THE INNER WORKINGS OF AN ETHICS REVIEW BOARD FOR SOCIAL SCIENCE RESEARCH: REFLECTIONS ON RESEARCH IN DIFFICULT CONTEXTS

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Introduction

The purpose of an ethics review board (ERB) is to uphold high standards in the conduct of research and ultimately to protect research participants from harm, principally through the process of informed consent, as well as the communities to which they belong. However, the ERB also assesses the possibility of harm to the research team and, if the ERB is 'in house', the possible risk to the institution's reputation and future research activities. The potential for risk and harm runs all the way through the research process, from finding a funder for the study and agreeing the research questions to the dissemination of findings and follow-up studies.

This article considers the position of the ERB in assessing social-science research applications that are deemed to be high risk, including those conducted in situations of conflict. I write from the perspective of both ERB applicant and ERB member, having submitted for ethical approval several studies deemed to be high risk, as well as having served on a university board for six years. In this article I outline how ERBs have evolved to encompass approval of social-science research and, as a result, how 'vulnerable' people have become one focus of their review of applications before offering some tips for how organisations can strengthen ethical oversight of the research they conduct.

The foundations of ethics review

In the context of research with human participants, four pillars support the ethical review process; autonomy, justice, beneficence and non-maleficence (Beauchamp and Childress 2001). These pillars are grounded in a biomedical research paradigm, itself developed through ethical guidelines and standards, including the Nuremberg Code, written in 1947 (BMJ 1996), the Helsinki Declaration (WMA 1964) and the Belmont Report (National Commission 1979). Although first developed in biomedical research, the ERB model of reviewing biomedical

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applications has slowly evolved to include review of social-science research. Although all disciplines have professional and/or ethical codes of practice to which their members must adhere, these do not always relate to what Guillemin and Gillam (2004) call 'procedural ethics', as distinct from 'ethics in practice', for social science researchers. Oversight at a level above a professional body can therefore allow for assessment of risk and harm 'in practice' for each study proposed. For example, Médecins Sans Frontières' ethics code followed the same scientific pathway until less than a decade ago, at first not considering qualitative work to fall under its remit (Ford et al. 2009; Schopper et al. 2009). This may be due to the relatively small proportion of qualitative versus quantitative research undertaken by the organisation until very recently, or to a view that qualitative research was in some way not as 'scientific' as that conducted using quantitative methods.

The transition for ERB members on single-board university panels to include review of social-science research has not been easy, primarily because members were not familiar with the methods used by social-science researchers and so do not always understand social-science methods and approaches, but also because ethical difficulties and their remedies are not easily translatable between the 'hard' and 'soft' sciences. For example, it is relatively straightforward to design and approve a coding system to ensure confidentiality for people donating their blood for research and to ensure that participants know exactly what their blood will be tested for, but it is more complex to protect these participants' confidentiality if, for example, they take part in a focus group or to alert them in advance to what the group's disclosures are likely to contain. Prolonged participant observation, of the kind that anthropologists do, further stretches the biomedical model of ethics review, as research boundaries becomes less contained and predicted 'findings' less certain. However, regardless of discipline, well-thought-out ethics review processes should have the same end. Ultimately, both the research team and the ERB are required to think carefully about the nature and extent of harm in each proposed research study and whether the benefits of the research outweigh the harm it might cause. Yet each 'benefit' and 'harm' can be contestable, unpredictable and unknowable.

For both quantitative and qualitative research, the ERB is extremely concerned with the storage, security and handling of data, and alongside ethical issues it will also seek to assure itself that legal obligations will be met. Typical questions that members of the ERB seek to be reassured about include: What will the data be used for? How will it be stored, moved and

accessed in the field? Who will have access to it? Will it be publishable or useable in particular political contexts? Who might learn what about the participants' world? In the context of social-science research, ERBs are also keen to understand what researchers would do with data that exposes illegal acts, poor organisational practices or abuses of human rights. Here, as with biomedical research, clear strategies to ensure security and confidentiality of data must be devised, for example, by using codes for participants, or writing notes instead of recording speech. However, there is no 'one solution fits all' for ethical review.

