**Trust and regulatory organizations: the role of local knowledge and facework in research ethics review**

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**Abstract**

While trust is seen as central to most social relations, most writers, including sociologists of science, assume that modern trust relations – especially those in regulatory relationships – tend towards the impersonal. Drawing on ethnographic material from one kind of scientific oversight body – research ethics committees based in the UK NHS – this paper argues that interpersonal trust is crucial to regulatory decision making and intimately bound up with the way in which these oversight bodies work , and that as such they build on, rather than challenge, the trust based nature of the scientific community.

**Key Words:** trust, ethics review, ethnography, regulation, research ethics committee (REC)

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When we think about the relationship between 'trust' and 'regulation', the chances are we echo Rebecca Bratspies when she considers pharmaceutical regulation in the US:

> I know the Food and Drug Administration (FDA) is dedicated to keeping food and drugs safe. The FDA has a good track record … I trust the FDA. Therefore, I feel confident taking this potentially lifesaving, but also potentially deadly medicine prescribed by my doctor and produced by a drug company under the watchful eye of the FDA. (Bratspies, 2009: 584)

Yet, as John Abraham has pointed out, trust is not only relevant at the end of this regulatory process, but also is present throughout:

> When a pharmaceutical firm begins to develop a drug, it organises and conducts laboratory and clinical tests … involv[ing] scientists fully employed by the company either directly, or through contract research organizations (CROs) … [in which case] … pharmaceutical manufacturers must decide how much trust to put in the data production techniques of the CROs involved.  (Abraham, 2008: 415)

Similar trust decisions confront regulatory authorities when the manufacturer presents its dossier of data in relation to the claimed safety and efficacy of the drug, the end users of the drug such as doctors (where the 'purveyor of that trust is crystallized in the drug's "label"'), and patients who, 'in turn, have little choice but to trust the prescribing advice of their doctors' (Abraham, 2008: 416). Thus the focus of Bratspies' analysis, what we might call 'trust in regulators', is only one of the ways in which trust plays a role in modern regulation. As articulated above by Abraham, drug regulation also involves other kinds of trust; kinds of trust that are not as easy to classify, and which are not as abstract or impersonal in form. For example, trust comes into play when doctors prescribe (Calnan and Sanford, 2004), or regulators reach decisions – the focus of this paper.

Trust has long been at the centre of thinking about scientific communities in STS – not only for Mertonians such as Harriet Zuckerman (1977: 127), but also scholars such as Harry Collins (2001: 82) who are associated with constructivist approaches – with the regulation of scientific practice and trust in scientists being presented as antagonistic. This is most clear with Steven Shapin, whose *The Social History of Truth* (1994) makes a sustained argument for the importance of trust in scientific work, showing how interpersonal trust – 'the world of familiarity [and] face-to-face interaction' (Shapin 1994: 414) – remains a feature of the modern scientific community, in contrast to modern society as whole where '[t]rust is no longer bestowed on familiar individuals; it is accorded to institutions and abstract capacities thought to reside in certain institutions' (Shapin, 1994: 411).

Yet Shapin also raises concerns about the development of systems of oversight set up to deal with various forms of scientific misconduct and the subsequent separation of scientists' qualities as researcher from their moral characters, arguing that such systems raise questions about the trust-worthiness of scientists and as a result 'can do serious damage to science for the reason that *trust relations* among scientists are constitutive of the making, maintenance, and extension of scientific knowledge' (Shapin 1995: 401).

Moving beyond trust in knowledge claims to other forms of scientific behaviour and their regulation,[1] this paper explores the role of trust in a very specific form of scientific regulation: decisions made before the clinical trial of a drug (or indeed the testing of any biomedical innovation) even begins, during research ethics review, a stage characterized as an example of 'anticipatory regulation', where decisions have to be made about actors' future behavior, and where decision-making about trust is explicit and thus open to

sociological investigation. The aim is to open the regulatory 'black box' of the Research Ethics Committee (REC) and to explore the relationship between trust decisions and the regulatory process, thus reflecting on the role of trust in modern regulation of scientific research.

**Research Ethics Committees: Organizations of anticipatory regulation**

The idea that research involving human subjects should undergo some form of prior ethical review is a taken for granted feature of modern biomedical science, which is built into national legislation, such as the US National Research Act of 1974 or the UK's Clinical Trials Regulations from 2004, guidelines for biomedical research, such as Good Clinical Practice (International Conference on Harmonization, 1996), and the Declaration of Helsinki (World Medical Association, 2008), as well as professional codes of practice (General Medical Council, 2006).

Prior to the development of Research Ethics Committees (RECs) in the UK, medical research was regulated by a paternalistic system of professional social control. Thus while the so-called 'Doctors' Trial' at Nuremburg articulated a set of rules to regulate the way in which patients and research subjects should be treated during medical experiments, these were largely overlooked by British medical researchers in the 1950s and 1960s, who regarded them as irrelevant to members of the medical establishment, which was still governed – in a striking resemblance to Shapin's portrait of Restoration-era science – by a 'gentlemanly code' (Hazelgrove, 2002, 2004). While the development of RECs in the UK in the late 1960s depended more on researchers' need to remain eligible for US Public Health Service grants than concerns about the way research subjects were being treated (Royal College of Physicians of London, 1967), the rapid expansion of such committees (238 were in place in hospitals by 1972 (Hedgecoe, 2009)) and the subsequent four

decades of complaints their existence has provoked from biomedical researchers can be seen to support the idea that such regulatory systems undermine the trust relationships in science – specifically trust in the way they treat the people they experiment on.

Since the late 1960s, the REC system in the UK National Health Service (NHS) has undergone a number of major changes, with the system currently consisting of 109 committees coordinated by a central organization: the National Research Ethics Service (NRES), which runs training for REC members and produces guidance for committees, such as Standard Operating Procedures (COREC, 2004), and the overall framework for REC composition and decision making (known as GAfREC: Department of Health, 2001).

