

Never mind the scientific quality, feel the ethics?: an analysis of decision letters by Research Ethics Committees and a reflection

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Abstract

Objectives: The performance of NHS Research Ethics Committees (RECs) is of growing interest. It has been proposed that they confine themselves to “ethical” issues only, and not concern themselves with the quality of the science. We aimed to identify current practices of RECs in relation to scientific issues in research ethics applications.

Methods: Letters written by UK RECs expressing provisional or unfavourable opinions in response to submitted research applications were sampled from the Research Ethics Database held by the Central Office for Research Ethics Committees. Ethnographic content analysis (ECA) was used to develop a coding framework. QSR N6 software was used to facilitate coding.

Results: “Scientific issues” were raised in 104 (74%) of the 141 letters in our sample. Our data suggest that RECs frequently considered scientific issues and that judgements of these often informed their decisions about approval of applications. Current processes of peer review seemed insufficient to reassure RECs about the scientific quality of applications they were asked to review.

Conclusions: Our study provides evidence that these issues are frequently raised in letters to researchers, and are often considered a quality problem by RECs. We reflect on how far issues of science can and should be distinguished from those of ethics, and on the policy implications.

Introduction

The practice of ethical review in health-related research has become increasingly contentious, with recent interventions in the debate arguing that ethical review of most health services research is fatuous.¹ In the UK, the performance of Research Ethics Committees has been widely criticised. Excessive demands and inappropriate conservatism on the part of research ethics committees (RECs) have been blamed for obstructing or impeding important research that would be of benefit to patients.² These charges have joined more long-standing complaints about the apparent capriciousness and inconsistency of RECs.^{3 4 5} The perceived growth in the influence and scope of ethical review has been a source of much comment.⁶ A particular and growing focus of criticism now concerns the perceived inclination of ethical review to stray onto the territory of science, rather than confining itself to more traditional ethical concerns such as not harming participants; informed consent; privacy; and avoiding deception of participants.⁷

At present, under the UK Research Governance Framework,⁸ responsibility for ensuring the quality of science technically rests with the so-called “sponsor” of any study. Protocols submitted for ethical review should, under the research governance arrangements, have already been peer-reviewed and had prior critique by methodological experts. The Governance Arrangements for Research Ethics Committees (GAfREC) state that:

It is not the task of an REC to undertake additional scientific review, nor is it constituted to do so, but it should satisfy itself that the review already undertaken is adequate for the nature of the proposal under consideration.⁹

However, GAfREC also commends that RECs be “adequately reassured” about particular aspects of the scientific design and conduct of the study, thus offering discretion to RECs about how far they accept prior assessments of the quality of the science.

The question of whether RECs should concern themselves with scientific matters has been raised in a number of countries worldwide. In a North American context, the term ‘ethics creep’ has been devised to denote:

a dual process whereby the regulatory structure of the ethics bureaucracy is expanding outward, colonizing new groups, practices, and institutions, while at the same time intensifying the regulation of practices deemed to fall within its official ambit.⁷

In the UK, the issue has been given renewed emphasis in the UK by the recent *Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*,¹⁰ which reported that it did ‘not believe that RECs should function as a secondary form of scientific review’ and that ‘RECs should deal with ethical rather than scientific review’. These recommendations raise important questions about how far RECs should assume that the quality of research ethics

applications is assured through the processes of peer review that are supposed to have occurred before their deliberations. In addition, some have argued that the science/ethics distinction incoherent, and that RECs should not only be permitted to consider the science, but are under an obligation to do so.¹¹

However, there is little systematic evidence about how far RECs currently do concern themselves with scientific issues, which issues are especially likely to engage their attention, and what might be the consequences if they were suspend judgement on the science. In this paper we report an analysis of letters composed by NHS RECs in response to applications by researchers, aiming to identify which types of scientific issue, if any, RECs identify as troubling them in their ethical review of applications.

Methods

Standard Operating Procedures issued by the Central Office for Research Ethics Committees (COREC) require that each REC in the UK register the applications it reviews onto the national Research Ethics Database (RED). Access to the RED was granted by COREC for purposes of our project.

Our project was concerned with 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 amendments previously requested by the REC.. Three possible decisions can be made by RECs when they first consider applications: favourable, provisional, and unfavourable (Box 1). We were interested in applications that received an unfavourable or provisional decision at first review, as such decisions indicated that there was an issue in the application that troubled the REC. For applications in our study that received a provisional opinion, the final decision was recorded where available (a small number of decisions were unavailable on the database).