ERBs and social-science research

Social-science research aims to understand a situation more fully through the collection and interpretation of rich data (Bryman 2012). Understanding an often complex issue using data analysis is the first step in being able to explain and then influence undesirable situations, for example, by recommending policy changes or disseminating new knowledge. In all the applications it reviews, an ERB is looking for an answer to the question 'so what?' No matter how small the study or 'answer' might be, why does it matter that the proposed research will be conducted in a particular setting, with a particular group of people, at a particular time? It is notable that, within the ERB I've been a member of, there have been a number of discussions around whether the 'science' should be reviewed by the ERB as much as the ethical issues raised by doing it. This is not a debate around whether the physical sciences are more ethical or more important than the social sciences or whether one discipline's method is more robust than another's, but what constitutes 'bad science' and whether bad science is always unethical. The general standpoint after these discussions is that conducting bad science in whatever discipline is unethical. Therefore, if the design or method is clearly unlikely to work in terms of practicalities, obtaining rich data, obtaining enough data or learning something new, the application is unlikely to succeed without further justification.

In universities it is academics from the physical and social sciences who sit on an ERB, together with a small number of lay members, whose positions are advertised widely and are drawn from roles outside the organisation. However, lay members may have much in common with the organisation's members. For example, a survey conducted with lay members of the British National Health Service ERB found that they are likely to be older and educated to degree level (Simons et al. 2009). As a social scientist sitting on one university board for six

years, I do believe that review is required in all settings to try to limit the likelihood of harm occurring. However, I also acknowledge that, in the UK at least, the bureaucracy of ethics review and the charge of 'ethics creep' (Haggerty 2004) has led some academics to decide not to conduct the projects they believe in passionately, since they perceive that approval will not be forthcoming or be too time-consuming to obtain. This has meant that those outside the ethics review system, such as journalists using covert observational methods, may be the ones who uncover and expose harmful situations, such as the cases of abuse recently investigated in older people's care homes in England (BBC 2014). Although the ERB may not initially appear open to research designs that are flexible and adaptable, involve people who may be vulnerable or appear to the research team to be 'high risk', applicants should be able to justify to the Board why these research designs are necessary and what will be achieved through them. This involves giving the ERB as much information as possible about the planned research to help it make a decision, thus allowing those members who are unfamiliar with the context and approach of the research to make as fully informed a decision possible.

Conducting research with vulnerable people

From my own applications and from being an ERB member, I have had to counter assumptions that, for example, all older people, dying people or people in care homes are vulnerable, and that vulnerable people should not be approached for research participation, especially when that research involves the investigation of issues that are deemed sensitive. The concept of vulnerability and protection is central to ERBs, yet much discussion takes place within meetings about what the boundaries of 'vulnerability' might be in the context of research participants and to what extent people should be protected in the context of the proposed study. Vulnerability can be intrinsic to the individual (e.g. limited cognitive capacity), extrinsic through situational factors that limit freedoms (e.g. being in a refugee camp), or relational, where autonomy is limited by another person (e.g. being a prisoner). Of course individuals may experience multiple vulnerabilities, especially in situations of violence and conflict, with vulnerability being a dynamic concept that is continually evolving over time and that is reflective of social values and beliefs; Delor and Hubert (2000) offer a useful discussion of the heuristic capacity and practical relevance of the concept of vulnerability. In my own research, I've examined how adults with cystic fibrosis who had lived past the current average survival age perceived their health and

risks of treatment; how bereaved parents experienced end-of-life care delivered to an adult child with cystic fibrosis; how schoolteachers have managed suddenly or unexpectedly bereaved students at their school; and how the first UK cohort of childhood liver transplant recipients experienced growing up and growing older. I believe that the increasing involvement of social scientists on ERBs will, through their experience in conducting research in these areas, help problematize and resolve the assumptions of vulnerability and sensitivity, provoking change in research ethics protocols and processes.

