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RHETORIC OR REALITY: WHAT IS THE LEGAL STATUS OF THE CONSENT FORM IN HEALTH-RELATED RESEARCH?*

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ABSTRACT

This article addresses the unresolved conundrum of the legal status of consent forms used in research involving tissue samples or personal data. It identifies which rights participants might have by virtue of any consent form they have signed and which legal remedies might be available to them should the research depart from the terms of the original consent. The paper demonstrates that, although the legal status of consent forms is not clear in the UK, the landscape is evolving. We suggest that the growing legal protection afforded to autonomy and judicial recognition of individual property rights in tissues may offer opportunities for remedies in law where the regulatory regimes controlling uses of human tissue and personal data do not. However, we argue that in the governance of research relationships—which depend crucially on trust—resort to legal remedy may be undesirable. We suggest that treating consent as a one-off event that can be effectively captured in a written document—as the law tends to do—is an inappropriate and counter-productive approach. The aims of ethical research governance will be better served by seeing consent as continuing relational process, requiring on-going mutual respect, opportunity for communication, and accommodation of changing circumstances. The consent form is merely a framing instrument and only the starting point for a

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partnership that will evolve over time. Crucially, the limits of consent must be recognised in the design and governance of modern research practices. The article concludes with recommendations to reconceive consent in these terms.

I. THE ROLE OF CONSENT FORMS IN HEALTH-RELATED RESEARCH

A. *The Ethical Basis for (Informed) Consent*

It is trite to observe that in recent decades, respect for the right to self-determination, or autonomy, has become the dominant ethical principle in bioethics.¹ This shift has led to a corollary emphasis on informed consent in both treatment and research settings. Seeking and obtaining informed consent for a medical or research intervention, the collection of tissue samples, or the use of samples and personal data in research has become the principal and ostensibly legitimate means by which patients and research participants are expected to understand risks and consequences of procedures and to determine whether they are prepared to submit to these.² However, the presumption that consent is the only, or best, way to protect autonomy has been challenged.³ In the context of health research, questions have also been raised about whether the importance of obtaining participant consent is emphasised at the expense of the pursuit of a legitimate public interest in generating research findings.⁴ Nevertheless, there can be little doubt that consent, and the signed forms that document this, now occupy talismanic status in a research culture that places central importance on protecting participants' autonomy and being seen to do so. Beyond this, consent is also frequently assumed to cement trust within the research relationship. Trust is self-evidently vital to the reputation of the researcher or institution involved, as well as to the future viability of all research involving human participants. Accordingly, consent today is asked to do a lot of work: to serve to protect individual interests, to promote personal autonomy, to act as

¹ TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (6th edn OUP 2009) at 417; see also O O'Neill, *Autonomy and Trust in Bioethics* Gifford Lectures, University of Edinburgh (CUP 2002). O'Neill argues against the equiparation of respect for autonomy with obtaining informed consent.

² JK Mason and GT Laurie, *Law and Medical Ethics* (8th edn Oxford University Press 2011) at 639.

³ GT Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge University Press, New York 2002) 335; NC Manson and O O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge University Press 2007) 212; O'Neill, above, n 1.

⁴ The Academy of Medical Sciences 'Personal Data for Public Good: Using Health Information in Medical Research' (2006).

a foundation for trust, and to stand as a cornerstone for the research enterprise. This article questions whether this is a sustainable position in the current research climate, particularly when this is increasing typified by 'legalisation' of the consent process and fetishisation of the consent form itself. It is argued that an ironic unlooked-for consequence of this legal phenomenon might end up being less emphasis on trust and the elements of a good researcher/participant relationship. This leaves the core ethical objectives of consent open to serious question and suggests a need to reconceive the role of the consent form.

In order to begin the analysis, it is important to be clear about both the form and the function of consent. The failure to consider this properly has led to considerable conceptual and practical confusion in both clinical and research settings and in the related literatures.⁵ As to function, O'Neill characterises consent as a 'propositional attitude', that is, a response to a proposition describing action yet to be undertaken. For O'Neill, the function of consent is to limit deception or coercion.⁶ Our own view is the subject of this entire paper. As to form, there are now many different qualifying adjectives that describe consent to research participation. These include: informed,⁷ broad,⁸ open,⁹ blanket,¹⁰ generic,¹¹ specific,¹² explicit,¹³ appropriate,¹⁴ valid, and written consent. Some of these categories are widely used and recognised. For

⁵ For example, there is a sizeable literature on the limitations of the translating an informed consent model into the context of biobanking, see *inter alia*, J-Å Skolbekken and others, 'Not worth the paper it's written on? Informed consent and biobank research in a norwegian context' (2005) 15 (4) *Critical Public Health* 335 and S Kristinsson and V Arnason, 'Informed consent and human genetic database research', in M Hayry et al. (eds), *The Ethics and Governance of Human Genetic Databases*, Law, Medicine and Ethics (CUP 2007) 199. In the context of research uses of genetic data, Taylor has suggested a need for greater clarity on the necessity and proportionality of consent requirements for under the European Data Protection Directive, Mark Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, Cambridge Bioethics and Law (CUP 2012) at 217.

⁶ O O'Neill, 'Some limits of informed consent' (2003) 29 (1) *Journal of Medical Ethics* 4, 5.

⁷ A MacLean, 'From *Sidaway* to *Pearce* and beyond: is the legal regulation of consent any better following a quarter of a century of judicial scrutiny?' (2012) 20 (1) *Med L Rev* 108.

⁸ T Caulfield and J Kaye, 'Broad consent in biobanking: reflections on seemingly insurmountable dilemmas' (2009) 10 (2) *Med L Int* 85–100.

⁹ JE Lunshof and others, 'From genetic privacy to open consent' (2008) 9 *Nat Rev Genet* 406.

¹⁰ T Caulfield, 'Biobanks and blanket consent: the proper place of the public good and public perception rationales' (2007) 18 (2) *King's Law Journal* 209.

¹¹ *Ibid.*

¹² M Otlowski, 'Tackling legal challenges posed by population biobanks: reconceptualising consent requirements' (2012) 20 (2) *Med L Rev* 191.

¹³ *Ibid.*

¹⁴ P Taylor, 'When consent gets in the way' (2008) 456 *Nature* 32.

example, valid consent is usually used to mean that which meets the three criteria of sufficient informedness, capacity, and voluntariness.¹⁵ Informed consent is usually taken to mean consent based on the disclosure of ‘any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment’, and this is true also in research.¹⁶ The principal aim of disclosure is to support patient or participant autonomy. This, however, is far from a straightforward objective chiefly because of the challenge of deciding what information it is necessary or possible to give and whether full comprehension is ever achievable.¹⁷ This is compounded in the research context because research itself is an inherently uncertain exercise. Future risks and benefits are largely unknown and the nature of the enterprise can take many unanticipated turns towards an elusive goal. This limits considerably what consent procedures can achieve in terms of informedness and suggests that the role played by trust is all the more important.

It is also important to appreciate that consent is asked to do different work for different groups. For example, research participants differ from patients in a number of ways. Research participants are not

¹⁵ General Medical Council, ‘Good Practice in Research and Consent to Research’ (2010) 8; the NHS National Research Ethics Service guidance on informed consent in clinical trials draws upon the International Conference on Harmonisation: Good Clinical Practice’s (ICH GCP) definition of informed consent according to which ‘a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate’ and should also be documented in a signed form (National Research Ethics Service, ‘Information Sheet and Consent Forms: Guidance for Researchers and Reviewers’ (March 2011) at 89). The UK Department of Health in guidance regarding treatment contexts refers not to informed, but valid consent, which it defines as that which is ‘given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question’, Department of Health ‘Reference Guide to Consent for Examination or Treatment’ (2nd edn 2009) at 9.

¹⁶ *Salgo v Leland Stanford Junior University Board of Trustees* 317 P 2d 170 (Cal, 1957), though this is a US case, and as such does not establish precedent in the UK.

¹⁷ In *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1984] QB 493, [1984] 1 All ER 1018 it was observed that ‘The doctrine of informed consent forms no part of English law’, per Dunn LJ at 517. Yet, the expression ‘informed consent’ has featured in many UK medical law cases since its first use *Chatterton v Gerson* [1981] QB 432, [1981] 1 All ER 257, including the influential House of Lords judgment in *Chester v Afshar* [2004] UKHL 41, [2005] 1 AC 134. Even though the doctrine of informed consent as such has not been applied by the UK Courts, and the legal question of what information must be supplied is still developing, this doctrine may nonetheless be seen as having set the tone for approaches to the role of consent and the consent form in the UK which focuses on the assumption that material information to a decision can be supplied in a one-off event and cover all relevant contingencies potentially affecting the consenter, see Mason and Laurie, above, n 2 at 108–11.

normally subject to interventions in the interests of their own health;¹⁸ instead, they can be seen as voluntary collaborators in a joint endeavour pursued in the public interest.¹⁹ It does not follow, of course, that the need to protect their interests and to engage them in a relationship founded on trust is any less pressing. Rather, the consent form as used in research is typically expected to fulfil a more complex role than that of its clinical counterpart. In the latter, its chief purpose is to record a patient's agreement to a particular procedure, thus protecting their interests in bodily integrity and autonomy and to ensure the procedure does not constitute battery. This is also true in research where there is physical contact, for example in a clinical trial, but much research also involves human tissues and data. In such circumstances, the principle of informed consent is also expected to cover privacy interests in respect of participants' personal data and, potentially, property interests in tissues as well. The research consent form is likely to document that valid consent has been obtained for the collection, conditions of storage, and most pertinently to our current inquiry, any proposed or prohibited use(s) of the tissue/data now and in the future.²⁰ The dilemma which arises is whether it is possible or reasonable to expect the consent form to perform all of these tasks when the future is uncertain, when circumstances and expectations might change over time and when trust is likely to depend more on what happens after the consent form is signed than on what is said beforehand.

This might be less worrying but for the increasing encroachment of law on the form and function of the consent procedure. In particular, it has been argued by Hall that '... optimal levels of trust and distrust emerge through private ordering, without the assistance of law'.²¹ The concern is that the legalisation of consent, by which we mean the reduction to rule-specific prescription with respect to the consent form itself, cannot only miss much about the nature and needs of the research relationship, but can actually perform a disservice to trust in that it perpetuates a view that those seeking consent are not to be trusted. Indeed,

¹⁸ Sheila Mclean, *A Patient's Right to Know: Information Disclosure, the Doctor and the Law*, Medico-Legal Series (Ashgate Dartmouth 1989) at 183.

¹⁹ Nuffield Council on Bioethics 'Human Bodies: Donation for Medicine and Research' (2011) at 151.

²⁰ The following discussion is based on a presumption that research participants are adult and competent at the time their consent was obtained and remain so. Specific legal issues are also raised by the ethical and practical challenges of obtaining valid consent for research from children or adults who lack capacity. These are important, but will not be considered further here. See further, JK Mason, and GT Laurie, *Law and Medical Ethics*, n 2 above, Chs 19 and 20.

²¹ MA Hall, 'Law, medicine and trust' (2002) 55 (2) *Stanford Law Review* 463 at 484.

counterproductively this can actually result in less trustworthy behaviour because the incentive to so act on professional grounds is removed and replaced by threat of legal sanction.²² While this article cannot hope to establish whether this is true as a matter of fact, it does seek to demonstrate a growing legal focus on the consent form—a tendency towards its fetishisation—and to suggest that this is an impoverished means of giving effect to the ethical objectives of consent and, indeed, of a responsible research relationship.

B. The Importance of Establishing the Legal Status of Consent Forms

Despite the ubiquity of the subject of consent in the academic and professional literature, we do not know the precise legal status of consent forms used in research in the UK. Much of the regulatory landscape has been heavily influenced by the requirements laid down in instruments such as the Clinical Trials Directive.²³ While important, these should not lead to a conclusion that a one-size-fits all approach applies across all forms of research. For example, the Clinical Trials Directive mandates written consent, but in other cases, as when tissues are collected from participants or where DNA analysis is to be conducted using identifiable samples, different forms of consent can be accommodated by law.²⁴ Thus, as will be demonstrated, obtaining the written informed consent of participants is not normally a legal requirement for research *per se*. Nevertheless, it is now standard practice to do so and often heralded as best practice.²⁵ This, however, is still to focus chiefly on the *form* of consent rather than its essential *function*.²⁶ The following sections demonstrate that a failure to be clear on the function of consent can lead to a tendency to overburden the consent process and to expect too much of the consent form.

For practical and legal purposes, it is important to recognise that, although it may be a convenient short-hand to refer to ‘the consent

²² NC Manson and O O’Neill, above, n 3 at 161.

