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Doing accountability: a discourse analysis of research ethics committee letters

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Abstract   Research ethics committees (RECs) are charged with adjudicating the ethical status of research projects, and determining the conditions necessary for such projects to proceed. Both because of their position in the research process and because of the controversial nature of ethical judgements, RECs' views and decisions need to be accountable. In this paper we use techniques of discourse analysis to show how REC decision letters 'do' accountability. Using a sample of 260 letters from three datasets, we identify a range of discursive devices used in letters written by RECs. These include drawing attention to: the process behind the decision, including its collaborative nature; holding the applicants accountable, by implying that any decision made by the REC can be attributed to the performance of the applicants; referring to specialist expertise; and calling upon external authorities. These tactics 'do' accountability by showing that routines of ethical assessment have been enacted, by establishing the factuality of claims, and by managing questions of fault and blame attribution. They may, however, also risk undermining legitimacy by failing to acknowledge the inherent contestability of ethical decision making or the limited nature of the cultural authority accorded to RECs, and thus may appear as an illegitimate exercise of power.

Keywords: research ethics committees, discourse analysis, accountability, complainability

Introduction

Regulation of research in health is a site of increasing contestation worldwide (Dixon-Woods and Ashcroft 2008). On the one hand, it is argued that regulation is required to defend against the direct risks of harm associated with the conduct of studies, the moral wrongs that can occur when researchers are insufficiently attentive to the wellbeing, rights, and dignity of their subjects (Pappworth 1967, Beecher 1966), and the risks that researchers' motives (including commercial imperatives) could overwhelm the interests of patients and compromise safety (Abraham and Lewis 1999). On the other hand, practices of ethical review in health-related research are much criticised by the regulated community both in the UK

and beyond (Bosk and De Vries 2004, Burris and Moss 2006, Robinson *et al.* 2007), with recent interventions in the debate arguing that ethical review of most health services research is fatuous (Dingwall 2006) and the subject of continual complaints about apparent capriciousness and inconsistency (Hannigan and Allen 2003, Lux *et al.* 2000). Excessive demands and inappropriate conservatism on the part of Research Ethics Committees (RECs – known in the USA as Institutional Review Boards or IRBs) have been blamed for obstructing or impeding important research that would be of benefit to patients (Academy of Medical Sciences 2006) and causing unwarranted burdens on researchers. The intensity of contestation about regulation of research makes the question of REC accountability an important one.

Under the Research Governance Framework (Department of Health 2005) in the UK, National Health Service (NHS) RECs are formally accountable for producing a fair and competent quality decision that ensures ethical practice. Applications for REC approval for research projects must be submitted for review at an REC meeting in compliance with the procedures specified by the National Research Ethics Service (NRES), including use of the correct application form. RECs are composed a maximum of 18 members; at least one-third of the total membership must be 'lay' members while the remainder may be 'expert' members such as registered health professionals or those with expertise in particular areas (*e.g.* statistics). Applicants are invited to attend REC meetings. Following discussion, RECs formulate a decision about applications, which must be one of three types of 'opinion': favourable, provisional, or unfavourable (Box 1). RECs then issue a letter giving their opinion, favourable or otherwise. The most common type of decision at first review (two-thirds

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- A 'favourable' opinion means that an application is approved without further amendments. These constitute ~15% of decisions made by RECs at first consideration of an application.*
- 'Provisional' opinions constitute ~64% of decisions at first review, and require applicants to make a response to the REC addressing issues raised in the letter before a final opinion can be issued. The final opinion may be either favourable or unfavourable.
- An 'unfavourable' opinion (~8% of all submissions) at first review amounts to a rejection. Researchers have the option to either resubmit a new application (taking into account the issues raised) or to appeal (in which case no changes can be made to the documentation).

Some applications are withdrawn (~10% before review by a REC (*e.g.* because the applicants have decided not to proceed), 3% after a provisional opinion has been issued). RECs may also decide that applications are 'outside remit' or that advice should be sought from an external expert (such as a methodologist or specialist clinician) before giving a formal opinion.

Data based on the period October 2005–March 2006

Box 1: Decisions RECs may make at first review

of all applications) is a 'provisional' opinion, which requires a response by the applicants before the REC issues its final opinion. Applicants have the right of appeal, allowing them to resubmit (without revision) an application that has received an unfavourable opinion to another REC for a second ethical opinion.