These committees meet on a monthly basis, are made up of volunteers (classed as 'expert' and 'lay' members) supported by professional administrators, and are formally unaffiliated with specific research institutions (the members are appointed, and administrators paid by, regional bodies called Strategic Health Authorities). As NHS organizations, RECs review research using NHS patients (including clinical drug trials), staff, medical records, human tissue and NHS property (such as social science research in hospital grounds).

When assessing a proposal, each committee reviews a standard application form and associated materials, such as informed consent forms and participant information sheets, investigators' brochures and trial protocols (for clinical drug trials), researcher CVs, insurance certificates, and reviews from other regulatory bodies. A committee's remit is to 'to protect the dignity, rights, safety and well-being of all actual or potential research participants' by paying attention to a range of features of an application, including:

> the appropriateness of the study design in relation to the objectives of the study,
>
> … the justification of predictable risks and inconveniences weighed against the

anticipated benefits for the research participants, … the adequacy of the research site, including the supporting staff, available facilities, and emergency procedures … the suitability of the investigator(s)'s qualifications and experience for ensuring good conduct of the proposed study (Department of Health, 2001: 6, 24-25).

The key feature of RECs is their prospective nature: they are a form of 'anticipatory regulation' (Murphy and Dingwall, 2007) or 'anticipatory audit' (Strathern, 2000). Applicants are asked to tell committees what they *will* do, the information they *will* give subjects (in the form of information sheets and consent forms), the possible harms that the proposed intervention *might* cause and the possible benefits that *might* arise (both for patients and society as a whole). It is this prospective, forward-looking element to REC review that means that, at the core of what they do, RECs have to make trust decisions: as Charles Bosk and Joel Frader note, research ethics review 'is completely forward looking and relies on an honour system: there is rarely, if ever, surveillance to assess compliance' (Bosk and Frader,, 1998: 95). Consequently UK RECs perform little or no oversight of research once it is under way, with reporting limited to brief annual and final reports, and the (unenforceable) requirement to submit substantial changes in research for re-review. In such contexts, 'when monitoring and formal controls are difficult and costly to use … trust represents an efficient choice' (McEvily et al., 2003: 92).[2]

RECs have to trust researchers in order to do what they say they are going to do: to use the same dose, the same procedures and the same information sheet that the REC has approved. Thus, despite evidence that researchers can and do circumvent ethics review systems (Martinson et al., 2005; De Vries et al., 2006) and high profile examples where doctors have been disciplined for ethics review related misconduct (General Medical

Council, 2010), there is a dominant view, summarized by one of my interviewees, that 'many members of RECs simply assume that fellow-professionals should be trusted to do what they say they'll do.' In the words of another interviewee, 'we have to trust them … most of it's down to trust. We don't know what any researcher's doing, do we?'

**Method and sample**

While ethics review bodies have been the subject of sociological scrutiny since the early days of their existence (Barber et al., 1973; Gray, 1975), the majority of such research has tended to use quantitative surveys either to focus on the composition of these bodies, the views of their members and applicants, or their processing of applications (e.g., Thompson et al, 1981; Allen et al., 1983; Easterbrook and Matthews, 1992; Holley and Foster, 1998; Reynolds, 2003; Feldman and Rebholz, 2009). In the UK, a number of studies, often by biomedical researchers, have compared the varying responses from a number of different RECs regarding a single (multicentre) application (e.g., Tappin and Cockburn, 1992; Black et al., 1995; Busby and Dolk, 1998; Lux et al., 2000; Hearnshaw, 2004).

While this work provides interesting insights, it remains locked 'outside' the decision-making process of research ethics review bodies. Data on the demographic composition of such committees, the variability of the decisions they make and the processes employed tell us little or nothing about the way in which committee meetings are actually conducted, the role of informal factors in decisions, and the influence of small group processes. Even recent research based on detailed and extensive access to the letters UK committees send to applicants explaining their decisions remains rooted in the REC's final, public decision (e.g., Angell Sutton, et al., 2006; Angell, Bryman et al., 2008; Dixon-Woods et al., 2007), and tells us little about the 'backstage' process through which such decisions were arrived at.

This article presents data from an ethnographic exploration of the internal decision making of UK NHS RECs, employing repeated observations of a small number of committees, and echoing US-based work (De Vries et al., 2004; Stark, 2006).[3] This represents an explicit decision to generate the kind of 'thick description' (Geertz, 1973) generally held to be one of the strengths of the ethnographic method, and which previous research on UK RECs has failed to achieve because of sampling strategies involving single observations at a large number of RECs (Dyer, 2005; Fitzgerald, 2005; Fitzgerald and Phillips, 2006). The ethnographic approach adopted here does not set out to assess the validity of REC decisions – whether the things that committee members *think* make applicants trustworthy *actually* mean that these people are less likely to infringe their ethics approval – but rather seeks to explore the internal ways in which RECs reach their decisions about applicants, regardless of whether or not these decisions make sense to people outside these committees.

This paper draws on research carried out between July 2005 and November 2006 at three UK research ethics committees: St. Swithin's, Northmoor and Coastal (see table 1).[4] St. Swithin's LREC (Local Research Ethics Committee) was founded in the late 1960s at the teaching hospital after which it is named and which is internationally renowned for its biomedical research. Despite no longer having formal links with the hospital, the REC draws all its expert members and most of its applicants from St. Swithin's or one of its satellite institutions. Northmoor and district LREC arose from the merger of two other committees in and around the town of Northmoor, which took place about a year before my observations began. The committee reviews a mixture of applications from local institutions and from around the country. Coastal MREC is one of the original 10 Multicentre RECs set up in 1997 and has never had any institutional affiliation, as it draws

its members from a wider geographical area than the LRECs. Many members served on LRECs prior to being recruited.[5]

**Table 1**

| | Observations | | | Interviews | | |
|---|---|---|---|---|---|---|
| | **Start date** | **End Date** | **Total number** | **Expert** | **Lay** | **Total** |
| **St. Swithin's LREC** | July 2005 | June 2006 | 10 | 9 (inc. Chair) | 2 | 11 + Administrator |
| **Northmoor & District LREC** | November 2005 | November 2006 | 12 | 6 (inc. Chair) | 2 | 8 |
| **Coastal MREC** | September 2005 | August 2006 | 11 | 7 (inc. Chair) | 5 | 12 + Administrator |
| **Totals** | | | **33** | 22 | 9 | **31 + 2** Administrators |

In addition to interviewing members of these three committees, I interviewed members of six other RECs, policy makers, representatives of pharmaceutical companies and 'commentators' – academics and medics who have written about RECs.

