting time working an application with a number of issues or concerns into a provisional opinion. When the RECs did render an unfavourable opinion, they aimed to phrase the letter in a positive light, 'welcoming a resubmission' to the REC provided the researchers took their (suggested) points into account.

Some see the '*proportionate*' approach taken by RECs to research applications as a mechanism to instantiate research promotion. By treating a 'simpler' study with a lighter touch than a more 'complex' or 'risky' study—typically seen as Phase 1 CTIMPs—RECs are contributing to the research enterprise. Others see protection as being '*balanced*' against promotion—or as one described it, as a 'halfway house' (P14)—with promotion as a value that can reign in a tendency to go overboard with protection:

> The idea that RECs are there to support ethical research for the common good, I think, is an appealing principle. It's one that I certainly support. But it's also one in which you're trying to balance the interests of the vulnerabilities of participants, the resources in healthcare and those kinds of thing. RECs definitely do feel very much, and they ought to, as they're there to offer a layer of protection for participants. But they can overstep the mark on that I think, and sometimes become too protectionist, or make some kind of claim about their own expertise, which oversteps what they can do. (P4)

Both a REC Chair in England and a Scientific Officer in Scotland opined that balance manifests in weighing the rights of the community against the rights of the individual, a balance that is difficult to achieve but fundamental to modern research. The primary interests will always be participants, but in contrast to the

Declaration of Helsinki's Paragraph 8 precautionary intonation that medical research can *never* take precedence over the rights and interests of individual research participants, sometimes, the REC Chair told me, we must 'recognise that there's more than one person at this party and that we have to accommodate their interests' (P10); RECs must support research for the benefit of the community. Humorously, he added that RECs should promote research as a civic good to the community, to 'educate them and say, actually, research is a good thing for you. Research, like Guinness, is good for you' (P10).

Research applications that are poorly designed disappoint REC members, not because it wastes their time, but because the underlying question may be valuable and could 'save some lives'. 'We want to find a way; we always want to find a way', the Chair of one REC said as they were agonising over the potentially too burdensome consent process for patients in an emergency setting. 'I love the idea of this proposal', a Secondary Reviewer of a CTIMP said at one meeting, who went on to express concerns about how the researchers planned to execute it (specifically, the changing of dosages). 'It's such a shame', he lamented. 'The study needs to be done, but perhaps in a different way.' Others agreed. 'I think it should be done, but they've got to get the application right.' Following a face-to-face interaction with the research team, the REC reached consensus on a provisional opinion, in which they would reiterate their concerns and hope to prod the research team to consequently redesign part of the CTIMP.

Whether through 'balance', 'ranking' or 'proportionality', RECs strive to work through protection and promotion, performing a twinned task that aligns their interests with that of their managing regulators, researchers, participants, and the public at large. The ways in which RECs help researchers navigate through thorny regulatory and ethically challenging areas can vary. In Chapter 7, I argue that this is in fact a *benefit* of next-generation regulation. Law has provided sanctioned spaces in which RECs and other actors can engage in 'regulatory play', with more flexibility to work through challenges and interact with others. Before I turn to this

argument, however, in the final part of this theme, I want to further suggest that actors within and connected to RECs serve as 'stewards' who help guide researchers (as well as sponsors), and their protocols, across stages of the research lifecycle.

Regulatory stewardship

Regulatory stewardship can be defined as the prudent guidance of one or more actors across regulatory thresholds—without which there is risk of impairment or harm—with a view to collective betterment.[570] In this thesis I have already hinted at the importance ascribed to specific actors within regulatory spaces, and specifically those actors connected with RECs. Regulatory stewardship draws attention to more than the REC; it highlights the role actors within or connected to them play in helping researchers, sponsors, and REC members navigate difficult regulatory spaces and improve the overall quality of research. In addition to the HRA, certain REC actors, namely the REC Chair, REC Manager and Scientific Officer (as well as the REC as a unitary actor), play a critical role in assisting researchers (and sponsors) navigate the demands of putting an application together—they are regulatory stewards that help researchers cross thresholds—serving as 'ethical research promoters'.

How does regulatory stewardship manifest in the operations of regulatory actors? An HRA regulator provided me with early insight in describing that Authority's vision for improving regulatory pathways, in part by providing support and working in partnership with other actors:

> …ethics committees 90 something per cent of the time say yes to research, so actually that's an arbitrary milestone and actually it's unhelpful because people are running towards it, putting in poor quality [research], which means that further downstream there are blockages. So what we want to do is try and allow there to be less [sic] blockages downstream by improving

[570] See Graeme Laurie and others, 'Charting Regulatory Stewardship in Health Research: Making the Invisible Visible?' Cambridge Quarterly of Healthcare Ethics (in press). Parts of this chapter's subsection on regulatory stewardship are adapted from the article, of which I am a co-author.

> the quality upstream and by providing support upstream and along the way we should be able to help with that.
>
> […]
>
> Medical research is hard. We see 6,000 applications a year for medical research; it is hard, and we need to be helping these people realise their ideas rather than just being what's seen as a bureaucratic block at the beginning of something that is a very long process. Also, I guess there's the obligation there again not to waste money by blocking things, not to stop things because they are illegal. Obviously we can't let them go through, but it's providing the support to enable people to realise their goals on an ongoing basis. But again, I think it's working in partnership with other people. (P2)

The HRA's role as a regulatory steward is manifest at varying levels. At a high level, there is guidance on the HRA website for researchers, in terms of best practices, policies, and regulations. HRA interlocutors told me they aim to provide researchers and sponsors with as much information as they can upfront so that when an application comes to the REC, it is as good as it can be at that point in time. At a more granular level, the HRA in the past has, on an interim basis, created 'Application Managers', who help researchers navigate through complex cases that straddle regulatory regimes, such as those involving multiple domains (e.g. data, tissue, and devices), and piloted an 'Ethics Officer' role that was referenced in Chapter 3,[571] and that I will discuss briefly below. In Chapter 7, I argue that in embedding regulatory stewardship into the regulatory framework, there is room for the HRA to improve their granular practices.

Regulatory stewardship is manifest in the REC itself. REC members, individually and as a group, see themselves as providing a kind of upstream pastoral support to researchers. They serve to protect the rights, interests, and welfare of research participants, but equally, they feel as though they serve to promote ethical research by *working with* researchers. RECs are removed from the 'real happening' of research, but in any event, their role is not to monitor the day-to-day practice of

[571] Chapter 3 (n 248).

research. There is a distinction to make here between a steward and a policeperson. A policeperson monitors, enforces, and sanctions; a steward helps others navigate terrain and inculcates values and principles that are embodied and instantiated in everyday practices.[572] A REC's role is to evaluate the ethical acceptability of a research study and to help researchers (and to some degree, sponsors) navigate complex regulatory terrain, insofar as that regulation is of an ethical nature, though we have seen that this necessarily overlaps with science and law. It is also a REC's role to encourage researchers to comply with approprate regulatory and professional standards in the way they conduct themselves as researchers. Researchers are in a position to inform RECs of the latest trends and issues in research, as well as to report back to them their experiences in working through ethics reviews and other regulatory processes. Viewed together, this dynamic is mutually reinforcing.

To be clear, the stewardship practised by REC members is not necessarily direct and deliberate (and indeed RECs cannot write an application or protocol for a researcher), but through nudges, comments, and responses to queries, members help assuage or even persuade research applicants to improve the quality of their research design or work around a false roadblock in law (e.g. a misinterpretation that data protection law or adults with incapacity law is stricter than it really is regarding research). Even though a few REC members and Managers were hesitant to view RECs as promoting research or serving as advisors to researchers ('we're not there to spoon-feed the researchers on how to do their job', one Manager told me), in practice, across all five RECs I observed instances of a stewardship function at every meeting. From this I gathered that for some members, research promotion is an unconscious role that is wrapped up in the process of their review. Ethics review is not a static event of compliance with a checklist of standards (though three members complained that it can feel as such with the HRA Ethical Review Form). Instead, it is a dynamic process whereby researchers, the application, and protocol

[572] Laurie and others, 'Charting Regulatory Stewardship' (n 570).

are carried across thresholds by various actors, including the REC, who suggest 'better ways' to devise a study and thereby shepherd it forward.

A few examples from my observations illustrate this finding. Scotland A REC members remind researchers that if they ask participants for consent to follow-up their medical records, it allows them five years of follow-up without any additional cost. Not infrequently, other RECs offer suggestions to improve recruitment numbers for a study, pleasantly surprising the attending researchers. 'Not a question, but a suggestion', a statistician remarked to one group of researchers. 'Speak with a local statistician and mention "case control" to them. What you're doing isn't wrong, but you may be able to get more out of what you're doing.' During a face-to-face encounter with a researcher proposing a substantial amendment to a genetic research study, the researcher explained that her original protocol and PIS stated that all data related to the participant would be destroyed if the participant chose to withdraw. A REC member intervened at this point and encouraged the researcher to think about modifying the documents, should she want to retain the data collected and analysed up to the point of withdrawal. The researcher, unaware of this possibility, thanked the REC member for this suggestion, but then wondered whether this approach would properly constitute withdrawal and would respect the participants. The REC Chair replied that 'there's no clear answer' but thought withdrawal would be unlikely anyway. He encouraged the researcher to 'think about it'.

Face-to-face interactions with researchers also illustrate this stewardship role. A Scotland A REC member relayed a story about the fluid ontological boundary between 'research' and 'audit' in contrast to its strict regulatory boundary:

> We had one very interesting study from [England] that was […] wanting to study care homes, and it was just going to be…it was a sociological study, and of course in the care homes were the people with incapacity. And we advised them that in Scotland, if they did this as an audit of what was going on in care homes, it would be very appropriate to go ahead. If they did it as research, then they couldn't look at patients in the care home who had…lacked capacity, because what they were trying to study had nothing

> to do with their disease. It took about four letters to the committee, to the researchers. So we gave them a solution. All they insisted on saying was, yes, they agree, we'll do this as an audit on one care home in Scotland, but because in their perception it had to be seen as being research, to get the funding or to get validated or whatever it was down south, they didn't grasp that we were trying to open up the way to let them do it, it wasn't actually going to involve any interventions in patients that were in the care home. But they just couldn't actually do it without getting consent from everyone if they did it as a research study. (P18)

REC members are encouraging of regulatory stewardship at different levels, from the more complex cases involving interpretations of law, to simpler instances of ensuring an IRAS application is correctly filled in. One member considered it useful to 'triage' the application *before* it comes to the REC (perhaps in coordination with sponsors or R&D offices), looking at mundane issues such as grammar but also regulatory issues. This suggests a need for stewardship at an earlier stage of research design and approval and, indeed, throughout the research lifecycle. Better triaged applications would lead to higher quality, more error-free applications at REC meetings, allowing RECs to focus their time on substantive issues. Instances of why this would be useful were observed in REC meetings. During one, the REC Manager explained to the REC that the researcher ticked a certain box in the IRAS project filter, which opens up certain questions for the IRAS ethics application form. Had the researcher clicked 'basic science' instead, it would have been much clearer for everyone when it came to performing the ethics review. The REC Manager further explained the application was transferred from one HRA Regional Office to another, which caused it to fall through the cracks. Neither a REC Manager nor Regional Manager went back to the researcher to support her before she submitted the application, and the application was accepted in the early round of the validation process. 'It has snuck through validation, unfortunately', the REC Chair sighed.

Though the REC itself can serve as steward, regulatory stewardship is evidenced most clearly in the work of actors in greater positions of authority or influence within a committee, namely Scientific Officers and the REC Chair and Manager, all

of whom have closer contact with researchers. Between the monthly full committee meetings, REC Chairs receive a volume of correspondence from researchers asking for advice. REC Chairs told me they are happy to provide support because 'it helps to create the right environment' and achieves the shared end goal of 'high quality good research that's going to make a difference to people's lives' (P3). Through this support service, REC Chairs see themselves as '…promoting research. I think the committee, as the committee's representative, I am promoting research in the UK and encouraging it, and trying to get it started as quickly as possible' (P3). Similarly, REC Managers see their role as stewarding researchers through the application process:

> I'm here to try and help the researcher really to make sure that their information gets put across as well as possible. […] Part of my role is almost trying to pre-empt the questions that the committee will be raising as well. So, something obvious that's missing and I know the committee will look for, I can ask the researcher beforehand and that's to try and facilitate to try and get the application through for them as smoothly as possible. (P25)

Throughout my year-long observations and interviews, the four Scientific Officers in Scotland's Research Ethics Service were universally praised for their role in providing educational and regulatory support.[573] The CSO created the position in 2008 in response to the 2004 Lord Warner Report's recommendation.[574] Appointing one Scientific Officer in each of Scotland's four main regions was seen as a way to: 1) have Scottish RECs conform to national standards, rather than local Health Board standards; 2) allow for Scottish RECs to better link with the CSO to ensure best practices were disseminated and ensure RECs were using the same documentation, databases, rules, and guidelines; and 3) help researchers get their applications through more efficiently and make Scotland an attractive destination in the UK to conduct research. Scientific Officers sit side-by-side with REC Managers on a daily basis, which unlike in England, allows for constant interaction and more efficient

[573] Indeed, one Scientific Officer (P23) told me that it is not unusual for researchers in England who are submitting applications to an English REC to contact a Scientific Officer for advice.
[574] Lord Warner Report (n 232).

communication with researchers and sponsors. Their side-by-side interaction with RECs also helps prevent RECs from getting bogged down in unnecessary details:

> …we [Scientific Officers] are appreciated by the committees – that we can kind of just protect them from just getting bogged down with too many queries and things. Where we absolutely come into our own is all the queries at the pre-application stage are completely directed towards us and nothing goes through to the committee members or Chairs at that stage. And I think that makes a big difference. (P24)

Scientific Officers provide researchers and sponsors with guidance and support on a variety of matters, including compliance with correct documentation and conformity with legal requirements, all of which could impact the success of their ethics application and their research as a whole. At the same time, Scientific Officers help guide REC members in evaluating research applications, particularly when it comes to understanding the regulatory context of a given application:

> ….the other part was making clear that the committees are not just there to be a gatekeeper, but they're also there to try and facilitate research. So we should be talking to...the Scientific Officers should be talking to researchers about how to do research, especially to sponsors about what the committee expects to see, and also to the members to explain that if you get a difficult application or an application that mentions previous ones, we should be helping the committee understand what's going on with applications, and keeping committees, committee members up to date with training. (P16)

Scientific Officers not only help researchers with the ethics component of their application; they can also help guide them to other regulatory steps needed for approval:

> The other thing is to remind [researchers] that ethics isn't the be all and end all. You're going to need R&D approval; that's going to take roughly this amount of time. And part of our job, which I might come back to, is because we have interactions with those people, we give researchers some guidance. […] So if I give advice to somebody, they might say, it's nothing to do with ethics. And so I'm not doing this from an ethics point of view, I'm doing this as it facilitates research point of view, because I know that R&D will ask for this. […] [Researchers] forget that part of [our] job is a facilitatory role and it's not just...it's not trying to catch people out who are doing the wrong things. (P16)

A Scientific Officer (P24) explained that if RECs see patterns of a local university submitting applications that 'aren't up to scratch for different reasons', then they look to identify what the specific problem areas are and work with the university to remedy them for improved future applications. Another Scientific Officer (P27) distinguished the REC's task of ethics *review* (which, in her mind, is focused more on compliance with standards) from the 'office' in which she sits, which focuses more on science and ethics *advice service*, with researchers viewed as 'clients':

> There's the committee and there's the office. And I think in the office we perceive the applicant, as it were, like our clients. So you do all that you can to help them get through the process so that you're not blocking that application. So we're quite…we're trying to be very friendly and, you know, trying to tell them the information that they need to give us. But sometimes it is a bit like Chinese…you know…well not quite Chinese whispers, but, you know, you're trying to help them through the process so we have that strong feeling. (P27)

England has not gone the route of Scientific Officers, but the HRA has been equally keen to support researchers. Unlike Scotland, however, embedding regulatory stewardship within a specific actor has presented challenges. As explained to me by an HRA regulator, the HRA conducted an 'Ethics Officer' pilot as a potential avenue for supporting researchers through the application stage by providing them with advice on preparing for attendance at the REC meeting following submission of their application. According to the regulator, it was not a success. REC Chairs, who took the lead as Ethics Officers, attended *other* REC meetings as supporters of researchers. REC members apparently felt uneasy or even threatened by having an 'outsider' REC Chair attend their meeting and comment on an application, which they felt was their responsibility (and considering the above discussion about black boxes between RECs and an ethics of space, we come to understand why). More recently, the HRA contemplated rolling out a 'REC Application Review and Advice Service' that encouraged REC Managers to conduct an 'enhanced check' on an application submitted to their REC. This would involve looking at the study

documents and thinking about potential administrative issues that need fixing. One HRA regulator explained that an example would be if a REC Manager

> …knew that their committee were likely to ask for a certain aspect of the information sheet to be changed, […] they would pick that up with the applicant and say you're likely to be asked to change this, you can either change it now before the meeting, but you may still be asked to make extra changes after the meeting depending on what the committee say in their review. (P26)

Of course, this role differs from what Scientific Officers do, as the latter also provide help on matters of scientific design and legal interpretation. A further twist is that with the introduction of HRA Approval in England, HRA Assessors are picking up administrative discrepancies and inconsistencies as well. If, for example, the protocol said one thing but it was described differently in the PIS, both HRA Assessors and REC Managers would be picking this up. Due to the duplication 'between the two teams' (P26) and the concern that it could cause more confusion for applicants in terms of being contacted by two different people for two sets of issues, the HRA has scaled back on REC Managers conducting enhanced checks, such that this is only now done for phase I studies in healthy volunteers, which are not eligible for HRA Approval and thus not looked at by an HRA Assessor. Regardless, my impression is that HRA Approval is more of a 'compliance check' process than an opportunity for stewardship whereby actors within the HRA not only remove barriers, but also help facilitate better research. Stewardship, to the extent it operates currently within the HRA, will be found in other processes carried out by other actors.

To this end, the HRA now encourages: 1) researchers to consult the HRA's online decisional 'toolkits'; 2) researchers to email queries to HRA staff; and 3) REC Managers to look carefully at the research applications before the REC meetings and 'think about what ethical guidance they might want to point their committees in the direction of' before the meeting (P26). The HRA also wants to 'empower' REC Managers to think about what laws and ethical guidance the REC might want to take into consideration when reviewing applications so that the discussion is

'focused more on the ethical issues' (P26) and so that in the opinion letters, there is more explicit reference to guidance to explain the REC's reasons for why they are requesting changes to the application or rendering a provisional or unfavourable opinion.

Whether this is a role that REC Managers can successfully take on, given their competing demands, remains to be seen. The Scientific Officers I spoke with contrasted their roles to REC Managers on numerous grounds, including the educational differences between them. Scientific Officers have tended to hold PhDs in a science discipline; REC Managers may or may not hold university undergraduate degrees. Because REC Managers are not scientifically trained, they may be unable to read an application as expertly to understand the ethical, scientific, and legal issues at play. Regardless of these challenges in England, the HRA is committed to providing a robust ethics guidance and support service to researchers. As I will argue in the next chapter, however, more can be done to embed regulatory stewardship in the health research regulatory framework, and the HRA should take a leading role here.

6.3 Conclusion

Informed by anthropology of regulation, this chapter has empirically examined the ways in which practices, people, and entities are structured in and by health research regulation, and vice versa. I set out to answer the research questions posed in Part I by presenting qualitative research findings undergirded by regulatory theory and liminality. The findings reveal a critical understanding of REC practices and the form and function of health research regulation. The findings also reveal a processual and experiential understanding of RECs and the ways in which they affect and are affected by regulation.

I had entered my year of empirical research with the expectation that I would be exploring how RECs experience and react to changes in statutory regulation. Contrary to what I was expecting, and critically for the purposes of this thesis, the

empirical data suggest that modifications to the health research regulatory space at the levels of statutory law and central regulatory authorities have not so much 'trickled down' to the day-to-day practices of RECs, as the day-to-day practices have long reflected what has only recently been enacted in law.[575] RECs, managing regulators, and researchers share a common goal of promoting research that is safe and of high quality. Actors in these regulatory spaces carry similar interests and shared responsibilities, helping each other to cross boundaries and deal with major moments of transition in the research lifecycle. However, a concern that emerges from the research, and which I address in Chapter 7, is that the respective roles, competencies, and influences among the actors are not always clear, and the regulatory conversations are sporadic and at times weak between regulators, though relatively strong between regulators and regulatees. Consequently, spaces can appear *within* the health research regulatory space where hazards may occur.

In the next chapter, I suggest a normative model of what a new regulatory framework, informed by these empirical findings, ought to look like. The empirical data suggest that RECs' knowledge control and gatekeeping activities have the potential to reach *beyond* the *ex ante* stage. The hybrid protectionist-promotionist model that operates in practice fosters an environment that both protects research participants *and also facilitates* responsible health research in the country through proportionate regulation and coordinated alignment of ethics review and other regulatory processes. This can be operationalised not only at the initial stage(s) of the research lifecycle, at the moment of research design and initial application, but also, I will argue, throughout the lifecycle in partnership with other regulatory actors where ongoing opportunities for 'regulatory play' can emerge.

[575] What remains unknown (and outwith the scope of this thesis and its methodology) is whether earlier regulations, such as the RCP Guidance dating back to 1984, influenced REC practices such that REC members transformed from (to use an extreme scenario) conservative paternalists to liberal facilitators of ethical health research.

Thus, in Chapter 7, I take up Veatch's important observation about the failure of health research regulation to offer a theory of what should happen when a proposed research project involves a conflict of principles,[576] arguing that, in the absence of an expressed theory of how these two objectives should be achieved, a theory (or decision framework) should be crafted that may not invariably hinge on balance. In so doing, I address arguments from scholars such as Whitney, who argue that there are 'two major moral considerations in research with human subjects' that ethics committees must 'balance': the rights and welfare of research subjects and the 'shared interest in better treatments for disease'.[577] As I have said, 'balance' is not necessarily the appropriate mechanism and indeed, the findings demonstrate that REC members and regulators are attuned to other possibilities. If we envision RECs as evaluating research studies in stages and acting as gatekeepers and stewards at *several* thresholds, how can health research regulation, including at the level of legal architecture, take up the insights from liminality to provide a suitable space to capture these stages of dual commitment and realms of possibility? How might a regulatory framework, that legally must be 'proportionate',[578] enable regulatory stewards to take charge in accommodating potential harms and maximising research outcomes? And how can law create a regulatory space within which there is more room to protect and promote, a space for more epistemic latitude—a realm of possibility—for RECs to 'roam in' and experiment together with other actors, including those who may have cross-cutting motives? We now turn to see how the empirical findings from an anthropology of regulation may help build an evidence-based regulatory framework.

[576] Veatch, 'Ranking, Balancing, or Simultaneity' (n 118).
[577] Whitney, *Balanced Ethics Review* (n 89) vii.
[578] Care Act 2014, s 111(3) and *Regulators' Code* <https://www.gov.uk/government/publications/regulators-code>.

Chapter 7
The liminality of RECs—charting a framework for regulatory stewardship

7.1 Introduction

In the previous chapter, I examined the ways in which actors—particularly RECs—are structured in and by health research regulation, and vice versa. I set out to answer the research questions posed in Part I by presenting qualitative research findings that are set within an anthropology of regulation methodology undergirded by regulatory theory and liminality. The findings reveal a critical understanding of REC practices and the form and function of health research regulation. The findings also reveal a processual and experiential understanding of REC practices and the ways in which they affect and are affected by regulation. Research ethics review is an essential component of health research regulation and the ethics review system overall appears to be viewed favourably, at least in comparison to previous decades. At the same time, though, the evidence suggests that several regulatory components can be refined.

Having made this theoretical and empirical contribution, I now want to chart the possible ways in which we might begin to answer the broader "so what?" question that Chapter 6 engenders. In this chapter, then, I unpack further the significance of liminality of RECs and the ability of actors within the health research regulatory space to serve as 'regulatory stewards'. I do so by taking up the normative dimension of anthropology of regulation, suggesting a normative model of what a regulatory framework for health research oversight ought to look like if it were to incorporate the findings from this empirical investigation. This would include explicit endorsement of regulatory stewardship and a charting of how protection and promotion can and should work together. To be clear, I focus only on suggestions that relate to my research questions and the empirical findings; I do not

address matters such as how to improve consistency within and across RECs, Proportionate Review, consent forms and PISs, professionalisation of REC members, or patient and public involvement (PPI). These issues are important but not directly related to the concerns that speak to the overall original contribution of this thesis, namely suggesting a regulatory framework that encourages a greater recognition of liminality, as expressed through regulatory stewardship.

This proposed framework has application at two levels, which can be seen as both top-down and bottom-up: 1) the government and managing regulators (e.g. Department of Health, HRA, CSO), and 2) the REC, ipsilateral regulators (e.g. MHRA, HTA), and regulatees (e.g. researchers, sponsors, institutions). As the evidence in Chapter 6 indicates, RECs are embedded in multiple overlapping, interconnecting regulatory spaces, yet their roles and the roles of other actors are not always manifest in regulation. Further, the regulatory conversations between regulators, namely between RECs and the HRA, can be sporadic and at times weakly effective as compared to the regulatory conversations between regulators and regulatees (here, being RECs and researchers). This can cause disconnected spaces to appear *within* a given regulatory space where hazards may occur. A reformulated framework could work to improve regulatory conversations between actors, provide ongoing opportunities for 'regulatory play' to emerge, and shift the burden and emphasis away from more procedural work and towards flexibility and experimentation in ethics review. What I suggest, in other words, is a *refinement* of the extant framework, not wholesale change. Nonetheless, this is a refinement that can be worth exploring to reveal the full range and weight of the impact of RECs within and throughout regulatory practices in health research regulation.

In what follows, first, I expand on the significance of the liminality of RECs and unpack the concept of regulatory stewardship. I argue that the latter serves as a manifestation of liminality and deserves greater instantiation in regulation. I draw on extant examples within the UK's Research Ethics Services that demonstrate how regulatory stewardship can play a vital role for researchers in navigating complex

regulatory terrain. Then, I return to Veatch's reminder of the need to offer a theory of what should happen when a proposed research project involves a conflict of principles or values—in this context, the potential for protection *versus* promotion. I then conclude with a proposal for a more *processual* regulatory framework that enables regulatory stewards to assist in accommodating potential harms and maximising research outcomes, and that creates a regulatory space within which there is more room for regulators to protect *and* promote, including room to *experiment* in working through these principles together with other actors.

7.2 The liminality of RECs—regulatory stewardship

The evidence from the empirical research indicates that ethics review is less an administrative process, where ethical considerations of proposed research end once a favourable opinion is given, than it is a process of ongoing support, dialogue, and education. If we accept Farsides's claim that '[t]he goal of an ethics committee is to facilitate ethically sound practice, and to encourage researchers to honour their moral responsibilities towards participants',[579] we must further accept that this cannot be adequately accomplished within a regulatory framework that charges ethics committees to engage merely in regulatory verification of ethical standards, scientific value, and accordance with law.

Facilitation of ethically sound practice and inculcation of moral responsibilities in researchers necessitates a framework of regulatory stewardship (defined as the prudent guidance of one or more actors across regulatory thresholds—without which there is risk of impairment or harm—with a view to collective betterment[580]), whereby a range of actors, including RECs, work with researchers and others not just to achieve regulatory compliance, but also to work *through* stages in the research lifecycle, all the while instilling ethical norms of good scientific conduct. Thus, I claim stewardship is a stand-alone regulatory role and collective responsibility that

[579] Calliope (Bobbie) Farsides, 'The Ethics of Clinical Research' in Eckstein (ed), *Manual* (n 96) 13.
[580] See Laurie and others, 'Charting Regulatory Stewardship' (n 570).

should be assumed by different actors at multiple stages. For their part, RECs should have an expanded role to play in the research lifecycle, but as I will discuss, they should not cover each and every stage. As regulatory stewardship permeates health research, all actors should view each other as crucial links in a chain that moves ethical research from design to approval to recruitment and action, and ultimately, to health improvement. With different actors embodying roles at different stages, connected by communicative channels that allow for a 'passing of the mantle', stewardship helps us think differently about what is going in research and how each link connects to the other.