Box 1: Decisions RECs may make

- 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 (for example because the researchers 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*

Criteria for inclusion of a letter in our sample were as follows:

- The letter conveyed a "provisional" or "unfavourable" opinion.
- The letter concerned an application considered by a REC for the first time during our "eligible periods": July 2005, October 2005, January 2006 and April 2006. These periods were chosen to minimise seasonal effects in application submission.

The 55 RECs that not upload letters to the RED during our eligible periods were excluded, leaving 115 RECs from which letters could be sampled. The first letter that met our eligibility criteria for each of the 115 RECs was chosen for inclusion in the study. Unfavourable opinions were purposefully over-represented to yield sufficient letters for analysis, so that they formed 20% of the initial sample. The remaining 80% of letters were those applications with provisional opinions. In addition, because applications that initially received a provisional decision but were subsequently issued with an unfavourable opinion were of particular interest, this type of application was also purposefully over-sampled by including all such applications between March 2004 and July 2006 for which a letter was available. More than one "provisional" letter from some RECs was therefore included in the study.

Descriptive information about each application – e.g. clinical drug trial, qualitative study, student project etc – was recorded. We also recorded whether the proposal had been peer-reviewed prior to submission to the REC. There are several different classes of peer review (ranging from review within project team to external independent review) and the tick-box categories for these have changed over time on the REC form. We report the categories ticked by applicants when they submitted.

In order to analyse the letters, ethnographic content analysis (ECA)^{12 13} was employed. ECA requires the development of a coding scheme or framework grounded in the data. The framework was generated initially through close inspection and comparison across the texts of letters used a previous study,¹⁴ but was modified extensively in response to the new data in this project. Explicit specifications were devised to aid data assignment, which was facilitated by the use of QSR N6 software.

Our study was deemed by COREC not to require research ethics committee review. Care has been taken to anonymise quotations from the letters and where appropriate identifying details have been modified or removed.

Results

Table 1 shows the outcomes of the 141 letters that were selected for inclusion in our study. Twenty-three applications were given an unfavourable opinion at first review and 118 were issued with a provisional opinion. Of these provisional opinions, 85 were later issued with a favourable opinion and 26 with an unfavourable opinion. Five were withdrawn by the researcher, one was withdrawn by the REC, and one was still awaiting a response from the researcher at the time we sampled (deemed "final decision unknown"). A mix of application and applicant types was achieved in our sample. Of applications where the final decision was known, 19/40 (48%) of applications to undertake intervention projects were approved, 36/56 (64%) of non-intervention projects were approved, and 30/38 (79%) qualitative studies were given a favourable final opinion.

Scientific issues were raised in a large proportion (104, 74%) of the 141 letters. Though any quantitative analysis of these data will necessarily be tentative given our sampling strategy, there is some evidence that RECs' judgement of scientific issues were decisive in influencing the outcome of applications. "Troubles" concerning scientific quality were raised in 51 (60%) of the 85 applications that were initially provisional and later favourable. However, issues concerning scientific quality were raised in 24 (92%) of the 26 applications given a final *unfavourable* opinion having been deemed "provisional" at first review. Scientific issues were also raised as troubles in all 23 applications that were unfavourable at first review, suggesting

that issues of scientific quality were strongly associated with applications that were initially or eventually deemed unfavourable.

Within the overall category of “scientific issues”, we generated nine sub-categories to characterise the types of issues raised by RECs (Table 2): the sample; choice of methods; the research question; the measuring instrument; analysis; bias; feasibility; equipoise, and “other” design issues. It is on the 104 letters where scientific issues were raised that our analysis will focus.

Sampling

Issues relating to sampling were raised in 68 (65%) of the 104 letters where “scientific issues” were raised by RECs. The most common trouble relating to the sample concerned inclusion and exclusion criteria (19 letters). RECs frequently requested further information, asked researchers to exclude certain groups of people, sought justification for the inclusion of particular vulnerable groups, or queried how potential participants would be identified. A concern for sampling criteria to be transparent and for a full justification of inclusion and exclusion criteria was prominent.