From an analytic perspective, a key questions is 'how do those making decisions decide whether someone is trustworthy or not?' The solution is to draw on work that 'treat[s] trust as the product of underlying trustworthy-making character features' (Bacharach and Gambetta, 2001: 150), and to focus on those characteristics of an interaction which lead one party in a relationship to conclude that the other is trustworthy. This approach proposes: 'a wide variety of sources of trustworthiness, which include not only one's self-interest but also moral principles, social norms, and even specific dispositions that … can make one trustworthy' (Gambetta and Hamill, 2005: 6). A central challenge in deciding whether someone is trustworthy then becomes working out whether they possess these 'sources of trustworthiness', which Bacharach and Gambetta call 'trust-warranting properties'.

Many of these properties, aspects of one's character for example, or one's values, are not directly observable; rather, a truster has to depend upon a range of external 'signs' that indicate the presence of such properties (Bacharach and Gambetta, 2001: 154-156). For example, one might observe 'physiognomic features – the set of the eyes, a firm chin – and behavioral features – a steady look, relaxed shoulders – and treat … them as evidence of an internal disposition' (Bacharach and Gambetta, 2001: 154). In the specific example of research ethics review, if a core aspect of what RECs do is to make trust-decisions about applicants and applications, then these decisions must revolve around the detection and interpretation of applicants' trust-warranting properties, and the signs that indicate their presence. For the ethnographer, the challenge centres on identifying those particular trust-warranting properties and their signs that particular communities view as important.

By drawing on this background, the rest of this paper sets out to explore two aspects of the REC/researcher relationship – members' local knowledge about applicants and applicants' attendance at meetings to answer questions about their proposed research – with a focus on the role they play in REC decisions about the trustworthiness of researchers. There are two important caveats about this treatment. The first is that REC analysis of *written* warrants of trust is beyond the scope of this paper, but would include examples such as RECs' preference for patient materials to be translated into different languages (depending on the ethnic groups in the recruiting area) and the role of apparently 'trivial' spelling and grammatical mistakes in patient material (on the latter point, see Stark, forthcoming). The second point is that by emphasizing these features, I am necessarily sidelining other sociologically interesting aspects of REC decision making, such as the role of different kinds of expertise, including that of lay members (Dyer, 2004), and the consensus based decision model that RECs employ (Moreno, 1995).

**The role of 'local knowledge' in REC decision making**

When RECs started in the UK, they were based within hospitals and were explicitly seen as institutional committees, reviewing research conducted within a single site (Hedgecoe, 2009). Over time, the formal links between RECs and specific institutions have been steadily eroded, a de-localization that has gone hand-in-hand with a steady reduction in the numbers of such committees, with, for example, a 40% drop from 195 RECs in England in 2003, to 111 in 2008 (NRES, 2009: 4).

While the de-localization of research ethics review – that is, the severing of institutional links between researchers and committees – was not an explicit goal of these changes, policy makers' scepticism towards the idea that there are local issues in ethical review could not be ignored. This was summed up by someone working in policy who posed the question to me: 'In England, is someone in Worcester that different from someone in Gloucester, and do you actually need an ethics committee in both places?' From this point of view, the ethical issues pertaining to a particular piece of research are unlikely to vary geographically, and thus there is no convincing reason for RECs to be locally placed.

However, this position contrasts sharply with the views of REC members, who value the localized placement of these committees. They suggest that changes to the system that break the links between committees and local researchers mean that, as one REC member put it:

> You're losing your proximity to your researchers and your local knowledge.  That was very helpful; I mean you did know who the bad apples were and you knew there were certain people who you had to keep tabs on because they had, in the past, perhaps slipped up a little.

A key point I aim to make in this paper is that the kinds of situated knowledge about REC applicants and their research that members gain through working at the same institutions as applicants, or through reviewing applications from the same people on a regular basis – what I call 'local knowledge' – plays a vital, yet largely overlooked, role in how RECs make decisions. While some limited space in the REC process has traditionally been allowed for the assessment of 'local issues' (mainly the availability of certain medical resources, such as resuscitation facilities) theoretical discussions have tended to criticize the idea that local context might play any substantive role in REC decisions (see, for example, Wainwright and Saunders, 2004). Yet such positions are in stark contrast to the way in which RECs make decisions and the views of committee members themselves. RECs are still deeply 'localized' in their decision-making, and local knowledge is still valuable for helping them think about applicants' trustworthiness. Although it rarely plays an important part in REC decisions when an application appears straightforward and the committee is relatively comfortable with the proposed research, in those studies where members have other concerns, not being known by members of a committee can make all the difference. As one member of Northmoor LREC put it:

> I find it quite difficult to gauge certain studies which maybe I'm not 100% happy with if I know nothing about the researchers … [if] … they're from somewhere, I don't know, Manchester or wherever … I find those more difficult to gauge than somebody who I know.

This position was echoed by a member of St. Swithin's LREC, who stated that:

> maybe if I knew them I'd feel differently, but I won't take a punt [i.e. take a chance] on somebody that I don't know … if the application's fine, it doesn't make a difference. It's when there's a doubt, I won't ever give the benefit of the doubt to somebody I don't know and I think I might to somebody I know.