Official guidance explicitly charges RECs with accountability for their decisions and the contents of their letters:

> *7.9 The REC should always be able to demonstrate that it has acted reasonably in reaching a particular decision. When research proposals are rejected by the REC, the reasons for that decision must be made available to the applicant.* GAfREC (Department of Health 2001)

In this paper we use an approach informed by discourse analysis to explore how RECs use their decision letters to applicants to produce accountability. We use the term 'produce' here in an ethnomethodological sense, where it is concerned with how discourses 'do' things rather than simply describing them (Potter and Wetherell 1987). We argue that RECs use texts not only to do their own accountability, using a range of discursive devices to display the quality of their own work and the resulting decisions, but also to establish the accountability of applicants for the quality of their applications. Although the data we use in this paper are UK-based, the analysis has relevance internationally.

This kind of analysis is important not only because of the substantive area of research governance, but also because of the growing interest in sociology and beyond in what might be termed practices of accounting. One distinct tradition in the sociology of accounting derives from studies of (financial) accountancy and auditing as social and institutional practices. We might, heuristically, characterise this tradition as being concerned with the practices and consequences of purposeful attempts to do accountability. This work has identified how financial accounting practices create particular ways of understanding, representing, and acting on events and processes (Miller 2001). It has focused on how financial auditing practices, even in their most mundane routines, involve 'making things auditable' through the construction of visible signs of 'reasonable practice' (Power 1996). A highly influential body of work drawing on the themes of the 'Audit Society' (Power 1997) has identified how auditing, through its ritualised practices, allows organisations to provide a satisfactory account of themselves if called upon externally. As Evans (2000) notes, in his discussion of bioethics in a US context, the bureaucratic form of ethics committees makes the ability to demonstrate rationality especially imperative.

A second tradition of studying accounting derives from conversation and discourse analysis, and heuristically we might characterise this tradition as being concerned more with the (often largely unconscious) production of accountability as a feature of social action. Within this tradition, accounting for actions within a setting or in terms of particular norms is seen as a fundamental social activity. This kind of situated accounting involves societal members making sense of and explaining their activities, and orienting to the relevant aspects of the circumstances at hand (Antaki 1994, Harré 1997). Written texts, as well as spoken language, engage in practices of accounting (Buttny 1993). Authors of texts can be held accountable for the factuality and/or quality of any claim or decision reported (Edwards and Potter 1992). The accounting functions of texts also extend to the ways in which texts do organisational and institutional work. Because documentary texts actively structure social relations and encode institutionalised discourses (Smith 1990, Berg and Bowker 1997, Bazerman and Paradis 1991) and reflect the dynamics of power within

institutions (Bremner 2006), documents are, sociologically, of enormous interest (Atkinson and Coffey 1997, Prior 2003). Their significance in providing the official, and thus privileged, representation of reality is now increasingly well recognised (Vaughan 2006, Scheffer 2007). There is thus a need to be attuned to the discursive practices that allow texts to do their work (Hagge and Kostelnick 1989, Drew and Heritage 1992) and to gain insights into the nature of the social actions texts can perform in specific contexts. Empirical work using documents is thus rich in potential for understanding the doing of accountability: in Smith's (1990) vivid phrase, 'the text enters the laboratory, so to speak, carrying the shreds and threads of the relations it is organised by and organizes' (1990: 4). Elsewhere (Dixon-Woods *et al.* 2007), and using a different dataset, we have reported on the social functions of REC letters. In this paper, we focus on how such letters produce or do accountability.

Methods

We used an approach based on discourse analysis to explore how RECs produce account-ability in their decision letters to applicants. Though difficult to define precisely and with full consensus, discourse analysis (DA) can be characterised as a commitment to studying discourse as talk and text in social practice. DA has a focus on language and its rhetorical organisation (Potter 1997), but goes beyond language to explore organised meaning and investigate how knowledge is organised, carried and reproduced in different ways and through particular institutional practices (Freshwater 2007). With the turn to language-based approaches, discourse analysis is an especially valued approach to analysing textual data (Gill 2000). Discourse analysis appeals to researchers as an analytic tool for its ability to reveal how institutions and individuals are formed, constructed and given meaning (Freshwater 2007).