As an applicant, I've come to understand that submitting a detailed application to an ERB allows me not only to think through the potential ethical issues around my research, but also to consider the practical ones. For example, how exactly will potential participants be able to learn about the research I want to conduct? How will they be contacted and invited to take part, and by whom? Can the study I propose really not be carried out in any other context or setting, or with less vulnerable participants? In the context of emergency, conflict and post-conflict research, does the research study have to be conducted at a time when the population has been displaced or is under extraordinary stress, for example? It is not hard to argue that most ethical issues that arise in this type of research are also found in more 'routine' social-science research in the west; however, I suggest that in the former case more ethical issues may come together in a single project than in the latter case. Thus, the likelihood and extent of risk and harm that could arise is greater, the context in which the research is to be conducted is more politically fragile and lacking in infrastructure and human resources (Ford et al. 2009: 1) and the respondents are likely to have more acute or immediate needs. This potentially raises many more dilemmas for the research team and makes it more challenging to find the 'right' solution to ethical and practical issues.

The justice principle of research ethics involves the ability to bear burdens and the appropriateness of placing an extra duty on people who are already carrying a heavy load (see Belmont Report: National Commission 1979), not only in their research participation, but also in the context of the publication of the findings. Research findings should enable dissemination and make it possible for the subject population to benefit, although not necessarily the research participants themselves. A key ethical issue for ERB members in this context is that of vulnerability, whether stemming from a personal characteristic, a behaviour, a situation or a wider environment, or an interplay of any of these. For example, in research in emergency or

post-conflict settings, the population might be mobile or migrant and have new language and/or literacy needs. The aim of the ERB is to protect and to prevent the participants or research team from becoming more vulnerable than they already are, or at least to ensure they understand the potential risks and consequences of the situation. Usually the ERB would look for evidence of support structures (e.g. psychological support) for participants during or after their research participation. This means that the research team must think ahead as far as possible about what might be the potential risks and harms arising from the study and how these can be avoided or mitigated. In this way, as noted above, there is in principle little difference between reviewing ethically a research proposal situated in an emergency context and reviewing one that is closer to home, although in practice they are far apart: a sensitive environment and potentially vulnerable communities 'heighten and amplify the ethical challenges faced by all researchers' (Goodhand 2000: 15). The research team can also be more vulnerable in emergency or (post-) conflict settings. ERB members would look to assure themselves that the applicants had a track record of research and relevant experience in their area or an experienced supervisor who was able to advise them, and that reasonable plans to ensure the safety of both the participants and the team had been made.

Gaining informed consent

It is crucial to have participants' informed consent in research of this type, but of course there are problems around what constitutes being fully 'informed' on the part of both the research team and participants, who consents and how, and to what (Corrigan 2003). One of the most difficult research approaches to have approved by a university ERB is covert research, except in psychological research, where for participants to learn the true purpose of the research may spoil the very thing that the researchers are trying to capture. In these kinds of psychological research, the participants must be debriefed after their participation if ethics approval is to be given. At some ERB meetings in the UK, members have expressed difficulties in understanding how informed potential participants can or should be, both generally in the context of qualitative research and more specifically in the context of participant observation – which some ERB members are liable to see as a type of covert observation. Anthropologists may seek to gain informed consent from an entire town or community as a more practical approach (Schopper et al. 2009), yet ERB members sometimes have difficulty in approving studies in more bounded

settings such as a hospital, where both patients and staff are the focus of the research. For example, how can an unconscious and perhaps unidentified patient consent to become part of the proposed research? Although I believe this difficulty has lessened over the past few years for many ERBs, with more board members being aware of the issues and open to the research team's local solutions to such problems, more progress still needs to be made in this area.

In the context of consent, the power relationship is a crucial element for both ERBs and applicants to consider, alongside local issues of language, culture, traditions and social norms. I believe that illiteracy and the potential mistrust of those who are perceived to be 'in authority' by local communities are issues that are now more widely recognised by ERB members. We are more flexible, I would argue, with participants giving limits to their consent in both contributing their data and in how widely and in what format that data can be disseminated. This does not mean, however, that researchers do not have to think about what they tell potential participants. There is most likely a greater degree of mistrust among communities caught up in emergency and aid situations. Being as detailed as possible as to what might happen, what you believe will happen and what you will do when things go wrong, in a language and style that participants will understand, is crucial. A key danger here is that of inadvertently misleading participants into thinking that their situation will soon change for the better because of the research. This can not only bias the research, but turn participants against it, as well as future researchers. One must be clear about the boundary between the care or aid participants might receive and the research. Significantly, this confusion is also a problem that occurs frequently for health researchers at universities who work closely with clinical staff, with any care benefits for participants needing to be clearly separated from their research participation.