The committee felt that the exclusion criteria for the study although sensible were not felt to robustly exclude subjects at risk of a severe reaction based upon experience to date. The committee could not identify alternative criteria that would fulfil this requirement. (Letter 67, provisional opinion, review within institution)

Eleven letters expressed concern about the size of the sample. They requested clarity, justification of the sample size or for calculations to be re-done, or suggested that the sample size might be too small, especially when derived without the help of a statistical expert.

The power calculation of 45% was too low and would not identify any real difference. The purpose of conducting the study is, therefore, under question. (Letter 137, provisional opinion, independent external review, review within company, internal review)

Choice of methods

Issues relating to choice of methods were raised in 52 (50%) of the 104 letters where scientific issues were raised. Most commonly, RECs expressed concern that the rationale for the methods was unclear (27 letters).

There was significant confusion over the title and the design throughout the application [...]. (Letter 24, unfavourable opinion, independent external review, review within institution)

RECs often made suggestions for alternative ways of designing studies (17 letters), including the usefulness of control groups, the sources of tissue samples or data, or randomisation.

Following discussions with you we thought that the control group would not be helpful given the large number of variables and that to treat one disease state using the research subjects as their own controls would help you achieve at least some of the answers you were trying to obtain. (Letter 10, provisional opinion, independent external review, internal review)

Research question

Issues relating to the research question were in 29 letters. The most common concern was lack of clarity (15 letters).

There appears to be some confusion about the status of this study. Although it is presented as a pilot study, statistical advice given for a similar study will be used in this present study (A45-2), which indicates that this is not actually a pilot study. Furthermore the research questions do not appear to be those of a pilot study. (Letter 90, unfavourable opinion)

Other concerns relating to the research question included queries about why the study was being undertaken (4 letters), suggestions for alternative research questions (4 letters), questions about whether the study would produce meaningful results (3 letters), and concern that the research question might be too ambitious or complex (2 letters).

Members suggested that it was preferable to do the research using routinely collected blood samples and simplifying the research question. (Letter 42, unfavourable opinion)

Measuring instruments

Queries or concerns about measuring instruments – for example questionnaires and interview schedules – were raised in 28 (27%) of the 104 letters.

Question 15 provides only negative responses. The committee suggested taking advice from the Clinical Psychologist in order to suggest some neutral/positive responses. (Letter 22, provisional opinion, review within institution)

The usefulness of the measures to be used (10 letters), rationale (8 letters), and the ability of the study design to answer the research question (8 letters) were also questioned.

The Committee considered that the study will not achieve the research question. The study design will only test the cream. This would leave the placebo patients denied a proven treatment for an investigation with no clear purpose. (Letter 33, unfavourable opinion, no peer review)

Members suggested that it was preferable to do the research using routinely collected blood samples and simplifying the research question. (Letter 42, unfavourable opinion, review within institution)

Data analysis

RECs were concerned about issues relating to the analysis of data in 23 (22%) of the 104 letters, and in 10 letters they expressed specific concerns about statistical analysis.

The Committee noted that the application provided no information whatever on the statistical analysis that would be undertaken, and I should be grateful if you could provide clarification and confirmation from a Statistician independent of the study of the validity of the proposed calculations. (Letter 74, provisional opinion, review within institution)

Bias

RECs queried aspects of the study design that might bias the findings in 16 (15%) of the 104 letters. The most common concern related to the relationship between the researcher and participants (8 letters), but other issues relating to the potential for bias resulting from the design of the study were also raised.

You indicated that financial limitations prevented you from undertaking transcription verbatim. The question came up whether being selective might lead to errors arising. (Letter 94, provisional opinion, internal review)

Feasibility

The question of how likely it was that the work proposed by the researchers would be feasible was raised by RECs in 12 (12%) of the 104 letters. In six letters, RECs were concerned that recruitment might be slower or more difficult than anticipated. Other issues included burdens on staff, methods for extracting data, or the suitability of the research site and competence of the researchers.

Members thought that the methodology used to recruit participants was unrealistic and as such recruitment could be a problem, as GPs may not find the time to distribute the information sheets, especially if the study was unlikely to produce

significant results. Members strongly recommended that an alternate methodology should be used. (Letter 42, unfavourable opinion, review within institution)

Equipoise

Concerns about lack of equipoise were raised in 10 (10%) of the 104 letters. Other design issues were raised by RECs in 27 (26%) of the 104 letters. These mainly related to scientific peer review (16 letters) – that it had not been submitted, that it was inadequate, or that the researcher should address the concerns therein.

