Optimising research ethics review: Combining regulatory support and ethics consultation to enhance efficiency of university research ethics review

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Research ethics review; regulatory support; research ethics consultation; research administration

ABBREVIATIONS

REC – Research Ethics Committee
IRB – Institutional Review Board
RGF – Research Governance Framework
ESRC – Economic & Social Research Council
NHS – National Health Service

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What this paper adds:

This paper provides discussion of administrative support of the research ethics review process. As such it is relevant to research administrators, staff and student researchers who engage with the research ethics review process, and members of research ethics committees who undertake reviews of ethics applications

Abstract

A significant factor in REC efficiency has been identified as the quality of administrative and regulatory support for researchers making applications to research ethics committees. Incomplete or poorly completed applications can result in significant delays for researchers. Evidence shows that good quality support for applicants prior to submission can facilitate efficient and expeditious review by improving the quality of applications. UK universities are urged to provide adequate resources to support provision of regulatory support and ethics consultancy services to researchers. In turn, this can reduce delays to research, and help ensure that research supported by universities is good quality and safeguards human research participants.

Introduction: Universities supporting research carried out by staff and students have a duty to protect the rights, dignity, safety and wellbeing of human participants. The accepted practice is for research to undergo review by a research ethics committee (REC) prior to initiation, being sanctioned to go ahead only once a favourable opinion has been secured. However, university REC review processes have been criticised for causing delays to research, with the associated impacts on project timescales and costs (Dixon-Woods *et al.,* 2016; Silberman & Kahn, 2011; Tzeng *et al.,* 2015). A range of reasons for these delays have been suggested, including inefficient procedures, risk averse attitudes, and undertrained reviewers.

While REC reviewers and procedures have been the main focus of criticism, there is evidence that the fault also lies with applicants (Cleaton-Jones, 2010; Dixon-Woods *et al.,* 2016; Desai *et al.,* 2017; Nicholls, 2018; Sonne *et al*., 2018). A significant factor in REC efficiency has been identified as the quality of administrative and regulatory support for researchers making applications to research ethics committees (Cleaton-Jones, 2010; Dixon-Woods *et al.,* 2016; Sonne *et al*., 2018).

Incomplete or poorly completed applications can result in significant delays for researchers before the REC can issue an opinion. When insufficient information about a study is submitted, or supporting documents such as consent forms and participant information sheets are missing, the review process is halted until applicants respond to requests to provide them. Evidence shows that good quality support for applicants prior to submission can facilitate efficient and expeditious review by improving the quality of applications (Cleaton-Jones, 2010; Sonne *et al*., 2018). In addition to administrative and regulatory support, it is proposed that provision of ethics consultation services to researchers can further improve both the quality of REC applications, and ethics knowledge of researchers.

Background: The focus on research ethics and integrity has intensified for UK universities in recent years[1]. In addition to the regulatory requirements that mandate research ethics review for certain categories of research, recent policy documents, such as the Concordat to Support Research Integrity (Universities UK 2012), have introduced funding implications for UK universities, linked to good practice. One of the main ways to demonstrate sound ethical practice, and to ensure that human participants are protected, is by pre-emptive ethics review of research protocols (Guillemin *et al.,* 2012). However, there has been a history of tensions between researchers and RECs, including mistrust and researcher perceptions of an adversarial and unnecessarily bureaucratic process (Burris and Moss, 2006; Gillam *et al.,* 2006; Gillam and Guillemin, 2018). In order to ensure that REC review can be as effective as possible in safeguarding human participants, and enhancing the integrity of research, it is important that systems are efficient and that researchers are supported to engage fully with the process (Burris & Moss, 2006).