Conclusion

To conclude, I offer ten insights from my experiences of being on both sides of ERB review for the benefit of researchers and organisations undertaking fieldwork in complex emergency settings:

1. Staff working in organisations concerned with providing aid or emergency relief might work towards drafting specific and nuanced local guidance for conducting social-science research in these situations and with specific countries or populations. These organisations have real-world

experience of putting people into the field and gaining information from local populations that the organisation can draw on and that ERB members could learn from. Aid and emergency relief staff might work with academics to develop knowledge and understanding of ethical research conduct in this specific area, both in conflict and post-conflict situations.

2. In the context of research ethics approval, organisations might construct working definitions of what constitutes research and what does not (e.g. service development or audit). Consider what activities or foci differentiate these activities and where ethics review would be needed within or outside the organisation. If your organisation does not have an ERB, think about building one within the organisation or joining an existing one that regularly reviews research in your field.

3. If you are working in an organisation that does this type of research regularly, construct an organisational code of research conduct or framework that all researchers will adhere to in specific research situations. This could be taken from the British Sociology Association's (BSA, 2002) or Association of Social Anthropologists' (ASA, 2011) codes of ethical research conduct, for example, and worked into an overview of the organisational position and response in different cultural contexts and emergency scenarios. For example, what is the organisation's stance on disclosing human rights abuses that the research might uncover?

4. If there is no time to put in a full ethics application for research in an emergency context, think about whether the researchers could confirm that they will adhere to the organisation's agreed code. Alternatively, could the organisation put in place an internal expedited review structure? Some university ERBs now stream applications into low or minimal risk and high risk categories and review these applications proportionately. Médecins Sans Frontières, for example, has put in place a retrospective review process (Schopper et al. 2009) for situations when time is pressing and the research project would risk failure if a longer review process were called for. Ultimately, the ERB system needs to be as flexible and responsive as the applicant's proposed research design, yet robust enough to maintain the highest standards of ethical research.

5. Plan as far as possible before the research starts. Think of a realistic Plan B and Plan C in case the ERB or local situation prevents the research team from following its proposed protocol. Alternatively, could the proposed project be split into discrete stages of research and therefore discrete stages of ethics approval?

6. As a social scientist working in the area of emergency or difficult situations, put yourself forward as a member of your institutional ERB or research ethics working groups so that you can inform and influence the process from within. There is still work to be done to separate institutional bureaucracy from fundamental ethical issues and high standards of ethical conduct in order to approve research that will make a difference to local communities.

7. When applying to ERBs that are likely to be unfamiliar with research in emergency or aid situations, be as detailed as you can in explaining your approach or responding to the ERB's questions on your applications. For example, why can't you collect participants' signatures indicating their informed consent, and how will you ensure that consent is given and will be as fully informed as it can be at that time? This will enable ERB members to understand more fully the context in which you are working and to highlight issues it thinks you have not considered, as well as enabling you to show your competence in your research planning. Aim to show that you do understand the inherent risks and how to mitigate them against harm, rather than trying to argue that the risks will not appear in your project.

8. Most ERBs in the UK will seek assurance that ethics approval has also been given by the host country or host institution, or confirmation by the research team that there is no organisation that can give this. Building relationships with overseas hosts before submitting an ERB application is likely to increase the chances that local ethical issues come to light quickly and can be planned for in the research approach.

9. Think about whether the research team will include people from the local population or be recruited solely from your organisation. If the latter, would your research be more fruitfully conducted with local people on board as researchers or project managers, for example? Whether

from the organisation or local context, train those conducting the research to increase their ability to use good judgement about more abstract organisational rules (see Wood 2006: 374).

10. All researchers need to leave the research site in a condition in which future researchers would be welcomed by its community. Think carefully about what training you provide for new or inexperienced researchers, from both the academic/research and emergency/conflict perspectives, and in both research procedures and ethical conduct. Ensure that experienced researchers are able to pass on their wisdom in this area to ensure that local or specialist knowledge is built upon for future research studies.

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