Local knowledge serves as a vital tool in helping RECs make trust-decisions about specific applications, as the following two fieldnote excerpts from St. Swithin's LREC show. St Swithin's could review applications for research going to be carried out both within and beyond its 'patch' (i.e. regional area) and while this did not necessarily restrict applicants to the hospital, of the three committees I observed, St. Swithin's was the most 'locally' placed in terms of where its applicants came from, from where it drew its members and its long-term institutional affiliation with a specific hospital. In these terms, this committee is at one end of the spectrum and is the closest committee in my sample to an Institutional Review Board (IRB) in the USA.

*Fieldnote excerpt 1: Heart attack monitoring study*

This study is a multi-site follow-up to a previous project run at the hospital, on an innovative piece of monitoring equipment used during a heart attack. Not only is this second study to be run at a number of different sites, but the equipment will be used in a slightly different way, which may potentially make it more intrusive.

There is general concern among members in the shift between the first study, where there was no interference, to a position where researchers will be in the room, potentially interfering in the resuscitation. One expert member suggests that cardiac arrests are most likely to happen in A&E [i.e. the Emergency room] or the cardiac unit. In the A&E there would be a safety issue, since the resuscitation team might not be aware of the proposed research, whereas in the cardiac care unit, the equipment could be set up in advance and staff pre-warned.

The chair sums up the REC's position: 'I think we're coming down on the idea that unless he can make a strong case, I think we would only agree on research happening in a special unit".'

The applicant is invited into the room. While he is not leading this research, he is the designated 'local researcher' for the project, an experienced, senior nurse who trains others in the hospital in resuscitation techniques. During the discussion with the committee, the researcher points out that limiting the research to heart attacks in the cardiac unit would cause problems, since cardiac arrests rarely happen in the cardiac unit because of the prophylactic treatments used there. The applicant states strongly that he would never allow the research project to interfere with his treatment of patients: very often he is working with a colleague who would be working on the patient, and that would free him up to set up the monitoring equipment being tested.

After the applicant leaves, the committee continues to debate the study. A GP member is still not happy about the chance that setting up the equipment will interfere with clinical practice. Another expert member responds: 'I know him [from ICU] and have no concerns about his priorities regarding patient care, but as a committee we should not have to rely upon *his* professionalism. The study design should remove our need to know the individual involved.' More importantly, since this study is to be carried out at a number of sites across the country 'we have to ignore our knowledge of the applicant' since the study would be, as a lay member puts it, 'run here by someone we trust and then expanded to the country as a whole'. The study was rejected.

The study would be largely unproblematic if it were *only* local, since the REC knows and trusts the local researcher, but the multicentre nature of the study means that it would also be carried out at a number of different sites. The REC has no knowledge of the individuals involved at those sites, and cannot attest to their trustworthiness. As the expert member quoted above said later in interview, 'that became a show stopper, didn't it, because so much of what was going to happen was dependent upon a particular personality'. Lack of local knowledge of other sites and researchers became the deciding factor.

Social theorists tend to argue that in modern societies, trust relations move towards the systemic and away from the personal. Niklas Luhmann for example suggests that while 'Trust remains vital in interpersonal relations … participation in functional systems like the economy or politics is no longer a matter of personal relations' (Luhmann, 1988: 102). Yet, in contrast, empirical research regularly emphasizes the importance of personal relationships in the generation of trust in the economic, private, and scientific spheres of modern societies (Ben-Porath, 1980; Gulati, 1995; Collins, 2001). It is perhaps unsurprising that personal knowledge of an applicant plays an important role in REC trust decisions. While this example shows how REC members use knowledge about applicants gained from working alongside them in a clinical context, the second excerpt below highlights how local knowledge of an applicant can be gained through that researcher regularly applying to the REC. In this case, the researcher in question has for a number of years submitted at least one application every couple of meetings, and as a result the committee is very familiar with his work.

> *Fieldnote excerpt 2: Basic physiological study*
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> This study is a re-application, previously rejected by another REC on safety
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> grounds; they were concerned about toxicology, since the research involved

putting complex organic molecules into healthy volunteers without prior approval from the MHRA, the drugs regulator [equivalent to the US FDA]. Technically, since this work is not aimed at drug development, but is rather researching basic physiology, MHRA approval is not required, but nonetheless the initial REC was concerned about the quality of the materials being used – what are known as Good Manufacturing Practice, or GMP, issues.

St. Swithin's committee starts with the Chair noting that this application is 'along the lines of many studies we've seen from him before'. Another member points out that: 'in the beginning we had similar concerns about the MHRA and toxicology, but we just got "worn down" by the sheer number of applications'. Overall the REC is happy with the application. They know from their previous experience that this researcher has done this kind of study many times before, and that there is a great deal of supportive toxicological data, much more than could be fitted into any one application, underpinning this study's safety. The applicant is asked to come into the room to answer a few questions, and following this the committee decides to approve the study with one or two changes.

After the committee makes its decision, there is a moment of reflection on the fact that, with only minor changes, the committee has approved a study that another committee has rejected. One member suggests that: 'we're alerted to the fact that someone else doesn't like it so we might feel a little guilty about our approval of this', to which another responds: 'It's useful for us that this has been rejected by another committee, to reassess our decisions' prompting the first member to conclude: 'to show we are not a pushover!'

A third member asks the committee administrator why the initial application went to the other committee: 'Did COREC [the Central Office for Research Ethics Committees, the body that coordinates applications] decide that he had to apply outside his home turf?', to which the administrator replies, 'probably our slots were full' [this does turn out to be reason].