An independent external scientific critique specific to this area of expertise is required, the review that was submitted was considered inadequate by the Committee (Letter 126, provisional opinion, independent external review, internal review)

Other issues

Other design issues were raised by RECs in 27 letters. These mainly related to scientific peer review (16 letters) – that it had not been submitted, that it was inadequate, or that the researcher should address the concerns therein.

An independent external scientific critique specific to this area of expertise is required, the review that was submitted was considered inadequate by the Committee (Letter 126, provisional opinion)

Other 'unspecified' issues relating to study design included concerns of a general nature (4 letters), missing or incorrect information (4 letters), issue relating to research governance approval (3 letters), and data monitoring (3 letters).

The Committee expressed unhappiness about the scientific presentation of this study and feels that it needs significant revision. (Letter 6, unfavourable opinion)

Questions A12 and A13 have been left blank and there is insufficient information in the remainder of the application about the tests being performed. (Letter 90, unfavourable opinion)

Discussion

Our analysis suggests that Research Ethics Committee letters frequently raised issues of "science", and sought clarification or amendment of methodological issues. Sampling appeared to be an area that was especially likely to be a focus of concern in REC letters, but many other categories of scientific "trouble" appeared to be important to RECs and may

influence the decisions they make. These findings suggest that RECs do not seem to find sufficient reassurance about the quality of science from peer review conducted before applications are seen by RECs.

Our study does have a number of important limitations. In particular, we did not analyse the applications themselves, only the letters written in response. Our sample aimed to represent different types of decision, and is not fully representative of all types of application. Nonetheless, our analysis does suggest that clarification of the case for regarding matters of research quality as ethical issues is needed, as is consideration of the limits and extent of the role of RECs in this area.

Clearly, one way of explaining our finding that RECs often concern themselves with matters of science is to treat it as evidence of “ethics creep”⁶ and territorial expansion. Other explanations should, however, be considered. One problem for RECs, for example, concerns how it is that they can be assured that the scientific review carried out before they see an application is adequate. At present, it is not at all clear how RECs should satisfy themselves that the application has undergone appropriate review, since the current application form requires applicants to state what kind of scientific review has been undertaken, but not necessarily to include the reports with their application.

The problem of being assured of the quality of prior review is of particular importance to RECs, because our data suggest that RECs tend to see research as a context in which the quality of research, considered broadly, has ethical implications.¹¹ RECs, faced with what they consider to be a scientifically poor or dubious project, are confronted with the dilemma that such studies may pose risks. Poor quality health research, may, for instance, be harmful to future patients, whose treatment could be based on inadequate or misleading evidence,¹⁵ and unfair to present research participants, in that they are subject to the risks and inconveniences of participation in unworthy research. RECs may therefore feel that they are entitled to concern themselves with issues of science, on the grounds that bad science is bad ethics.

In this respect, RECs may have a particular concern with ensuring that patients taking part in studies are not harmed. In the detail of what the REC letters in our sample were raising were many issues that were concerned with the direct impacts of poor study design on the well-being of people – for example, the possibility that people in the placebo arm of a trial would be denied a known effective treatment (the cream mentioned in letter 33, for example) for no clear benefit. Such examples legitimate the interest of RECs in scientific issues, and strengthen the argument that RECs should adjudicate on these matters.

Clear examples such as this should not, however, obscure the fact that there were many examples in our dataset where there was unlikely to be scientific consensus about the issue at hand – for example in relation to construction of questionnaires or sample size. The parlaying of such issues into matters of “harm” is arguably more problematic. As all those in the research community are aware, referees of research proposals often vary in their understanding of what is “good science”, and scientific review conducted within the context of a REC system is unlikely to be any different: there is no external infallible scientific authority to which appeals might be made. There is thus the potential that RECs might reject applications on scientific grounds that within the scientific community of practice in which they originated are regarded as having satisfactory study designs.

A related process is that RECs may parlay scientific issues into harm-related form in order to deem them “ethical” issues, and this may be because RECs are concerned with issues of fairness. Fairness is problematic in ethical review for two reasons. First, issues of fairness are often debatable and obscure, whereas issues of harm are more clear-cut. Second, although researchers are under clear obligations not to harm their subjects, it is not clear that they are obliged to treat participants and non-participants fairly. Our analysis revealed a widespread concern among RECs about issues of sampling, and inclusion/exclusion criteria. Thus a scientific issue (exclusion/inclusion criteria) can be redefined as an ethical one (protecting individuals from unfair and harmful discrimination).

