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Title

Ethical review and qualitative research competence: guidance for reviewers and applicants

Authors

Julie Mooney-Somers

Centre for Values, Ethics and the Law in Medicine, University of Sydney, Australia

Anna Olsen

National Centre of Epidemiology and Population Health, Australian National University,
Australia

Corresponding Author

Julie Mooney-Somers

Centre for Values, Ethics and the Law in Medicine

Level 1, Medical Foundation Building K25

University of Sydney

Camperdown NSW 2006

Australia

Julie.mooneysomers@sydney.edu.au

Abstract

It is difficult to consider, describe or address the ethical issues particular to qualitative research without experience and understanding of the technicalities of qualitative methodologies. The Australian *National Statement on the Ethical Conduct of Research Involving Humans* charges researchers with a responsibility to demonstrate that they have the appropriate experience, qualifications and competence for their proposed research. Ethical review committees have the responsibility to judge claimed research competence. This paper provides practical guidance to researchers and review committees on using formal

qualifications and training, explicit claims of competence, and markers of in/competence to assess qualitative research competence.

Keywords:

Qualitative research; ethical review; research ethics; competence; methodology

The role of ethical review is to ensure that ethical standards in research are met. In Australia this process is governed by the *National Statement on the Ethical Conduct of Research Involving Humans* (National Health and Medical Research Council, 2007 (revised 2015)). The *National Statement* (as it is called) provides both guidelines on ethical research conduct for those designing and conducting research, and guidelines for the process of ethical review. Discussions of research ethics often highlight issues such as participant consent, participant confidentiality, data security and so on, with a focus on minimising harms to participants. All go to the implementation and conduct of a project. Also essential to the ethical assessment of a research project is design, and the methodological competence of the researcher to adequately undertake the project.

Research competence is an ethical requirement

Research competence is fundamental to the conduct of ethical human research. The Australian *National Statement* makes this explicit and requires Human Ethical Review Committees (HRECs) undertaking ethical review to consider if researchers have the appropriate research skills and experiences to conduct the research they propose to undertake. That is, is the research ‘conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research’ (National Health and Medical Research Council, 2007 (revised 2015)). Note that the demand here is not about competence in ethical practice, but in the design and methodological rigour of research; this is the focus of this paper. Judging *research* competence is part of the assessment of research merit that should occur within ethical committees. Particular issues of research merit mentioned in the *National Statement* that speak to research competence include whether the research is:

- ‘designed or developed using methods appropriate for achieving the aims of the proposal’

- ‘designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results’
- ‘conducted using facilities and resources appropriate for the research’

Ethical frameworks outside of Australia evoke similar characteristics when outlining guidelines for review such as: posing an answerable and important question; using appropriate research methods; and conducting research in a transparent and accountable manner (National Academy of Academics, 2015; Economic and Social Research Council, 2016). The Economic and Social Research Council Framework for Research Ethics framework from the UK allows research proposals to be rejected by reviewers if there are doubts about research competence (Economic and Social Research Council, 2016).

The Australian framework is explicit about the need for researchers to have research competence; although a request for a demonstration of technical research competence is not routinely sought beyond a declaration of qualifications. The National Ethics Application Form (NEAF) limits its focus to any students involved and asks: “What training has the student received in the relevant research methodology”. Explicit request for evidence of the research competence of all researchers is found in review guidelines for clinical trial studies. For example, ‘training, experience and other indicators of competency that demonstrate each person’s [investigator’s] ability to perform their tasks on the clinical trial’ is sought by some institutions (eg (University of Sydney, n.d.; Bellberry, n.d)).

With respect to *qualitative* research competence, the requirement for an explicit declaration of capability is often overlooked by ethical review committees. Yet, it is difficult to consider, describe or address ethical issues particular to qualitative research without experience and understanding of the principles and technicalities of qualitative methodologies. As members of (different) ethical review committees and experienced qualitative researchers we see many applications involving qualitative research. We are interested in two issues related to assessment of research competence in ethical review. First, applications involving qualitative research rarely include specific claims about qualitative skills and experience so it is not clear how judgements of research competence can be made (assuming they are). Second, it is not clear that ethical review committees always have members with sufficient qualitative expertise to make such judgments. For example, a properly constituted HREC in Australia is

only required to have ‘at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend’ (National Health and Medical Research Council, 2007 (revised 2015)). Although the HREC may have a ‘pool of inducted members with relevant expertise’ there is no particular requirement for experts in specific methodologies. In practice, ethical review committees have members who call themselves qualitative researchers, members who have done some qualitative research, members who have some knowledge about qualitative research and members whose only exposure may be through sitting on an ethical review committee. Committees that review few qualitative research proposals may not have access to any expertise. Moreover, the broad array of methodologies and methods of data collection and analysis in qualitative research can create confusion and controversy related to appropriate use in different contexts (even among qualitative researchers). This very diversity underscores the importance of a competent researcher explaining and rationalising their chosen approach through their ethics application.

