




5-1-2011

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Recommended APA Citation

Ells, C. (2011). Communicating Qualitative Research Study Designs to Research Ethics Review Boards. *The Qualitative Report*, 16(3), 881-891. <https://doi.org/10.46743/2160-3715/2011.1093>

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Abstract

Researchers using qualitative methodologies appear to be particularly prone to having their study designs called into question by research ethics or funding agency review committees. In this paper, the author considers the issue of communicating qualitative research study designs in the context of institutional research ethics review and offers suggestions for researchers to consider in their communication of study designs to research ethics review boards. General information about the mandate of research ethics review boards is provided. In light of wide international variability with respect to research ethics regulatory environments and review board processes, specific considerations and suggestions about communicating qualitative study designs effectively are presented within a Canadian case study example.

Keywords

Canada, Institutional Review, Qualitative Research, Research Ethics, and Research Methods

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Communicating Qualitative Research Study Designs to Research Ethics Review Boards

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Researchers using qualitative methodologies appear to be particularly prone to having their study designs called into question by research ethics or funding agency review committees. In this paper, the author considers the issue of communicating qualitative research study designs in the context of institutional research ethics review and offers suggestions for researchers to consider in their communication of study designs to research ethics review boards. General information about the mandate of research ethics review boards is provided. In light of wide international variability with respect to research ethics regulatory environments and review board processes, specific considerations and suggestions about communicating qualitative study designs effectively are presented within a Canadian case study example. Key Words: Canada, Institutional Review, Qualitative Research, Research Ethics, and Research Methods

Researchers using qualitative methodologies appear to be particularly prone to having the quality of their study design called into question by research ethics review boards (Lincoln & Tierney, 2004; Macdonald & Carnevale, 2008) as well as funding agency review committees (Morse, 2003a, 2003b). Various reasons are proposed to help explain the problem, including inadequate expertise and understanding of qualitative research methodology and design among reviewers (Lincoln & Tierney; Richardson & McMullan, 2007), inappropriate review criteria (Morse, 2003a, 2003b; Daly, Bandyopadhyay, Riggs, & Williamson, 2008; Macdonald & Carnevale; Social Science and Humanities Research Ethics Special Working Committee, 2004), bias against what constitutes good science (Lincoln & Tierney), aspects of the study design not clearly articulated (Daly et al.; Morse, 2003b), and review boards being more restrictive than the regulations they are mandated to follow (Ells & Gutfreund, 2006).

In light of these challenges that beset researchers proposing qualitative methodologies, my intent in this paper is modest: to encourage better communication of a defensible study design and research plan to research ethics review boards and their members. I do not address the full range of struggles that qualitative researchers have with respect to review of their research. I do not engage disciplinary debates among researchers about what counts as quality qualitative research. Instead, I use a case study of the Canadian context of research ethics review to explore the challenge of communicating qualitative research study designs to research ethics review boards, and offer suggestions—within the power of individual researchers to enact—that may help them to better communicate their study designs to research ethics review boards.

Certainly obtaining research ethics review board approval is a crucial step in the research process. Approval must be granted prior to recruiting human participants, and preparing a submission for research ethics approval takes time, effort, and attention to

numerous details. Yet, the major hurdle should not rest with the research ethics application. Rather, the major challenge should involve designing the study itself, with attention to theoretical grounding, best practices, legal implications, and ethical considerations. Once the study is designed well (with a solid justification for each of its components), the rest (i.e., the funding, support of colleagues, review board approval, conducting the study, analysis, publication) should fall into place, or easily be addressed. While designing an effective and ethical research plan is the focus of many an entry-level research course, many qualitative researchers are confounded on how to clearly communicate their study designs to their institutional review boards (Hemmings, 2006). Writing a research plan in advance is more difficult than describing the same procedures after the research is completed, but it is an essential skill for researchers to develop, as is the elaboration of ethical considerations in the research plan and effective communication of the plan to a multi-disciplinary review board where most members will not be experts in the methods researchers propose to use.

My analysis and insights are formed and based on a Canadian review board context and through my own experiences as a chair and member knowledgeable in ethics on two Canadian research ethics review committees, a member of a multidisciplinary and multi-institutional qualitative research interest group where colleagues regularly engage in discussion of their research and research ethics experiences, and a collaborator on qualitative research projects. Many Canadian qualitative researchers view getting research ethics review board approval as the major hurdle in conducting their research (Adler & Adler, 2002; Bruner, 2004; Grayson, 2004; O'Neill, 2002; Social Science and Humanities Research Ethics Special Working Committee, 2004). A number of major hurdle experiences are recounted by Canadian researchers in the Social Science and Humanities Research Ethics Special Working Committee report (see p. 11 and pp. 51-86 of report) and the issue of communication (including understanding) of study designs arises in many of them. I hope qualitative researchers in other contexts or with specific disciplinary or methodological experience will consider the following Canadian case study and the analysis I offer in light of their own research milieu.