²³ Directive 2001/20/EC of 4 April 2001, of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. It is telling, for example, that the UK Government used the advent of the Clinical Trials Directive to undertake an overhaul of the governance of medical research generally in the UK.

²⁴ See, for example s 45 of the Human Tissue Act 2004 and Schedule 4 with respect to DNA analysis.

²⁵ P Boddington and others, ‘Consent forms in genomics: the difference between law and practice’ (2011) 18 (5) *European Journal of Health Law* 491, 517.

²⁶ On the legal function of consent in a range of fields, see D Beyleveld and R Brownsword, *Consent in the Law*, Legal Theory Today (Hart Publishing, 2007) Ch 3.

form', in reality this is likely to refer to multiple consent-related documents, encompassing not only the signed form but also the accompanying information sheet.²⁷ Additional documentation, such as correspondence, might provide further material from which the participant may draw inferences about the nature of that to which they are consenting.²⁸ The National Research Ethics Service (NRES) advises that '[t]he participant is consenting to everything described in the text of the information sheet'.²⁹ However, it has been observed that the information sheet may be called upon to play a dual role, as both a 'prospectus' inviting participation and a legal document setting out matters such as insurance responsibilities, which complicates its function as a decision-making tool.³⁰ Indeed, the idea that the consent form can simultaneously protect the patient from harm and protect the researcher from liability is a clear example of how the consent form as quasi-legal instrument can set up an oppositional dynamic which is more reflective of a situation where trust is absent than one in which trust is a central concern.

There are no mandatory standard formats for research consent forms, although NRES does provide detailed guidance on optimal structure and content for health-related studies.³¹ A recent review of genomic studies found that the content of consent forms in this field is a 'mix of legal requirements, ethical principles, and accrued practice' and is likely to vary between research contexts.³² That review cited evidence that the choice of what is included in a consent form might not always reflect the highest priorities in terms of what the participant is legally bound to be told or which information is most likely to protect

²⁷ It is possible that the participant is unable to sign or mark a consent form her/himself, in which case it may be acceptable for them to give their consent orally in the presence of a witness and have this recorded in writing (for example, Part 1, paragraph 3(i) to Schedule 1 to The Medicines For Human Use (Clinical Trials) Regs 2004)—for the purposes of this paper these will be taken as equivalent.

²⁸ NRES advises that RECs attend not only to the context of consent forms and information sheets, but also to other accompanying documents, such as questionnaires, letters of invitation, letters to GPs or other clinicians, or information sheets for relatives or carers, NHS National Research Ethics Service 'Standard Operating Procedures for Research Ethics Committees in the United Kingdom' v5.1 (March 2012) at 111.

²⁹ NRES 'Information Sheets and Consent Forms Guidance', above, n 15 at 27.

³⁰ N Armstrong and others, 'Do informed consent documents for cancer trials do what they should? A Study of Manifest and Latent Functions' *Sociology of Health and Illness* (in press and available online from 22 March 2012, DOI:10.1111/j.1467-9566.2012.01469.x).

³¹ NRES Information Sheets and Consent Forms Guidance, above, n 15 at 27.

³² Boddington and others, above, n 25 at 492. The reference to 'legal requirements' here refers to the requirement to obtain informed consent, not to document it in a form.

or enhance their interests, which suggests a net failure to reflect appropriately on what the consent form is trying to achieve.³³ For example, a form might include a description of the study's aims, but neglect to document what advice the patient has been given about potential future uses of samples or data. Indeed, as we have indicated, it might not be possible to provide information about future uses at the time that consent is obtained as these are not known and cannot yet be anticipated. This is typically the case in biobank research and has necessitated radical rethinking of the nature and role of consent and a shift away from the conventional paradigm of *informed* consent, that is, one that assumes that material facts are known and can be effectively communicated at the time consent is obtained—to *broad* consent.³⁴ A broad consent approach recognises the impossibility of providing all material information up-front and focuses, rather, on the notion of consent as a threshold device to the beginnings of a research relationship.³⁵ Broad consent models tend to be accompanied by oversight mechanisms that monitor the research relationship over time.³⁶ Research governance faces the challenges of being in a transition phase, one implication of which is that the role of the consent form requires reconsideration. There are, however, two particular hurdles to the kinds of reconsideration that are required. First, the dominant paradigm remains the informed consent model and this has implications for the expectations of researchers, participants, research ethics committees, and, ultimately, the courts. Secondly, the tendency to focus attention on the consent form as the source of evidence about these expectations raises questions

³³ Ibid at 517–8. This study found that while information about project aims was the most common feature of the genomic research consent forms they surveyed, information about storage and future uses was only ‘sometimes’ included.

³⁴ Most recently, LifeGene biobank in Sweden has run into serious difficulties after the Swedish Data Inspection Board ruled that it could no longer collect prospective data from its 500,000 participants nor, indeed, process those already collected. The reasoning was that participants could not give valid consent to a proposition about future health research because it was insufficiently explicit. See further here: <<http://ethicsblog.crb.uu.se/2011/12/20/the-swedish-data-inspection-board-stops-large-biobank/>> accessed 11 August 2012.

³⁵ For example, M Otlowski, ‘Developing an Appropriate Consent Model for Biobanks: In Defence of “Broad” Consent’, in J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate 2009) 79. The Nuffield Council on Bioethics report in donation of bodily materials endorses the position ‘that it is appropriate routinely to seek generic consent [of which broad consent is one kind] (where necessary in addition to specific consent) for the research use of blood and tissue’, above, n 19 at 204.

³⁶ For suggestions about ways to approach this, see GT Laurie ‘Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law’ (2011) 130 *Human Genetics* 347.

about entitlement and reliance on its terms. In particular, it leads us to ask when, if at all, might a consent form function as a kind of legal instrument, for example as a contract or quasi-contract, and what consequences might follow from this?

Seeing consent forms as legal or quasi-legal documents predisposes us towards certain ways of thinking about them. For example, a legalistic approach to consent forms will necessarily focus on the *precise terms* in which these documents are framed. *Prima facie*, these forms are suggestive of assent by a person to a particular proposition put to them, viz, to participate in research; but as we have seen, the proposition is highly uncertain. Thus, to consider the function of the consent form in these circumstances, it is one of framing an instrument that has to deal with considerable uncertainties and a *prospective* enterprise that might change over time. The wording of a form will become crucial in any future attempts to understand *retrospectively* what someone has consented to, and there are significant challenges of interpretation. For example, should words be interpreted literally or in a common sense fashion? Should we be concerned to understand what the 'reasonable research participant' would understand by the words, or the particular participant? And, do participants only consent to that which is explicitly mentioned, thereby necessarily excluding that which is not? Moreover, can we proceed on the assumption that the wording of a consent form actually reflects participants' genuine expectations? Many studies provide evidence of mismatch between the wording of consent forms (or the accompanying information documents) and participants' understandings and expectations.³⁷

Questions about the legal status of consent forms grow ever more pressing as secondary research uses of existing collections of samples, data, or products derived from these become increasingly common. These uses may or may not be covered by the terms of the original consent. Where new studies are planned using existing collections, the terms of participants' consent forms might provide the basis for deciding whether their existing consent covers the new research purpose.³⁸ It is worthwhile noting that such exclusions might not only take an explicit formulation as in 'your tissues/data will not be used for purpose x', but could also be implied by positive formulations such as 'your tissues/data

³⁷ Armstrong and others, above, n 30; M Dixon-Woods and others, 'Beyond "misunderstanding": written information and decisions about taking part in a genetic epidemiology study' (2007) 65 (11) *Social Science & Medicine* 2212; Y Freer and others, 'More Information, Less Understanding: A Randomized Study on Consent Issues in Neonatal Research' (2009) 123 (5) *Pediatrics* 1301; E Fried, 'The therapeutic misconception, beneficence, and respect' (2001) 8(4) *Accountability in Research: Policies & Quality Assurance* 331.

³⁸ Boddington and others, above, n 25 at 492.

will be used for purpose *y*' which might be interpreted by access committees as excluding uses other than *y*.³⁹ Currently, while the wording of a consent form in the above terms might well offer a pragmatic or ethical basis for determining which research purposes are prohibited, it is less clear whether it provides anything with more legal teeth than this.

The recent judgment of the European Court of Human Rights in *Gillberg v Sweden* illustrates just how precarious the legal status of apparent commitments made by researchers to research participants may be when tested in the courtroom.⁴⁰ In the instant case the applicant, a university professor, had refused to share with external researchers data from participants in a study for which he was responsible, despite a court order requiring him to do so. His grounds for refusing were that he had twice made written commitments to participants (and their parents) that their data would remain confidential, and that breaking these would run contrary to ethical research practices, discredit research, and deter future participation.⁴¹ The Grand Chamber declined to recognise the applicant's claim that his criminal conviction for refusing to disclose the data constituted a breach of his 'negative right' under Article 10—the right to refuse to impart particular information.⁴²

In finding that no such a right was engaged in the instant case, the Grand Chamber held that it was not possible for a public authority such as a university to enter into an agreement with another party that that unconditionally exempted publically owned documents from public access.⁴³ Furthermore, it found that no legal or other obligations prevented the researcher from disclosing the data, his only impediment was his belief that it would be wrong to do so.⁴⁴ Despite not concerning consent forms *per se*—and we have already noted the ambiguity in what is included under this label—this case confirms just how little legal force written commitments regarding the handling of participants' personal data can have. The judgment indicates that this might be particularly

³⁹ For an example of such an interpretation of an instance in which a consent form specified samples would be used for 'medical research studies' see P Burton, 'Policy for use and oversight of samples and data arising from the 1958 birth cohort (National Child Development Study)' (Unpublished, Access Committee for CLS Cohorts, 2009) 14, available here <<http://www2.le.ac.uk/projects/birthcohort/document-downloads/POLICY.DOCUMENT.120609.pdf>>.

⁴⁰ *Gillberg v Sweden*, Application no 41723/06, 3 April 2012.

⁴¹ *Ibid* at [37].

⁴² *Ibid* at [97].

⁴³ *Ibid* at [87] The participants' data were held to be the property of the University by whom the applicant was employed and as such were held to be public documents subject to subject to the principle of public access under the Swedish Freedom of the Press Act and the Secrecy Act.

⁴⁴ *Ibid* at [91].

true where the commitments made by researchers seek to impose stricter or more absolute obligations (in the instant case, of confidentiality) than those required or permitted in law.

C. Locating the Legal Status of the Consent Form: Three Suggestions

The *Gillberg* judgment notwithstanding, where researchers make commitments to participants as part of the consent process and research is then conducted in a way that is at odds with these commitments—for instance by the pursuit of apparently precluded activities using donated tissues or personal data—one might be concerned that this departure fails to respect the interests of the research participants in determining how their data or tissues are used. Assuming the broken commitments are not in themselves in tension with domestic laws governing the handling of data or tissues, we might then ask whether participants' interests enjoy any protection in law by virtue of being recorded in written consent documents. In order to address this question, the following three sections consider the legal force of the terms in which consent forms are couched and what redress might be available to participants if these terms are violated. This does not commit us to any view of whether such a legalistic approach is warranted, or indeed desirable. That question is considered in Section V below.

As already indicated, the precise legal standing of the consent form in health-related research has not been tested in the UK courts. We know in the treatment context that failure to obtain valid consent renders touching an unwarranted act and is likely to constitute battery or assault.⁴⁵ We also know that the courts in the UK have shown decreasing deference to the medical profession in recent years in terms of what patients must be told as a matter of law, moving from a professionally determined standard (what would a responsible body of health care practitioners consider appropriate to disclose?)⁴⁶ to a form of prudent patient standard (what would a reasonable patient need to know in terms of significant risks?).⁴⁷ We also know that the courts are willing to bend the rules of causation where it is thought that sub-optimal information procedures have undermined patient autonomy.⁴⁸ We cannot assume, however, that these legal positions regarding treatment are reflected in the research context.⁴⁹ Accordingly, the following

⁴⁵ *Chatterton v Gerson* [1981] QB 432 and *Appleton v Garrett* (1995) 34 BMLR 23.

⁴⁶ *Sidaway v Board of Governors of the Bethlem Royal Hospital*, above, n 17.

⁴⁷ *Pearce v United Bristol Healthcare NHS Trust* (1999) 48 BMLR 118.

⁴⁸ *Chester v Afshar*, above, n 17.

⁴⁹ It is also important to note that these treatment consent parameters have been developed exclusively in the context of the negligence action; this article

commentary is speculative and adopts a first-principle approach of considering a range of possible legal conceptualisations or qualities that could be attributed to the research consent form. For each of these, the likely legal significance of the consent form and the opportunities for redress for participants will be explored. We argue by analogy and with reference to existing precedents in order to understand how existing law might apply when research departs from the terms of the consent as documented.