As a result of frequent applications, there is clearly a relationship between the applicant and the St. Swithin's LREC. The members' discussion in this excerpt suggests that the committee is aware of how their treatment of this researcher's applications might be seen by the outside world; there is concern that the centralized system run by COREC (NRES's predecessor) even re-allocated this application the first time round to an alternative REC. Members are also aware of the value of this kind of local knowledge (about both the applicant and his research programme) that they have accrued over the time he has submitted his applications. With regard to the researcher himself, one member emphasizes the value of knowing an applicant: 'It's just a natural thing, you say okay he's very trustworthy because he's doing good research [that] appears to be ethical, you … have a bit more faith in him than somebody new who you don't know.' Such local knowledge also relates to his research programme, as this member elaborates:

You get an understanding of what the particular research programme is all about, the kind of issues they're trying to solve … you get a feel for the way in which the direction of the research is moving and so you start to see, 'oh that's interesting, in a few months time there'll be a proposal on X and Y' because you start to see where it's leading.

Such emphasis on context highlights the point that to trust someone is to trust the person to do something *specific*. In the case of RECs, they are making decisions that trust applicants

to carry out specific pieces of research, rather than making general 'carte-blanche' assumptions about researchers' trustworthiness.

In an interview, this researcher was reluctant to describe the situation in terms of a 'relationship' between himself and the committee, a concept he saw in negative terms, and preferred to frame it as a case of expertise: 'I'm friendly with the chairman or something and he's giving me special favours, I don't think that's true.' Yet, St. Swithin's LREC is not obviously more expert in terms of his specific research area than was the first committee when this application went to it and was rejected. Neither committee has anyone qualified in his specific discipline. Any expertise the St. Swithin's committee has is by virtue of this applicant's repeated submissions of research studies to them over a period of time. The committee developed a form of 'interactional expertise' (Collins and Evans, 2007) gained through its local relationship with this researcher, attaining knowledge from being based in the same institution and regular long-term exposure to his ideas and work.

Given the localized nature of St. Swithin's and its applicants, perhaps this is not surprising (however absent such local knowledge is from previous discussions of REC decision making). More interesting is the case of Coastal MREC, which, has never had any institutional links, but which I observed deliberately creating a form of 'localized knowledge' in the case of applications from one specific organization. For a variety of reasons, members of the committee were uneasy with this organization's programme of research and laid down specific conditions for future proposals concerning the kind of data that could be gathered. The MREC also requested that all future proposals be sent to them (rather than another committee) in order to ensure that the researchers stuck to the letter of the original approval. As expected by the committee, in subsequent applications the

researchers tried to push the boundaries of what they could gather, but they were limited by the original approval and the Coastal MREC's vigilance, as one member explained: 'Because the rules that they originally agreed to, they would have agreed to almost anything, to be allowed to get [the research] off the ground … and now of course they're established, they want to undo it. And they want to make different sorts of use of the data.' As this member put it when I asked explicitly about the decision to require future applications to return to Coastal, this was done because: 'We knew what they were up to.' As was clear in the case of the regular applicant to St. Swithin's, such local knowledge can also serve the interests of researchers. Thus while the origins of this requirement might lie in the committee's being 'suspicious … I don't think we can trust them as far as we can throw them.' Other members suggested that, over time, the committee's knowledge of this research reduced the repetition of specific questions that might crop up if the applications went to different RECs. One member of the committee noted that: 'I think they would have trouble with any new committee that they did it [i.e. applied] to … we understood it better, and we've rehearsed the arguments often, repetitively, in the beginning, now we'll take it a little bit more on trust.' In essence, having learnt more about the programme of research, the committee is more willing to give these researchers some leeway. Regular exposure to these applications has led to trust.

While the motivation to generate this 'local knowledge' lay in mistrust and suspicion, one effect was to allow the committee to approve further studies from this programme with greater ease. Indeed, during my ethnography I observed the review of a number of these applications, and while members' comments suggested they were still sceptical about the scientific value of this work, the committee settled into a routinized approach to these studies. They were often the least problematic and debated applications discussed during these meetings. In this example, the local knowledge was less about personal knowledge

of the individual researchers involved, and more about the 'feedback loop' created by requiring future applications to come back to Coastal. As Luhmann (1979) points out, such feedback is typical in many trust relations where those who exercise trust tailor their expectations in the light of others' continuous behavior. Yet by mimicking a typical feature of the relationship between a local researcher and an LREC, Coastal MREC created a situation whereby they could review applications from this organization more confidently and with fewer queries.

The value of local knowledge in REC decision-making is such that, not only do Local RECs employ it to help make trust decisions about applicants, but so do Multicentre RECs, with no local institutional affiliations; on occasion, they arrange situations to mimic such institutional relationships and generate local knowledge. At one level, local knowledge simply augments features of the written application form, for example, an applicant's CV. But a great deal of local knowledge is knowledge, not just of a person's education and training but also of their character, and other trust-warranting properties. As one member of St. Swithin's put it:

> … members of the LREC will of course know the people applying personally, and
> I'm quite sure that affects the way you think about it, if you know somebody to be
> a really good person with genuine concern and who's moral and ethical in
> themselves. … If you know somebody's a bit of a cowboy, you look at it more
> carefully.

Depending on the network of relationships the committee members have with researchers based at the institution, research ethics committees with strong local connections can employ considerable local knowledge. This knowledge is partly about people's research and the facilities available to support applicants (resuscitation facilities where there is a risk of anaphylactic shock, for example), yet it is also knowledge about the character and

qualifications of the applicants themselves. Not all RECs have access to this kind of knowledge, but in the case of those committees that retain (despite the various re-organizations of the system) a close relationship with a specific institution, then local knowledge is an important way of helping the committee make trust-decisions about specific applicants (for an early discussion of this see Hendrix, 1977). Of course, the 'local' aspects in the case of knowledge generated through regular application to a REC, and hence long-term interaction between applicant and committee, are largely incidental. It is possible for someone to regularly apply to a committee several hundred miles away, producing the same sort of effect as in the case of the researcher in the second fieldnote excerpt above. Yet, as the next section of this paper suggests, the key aspect of such 'long-distance-local' applications would be the face-to-face meetings that take place between applicants and committees, and these are more likely to occur in cases where applicants are 'local' to specific RECs. In the examples discussed above, REC members had direct experience of applicants' trust-warranting properties, either because of working with applicants in a clinical setting, or because of regular applications to the same committee. Both these contexts allow members to judge an applicant's character. Yet in many cases, a REC may not know the particular applicants. The next section of this paper explores a feature of the REC process in the UK that generates personal knowledge about applicants: during the assessment of their application, researchers are invited to meet the committee, answer questions about their research and discuss the ethical issues raised.