[1] See for example the Commons Science & Technology Committee's Research Integrity Inquiry: https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2017/research-integrity-17-19/ (viewed 15.06.18)

University research ethics review in the UK: The governance of good research practice in UK universities has transformed over the last decade and a half. Tinker and Coomber's (2004) report into university research ethics review procedures provides a snapshot of the process at a time when many universities were working on establishing institutional RECs. The report highlights many funders' concerns with the lack of consistency regarding ethical scrutiny across the sector at this time, and uncovers a diversity of standards relating to REC remit and operation (Tinker and Coomber, 2004, p6). While the majority of universities did have research ethics committees at the time of the report, almost half of them had only been established since 2000 (*Ibid,* p11). Scrutiny did not appear to extend to all of the research being undertaken, with student research often being completely excluded from review (*Ibid*, p10).

Broadening remit: Ethical scrutiny has been part of clinical research for some time (Rhodes, 2005). Certain types of research, for example involving human tissue samples, or people lacking capacity to consent, are covered by legislation that makes research ethics review a legal requirement (e.g. Animals (Scientific Procedures) Act, 1986; Human Tissue Act, 2004; Medicines for Human Use (Clinical Trials) Regulations, 2004; Mental Capacity Act, 2005). However, during the last decade and a half, ethical scrutiny has been applied much more widely, and to areas of research which have traditionally not been subject to independent ethics review (Rhodes, 2005; Hedgecoe, 2008; McCormack *et al.,* 2012; McCarthy *et al.,* 2017; Hedgecoe, 2016). This 'ethics creep' has not been without its critics (Haggerty, 2004, p391). It has been claimed that the existing bioethics model is not well suited to research utilising social science methodologies, and that adapting to incorporate this kind of research in review processes has been problematic (De Vries and DeBruin, 2004; Schrag, 2011). Also that the research ethics review process, and the bureaucracy it entails, have become disproportionate to the potential risks of harm of the activities to which they are applied (Haggerty, 2004).

The broadening scope of research ethics review has resulted in larger numbers of applicants, with less familiarity with the process, needing more intensive support to successfully navigate procedures (McCormack *et al.,* 2012; Sonne *et al*., 2018). In order to carry out an ethics review, RECs need a large amount of information about the proposed research, usually collected via an application form. They must also check all supporting documentation such as participant information sheets and consent forms, to ensure they are suitable for the intended participant population. This requires a lot of work up-front from researchers and the potential for errors can be great (Dixon-Woods *et al.,* 2016; Sonne *et al*., 2018).

REC review: The autonomy of UK research establishments, as recognised in the Concordat to Support Research Integrity (Universities UK, 2012) means that there are variations in the standard operating procedures for institutional RECs. However, after carrying out a review of an application, either at a convened meeting, or via virtual correspondence, the REC will come to a decision which will be communicated to the applicant. Decisions RECs may make generally follow a similar format. A 'favourable' opinion is granted when an application is approved without the need for further amendments. A

'provisional' opinion requires the applicant to make a response to address the issues raised by the review. An 'unfavourable' opinion amounts to a rejection, and in order to be able to proceed with the research, the applicant must make a new, fully revised, application to the REC (Angell and Dixon-Woods, 2009, p131).

There has been criticism of inconsistencies within REC review, with similar proposals being subject to different requirements or issued with different opinions by RECs (Anthony, 2005; Patel *et al.,* 2013; Redshaw *et al.,* 1996). However, as Trace and Kolstoe (2017, p1) observe, '[t]he review of human participant research by Research Ethics Committees…is a complex and multi-faceted process that cannot be reduced to an algorithm'. While it is agreed that certain standard research activities are essential to good ethical practice, each research project will have unique ethical implications, and must generally be reviewed on a case-by-case basis. With research ethics being quite nebulous, sometimes with no obvious right or wrong answers, opinions can be subjective, due to the 'inherent contestability of ethical decision-making' (O'Reilly *et al.,* 2009). Reviewers may find fault with issues the researcher considers acceptable, and this often leads to a provisional opinion after the initial review, with the researcher required to make amendments to their methodology or documentation to bring it into line with the views of the REC. This of course leads to a delay while the applicant responds to the committee to address the issues raised, and while the committee considers the response.

