How does Voluntary Ethics Improve Research?

Introducing a Community Research Development Initiative

by PAUL FLANAGAN and EMMA TUMILTY

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ABSTRACT

Until recently, community organisations in Aotearoa New Zealand (NZ) have not had any avenue for ethical review of research involving human participants unless they were connected to researchers involved with health and disability research (narrowly-defined), or tertiary education institutions. The New Zealand Ethics Committee (NZEC), a recent community research development initiative, has invited organisations to submit their proposals for voluntary ethics review and provides research methodology support where sought. This paper introduces this initiative, describing both its make-up and processes. It also explores the relationship between reviewer-applicant in the NZEC as distinctive to the relationship of reviewer-applicant in traditional ethical review settings, explaining this difference of power relations and philosophy. Those in the community see research ethics review as something to be learned along with research methodology/practice.

INTRODUCTION

Compulsory ethical review of research with human participants has been mandated within the health, disability and tertiary education sectors in Aotearoa New Zealand since the findings of the Cartwright Inquiry in 1988 (Tolich and Smith, 2015). There have been a number of iterations in the Health and Disability Ethics Committees’ (HDEC) structure and governance (namely, Ministry of Health reforms of HDECs in 2004 and 2012 [Tolich and Smith, 2015]). An effect of these changes is that groups engaged in research outside of health/disability and tertiary education have found it increasingly difficult to seek advice or guidance for their projects, let alone receive formal ethical approval.

Until the 2012 Ministry of Health restructuring of purpose and process for health and disability research ethical review, community groups could approach these HDECs – and were largely responded to in good faith. However, these doors are now firmly closed. In fact, a number of health and disability projects also no longer comply with criteria set for HDECs by the Ministry of Health, as these criteria have been reduced to focus on high risk, interventionist, well-funded trials, and mainly randomised clinical trials. It appears that health and disability research has now been shaped into medical research – and the review of ethics is now returning to the landscape of 1988 where there were concerns about the absence of cultural and lay voices within ethical review processes. Inclusion of these voices was a significant consideration when HDECs were introduced. But in the current context social researchers within the voluntary and low-paid social service/practice community are not guided or supported to engage with ethics review for their research.

1 Within the international research community, such Research Ethics Committees (RECs) are sometimes known as Institutional Review Boards (IRBs).

2 This change will potentially increase workload for tertiary institution ethics committees from applicants who can no longer approach an HDEC for ethical review of their project.
The formation of the New Zealand Ethics Committee (NZEC) by a group of former HDEC chairs has been welcomed by governmental and non-governmental groups, as it aims to support researchers in the community. Initially, this group of chairs established New Zealand Ethics Limited in 2008 to explore alternative possibilities for ethics research in the New Zealand health and disability research environment (Tolich and Smith, 2015), from which came the NZEC. This independent committee has taken a clearer direction since the Ministry of Health review and reform of HDECs in 2012. NZEC is now clearly established as an ethics committee for researchers who cannot access an HDEC or an institutional committee. As the work of this committee has become gradually more widely known, a growing number of researchers and community organisations have approached the committee for advice.

**WHAT IS NZEC?**

NZEC has taken up a unique position within the ethics review sector in New Zealand. It is focused on community-based research initiatives conducted by not-for-profit groups who are independent of health and tertiary education institutions. It also accepts applications from national and local governmental agencies who ironically also have no avenue of ethics review outside of health ethics review in New Zealand. As such, it holds a distinctive place within the ethics committee landscape in New Zealand given the relations of power concerning ethical review of research: it cannot approve research in the traditional sense; it is not an accredited committee (as determined by the Health Research Council); and its legal status is simply one of being a charitable limited liability company—functioning due to the goodwill of a group of volunteers with an indemnity clause outlining the limits of its responsibilities.

This means that the committee cannot be charged with competing interests. Discourse in the research ethics review literature charges Institutional Review Boards (IRBs) with risk adverse positions—IRBs have a focus on research governance and institutional reputation over and above their commitment to participant safety (Feeley, 2007). We understand this to mean that these IRBs can have considerations regarding their institution that make them more likely to be restrictive in their recommendations. The NZEC, as an independent group with an indemnity clause, has no other priority than participant safety and ethical practice, and operates with no external pressures.

**ACCRREDITATION**

The NZEC Committee is not accredited. While discussions were originally held with the Health Research Council (as the legislated ethics committee accrediting body in New Zealand based on the Health Research Council Act 1990) and the Royal Society of New Zealand regarding the potential for accrediting NZEC, the former found NZEC fell outside of its mandate (health) and the latter found it had no mandate (to accredit an ethics committee). This affords the NZEC freedoms as well as creating obstacles for serving those communities left out by traditional ethical review.

Firstly, freedoms are afforded insofar as its processes and standards are dynamic and reflexive. NZEC subscribes to the view that ethical practice evolves and as such trenchant prescriptivism will not do. Secondly, obstacles are created insofar as those applying, while receiving ethical review and guidance, cannot claim a recognised (accredited) review process has been completed. Nonetheless, the NZEC has received growing numbers of applications (see below), showing that regardless of the non-accreditation status of the committee, groups in the community find benefit in voluntarily completing ethical review through the NZEC process.