The many variants of DA pose challenges for providing a fully specified account of its methods, and indeed its lack of universally agreed upon procedures means that it is perhaps better understood as an orientation towards analysis rather than a set of executable techniques. In this paper, we were informed by the form of DA proposed by Potter (1997), which was developed in the fields of sociology, psychology and communications studies. Though rejecting some of the principles of the approaches to discourse that have developed within linguistics, post-structuralism, literary theory and speech act disciplines, this type of DA has nonetheless been influenced by some of the insights of these approaches, and is further influenced by ethnomethodology and conversation analysis. We were interested in using this form of DA to demonstrate how versions of the world are produced through text (Potter 1996). We were especially concerned with rhetorical features of text: how the text persuades the reader, and the rhetorical devices drawn upon to get across a particular point of view (Atkinson and Coffey 1997).

The data on which we worked comprised 260 letters written by Research Ethics Com-mittees in the UK in response to applicants. Standard Operating Procedures issued by the National Research Ethics Service (NRES) require that each REC in the UK registers the applications it reviews onto the national Research Ethics Database (RED). Letters are usually signed by the Chair of the REC, though they may also be signed by the coordinator/administrator on behalf of the Chair. We were granted access to letters on the RED by NRES for purposes of our project. Letters were fully anonymised before being used in the project. The project was deemed 'service evaluation' by NRES and research ethics committee approval was not required.

Table 1 *REC decision letters used in analysis*

Study type	Time period	Number of letters	Inclusion criteria
Adult oncology trials *(Indicated by labels beginning ID)*	March 2004– December 2006	80	Applicant indicates children are excluded; limited to clinical trials; appropriate oncology-related word(s) in the study title
Studies involving the use of human tissue *(Indicated by labels beginning TID; B = before and A = after Human Tissue Act)*	March 2004–September 2005 and September 2006 – December 2006 (before and after implementation of Human Tissue Act 2004)	100 (50 from each time period)	Applicant indicates taking new or accessing stored tissue samples
Studies involving children *(Indicated by labels beginning PID)*	March 2004–December 2006	80	Applicant indicates inclusion of children under 16

In the project, we included letters written by RECs to applicants following the first meeting at which an application was considered (*i.e.* we did not include letters arising from consideration of researchers' responses to earlier correspondence). We included applications that received an unfavourable or provisional decision (Box 1) at first review, as such decisions indicated that there was an issue in the application that troubled the REC. We excluded 'favourable' opinions (which typically had little text available for analysis), and we also excluded correspondence related to requests for protocol amendments and site-specific assessments, and any applications still awaiting a final decision.

Decision letters about applications for three different types of study were included in our analysis: cancer trials, studies involving the use of human tissue, and studies involving children under 16 (see Table 1, which also explains the tags used to label extracts). For the purposes of this paper, however, these substantive topics are not a focus of interest (we report on this elsewhere, e.g. Dixon-Woods *et al.* 2008), nor are we aiming to compare across the datasets. Use of three slightly different datasets does, however, illustrate the ubiquity of practices of accounting in REC letters and the characteristics of these practices.

Findings

Our analysis reveals a number of discursive devices and rhetorical strategies used by RECs to account for their decision (and related requests) and display the quality of that decision. These devices and strategies include: drawing attention to the process behind the decision; holding the applicants accountable; referring to specialist expertise among the REC members; and calling upon external authorities to justify particular opinions, requests, or statements. We organise our account of the findings around these four themes, noting that our interest is in the ways in which the texts *perform* 'accountability work', rather than in the normative evaluation of this work or in assessing the extent to which the texts describe some 'reality'.

The process behind the decision

REC letters emphasise that a proper and well-executed process underlies REC decisions. To achieve this, letters do three key things: they report (as in extracts 1–3) that a thoughtful discussion took place, often highlighting the energy and time spent on considering the application; they note that serious consideration was given to detail of the proposed study; and they emphasise the collaborative nature of the process.

1. 'The Committee discussed the protocol at great length . . .' (TIDB1684, provisional opinion then favourable)
2. 'The Committee considered carefully the rationale for including a placebo group in this study.' (TIDB1768, unfavourable opinion)
3. 'After discussion, the Committee agreed to review the first part of the application only and to give an opinion on this aspect of the study.' (PID1624, provisional opinion then favourable)

Letters sometimes reinforce the quality of the review process by upgrading the diligence of those discussions: in extract 1, for example, the Committee discussed '*at great length*' and in extract 2 they '*considered carefully*'. Drawing attention explicitly to the *collaborative* nature of the process (extracts 1–6) further helps to 'do' accountability. Collaboration and citing others are strategic devices that function to authenticate and validate a statement (Dickerson 1997). Presenting a united decision directs the reader to the quality of that decision: in signalling the collaborative nature of the process, letters imply that the decisions, questions, requests and demands of the RECs are warranted and proper because they have been reached unanimously by all knowledgeable members.