How then can ethical review committees make the required judgement about appropriate qualitative experience, qualifications and competence? While previous articles (including in this journal) have examined the ethical issues arising in qualitative research practice (Walker et al., 2005; Shaw, 2008; Richards and Schwartz, 2002; Miller et al., 2012), none address the specific issue of research competence. Thus the aim of this paper is to provide guidance to members of ethical review committees; who have a responsibility to assess qualitative research competence. It will also serve as a useful guide for researchers who have a responsibility to clearly state relevant qualifications and set out and justify claims of competence. To do this we draw on our experience of assessing both qualitative research rigour and ethical review.

Ascertaining research competence

Some research methodologies or disciplines have established sets of core competencies, recognised qualifications or accreditation processes. For example, the Statistical Society of Australia provides accreditation for statisticians based on formal qualifications, practical experience and professional competence. Completing an accredited degree gives access to recognition as a Graduate Statistician (Statistical Society of Australia Inc, n.d.). In work to enhance the conduct of clinical trials, the Australian Government’s Department of Industry, Innovation and Science has been working with the National Health and Medical Research

Council to develop a set of core competencies for clinical trial investigators (National Health and Medical Research Council, 2015). This parallels international efforts, which include several sets of existing core competencies (Sonstein et al., 2014). The Therapeutic Goods Administration, the authority that oversees regulation of medicines in Australia, already has guidance that calls on clinical trial investigators to both be qualified to undertake the proposed trial and to provide evidence of these qualifications to a HREC (Therapeutic Goods Administration, 2000).

There is no accreditation process for qualitative researchers in Australia and no set of agreed core competencies (nor are we aware of successful attempts to develop any nationally or internationally). That is not to say there is not much discussion about a curriculum for qualitative research (Delyser, 2008; Breuer and Schreier, 2007) or the qualities of a good qualitative researcher (Hill, 2007). The broad range of methodologies and methods encompassed by the term *qualitative research* likely makes any attempt to identify core competencies very challenging (just as the characteristics of good quality qualitative research are highly contested (Dixon-Woods et al., 2004)).

There are three ways that ethical review committees can ascertain qualitative research competence: 1) formal qualifications; 2) explicit claims to competence; and 3) markers of in/competence. These are not intended to be mutually exclusive.

1) Formal qualifications and training

A Master of Biostatistics is recognition of competence in that particular field. Why not, as a starting point, expect the same of researchers planning to undertake a qualitative project? We've come a long way since qualitative methods had to be self-taught or when the attitude of 'how hard can it be to do a few interviews' was acceptable. There are several ways researchers can gain qualitative research training. A few universities offer specialist degrees in qualitative research; a simple declaration of having achieved this qualification demonstrates a researcher has undertaken a formal, structured high-level program of theoretical and practical training and been assessed as competent. More common are embedded units on qualitative research (or research methods) as part of undergraduate or postgraduate programs. Ethical review committees should bear in mind that curriculum coverage may have been as little as a single lecture or as much as a whole semester. Researchers can demonstrate these qualifications by declaring, for example, that their

Bachelor of Arts in Sociology included a full semester unit in qualitative research methods. They may wish to mention specific content relevant to the proposed research, such as interviewing theory and skills. Completion of a large project, such as a PhD program, is perhaps the most advanced of the formal qualifications.

Many higher education institutions and professional bodies offer professional development opportunities in qualitative research. Finally, peer networks regularly offer seminars and informal mentoring. Professional development opportunities such as these are a valid way for researchers to gain practical skills in qualitative research (although they rarely gain a thorough grounding in theoretical underpinnings).

Any of the above indicates a researcher has engaged in some structured learning in qualitative research. However, just as an ethical review committee should be cautious about relying on a degree in statistics as the sole indicator of competence, certification of qualitative-related study has limitations. A formal program that involves assessment of skills and knowledge – a research degree, a research methods unit of study – is significantly more reliable than professional development opportunities where researchers merely attended brief, unassessed classes/seminars. Moreover, just because an individual has acquired formal knowledge it does not mean they are able to translate this into practice. Lack of methodological experience or skills can become apparent in the design of the project under review (as detailed below).