**Attendance, facework and the presentation of character**

While inviting researchers to attend REC meetings has been the long-standing policy of a small number of committees, since 2001/2002 it has become a national policy. Following submission of an application for REC approval, the committee administrator writes to the researcher to inform him or her that the application was received, the date at which the

study will be considered by the committee and to invite the applicant to attend the meeting and answer questions about the application. When applicants attend, they wait outside the room where the REC is meeting until they are called in, which happens after the committee has discussed the application and typically has formulated a number of questions or points it wishes to put to the applicant. It is not unusual for more than one applicant to attend for each study: industry trials may well involve both the principal applicant (an academic physician, for example) and an industry representative; Ph.D. supervisors are strongly encouraged to attend with their students. More often than not, a committee will reserve judgment on an application until it has met with the researcher.

Despite the fact that having applicants attend tends to lengthen meetings, the inconvenience is seen to be worthwhile. At one extreme was the member of Northmoor LREC who suggested that 'it's *absolutely* invaluable to have them along … it's virtually impossible to make a decision based on a form without having a researcher along.' Asking applicants about their studies is deemed a far more efficient way than the alternative of exchanging letters for clarifying issues about which a committee might be unsure: 'It probably takes out a layer of correspondence that could really get into the sand and get nowhere' [St. Swithins]. (This may not be the case with US IRBs (Taylor et al., 2008).) Members generally hold the view that meeting with applicants face-to-face allows the committee to 'short circuit a lot of misunderstandings … just seeing the individual and asking them specific questions can actually get through a lot of misunderstanding' [St. Swithins]. This view seems to accord with that of the researcher in the second fieldnote excerpt above, who regularly applies to St. Swithin's LREC:

> It allows me to answer questions that worry people, like what happens if you get
>
> the dose wrong ….  I explain that we go to great lengths to make sure that the dose
>
> is correct and detail what it is. Now, I hadn't thought to put that in [the application

form] … But it's that sort of technical problem, if I hadn't thought to put it in, I hadn't realised it would worry them, actually it's well covered and I can give them the answer.

Perhaps because researcher attendance at US IRB meetings is so rare (Bell et al., 1998), its influence has been overlooked in academic discussion of ethics review. Yet such 'facework commitments' – 'trust relations which are sustained or expressed in social connections established in circumstances of copresence' (Giddens, 1990: 80) – are a key (if recent) aspect of NHS REC decision-making. In addition to answering technical questions about an application, attendance at a meeting provides 'a lot of sort of meta-information, information that isn't in the application … very useful but indefinable stuff about the investigators themselves', essentially signs that indicate underlying trust-warranting properties.

For some, such as this member of St. Swithin's, meeting the applicant face-to-face allows the committee to know that 'we're comfortable with them approaching patients … because they seem to be a decent person.' While some research suggests that attendance increases an applicant's chances of getting a provisional approval rather than an outright rejection (Heasman et al., 2008: 58), opinion on this point varies among committee members. Even those who tend to think that attending improves an applicant's chances, like this member of Northmoor LREC, also think that 'sometimes people damn themselves even more, if you like, in their lack of knowledge and thoughtfulness.' There is a view expressed by some members that inadequate researchers may 'slip through' the system since, on paper, their application may be seem unproblematic. Thus, according to another member of Northmoor LREC 'It's important to get an idea of the researcher themselves. … They may be exceptionally good at English and filling out forms but might be a complete muppet

when it comes to research.' As one REC member put it; 'If they didn't turn up we wouldn't know they're an idiot and we'd just think it's okay.'

The first characteristic that REC members mention is 'clarity': whether an applicant, when talking to the committee, is clear about what he or she wants to do, why they want to do it and what consequences might arise. At one level, how particular applicants communicate with the REC serves as an indicator for how they will communicate with people enrolled in their research study. In the same way that IRB members pay particular attention to investigators' writing skills, as way of determining how well they will communicate with research subjects (Stark, forthcoming), so, according to a member of St. Swithin's, in RECs 'somebody who can't make it clear to us what it's about and why, makes you wonder about how clear they're going to make it to their [fellow] researchers or their patients.' But clarity in communication also cuts to deeper questions of character, in that such communication requires effort on the part of the applicant, and requires the applicant to take such a process seriously. As the Chair of St. Swithin's noted: 'somebody who appears to not think it's important at all to explain things to the committee … the likelihood is that they won't take the trouble to explain things properly to a participant either, and that they will have a rather paternalistic attitude to them.' As another member of this committee put it, 'I think there is a lot to be said for us to be seeing people in person and then you can tell how flippant some people are in their research attitudes.'

Related to the need to be open to clear communication of one's ideas is the need to accept comments and suggestions from a REC, the need to be 'receptive'. As a member of Northmoor LREC put it: 'If they're [i.e., an applicant] not very receptive, then you become a little concerned.' Such openness to the committee's comments may well be demonstrated in those cases where, perhaps, the written aspects of the application are not

as good as they might be. This provides a space for the committee to provide extensive comments on the application and, in return, for the applicant to demonstrably take these ideas on board. A member of Coastal MREC explained that: 'Sometimes their thinking develops in conversation with the committee. That's what you're looking for in a way, because it isn't exactly hard and fast and it's not *really* in the end whether they've ticked the right box or not'. The idea of 'tick box' ethics is often dismissed by committee members, who clearly distinguish between an applicant's ability to tick boxes on a form and their qualities as a researcher. Thus researchers who submit applications complete with considerable errors will *not* necessarily have their applications rejected by the committee. Rather, if they meet with the committee and are receptive to the members' comments, they may well receive a provisional approval (albeit with required changes to the application).