4. 'The Committee members agreed that the Genetics part of this study should be made clearer in the protocol [. . .]' (TIDB0506, provisional opinion then unfavourable)
5. 'the Committee agreed that the Patient Information Sheet must be much more explicit regarding the insertion of the central line.' (ID176, provisional opinion then favourable)
6. 'The Committee agreed that an information sheet for the children as well as the parents should be provided.' (PID346, provisional opinion then favourable)

The collective nature of the process is signalled through explicit use of third-person terms, such as 'the Committee' and 'Committee members', thus denoting the REC as a collective unit acting in concert. This is important as a legitimatory tactic, since the absence of an implied personal author is a rhetorical device for constructing 'authoritative', 'official' or 'factual' accounts (Atkinson and Coffey 1997). Citing others as sharing the authorship of an utterance functions to endorse, corroborate or in other ways warrant the speaker's/writer's utterance (Dickerson 1997). Presenting a collaborative decision, which goes beyond the subjectivity of any single individual, allows the REC to strengthen its claim that the action or change required of the applicants is non-negotiable and necessary. REC letters also use collaboration to construct the points they make as necessary and factual, rather than subjective, strategically using agreement with one another to stake their claim to epistemic authority (Heritage and Raymond 2005). Further, just as Berg and Bowker's (1997) analysis of the medical record showed how the record functions as a meta-affirmation that doctors did everything they were expected to, and thus tends to offer a 'preferred account' of what happened, these letters also render the account of the REC process as rational, ordered, polished, and above

all consensual. But, importantly, the account of the REC and its decisions and processes proferred by the letter is the 'front stage' (Goffman 1959) of the REC's processes: it bears an unknown (or at least uncertain) relationship to what has happened 'back stage'.

Holding the applicants accountable

One of the key discursive strategies used by RECs in their letters is to hold the applicants accountable, especially for inadequacies in the application that then account for the decision made by the REC. The applicant is thus constructed as 'complainable' (Schegloff 2005). By demonstrating deficiencies in the application (Angell and Dixon-Woods 2009), the REC is able to deflect responsibility for its decision to withhold approval onto the applicants and to justify its requests and demands. In extracts 7–9, RECs do this by suggesting that some feature of the application is 'unethical'.

7. 'It is unethical for blood samples to be retained indefinitely for a future, as yet, unavailable test.' (ID082, provisional opinion then favourable)
8. 'The Participant Information Sheet (PIS) and Consent Form were totally inappropriate and far too brief.' (TIDA0324, provisional opinion then unfavourable)
9. 'Without this information presented in the clearest terms this research in this patient group would be considered unethical.' (ID237, provisional opinion then favourable)

Here, the applicants are represented as violating the normative expectations governing the conduct of research. We see REC members' views rhetorically positioned (by virtue of their category entitlements as members) as the authoritative judgements on the ethical standing of the application. These views are further represented in the letters as the working out of institutional logics. Such logics encode the criteria by which role identities, organisational norms and forms, and relationships between actors are constructed and sustained as legitimate, and permit the prescribing and proscribing of actions (Suddaby and Greenwood 2005). Thus, though there is often no single correct answer relating to the ethics of health research, the letters paradoxically use subjective emotive terms – such as 'totally inappropriate' (extract 8) – to promote the objectivity of the decision, by implying that the proposed practice is one that would provoke repugnance in anyone employing the appropriate logics. Moreover, this use of extreme case formulations (Pomerantz 1986) to upgrade the criticism of the applicants (from 'inappropriate' to 'totally inappropriate') allows the REC to show that the applicants have demonstrated more serious failings.

REC letters also identify non-ethical 'errors' in applications, again (as in extracts 10–12) positioning the applicants as accountable when they commit errors, usually through a direct attribution of blame. By framing criticisms in a way that indicates a correction is needed, the REC is allowed to defer its final decision until satisfied. Such statements simultaneously perform the accountability of the REC (showing that it is responsible for ensuring the correctness of the application, and that it has done this in exacting detail), and perform the accountability of the applicants (showing that they are responsible for conforming to the proper standards of conscientiousness and attention to detail).