We consider each of the following possible conceptualisations in turn:

- (i) the consent form as a regulatory requirement;
- (ii) the consent form as a pseudo-contractual basis for the allocation of property rights; and
- (iii) the consent form as the basis for actions protecting personal autonomy.

II. THE CONSENT FORM AS A REGULATORY REQUIREMENT

A. *When Is Consent Required?*

Conducting research that involves physical contact (including obtaining tissue samples) without research participant consent would undoubtedly amount to battery under the common law in precisely the same way as it does in the treatment context. This arises from the principle of the inviolability of a person's body as an aspect of their right to self-determination.⁵⁰ Where tissue is removed in a research context, rather than for therapeutic purposes, the consent must be informed, explicit, and for reasons in the public interest, but need not be given in writing to be valid.⁵¹ The subsequent storage and use of human tissues comprising cells from living donors (excluding gametes, embryos, and genetic material) for research purposes are then regulated under the Human Tissue Act 2004 (HTA 2004).⁵²

addresses research conducted under a far wider set of legal regimes, both statutory and common law.

⁵⁰ A Grubb and others, *Principles of Medical Law* (3rd edn OUP 2010) 1205 at [8.01]. Cases confirming this in both the treatment and research contexts are: *Airedale NHS Trust v Bland* [1993] AC 789, [1993] 1 All ER 821 and *Malette v Shulman* (Canadian), *Re F (Mental Patient: Sterilisation)*, and *Re T (Adult: Refusal of Treatment)*, *Chatterton v Gerson* [1981] QB 432, [1981] 1 All ER 257 and *Simms v Simms, A v A* [2002] 2 WLR 1465, [2003] 1 All ER 669. On the continuum from treatment, experimentation, and research see *Walker-Smith v GMC* [2012] EWHC 503 (Admin) at [12].

⁵¹ Grubb and others, *ibid* at [8.38].

⁵² This Act for the most part only applies in England and Wales. There is no equivalent legislation in Scotland, where the Human Tissue (Scotland) Act

Consent is the fundamental principle according to which use and storage of human tissues may be rendered lawful under the HTA 2004, but it is not legally mandated under all circumstances.⁵³ Purposes requiring ‘appropriate consent’ under the Act—which means, when the person concerned is alive, the tautologous act of ‘obtaining his consent’⁵⁴—include the storage and use of tissues for ‘research in connection with disorders, or the functioning, of the human body’.⁵⁵ However, tissues taken from living persons may be used for research without consent if the researcher would not be able to identify the donor and the research has ethical approval.⁵⁶ Social research is not among the ‘scheduled purposes’ of the Act requiring consent, nor do the consent conditions apply to ‘existing holdings’ of tissues collected before this legislation came into force.⁵⁷ The Human Tissue Authority (HTA) Code of Practice on consent advises that: ‘it is good practice to request generic consent because this avoids the need to obtain further consent in the future’.⁵⁸ The Code of Practice contrasts ‘generic consent’ with ‘specific consent’ and advises that the former is more appropriate in research contexts. The HTA does not itself provide a definition of generic consent beyond that implied by the passage quoted above. The Nuffield Council on Bioethics has offered a definition where ‘[g]eneric consent may be understood as “blanket” consent, where no limits at all are placed on the future use of the material’.⁵⁹

Section 45 of the HTA 2004 makes non-consensual DNA analysis a criminal offence.⁶⁰ There are exceptions to this prohibition. Non-consensual DNA analysis of identifiable tissues is lawful if these were part of existing collections when the HTA 2004 came into force and the purpose of analysis is one of a specified list, which includes medical research. Non-consensual DNA analysis for research concerning ‘disorders, or the functioning, of the human body’ is lawful under a specific exemption using collections made subsequently to the introduction of the Act on three conditions: the tissue donor is alive, the research has ethical approval, and the researcher cannot identify the

2006 covers only tissues obtained for transplant purposes or from deceased persons.

⁵³ JA Bovenberg, ‘Inalienably yours? The new case for an inalienable property right in human biological material: empowerment of sample donors or a recipe for a tragic anti-commons?’ (2004) 1 (4) SCRIPT-ed 553.

⁵⁴ Section 3(2) of the Human Tissue Act 2004.

⁵⁵ Part 1, Paragraph 6, of Schedule 1 to the Human Tissue Act (HTA) 2004.

⁵⁶ ‘HTA Code of Practice 1: Consent’ (Human Tissue Authority) at [117].

⁵⁷ HTA 2004, s 9. The relevant date is 1 September 2006.

⁵⁸ ‘HTA Code of Practice 1’, above, n 56 at [36].

⁵⁹ Nuffield Council on Bioethics (2011), above, n 19 at 204 [box 7.3].

⁶⁰ This section of the HTA 2004 also applies in Scotland.

donor.⁶¹ However, the HTA Code of Practice recommends once again that, where practicable, consent should nevertheless be obtained.⁶²

When research involves data from which individuals can be identified, it must comply with the provisions of the Data Protection Act 1998 (DPA 1998). The DPA 1998 regulates 'personal data' and, for the purposes of the Act, this excludes anonymised data.⁶³ The effect of the application of the DPA is that certain requirements and principles must be observed with respect to the 'processing' of the personal data, including its obtention, retention, and use.⁶⁴ Personal data can only be processed on a limited number of specified legal grounds, including consent. However, consent is only one of the sufficient conditions for lawful processing of personal data under the DPA 1998. If consent is sought and the processing involves 'sensitive data', a category to which health information belongs, then the consent must be 'explicit', which suggests a role for the written form. This additional condition is not required if the data are to be used for 'medical purposes'.⁶⁵ These include 'medical research' if the research is conducted by someone bound by the same kind of duty of confidentiality as a health professional.⁶⁶ Furthermore, the research exemption in the DPA 1998 permits personal data to be used for research purposes other than those for which they were originally collected; there is no obligation under the Act to re-contact participants to inform them of new research purposes and access to the data need not be given to the data subject even if requested.⁶⁷ Moreover, such data can be kept indefinitely. However, the research exemption only applies in limited circumstances provided

⁶¹ Part 2, paragraph 10 to Schedule 4 of the HTA 2004.

⁶² 'HTA Code of Practice 9: Research' (Human Tissue Authority) at [52]. It is relevant to note here that although exemptions from s 45 also apply to non-consensual DNA analysis for the purposes of clinical audit, education or training relating to human health and public health monitoring, there is no exemption for research conducted for non-health-related purposes.

⁶³ DPA 1998 s 1(1). Under the Act 'personal data' means data, which is held by a public authority or on an automatically searchable filing system, that relates to a living individual who can be identified (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

⁶⁴ Schedule 1 to the DPA 1998.

⁶⁵ Both the broad requirement for explicit consent for the processing of sensitive data and the exception in the case of data processed for medical purposes under the European Data Protection Directive 95/46/EC that forms the basis for the UK DPA 1998 have recently been reinforced by the Anonymous, 'Opinion 15/2011 on the Definition of Consent' (01197/11/EN WP187: Article 29 Data Protection Working Party) at 6, 25.

⁶⁶ Schedule 3 to the DPA 1998.

⁶⁷ DPA 1998, s 33(2).

the following conditions are observed: the data must not be processed to support measures or decisions with respect to particular individuals, nor should they be processed in such a way that substantial damage or substantial distress is (or is likely to be) caused to any data subject, and the results of the research or any resulting statistics must not be made available in a form which identifies data subjects.⁶⁸

The latest draft of the new Data Protection Regulation, if adopted in its present form, would continue to treat 'data concerning health' as sensitive data requiring special protection⁶⁹ unless the data were anonymised.⁷⁰ Moreover, handling of human tissue would now seem expressly to be caught by data protection⁷¹ and consent would, in all cases, require to be 'specific' and 'explicit'.⁷² Draft Article 4.8 makes it clear that:

'...the data subject's consent' means any freely given specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed;⁷³

This would mean in turn that both implied and opt-out options would not be a valid basis for processing data by consent and some form of positive act by the participant, such as signing a written consent form, would always be required. Such provisions might drive the written consent form culture all the more strongly. By the same token, if this type of consent is likely to be difficult to obtain—for example, in the biobank context—this does not mean that processing of data cannot be lawfully conducted. Rather, it means that consent cannot be the basis for this. To proceed without consent requires conformity with

⁶⁸ DPA 1998, s 33(1) and (4).

⁶⁹ Proposal for a new Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) Brussels, 25 January 2012 COM(2012) 11 final accessible at <http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf>.

⁷⁰ Draft Recital 23 and draft Art 83(1).

⁷¹ Draft Recital 26.

⁷² Draft Art 4.8. See further Recitals 25, 38, and 41 on the requirement that consent be 'explicit'. The only further elucidation offered is in para 3.4.1 of the Commission Proposal, n 69 above: 'In the definition of consent, the criterion "explicit" is added to avoid confusing parallelism with "unambiguous" consent and in order to have one single and consistent definition of consent, ensuring the awareness of the data subject that, and to what, he or she gives consent.'

⁷³ The change to a gender-inclusive approach arguably introduces an element of ambiguity regarding the meaning of 'them'.

draft Articles 81 and 83 that allow processing of data concerning health for research purposes so long as a series of requirements are met, including processing in the public interest. Discussion of this is beyond the scope of this article. Suffice to say that the draft Regulation is reflecting a somewhat traditional view of consent in the form of ‘written informed consent’ and threatens to create two parallel approval pathways for research which might simply add to the regulatory burden without any necessary gain in research participant protection. Equally, both the data protection regime—old and new—and the tissue regulation regime make considerable use of the ‘consent or anonymise’ paradigm whereby it is accepted that consent might not always be required *so long as* data or samples are sufficiently anonymised with respect to participants from whom they were obtained. We return to the significance of this presently.

B. Regulatory Requirements for Written Consent

There is a crucial distinction between a statutory obligation to obtain consent and a requirement that this be given in writing—there is no consistent policy or approach to this in legislation. Furthermore, we cannot assume that simply because consent has been documented in writing that this document has independent legal force, or that it is in some sense constitutive of the consent itself, rather than merely a record of a prior consent procedure.

The first of these distinctions is manifest in both the DPA 1998 and the HTA 2004. Even where these statutes do require consent for a particular research use of tissues or data, neither of them currently requires this to be given in writing. Although the definition of ‘explicit consent’ under the DPA 1998 remains somewhat ambiguous, it is considered advisable rather than obligatory that this be obtained in writing.⁷⁴ Under the HTA 2004, the only occasions in which an adult’s ‘appropriate consent’ must be given in writing is where this records the prior agreement of a deceased person for certain posthumous uses of their tissues.⁷⁵ The absence of statutory requirements for written consent under these two regimes may be contrasted with the provisions of the Human Fertilisation and Embryology Act 1990, as amended (HFEA 1990). Consent is a central pillar of the law governing assisted reproduction in the UK.⁷⁶ Under the HFE Act 1990, consent to the storage and

⁷⁴ Art 29 Working Party Opinion 15/2011 on the Definition of Consent at 25.

⁷⁵ HTA 2004, s 3, these uses include public display and anatomical examinations conducted on no-excepted materials.

⁷⁶ As confirmed most emphatically by the Grand Chamber of the European Court of Human Rights in *Evans v United Kingdom* (2007) 95 BMLR 107.

use (including research uses) of a human embryo, or storage of gametes, must be given in writing.⁷⁷

In terms of statutory consent regimes, the Clinical Trials Regulations 2004 (CTR 2004) contain perhaps the clearest available statement of the legal status of written consent forms in research. In this context, a person has given informed consent to take part in a clinical trial only if their decision to consent is informed and freely given *and* this is 'evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent' or, where they are unable to sign a document, their witnessed, oral consent is recorded in writing.⁷⁸ So lawful consent in the context of these Regulations must be written and the form is itself a legal document, not merely a contingent record of a discrete legal requirement. However, the CTR 2004 are not legally binding in other research contexts, such as non-interventional research using existing collections of tissues and data. This notwithstanding, these Regulations are of relevance in the context of our present discussion because it is the UK Department of Health's position that:

the operating procedures required by the EU [Clinical Trials] Directive and the Clinical Trials Regulations should also apply in general to the review by RECs [Research Ethics Committees] in the UK of all other health and social care research reviewed under GAFREC [the Governance Arrangements for Research Ethics Committees].⁷⁹

This means that as a matter of policy, if not law, the procedures required for clinical trials will also apply to the ethical review of all kinds of research.⁸⁰ We may infer that the benchmark for 'appropriate'

⁷⁷ Paragraph 1 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended).

⁷⁸ Paragraph 3 of part 1 to Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

⁷⁹ NRES SOPs v5.1, above, n 28 at 14. The Directive referred to here is Directive 2001/20/EC.