However, the most common reason for the REC granting a provisional opinion rather than a straightforward favourable opinion, is the poor quality of the application.

Process errors: Research (e.g. by Angell and Dixon-Woods, 2009; Cleaton-Jones, 2010; Dixon-Woods *et al.,* 2016) has shown that the time applicants wait for a final decision is strongly linked to the REC's decision at first review. Studies looking at both NHS RECs and university research ethics committees have found that relatively few applications receive a favourable opinion at first review, and that for NHS RECs this can be as low as around 15% of applications (Angell and Dixon-Woods, 2009, p131).

'Process errors', rather than ethical issues, have been identified as the main reason for the majority of provisional and unfavourable opinions at first review (*Ibid,* p130). One study found that 87% of applications to NHS RECs that did not receive a favourable opinion contained process errors (Angell and Dixon-Woods, *op. cit.*).

These process errors were classified into four types, in order of prevalence:

- procedural violations;
- missing information;
- slip-ups; and
- discrepancies.

'Procedural violations' include failure to comply with correct procedures, for example, not following application requirements or not obtaining necessary signatures. 'Missing information' includes missing documents, such as consent forms or participant information sheets, or missing details from the protocol. 'Slip-ups' include minor errors such as spelling and grammar mistakes and typos, and failure to tick boxes in the application form. 'Discrepancies' are described as inconsistencies in details between different parts of the application form, or differences in the description of the research between the application form and the participant information sheet (*Ibid,* p131).

In addition to causing delays to research, there is evidence to show that these kinds of mistakes and errors have a wider negative impact on the REC review process. Applications that ultimately receive an unfavourable opinion from a REC take significantly longer not only to review, but also for the initial administrative checks required before being forwarded to the reviewers (Tzeng *et al.,* 2015). As well as increasing review time, ill-prepared applications have a negative effect on 'overall [REC] efficiency and workflow' (Sonne *et al.,* 2018, p2) which potentially also causes delays to those submissions that have been well-prepared.

If applicants were to get applications 'right first time' resulting in a favourable opinion at first review, this would reduce frustrations with the review process on the part of both researchers and reviewers (Dixon-Woods *et al.,* 2016, p3). A better experience should improve trust and confidence in the process on both sides.

Regulatory support: There is evidence that the majority of applications that are deemed 'not ready for review' (or NRR) at submission are from trainee or early career researchers (Sonne *op. cit.* p5; Cleaton-Jones, 2010; Klitzman 2011). While provision of training in research ethics and REC review procedures and systems is commonplace at most universities, Sonne *et al.,*2018, observe that it may not be provided at a time when post graduate students, for example, are at a stage in their own research where they are actively engaging with the process. Without context the information and guidance means little, and can often be lost by the time students are putting together their applications (*Ibid,* p5).

Evidence from the United States and South Africa shows that provision of a 'regulatory support' service has been shown to improve rates of favourable opinion after first REC review (Cleaton-Jones, 2010; Desai *et al.,* 2017; Nicholls, 2018; Sonne *et al.,* 2018). Support of this type includes advice on regulations and policy, identifying documents required for submission, provision of template documents for consent forms and participant information sheets along with standard wording, and checking documents for completeness and accuracy before

submission to the REC (Sonne *et al., op. cit.* p2). Generally provided as an optional service, and one that cannot guarantee that the REC will deliver a favourable opinion at first review, regulatory support can nevertheless improve the quality of applications to an extent that this is much more likely (Desai *et al.,* 2017).