Understanding the Research Ethics Review Board

There are numerous examples of unethical research involving human participants, many which have ultimately precipitated the development of the research ethics review board (also called institutional review board, independent ethics committee, research ethics board, or human research ethics committee). Landmark examples of unethical research, such as those reported at the Nuremberg doctor trials, the Tuskegee syphilis study, and Milgram's research on obedience to authority figures, remind us of the important role review boards have in protecting human participants in research.

A research ethics review board is a committee mandated to review and monitor research that involves humans. Review boards are usually established at or affiliated with a local institution where research involving humans takes place. There are numerous policies, laws, and practice standards, from professional groups, research sponsors, governments, and others at the local, state or provincial, national, and international levels, that govern and guide how review boards operate. These set parameters for the composition of membership on the review board, its decision-making

authority, the research that requires ethics review, what documents and factors must be reviewed, benchmarks for ethical study designs and ethical research practices, conditions for allowing exceptions to usual procedures, and more.

Research requiring formal ethics or scientific review will vary according to who the researcher is, where the research will take place, the type of research, and other factors. In this paper, I am concerned primarily with the institution-level research ethics review board reviewing academic research. Not all research will require review at this level. For example, in Canada's academic institutions, undergraduate student research for course credit may be reviewed at the department level, and some humanities and social science research is exempt from formal research ethics review at the institutional level (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada [CIHR, NSERC, SSHRC], 2010). Exemptions are also found in US regulations applicable to research funded by federal public funds (Department of Health and Human Services, 2005).

Canada's Regulatory Environment

In Canada, parameters and other minimum standards for academic research involving humans are found in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* (CIHR, NSERC, SSHRC, 2010). The major national and some provincial research funding agencies require institutions' compliance with the TCPS as a condition of continued funding. Federal and provincial governments may also impose additional requirements. For example, Health Canada, a federal government department develops and enforces numerous requirements for research that uses drugs, medical devices, natural products, and genetic therapies that are not yet approved for use in Canada (Health Canada, 2008). In the Canadian province of Quebec, additional provincial governmental requirements for the conduct and review of research involving humans are found in the *Civil Code of Quebec* (Canadian Legal Information Institute, 1991) as well as the *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (Ministère de la Santé et des Services Sociaux [MSSS], 1998). Additionally, universities and other settings where research is conducted, such as hospitals and public schools, have standard operating procedures to guide research and its ethical review. These will attempt to synthesize all of the regulations and standards typically required of researchers in that setting, as well as account for any local considerations.

Additional guidelines or requirements may apply when research involves specific groups, such as Aboriginal people. For example, *Guidelines for Health Research Involving Aboriginal People* (Canadian Institutes of Health Research [CIHR], 2008); *Considerations and Templates for Ethical Research Practices* (First Nations Centre, 2007); and *Negotiating Research Relationships with Inuit Communities: A Guide for Researchers* (Inuit Tapiriit Kanatami and Nunavut Research Institute, 2007). Some Canadian regions even require additional ethics approval, such as a license from the Aurora Research Institute to conduct research in the Canada's Northwest Territories. For all the requirements of policies, laws, and standards that variously apply to review boards in Canada, Canadian review boards are not subject to an accreditation process. They are

rarely audited to assess compliance with requirements. The complexity and numerous sources of these requirements, as well as differences across jurisdictions and lack of comprehensive oversight account for some, but not necessarily all, of the variances in practice and decision-making of review boards in Canada. A recent US study on variance in review board practice reported similar instances of variance in requirements of standards evident in the review and approval of qualitative applications in the US (Green, Lowery, Kowalski, & Wyszewianski, 2006).

Canada's Review Board Process

The initial and most comprehensive ethics review by the review board occurs relatively early in the research process, mainly in evaluating the research plan before human participants are recruited and data collection begins. This is the point that the researcher submits documents to the review board for assessment, which in Canada lead to a decision to “conditionally approve,” “approve,” or “decline” the researcher’s proposed plan. Typically, researchers can expect that the first decision following the review is “conditional approval.” The review board provides researchers with any queries, need for clarification, areas of conflict with regulatory requirements, or other issues it has with the application that must be addressed before an “approval” will be granted.