⁸⁰ Mason and Laurie, above, n 2 at 616; see also Annex 8 to NRES Information Sheets and Consent Forms Guidance, above, n 15 which also cites the International Conference on Harmonisation—Good Clinical Practice as authority for the necessity for the requirement to obtain written documentation for informed consent. The UK and Scottish governance frameworks for health and (respectively) social or community care research, which cover non-clinical non-invasive research, simply state that '[m]ost studies involving individuals must have appropriate arrangements for obtaining consent, and the [NHS] ethics review process pays particular attention to those arrangements.'; Department Of Health, 'Research Governance Framework for Health and Social Care' (2nd edn, 2005) at 7; CSO Scottish Executive, 'Research Governance Framework for Health and Community Care' (2006) at 5.

consent arrangements in any health and care research to which GAfREC applies will be determined with reference to the requirement for written consent under the CTR 2004.⁸¹ This is potentially significant in that the design and requirements of the clinical trials model of consent then become the expected ethical norm across the research spectrum. *Prima facie* this might look like a positive development if it means a greater ubiquity of practices that seek to respect autonomy. However, it might also have the unintended consequence of creating more widespread expectations that consent forms have some force in law and provide grounds for remedy if research departs from their terms. It might also perpetuate a particular kind of ‘culture of consent’ when, as we have seen in the context of tissue and data research, consent (let alone written consent) is not a legal requirement in all circumstances. This threatens to undermine the legitimacy of perfectly lawful research where consent practices more suitable for clinical trials are not followed. Moreover, it perpetuates a faith in the consent form and what it can deliver that is largely unfounded, not least because clinical trials research is of a very different nature to that involving data and samples. One illustration of which is the fact that the respective regulatory regimes for data and samples provide that in certain circumstances consent can be removed from the equation if research is to be conducted in an anonymised fashion.

C. *The Status of Regulatory Consent Forms as Evidence of Consent*

Where explicit consent is required by the statutory provisions outlined above, but there is no correlate legal requirement for written consent, then a signed document indicating the participant’s assent, for example to use of their tissues, would at most constitute evidence that appropriate, legally required consent procedures had been undertaken.⁸² In the context of the lawful processing of personal data, the Article 29 Working Party on Data Protection has advised that ‘oral consent may be difficult to prove and, therefore, in practice, data controllers are advised to resort to written consent for evidentiary reasons’.⁸³ This evidence may be admitted in civil proceedings where it can be ‘shown to form part of the records of a business or public

⁸¹ GAfREC applies to all health and social care research that falls within the remit of the NHS and the departments of health of the four UK administrations, Department Of Health, ‘Governance Arrangements for Research Ethics Committees: A Harmonised Edition’ (2011) at 9.

⁸² Nuffield Council on Bioethics, ‘Human Tissues: Legal and Ethical Issues’ (1995) at [6.21].

⁸³ Art 29, Working Party Opinion, above, n 74 at 25.

authority'.⁸⁴ The absence of such a form might indeed favour a claimant in civil proceedings as a prima facie indicator of sub-optimal procedures. Equally, where a tangible form exists, its evidentiary value can only imperfectly reflect the nature of the participant's act or (perhaps more properly) their intention in consenting. In the case of *AB v Leeds Teaching Hospital NHS Trust* (which preceded the HTA 2004), the consent form signed by a bereaved mother was cited as evidence that she had *not* imposed conditions upon a post-mortem examination carried out on her stillborn child.⁸⁵ Specifically, the terms of her consent had not precluded retention of the infant's organs by the hospital trust.⁸⁶ This illustrates the legalistic framing of the document as direct evidence of the categories of activities which had (or had not) been excluded by its signatory's consent. Nevertheless, illustrating the limitations of such evidence, in the instant case the judge speculated that the mother's emotional distress might have prevented her from calling to mind her existing knowledge of what a post-mortem entails, thus raising questions about her comprehension of that to which she apparently consented.⁸⁷

We are reminded of Lord Diplock's observation in *Sidaway* that consent 'is a state of mind personal to [the individual]'; albeit that this was said in the context of consent in a treatment setting, it has equal resonance here.⁸⁸ A signed form only proves that it was signed. Making a connection between the form as an evidentiary artefact and the intentions of the research participant depends on inference, the soundness of which will rely on the wider facts of any particular case. Even if this can be shown to capture accurately a participant's state of mind, it only does so at a single point in time. The standard response that participants can always withdraw at any time and for any reason if they change their mind is scarcely adequate if our concern is to maintain both trust and the continuity of the research relationship.⁸⁹

⁸⁴ Civil Evidence Act 1995, s 9(1). In Scotland, the equivalent provision may be found in the Civil Evidence (Scotland) Act 1988, s 5(1).

⁸⁵ [2004] 2 FLR 365, [2004] 3 FCR 324, at [105].

⁸⁶ However, in the instant case it was found that the clinicians had been negligent in failing to discuss with the parents the possibility of organ retention following post-mortem examination, so the consent forms were in effect documentation of negligent consent procedures. The relationship between consent forms and action in negligence is discussed further in section IV below.

⁸⁷ *AB v Leeds Teaching Hospital NHS Trust*, above, n 85 at [105].

⁸⁸ *Sidaway*, above, n17 per Lord Diplock at [658].

⁸⁹ For an account of the sources of this right and critical reflection on its existence, see GO Schaefer and A Wertheimer, 'The right to withdraw from research' (2010) 20 (4) Kennedy Institute of Ethics Journal 329.

D. Sanctions and Remedies following Violations of Written Consent

The key question for this paper is what legal consequences follow if research is conducted in ways that deviate from the terms of a consent form where one has been signed and fails to meet individuals' expectations about what will be done with their tissues and data. If investigators pursue research of a kind that is *prima facie* excluded by the terms of the consent form, then whether this form is of any consequence for regulatory purposes will depend on whether the particular research use is one requiring consent. If the answer to this question is affirmative, it is most likely that, under the consent requirements of the regulatory regimes outlined here, the terms of consent (as evidenced by the form) must be respected for fear of penalty or fine. But this does not mean that *all* research conducted beyond the limits of the consent form would necessarily result in sanction (the statutes only prescribe certain matters). Moreover, it does not follow that the aggrieved research participant *qua* individual has any remedy in law *even if* statutory requirements have not been followed.

For example, it is an offence punishable by fine or imprisonment for a researcher to undertake an activity falling under the HTA 2004 definition of a 'scheduled purpose' without the appropriate consent, or to conduct non-consensual DNA analysis.⁹⁰ However, the HTA 2004 does not provide any direct remedy for the individual who feels their interests have been harmed, for example, by research conducted outwith the terms of their written consent and thus affronting their autonomy. In the context of data protection, the UK Information Commissioner can serve data controllers with enforcement notices if satisfied that they have contravened any of the principles contained in the DPA 1998.⁹¹ Such a notice, however, only constrains the activities of the data controller and does not offer personal remedy to the individual. It is the case that a data subject who has suffered substantial distress or damage as a result of the data controller or other party contravening the DPA 1998 might be entitled to compensation under the Act. However, distress alone is insufficient grounds for compensation unless the data were processed for one of the 'special purposes', of which research is not one.⁹² A data subject might also give written notice to a data controller to require them not to process data in a

⁹⁰ Human Tissue Act 2004, ss 5 and 45.

⁹¹ Data Protection Act 1998, Part V.

⁹² 'Data Protection Act: Claiming Compensation' (Information Commissioner's Office 2007) <http://www.ico.gov.uk/upload/documents/library/data_protection/practical_application/claiming_compensation.pdf> accessed 13 November 2011; Data Protection Act 1998, s 3.

way that would cause substantial and unwarranted distress or damage. In other words, any person can alert a data controller of the strong likelihood that particular attempts to process particular data (as identified) will affect their interests and could result in a breach of the Act.⁹³ This does not mean, however, that a remedy in law will necessarily result. A court must still determine if the notice is justified (on application by the person) and if so can order a data controller to comply.⁹⁴

As noted above, written consent is required for most activities using reproductive materials to be lawful under the HFE Act 1990. As illustrated by the case of *Leeds Teaching Hospital NHS Trust v A and others*, the precise scope of the terms of the recorded consent is likely to be forensically applied.⁹⁵ In the instant case (which did not concern research), the consent forms signed by the husband and wife seeking treatment were used to determine the exact scope of that to which the husband had agreed.⁹⁶ The HFE Act 1990 creates an offence, punishable by fine or imprisonment, of creating or using embryos or storing or using gametes in ways that are not authorised under a licence.⁹⁷ Facilities may have their licences revoked if the person responsible is guilty of such an offence or fails to ensure that licence conditions or 'suitable activities' are adhered to, including obtaining appropriate consent.⁹⁸ However, once again no direct remedy is available to individuals under the HFE Act 1990 in these circumstances.⁹⁹

Under the CTR 2004, it would be unlawful to conduct a trial that departs from the terms of the consent form and supporting information documents as approved by the REC to the extent that this breaches the requirement that (barring emergency safety measures) authorised clinical trials must be conducted in accordance with the research protocol, the terms of the authorisation, the decision of the REC, and 'any particulars or documents' accompanying the application.¹⁰⁰ It is an offence to embark upon a trial without a favourable REC opinion or to provide the licensing authority or REC with 'any relevant information which

⁹³ Data Protection Act 1998, s 10.

⁹⁴ *Ibid* at s 10(4).

⁹⁵ [2003] All ER (D) 374 (Feb), [2003] EWHC 259 (QB).

⁹⁶ *Ibid* at [27]. The husband was found not to have consented to the accidental fertilisation of his wife's egg with a stranger's sperm, so under the terms of the Act was not the legal father of the resultant twins.

⁹⁷ Human Fertilisation and Embryology Act 1990, s 41.

⁹⁸ Human Fertilisation and Embryology Act 1990, s 18.

⁹⁹ The only direct remedy available to individuals is under the HFE Act 1990 s 44 which pertains to the civil liability to children born disabled due to acts or omissions on the part of the treatment facility.

¹⁰⁰ CTR 2004, Regulation 29. The consent forms comprise key elements of the information that must, under the CTR 2004, be supplied to the REC to inform their decision (Paragraph 3 of part 1 to Schedule 3).

is false or misleading'.¹⁰¹ However, as noted above, these regulations only provide an aspirational standard for health-related research other than clinical trials, so the sanctions available under them are of limited relevance to other kinds of health-related research. Furthermore, and as with other regulatory regimes, the CTRs do not provide individual research participant remedies but rather rely on the threat of criminal sanction to police the system.

All of this having been said, the requirement for REC approval is not restricted to clinical trials; it is needed for any research using NHS resources or involving NHS patients.¹⁰² However, the role of RECs in ensuring research proceeds according to existing consent terms can be limited. For example, tissue-banks may now apply for overarching up-front 'research tissue bank' approval, with only limited requirements to report back to RECs.¹⁰³ Furthermore, although the REC approval process is highly likely to include approval of consent documentation, it is not the REC's responsibility to offer a legal opinion on research proposals and RECs do not have any clearly established responsibility for projects after they have received approval.¹⁰⁴ RECs are not responsible for enforcement if research is not carried out as agreed; this is the role of the relevant regulator.¹⁰⁵ Yet, as we have seen, there are limits to what sanctions either the HTA or the Information Commissioner is able to impose. The new Health Research Authority is charged with both protecting participants' rights and facilitating and promoting health research.¹⁰⁶ No legislative instrument has yet addressed its powers of sanction. As to self-help, participants might claim for compensation under the law of tort and REC-approved trials must have adequate insurance and

¹⁰¹ CTR 2004, Regulations 12 and 50. For offences and penalties see Regulations 49 and 52.

¹⁰² GAFREC, n81 above, at 2.3.1–2.3.6.

¹⁰³ NRES SOPs v5.1, above n 28, at para 11.31c–d. A research tissue bank is defined as 'a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending' (NRES SOPs v 5.1 at 181–8). Although research tissue bank must be licensed by the HTA and approval must be renewed every five years, REC approval will not be required at an individual project level for studies using biobank resources.

¹⁰⁴ GAFREC, above, n 81 at [3.2.11]; S McGibbons, 'Mapping the Regulatory Space', in J Kaye et al (eds) *Governing Biobanks: Understanding the Interplay between Law and Practice* (Hart 2012) 51, 78.

¹⁰⁵ GAFREC, *ibid* at [3.2.15].

¹⁰⁶ The new Health Research Authority was established by The Health Research Authority Regulations 2011, SI 2011/2341, which came into force 1 December 2011 in the wake of the publication of the Academy of Medical Sciences, 'A New Pathway for the Regulation and Governance of Health Research' (2011). Its functions are laid out in the Health Research Authority Directions 2011 (1 December 2011).

indemnity arrangements to meet such claims.¹⁰⁷ However, as will be discussed further below, there have traditionally been barriers to bringing an action in tort if the harm suffered is neither material nor significantly affects the participant's mental or psychological integrity.