Chapter 6 illustrated in several ways how RECs are liminal actors. Relative to each other and to publics, RECs are black boxes, existing in multiple spaces, despite a surprising degree of group homogeneity in approach and rituals. RECs engage in various mechanisms to evaluate research applications (e.g. balance, ranking, negotiation) that manifest themselves at a lower level of abstraction—'good research design', 'competent investigator', 'favourable balance of harm and benefit', 'adequate informed consent'—which in turn yield 'ethical' judgements. Embodying a liberal approach that aims to eschew a paternalistic stance towards participants, RECs adopt a pragmatic ethics that is informed by members' intuition, feeling, and experience.

RECs do not fit the mould of a classic risk-based regulator; for example, we saw that they are also attuned to potential burdens as well as issues surrounding scientific design and law. Returning to the discussion first opened in Chapter 2, we saw that RECs' operative ethical deliberation is the facilitation of a context in which a *fair choice* is offered to participants whereby they can decide whether to participate in a study that presents ethically acceptable risks and burdens and is likely to answer, or at least contribute to, the research question it purports to address. Members adopt rituals in undertaking the process of ethics review that work best for them as individuals and as a committee. Through teamwork and consensus, they render an opinion that mediates the demands of science and society and achieves a kind of

optimisation of the similarly appreciated values of protection and promotion. The opinion allows a research protocol to transition '*from a mere proposition of involvement with participants to an actual plan of action with participants*. This implicates a range of actors, and importantly, it further transforms individuals (be they healthy "volunteers" or patients) into active research participants'.[581]

Given the fluid jurisdiction between ethics, science, and law, and given their active role in steering behaviour, what kind of regulators are RECs? Can we accurately label them 'ethics committees'? Earlier in this thesis, I suggested that as RECs become institutionalised and professionalised, acting as multi-faceted and multidisciplinary micro-*regulators* of health research (concerned with e.g. minimising risks, ensuring scientific and social value), and as more national and international regulations come into force that impact health research, RECs might be expected to act more as 'health research regulatory committees'. Indeed, the evidence from my empirical research suggests that RECs are not mere consultation groups. They do certainly engage in some form of ethics deliberation and discussion, but much more *regulatory* work is also being performed alongside other actors, including researchers. 'Health research regulatory committees' may well be a more accurate name to reflect what they do.[582] And, if we do treat RECs more as health research regulatory committees, we would be well served to rethink their roles and the regulatory frameworks that govern them to better incorporate the regulatory processes they undertake.

Returning to a quote that largely inspired my research questions, what can we make of Beyleveld's claim that a 'dog cannot serve two masters, and the role of RECs, in fact, is solely to try to prevent unethical research. The facilitation of research is the role of other bodies'?[583] Let us recall that liminality draws our attention to how

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[581] Agomoni Ganguli-Mitra and others, 'Reconfiguring Social Value in Health Research Through the Lens of Liminality' (2016) 31 Bioethics 87, 89 (emphasis in original).
[582] See also McGuinness (n 102) 695 ('RECs act as regulatory authorities with concerns beyond those of ethical deliberation. I argue that RECs are regulatory rather than advisory').
[583] Beyleveld (n 111) 73.

actors experience and react to change, and that the evidence from Chapter 6 suggests that, if anything, recent changes in the law reflect already-existing practices of RECs. RECs, managing regulators, and researchers share a common and desired goal of promoting research that is safe and of high quality.[584] The relationship between RECs, researchers, and participants cannot, I submit, be likened to master-dog. Actors in these regulatory spaces constitute one 'species' (albeit of varying familial nodes) that carry similar interests and shared responsibilities, helping each other to cross boundaries and deal with major moments of transition in the research lifecycle. My investigation has not indicated that RECs are guided by a single principle of participant protection. Research promotion is also very much present and at play—and welcomed—in their functions.

As we saw, regulators can have a problematic relationship between each other, much more so than between regulators and regulatees. The HRA strives to chart a regulatory environment that enables researchers to bring a research study to light in a smooth and efficient manner; a critical component of this charting involves interactions with RECs. The relationship between the HRA and RECs can be politically fraught, though, drawing RECs into struggles for power with their managing regulatory authority. There is a strong desire by RECs, including REC Chairs and Managers, to preserve the sanctity of *their* black box and ethics of space. RECs simultaneously want more guidance from the HRA on regulatory developments such as HRA Approval and limited imposition on their everyday workings. That possible imposition of power is exemplified in the HRA's Ethical Review Form, which influences the processes of ethics review. The 'balance' managing regulators must achieve between sound coordination and overreaching diktat is a difficult one, particularly in a country with devolved administrations. The relatively limited communication channels with the HRA generally are viewed not as problematic *per se*; indeed they may be beneficial. The HRA sees itself as

[584] Such a finding accords with Hedgecoe's empirical research, which found that NHS RECs can proactively promote research. See Hedgecoe, 'Research Ethics Review' (n 116).

providing a steering (i.e. catalysing), not controlling role, for RECs. For many REC members, that relatively light-touch approach is a value that reinforces the RECs' independence (or phrased somewhat differently, preserves their autonomy) and ability to reach decisions without fear of external pressure or loss of power over their domains of control.

More profoundly, the interactions between RECs and their managing regulators suggest that something other than 'decentred' regulation is occurring. There is evidence of increasingly 'centred' regulation where the state, through the HRA, CSO, and other authorities, is exercising growing influence, but not necessarily control. There is also evidence that, as Scott and others have written about regarding regulatory spaces,[585] the resources relevant to holding regulatory power and exercising capacities in human subjects research are dispersed. Never have the resources in this space been restricted to formal, state authority derived from legislation. Historically, and continuing through the present, those resources have included expertise and organisational capacities shared between state and non-state bodies, including sponsors and funders.

RECs do serve to control access to the potentiality of research involving humans, but controlled access through their 'event licensing' system is buttressed by a facilitative ideology set within an 'ethics of space'—a conscious desire to promote research and in turn, advance human health. And this, arguably, is the 'ethics' in the REC. Ethics is not about compliance or control, but rather about debate, reflection, values, argument, and justification. Legitimate and diverse disagreement can (and ought) to occur. As a matter of regulatory practice, then, an ethics of space must accommodate diversity, disagreement, and dissent across applications and across time. This in turn suggests that by their nature, liminal regulatory spaces must be provided for RECs and applicants alike to explore and deliberate on the 'ethics'. Not surprisingly, a substantial majority of REC members I interviewed and

[585] Scott, 'Analysing Regulatory Space' (n 367).

observed did not view protection and promotion as creating an ontological conflict. Rather, their practice of working through both seems to instantiate the *Declaration of Helsinki*'s Paragraph 23 recommendation to not only consider, comment on, and potentially approve a research protocol, but to offer 'guidance' on it as well.[586]

More questionable, though, is whether this practice instantiates Paragraph 8 of the *Declaration of Helsinki* and the GAfREC guidance, i.e. that the goals of research and the researcher, while important, should always be secondary to the dignity, rights, and wellbeing of the research participant. Certainly, the dignity, rights, and wellbeing of research participants were always considered and respected in the 24 meetings I observed, but it cannot be said that the interests of researchers and research were '*always*' treated as 'secondary to the dignity, rights, safety and well-being of people taking part in research'.[587] Instead, the interests of researchers, research, and participants were often treated as aligned or even merged. Some REC members and regulators actively questioned the absolutist position taken in ethical guidelines that prioritise the individual over society. REC practices demonstrate that to protect *is* to promote. The blurring of the role hierarchy, or this long-standing ambiguity of role hierarchy in the UK if we consider the RCP Guidelines, reflects, as with the fluidity of science and ethics review, an incongruence between certain regulatory strategies and general practices that the HRA and other managing regulators may need to reassess.

Does this finding of regulatory connectivity impact the overall quality and effectiveness of health research regulation? Not in terms of REC practices, I would argue, but it does invite questions about the role RECs and other actors can play if provided more room to 'roam' throughout the regulatory space. RECs, I would argue, engage in a pragmatic form of *instantiated regulation*, translating written regulatory guidance from the HRA and other managing regulators into practical action that capitalises on the relative interpretative flexibility of their regulatory

[586] *Declaration of Helsinki* (n 17) para 23.
[587] GAfREC (n 1) para 3.2.2.

texts.[588] They enact situationally-specific ways to implement the risk-calibrated regulations (from the SOPs, GAfREC, and so on) that govern their practice in determining the ethical acceptability of research applications. And, their role as regulatory steward reflects a collectively negotiated, practical, doable solution that satisfies the spirit of the regulations. RECs indeed have more regulatory flexibility than first appears and part of this flexibility is based on 'interpersonal trust in instantiating and maintaining system trust'.[589] Even so, later in this chapter I want to argue that *more flexibility* should be provided in the regulatory framework to enable specific actors to engage in this stewardship role and experiment with different ways of working through the stages of the research lifecycle. Liminality can help us both to recognise uncertainties that may arise across the research lifecycle, embrace them to a certain extent, potentially even exploit them, and pay attention to what is required to work through them.

I want to argue for regulatory stewardship's embeddedness in the regulatory framework because the empirical data suggest that RECs' knowledge control and gatekeeping activities have the potential to reach *beyond* the *ex ante* stage. The hybrid protectionist-promotionist model that operates in practice fosters an environment that both protects research participants *and also facilitates* responsible health research through proportionate regulation and coordinated alignment of ethics review and other regulatory processes. This can be operationalised not only at the early stage(s) of the research lifecycle, at the moment of research design and initial application, but also throughout the lifecycle in partnership with other regulatory actors where ongoing opportunities for 'regulatory play' can emerge. Crucial to this argument are the findings from my research and analysis, which suggest that the currently existing arms-length approach from *law* is beneficial. By avoiding clearly defined roles of RECs and their procedural and substantive aspects, the law is actually helpful in promoting the normative behaviours that I recommend.

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[588] Stephens, Atkinson, and Glasner (n 356).
[589] ibid 808.

In what follows, I propose changes to the extant regulatory framework by suggesting elements of regulatory stewardship that allow for RECs to act as 'work groups' with their managing regulators, as well as regulatees. In so doing, I contend that if the 'regulatory conversations'[590] that RECs engage in with other actors are structured well (e.g. steps are enacted to avoid regulatory capture or inequity), one can mitigate the concerns about co-constructed 'organisational deviance' that Hedgecoe warned about in his discussion of the TGN1412 drug trial scandal at Northwick Park Hospital.[591] Embedding regulatory stewardship, I contend, allows RECs to better engage with the processual and experiential dynamics of health research and instantiate a processual-oriented mode of regulation.

First, however, I propose a framework for working through protection and promotion, namely a deliberative and accommodating mode supported by a looping mechanism of transition for a research protocol that transforms it into something 'ethical' within a given moment of time and within particular spaces. Research passes through multiple liminal phases; ethicality is not guaranteed across each stage. As different actors and regulatory and ethical implications arise with each stage, RECs and others can play a crucial role in helping research and researchers follow these processes through each stage. Of course, stewardship is only as good as its weakest link in the chain. As different actors come into the fold across the research lifecycle, the mantle of stewardship through each of these stages must be passed smoothly and efficiently. Key to this is an effective regulatory design that enables robust and dynamic communication among all actors.

7.3 Working through protection and promotion

We have seen that REC members can utilise several different mechanisms to work through protection and promotion. As Michael Dunn writes, '…aligning normative justification with policy and practice in research ethics is likely to require the introduction of novel governance frameworks that support an ethics committee's

[590] See Julia Black, 'Talking about Regulation' (1998) Public Law 77.
[591] Hedgecoe, 'A Deviation from Standard Design?' (n 175).

adjudication between general principles upon which people can reasonably disagree'.[592] Here, I want to return to Veatch's observation about the failure of health research regulation to offer a theory of what should happen when a proposed research project involves a conflict of principles (albeit, in Veatch's context, the Belmont Report's ethical principles).[593] In the context of this thesis, the absence of an expressed theory of how the two objectives of protection and promotion should be achieved necessitates the crafting of a theory (or decision framework).

Whitney argues that there are 'two major moral considerations in research with human subjects' that ethics committees must 'balance': the rights and welfare of research subjects and the 'shared interest in better treatments for disease'.[594] My concern with this argument is that Whitney falsely assumes that 'balance' is an operative mechanism that can adequately reconcile the two objectives of participant protection and research promotion. 'Balance', I argue, is both an empty metaphor (for a scale of measurement) that is cognitively ambiguous in health research and also a mechanism that wrongly antagonises the values at stake.

Regarding the former claim, there is no mechanism within 'balance' that enables one to weigh competing claims. As Patterson and Lee write: 'On the one hand, "balance" evokes the precision of the objective scale; on the other, it evokes the democratic value of equity. As a result, "balance" connotes a process that is simultaneously precise and fair.'[595] If there is no agency of balance, balance becomes a rhetorical construction of fairness and (pseudo-)objectivity. At most, one can trust that individuals and groups intersubjectively reach an *acceptable* balance between protection and promotion, whereby acceptability reflects a range of ethical acceptability. Regarding the latter claim, the evidence in my research suggests that

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[592] Michael Dunn, 'Getting the Justification for Research Ethics Review Right' (2013) 39 Journal of Medical Ethics 527, 528.
[593] Veatch, 'Ranking, Balancing, or Simultaneity' (n 118). The three core principles identified in the Belmont Report are: respect for persons, beneficence, and justice.
[594] Whitney, *Balanced Ethics Review* (n 89) vii.
[595] Patterson and Lee (n 117) 35.

protection and promotion are not seen as oppositional values. 'Balance' would fail to capture the iterative, communicative, and fluid nature of ethical deliberations that seek to have protection and promotion work together. In sum, balance as a mechanism is insufficient. The values of protection and promotion, I submit, are simply unsuitable for a utilitarian calculus that positions them as oppositional. And, to the extent this 'balance' currently happens, it may well suffer from the same flaws or weaknesses as the risk-benefit calculus noted by several scholars.[596]

Thus, I advocate instead an iterative view of protection and promotion defined by *process* and *tolerance*, where both protection and promotion are generally treated simultaneously and relationally. Specifically, protection and promotion *should* be treated as twin objectives for regulators. The liminality of RECs suggests that there is a need for a deliberative space within which RECs both can negotiate the risks relevant to a research application and work with researchers to get to a point where the application can be deemed ethically acceptible. This deliberative space ought to be protected to capture and promote the fluid, processual nature of those deliberations. Tolerance indicates that within this space, REC members should feel comfortable debating the strengths and weaknesses of a research study, and achieving some consensus position on how much risk they are willing to tolerate. This risk toleration, in turn, needs to be considered relative to the notion of research promotion. Thus, rather than viewing protection as a bright-line test, tolerance accomodates the fluid nature of ethics deliberation and the relative nature of risk, i.e. a higher tolerance of greater risk if it is seen as reasonable in relation to the benefits to participants and society.