Being receptive to a committee does not necessarily mean agreeing to everything that a committee suggests. In their study of written communications from RECs, Mary Dixon-Woods and colleagues stress the submissive nature of the relationship between applicants and committees. They note that '[a]pplicants must 'submit' (the verb is used explicitly) to the committee; must make full disclosures and display their credentials as competent, trustworthy researchers; and must permit the exposure of their proposal to critical scrutiny' (Dixon-Woods, et al., 2007: 799). This is correct so far as it goes, but one must be careful not to over-emphasize the submissive nature of the facework between applicants and committee members. RECs do not expect applicants to adopt every suggestion they make: in meetings at St. Swithin's, the Chair would occasionally ask the committee's coordinator to make particular suggestions 'below the water line', indicating that they were optional changes. Attendance of a meeting by an applicant sits on a continuum between submission and outright resistance, with the REC and applicant negotiating the final form of the

proposed research. Obviously an outright dismissal of a REC's concerns would not work in an applicant's favor (see below for a discussion of the issue of 'arrogance'), but more senior researchers are likely to have a wider range of resources to draw upon, whether intellectual (knowledge of the literature) or political (a reputation for good quality research, or years of experience of both science and ethics applications). Thus senior researchers are more likely to be able to negotiate a particular outcome with a REC than early stage applicants.

Lack of receptiveness to a committee's suggestions is seen as 'arrogance', because, according to a member of Coastal MREC, arrogant applicants 'won't admit that the change is necessary'. What a committee actually regards as arrogant behavior is hard to articulate, but certainly RECs react badly to what is perceived as a lack of respect, not just to the committee itself, but also, extrapolating from present to future behaviour, to those people who will be enrolled in the proposed research. As a member of Northmoor LREC remembered:

> … a couple of really cocky researchers. They were young, arrogant, very bright … and I think their bearing did work really badly against them, [otherwise] I think we might have actually passed a piece of quite poor quality research because it wasn't dangerous or anything. Actually, we were all saying that they were so arrogant and they really should think again how they thought about people.

Meeting applicants face-to-face provides RECs with an important opportunity to develop a form of attenuated local knowledge about researchers. Drawing on signs that reflect trust-warranting properties, this knowledge about character is the basis from which assumptions may be drawn about how applicants will treat people enrolled in their research. Characteristics, such as lack of clarity and responsiveness, which clash with the underlying

values of RECs – the need to be open with subjects about the aims, risks and benefits of research – undermine the chances that applicants will be regarded as trustworthy to run the study as described in the eyes of a REC. While the application may not be rejected outright, the committee may impose a long and possibly unworkable (from a researcher's point of view) list of required changes.

Although the majority of the members I spoke to were positive about inviting applicants into their meetings, they expressed some reservations. Some concerns related to researchers' reactions to the process, with one of the committee chairs pointing out that 'when we've had complaints, quite often the complaints have been to do with researchers' perceptions of the questioning at the meeting ... even more so than the paper rejection, which is interesting … people feel very personally affronted.' Another member's comments cut directly to the way in which RECs assess applicants' character, and the limited opportunities the committee has to make such assessments: 'sometimes we judge what we see as the inadequacies of the researchers … it's just like you're assessing that person's personality for five minutes, and their capabilities for actually conducting the research.'

The one REC member who expressed clear concerns about applicants attending meetings was worried, not just by the impact of such attendance on the committee's timing and the duration of meetings, but also on the subjective nature of evaluations of the interactions and the committee's lack of formal expertise in assessing applicants in an oral setting. This emphasizes the potentially subjective elements of a REC's trust decision, and the inherent problems resulting from attempts to interpret people's behavior as signs of underlying trustworthiness; an applicant's nervousness may be interpreted as a sign of evasiveness. For this member the key issue is: 'What have we got here if somebody gives us assurances

orally? What does that mean? Nothing.' For other members of this and other RECs, it is exactly this personal contact that supplements the *written* assurances that committees receive in an application. Underpinning all of these concerns is the fact that RECs have to trust that applicants will do what they claim they will do. Neither written nor oral assurances can guarantee this of course, which is why decisions about applicants' trustworthiness are important aspects of what a REC does.

**Discussion**

The conclusions we can draw from this paper swim against the tide of much conventional thinking about trust, regulation and science. Social theorists such as Giddens and Luhmann characterize modern societies and their systems of regulation and control in terms of a move away from trust based on personal relationships towards more impersonal, systems-based trust. In parallel, from within STS, Steven Shapin (1994, 1995) contrasts the interpersonal, trust-based internal mechanisms of the scientific community with concerns about the impact of systems set up to regulate and control scientists' behavior.

By raising concerns about the impact of oversight systems on professional trust relations, Shapin is echoing debates in the UK around 'clinical governance' in healthcare. Drawing on longstanding concerns about the 'audit culture' (Power, 1999) these debates emphasize the costly nature of strict control mechanisms – such as measurement and monitoring – not just in terms of the expense of the information systems such approaches require but also the opportunity costs incurred (Davies and Mannion, 2000). The rise of these mechanisms is associated with an erosion of trust in professionals, resulting in a situation where a 'system that does not trust people begets people that cannot be trusted' (Davis and Lampel, 1998: 159).