E. Gaps in the Protection of Participants' Interests

The above paragraphs indicate that there are only very limited opportunities for individuals to access direct legal remedy under the statutory regimes governing health-related research, including the lawful use of personal data or human tissue. The lack of remedy for non-consensual use of their samples becomes even more apparent when we attend to the limited legal requirements for consent. Consider the contentious issue of commercial uses of, and access to, research resources compiled using participant data and samples. What remedy, if any, might a participant have if she or he objects to this at a future stage? The consent form might or might not make mention of the potential for such commercial uses. If the terms of a consent form signed by a participant clearly and explicitly excludes these types of secondary uses of their tissues or data (that is, for 'commercial research'), but these uses fall outwith the requirements for consent under the DPA 1998 or the HTA 2004 (for example because the data or samples will be adequately anonymised), then these statutes would neither prohibit the research nor would they offer the participant any legal remedy if the excluded research were to go ahead. These statutory frameworks in themselves cannot deter or compensate for such research uses.¹⁰⁸ It has been noted that the presumption apparent in much professional research guidance¹⁰⁹—that anonymisation is sufficient to legitimise research

¹⁰⁷ NRES SOPs v 5.1, above, n 28 at [3.56] and Annex G.

¹⁰⁸ It is true that research ethics approval is a requirement for non-consensual medical research using tissues from living donors under the HTA 2004, and so we might reasonably doubt whether a Research Ethics Committee would approve a secondary research use that specifically went against the terms of the original consent, but what would be the position if the consent form was silent? A REC might require that re-consent is sought, although this is not always practicable; equally, it might adjudge that the research can proceed so long as data or samples are adequately anonymised. This is the classic 'consent or anonymise' approach as outlined earlier and discussed by the Academy of Medical Sciences (2006), above, n 4.

¹⁰⁹ General Medical Council, *Good Practice in Research and Consent to Research: Supplementary Guidance* (GMC, 4 May 2010); British Medical Association, *Confidentiality and Disclosure of Health Information Tool kit* available at <<http://bma.org.uk/practical-support-at-work/ethics/confidentiality-tool-kit>> accessed 11 August 2012; Royal College of Physicians, Royal College of Pathologists and British Society for Human Genetics, *Consent and Confidentiality in Clinical Genetic Practice: Guidance on Genetic Testing and sharing genetic Information*, 2nd edn, Report of the Joint Committee on Medical Genetics (RCP, RCPATH, London 2011).

without seeking further consent—fails to recognise that anonymisation (even if practically achievable to a degree sufficient to protect the participant's privacy interests) 'does not obviate an individual's wish to exercise control' over what may be done with their information or tissue.¹¹⁰ While the use of anonymised samples and data might not be unlawful, one practical consequence might be that this nevertheless undermines the trust relationship between researcher and research participant. The further consequences of this are axiomatic and include wholesale withdrawal of participants who no longer trust a project.

But in terms of legal remedies, the logically prior question is: what is the legal interest that might be harmed in such circumstances? In keeping with wider developments in medical law that display growing recognition of autonomy interests, we might judge that the entitlement of research participants to self-determination has been interfered with inappropriately because their expectations have not been met, because the basis upon which they agreed to participate has not been respected or perhaps simply because there has been a unilateral change in 'the rules of the game' by the researcher. However, where there is no regulatory requirement to obtain consent or to do so in particular terms, the consent form has no legal teeth.

Whether a legal remedy is available for harm to participants' interests on different grounds is another matter. We do not, yet, have a stand-alone right to respect for individual autonomy—that is, a recognised remedy for mere affront to autonomy in circumstances when choices were not respected, expectations not met or full options not disclosed.¹¹¹ This notwithstanding, two further possible routes present themselves. The first is to consider the consent form as contract and the second is an action in negligence. We now turn to the former through an examination of recent jurisprudence recognising property interests in human samples; contract being the primary means by which property dealings are regulated.

III. THE CONSENT FORM AS A BASIS FOR ALLOCATING PROPERTY RIGHTS: THE PSEUDO-CONTRACT

A. Tissue Samples as Property

The position in the UK regarding property rights in tissues obtained from living persons is unclear and evolving, although at common law

¹¹⁰ Laurie, above, n 3 at 110, 294; quoted section is from Grubb et al, above, n 50 at [13.98].

¹¹¹ Note that a state's failure to provide adequate remedies for the protection of interests caught by the European Convention on Human Rights can be grounds for citizen action: *Pretty v UK* (2346/02) [2002] 2 FLR 45, (2002) 35 EHR 1 at [61].

tissue donors have not historically been treated as having property rights or interests.¹¹² The HTA 2004 does not itself preclude the possibility of property in human tissue. Although it prohibits commercial dealings in ‘controlled material’ (ie tissues intended for transplant), it equally reflects the common law position by permitting property in tissue where there has been an application of human skill.¹¹³ This, of course, implies that property accrues to the person who carries out such work and not necessarily to the source of the material unless this is one and the same person.

The case of *Yearworth and others v North Bristol NHS Trust* has introduced the possibility that living donors might have property rights in their own tissues or at least in their own reproductive material.¹¹⁴ It concerned the accidental destruction of semen samples stored for reproductive purposes on behalf of men undergoing cancer treatment. If this judgment can be extended beyond its own facts and applied to tissue samples in research contexts,¹¹⁵ then it might provide the basis for recognising participants’ property rights in donated samples.¹¹⁶ The consequences for the status of the consent form in such an eventuality include the possibility that it becomes the legal vehicle for the transfer of said property, operating in a dispositive, contractual, or pseudo-contractual fashion.

We have reflected previously on the respective roles of consent and property rights in the context of legitimate uses of human tissue and suggested that recognition of property rights in human tissue potentially

¹¹² Grubb and others, above, n 50 at [19.61]; SHE Harmon and GT Laurie, ‘*Yearworth v. North Bristol NHS Trust*: Property, Principles, Precedents and Paradigms’ (2010) 69 (3) *The Cambridge Law Journal* 476, 484.

¹¹³ HTA 2004, s 32(8) and s 32(9)(c). The common law position is probably best reflected by the case of *R v Kelly* [1999] QB 621 which recognised property in human materials taken without authorisation and so constituting theft under the Theft Act 1968. The caveat here is that the recognition of property might be couched in terms of the 1968 Act itself and not necessarily as a general principle. The point remains moot.

¹¹⁴ [2009] EWCA Civ 37, [2009] All ER (D) 33 (Feb).

¹¹⁵ Cf S Cordell and others, ‘Lost Property? Legal Compensation for Destroyed Sperm: A Reflection and Comparison Drawing on UK and French Perspectives’ (2011) 37 (12) *Journal of Medical Ethics* 747 and B Lyons, ‘“The Good that is Interred in Their Bones”: are there property rights in the child?’ (2011) 19 (3) *Med L Rev* 372.

¹¹⁶ This extension remains to be tested in law. It has been observed that by logical extension, the Court’s reasoning in *Yearworth* could be applied to other bodily tissues, or even whole removed organs and body parts, see M Quigley, ‘property: the future of human tissue?’ (2009) 17 (3) *Med L Rev* 457. However, it has also been noted that the wording of the decision gives little direction as to which, if any, other types of tissues it might legitimately be extended, see S Harmon, ‘*Yearworth v North Bristol NHS Trust*: a property case of uncertain significance?’ (2010) 13 (4) *Medicine, Health Care and Philosophy* 343.

provides a more effective means of protecting donors' autonomy than consent alone.¹¹⁷ We have argued that in a research context, property rights would establish a strong justiciable legal interest on the part of participants to exercise control over how their tissues might be used.¹¹⁸ The aim of the current discussion is not, however, to contrast consent and property in this way. Rather, our intention is to explore the role that consent forms might play in defining the nature and limits of this 'strong justiciable interest', as it applies to participants who donate tissues for research.¹¹⁹ The parameters of any such property paradigm are likely to be set within the frame of existing precedents; it is important, then, that this frame is considered.

B. Bailment of Tissues: Legal Requirements for Consent or Other Formalities

In *Yearworth*, the Court of Appeal found that the hospital providing storage for the sperm samples was providing a service of 'gratuitous bailment' of the men's property.¹²⁰ A bailment arises when one party (the bailor) voluntarily hands over possession of their property to another (the bailee) without relinquishing their property rights. The bailee assumes responsibilities in respect of the safekeeping of the property while in their possession. These may include a duty to take reasonable care of the material in line with any special skill they have presented themselves as having, or promises they have made to the bailor.¹²¹ Bailment does not depend on the existence of a formal written document, such as a consent form. Nor is there a requirement for the legal relationship between bailor and bailee to be based in contract; it can be established simply by the voluntary transfer of possession.¹²² Nevertheless, the overlap between bailment and contract has been long-recognised.¹²³

¹¹⁷ K Mason and G Laurie, 'Consent or property? Dealing with the body and its parts in the shadow of bristol and alder hey' (2001) 64 (5) *The Modern Law Review* 710.

¹¹⁸ Harmon and Laurie, above, n 112 at 492; Mason and Laurie, above, n 2 at 452.

¹¹⁹ Ursin has argued that if research participants are recognised as having property interests in the tissues that they provide to biobanks, then the consent form holds the potential to be transformed from 'a confusing statement of autonomy and altruism, dependent on the vagueness of trust' to a more transparent and concrete contract protecting participants' property interests, see LO Ursin, 'Privacy and Property in the Biobank Context' (2010) 22 *HEC Forum* 211, 219.

¹²⁰ *Yearworth*, above, n 114, at [48].

¹²¹ *Ibid.*

¹²² *Yearworth*, above, n 114, at [59(h)].

¹²³ *Sandeman Coprimar SA v Transitos y Transportes Integrales SL* [2003] EWCA Civ 113, [2003] QB 1270, 'The principles of the law of bailment have always overlapped with those of the law of contract, for bailment and contract often go hand in hand.' per Lord Phillips MR at [63].

The Court of Appeal in *Yearworth* held that the storage arrangements in this case were ‘closely akin to contracts and should fall within the ambit of these principles’.¹²⁴ In the instant case, the forms signed by the men consenting to the storage of their sperm were one of three sets of documents produced as evidence before the Court of Appeal (alongside the storage request form they had signed and a document stating the commitments made by the health trust in respect of the conditions of storage and level of care the men could expect).¹²⁵ The Court found that donors, as the owners of the sperm samples, were entitled to damages for the loss of their sperm ‘akin to that referable to breach of contract’ because the health trust responsible for their storage had breached specific commitments made in these documents.¹²⁶ That is, the court found legally enforceable obligations arising from the documentation, including the consent forms.

The consent form might therefore, as in *Yearworth*, constitute part of the legal documentation of a pseudo-contractual relationship between the parties to a transfer of human tissue as property in bailment. This form and the terms in which it is framed would then provide evidence of the underlying agreement between the parties and thus serve to regulate the relationship between them by setting out the nature and conditions of this agreement.¹²⁷ If a consent form is treated as establishing the scope of the bailment of tissues donated for research, then any research purposes excluded by its terms would establish important limits of this relationship, at least with respect to the samples. Therefore, should researchers pursue such excluded purposes, the consent form could provide grounds for remedies related to bailment, or indeed more traditional remedies for breach of contract.

Questions arise about the limits to the transitivity of the relationship between bailor and bailee where the person or organisation responsible for collecting and taking possession of the original samples and obtaining written consent might not be the same as the person or organisation conducting the research. This is a particularly pertinent issue in complex longitudinal projects, such as biobanks. Contracts are normally only valid with respect to the legal persons between whom they are concluded.¹²⁸ This notwithstanding, it is possible in law for a third party

¹²⁴ *Yearworth*, above, n 114, at [57].

¹²⁵ *Yearworth*, *ibid* at [6].

¹²⁶ *Yearworth*, *ibid* at [48(i)], [58], [60].

¹²⁷ NE Palmer, *Bailment* (2nd edn, Sweet & Maxwell 1991) Ch 1, Parts IV(B) and (VI).