Moreover, I claim this approach should be *iterative* as the REC's regulatory roles should manifest themselves not only at the singular stage of ethics review, but also before and after in the research lifecycle. An ethically approved research study does not necessarily remain ethical throughout its duration. Both time and space can

[596] See e.g. Rid, 'Rethinking Risk–Benefit Evaluations' (n 399) 153; Meyer, 'Three Challenges' (n 78).

impact this judgement and liminality encourages actors to follow processes through their stages of transition. 'Ethical research', as determined by achievement of protection and promotion, must continually be created and re-evaluated as a research study progresses. Feedback loops (that is, opportunities for, and various channels of, communication, dialogue, and negotiation) should be built into the regulatory framework to prevent a static and putatively binding approach to 'ethical research', thereby encouraging greater regulatory conversations that allow RECs to continually ensure research is ethical—which is to say, protecting participants and optimising its social and scientific value as it evolves.

Such an iterative view of protection and promotion would better recognise the liminal and thus processual enterprise of health research. It would also operationalise the language already contained in the Care Act 2014,[597] the latest edition of the RCP Guidelines, [598] and HRA guidance for REC members.[599] Further, it would reinforce the *Declaration of Helsinki*'s Paragraph 8: 'While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.'[600] A couple of my interlocutors expressed concern that this statement might imply the interests of science and society should not be considered in *any* assessment. As a REC Chair told me, 'you may attach less weight to them, but you need to attach some sort of weight to them' (P10). But if this assessment was treated as a weighing (i.e. balancing) of interests, undoubtedly they would always be weighed in favour of 'individual research subjects'. Thus, the problem is that balancing would fail to reflect the REC's role as not merely internally consultative—deliberations among

[597] Care Act 2014, s 110(2) (stating that one of the HRA's objectives is 'to promote the interests of those participants and potential participants and the general public by facilitating the conduct of *research that is safe and ethical*') (emphasis added).
[598] Royal College of Physicians, *Guidelines on the Practice of Ethics Committees* (n 95) 4 ('RECs have a duty to encourage important ethical research').
[599] Health Research Authority, 'Information for Potential Research Ethics Service Committee Members' (n 56) ('The key duty of a REC is to protect the interests of research participants whilst at the same time facilitating ethical research').
[600] *Declaration of Helsinki* (n 17) para 8.

themselves as to whether participants are adequately protected—but also as a *promoter* of ethical best practice that necessitates ongoing dialogue with other actors, foremost researchers themselves.

Such an approach to protection and promotion would, I submit, work to avoid a 'bureaucratisation of ethics', where research ethics is treated as equivalent to REC processes (and in particular, approval of consent forms and PISs) and the scope of ethical concerns is narrowed to the front-end of approvals of research proposals. Coupling this approach with regulatory stewardship allows for smoother navigation of spaces that emerge in-between actors and between stages in the research lifecycle. An iterative view allows RECs to escape the institutionally delineated time-space trap where their work is fixated on a specific moment in time and within a specific space of the committee meeting, and thereby possibly avoid a 'permanent liminality—where uncertainties and anti-structures prevail'.[601] RECs, along with other actors, may instead come to be seen as stewards that help guide health research through multiple thresholds: from research design, to ethics approval, to participant recruitment and consent, to data generation, to data analysis, to knowledge translation, and so on.

Having set out to offer a theory of working through protection and promotion that incorporates liminality as an analytic and normative frame, I now turn to suggest a normative model of what a new regulatory framework for health research oversight ought to look like if it were to explicitly endorse regulatory stewardship and chart how protection and promotion can work together. As Chapter 6 explained, regulatory stewardship can be defined as the prudent guidance of one or more actors across regulatory thresholds—without which there is risk of impairment or harm—with a view to collective betterment.[602] While stewardship is a relatively

[601] Taylor-Alexander and others, 'Beyond Regulatory Compression' (n 2) 174.
[602] See Laurie and others, 'Charting Regulatory Stewardship' (n 570).

well-known concept in the literature,[603] *regulatory* stewardship is not. I argue that it can demonstrate considerable added value for all actors implicated in the network of health research ethics oversight in delivering and benefiting from efficient and effective navigation of regulatory landscapes. In so doing, I also chart the nature of regulatory stewardship's features and functions, and the different types of stewards that can exist to take on different functions.

7.4 Charting a new regulatory framework

In what follows, I propose three elements (some with sub-parts) to improve the current regulatory framework for research oversight of health research involving human participants. These elements flow naturally from the empirical results and as such should be charted. I begin with the element that imposes the least transaction cost and reflects most accurately what already occurs in practice, based on my research, and thus requires minimal regulatory change. I end with the element that may be more potentially disruptive to the current system and thus requires more extensive reform. The elements are proposed with a view towards a realistic, practical view of current resource constraints, both within the NHS and within RECs themselves. It is clear that RECs must be properly resourced to fulfil the roles expected of and practised by them. Moreover, regulatory administration must be in lock-step with research growth: to the extent the UK's research environment is in good health, so too must be the regulatory actors responsible for regulating research. The overall approach taken here is one that encourages greater cooperation among and integration of regulators and regulatees.

7.4.1 Regulatory flexibility

As this thesis has argued, RECs operate within a hybrid regulatory design: social control of research is divided between state (e.g. MHRA, HRA, NHS R&D offices) and non-state actors (e.g. volunteer REC members, sponsors), decision-making

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[603] See e.g. World Health Organization, 'Stewardship' <http://www.who.int/healthsystems/stewardship/en/>; Lynn Jansen, 'Between Beneficence and Justice: The Ethics of Stewardship in Medicine' (2013) 38 Journal of Medicine & Philosophy 50.

combines central and regional or local controls, and a multiplicity of actors are engaged in regulatory policymaking.[604] Hybrid design is seen as fostering greater regulatory flexibility, but we have seen that within the health research regulatory space, RECs are increasingly tacking *towards* the state; a reverse 'decentred' regulation is occurring that may limit the potential for regulatory flexibility. RECs may feel curtailed in their ability to adapt ethical frameworks or standards to a given research study when faced with the threat of sanction from above. As I have argued, an ethics of space must accommodate diversity, disagreement, and dissent across applications and across time. Likewise, researchers may feel curtailed in their ability to adapt their research as it develops, still within reasonable ethical boundaries, out of fear of falling foul of an already-approved protocol. In both instances, a culture of caution and rigidity can come to dominate decision-making. RECs and researchers therefore should be enabled to decide and act on matters within a range of reasonableness. Not only will this allow the flourishing of sound and ethical health research grounded in conscience rather than compliance, it will allow RECs and researchers to adapt regulatory responses to changing environments (both within a specific research study and across types of research).

For example, REC SOPs have served to greatly improve clarity and consistency in structure and processes, but positivistic rule-following is not the only value at stake in ethics review; 'responsible conduct often runs obliquely to compliance with rules'.[605] The length of REC SOPs have become colossal (a document now running to over 300 pages), and one wonders if something—flexibility and an opportunity to innovate—is getting lost in the drive to conform to such numerous standards. Through issuance of *guidance* with best practices, RECs should be encouraged to act with greater discretion to enable them to develop more innovative, experimental, and strategic approaches to their reviews. To this end, Rid has called for a comprehensive and detailed ethical framework for risk–benefit evaluations centred

[604] See also Sydney Halpern, 'Hybrid Design, Systemic Rigidity: Institutional Dynamics in Human Research Oversight' (2008) 2 Regulation & Governance 85.
[605] Johnsson and others (n 102) 40.

on social and scientific value.[606] I support this call, provided, however, that such a detailed ethical framework allows for RECs to experiment in how they undertake such evaluations. A rigid application of a framework, especially one that is comprehensive, may well lead to pushback or failure. As another example, managing regulators should reduce procedural requirements that restrict what RECs can accomplish in conducting reviews both within and outwith scheduled monthly full committee meetings (e.g. rushing to get through six applications in three hours). Checklists should be treated as aide-memories, not rigid forms to judge REC performance. As Johnsson and colleagues write: 'If ethical guidelines are to actually inspire researchers to make better decisions, they must have a sufficiently high level of abstraction to give room for deliberation. They must never be allowed to degenerate into checklists.'[607]

Perhaps the best example of enhanced regulatory flexibility, though, is greater tolerance for an ethics of space that encourages deliberation and debate over protection and promotion.

An ethics of space to tolerate deliberation of protection and promotion

The evidence from the empirical research suggests that REC members treat participant protection and research promotion as intertwined values that manifest themselves through the process of their review and in the course of their deliberations at REC meetings. In some cases it may be possible for RECs to focus first on protection and only thereafter on promotion, but for the majority of research applications, an ethics of space requires room for deliberation and fluidity in the assessment of risks, benefits, and social and scientific value. Little change would need to occur in the extant regulatory framework to acknowledge the importance of 'tolerances' (as opposed to bright lines or thresholds) in REC deliberation regarding whether participants are adequately protected and the ways in which research can be improved. Regulations could be more explicit in delineating the functions of

[606] Rid, 'Rethinking Risk–Benefit Evaluations' (n 399).
[607] Johnsson and others (n 102) 42.

RECs to protect and promote. While the GAfREC suggest that RECs have a primary role of participant protection and a secondary role of promoting the interests of research, researchers, and the public, a clearer charting of functions—treating these not as primary and secondary *per se*, but rather as relational values that are deliberated in a fluid manner—would likely improve inter-regulator relations as well as researchers' (and publics') understanding of what RECs do. RECs, it is suggested, have the twin role of participant protection and research promotion, but they also have an educational role in increasing knowledge and awareness of ethical issues and regulations; an advisory role in guiding researchers, sponsors, and institutions; as well as a conciliatory role in helping adjudicate potential conflicts between researchers and participants.[608]

One area in the regulatory framework that can be developed is in feedback loops. These are closely connected to 'regulatory conversations' as discussed below. A processual-oriented mode of regulation recognises the inherent flexibility and fluidity (and indeed uncertainty) in health research, enables adaptive responses to changes in law and regulation, and helps guide actors through the research process.[609] Currently, there is weak association between rendering an ethics opinion and learning about its outcome. As I have indicated already, 'ethical research' is not a static concept; feedback loops in the form of electronic communication and face-to-face meetings should be strengthened to encourage RECs to engage in dialogue with researchers, sponsors, and others to continually ensure research is ethical—that is, to maintain a situation in which participants are adequately protected and research optimises social and scientific value. Mechanisms also should be developed to foster feedback loops where researchers can re-engage in discussions with RECs and the HRA so as to adapt regulatory processes—leading to ongoing improvement and an evidence-based framework. This would help ensure regulatory processes are effective and cost-justified, and also increase expertise in decision-making. A more

[608] See HSE Research Ethics Committees Review Group, *Review of Research Ethics Committees & Processes in Republic of Ireland* (Health Service Executive 2008) 7.
[609] Taylor-Alexander and others, 'Beyond Regulatory Compression' (n 2) 158.

evidence-based framework would not only enable REC members to improve their ability to make good decisions, it would also make the process more transparent and enable (managing) regulators and publics alike to evaluate the effectiveness of REC decisions in protecting participants and promoting research.

Enhanced regulatory connectivity between law, science, and ethics

We saw in Chapter 6 that regulations such as the GAfREC are ambiguous in delineating the relationship of science and law to ethics review, and fail to capture the inherent connections between these regulatory spaces. A relatively minor amendment to the regulatory framework would be to revise the GAfREC and other regulations to account for regulatory connectivity that occurs in practice. The REC's opinion is not a legal opinion, but it is necessarily informed by the law. Likewise, an ethical opinion cannot be achieved without an adequate investigation of and satisfaction with the science. Regulations also should not encourage delegation to other regulatory bodies out of concern for potential overlap; such overlaps tend to occur inevitably. Rather, regulations should encourage greater synergy, not to mention greater efficiencies, among RECs and other bodies such as the MHRA, data monitoring committees, and data access committees.[610]