2) Explicit claims to competence

Competence might also be developed through research practice as a research assistant, PhD candidate or professional researcher. A researcher may experience informal learning and mentoring from a supervisor or other experienced qualitative researcher. More advanced competence may be developed (and demonstrated) through teaching qualitative research, recognition as a qualitative methodologist (e.g. publishing on methodology), supervising PhD candidates, or running qualitative research projects.

An experienced researcher with no formal qualifications might convince a HREC of her qualitative research competence by saying something like: *I have over 20-years of experience in the development and use of qualitative research in health and psychology, including in my PhD research. I have employed several qualitative methodologies across funded projects, and conducted research with a range of populations and on sensitive topics. I have taught*

qualitative research methods to postgraduate students for five years and supervised students undertaking qualitative methods from Honours to PhD level. A researcher may wish to draw attention to a specific area of competence that is relevant to the proposed research project by saying something like: The proposed study employs narrative analysis. I have used this analytical approach in earlier studies employing interview data and online blogs; this work has been published in several peer reviewed papers.

Explicit claims of competence will likely be found on applications for ethical review under the heading of qualifications or expertise. However, ethical review committees may also notice researchers claiming competence in other sections by referring to previous research experience and how it has informed their practice. For example: *In the past I have used ranking exercises in focus groups to successfully engage young people in conversations about X.*

3) Markers of in/competence

Finally, regardless of formal qualifications, training and claimed competence, applications for ethical review will hold other clues as to qualitative research competence. Indeed, a qualification may be decades old and the skills rusty. A researcher may be competent in one qualitative methodology; this does not mean they are competent in them all; each methodology – ethnography, narrative inquiry, grounded theory – has its own specific competencies. Moreover, a claimed competence may be contradicted by the quality of the proposed project presented through the application. A badly written application does not necessarily mean a lack of qualitative research competence but it certainly raises concerns about competence. Markers of in/competence will be spread throughout the application but likely concentrated in sections on sampling, recruitment, protecting participant privacy and confidentiality, risks to participants and of course, research methodology, tools and analysis.

The *National Statement* provides a framework for reviewers and researchers to help them think through the ethical issues facing a proposed piece of research (National Health and Medical Research Council, 2007 (revised 2015)). We have used these guidelines to categorise the specific questions we consider when looking for markers of in/competence in qualitative research. To be clear, these are our rules-of-thumb not a check list for an exhaustive set of criteria for qualitative research competence. While all the questions work on a general level

across qualitative methodologies there will be additional markers of in/competence for specific methodologies.

1. The *National Statement* calls for research with merit to be ‘designed or developed using methods appropriate for achieving the aims of the proposal’. Some indicators of research in/competence related to research design, methodology and methods include:

Does the researcher present a methodology that justifies their proposed actions and explains how it will meet their stated research aims? Researchers do not need to use an extant methodology, simply present an underlying logic for their actions, a coherent justification that ties the research aims/questions to the methodology and the methods (Carter and Little, 2007). Indicators of this kind of logic include statements like: *In line with the ethnographic methodology adopted for this project we propose to conduct observations in three sites.* Or, *Following Charmaz (2014) this constructivist grounded theory study will...* Do the researchers simply gesture towards a recognised methodology (e.g. Grounded Theory) or do they draw on a specific version/methodologist that indicates an awareness of the considerable variation within that methodology (Barbour, 2001). For example, there is no single Ground Theory methodology, so we would expect to see a reference to Constructivist Grounded Theory (Charmaz, 2014) or to ‘Straussian’ Grounded Theory (Corbin and Strauss, 2008). Are the methods and language consistent with the claimed methodology?

Does the researcher make appropriate claims about methods such as sampling, data collection and analysis? In terms of sampling, is the researcher making claims about representative sampling or generalisable findings where we would expect discussion of purposive or criterion sampling? Qualitative samples are designed to facilitate investigation of meaning, understanding, experience, or process; that is, understanding rather than determining the extent of a phenomenon.

In terms of data collection, how is data being generated and is this approach coherent and consistent with the research aims/questions and methodology? For example, a narrative study that relies only on focus groups would raise a flag for us as this method tends not to generate individual stories. Or that uses an interview schedule

containing heavily structured and/or mainly closed-ended questions rather than open, exploratory questions that encourage story telling.

Finally, is the method of data analysis described and is it consistent with the methodology and methods? We are looking for evidence that the researcher has developed an analytic strategy and considered how analysis will produce knowledge that addresses the stated aims or research questions.