¹²⁸ According to the doctrine of privity of contract, *Price v Easton* (1833) 4 B and Ad 433 *Tweddle v Atkinson* (1861) 1 B and s 393.

to undertake sub-bailments.¹²⁹ The consent form (and accompanying information documentation) might therefore provide important evidence as to which parties the relationship of bailment extends and to whom any remedy might be due. To the extent that this provides a degree of traceability with respect to samples and their use, it might serve a helpful purpose both with respect to lines of communication—that is, who must keep who informed of which uses—and also accountability for any downstream exploitation of donated samples. Mechanisms which facilitate these objectives can assist in instilling trust in the research process by identifying parties involved and providing means to determine whether they are indeed trustworthy.¹³⁰

C. *Bailment in Research Contexts: Obligations and Limits*

It is, however, open to question whether transfer of possession of human tissue for research purposes, for example when donated to a tissue-bank, would qualify as bailment. In the US case of *Washington University v Catalona et al*, the District Court held that the relationship between researcher and participants could not be of this kind.¹³¹ The first reason given by the Court was that ‘the medical research community itself

¹²⁹ Whether this then gives rise to a pseudo-contractual relationship between the original bailor and the third party will depend on the bailor having consented to the sub-bailment. Without this consent, the original bailee (the legal person responsible for obtaining the samples and consent) occupies a position of co-bailor with the donor. The law on sub-bailment is not wholly clear or consistent in the relevant legal authorities. The original case is *Morris v C. W. Martin & Sons Ltd* [1966] 1 QB 716 (CA). A more recent case concerning sub-bailment on terms is *KH Enterprise v Pioneer Container* [1994] 2 AC 324, [1994] 2 All ER 250, para 257, although this is not strictly an authority in English law. A more recent authority affirming the significance of the bailor’s consent in creating a relationship them and the sub-bailee may be found in *Sandeman Coprimar SA*, above, n123.

¹³⁰ Questions about the possible limits to bailment of human tissues should not distract us from the fact that human tissues can be, and are, held on behalf of their ‘owner’ under more straightforward contractual arrangements. This kind of arrangement may be seen in circumstance where commercial storage of umbilical cord blood is carried out on behalf of parents on the chance that the blood might be a future source of therapeutic stem cells. See GJ Annas, ‘Waste and longing—the legal status of placental-blood banking’ (1999) 340(19) N Engl J Med 1521. Annas observes, in the context of commercial placental-blood banking in the USA, that such contracts record the parent’s consent to certain uses of the banked tissue, but may also impose contractual conditions of questionable ethical defensibility such as indemnity clauses.

¹³¹ *The Washington University, Plaintiff v William J. Catalona, et al., Defendants*. 437 F. Supp. 2d 985; 2006 US Dist., United States District Court For The Eastern District Of Missouri, Eastern Division, Case No 4:03CV1065SNL, at 44–6. This case, including its conclusions regarding bailment, was affirmed by the (Federal) Court of Appeals for the Eighth Circuit, *Washington University v Catalona* 490 F.3d 667 (8th Cir. 2007).

has never considered the relationship between an RP [research participant] and a medical research institution to be one of bailment'.¹³² This, however, is merely a matter of convention and not law. Conventions can, and do, change. The second reason given was that bailment implies an expectation that the property will be returned.¹³³ This reasoning was called into question by the English Court of Appeal in *Yearworth* where it was noted that contractual bailment does not always require the property be returned to the bailor.¹³⁴ Nevertheless, the factual circumstances of *Yearworth* were such that there was a clear expectation that that the sperm be returned for reproductive purposes. This also possibly suggests that if an intention of return—or at least one of continuing control—is communicated, perhaps through the consent form, then the type of limits set by *Catalona* could be distinguished. A more legalistic approach to the consent form as pseudo-contract in which terms and conditions need to be specified might, then, come to be the vehicle by which expectations and obligations are communicated and embodied in law.

There are other limitations of the bailment paradigm that could prove less favourable to the legalistically minded research participant. It is the nature of tangible research resources such as banked tissues that they are depleted through their use, for example as samples are used for the extraction of DNA or to create cell cultures. This means that their donation might be seen to fall outwith the normal conditions of bailment whereby the bailee is responsible for the temporary safe-keeping of the property.¹³⁵ Thus obligations under the bailment paradigm might not arise at all. Furthermore, even if it can be shown that there exists a legal relationship of bailment, the participant's legal property rights in samples would not extend to new products derived from their tissues, such as the products of genetic analysis or cell cultures. It is well established in English law that property interests can be acquired by those who apply skill to human tissues such that it acquires new attributes.¹³⁶ This consideration is particularly germane to research contexts. The materials that may be of greatest use for research purposes, or consequent commercial exploitation, are likely not to be the original donated samples, but the products of these or of an aggregated research resource comprising multiple individuals' donations from which are created something greater than the sum of its parts. To quote the old

¹³² *Catalona* (US Dist), *ibid* at 45.

¹³³ *Ibid*.

¹³⁴ *Yearworth*, above, n 114, at [48].

¹³⁵ *Gilchrist Watt and Sanderson Pty Ltd v York Products Pty Ltd* [1970] 1 WLR 1262.

¹³⁶ *Grubb and others*, above, n 50 at [19.66]; *Doodeward v Spence* (1908) 6 CLR 406.

cliché from *Moore*: these materials are likely to be both ‘legally and factually’ distinct from the individual samples provided.¹³⁷ This would considerably restrict the reach of any excluded research uses set out in consent forms, insofar as these operate as pseudo-contractual bases of property rights, to the ‘unprocessed’ donated tissue samples only.

D. Tissue Samples as Gifts

It is common research parlance in consent forms to talk of samples and other contributions as gifts. The metaphorical power of this is self-evident, but what does it imply in legal terms if property does indeed exist and consent forms are to act as a dispositive instrument with respect to research contributions *qua* gift? The role of intention is key here, as identified by the Nuffield Council on Bioethics which has offered the view that:

... tissue removed in circumstances other than treatment, which is voluntarily donated, will be regarded as a gift. Use for purposes other than those for which consent was given could give rise to a claim on the part of the person from whom the tissue was removed. Such a claim will depend on the terms of the original consent.¹³⁸

The concept of donations as gifts, the use of which may be limited by the conditions established through consent, remains at the heart of the Council’s more recent report on the donation of bodily materials.¹³⁹ However, as that report observes, the control afforded by consent will at best be the negative power to preclude certain uses. It does not supply the positive freedom for participants to specify desired uses.¹⁴⁰

Salutary lessons come once again from across the Atlantic. In *Catalona*, the District Court found that the research participants had unconditionally gifted their samples to the University, meaning that the University had exclusive property rights in the samples.¹⁴¹ In this case the terms of participants’ consent forms, including the use of the word ‘donation’ and of logos indicating the University was the organisation seeking consent, were crucial in the Court’s decision that the tissues had been gifted to the University.¹⁴² While the Court acknowledged that a written document was not required under State law to establish a gift relationship *per se* (this is established by the three conditions of

¹³⁷ *Moore v Regents of the University of California* (51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479).

¹³⁸ Nuffield Council on Bioethics (1995), above, n 82 at [9.14].

¹³⁹ Nuffield Council on Bioethics (2011), above, n 19 at 124–5.

¹⁴⁰ *Ibid* at 151.

¹⁴¹ *Catalona*, above, n 131.

¹⁴² *Ibid* at 33.

intention to make a gift, delivery, and acceptance), the existence of documented 'legally effective consent' is required under federal regulations governing research using human tissue and the terms became of material import as a result.¹⁴³

In the UK, as we have seen, obtaining written consent is only a legal requirement for lawful participation in a clinical trial. It is only best practice in other kinds of research involving human participants. Furthermore, under English law, a written document stating the donor's intention in giving is not a necessary condition for an effective gift, provided there is physical delivery of the goods to recipient and there is sufficient evidence of the requisite intention.¹⁴⁴ The robustness of a gift transaction depends entirely on evidence of the clarity of the donor's intention.¹⁴⁵ In Scots law, for example, implied consent to making a gift will not be sufficient, there must be convincing evidence or proof of an intention to donate.¹⁴⁶ Thus, although not necessary, a consent form would be highly persuasive in this regard, if not determinative if the reasoning in *Catalona* were followed. This is particularly significant because there are growing instances of consent forms for UK-based research explicitly stating that participants' samples will be regarded as a gift.¹⁴⁷ This may be compared with the *Gillberg* judgment discussed earlier, which provides some indication that in a European legal context, in the absence of evidence to the contrary, participants' personal data might be assumed to be the property of the research institution.¹⁴⁸ Factors such as these betray a power imbalance which belies the putatively empowering nature of the consent process. It is not current convention for research participants to negotiate or bargain over the terms upon which they participate in research. The consent form is invariably presented as an all or nothing affair. A signed consent form might not, therefore, accurately reflect participants' intentions or expectations. If, however, rulings such as *Catalona* and *Yearworth* focus attention on the consent form for its probative value,

¹⁴³ Ibid at 35; Code of Federal Regulations 45 CFR Part 46: Federal Policy for the Protection of Human Subjects ('The Common Rule').

¹⁴⁴ In English law, a gift requires a clear intention on the part of a donor to donate and either physical delivery of the goods or the execution and delivery of a deed or the effective declaration of a trust that will make a promise to give binding, M Bridge, *Personal Property Law* (3rd edn, Clarendon Law Series, Oxford University Press, 2002) at 94.

¹⁴⁵ Ibid; *Cochrane v Moore* (1890) 25 QBD 57; *Dewar v Dewar* [1975] 1 WLR 1532 (CA).

¹⁴⁶ Stair Memorial Encyclopaedia, *The Laws of Scotland*, Donation (reissue) 6. Animus Donandi at [21] Reliability of Evidence; Laurie, above, n 3 at 313.

¹⁴⁷ Boddington and others, above, n 25 at 504.

¹⁴⁸ *Gillberg v Sweden*, above, n 40 at [87] and [93].

this will further reinforce the legalistic as opposed to metaphorical role that they play. A consequence might be a move to more confrontational engagement around the terms of consent forms as a matter to be negotiated rather than as an expression of trust and a willingness to engage in the research proposition.

E. Available Remedies Based on Property Rights

Although gifts are perhaps most commonly thought of as unconditional, in law they can be conditional and revoked upon breach of specified conditions, with ownership reverting to the donor.¹⁴⁹ There are complex rules about the kinds of conditions that can be placed on gifts—for example, it is not possible to prevent alienation of the property—and public policy also has a role to play. This might be relevant, for example, if a court were to take the view that overly restrictive conditions were not in the public interest which supports freedom of research. Subject to these caveats, however, if a valid condition of gifting as detailed in a consent form is breached, the gift will be treated as if it had never occurred and the property must be returned.¹⁵⁰

Where a gift is conditional, or where the transfer constitutes bailment, and the donor retains some property interests in their goods, there might be scope for remedy under the common law tort of conversion.¹⁵¹ One of the accepted legal grounds for an action in conversion is that the goods have been dealt with ‘in a manner inconsistent with the rights of the true owner’.¹⁵² If we accept that written consent constitutes a pseudo-contract establishing the scope of the participant’s property interests, then research uses that conflict with the terms of the consent form could be deemed to constitute unlawful interference with the participant’s property rights.¹⁵³ This could then provide grounds for action

¹⁴⁹ R Chambers, ‘Conditional Gifts’, in N Palmer and E Mckendrick (eds) *Interests in Goods* (2nd edn, London LLP 1998) 430.

¹⁵⁰ *Re Macleay* (1875) LR 20 Eq 186; Bridge (n 116) 99.

¹⁵¹ See D Sheehan, *The Principles of Personal Property Law* (Hart 2011) Ch 8, Part II; see also Palmer, *Bailment*. Ch 3 Part III.

¹⁵² *L. & Y. Ry Co. v McNicoll* (1919) 88 LJKB 601, per Atkin J approved by Scruton LJ in *Oakley v Lyster* [1931] 1 KB 148, at [153].

¹⁵³ The US case, *Evanston Insurance Company v Legacy of Life Inc*, Court of Appeal 5th Cir 2011645 F.3d 739 (2011) concerned matters raised by an underlying legal action brought by the daughter of a deceased woman on the grounds that the company, to which the deceased woman’s estate had donated her organs and tissues for non-profit research, had breached the conditions of consent by using these for commercial purposes. The lawsuit in which the daughter sought to argue this amounted to theft of property has been settled by confidential agreement (see fn 4 of the above case report). Upon referral of the separate question of whether, for the purposes of the company’s insurance coverage, the use of the donated tissues constituted damage to property, the Supreme Court of Texas held that loss of the use of tangible property does not include the loss of use of the mother’s

based in conversion.¹⁵⁴ According to the separability requirement, a thing will only meet the necessary conditions for an action in conversion if it has the necessary property of separateness from the body.¹⁵⁵ It has been argued that excised body parts may meet this condition.¹⁵⁶ If there is found to have been unlawful conversion then a research participant may be due remedy in the form of return of their 'goods', as well as or in place of damages, under the Torts (Interference with Goods) Act 1977.¹⁵⁷ The doctrine of specification in Scots law, meanwhile, offers the possibility that the original source of property may be entitled to compensation for the loss of that which has become irreversibly altered without their consent, such that it has become a new entity precluding the return of the original property.¹⁵⁸ However, neither return of the original tissue samples nor compensation may adequately address the interests of participants insofar as neither of these remedies will preclude the on-going use of research products already derived from the participant's tissues and data which, as noted above, are most likely to be found to be the property of those responsible for their skilled production.

tissues by the daughter or her mother's estate (*Evanston Insurance Company v Legacy of Life, Inc.*, No 11-0519 (Tex. Supreme Court, 29 June 2012) online report available here <<http://www.supreme.courts.state.tx.us/historical/2012/jun/110519.pdf>>).