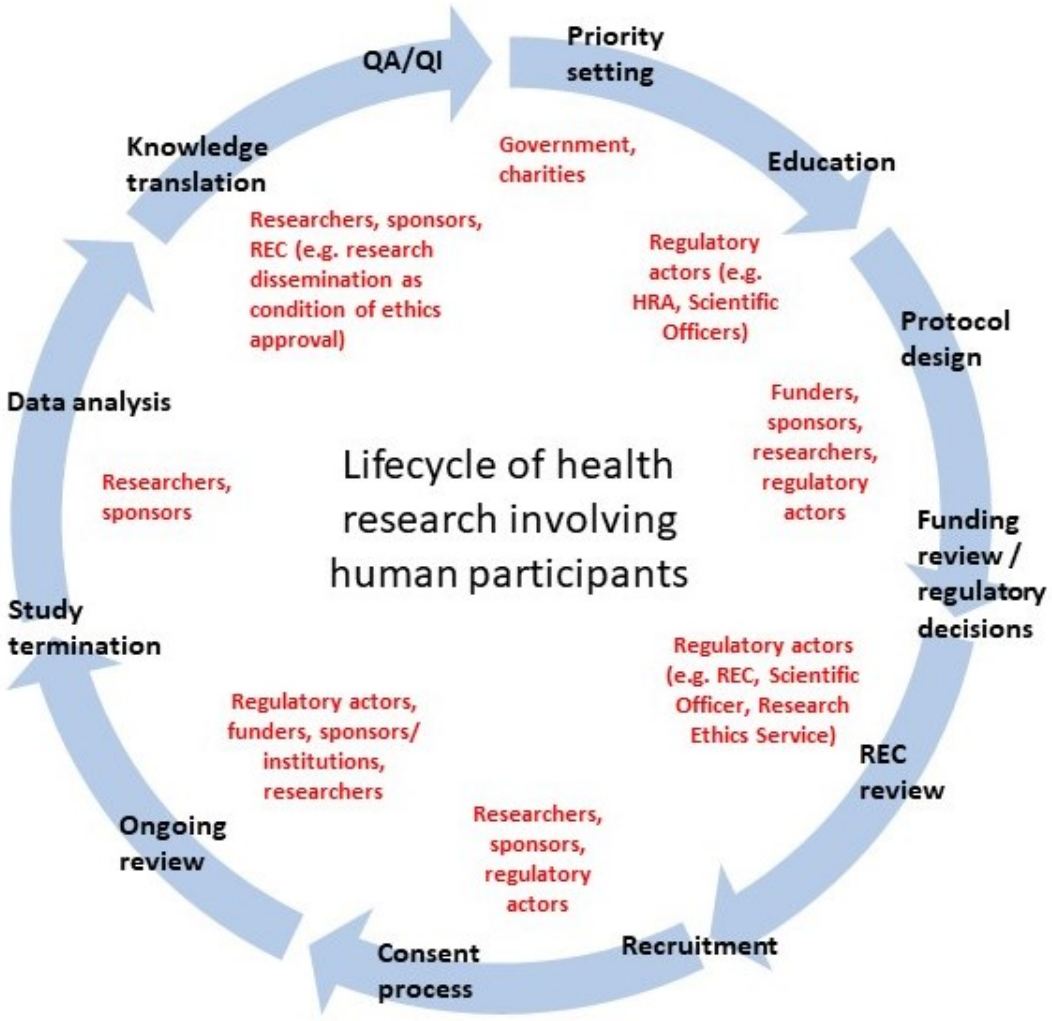
7.4.2 Regulatory conversations

To foster regulatory responsiveness, RECs should be encouraged to engage in discussions and negotiations with researchers, sponsors, and other actors before submission to the REC as well as after a proposal has received a favourable opinion. These conversations may revolve around ethical concerns that have arisen during the course of the study, but they may also go beyond this. Figure 7.1 represents

[610] An exemplar of regulatory efficiency, defined in terms of reducing the number of bodies performing the same or similar functions, is METADAC (Managing Ethico-social, Technical and Administrative issues in Data ACcess). METADAC is a multi-agency, multi-study data access structure that oversees applications for bio-data (i.e. genetic data linked with phenotypic data) and samples from several of the UK's major cohort studies and aims 'to provide a scalable mechanism to incorporate additional cohorts in the future'. See METADAC <http://www.metadac.ac.uk/>.

where opportunities arise for RECs and other actors to engage in 'regulatory conversations'[611] with researchers, sponsors, and institutions across the lifecycle.

Figure 7.1. Lifecycle of health research involving human participants, with proposed augmented roles for actors to engage in 'regulatory conversations' across different elements of the lifecycle. Figure adapted from Anderson and others (n 612).



[611] See Black, 'Talking about Regulation' (n 590) Black proposes the concept of 'regulatory conversations' between regulators and regulatees that 'are both a necessary and inevitable part of the regulatory process, almost regardless of the form that process takes'. ibid 104. Black argues regulatory conversations promote flexibility, adaptability, and responsiveness.

Anderson and colleagues identify twelve elements in the lifecycle of health research involving human participants: (1) priority setting; (2) education—scientific and ethical; (3) protocol design; (4) funding review; (5) ethics review; (6) recruitment; (7) informed consent; (8) monitoring; (9) study termination; (10) data analysis; (11) knowledge transfer; and (12) quality assurance and quality improvement.[612] At first glance, it would seem that RECs address only a narrow portion of issues within the lifecycle. Yet the evidence from the empirical research suggests that RECs, as health research regulators, in fact address many other (but certainly not all) elements in the lifecycle.

A revamped regulatory framework should enable managing regulators (e.g. HRA and CSO), RECs (and particularly REC Chairs), and actors such as (or similar to) Scientific Officers to support researchers and sponsors in working through other elements in the lifecycle, including ethical and regulatory education (i.e. how to work through the ethics review process), protocol design, and issues concerning recruitment, consent, ongoing review, and knowledge transfer (e.g. communication of results). This is not to suggest these regulatory actors must *necessarily* play a *substantive* role in these other elements of the lifecycle (and indeed such a normative position would require consideration of resources and infrastructure). Rather, it is to suggest that these regulatory actors should be encouraged to further engage others and each other in these additional elements—reflecting to a large degree what they already do in practice—with a view towards promoting socially valuable and ethical research. Likewise, it is to suggest that researchers and sponsors should be strongly encouraged to engage in regulatory conversations with their regulators, before, during, and after the launch of a research study.

[612] James Anderson and others, 'Research Ethics Broadly Writ: Beyond REB Review' (2011) 19 Health Law Review 12, 13-14.

Sounding board and discourse ethics

We saw in Chapters 2 and 3 that a common past criticism of RECs has been that they engage in a 'tick-box' bureaucratic ethics rather than a deliberative ethics. If research ethics is to be seen as more than rigid application of rules and standards, it must be allowed to flourish through discourse.[613] Johnsson and colleagues argue that ethics review should be 'an arena for researchers to discuss their research, receive advice, and practise their ethics skills, and guidelines to be generally applicable, value-based and inspirational rather than specific, rule-based and regulative'[614] (if we take the term 'regulative' to mean controlling and compliance-driven). Regulatory actors such as the HRA, RECs, and Scientific Officers should be encouraged to engage in informal dialogue with researchers (as well as institutions and sponsors) to offer them guidance through regulatory pathways.[615] Similarly, researchers and sponsors should be encouraged to speak with regulatory actors to provide them on-the-ground information regarding a research study: how it is developing, whether any roadblocks or surprises have emerged, or whether there has been any deviation between the approved protocol and the actual conduct of the research.

In-person REC meeting attendance by researchers should continue to be strongly recommended, but not required. Researchers should be made aware that deliberations can be unpredictable (a REC that favourably approves an application upon internal deliberation will not need to then speak with the researcher, and thus a researcher may risk 'wasting' resources in attending). A face-to-face meeting will not guarantee a certain outcome, but it may increase the chance that a REC will render a provisional opinion as opposed to an unfavourable opinion.[616] Thus, a

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[613] This argument is advanced in David Townend and Edward Dove, 'Approaching Ethics Review Equivalency Through Natural Justice and a "Sounding Board" Model for Research Ethics Committees' (2017) 36 Medicine and Law 61.

[614] Johnsson and others (n 102) 43.

[615] Klitzman refers to this as 'curbside consults' with researchers. See Klitzman (n 123) 330-31.

[616] Peter Heasman, Philip Preshaw, and Janine Gray, 'Does Researchers' Attendance at Meetings Affect the Initial Opinions of Research Ethics Committees?' (2008) 4 Research

recommendation for face-to-face meetings should clarify the benefits that may accrue: not only a decreased risk of an unfavourable opinion, but an opportunity to engage with a REC to protect participants and promote ethical research through a dynamic, nuanced ethical discourse. Ideally, this encounter should be in-person, but if not, managing regulators should ensure there are proper resources for RECs to engage in reliable telecommunication (e.g. video or teleconference) with researchers.

7.4.3 Regulatory stewardship

Regulatory stewardship involves different actors helping researchers, sponsors, and institutions navigate complex regulatory pathways and work through the thresholds of regulatory approvals. Collective responsibility also defines regulatory stewardship. In the case of health research, collective responsibility involves regulators and regulatees alike working together to design and conduct research that is ethical and socially and scientifically valuable, and that ultimately aims to improve human health. This can only be accomplished if regulators and regulatees communicate with one other and make clear who has what responsibility and role to be played (if any) at each stage in the research lifecycle.

To be clear, then, regulatory stewardship involves different actors serving not in a protecting capacity alone, but also in a capacity to promote the pursuit of clearly identified ends, including ethically robust, scientifically sound research. In so doing, stewards can help reduce regulatory burdens and achieve proportionality in research ethics review and oversight. While this function is performed currently by different non-REC actors relatively well (e.g. NHS R&D Forum,[617] MRC Regulatory Support Centre,[618] institutions that may create regulatory knowledge and support

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Ethics Review 56 (finding that researchers' attendance does not appear to increase the likelihood of being given a favourable opinion, but does appear to increase the likelihood of being given a provisional rather than unfavourable opinion).

[617] NHS Research & Development Forum <http://www.rdforum.nhs.uk/>. The NHS R&D Forum serves as a resource and facilitator of best practices in health research management and research strategy development. It offers training courses in areas such as the basics of quality research and how to prepare for regulatory inspections.

[618] MRC Regulatory Support Centre <https://www.mrc.ac.uk/research/facilities-and-resources-for-researchers/regulatory-support-centre/>. The MRC Regulatory Support Centre

programmes to support researchers[619]), more stewardship support can and should be provided by RECs and managing regulators such as the HRA. Indeed, a key feature of regulatory stewardship is that it may be practised as much by non-state actors as by state actors charged with formally proscribing actions under the law. Here, opportunities are present for volunteer REC members and others to assist researchers and others in manoeuvring complex regulatory regimes.

We have seen that the four Scientific Officers in Scotland provide an immense amount of support to both RECs and researchers; the CSO should consider funding academic researchers to conduct an evaluation of Scientific Officers, to see whether and how they add value to effective and proportionate regulation. There is no Scientific Officer equivalent in the other three nations. The HRA's current effort to shift some of the support service onto REC Managers is likely to be inadequate in helping researchers achieve their aims, RECs in receiving higher quality applications, and boosting REC Manager morale. Instead, the HRA should take up the Lord Warner Report recommendation in 2004[620] and create equivalent positions in England. To do so, it may not need to create multiple Scientific Officers in each of the Regional Offices; instead, it can revive its effort to create a REC Application Review and Advice Service staffed by independent experts who may have had previous experience in chairing or managing RECs, as well as experience in health research and regulation.

Regulation should more clearly provide channels for RECs (and members within them who may have closer contact with researchers and sponsors) and managing

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provides expert support and guidance, including freely available online toolkits and resources, for those conducting research with human participants, their tissues, or data.

[619] Institutions may have 'regulatory knowledge and support' programmes staffed with knowledgeable people who assist researchers in the development of health research proposals and the REC applications. Such programmes are especially designed for young researchers who are often unfamiliar with regulatory requirements and could benefit from guidance from experienced research staff. See e.g. University of Edinburgh, 'Research Support and Governance' <http://www.ed.ac.uk/medicine-vet-medicine/research-support-development-commercialisation/research-support-governance>.

[620] Lord Warner Report (n 232).

regulators to engage with researchers and sponsors in improving the quality of research protocols and applications and in working through law, regulation, and regulatory approvals. These channels could include online toolkits provided by the REC Application Review and Advice Service and one-on-one support via email, telephone, or meetings in HRA Regional Offices.

Regulatory stewardship also could be put on a legal basis. For example, in New Zealand, one of the purposes of the State Sector Act 1988, as amended, 'is to promote and uphold a State sector system that […] fosters a culture of stewardship.'[621] The Act defines 'stewardship' as the 'active planning and management of medium- and long-term interests, along with associated advice'.[622] The Care Act 2014 goes to some length to enact stewardship by confirming as a matter of law that health research regulatory agencies have responsibilities not just to protect research participants' interests, but also to promote ethical and safe research. Yet further legal footing can be provided by declaring that health research regulatory agencies are expected to bring a more systematic, comprehensive, lifecycle approach to the management of existing regulation,[623] which in this context, would mean ensuring that regulations are: 1) proportionate; 2) fit-for-purpose; 3) enabling for stewards to work with researchers and others in achieving their desired ends; and 4) enabling for regulators to articulate how the public interest will be promoted through research. Such a legal footing would clarify the value of different actors in enacting regulatory stewardship across the research lifecycle, and also avoid constricting the roles and procedural and substantive aspects of actors in rigid law that can be counter-productive to the value of flexibility that is inherent in liminality.

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[621] State Sector Act 1988, as amended 2013 [NZ], s 1A.
[622] ibid s 32.
[623] See also The Treasury [NZ], 'Regulatory Information Release, April 2013, Release Document' <http://www.treasury.govt.nz/regulation/informationreleases/pdfs/reg-2597298.pdf>.

Stewardship is a heterogeneous concept, and given the various actors who can serve in a stewardship capacity, regulation should be designed to promote specific (but not necessarily narrow) tasks for different actors, such as: state stewards (acting in a manner deemed to contribute to the public interest, e.g. as established by law); operational stewards (e.g. REC Chairs, Managers, or Scientific Officers who help usher researchers through the complexity of established procedures such as ethics application processes); and ethics stewards (e.g. RECs that act to protect participants and promote research). At the same time, as I and colleagues have argued elsewhere:

> It would follow also from this that researchers must be trained in, and made aware of, this central role in making (good) research happen. As a minimum, this would require researchers to acknowledge their role in contributing to streamlined regulation by responsible discharge of duties to work with regulators effectively.[624]

By stating clearly what roles each actor should play at the different stages in the research lifecycle, and how each actor should work with others to move from one stage to the next (i.e. how and when 'the mantle should be passed'), health research regulation could achieve more robustly the twin aims of participant protection and research promotion.

7.5 Conclusion

In this chapter, I further unpacked the significance of liminality of RECs and the ability of actors within the health research regulatory space to serve as regulatory stewards. I did so by charting how protection and promotion can and should work together, and by suggesting a normative model of what a new regulatory framework for health research oversight ought to look like if it were to explicitly endorse regulatory flexibility, conversations, and stewardship. I suggested that an iterative view of protection and promotion defined by tolerance for fluidity would better recognise the liminal and thus processual enterprise of health research. I also argued that regulation would be well served if it accounted for the roles that RECs

[624] Laurie and others, 'Charting Regulatory Stewardship' (n 570).

and other actors (such as Scientific Officers) can play across the lifecycle of research by engaging in 'conversations' with researchers and sponsors (among other actors, such as funders). Providing such a space for flexibility and experimentation across the research lifecycle would allow for greater opportunities for 'regulatory play' to emerge, and in so doing foster an environment that both protects research participants *and also facilitates* responsible health research through proportionate regulation and coordinated alignment of ethics review and other regulatory processes.