2. The *National Statement* calls for research with merit to be ‘conducted using facilities and resources appropriate for the research’. Some indicators of research in/competence:

Who is actually generating or analysing the data (named investigators, unnamed research assistants, students) and are they appropriately qualified/trained/experienced in the method? If it is a student or relatively inexperienced research assistant, do they have an experienced qualitative supervisor? Is there explicit mention of training and mentoring?

3. The *National Statement* calls for research with merit to be ‘designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results’. Some indicators of research in/competence related to ethical practice:

Does the researcher seem to have an awareness of, and address, specific ethical issues related to their chosen methodological design? Literature on ethical practice in qualitative research provides a useful resource here (Walker et al., 2005; Shaw, 2008; Richards and Schwartz, 2002; Miller et al., 2012), as does the *National Statement’s Chapter 3.1 Qualitative Methods* (National Health and Medical Research Council, 2007 (revised 2015)). Areas we’d expect to be addressed include:

- Relationships between researcher and participants, especially in designs involving participant observation and repeated engagements (e.g. ethnographic, longitudinal).
- Emergent designs where research questions and data generation tools (e.g. interview questions) are developed through the research process and not available to the ethical review committee in advance.

- Risk of participant distress – qualitative research seeks in-depth understandings of participant experiences/perspectives and necessarily involves probing; with little knowledge of participant biographies it can be difficult to anticipate what may produce distress but strategies should be put in place. The extent of these strategies will differ not only based on the research topic, but the chosen methodology and methods.
- Privacy and confidentiality – small samples, compelling stories, unique speech patterns, etc., can all increase the likelihood of participant identification. The extent of the risk to participant confidentiality will differ not only based on the research topic, but the chosen methodology and methods.

Is attending to research competence exceeding a HREC's remit?

Over the past three decades heightened concerns regarding human participants in research have led to large changes in the way that researchers do their research and how that research is regulated. This has produced expressions of concern about ethical review bodies 'becoming distracted from their core role and venturing into territory that was not properly their concern' (Gillam et al., 2009). This shift has been attributed to an increasingly legalistic society, the consequence of which is progression from assurance of patient safety to the monitoring and censoring of many research projects (Gillam et al., 2009). Particularly contentious is whether committees should provide commentary or advice on methodological issues (Gillam et al., 2009; Guillemin et al., 2012). A growing body of literature expresses specific concern about the over-regulation of social science research by ethical review bodies (Haggerty, 2004; Macintyre, 2014; Bledsoe et al., 2007). Authors report a lack of understanding of the qualitative paradigm, or prejudice toward research that isn't clinical or quantitative (Lincoln and Tierney, 2004). Within this shift, many qualitative researchers feel that their approaches to knowing and knowledge cannot fit into the common ethical guidelines and their projects are therefore dismissed as lacking merit and integrity. We are keenly aware that for some researchers, the notion of inviting ethical review committees to judge qualitative research competence may sound preposterous, even risky. However, we believe that in recommending that researchers make explicit their expertise, and that ethical review committees formally consider the competence of researchers, the merit and integrity of proposals are more likely to be appropriately understood. These efforts should raise the status of qualitative research in demonstrating it is not an endeavour that can be lightly

undertaken by novices. Instead, it encompasses a diverse range of approaches that require training, expertise and reflection if they are to be used ethically.

Conclusion

Ethically conducted qualitative research can only be undertaken by researchers with the appropriate experience, qualifications and competence. It is difficult to consider, describe or address the ethical issues particular to qualitative research design without a thorough understanding of the technicalities of qualitative methodologies. Researchers have a responsibility to demonstrate their research competence, while ethical review committees have a responsibility to judge it. Yet qualitative research competence is a rarely discussed ethical issue, it is either not assessed or the criteria are opaque.

We anticipate resistance from some social scientists who may feel that ethical review committees cannot undertake this work. Or that only a qualitative researcher can make these judgements. We echo calls for the development of ethical review committee skills in assessing the rigor of qualitative applications. We endorse calls for more qualitative expertise to be available to review panels, either through permanent or co-opted members. Our paper contributes to this capacity development by providing practical guidance on using formal qualifications and training, explicit claims of competence, and markers of in/competence in the assessment of qualitative research competence as part of ethical review.

Declaring conflicting interests

Both authors sit on ethical review committees – one a properly constituted NHMRC-registered HREC, the other a committee based in a large community organisation. Both authors are employed to teach qualitative research in health. We do not believe that these pose actual conflicts of interest.

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