10. 'The flow chart is incorrect – shows 2 doses to be the same although they should be different.' (TIDB0380, provisional opinion then favourable)
11. 'Incorrect phone number on GP letter (page 2) please correct.' (ID439, provisional opinion then favourable)

12. 'There are a number of typographical errors on the PIS.' (PID0755, provisional opinion then favourable)

The claimed competence of the REC in identifying such errors underlines the quality of the process of decision making: an application would, evidently, need to be considered thoroughly to identify specific areas such as '*incorrect flow charts*' (extract 10), '*incorrect phone number*' (extract 11) and '*typographical error*s' (extract 12).

Emphasising missing or inadequate information further demonstrates the importance of that information in the decision-making process and orients to the process of the decision and its quality. The language used in identifying these problems and calling for corrections is impersonal and directive. It functions as a display of power, and reflects the general finding that when those in a position of power make requests, there is (as shown in extracts 13–15) frequent use of the passive voice and a general absence of personal pronouns (Bremner 2006).

13. 'Copies of the questionnaires should be provided.' (TIDA0088, provisional opinion then favourable)
14. 'A suitable Consent Form needed to be submitted for approval.' (ID237, provisional opinion then favourable)
15. 'A copy of the researcher's CV was not provided. The Committee was unable to determine the competence of the applicants therefore to carry out this very sensitive study.' (PID0116, unfavourable opinion)

The use of modal verbs (*i.e.* verbs that indicate level of necessity) reinforces this strategy, as well as underlining the complainable nature of the applicants. The modal verb *should* is the weaker directive of *must*, and can demonstrate either advice-giving or obligation. It may also, as Edwards (2006) notes, convey a sense of the normative expectations that govern the situation. Thus, the use of the modal verb 'should' in extract 13 carries with it an obligation or necessity and implies fault on the part of the applicants, and demonstrates the limited range of options open to the applicants in their response. Likewise in extract 14, the REC argues that the Consent Form '*needed to be submitted*'. In this context the use of 'needed' is used as 'should' and demonstrates to the applicants the necessity of the document if they are to secure a favourable outcome for their application. In both of these extracts, it is notable that the REC does not present reasons to the applicants for how and why the information adds to the quality of their decision, or to ethical practice. The absence of explanation may imply that any competent applicant should be aware of the process, and to emphasise that the REC is not being unreasonable in asking for the correct material to be provided. In extract 15, by contrast, the need for the CV is highlighted by emphasising how seriously the Committee takes its responsibilities and the accountability of the applicant for allowing the REC to discharge these appropriately; the failure to provide a CV, it is implied, is a procedural lapse, but a lapse whose significance goes simply beyond a failure of process, and indicates a moral failing on the part of the applicants.

Requests for clarification or additional information similarly underline the accountability of applicants, implying that it is the applicants' fault if the REC is not content to give a favourable opinion. Such requests imply that the research team have failed to provide enough relevant information for the REC to perform its duties, thus positioning the applicants as accountable for the REC's inability to render a decision.

16. 'Before making a decision the Committee would like to know what percentage of samples were stored without consent.' (TIDB1551, provisional opinion then favourable)
17. 'Clarification is required as to how women are recruited to the study, and how they are linked with their partners.' (TIDA0073, provisional opinion then favourable)
18. 'Clarify if the drug will definitely be made available at the end of the study and what arrangements there are to fund this.' (ID170, provisional opinion then favourable)

These accounts are clearly organised to be persuasive; the use of peremptory language functions to demonstrate the power of the REC to compel alterations and the disclosure of any information it requires. This persuasive function is also evident in the reported compliance of the research teams, especially when letters report on attendance at REC meetings.

19. 'It was not acceptable that patients could be recruited over the telephone without any prior warning. You agreed that patients should only be contacted by telephone if they had agreed to this at their clinic visit. Please amend application documents to reflect this.' (TIDB2220, provisional opinion then favourable)
20. 'Professor <name> said that he would not like to highlight this fact but he would be happy to be guided by the Committee.' (ID070, provisional opinion then favourable)
21. '<Named applicant> responded that he had used a similar method in previous studies, but would comply with the Committee's wishes.' (PID2052, provisional opinion then favourable)

These three examples all differ in terms of the essence of the compliance reported, but all demonstrate that the applicants must comply with the requests/directives of the REC. In extract 19, there is a straightforward agreement reported '*You agreed that . . .*'. This demonstrates the applicant is persuaded by the argument of the REC and complies on the grounds that it is right. Notably, however, extracts 20 and 21 demonstrate that compliance involved submission to the authoritative position of the REC. In extract 20, disagreement on the part of the applicant is identified by '*he would not like to highlight this fact*' but nonetheless the applicant (as he is required to) submits: '*happy to be guided by the Committee*'. In extract 21, the applicant points to previous successes, but is nonetheless required to submit: '*he had used a similar method in previous studies, but would comply with the Committee's wishes*'. What this shows is that ultimately the power for the ways in which research is conducted lies with the REC, and that (notwithstanding the attendance of the applicants at meetings), negotiation takes place within that framework.

