Head-to-Head:

Can a one-size-fits-all research ethics review process work across all disciplines?

Simon Kolstoe ⓘD and David Carpenter 🔗   May 2023

Introduction

Research ethics review is a practical task. The aim is to provide an opinion as to whether a proposed research activity meets principles and standards, broadly relating to accepted ethical norms, to the satisfaction of designated reviewers sitting as members of a research ethics committee (REC). Exactly what these ethical norms are is not the concern here. Instead, our aim is to debate whether or not a REC process can be proposed that will get to this ethical opinion, in a robust and timely manner, in a way that is relevant to all researchers no matter their academic discipline or area of research.

Key to any REC review is a description of the proposed research in the form of a detailed written protocol. The protocol is read and discussed by the REC, whose members should be independent from the researchers, the sponsoring institution, and the funders, to reduce bias from conflicts of interest. The REC provides feedback in the form of requested updates to the research plan guided by their understanding of ethical norms. If the REC is independent, it cannot, by definition, give **approval** for the research to go ahead. Instead, the REC gives an **opinion** that must be considered in parallel with other requirements such as those relating to data protection, health and safety, insurance, finance or legal arrangements, and other more general management issues.

Within most Western research systems, the process of ethics review evolved out of the medical and human sciences, e.g., psychology, sports science, and sociology. This is not surprising due to the risk of harm to human and animal participants in such research, and particularly a history of abuse in the name of research. These abuses, and subsequent requirements for safeguards, created the need for robust and independent review processes. Over recent years the role of RECs has increasingly been understood as a vital component of research culture and wider moves to strengthen and improve research integrity. Consequently, the REC model has increasingly been expanded outside of the medical and human sciences to incorporate research within all disciplines. This has led to tensions from some within the wider research community who argue that the "medical" model of REC review is not always appropriate.

Head-to-Head

Can a one-size-fits-all research ethics review process work across all disciplines? – YES (Simon Kolstoe)

Research is a difficult activity. While data/conclusions generated by research are transformative, much harm can be done if misleading or simply incorrect results are used to inform policy, processes, technology, or opinions. It must always be remembered that research is a human activity and as such mistakes, and occasionally misconduct, are bound to occur. Likewise, the highly competitive nature of research funding in particular can lead to a negative culture driven by incentives that reward quantity over quality, novelty over reliability, or profit over human well-being. There is no such thing as the objective researcher, and as such checks must be in place to ensure research is robust, reliable, and carried out to agreed standards.

Systems of research accountability have therefore been developed both internationally (through peer review) and also more locally (in the form of national research governance processes) to guard the quality of research. One important aspect of research governance includes ensuring that all research comes under the legal authority of a research sponsor such as a university, company, or research institute. Research sponsors ensure that all research they are responsible for is legal, conforms to agreed national/international standards, and ideally is both suitably financed and indemnified. If ethical accountability is also expected, it makes sense from a pragmatic perspective for sponsors to also ensure and arrange suitable independent ethics reviews including of any subsequent modifications of the research plans. Although the task of an ethics review is certainly more complex than other governance checks, it can still broadly be viewed as an important part of the wider research governance process that is designed to embed accountability, integrity, and reliability into the culture and thus outputs of research.

But one of the reasons why research is a complex activity is the wide range of subjects, and subsequent methodologies, examined and employed by researchers. Research sponsors, therefore, have a significant challenge in ensuring that their processes are able to suitably assess, and facilitate, the research they intend to sponsor. This can be achieved through continuing dialogue with researchers and the ongoing evolution of policies and practices. There are no doubt challenges facing ethics reviewers in particular, but a focus on context and reflexivity can meet these challenges. Ethics review approaches developed in one area (e.g., medical research) may well not be entirely relevant to other areas, but this does not mean that all the principles or concerns are different or need to be reinvented. For instance, formulating research aims, identifying participants, collecting data, analysing data, formulating conclusions, disseminating results, relating new data to the literature, and many other aspects of the research process are common across all disciplines for the simple reason that they **are** the activities that define research, as opposed to other types of activity.

When considering this topic, it is therefore important to note that if the research itself can be defined, research ethics (and other governance processes) can be

sculpted to assess activities that fall under this definition. While it is no doubt true that processes are seldom perfect, so long as ethics review remains flexible and open to evolution, it is likely that any activity or project that simply cannot be accommodated probably does not meet the rigorous standards required to be defined as research.

Can a one-size-fits-all research ethics review process work across all disciplines? – NO (David Carpenter)

The current dominant approach to ethics review of research comes from a medical, or perhaps more widely, a STEM (science, technology, engineering, and mathematics) model. There is a strong emphasis on the need for individual informed consent and confidentiality; RECs tend to focus their reviews on these and related issues. Scientific methodologies tend to focus on quantitative data collection and hypothesis testing. In undertaking reviews, RECs rarely consider matters of ethics in the sense of drawing on practical theories of ethics; they tend to be regulatory and are often '**compliance checkers**'. Ethics opinions are typically front-loaded, in advance of any actual research, in most cases without further review, in a binary fashion – the study is either ethical or it is not. I contend that these approaches are not appropriate in all disciplines, particularly the arts and humanities and, to some extent, the social sciences.