In addition to protecting research participants, review boards in Canada are mandated to consider several scientific, financial, and ethical factors when reviewing research (CIHR, NSERC, SSHRC, 2010). The review board is also required to review and keep on file documentation that justifies their board’s decision and diligence (CIHR, NSERC, SSHRC, 2010). Accordingly, the required documentation includes: a submission form or checklist, proposed research description (including recruitment strategies, procedures used in the informed consent process, and budget), all documentation that is given or presented to participants (e.g., questionnaires, recruitment advertisements, and consent documents). These are some of the reasons why many Canadian review boards, but not necessarily just Canadian review boards, generally require much in writing from researchers.

How to Communicate the Justification of Study Design and Research Procedures

A researcher should be able to describe and justify the particulars of her or his study design, and all the procedures and protections that will be used and why (Daly et al., 2008). It is important to put all this information in writing in the protocol submitted for research ethics review (Daly et al.). The researcher should be cognizant of the need to honestly convince members of the review board that it is acceptable to involve human participants in her/his research (as well as the need for the review board to have sufficient evidence on file to justify its approval of the research). Being very clear about the research question(s) is especially important for it is a point of reference to understand the many substantive aspects of the study. As Eakin and Mykhalovskiy (2003) explain, reviewers will use the research question(s) as a “positioning device” to grasp the nature of the investigation including the kind of knowledge being sought and the stance needed to interpret the data. Whether seeking an explanation, understanding a phenomenon, or

confirming a hypothesis, assessing the quality of any research design begins with and relies on correctly clarifying the research question(s) (Eakin & Mykhalovskiy; Sandelowski & Barroso, 2003).

Justifying the researcher's study plan requires many "because" clauses such as:

"This study is important because...", "This method and analysis strategy is chosen because...", "Potential participants will be recruited from this group because...", "Potential participants will be approached and invited to participate in the following manner because...", "The data will be used and stored in the following ways because..." and so on.

The reasons for proposing procedures that deviate from the review board's own submission guidelines are particularly important to note since review board members are usually particularly attuned to review for compliance with their own institution's review board submission guidelines. Accordingly, if the review board submission guidelines expect use of a particular format for a consent form that is not ideal for the proposed study, then an alternate strategy and its rationale should be given (e.g., "The consent form/process differs from review board guidelines because..."). Similarly, the researcher should explain and justify other variances from usual research procedures if applicable (e.g., "Anonymity will not be guaranteed because...", "Participants in the following vulnerable situation will be recruited because...", "Deception is necessary because..." and so on). Measures taken to minimize risks or otherwise protect the well-being or rights of participants in such circumstances should also be communicated (e.g., focus group participants will be reminded of the importance of protecting each others' privacy and asked not disclose to third parties what each other says during the focus group). In some cases it may be prudent in the research protocol to follow statements that could raise a red flag to research ethics reviewers (e.g., "consent will not be sought...") with statements that reveal corresponding justifications (e.g., "...since participants can be expected to have attended the public event voluntarily with the expectation to be seen and heard") and protections (e.g., "researchers will not record identifying information of rally participants").

Remembering that a great many regulatory policies apply to the full range of research that a particular review board reviews, it may be helpful for researchers to reference criteria in the relevant normative texts that allow exceptions to usual ethical processes and describe how the research plan in question is consistent with that criteria can be helpful to reviewers (Ells & Gutfreund, 2006). For example, a review board that mainly reviews clinical trials research will typically expect research procedures to follow certain hypothesis-driven experimental designs and include written consent of a certain format. The review board even may have created submission guidelines for researchers within the institution that correspond to such expectations. Researchers proposing research with differing procedures may find it helpful to justify their study designs with reference to other relevant regulatory policies (e.g., CIHR, NSERC, SSHRC, 2010) that support their study designs.

In thinking through the study design and submission package for the review board, it can be useful for researchers to imagine potential critique and constructive feedback from peers, journal reviewers/editors, and review board, and try to prevent

critique in the study design and its written justification. For instance, if the study were carried out, might someone claim that the results seem biased, the participant selection criteria are too narrow or sample size was too small to answer the research question(s), the rights of participants were jeopardized, or the researcher seems to lack sufficient skill in a chosen analysis technique? Good study designs (and good explanations) should minimize such claims and comments. Supplying references that back up the study design (particularly the target population, methods and means of analysis) and confirm the skill-set and experience of members of the research team can help to establish credibility and confidence in the research.

While some researchers may try to satisfy review boards by describing qualitative research in terms of a cause and effect, science paradigm, such practice grossly misrepresents and undermines the research planned (Eakin and Mykhalovskiy, 2003; Richardson & McMullan, 2007), reinforces misconceptions and devaluation of qualitative research, and mars the integrity of the researcher. From the perspective of the research ethics review, doing so disorients reviewers, throwing off their ability to ground their review on a legitimate research question(s). For example, presenting a (fictitious) closed-ended, measurable hypothesis with a plan to use only open-ended data collection methods and no quantitative analysis may appear illogical or non-sensical to reviewers. A strategy for researchers that remains true to their research is to put their effort into clear and accurate communication of the research question(s) and the study design and research procedures that best serve that question and the research participants who will be involved (Daly et al. 2008; Richardson & McMullan).