In the concluding Chapter 8, I recap the arguments of this thesis, my main research findings, and possible future directions for research.

Chapter 8
Summary and future directions for research

8.1 Introduction

This thesis has provided insight into the everyday workings of RECs and other regulatory actors in light of 'next-generation' health research regulation that seeks to both protect participants and promote research. It has done so through an empirical investigation—set within an anthropology of regulation methodology—of the nature of health research regulation and of the behaviours and experiences of actors within regulatory spaces, and the ways in which they themselves affect and are affected by processes of regulation. Further, it has positioned liminality and regulatory stewardship as key components in a regulatory framework for health research.

The research set out to explore how and why RECs make the decisions they do, and how the dynamics of RECs and central 'managing' regulators play into decisions in an emerging regulatory backdrop of twinned 'protection and promotion'. It also set out to go inside RECs to ask and examine how they, as individual members and as a collective body, see themselves in a changing regulatory environment. In addition, perspectives were gathered on the roles of RECs and the relationship between the HRA and RECs. In so doing, I queried the precise nature of the interaction between central regulators and RECs, and queried the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion. To date, this topic has received little coverage in the literature despite its significance, much less through a qualitative study from a regulatory perspective.

This final chapter draws together the findings from this body of work and lays out the original contribution to which claim is made in this thesis. First, I recap the

findings from Parts I through III of the thesis. Second, I revisit and respond to the research questions. Finally, I consider possible next steps for the research.

8.2 Thesis recap

8.2.1 Part I – Chapters 2 and 3

Part I began by providing a conceptual framework and historical regulatory tracing of RECs. Chapter 2 argued that RECs have been central in regulating the ethical acceptability of health research—and by extension, much of health research's very existence—since the late 1960s. They serve as gatekeepers that determine whether a proposed research study is ethically acceptable and therefore may proceed. Since its formation in late 2011, the HRA has been tasked with both protecting research participants from harm *and* also facilitating a productive research environment by streamlining health research regulation. The HRA is a central regulatory body that is seen to help make the UK once again an attractive place to conduct health research such as clinical trials. The HRA, particularly through its RES, and equivalent bodies such as the CSO, is working to make REC processes more effective and efficient. I therefore raised the question of whether the roles and practices of RECs are shifting in response to 'next-generation' regulation such as the Care Act 2014, and whether modifications to the health research regulatory space at the levels of statutory law and central regulatory authorities (i.e. central administrators) 'trickle down' to the day-to-day practices of RECs.

Chapter 3 traced the regulatory development of RECs and health research regulation within the UK, with a view to demonstrating both the growth of health research regulation and the increasingly central role that RECs play in regulating health research. Tracing history over the past half-century, we saw that as health research gained prominence in the UK as both a driver of scientific knowledge *and* economic development, self-regulation of health research—*ad hoc* peer review by fellow scientists based on professional norms and local customs—gradually gave way to stricter, stronger, more centralised forms of regulation, particularly through policies and guidelines set by the UK's constituent governments. The central claim I

made is that while to a certain degree, research promotion has always been embedded in the regulatory techniques of RECs, it has not until now been instantiated in law with the creation of the HRA and rules promulgated under the Care Act 2014. Participant protection and research promotion have had an uneasy, unequal, but sustained marriage across the RECs' lifespan. And along the way, REC members have faced the challenging task of working in regulatory spaces that demand that they work with various regulatory actors and that they not only operate within the (shifting) regulatory spaces' confines, but also help shape their contours. It is this finding that led me to query whether this instantiation of research promotion in law has a (hitherto absent) trickle-down effect that impacts the day-to-day practices of RECs, and if so, how, or indeed, whether the law is only now coming to reflect an everyday practice that has long existed.

8.2.2 Part II – Chapter 4 and 5

Part II described the methodology and methods. In Chapter 4, I explained the research approach, theoretical underpinnings, and analytical concepts that drove my thesis. I argued that there is a need for an empirically-grounded discussion of regulatory practice, but that extant socio-legal and legal anthropology approaches are insufficient to answer my research questions. Therefore, I proposed an anthropology of regulation that blends the theoretical with the empirical, and which affords critical methodological improvements to common research approaches. As anthropology of regulation draws explicit attention to processes, passages, and change, I further drew on the anthropological concept of liminality, which served as a sensitising concept in addition to concepts provided by regulatory theory. Together with regulatory theory, liminality helped me to better understand the *nature* of transformations of actors within the regulatory space, the *form* of regulation in this space, as well as the *behaviours* and *experiences* of actors as they go through processes of change.

In Chapter 5, I described the research methods undertaken for my empirical work that define an anthropology of regulation, including the justification for

undertaking a 'research trinity' of document analysis, semi-structured interviews, and naturalistic observation. I explained how my research methods serve as the most robust platform for answering my research questions and making sense of the empirical data.

8.2.3 Part III – Chapters 6 and 7

Finally, Part III presented the empirical research findings from the interviews and observations and extended the examination of protection and promotion from an historical basis in Chapter 3. In Chapter 6, I presented three main themes from my findings: the 'black boxes' of ethics review; regulatory connectivity; and regulators as facilitators and stewards. I found that RECs serve as liminal actors; relative to each other and to publics, they are black boxes existing in multiple spaces, despite a surprising degree of group homogeneity in approach and rituals. Significantly, I also found that RECs and other actors can serve as 'regulatory stewards' in helping researchers and others navigate difficult regulatory spaces and improve the overall quality of research. They can play a critical role in assisting researchers navigate the demands of putting an application and protocol together; as regulatory stewards, they can help researchers cross thresholds—serving as 'ethical research promoters'.

Contrary to my early expectations, and critically for the purposes of this thesis, the empirical data suggested that modifications to the health research regulatory space at the levels of statutory law and central regulatory authorities have not so much 'trickled down' to the day-to-day practices of RECs, as the day-to-day practices have long reflected what has only recently been enacted in law. The data also suggested RECs, managing regulators, and researchers share a common goal of promoting research that is safe and of high quality. Actors in these regulatory spaces carry similar interests and shared responsibilities, helping each other to cross boundaries and deal with major moments of transition in the research lifecycle. This led me to further investigate how, normatively speaking, protection and promotion ought to be worked through, as practised by RECs, the HRA, and other actors (such as Scientific Officers), and what a model of a new regulatory framework for health

research oversight ought to look like if it were to explicitly endorse regulatory stewardship.

Chapter 7 unpacked the significance of the liminality of RECs and the ability of actors within the health research regulatory space to serve as 'regulatory stewards'. I charted how protection and promotion can and should work together. Specifically, I argued that protection and promotion *should* be treated as twin objectives for regulators. The liminality of RECs suggests that there is a need for a deliberative space within which RECs can both negotiate the risks relevant to a research application and also work with researchers to get to a point where the application can be deemed ethically acceptible. This deliverative space ought to be protected to capture and promote the fluid, processual nature of those deliberations. Within this space, REC members should feel comfortable debating the strengths and weaknesses of a research study, and achieving a consensual position on how much risk they are willing to tolerate. This risk toleration, in turn, needs to be considered relative to the notion of research promotion. Thus, rather than viewing protection as a bright-line test, a tolerance perspective accomodates the fluid nature of ethics deliberation and the relative nature of risk, i.e. a higher tolerance of greater risk if it is seen as reasonable in relation to the benefits to participants and society.

I concluded that a reformulated regulatory framework could work to improve regulatory conversations between actors, provide ongoing opportunities for 'regulatory play' to emerge, and shift the burden and emphasis away from more procedural work and towards flexibility and experimentation in ethics review. Three principal elements, flowing from the empirical research, were offered to improve the extant framework and were organised by starting with those less potentially disruptive to the current system:

- **Regulatory flexibility**
    - I argued that the regulatory framework should provide RECs sufficient room to roam in an ethics of space that accommodates diversity, disagreement, and dissent across applications and across time. This requires little change to the current system, as RECs are already permitted to protect and promote. However, room for improvement is called for in two areas, namely feedback loops and enhanced connectivity among the regulatory spaces of law, science, and ethics.
- **Regulatory conversations**
    - I argued that to foster greater regulatory responsiveness, RECs should be encouraged to engage in discussions and negotiations with researchers, sponsors, and other actors before submission to the REC as well as after a proposal has received a favourable opinion. These conversations may revolve around ethical concerns that have arisen during the course of the study, but they may also go beyond this. RECs are not expected to play a role in each element of the research lifecycle. Rather, I suggested that RECs, along with other actors, should be encouraged to engage in regulatory conversations with each other, before, during, and after the launch of a research study, clarifying both their respective roles and when they should intervene to assist in helping move research across the stages of the lifecycle.
- **Regulatory stewardship**
    - I argued that regulatory stewardship involves different actors helping researchers and sponsors navigate complex regulatory pathways and work through the thresholds of regulatory approvals. Collective responsibility, as a component of regulatory stewardship, requires relevant actors to work together to design and conduct research that is ethical and socially and scientifically valuable and that ultimately aims to improve human health. This can only be

accomplished if a framework delineates how and when regulators and regulatees should communicate with one another and makes clear who has what responsibility and role to be played (if any) at each stage in the research lifecycle. To this end, I suggested that a regulatory framework for health research could chart different kinds of regulatory stewards, such as operational stewards (e.g. REC Chairs, Managers, or Scientific Officers that help usher researchers through the complexity of established procedures such as ethics application processes) and ethics stewards (e.g. RECs that deliberate in an ethics of space to protect participants and promote research).

8.3 Revisiting the research questions

Three research questions drove this thesis. The primary question was:

> How do RECs act among themselves and interact with other actors within a reformed health research regulatory space that aspires to both protect research participants from harm *and also* promote health research through streamlining perceived regulatory barriers—and what might this mean for the bond of research and ethics as seen through the ostensible REC processes of ethical deliberation and decision-making?

Two subsidiary questions that flowed from this primary question were:

1. What is the precise nature of the interaction between central regulators and RECs in the health research regulatory space?
2. What are the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion?

Returning to these questions, we can now satisfactorily summarise the responses as follows. While there has been reform in the health research regulatory space at the level of legal architecture to foster an environment that promotes health research in

addition to protecting participants (particularly through the method of streamlining perceived regulatory barriers), there has not been a consequential change in how RECs act among themselves. Legal reform such as the Care Act 2014 reflects already-existing, everyday workings of RECs. RECs are remarkably similar to each other in terms of demographics and practices, yet they are relatively black boxed to each other; they operate in fairly splendid isolation despite having a fair degree of homogeneity in culture. This said, an area of concern in light of recent regulatory reform is the nature of the interaction between RECs and their managing regulators, namely the HRA. Perhaps because of their homogeneity in culture, there is a strong desire by RECs, including REC Managers, to preserve the sanctity of *their* black box and ethics of space. Initiatives by the HRA that try to improve the regulatory pathways for researchers can backfire if there is improper consultation with RECs. As we saw, regulatory tension or failures are more likely to exist between regulators than between regulators and regulatees.

Finally, we can say that while the bond of research and ethics remains strong, there is some room for improving the regulatory framework. RECs, managing regulators, and researchers share a common goal of promoting research that is safe and of high quality. Actors in this health research regulatory space carry similar interests and shared responsibilities, helping each other to cross boundaries and deal with major moments of transition in the research lifecycle. The respective roles, competencies, and influences among the actors in these spaces are not always clear, and the regulatory conversations are sporadic and at times weak between regulators, though relatively strong between regulators and regulatees. To avoid dangerous spaces from appearing *within* the health research regulatory space where hazards may occur, in Chapter 7 I suggested several elements to improve the regulatory framework and prevent these spaces from appearing or opening too widely or disjointedly.

8.4 Future directions for research

Having considered the core contribution which this body of work makes, a final task lies in considering how this work can be further developed. Areas for future investigation include:

- evaluation of the added value Scientific Officers bring to health research regulation and consideration of how they can be brought into the Research Ethics Services in the three other nations;
- assessment of how NHS R&D offices are coping in light of HRA Approval (e.g. how do R&D officers now see their role; what is their relationship with HRA Assessors and other regulatory actors?);
- cross-jurisdictional comparisons of health research regulation to evaluate similarities and differences among RECs, managing regulators, and other actors. Such an assessment may lead to formulation of best practices for health research ethical oversight;
- horizon-scanning to assess the potential impact of 'Brexit' on UK regulatory flexibility (i.e. will a formal de-coupling from EU regulation lead to regulatory fragmentation, harmonisation, or something else?);
- how regulatory flexibility might afford opportunities for 'regulatory play', i.e. opportunities to think beyond rules and engage in innovation and experimentation ('sandboxes' to design and experiment without fear of falling foul of regulatory infraction);
- deeper understanding, through empirical investigation, of the actual blockages and perceived impediments to health research so as to promote a culture of confidence and proportionate regulatory practices; and
- charting a path for collective responsibility for the (co-)design and delivery of health research and health improvements therefrom. Such investigation may explore how actors *other than* regulators (e.g. researchers, sponsors, publics) can view themselves as responsible for designing and delivering ethical and scientifically robust health research.

In each of these areas, anthropology of regulation can play an invaluable role in investigating empirically (particularly through observation) the form and function of regulation across different contexts (e.g. locales, cultures, time periods). It allows the researcher to uncover the experiences and practices of regulators and regulatees and the ways in which they understand themselves and their roles. In so doing, it can also problematise the notion of regulation, challenging us to consider the multiple phenomena that it may constitute and the ways in which it manifests and shapes behaviours. Anthropology of regulation, underpinned by regulatory theory and liminality, helps us make sense of the nature of regulation as a form of social control (an ontological concern), as well as how regulation structures our living in the everyday and in the in-between (a functional concern). Analytically, it has the potential to contribute to deeper understandings of local dynamics and contexts, as well as the multiple roles regulation plays in a complex world as a social form of control. Finally, it can offer normative prescriptions that are developed from the empirical investigation to guide actors in achieving regulatory goals.

Undoubtedly, there are numerous further lines of inquiry that flow from this research. The findings of the empirical research demonstrate a wide applicability to a diverse array of settings. While such inquiries are left for the future, this thesis has in its own right contributed to a deeper theoretical and practical understanding of the precise nature of health research regulation; the roles of actors within regulatory spaces; and the processual, iterative realisation of the public interest aim of health research oversight—namely to protect the rights, interests, and welfare of research participants *and* to promote valuable research that advances human health for the benefit of the public.