In the arts and humanities, there might not be any human participants in the normal sense. An obvious example is research involving historical records and artefacts. Research of this nature requires an ethics review, but the medical model will certainly not fit. Whilst consent is normally required when recruiting human participants, a focus on individual consent is clearly contentious: why should individual consent trump all other considerations, including those of the communities of which they are part? Most anthropological research focuses on communities; the individual consent of their members may not represent the interests of the communities. Consent is more likely to be obtained through means such as community meetings rather than a pile of individually signed consent forms. Arguably, similar issues apply in the case of scientific environmental and ecological research, where the medical model has clear limitations. Individual consent reflects Western culture; its imposition in wider contexts faces criticisms of neo-colonialism.

Research in the performing and creative arts rarely fits the medical model of ethics review. Examples such as performance art and immersive drama used in the context of research cannot be pigeonholed into the agendas of typical RECs in universities and beyond. New frameworks underpinned by sound practical ethics are needed.

Research in the social sciences poses challenging examples: qualitative methodologies, where objectives and testable hypotheses cannot always be determined in advance; much research is iterative and exploratory – this is never well-received by a typical medical-model REC with its front-loaded, binary approach to review; participatory action research, commonly undertaken in the social sciences, at its best ensures co-production of research. With no obvious hierarchy (another contentious issue), who exactly needs to acquire consent from whom?

I will conclude my argument against the idea of a one-size-fits-all approach with a somewhat contentious example, autoethnography (where a researcher connects their own personal experience to self-reflect, describe, and understand cultural beliefs, societal expectations, and behaviours). There are numerous ethical issues, not least for the 'participant'.[1] No standard medical model REC could ever cope with it!

Response

Response to David

David's argument focuses on specific areas of the content discussed during ethics reviews, not whether the ethics review process is suitably flexible to allow the review of research in all fields. For instance, I entirely agree that different forms of consent are appropriate for different types (or contexts) of projects. Such discussions are precisely the job of the REC.

While committee reviews are not perfect, I disagree that they mostly consider issues of compliance. One compelling argument for drawing a distinction between governance processes and the role of ethics reviews rests precisely on a distinction between compliance (a governance task that can be delegated to suitably qualified individuals) and more complex "ethical" issues that require discussion by a group. Granted, not every ethics/governance process gets the compliance vs ethics distinction correct, but things are getting better.

Ethics review is also particularly important for projects with adaptive designs. The role of the ethics committee is to consider whether such methodologies are appropriate, and especially how the rights and values of participants will be respected throughout the research process even if the methodology changes. It is entirely feasible for research teams to return to RECs with amendments as and when projects evolve.

My challenge to David is to ask for his alternative to an ethics committee review. Unfortunately, the history of research ethics and integrity shows that not all researchers can be trusted to do the right thing or make the right decisions (for evidence see Retraction Watch). If "research" is the name we give to the process that generates high-quality and reliable information, there must be something that distinguishes research from anecdotes, opinions, gossip, or lies. A fundamental part of this distinction comes from the accountability generated by the research ethics committee review.

Edwards, J. (2021). Ethical Autoethnography: Is it Possible? *International Journal of Qualitative Methods*, 20. https://doi.org/10.1177/1609406921995306

Response to Simon

Simon opens his discussion with an emphasis on the need to ensure high-quality research that is conducted with integrity. He rightly highlights the issues that might lead to compromising research quality. In a similar vein, Simon discusses the role of the sponsor in terms of accountability, including that related to matters of law. These matters are not the concern of an ethics committee: many researchers complain that RECs extend their remits to this wider agenda, and I support them in raising these concerns. The role of ethics committees is to evaluate the **ethics** of proposed studies.

I am not suggesting that ethics review is unnecessary; all research activity requires ethics review. My argument is simply that the STEM model, which predominates, is not fit for wider application beyond that for which it is intended. I agree with Simon that research is complex, involving a range of activities and methodologies and I agree that there might well be some research ethics principles that might be shared across these subjects. However, common principles will vary in their application depending on the nature and context of the proposed research. My simple point is that RECs should be to some extent discipline-specific. This ensures that REC members develop their skills through the use of discipline-specific, relevant reviewing tools.

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Dr Simon Kolstoe is a Reader in Bioethics at the University of Portsmouth and chairs research ethics committees for the UK's NHS, Ministry of Defence, and Health Security Agency (UKHSA). His research looks at how ethics and governance processes can be used to promote research integrity and culture.

David Carpenter is a retired lecturer in moral and political philosophy who now works as an independent trainer and consultant in research ethics. He chaired the NHS REC that was responsible for the ethics reviews of all the main vaccine studies conducted by the Oxford Vaccine Group.

Contributors and Reviewers

Matt Hodgkinson [iD] – *reviewed and commented on draft*.

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Competing Interests

Dr Simon Kolstoe is a UKRIO trustee. He has chaired the Fast-track REC, HRA, Sept 2021-Jul 2022, REGG, UKHSA Apr 2019-present, and MODREC, Apr 2016-present, and

is a member of the NHS Human Challenge REC. He is also an employee of a subscribing institution to UKRIO, the University of Portsmouth.

David Carpenter chairs the South Central – Hampshire A NHS REC and has provided training for UKRIO.

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