   REC letters can also retreat from these highly insistent directives, but nonetheless persist in making the applicants accountable. Letters sometimes collaboratively frame the directive as a suggestion or a request, and thus minimise the 'face threatening act' (Brown and Levinson 1987: 281) associated with the imposition of a desire on the part of the sender at the expense of the hearer in any particular exchange.

22. 'The Committee also request that a paragraph outlining the role of the Research Ethics Committee be inserted.' (TIDA0073, Provisional opinion then favourable)
23. 'The Committee requested that the letter to the parent/carer could be "softer" and more "reader-friendly."' (PID0755, provisional opinion then favourable)
24. 'A20 – the Committee suggest that participants are not contacted by telephone, but sent a second letter.' (TIDB0194, provisional opinion then favourable)

In these terms, RECs frame their directives as suggestions or requests in ways that may appear to give a suggestion of choice. In extract 23, the REC proposes that the applicant's letter '*could be "softer"*' and in extract 24 the Committee '*suggest*' rather than insist. Hagge and Kostelnick (1989) argue that modal verbs like 'could' and 'may', like other hedging constructions, 'mitigate the force of the prose' (1989: 317). In these extracts, this works primarily by indicating that the REC, while strongly directive and leaving little doubt about the compulsory nature of the amendments for the accountable applicant, is not expressing extreme disapproval.

Specialist expertise as an indicator of quality

Discursive research has shown that when a message is attributed to an expert, the audience is more likely to be persuaded (Dickerson 1997). REC letters strategically orient to the expert knowledge that underpins the requests, suggestions or directives, and by so doing help to perform accountability. Talking about roles and responsibilities is a form of discursively accounting for behaviour (Edwards and Potter 1992). People in particular categories of role and responsibility are seen to have certain expertise to form a judgement and to be entitled to have that judgement deemed accurate (Potter 1996). Thus, letters display the quality of the REC decision by singling out individuals on the committee with a particular expertise.

25. 'The MREC statistician <named statistician> expressed slight concern over the power of the study.' (TIDA0375, provisional opinion then favourable)
26. 'The expert Committee members felt it would not be practical for participants with ADHD to undertake a two-hour test.' (PID2248, provisional opinion then favourable)

In both extracts 25 and 26, the letter specifically refers to particular members with expertise in particular areas. Extract 25 points to the '*MREC statistician*' as being a valued member able to judge the quality of the statistics being questioned. In extract 26 the '*expert Committee members*' able to comment on the topic of ADHD are invoked to pass judgement. These expert categories upgrade the ability of the Committee to comment on the quality of the research application and entitle them to express the need for change.

External authorities

In institutional texts the writer is likely to be mindful of the audiences of that text. Official processes that are sanctioned by the institution, including policy and procedures, may be referenced (Bremner 2006). One legitimatory tactic used by REC letters involves invoking official guidance (for example from COREC – now the National Research Ethics Service) to demonstrate how the applicants' submission deviates from expectations, and to make the applicants accountable for amending their application to ensure conformity.

27. 'It was agreed that the Consent Form must follow the standard format as outlined on the Central Office for Research Ethics Committees website at www.corec.org.uk. This standard format must include the study title at the top of the Consent Form.' (ID461, provisional opinion then favourable)

28. 'Committee took note of the recently published MRC Ethics Guide on Medical Research Involving Children which generally advocates no re-consenting.' (TIDB1551, provisional opinion then favourable)
29. 'For the storage of samples, patient information sheets and consent forms should conform to the current MRC publication on Human Tissue and Biological Samples for use in Research – Operational and Ethical guidelines. These are available from the MRC website, www.mrc.ac.uk' (ID038, Provisional opinion then favourable).