One solution to the problems with current bureaucratic systems of clinical governance is to fall back on the 'civilizing' influence of trust in professional groups and their values (Brown and Calnan, 2011). I suggest that it is this approach – contra researchers' claims about the imposition of an external ethics bureaucracy – that characterizes research ethics review in the NHS. The kinds of restrictions that RECs impose on doctors when they perform research bear very little resemblance to the checks and balances facing the same doctors when they fulfill their clinical roles. RECs represent an example – perhaps more through chance than design on the part of policy makers – of regulation through trust decisions. While research ethics committees may not be typical of regulators as a whole, there are a number of other examples of regulation where interpersonal relationships and trust seem to play a role, whether it be environmental or financial regulation, or the regulation of aviation technology (Pautz, 2009; McCaffrey et al., 2007; Downer, 2010). If interpersonal trust is important for the social interactions that underpin the relationships between regulators and the regulated in society as a whole, then perhaps we should not be surprised if the same is true of modern science.

In broader theoretical terms, this case allows us to draw out features of the kinds of trust relationship that develop in these regulatory contexts, in particular their asymmetric nature. The trust relationship between a REC and an applicant, emphasized by the prospective nature of research ethics review and the historic lack of oversight, is asymmetric in two different ways. It may well be that this 'double asymmetry' is characteristic of the role trust plays in regulatory systems as a whole. The first asymmetry between the REC and the applicant revolves around the one-way nature of the trust relationship. Unlike the participants in many trust relationships where trustworthiness cuts both ways and each participant has to assess the trustworthiness of the other, RECs are required to make trust decisions about applicants, while the reverse is not the case. Indeed, given the

longstanding nature and range of UK researchers' complaints about the iniquities of research ethics review – the flabby bureaucracy, the time taken to review applications, the inherent injustice in having to submit an application to bodies lacking the required expertise (e.g. Anonymous, 1981; Marshall and Moodie, 1988; Dewhurst, 1992; Martyn, 2003; Stewart et al., 2008) – one might conclude that researchers have very little trust in such committees. Yet they have to submit applications if they wish to carry out research. While public expressions of mistrust in the system on the part of researchers can feed into wider policy debates and hence influence changes in such systems, researchers are still obliged to use such systems, whether they trust them or not.

This differs from many views of trust that tend to assume that both parties in a trust relationship need to earn the trust of the other. In terms of the trust relationships developed, RECs are thus less like commercial companies seeking to collaborate (Gulati, 1995), members of a conductorless orchestra (Khodyakov, 2007), or diamond merchants lending thousands of dollars worth of merchandise without contract or insurance (Coleman, 1988), and more like taxi drivers deciding whether to pick up a fare (Gambetta and Hammill, 2005), residents of a town contemplating the local chemical works (Phillimore and Bell, 2005) or patients deciding whether to trust a doctor (Brown, 2009). This feature of the REC system would seem to be characteristic of regulatory systems as a whole (whether anticipatory or not): while it matters whether regulators trust those they regulate to do what they say, it is far less important for those who are subject to regulation to actually trust, or have faith or confidence in the regulatory authority. While in broader terms it may be important that society as a whole should trust regulators to do their jobs, in the case of the day-to-day activities of regulatory bodies trust decisions are one-way.

The second asymmetry concerns who would be harmed should the REC incorrectly trust a researcher. There is a strong theme within literature on trust that a key aspect of trusting someone is making oneself 'vulnerable' to the trustee, with one review suggesting that 'research on the topic of trust appears to be premised on the general idea that actors become, in some ways, vulnerable to one another as they interact in social situations' (Bigley and Pearce, 1998:408; see also Rousseau et al,, 1998: 394-395). Or, as Paul Dumouchel puts it: 'To trust is to act in such a way as to give another agent power over us' (Dumouchel, 2005: 425). Yet it is not at all clear that when a REC decides to trust an applicant and approve their research it has become in any meaningful sense 'vulnerable', even in Luhmann's sense that those who misplace their trust experience 'regret'. If the researcher proves untrustworthy it is not the REC or its members who are harmed, but rather the research subjects enrolled in the study. Indeed, given that in the UK RECs are voluntary bodies, there are few sanctions that can be imposed on committees should their decisions be viewed as flawed. Thus the second asymmetry is that the REC is making a trust decision *on behalf of* research subjects. If trust is about risk, then it is not RECs that are exposed to the risks about which they make trust decision.

Through its exploration of REC decision-making, this paper serves as a starting point to bring ideas around trust into the centre of discussions about regulatory organizations and their relationships with those they regulate, drawing connections between regulation in the sciences and regulation elsewhere in the society.

**Notes**

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[1] While the focus of Shapin's empirical concerns is the trust between scientists that underpins the credibility of their scientific statements, he explicitly suggests his claims have relevance to broader 'concerns about the moral authority of science' (1995b: 405) such as those behaviours more typically considered under the terms research ethics or human subjects protection.

[2] One obvious difference between the UK NHS and US systems is the tendency of IRBs in the US to go back to previously approved applications and 'audit' a small number of them, in order to see how research has been carried out. This raises a different set of trust decisions, around which projects get chosen for audit (Stark, forthcoming).

[3] The US/UK distinction is important, since, although it is generally assumed that IRBs are much the same as UK NHS RECs, there are important differences (in terms of institutional affiliation, composition, funding etc.) any of which might influence the internal decision making. Therefore while the present paper may be suggestive for IRBs (other other jurisdictions), its conclusions are specific to the NHS system.

[4] The RECs have been given pseudonyms, and some of their details have been altered to preserve anonymity for particular committees and members. This extends to the ethnographic fieldnotes presented below: details of specific treatments and research have been deliberately obscured.

[5] The MRECs were set up to give a single review to research taking place at more than 4 sites and thus to aid multicentre research (such as pharmaceutical trials). At the time of my fieldwork, distinctions were still made between LRECs and MRECs, though over time, as more LRECs have been given MREC-like powers (for multisite review), the terminology has moved away from this distinction.

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