Any account of the distinction between science and ethics must also recognise the more general problem of distinguishing between science and non-science. To require RECs to deny themselves consideration of scientific issues, one has to accept an unambiguous distinction between ethics and science. The evidence we present here suggests that it is difficult to sustain such a distinction in practice, even if it is available in theory. Our data suggest that the science/ethics distinction can be seen as the outcome of a social process, rather than an *a priori* conceptual distinction. As Gieryn's¹⁶ analysis of boundary work has shown, philosophers and sociologists of science have long struggled with the problem of “demarcation”: how to identify the unique and essential characteristics of science. Gieryn identifies boundary work as a rhetorical effort that involves the attribution, by scientists, of selected characteristics to the institution of science, for purposes of constructing a social boundary that distinguishes “science” from “non-science”. On this account, attempts to protect the “science” from the criticism of RECs involve boundary work rather than resting on an unchallengeable and uncontested distinction between “science” and “ethics”.

Our findings raise questions about the appropriate policy response. Better assurance of the quality of the science might reduce the potential for conflict between RECs and researchers. One response might be to focus on improving the quality of peer review before applications reach the committee stage, and to ensure that all scientific review reports are made available

to committees, the better to discourage RECs from considering scientific issues. One possibility might be that some types of peer review are considered more authoritative than others – in the UK, for example, research proposals that have been through certain funders will already have been subjected to rigorous peer review. It should be recognised, however, that prior scientific review by funders may not guarantee that all of the issues that our data suggest are of concern to RECs have been reviewed in detail; some funders require only brief details of such issues, and project specifications may change between approval by the funder and submission to the REC. Any system that relies on improved peer review before submission to the REC would also require caution to avoid creating an overly bureaucratic process to oversee the referee reports.

A second response might be to accept that RECs may find it difficult to stop themselves from considerations of the science, for the reasons we outline above. If RECs are to consider such matters, then their membership needs to include the appropriate expertise to provide the knowledge and credibility necessary to the (legitimate) exercise of power. To avoid the outcome of an application being (overly) dependent on the particular compositions of individual committees, committees would also need to be constituted so that their expertise was commensurate with the applications being submitted. Indeed the present situation, where RECs are encouraged to include a statistician among their membership, goes some way towards acknowledging this implicitly. An argument might more strongly be made that committees should be constituted explicitly with methodological expertise in particular domains – clinical trials, qualitative research, and so on – and only review applications within those areas. However, given the increase in multi-disciplinary, multi-method studies, some flexibility in this approach would be needed.

None of these remedies is likely to completely resolve the problems (at least from the point of view of researchers) of RECs functioning both as scientific authorities as well as moral authorities in having a role in assessing both the scientific and the moral credentials of researchers and research proposals. For the present, researchers intending to conduct investigations in the health care field should recognise the degree to which their proposed research is likely to attract scientific scrutiny from RECs, and debates in the area should recognise that there may be more to this scrutiny than simply “ethics creep”.

Table 1 REC letters and outcomes of the ethical review process

Full decision	Total letters	Intervention studies	Non-intervention studies	Qualitative studies
Provisional then favourable	85	19 (22%)	36 (42%)	30 (35%)
Unfavourable at first review	23	8 (35%)	11 (48%)	4 (17%)
Provisional then unfavourable	26	13 (50%)	9 (35%)	4 (16%)
Provisional, final outcome unknown	7	3 (43%)	4 (57%)	0 (0%)
Total letters	141	43 (30%)	60 (43%)	38 (27%)

Table 2 Types of issues raised by RECs in the 104 letters where scientific quality was raised as a "trouble"

Final decision	Total letters	Sampling	Choice of methods	Research question	Measuring instrument	Data analysis	Bias	Feasibility	Equipoise	Other / unspecified design issues
Provisional then favourable	51	30	15	9	15	9	7	2	5	8
Unfavourable at first review	23	16	19	10	6	8	4	6	2	7
Provisional then unfavourable	24	18	16	7	5	5	3	3	3	10
Provisional, final decision unknown	6	4	2	3	2	1	2	1	0	2
Total letters	104	68	52	29	28	23	16	12	10	27

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