In these extracts, external authorities are called upon to authenticate the need for changes. This is a useful strategy for those engaged in accounting, because accountability requires a display of disinteretestedness (Edwards and Potter 1992). Citing the external '*MRC publication*' (extract 29) manages to disqualify any stake or interest the Committee may have in the application and displays a neutral position guided by external expert sources, thus rendering disagreement difficult. As Atkinson and Coffey (1997) point out, documents often depend upon or are linked to other documents; these extracts are striking because of the way in which this inter-textuality is being played out here. These extracts are also striking for the way in which ethical principles, such as those relating to informed consent, are constructed as procedural requirements rather than contestable or disputed positions located within broader debates – '*the recently published MRC Ethics Guide on Medical Research Involving Children which generally advocates no re-consenting*' (extract 28).

Often absent from these requests are specific details of the changes required. Extract 27 is both specific and vague in its orientation to the guidelines. Specifically, the Committee ask the applicants to make changes to their Consent Form, referring particularly to one element of the application. They ask the applicants to '*follow the standard format*', but do not identify the specific elements of the Consent Form that need attention. What this achieves is an attribution of blame to the applicants for failing to comply with the process required for applications.

Other external authorities invoked by the REC include the law, but this tends to be handled much more cautiously.

30. 'Q.A44 Appears to contravene the *Data Protection Act*: data can only be stored for the purposes of the study for a specified period of time.' (PID0337, provisional opinion then favourable)
31. 'Please contact your sponsor for further guidance on your responsibilities with regard to the *Human Tissue Act 2004*.' (TIDA0130, provisional opinion then favourable)
32. 'in line with GCP guidelines, the Committee strongly advised the establishment of an IDMC.' (TIDA0051, provisional opinion then favourable)

The importance of compliance with legislation is displayed within the letters, but the RECs deflect responsibility and knowledge through hedging devices (probably because officially RECs are not constituted to give legal advice). Some extracts show that certain elements of the application are beyond the remit of the REC: extract 30 reports that the element of the application '*Appears to contravene the Data Protection Act*', and extract 31 requests the applicants to '*contact your sponsor*' regarding the Human Tissue Act.

Discussion

Research Ethics Committees have to be accountable for several reasons. They are formally required to be accountable through their institutional structure. But they are also required

to be accountable in order to defend their actions and decisions against challenge, both at a micro-level (to avoid individual applicants using the appeals mechanism to challenge their decisions) and at a general level (to rebuff the macro-level contestation of the process). Regardless of what has happened during the REC meeting, the decision letter goes on to create its own 'documentary reality' (Atkinson and Coffey 1997). Our analysis has shown how, in REC letters, descriptions are put together to perform accountability work, manage questions of fault and blame attribution, and legitimate courses of action (Potter 1996b). REC letters use discursive tactics to display how RECs have executed a rigorous and diligent process, and take their decisions seriously and with proper authority. They use such tactics to show that what is proposed by the applicants is not recognised by the REC as desirable, proper, or appropriate. They suggest that the issues raised in their letter are not their fault, but rather they have been obliged to raise them: the applicants are to blame for missing information (forcing the REC to ask questions and request the missing documents) and making mistakes and ethical blunders that require correction. The rhetorical organisation of the texts often disallows alternative accounts of 'ethical' practice (including those proposed by the applicants), instead asserting the REC's own account as the privileged one. This privilege is claimed through the category entitlements conferred by REC membership, but may also be bolstered through reference to external authorities.

Our analysis demonstrates the salience of both the 'audit society' and the 'accounting as social action' approaches to accountability that we introduced at the beginning of this paper. It shows that, like accounting systems (Power 1997), which we characterised as purposeful attempts at accountability, the ethical review system serves to constitute a realm of facts, and to make a world of action visible and controllable. Letters do not so much 'discover' ethical issues in applications so much as construct them. The letters, then, can be understood as functioning as a system of classification that calls into being ethical 'troubles' and the means of their resolution. In this way, REC letters 'do' accountability by demonstrating that the routines of ethical assessment have been enacted, that ethical troubles have been identified, and that calls have been made to put things right. Thus, the ethics review process is one that requires *both* the applicant *and* the REC to prove their trustworthiness.