- ¹⁵⁴ It is sufficient that the person in possession of the goods acts in such a way as to deprive the claimant of their property rights in the goods, this must be through action not omission, but harm need not be intended. Because a claimant must retain immediate possessory rights to be able to sue in conversion, this action is unlikely to be available to a research participant whose consent form recorded that they had relinquished these, see Sheehan, above, n 151 at Ch 8 Part II.
- ¹⁵⁵ *R v Bentham* [2005] UKHL; [2005] 1 WLR 1057 'One cannot possess something which is not separate and distinct from oneself. An unsevered hand or finger is part of oneself. Therefore one cannot possess it.' per Lord Bingham at [8].
- ¹⁵⁶ RJ Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control* (Hart 2007) 161; JE Penner, *The Idea of Property in Law* (Oxford University Press 2000) 122.
- ¹⁵⁷ It has been suggested that the courts would be more likely to order return of biological materials to their source than to award damages, given the personal nature and likely lack of market value of such materials. Hardcastle, *ibid* at 163.
- ¹⁵⁸ Stair Memorial Encyclopaedia, *The Laws of Scotland*, 11 'Corporeal Movable Property, (5) Original Acquisition of Ownership of Corporeal Movable Property (g) Specificatio or Specification'. The doctrine of specification does not exist as such in English law, but an approximate equivalent may be identified in some older texts. There is precedent law for extending the doctrine of specification to include living organisms, albeit not human tissue (*Kinloch Damph Ltd v Nordvik Salmon Farms Ltd* (Outer House, Court of Session, 30 June 1999) unreported—available here <<http://www.scotcourts.gov.uk/opinions/ca291499.html>>—cited in Hardcastle, above, n156 at 166).

We can see then that a consent form could operate in a variety of ways if property in research samples is recognised as accruing in the first instance to their original source. No written or formal document is necessarily required for a gift or bailment to have been made in law. However, where such a form exists, it might function as documentation of the nature and scope of a contract-like legal arrangement between the donor and the recipient, including any conditions placed upon the donation by the donor. If the terms of this pseudo-contract are then violated by the researcher, for example by the pursuit of research outwith the terms of the written consent, then the donor might have grounds for a range of legal remedies. The one serious, and obvious, limitation here is the very real possibility of waiver. An increasing number of research projects now specifically include a term in the consent form stating that property is transferred or any rights waived. Unless means are instituted to prevent this happening, the role of consent form as pseudo-contract is likely to be very limited in practice. This could be addressed relatively easily by legal provisions akin to those in the Unfair Contract Terms Act 1977 (as amended) whereby specific restrictions or exclusions of liability would simply be illegal in a research relationship.

More fundamentally though, this route involving the consent form as pseudo-contract results in a remedy for breach of contract that reduces the concern to the contractual moment. This, we contend, fails to capture the more deep-seated concern about the breach of trust that occurs when the research relationship breaks down. It also suggests that contract-like remedies such as return of property or damages satisfactorily address the underlying harm. This is not so if the interest lies in the specific implementation of what was promised, that is, to conduct the research in trustworthy fashion and to deliver valuable findings.

IV. THE CONSENT FORM AS THE BASIS FOR ACTIONS PROTECTING AUTONOMY

A. The Role of Consent Forms in Establishing Negligence: Legal Requirements

When the research uses of a participant's voluntarily donated tissues or data depart from the purposes that she or he might expect (either because consent for these was never sought, or because these uses were clearly excluded by the consent that was obtained), it falls to be considered whether there is negligence on the part of the researcher. That is, has the researcher in some way breached a duty of care to the participant and does this result in a harm for which damages are due? The following analysis considers the standard criteria for a successful negligence action but in the context of thwarted expectations. That is,

can a departure from consent terms (or subjective expectations) provide a justiciable basis for a remedy in negligence against the researcher when the affront is in effect a breach of trust?

B. Establishing a Duty of Care

Where researchers are also clinicians, with attendant professional duties, the existence of a duty of care in respect of participants' health is unambiguous.¹⁵⁹ Research and experimentation are often conducted within the clinical setting and this will delimit the duty and the boundaries of appropriate conduct. Where this is not so, a common law duty of care will arise in a research relationship provided that it is not unreasonable to impose one, harm is reasonably foreseeable, and there is sufficient 'proximity' in the relationship between the parties.¹⁶⁰ A duty of care might also arise if there is a contractual relationship.¹⁶¹ This can be important in the context of healthy volunteers and private research organisations and might be of increasing importance in the future in light of the discussion in section III above. However, even in the absence of an explicit contract, any consent form will undoubtedly be scrutinised for evidence of the requisite relationship between researcher and participant to found a duty of care in tort.¹⁶² For example, in the US case *Grimes V Kennedy Krieger Institute, Inc.*, the research consent form was regarded both as evidence of a close relationship and of a contract between the researchers and participants—each of these giving rise to a duty of care.¹⁶³

In the UK, a straightforward application of the general principles of a duty of care is likely to yield the same result, viz, that researchers most certainly owe such a duty to their research participants when there is a consent form provided by the first party and signed by the second.¹⁶⁴

¹⁵⁹ HS Richardson and L Belsky, 'The ancillary-care responsibilities of medical researchers: an ethical framework for thinking about the clinical care that researchers owe their subjects' (2004) 34 (1) *Hastings Center Report* 25.

¹⁶⁰ These are the conditions of the 'Caparo test', *Caparo Industries plc v Dickman* [1990] 2 AC 605.

¹⁶¹ Mason and Laurie, above, n 2 at 133–4.

¹⁶² See eg *Goodwill v Goodwill Pregnancy Advisory Services* [1996] 2 All ER, [1996] 7 Med LR 129; *Vowles v Evans* [2003] 1 WLR 1607, CA; *Fairlie v Perth and Kinross Healthcare NHS Trust* 2005 SLT 1200 (OH)—these cases address the necessary characteristics of relationships giving rise to duty of care, rather than the specific facts of research relationships.

¹⁶³ *Grimes v Kennedy Krieger Institute, Inc.* 366 Md 29, 782 A2d 807 (2001) at [842]–[843]; G Johnson, 'Grimes v Kennedy Krieger Institute, Inc: The Court of Appeals Maryland distinguishes special relationships that may arise to the level of a contractual relationship between researchers and non-therapeutic research participants' (2001) 9 *University of Baltimore Journal of Environmental Law* 75.

¹⁶⁴ Though it is worth noting that the European Court of Human Rights rejected the proposition that the applicant in *Gillberg v Sweden* (above, n

This will be harder to establish in cases where research is conducted on anonymised data and samples.¹⁶⁵ There are no precedents on this point and a court faced with the scenario might find it counter-intuitive to hold that researchers have a duty of care to individuals whose identity is unknown to them. Proximity is likely to be a pivotal consideration, with duties of care more likely to arise with respect to intermediary authorising bodies, such as research ethics committees, tissue bank custodians, or data controllers, rather than researchers themselves.

Assuming a duty of care can be established, it must then be determined what *standard* of care it would be reasonable to expect from researchers and which acts or omissions might be said to breach this standard. In particular, we can ask whether researchers' duties might reasonably be said to extend beyond protecting the immediate health and bodily integrity of participants to respecting participants' interests in exercising their autonomy over the use of their samples or data, as suggested earlier.

C. The Role of Consent Forms in the Expected Standard of Care: Legal Obligations

The consent form, insofar as it details commitments made by the researchers to participants and creates expectations about the limits to permissible research uses, might itself be seen as embodying the standard of care that the research participant is *reasonably* entitled to expect. The form would then function as the benchmark against which any breach of this standard leading to harm might be assessed. For example, in *Yearworth* (although this case did not concern a research relationship), the Court of Appeal had recourse to lodged documentation, including the appellants' consent forms and accompanying documents containing specific commitments by the hospital trust to the men about the way their semen would be stored. It was held in part that this gave rise to particular responsibilities in looking after this property.¹⁶⁶ In this context, the precise terms of the consent form become markers of the expected standard below which care is likely to be seen as negligent. This is no different to the approach in information disclosure negligence actions in the wider treatment context, albeit that the actual legal standard that is required is always context specific;

40 at [96]) owed a professional duty of confidence to his research participants, despite his written commitments to them assuming such a duty, as they had not appointed him to be their doctor.

¹⁶⁵ A related complex question is who would owe a duty of care when there might be a chain of researchers dealing with (anonymised) data and tissues and who have no direct relationship with the research participants.

¹⁶⁶ *Yearworth*, above, n 114, at [13].

it is set by the *Bolam* principle for determining professional misconduct.¹⁶⁷

According to *Bolam*, the standard of care to which someone will be held is that of 'the ordinary skilled man exercising and professing to have that special skill'.¹⁶⁸ There are few indications of how this would apply in the research context. We have suggested elsewhere that the CTR 2004 provide a clear benchmark for the standards expected in clinical trials, such that harm arising from departure from these regulations could found a successful negligence action.¹⁶⁹ As outlined above, the research governance frameworks for health and care research require all health-related research to mirror the statutory requirements of the CTR 2004, at least with respect to best practice and the consent form. If this is indeed taken to establish the benchmark outwith the strict confines of clinical trials, then it would mean that only those studies that proceed with valid written consent and in accordance with the information contained in the research documentation approved by a REC would meet the expected professional standard of care among researchers. On this reasoning, research practices might be seen as negligent where they fall below the broad standard of adhering to the practices and documentation that have been approved by a REC. However, we cannot assume that RECs will always be involved, particularly in cases where anonymised data and sample research are involved or in cases where consent has not been sought. In both circumstances, the courts would have to look to the research 'profession' to determine what the 'ordinary skilled man' would do. Consider, for example, *Simms v Simms and Another* which dealt with the lawfulness of highly experimental treatment in incapacitated patients.¹⁷⁰ In this case, there was no consent form and the matter fell to be decided on the basis of responsible professional opinion; this was held to be satisfied on evidence from three professionals that they would be willing to proceed despite the fact that there was no body of opinion in the field. This raises a dichotomy for the courts in establishing appropriate standards of care. The CTR route is clearly appropriate when research involves physical contact and where the written consent form is the

¹⁶⁷ *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118, para 121. Johnston and Kaye have suggested that UK Biobank could have a duty of care such that it would be negligent in not feeding back to participants' incidental findings of serious treatable conditions uncovered in the course of research, C Johnston and J Kaye, 'Does the UK biobank have a legal obligation to feedback individual findings to participants?' (2004) 12 (3) Med L Rev 239, 261.

¹⁶⁸ *Bolam*, *ibid* at [121].

¹⁶⁹ Mason and Laurie, above, n 2 at 620.

¹⁷⁰ *Simms v Simms and Another* [2003] 2 WLR 1465.

norm; but research itself takes many forms and *Simms* highlights the importance of professional opinion or custom in cases where consent has not been obtained or in other instances outside the CTR regime. While the courts will always be ultimate arbiters of appropriate standards, the relevance of this lies in how far professional research custom or practice—for example by including or excluding particular terms in a consent form or, indeed, seeking consent at all—will hold sway in setting professional standards. Consider the words of JS Mill: ‘He who does anything because it is the custom, makes no choice.’¹⁷¹

Even if a claimant is successful in convincing a court of the existence and breach of a duty of care, there remains the significant hurdle of being able to fit her or his claim into the accepted categories of harm. The claimant would have to show that she or he suffered damage to property, psychiatric injury, or economic loss within the strict rules governing that particular head of damage.¹⁷² At first blush, this seems highly problematic because the affront of not having one’s consent respected or expectations met is not self-evidently captured by any of these categories. Most recently, however, the courts have begun to recognise other forms of harm, notably to autonomy interests, and in ways that might signal yet another important role for the research consent form.¹⁷³

D. *The Consent Form as Evidence of Harm to Autonomy*

Yearworth relied on property to show that a legally recognised form of harm had been constituted, viz, destruction of the property of the claimant.¹⁷⁴ However, if this is set aside and the research in question involves no direct intervention with participants and no destruction of their ‘property’, then it seems unlikely that any of the traditionally accepted categories of harm will apply. The kind of harm most likely to be engaged by departure from consent terms is harm to the participants’ interest in affront to their autonomy and loss of control in determining the kind of research in which they are involved or the kinds of uses to which their data or tissues might be put. Harm to such interests

¹⁷¹ JS Mill, *On Liberty*, in *J S Mill: Utilitarianism, On Liberty and Representative Government* (Everyman’s Library, London 1971) at 116.