Ethics consultation: Ethics consultation is a service that has been available to clinicians seeking advice on challenging ethical issues in healthcare for many years (de Melo-Martin *et al.,* 2007; Porter *et al.,* 2018). A number of universities in the United States have initiated establishment of ethics consultation services to provide advice to researchers on complex ethical dilemmas that may arise during the conduct of their research (Beskow *et al.,* 2009; De Panfilis *et al.,* 2018; Dixon-Woods *et al.,* 2016; Greenbaum, 2018; Master *et al.,* 2018; McCormick *et al.,* 2013; Paquette & Ross, 2018; Porter *et al.,* 2018). The focus of these services is not on improving research ethics applications, but on providing guidance to researchers at all stages of a project, from planning to dissemination of results (Porter *op. cit.*). Ethics consultation has also been suggested as a useful mechanism for promoting research integrity and a culture of responsible research conduct in universities (Master *et al.,* 2018; Porter *et al., op. cit.*).
However, it is proposed that ethics consultation could also be effective in helping to improve the quality of applications to RECs. If ethics consultants were to advise researchers on the ethical implications of their studies, and suggest measures to mitigate them, REC applications may be more likely to receive a favourable opinion at first review.

Optimising review procedures: REC review: There are a number of advantages to optimising research ethics review that can benefit researchers, reviewers and research participants. There is evidence that good quality applications save reviewers time and enable in-depth deliberation of complex ethical dilemmas presented by issues such as new research areas and technological advances. Time saved by not having to concentrate on process errors could also provide an opportunity for RECs to build a repository of knowledge that could contribute to better consistency of future decision-making (Cleaton-Jones, 2010).
It has been demonstrated that more intensive up-front support for applicants results in enhanced turnaround times for review (Desai *et al.,* 2017). In addition, there is evidence that researchers who perceive the research ethics review process to be fair and efficient are more likely to comply with review requirements. Researchers who feel unfairly treated, or that the REC has been overly pedantic or 'nit-picky', may be more likely to feel justified in avoiding REC review altogether (Keith-Spiegel *et al.,* 2006; Klitzman, 2001).
Together, regulatory support and ethics consultation can address the two main elements of research ethics review: ethical implications of the planned research, and process errors in the application form and supporting documentation. The enhanced quality of the resulting ethics applications would contribute to efficient and effective REC review and reduce potential delays to researchers.

Conclusion: It has been suggested that there is a general lack of knowledge about the operation of RECs among researchers. While there has been much discussion in the literature about REC review, this has tended to concentrate on 'structural and process issues and problems in the ethics review system' rather than what actually happens during REC meetings and review of applications (Fitzgerald *et al.,* 2006, p377). Indeed, it has been claimed that, for many researchers, the ethics review process is 'like the proverbial black box…researchers put an application in on one side…and out the other side comes the "please explain" letter, an often decontextualized request or demand for additional information or changes in some aspect of the research' (*Ibid,* p378).

In order to improve the REC review experience for researchers, it is necessary first to demystify it. Regulatory support, by reducing process errors in REC applications, has been demonstrated to improve REC efficiency and hasten turnaround times. Ethics consultancy, by assisting researchers to identify and address the ethical implications in their research projects, can help them to prepare comprehensive applications with which RECs are less likely to find fault. In combination, these services can lead to greater numbers of research ethics applications receiving a favourable opinion at first review, and thereby reduce delays to research and enhance the researcher's review experience (Sonne *et al.,* 2018).
Regulatory support and ethics consultancy services can also improve the knowledge and experience of academics tasked with supervising student researchers or providing mentorship of early career researchers. Where they engage with the advice and guidance provided, they will incrementally build a comprehensive knowledge of REC review procedures and research ethics (*Ibid.*).
UK universities are urged to provide adequate resources to support provision of regulatory support and ethics consultancy services to researchers. It is recognised that while provision of this kind of support in UK universities is variable, resources are key, as sourcing staff with a suitable level of expertise and experience can be costly (Greenbaum, 2018). However, the benefits are improved efficiency and effectiveness of research ethics review,

which, in turn, results in reduced delays to research, better quality research outputs and better safeguarding of human participants.

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