If we turn to the second tradition of accounting as a feature of discourse, it is clear that identifying the discursive strategies used to establish accountability is important because of the implications for legitimacy. Here, it is important to distinguish between the normative and sociological senses of legitimacy. To say that an institution is legitimate in the normative sense is to claim that it has the *right* to rule, whereas an institution is legitimate in the sociological sense when it is widely *believed* to have the right to rule (Buchanan and Keohane 2006). In this paper, we are not concerned with establishing the normative basis of RECs' legitimacy, nor are we concerned to comment on whether RECs are behaving reasonably or justifiably in the opinions expressed in their letters. Our analysis does, however, allow some insights into why REC letters may cause problems of legitimacy in the sociological sense.

These problems of legitimacy are evident in the continued publication of complaints from researchers (referred to in our Introduction) about the REC process. It could be argued that, paradoxically, some of the tactics used by RECs in their letters, while on the one hand 'doing' accountability, at the same time function to diminish legitimacy in this sociological sense. This can be seen by looking at how RECs tend to present their views as ethical 'facts', even though the issues at hand are opinions and judgements that are inherently contestable. In the letters in our sample, establishing the facticity of ethics was done in the letters using several tactics, including: deployment of externalising devices

(Wooffitt 2005); use of an impersonal style; emphasising the rationality and diligence of the process that has been executed; promoting the collaborative and consensual nature of decisions; suggesting that agreement between members means that ethical issues have an independent or objective existence; citing specific experts on the REC who have category entitlements that allow them to make credible claims; and referring to external authorities. But few of these tactics are likely to provide sufficient defence against criticisms of the decisions. For example, the REC's invoking of individual scientific experts to account for its rulings on scientific issues is a relatively weak means of conferring legitimacy (*i.e.* generating faith in its right to rule), since science is in a continual and dynamic state of contestation in which claims to expertise are constantly being remade (Gieryn 1999). As very often ethics and science are not 'facts' beyond the realm of dispute, these discursive attempts to construct ethical and scientific issues as 'facts' therefore have the potential to undermine legitimacy.

Threats to legitimacy (in the sociological sense) are reinforced by the lack of formal ethical reasoning in the letters; there are few examples of ethical arguments being rehearsed. When issues such as informed consent are raised, it is usually as a procedural norm embedded in institutional logic rather than as a (contestable) ethical principle. A good example of this is the reference by an REC to a requirement for informed consent to data processing under the *Data Protection Act*, where there is no acknowledgement in the REC letter that the interpretation and indeed ethical justification of this requirement are widely contested (Manson and O'Neill 2007). Thus, by promoting judgements as 'facts', and asserting their (administratively conferred) privilege to make rulings based on these judgements, RECs may risk appearing as though they are indulging in an illegitimate exercise of power.

These are important findings in understanding the continuing conflict about the role of Research Ethics Committees in governing research, where RECs and researchers see the conduct of the other as 'complainable'. Our analysis shows that REC letters use a range of tactics to do accountability, but there is potential for these tactics to backfire: the adjudications of the REC may remain complainable despite the attempts at accountability, and these efforts at accountability may themselves be the focus of complaints. As Schegloff (2005) notes, the complainability of some forms of conduct can be contingent on the identity of the agents and of the recipients of the conduct – identities often grounded in category membership. Tacit conventions about knowledge, attitude and expertise are inferentially available when people are assigned to a category which entitles them to certain knowledge claims (Potter 1996). The REC letter can be understood as a solution to the administrative problem that there is a need for a single authoritative ruling on the ethical standing of any application, but there are competing claims as to how that standing should be assessed. The contestation about REC conduct suggests that RECs seem to suffer from the problem that they are not seen by the regulated community to have full legitimate entitlement to make such claims. The critical problem here, we suggest, derives from the insecurity, for RECs, of their 'cultural authority', a concept used by Paul Starr (1982) and rooted in Weberian sociology, that refers to the power to define reality and have those definitions prevail as valid and true. We can see some of the resistance to RECs and their rulings as forms of credibility contests about who (*i.e.* the category of person or institution) can legitimately describe 'the ethics' of individual projects. RECs struggle for legitimacy because of the difficulties of policing the boundaries of ethics: whose view gets to prevail is, to a large extent, a function of institutional location rather than highly specific claims of specialist expertise, and thus is open to challenge. Complaining about RECs points to an unwillingness to accept the cultural authority of RECs as an occupational group to do

their work and have their judgements accepted as legitimate by their audiences. Equally, however, the apparent complainability of applicant conduct provides RECs with a justification for their own work. Any rapprochement is likely to involve both 'sides' in reflecting on how they do accountability.

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Acknowledgements

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