¹⁷² For a landmark consideration of the issues, especially regarding psychiatric injury, see *McLoughlin v O’Brian* [1983] 1 AC 410 (HL); for critical commentary, see R Muheron, ‘Rewriting the requirement for a “Recognized Psychiatric Injury” in negligence claims’ (2012) 32(1) *Oxford Journal of Legal Studies* 77.

¹⁷³ Harmon and Laurie, above, n 112.

¹⁷⁴ *Yearworth*, above, n 114, at [50]. It has been suggested that Scots Law could deal with the same scenario as an example of ‘gratuitous contract’, see WW McBryde, ‘Contract Law—a solution to delictual problems’ (2012) 8 *Scots Law Times* 45.

simply does not fit the established categories to constitute negligence unless (improbably) this could be shown to cause real mental distress. Mere upset at the unauthorised use of one's samples or data would not be sufficient because the law requires psychiatric injury of a level of mental distress more or less equivalent to clinically recognised mental disorder.¹⁷⁵

This notwithstanding, several recent judgments in medical negligence cases, albeit in the context of clinical care, indicate a notable new direction in the law in the UK.¹⁷⁶ These cases each concern circumstances in which no straightforward causal relationship could be established between failings on the part of the clinicians in information disclosure and the harm suffered by patients normally required for an action in negligence. The lead English case is that of *Chester v Afshar*.¹⁷⁷ Here the patient did suffer a physical injury, the risk of which she had not been informed about. However, crucially the patient could not say that she would not have undergone surgery had she been more fully informed. On classic causation doctrine, this presented a seemingly insurmountable hurdle to tracing the causal connection between the surgeon's failure to disclose the risks of surgery adequately and the physical injury the patient suffered. The House of Lords nevertheless awarded a remedy holding that, in a case such as this, negligence should be used to protect the right of the patient to choose what risks to undertake in a manner reflecting her autonomy and ability to determine her own life course. The harm, then, was to autonomy itself. This is not an aberrant judgement. The protection of autonomy interests was also the basis for recognising property rights in *Yearworth*:

In reaching our conclusion that the men had ownership of the sperm for the purposes of their present claims, we are fortified by the precise correlation between the primary, if circumscribed, rights of the men in relation to the sperm, namely in relation to its future use, and the consequence of the Trust's breach of duty, namely preclusion of its future use.¹⁷⁸

Harm to autonomy is thus starting to emerge as recognised grounds for remedy in common law. The question remains open whether these cases may be read as introducing infringement of autonomy as a harm

¹⁷⁵ For example, *Reilly v Merseyside RHA* [1995] 6 Med LR 246 (CA); *Fairlie v Perth and Kinross Healthcare NHS Trust* 2004 SLT 1200 (OH); *Grieve v Salford HA* [1991] 2 Med LR 295 (QBD).

¹⁷⁶ *McFarlane v Tayside Health Board* [2000] AC 59, 2000 SC 1, HL; *Chester v Afshar* [2005] 1 AC 134, [2004] UKHL 41, above, n 17; *Rees v Darlington Memorial Hospital NHS Trust* [2004] AC 309, (2003) 75 BLMR 69.

¹⁷⁷ *Ibid.*

¹⁷⁸ *Yearworth*, above, n 114, at [44(f)(v)].

within a negligence action, or whether they may alternatively be seen as the beginnings of a legal recognition of a free-standing tort of infringement to autonomy.¹⁷⁹ In *Chester v Afshar*, Lord Hope acknowledged that a ‘patient’s right to make his own decision might be seen as a basic human right’ warranting protection under common law in the UK.¹⁸⁰ What this might mean for the role of informed consent in research contexts is that a failure to inform a participant of the potential uses to which their data and tissues might be put could be treated in law as a failure to respect their interests in autonomous decision-making where intimate aspects of their physical selves or their sensitive personal data are concerned. If a failure to inform a participant is an interference with autonomy, it could be argued that a failure to respect research uses they believe to have been specifically excluded by their consent is equally a violation of their right to self-determination. In either of these circumstances, the consent form might function as evidence that the researchers fell short of the expected standard of care in respect of the kinds of information provision or adherence to consent conditions required for participants adequately to exercise their autonomy.¹⁸¹ This, however, must be set against the role of professional custom as outlined above; that is, what would a body of responsible researchers in the field consider it appropriate to disclose or, indeed, expect of the consent form in regulating the research relationship?

In negligence, then, we thus face the possibility of successful actions depending on how the courts view: (i) the interests in play (notably autonomy) and (ii) the custom and practice of the ‘profession’ (particularly with respect to the kinds of terms normally included in consent forms—for example, exclusion of any property claims). Importantly, *Chester* and *Yearworth* taken together reveal two core sets of research participant interests: (1) being sufficiently informed at the time that consent is obtained, and (2) being able to exercise *continuing* control of one’s contribution to a research initiative. This reveals where the proper focus of our attention should lie in the design of responsible research conduct. Whether, however, this should be regulated primarily by the consent form itself is open to serious question as we argue below.

¹⁷⁹ Laurie, ‘Personality, Privacy and Autonomy in Medical Law’, in NR Whitty and R Zimmermann (eds) *Rights of Personality in Scots Law: A Comparative Perspective* (Dundee University Press 2009) 453, 467; Mason and Laurie, above, n 2 at 120.

¹⁸⁰ *Chester v Afshar*, above, n 17 at [30].

¹⁸¹ It has been suggested that under Scots law, damages may be awardable in *solatium* for the non-material injury to dignity that may follow from conduct that fails to respect someone’s autonomy—see NR Whitty, ‘Rights of personality, property rights and the human body in Scots Law’ (2005) 9 *Edinburgh Law Review*, cited in Laurie(2), above, n 179 at 473.

V. CONSENT AS RELATIONAL PROCESS

Albeit speculative, the preceding legal analysis suggests the following conclusions about the emerging legal status of the consent form in medical research:

- (i) There is a drive towards the 'written informed consent' configuration across regulatory regimes, even when this is not (yet) mandated by law.
- (ii) The law will often regulate the form that consent should take without considering the underlying interests at stake or the function that consent needs to perform.
- (iii) Legal remedies recognised to date might result in damages, return of samples, and destruction/non-use of data, but all of these signal a breakdown of the trust that is so central to the research relationship.
- (iv) The legalisation of the consent process as a one-off, up-front event is a distraction from the fundamental importance of fostering trust and respecting the underlying interests.
- (v) There is some legal recognition that these underlying interests relate both to what participants are told at the beginning of the process *and* what participants can expect is done with their research contribution throughout the process.

To be clear, we do not take issue with law's involvement in research. Indeed, given the centrality and growing importance of autonomy interests in human rights terms, there is a need for states to provide adequate recognition of these interests and appropriate legal remedies where these are interfered with lest they face claims from their citizens of infringement of the European Convention on Human Rights.¹⁸² Rather, our concern lies with the drift towards form over function when this seems to fail on so many levels. This is in part because it draws attention to matters at the beginning of the research enterprise rather than seeing initial consent as merely the start of a research relationship. We envisage

¹⁸² The most likely article to be engaged in this context is Art 8, see *Pretty v UK*, above, n 111. The European Court of Human Rights has held that obligations on the State might 'involve the adoption of measures designed to secure respect for private life even in the sphere of the relations of individuals between themselves': *X and Y v The Netherlands* (1985) 8 EHRR 235, [1985] ECHR 8978/80 at paragraph [23] - such measures might include the provision of legal remedies; see also *Airey v Ireland* (1979) 2 EHRR 305 at [32]. All of this is of course subject to a state being able to show that interference with citizen rights was both necessary and proportionate to achieve a legitimate social end: *Powell and Rayner v United Kingdom* (Application 9310/81) (1990) 12 EHRR 355, [1990] ECHR 9310/81, para 41 and references therein.

the research relationship as constituted by the trust which research participants place in researchers to act as custodians of their research contributions, to strive to achieve the stated research objectives, and to respect their interests throughout the life course of the research. Such a relationship of trust exists *irrespective* of whether there is direct contact between researcher or participant after initial consent is obtained, even when a participant has signalled no interest in their research contribution (for example through blanket or generic consent), and even in circumstances when data samples are used without consent. This is because the custodian role, if improperly executed, can nonetheless result in harm to those who participate in research.

Overriding focus on the consent form has many drawbacks for both parties to the research relationship. For one thing, it suggests that researcher obligations are discharged and exhausted with the signing of the form. This is not true from either an ethical or a legal perspective and is a dangerous pretext on which to proceed. Furthermore, this snapshot approach to capturing participant expectations ties the hands of all parties. Participants might change their minds positively towards a research project but have no means of communicating this. Equally, researchers and research ethics committees will be constrained by a consent form that appears to provide evidence that limits the research project when no one can be sure that it remains an accurate reflection of participant attitudes many years after the signing of the form. An obvious retort is the option of re-consent, but this is not always a viable option, either practically or economically. A legalistic approach to the consent form merely exacerbates the evidentiary fallacy. It reduces our concerns to a single moment—the moment of signing—which, while important as an instance of presumptive evidence, misses the point that a breach of trust can arise as much from a failure to realise research objectives as from a departure from original consent terms. Research is uncertain and attitudes change. The consent form alone simply cannot deal with these realities.

All of this speaks to the importance of communication in the research relationship. By this we do not mean necessarily direct communication between researchers and participants, but the opportunity for, and arguably obligation of, researchers to disseminate details of the research widely. This might include information about the protocol and findings (in accessible formats), changes to research design (including REC-approved departures from original consent), information about which parties have access to research resources (and for which purposes), and, ultimately, which benefits have come from research. This offers multiple opportunities for mutual engagement throughout the life of a project. This is particularly true with longitudinal research projects requiring long-term cooperation and buy-in from participants.

Crucially, from the participant perspective, it offers opportunity for on-going informedness, enquiry, interaction, and clarification; this serves not only to render the absolute right to withdraw from research meaningful, but it can also assist in securing an on-going trusted basis for research, helping to ensure that the nuclear option of withdrawal is rarely exercised and that recourse to law and legal remedies is unnecessary. Finally, this approach could serve as important additional evidence on the reasonableness of research conduct in keeping participants informed and, perhaps, as an indication of participants on-going acceptance of a protocol—even one which changes over time—if there is continued participation and so acquiescence in the research enterprise.

We suggest that for all of these reasons, consent ought to be reconceived as a *continuing relational process*. In these terms, the function of consent is to signal acceptance and trust in the research endeavour with all of its uncertainties and vicissitudes over time. This re-orientes our focus to the obligations of researchers to ensure that trust remains a central consideration; it allows for more flexibility in the conduct of research, where appropriate, and requires that consent forms communicate this function and the means by which it will be discharged moving forward. It determinedly avoids giving the consent form pride of place in the regulation of the research relationship. The process promotes commitment to openness, on-going informedness, and, where appropriate, re-visitation and re-negotiation of the basis upon which participants are willing to take part in research.

VI. CONCLUDING REMARKS

This article contributes to the growing realism about the limits of what (informed) consent can achieve in protecting and empowering participants' autonomy. The analysis strongly suggests that current approaches to research regulation focus to an excessive degree on up-front, one-off consent, and that the mechanism of 'written informed consent' is becoming increasingly entrenched in regulatory and research ethics cultures when this simply cannot offer the flexibility and responsiveness that modern research practices require. Albeit that some legal remedies are emerging, the legalisation of the consent process that this represents potentially acts counter to the interests of both parties in the research relationship. We suggest that these developments are misguided in privileging form over function. We advocate a clarification of the function of consent as a means to signal acceptance and trust in the research endeavour over time. Trust must endure throughout the research period lest participants exercise the one true power that they have: to withdraw. Failure to respect research participants is a fundamental breach of

trust. This cannot be reflected or deterred by a consent paradigm that is based on an oppositional premise, nor can it be captured at a single moment in time or in a single format. Rather, this reconception of the function of consent re-orientates attention away from the consent form and towards the on-going obligations of researchers to demonstrate their trustworthiness with respect to participants' interests and contributions to research throughout the research relationship.

This is not to suggest that consent forms cannot provide important evidence about expectations concerning the nature and limits of the relationship between the researcher and the participant; but it is important to understand that these can change and appropriate governance mechanisms must be established to accommodate this. Equally, it is not to deny that consent forms can play an important role in cases where trust breaks down; even in the pursuit of legal redress. Rather, we contend that much can be done to avoid these outcomes by turning the rhetoric of the research relationship into more of a reality.