Additional Peer-Review

Those seeking funding to support their research typically prepare a detailed study design for the funding application protocol. Some may claim that if funding is received, the review board should conclude that the quality of the science is already established. Similarly, since peer-review takes place when research reports are submitted to peer-review journals for publication, some may claim that a plan for publication in a peer-review journal should exempt a review of science by the review board. However, even if the methods and modes of analysis are reviewed satisfactorily prior to submission for research ethics review, the review board must also consider these aspects of a study design in order to inform their assessment of ethical and financial aspects of the research. Moreover, researchers should be aware that funding agencies and journal editors typically require review board approval for research involving humans, precisely because some of the protections of human participants are better addressed at the local level, and before human participants are enrolled. Note that a protocol submitted in an application to a public funding agency typically contains much of the research plan. It usually includes a literature review that clearly demonstrates the value of the proposed research, as well as a description of and justification for the methods, analysis, and target population, and assurances about feasibility including adequate budget and various contributions and qualifications of the proposed research team. However, – what are most notably absent from protocols submitted to Canada's three major public funders of research – CIHR, NSERC, and SSHRC – are sufficient details about the potential benefits for participants, the risks that exist for potential participants and how will they be minimized, the process

for recruiting participants, the protections for confidentiality and assurances/permissions that the research can be conducted effectively in the proposed location. Instead these agencies require these and other factors to be reviewed at the local level according to strict criteria (CIHR, NSERC, SSHRC, 2010) before the funds are released to researchers (CIHR, NSERC, SSHRC, 2008).

Similarly, much of the above are not recorded (and thus not assessed) in manuscripts undergoing peer-review for publications, and in any case peer-review prior to publication occurs too late to protect research participants from harms resulting from participation in research lacking sufficient scientific justifications. To provide added assurance that ethical research standards are met, many journals now require proof of research ethics approval and declarations of any conflicts-of-interests from authors.

Opening up Communication

Many commentators note the need for researchers and research ethics review boards to communicate better. One study (Carline, O'Sullivan, Gruppen, & Richardson-Nassif, 2007) that aimed to identify means to improve relationships between medical education researchers and review boards found three major themes in successful researcher-review board relationships: education (of both researchers and reviewers), communication, and certain structural and procedural characteristics. The participants revealed numerous communication strategies regarding study design and ethics review, including meetings between researchers within the discipline and review board members to review interventions and risks to participants with respect to different research scenarios, materials that provide "how to" information, contact people from the review board for researchers to consult. In addition to calling for review boards to make their processes and expectations more transparent to researchers, Burke (2005) calls on researchers to become familiar with relevant ethical issues in their research, to document in their applications considerations and information that will assist reviewers in their assessment of the research plan, pretest consent forms with a non-scientist, and serve (if time permits) on a review board.

Recognizing the dynamic aspects of qualitative research study designs and unanticipated ethical issues emerging throughout the course of the research, Tolich and Fitzgerald (2006) propose consideration of a "post research ethics report" to be reviewed by review board, academic examiners or qualitative journal editors. An intriguing aspect of this proposal is its potential to expand the research ethics research and understandings by fostering routine evaluation of ethical issues arising in qualitative research.

Conclusion

For many researchers, fine tuning the details for carrying out a proposed research project occurs as they prepare their submission for research ethics review, and as they respond to the concerns and questions of the review board. While fine tuning can be expected to continue as the researcher starts to recruit and involve participants, and collect and store data, communication exchanges with a review board can be time-consuming, especially if the review board is asking for confirmation of details that seem either obvious or at odds with what the researcher is trying to achieve. It can be more

efficient and effective for researchers to take the time to provide the details about how the research will be accomplished and why in their initial submission to the review board. By communicating much of the particulars and the rationales behind the study plan and research procedures, and answering all the review board's questions in their submission guidelines, the research ethics reviewers will have more confidence in the strength of the research plan and in the researcher's ability to follow through with it to obtain useful results. Moreover, there will be fewer questions or concerns that the review board will want answered or "fixed".

Beyond communicating qualitative research study designs and their ethical implications to review boards in applications for review and the correspondence that stems from that review, researchers and review boards should strive to develop effective ways to share their knowledge, experience, and views towards promoting and achieving best practices in qualitative research.

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Article Citation

Ells, C. (2011). Communicating qualitative research study designs to research ethics review boards. *The Qualitative Report*, 16(3), 881-891. Retrieved from <http://www.nova.edu/ssss/QR/QR16-3/ells.pdf>