Appendices

Appendix 1: Interview guide for REC members

OBJECTIVES

- to explore the dynamics of interaction between RECs and regulators, policymakers and other actors in the health research regulatory space;
- to determine the characteristics of different components of research ethics and RECs;
- to gather reflections on their experience(s) as REC members;
- to examine whether the practices/functions of RECs have changed in response to new regulations (e.g. Care Act 2014) and new actors (e.g. Health Research Authority);
- to understand whether and how law and regulation are operationalised in REC practices.

INTRODUCTION

- introduce myself, PhD project and funder;
- general informed consent information, e.g. how the data will be used, confidentiality, timing (~60 minutes), permission to audio-record and transcribe interview

1. BACKGROUND INFORMATION

Overarching Idea: REC members' life experiences (within and outwith research ethics) may shape their views as a REC member.

- What is your role in the REC (chair, administrator, member, etc.)? What does your activity in this role consist of?
- How long have you been involved as a REC member?
- How did you get involved in your REC?
- How many hours/week on average do you spend working on REC matters?
- Are you also actively involved in research? If so, what role(s) do you play (PI, co-PI, etc.)? What kinds of projects are you involved with (e.g. clinical trials, epidemiological studies)? What per cent of your time is spent doing research?
- How did you learn how to do ethics review – through training sessions? Reading? What were your expectations? Were the trainings or readings helpful? Did they match your later experience? If not, how and why?
- What has been your experience in serving as a REC member? What stands out for you in your experience?

2. REC CHARACERISTICS

Overarching Idea: REC members may have widely varying ideas as to what constitutes a 'good' REC and 'good' ethics review – and how (if at all) ethics is instantiated in reviewing/monitoring a research project.

- What is the 'usual procedure' in your REC for reviewing (and monitoring, if at all) the ethical standards of research proposals?
- Are clinical trials research proposals reviewed differently from other types of health research proposals? If so, how?
- How closely are the SOPs and GAfREC followed in your REC operations and in ethics review? Is reference ever made to any laws or regulations? If so, which ones and in what ways?
- Approximately how much time is spent at your REC meetings discussing each research proposal, as opposed to other matters (e.g. administrative)? Do you think the amount is too much, too little, or adequate?
- What do you think makes a REC work well or not in monitoring and responding to research ethics issues?
- In assuring ethical research, what do you think constitutes a 'good' REC Chair/Committee and what should be their roles?
    - If a REC Chair: When is the Chair's discretionary authority exercised?
- What administrative support is available to your REC?
- Do you and other REC members feel able to keep up with the workload satisfactorily?
- Is your REC 'more cautious' about some research/researchers than others? Why?
- Do you think that health research is adequately guided *throughout* the research lifecycle? Should RECs or other bodies (e.g. HRA) do more to guide researchers and research participants across the research lifecycle, not just at the preliminary stage of ethics review?
- Have you seen problems in research noncompliance with REC rules or mandates? If so, what kinds of problems? How comfortable are you with PI self-reporting? Are annual review forms submitted to RECs sufficient?
- Has your REC discussed sanctions against PIs? Has your REC ever discussed reporting research ethics problems to an outside body (e.g. researchers' employer and sponsor and the care organisations where the research takes place)? If so, what kinds of issues arose? Do challenges arise in reporting problems to outside bodies? If so, how?
- What does 'good' ethics review look like for you? What supports this, and what gets in the way of it? Do you do things you should not do, and equally, are there things you do *not* do that you think you should do?

3. REC LOCATION / HEALTH DISTRICT CHARACTERISTICS

Overarching Idea: REC members' experiences may differ from one REC to another (i.e. no two RECs are like in organisational dynamics); and RECs may have complicated relationships with NHS Trusts/Health Boards.

- Have you served on RECs in more than one location? If so, where and for how long?
- Do you think local contexts or settings affect RECs' roles and decisions? If so, how? Or are local context issues best addressed by R&D offices?
- How do you think your REC is viewed within your health district by researchers and NHS bodies?
- What kinds of conflicts, if any, has your REC faced with your health district? Have these conflicts been resolved?
- Have you or your REC ever had input from your health district, Research Ethics Service or the HRA/CSO concerning research ethics? If so, how and concerning what?

4. PI CHARACTERISTICS

Overarching Idea: REC members may recognise the limited ability to work with researchers throughout the research lifecycle as opposed to the preliminary stage before any research even begins. There may be uncertainty about what happens <u>after</u> ethics approval, including the potential downstream social value to accrue.

- Would you like additional data about PIs or studies concerning the ethical dimensions? If so, what kind of data?
- Do you find that PIs treat your REC with respect? Take advantage to be educated about relevant policies? Maintain accurate records? Respond in a timely and appropriate way to REC requests?
- Does your knowledge of the PI affect how you look at his or her protocols? If so, how?
- Do you think the face-to-face – i.e. a dialogue-based approach – to 'doing ethics' with the PI works, works well, is optimal or sub-optimal? How often does this happen? Do you want it to happen more often?
- Do you think your REC can or should guide PIs through the research pathway, including beyond the preliminary stage of ethics review? Is there a distinct role for the Chair, Deputy Chairs, or Administrators in this regard?

5. THE ROLE OF CONSENT

Overarching Idea: Consent is seen to play a sine qua non role in health research regulation, for various or even arguably misplaced reasons.

- Do you think there is an appropriate degree of emphasis placed on consent in health research regulation?
- What do you think should be the role of consent in health research?

- How do you think RECs should treat consent, including in the information sheet, the form itself, and the process of communication that occurs between researchers and participants?

6. NEW REGULATORY ENVIRONMENT

Overarching Idea: Protection and promotion may not necessarily be twinned objectives for RECs.

- Can you describe the relationship between your REC and regulators and other bodies involved in health research (e.g. HRA/RES, CSO, NHS R&D offices)?
- Is the relationship cooperative? If it is cooperative, do you feel like you produce ethics review in partnership with regulators, or do you view them as distant, top-down regulators?
- What are the perceived practical changes, if any, with recent regulatory reform such as the Care Act 2014 and establishment of the Health Research Authority? Has there been a perceptible change in your REC with this regulation, and if so, when were these changes first apparent?
- Do you perceive a regulatory shift that now seeks to both protect research participants and also facilitate responsible health research in the country through proportionate regulation and alignment of REC processes? If so, do you think this shift will become (or has become) operationalised in REC practices? Should it?
- How do you think a suitable alignment between research participant protection and research promotion can be achieved in practice?
- What would constitute research 'promotion' in the operations of a REC?
- By what standards do you think RECs are evaluated/measured to determine whether they are functioning appropriately (i.e. efficiently or effectively) to achieve the demands set by regulation?

7. FUTURE HORIZONS

Overarching Idea: RECs are an important regulatory body in their own right, but are only one regulator (and actor) among many in the health research regulatory space. There is a potential role for RECs to act as a Shepherd, guiding ethical researchers and research documents throughout the research lifecycle.

- Do you think RECs are performing well overall? If not, what are the perceived problems? How could they be improved?
- Would any changes help your REC's ability to monitor research ethics? If so, what?
- Would your REC benefit from more training in monitoring or responding to research ethics? If so, how? In what form (e.g. conference, printed materials, website)?

- If there has been a shift in REC functions and practices in light of the new regulation and actors such as the HRA and CSO, what impact might this have on research, researchers, and research participants?

Do you have any other points that you wish to be discuss? Do you have any questions?

CLOSING

- thank participant for their time;
- reminder of confidentiality;
- ask for potential to re-contact if there is a follow-up element in the research;
- ask for other potential interviewees.

Appendix 2: Interview guide for regulators/policymakers

OBJECTIVES

- to explore the dynamics of interaction between regulators, policymakers and other actors (especially RECs) in the health research regulatory space;
- to determine the characteristics of different components of research ethics regulation;
- to gather reflections on their experience(s) as regulators or policymakers;
- to examine whether the practices of research ethics oversight have changed in response to new regulations (e.g. Care Act 2014) and new actors (e.g. Health Research Authority);
- to understand how regulators check whether regulations have been operationalised, how comfortable they are with changes when regulations are actually implemented, and how far they consider regulation as an evolving, potentially co-produced dynamic.

INTRODUCTION

- introduce myself, PhD project and funder;
- general informed consent information, e.g. how the data will be used, confidentiality, timing (~60 minutes), permission to audio-record and transcribe interview

1. BACKGROUND INFORMATION

Overarching Idea: Regulators'/policymakers' life experiences (within and outwith research ethics) may shape their views as a regulator/policymaker.

- What is your role in the regulatory or policymaking body?
- How long have you been involved with the current regulatory or policymaking body?
- How did you get involved in the regulatory or policymaking body?
- How many hours/week on average do you spend working on regulatory matters that impact RECs, if any?
- Can you summarise your current activity in the regulatory or policymaking body (a day-in-the-life as a regulator/policymaker)?
- What has been your experience in serving in your capacity? What stands out for you in your experience?

2. RESEARCH ETHICS AS POLICY AND REGULATION

Overarching Idea: Law and regulation play a critical role in shaping health research that is ethical and therefore protective of participants, but also valuable and therefore beneficial for society.

- What do you think is the role of law and regulation in governing health research?
- How has the role of law and regulation changed over time, if at all?
- What is the role of a regulator or policymaker in this space: to enforce law and regulation, to monitor compliance, or something else?
- Is there a perception (by others) of under- or over-regulation of health research, or a right balance? What evidence do you have for this response?
- How do you see the role of RECs in the entire regulatory framework? Do *you* think RECs are under- over-regulated?
- Who are other important actors in health research, aside from regulators or advisory groups (HTA, HEA, CAG, HRA) and RECs? Is each actor seen as playing a critical role, or some more than others, and if so, how?

3. THE ROLE OF VARIOUS ACTORS

Overarching Idea: RECs are an important component in the health research regulatory space, but they are far from being the only actors.

- Can you describe the relationship between your regulatory/policymaking body, RECs and other bodies involved in health research (e.g. HRA, NHS R&D offices)?
- Is the relationship cooperative, or is the impression one of top-down 'command-and-control' with a central regulatory body like the HRA setting standards or rules that other bodies must/are expected to follow?
- In your own role, how do you interact with the various bodies (regulatory and otherwise) in health research? Do you interact with some more than others, and if so, how and why? For example, how does RES interact with the rest of the HRA, and other bodies such as the CSO in Scotland?
- Do you view RECs as *co*-regulators of health research (along with the HRA, CSO, etc.)?
- In your view, are certain bodies more important than others in both protecting research participants, and also promoting health research? For example: NHS Heath Boards/Trusts, R&D offices, sponsors, etc.?
- Do you think RECs interact or cooperate well with these other bodies?
- Do you think the various bodies in health research interact well together? Is the HRA making good headway, as the Care Act 2014 requires, to make some of these work more closely together? Do you think sponsors and/or NHS Trust/Health Boards and R&D offices should take on more

responsibility or should also cooperate more closely with the regulatory bodies?

4. THE ROLE OF RECS

Overarching Idea: Regulators/policymakers may have widely varying ideas as to what constitutes a 'good' REC and 'good' ethics review – if they consider RECs to actually engage in 'ethical' review.

- Do you think that health research is adequately guided throughout the research lifecycle? Should RECs or other bodies (e.g. HRA, research sponsors) do more to guide researchers and research participants across the research lifecycle, not just at the preliminary stage of ethics review?
- Have you seen problems in research noncompliance with REC rules or mandates? If so, what kinds of problems? How comfortable are you with PI self-reporting? Are annual review forms submitted to RECs sufficient? Is there a role for sponsors here?
- Do you believe RECs engage in 'ethical' deliberation, or do you see their function more as risk assessment committees?
- Should RECs also undertake some form of scientific review of a research study?
- What does 'good' ethics review look like for you? What supports this, and what gets in the way of it? As a regulator/policymaker, do you do things you should not do, and equally, are there things you do *not* do that you think you should do – in the interest of robust health research regulation?
- Do you think local contexts or settings affect RECs' roles and decisions? If so, how?
- In your capacity as regulator/policymaker, have you ever specifically communicated with a REC concerning research ethics? If so, how and concerning what?

5. THE ROLE OF CONSENT

Overarching Idea: Consent is seen to play a sine qua non role in health research regulation, for various or even arguably misplaced reasons.

- Do you think there is an appropriate degree of emphasis placed on consent in health research regulation?
- What are your views on alternatives to consent (e.g. authorisation by competent authority, public interest grounds to 'waive' consent)? Might this depend on the different types of health research, e.g. clinical trials vs. data vs. tissue? Or something else (e.g. trustworthiness of researchers, regulators, etc.)?
- What do you think should be the role of consent in health research?

- How should RECs treat consent, including in the information sheet, the form itself, and the process that occurs between researchers and participants? Can or should RECs do more to emphasise communication among themselves, researchers, and in turn, researchers and participants? To what extent does your assessment look at the broader governance picture of a research protocol and how consent sits within it?

6. NEW REGULATORY ENVIRONMENT

Overarching Idea: Protection and promotion may not necessarily be twinned objectives for RECs.

- As you are aware, there have been some recent regulatory changes in health research (e.g. HRA creation in late 2011, Care Act 2014, proposed revision to the *Research Governance Framework*, 'HRA approvals' etc.). What do you think *the factors* were that led to these changes?
- What are the *perceived practical changes, if any*, with recent regulatory reform such as the Care Act 2014 and establishment of the Health Research Authority?
- Do you perceive a regulatory shift that now seeks to steer a research environment that both protects research participants and also facilitates health research in the country through e.g. proportionate regulation and alignment of REC processes? If so, do you think this shift will become (or has become) operationalised in REC practices? Should it?
- How do you think a suitable alignment between research participant protection and research promotion can be achieved in practice?
- What would constitute research 'promotion' in the operations of a REC? Is there a role here for regulators and RECs to co-produce regulation?
- What happens when things go wrong? How far do you think RECs rely on law to help them work out a problem, or how far do other factors play a role?
- By what standards do you think RECs are evaluated/measured to determine whether they are functioning appropriately (i.e. efficiently or effectively) to achieve the demands set by regulation?

7. FUTURE HORIZONS

Overarching Idea: RECs are an important regulatory body in their own right, but are only one regulator (and actor) among many in the health research regulatory space. The HRA plays a critical role, but ultimately the 'success' of health research regulation is defined by how each REC views its ability to be more than a (preliminary) gatekeeper – namely as a Shepherd for guiding ethical researchers and research documents throughout the research lifecycle.

- Do you think RECs, sponsors and other actors in health research (regulation) are performing well overall? If not, what are the perceived problems? How could they be improved?
- Would any changes help RECs' ability to monitor research ethics? If so, what?
- Would RECs benefit from more training in monitoring or responding to research ethics? If so, how? In what form (e.g. conference, printed materials, website)?
- If there has been a shift in REC functions and practices in light of the new regulation and actors such as the HRA and CSO, what impact might this have on research, researchers, and research participants?

Do you have any other points that you wish to discuss? Do you have any questions?

CLOSING

- thank participant for their time;
- reminder of confidentiality;
- ask for potential to re-contact if there is a follow-up element in the research;
- ask for other potential interviewees.

Appendix 3: Governance approval letters and emails

University of Edinburgh
School of Health and Social Science
Medical School, Doorway 6
Teviot Place
Edinburgh
EH8 9AG

11th November 2015

Mr Edward Dove
Edinburgh Law School
Old College
South Bridge
EH8 9YL

Dear Mr Dove

IRAS ID: **194243**
Study Title: **The changing health research regulatory environment and NHS RECs**

Under the requirements of the Scottish Executive Health Department's Research Governance Framework for Health and Community Care, the University of Edinburgh agrees in principle to act as Sponsor for this project. Sponsorship is subject to you obtaining a favourable ethical opinion from the appropriate school ethics committee local NHS R&D management approval and all other appropriate approvals relevant to your study

As Chief Investigator, you must ensure that the study does not commence until all applicable approvals have been obtained. Following receipt of all relevant approvals, you should ensure that any amendments to the project are notified to the Sponsor, school ethics committee and relevant NHS R&D office(s).

Yours sincerely

Jo-Anne Robertson
Research Governance Coordinator

University Hospitals Division

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

FM/GM/approval

12th November 2015

Mr Edward Dove
University of Edinburgh
PhD candidate
School of Law
Old College, South Bridge
Edinburgh
EH8 9YL

Research & Development
Room E1.12
Tel: 0131 242 3330

Email:
R&DOffice@nhslothian.scot.nhs.uk

Director: Professor David E Newby

Dear Mr Dove

Lothian R&D Project No: 2015/0402

Title of Research: Promoting Health Research and Protecting Participants? The Impact of 'Next-Generation' Health Research Regulation on Research Ethics Committees

Participant Information Sheet:	**Consent Form:**
Version 1.0 Dated 11th November 2015 (Interviews)	Version 1.0 Dated 11th November 2015 (Interviews)
Version 1.0 Dated 11th November 2015 (Observation)	Version 1.0 Dated 11th November 2015 (Observation)

Protocol: Version 1.0 Dated 11th November 2015

The above project has been considered by the NHS Lothian R&D Office and you are advised that, based on the submitted documents, this study does not require NHS Lothian R&D approval.

You should retain a copy of this letter with your project file as evidence that you have sought advice from NHS Lothian R&D office.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, funding, personnel or resource input required of NHS Lothian.

Please inform this office when the study has been completed.

Please note that attendance at NHS REC meetings is subject to written invitation setting out the terms under which observer status is permitted, the signature of a confidentiality agreement, and the agreement of the REC at the meeting to be attended. To arrange this please contact Alex Bailey (alex.bailey@nhslothian.scot.nhs.uk)

I wish you every success with your study.

Yours sincerely

Fiona McArdle.

Ms Fiona McArdle
Deputy R&D Director

STA034

From: Jolanta.Lisicka@gov.scot
To: DOVE Edward
Cc: Alex.Bailey@nhslothian.scot.nhs.uk; ROBERTSON Jo-Anne; LAURIE Graeme; HARMON Shawn
Subject: RE: Doctoral research project on NHS RECs - request for CSO approval
Date: December 9, 2015 9:44:34 AM

Dear Edward
First of all let me apologise for delay in responding to your request. Thank you for outlining your project and for all associated documents you forwarded to myself. After discussing with Mike Stevens, Head of CSO, I can confirm that CSO has no objection to your approaching NHS RECs in Scotland for the purpose of your project.

I understand that you are in contact with [redacted] who can guide you through the process and provide with further details and contacts.

Kindest Regards
Jolanta

Jolanta Lisicka
NHS Funding and Policy Manager (Tue-Thur)
Chief Scientist Office | Scottish Government | St Andrew's House | Regent Road | Edinburgh | EH1 3DG
E-mail: Jolanta.Lisicka@gov.scot Tel: 0131 244 2251

From: Oliver Sheila (HEALTH RESEARCH AUTHORITY)
To: DOVE Edward
Subject: RE: Doctoral research project on NHS RECs and possible collaboration with NREAP/HRA
Date: November 10, 2015 12:59:33 PM

Dear Edward,
Please accept my apology for the delay in getting back to you. Yes absolutely fine to pursue with RECs in England and the NREAP.
I've already spoken to the REC Chair of the [redacted] and [redacted] is very happy to be involved and for you to attend a meeting of the REC and I have emailed [redacted] and I'm sure [redacted] will also be happy for [redacted] REC to be involved.

[redacted] is also happy to be involved and [redacted] will make arrangements for you to speak to [redacted] and the NREAP Chair, emails to follow to assist with the arrangements.

Kind Regards

Sheila

Sheila Oliver, Head of Research Ethics Service (England)
Health Research Authority
c/o Mrs Sharon Melbourne, HRA Centre Manchester, 3rd floor, Barlow House, Manchester M1 3DZ
E: sheila.oliver1@nhs.net
M: 07824406749 (Sharon – 0161 625 7822)

HRA: 020 797 22545 | www.hra.nhs.uk

Appendix 4: Sample copy of HRA confidentiality agreement

NHS
Health Research Authority

REC

XXX
XXX
XXX
XXX

[Date]

CONFIDENTIALITY AGREEMENT WITH OBSERVER AT REC MEETING

In return for being permitted to attend as an observer at the meeting of the Research Ethics Committee (REC) to be held on **[date]** I agree to treat in complete confidence all information disclosed to me either in the meeting documentation or matters discussed at the meeting. This undertaking does not apply to:

- Any information which, at the time it is disclosed to me, is already public knowledge
- Any information which, after disclosure to me, becomes public knowledge by reason of publication or otherwise, except through my actions in breach of this agreement
- Any information which I can establish by competent proof was in my possession at the time of its disclosure to me at the REC meeting.

Name of observer: ……

Occupation: ……

Organisation: ……

Address: ……

Signed: ……

Date: ……

Agreed on behalf of the REC by:

Name: ……

Role on Committee: ……

Signed: ……

Date: ……

Appendix 5: Sample copy of HRA Ethical Review Form

NHS
Health Research Authority

Ethical Review Form (Lead Reviewer/REC Member)

The HRA has an established role to promote transparency, largely through RECs and the publication of research summaries; this will now be extended to include the publication of the summary of REC opinion.

The lead reviewer(s) should complete this form in preparation for the REC meeting. The form may also be used by other REC members. The REC Chair should use the headings as an aide memoire to structure the discussion at the meeting. Completed forms should be given to the REC Manager who will arrange for them to be destroyed once the minutes of the meeting have been ratified.

Meeting Date:

REC Reference Number:

Study Title:

Brief overview of study (optional depending on REC practice)

1. Social or scientific value; scientific design and conduct of the study (IRAS A6, A7-14, A 57-62, A75) Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge. RECs should take into account the public interest in reliable evidence affecting health and social care. Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data. Is the research question important and necessary? Is the research design and proposed statistical analysis able to answer the question? Is there equipoise; are all treatment arms viable options for the research participants? • **Public Involvement** - Is there involvement of patients, service users, the public, in the design, management, and undertaking the research? (IRAS A14-1)
Comments/issues for discussion

2. Recruitment arrangements and access to health information, and fair research participant selection (IRAS A16, A 17-1, A17-2, A 27-29, A46, A47). Inclusion and exclusion of potential research participants. Selection of research participants so that vulnerable individuals are not targeted for risky research and the rich and socially powerful not favoured for potentially beneficial research. The benefits and risks of research should be distributed fairly among all social groups and classes, taking particular account of age, disability, gender, race, religion or belief and sexual orientation, as well as economic status and culture. How are research participants recruited? How does participation impact on their clinical care? Are compensation arrangements in place? Insurance (negligent/ non-negligent harm)**.**
Comments/issues for discussion:

3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future) (IRAS A 18- 25 & part B3 if radiation, and part B 5 if samples).Minimization of risks. Is there evidence of the consideration of any benefits/risk for individual research participants, past/future research participants, including whether the risk/intervention is sufficiently minimal to require no SSA. Are benefits/risk clearly identified for the research participant? Have steps been taken to minimise or eliminate the risk, hazards, discomfort, and distress and enhancement of potential benefits; risks to the research participant are proportionate to the benefits to the research participant and society? Is the balance between risk and benefit equitable?
Comments/issues for discussion:

4 Care and protection of research participants; respect for potential and enrolled research participants' welfare & dignity (IRAS A25, A50-53, A 76, A 77). *permitting withdrawal from the research * protecting privacy through confidentiality *informing participants of newly discovered risks or benefits * informing participants of results of research *maintaining welfare of participants *what will happen at the end of the study *provision of appropriate indemnity and insurance **Trial Registration** (IRAS A50) **Are trial registration arrangements in place?** (note, this is a condition of the favourable opinion, and is mandatory for the first four categories of study on IRAS) **Data protection & research participant's confidentiality** (IRAS A 36 - 43) Where and how (anonymised/coded) and for how long will data be stored? What purpose will be served by the data? Who will access? Are research participants informed that access to their medical notes may be required? Arrangements made to deal with incidental disclosure?
Comments/issues for discussion:

5 Informed consent process and the adequacy and completeness of research participant information (A30 -34, A46, A49 & PIS).Provision of information to research participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate. Is the language used clear and understandable to the research participant it is aimed at? Does it include all the procedures as describe in the protocol? Have uncertainty and randomisation been explained to the research participant? Is consent taken as part of a process with research participants having adequate time to consider the information, and opportunity to ask questions? Is it clear to what the research participant consents or assents? Is there any inducement

or coercion? Are vulnerable research participants involved? Is consent obtained to allow GP's to be informed? (Is the Welsh version an accurate translation of the given English version? Wales only)
Comments/issues for discussion:
6. Suitability of the applicant and supporting staff (investigator CV & IRAS question A47, A48) Applicant and supporting staff are suitably qualified and have experience relevant to the proposed research. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. Are the local facilities and arrangements suitable? Have community issues been considered? Have any conflicts of interest been considered?
Comments/issues for discussion:

7. Independent review (IRAS A 54-56) Review of the design of the research trial, its proposed research participant population, and risk-benefit ratio by individuals unaffiliated with the research. The REC may be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.
Comments/issues for discussion:

8. Suitability of supporting information E.g. GP letter, interview schedules, questionnaires, lone working policies etc.
Comments/issues for discussion:

9. Other general comments. E.g. missing information / typographical errors / application errors.

10. Consider and confirm the suitability of the summary of the study (IRAS A6-1). This summary will be published on the HRA website in this format together with the summary of the REC's ethical opinion.
Confirmed satisfactory **Changes requested**

Appendix 6: Glossary of acronyms

AHRC	=	Arts and Humanities Research Council
AMS	=	Academy of Medical Sciences
BMJ	=	British Medical Journal
CAG	=	Confidentiality Advisory Group
CBS	=	Central Booking Service
CIOMS	=	Council for International Organizations of Medical Sciences
COREC	=	Central Office for Research Ethics Committees
CRC	=	Clinical Research Committee (NIH)
CSO	=	Chief Scientist Office
CTIMP	=	Clinical Trial of an Investigational Medicinal Product
DHEW	=	Department of Health, Education and Welfare (US)
DoH	=	Department of Health
ESRC	=	Economic and Social Research Council
FDA	=	Food and Drug Administration (US)
GAfREC	=	*Governance Arrangements for Research Ethics Committees*
GTAC	=	Gene Therapy Advisory Committee
HARP	=	HRA Assessment Review Portal
HEI	=	Higher Education Institution
HFEA	=	Human Fertilisation and Embryology Authority
HRA	=	Health Research Authority
HTA	=	Human Tissue Authority
ICH GCP	=	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice

IRAS	=	Integrated Research Application System
IRB	=	Institutional Review Board
LREC	=	Local Research Ethics Committee
MHRA	=	Medicines and Healthcare products Regulatory Agency
MoDREC	=	Ministry of Defence (MoD) Research Ethics Committee
MRC	=	Medical Research Council
MREC	=	Multi-site Research Ethics Committee
NHS	=	National Health Service
NIH	=	National Institutes of Health (US)
NIHR	=	National Institute for Health Research
NPSA	=	National Patient Safety Agency
NREAP	=	National Research and Ethics Advisors' Panel
NRES	=	National Research Ethics Service
OECD	=	Organisation for Economic Co-operation and Development
OREC	=	Offices of Research Ethics Committees
ORECNI	=	Office for Research Ethics Committees Northern Ireland
PIS	=	Participant Information Sheet
PPI	=	Patient and Public Involvement
PRS	=	Proportionate Review Service
RCP	=	Royal College of Physicians of London
RCUK	=	Research Councils UK
REB	=	Research Ethics Board
REC	=	Research Ethics Committee
REC SOPs	=	Standard Operating Procedures for Research Ethics Committees

RED	=	Research Ethics Database
REIC	=	Edinburgh Law School Research Ethics and Integrity Committee
RES	=	Research Ethics Service
RGF	=	Research Governance Framework for Health and Social Care
R&D	=	Research and Development
ShED	=	Shared Ethical Debate
SOPs	=	Standard Operating Procedures
UKECA	=	United Kingdom Ethics Committee Authority
WHO	=	World Health Organization

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