The committee provides the minimum of guidelines, directing applicants to the Royal Society of New Zealand website for Code of Professional Standards.

A small seeding fund was received from the Ministry of Social Development in 2013 to support the committee’s members to meet and review processes and applications as received. In 2014, NZEC received funding for two years from the Tindall Foundation to establish a secretariat, plan for an increase in business, and explore members’ professional development and attendance at a conference (Ethics in Practice, University of Otago, May 22-24, 2015).

Available from: http://www.royalsociety.org.nz/organisation/about/code/
resource created to share ethical expertise (TEAR – The Ethics Application Repository)\(^3\) have discussed the need to conceive of ethics committees as learning institutions rather than mechanisms of research governance (Toich and Tumilty, 2014), which is operationalised in the NZEC setting.

The question of accreditation, therefore, is currently a double-edged sword. On one side, firstly, there is the sense that accreditation is unnecessary, as the current functioning of the committee, as a provider of ethical review and as an advisor of research design and method, is clearly effective. Secondly, not having accreditation offers flexibility to focus on ethical review within a context of relational dialogue that offers a shift in power relations, different from those of traditional committees which tend to have a mandate to focus on governance of research ethics and risk management. On the other side, the question remains: what benefits would NZEC have in being accredited, but more directly (and importantly) what benefits would community researchers receive if NZEC were to be accredited?

**PROCESS**

Currently there are thirteen members of the committee, including a mix of gender, ethnicity and expertise. Their experience includes research, ethics, law, education, health and social practice – and they come to the committee from academia, government and community settings. Three members are previous HDEC chairs (who, upon recognising the shortcomings in the HDEC system reviews for community groups, then established NZEC), and multiple members are currently chairs or members of other institutional or accredited ethics committees. This inclusion of previous HDEC chairs and other institutional chairs/members goes some way to legitimising the committee regardless of its accreditation status. By including members who have experience in the ‘accredited’ system, the committee demonstrates appropriate knowledge and expertise of regulation in addition to its knowledge and expertise surrounding applicants’ settings (i.e. community, social, or non-medical research).

The review process itself is conducted via email. Each application is received and is assigned a lead reviewer, plus two to four additional review team members. This team reviews an application (see Appendix 1) and may discuss it amongst each other as they review (via email or phone) and may also contact the applicant during this stage for clarification (via the lead reviewer). The lead reviewer collates responses and then provides the applicant with a table of responses and the offer of further discussion (either in person or over the phone) regarding any of the items in the table. Table 1 is an example of how a review table of responses might look to an applicant with recommendations from committee members.

<table>
<thead>
<tr>
<th>Item</th>
<th>Issue</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. Consent Form</td>
<td>Statement regarding withdrawal is not consistent with the process outlined in the application.</td>
<td>Please clarify whether participants can withdraw their data and at what stage. Please correct documentation to be consistent once decided, so that participants are clear on what is possible and when.</td>
</tr>
<tr>
<td>e.g. Recruitment process</td>
<td>How are potential participants approached or contacted?</td>
<td>Please explain how contact information will be shared with potential participants, or how participants are being approached, i.e. when, by whom, where, etc.? Be mindful of the relationships between different parties and what this might mean in terms of people feeling obligated to take part, as well as the Privacy Act and how information can be used.</td>
</tr>
</tbody>
</table>

*Table 1. Example of Review Table Responses sent to Applicants*

\(^3\) This is an open, online archive of exemplary ethics applications shared by scholars to encourage the sharing of ethical practice/knowledge in the international research setting. Available from: www.tear.otago.ac.nz
Applicants submit to the NZEC using a simple application form (Appendix 1). The form is user-friendly and contains direct and open questions about the work being conducted. The committee has revised the form over time to ensure that the questions elicit the responses required to evaluate a project. The committee also believes that by not prescribing formats for the information sheet or consent form that groups applying design their own forms in modes more appropriate to their settings. There is discussion in the ethics review community about how ineffective traditional information sheets and consents forms can be; committee templates may hinder rather than help (Loverde et al., 1989; Paasche-Orlow et al., 2003; Waggoner and Mayo, 1995). As a committee serving a diverse, largely non-academic community, the NZEC wanted to be open to innovation and responsiveness regarding the design of forms from a range of disciplines. Review will always aim to ensure the appropriate information is provided to facilitate informed consent; i.e. that the layout, design, language and extent of content in the form, as well as the process, can be described by the applicant. This is particularly important in the community setting where projects often require a nuanced understanding of their context.

Thus, the committee’s contribution to community-based and governmental researchers responds to the specific circumstances of their research. During the process of communication between committee members and researcher applicants, NZEC review and advice is shaped by the context of the researcher(s) and research space, and in this process, the committee intentionally engages applicants in relational dialogue. Research is considered a unique site of knowledge production, within time and space, and particularly because of who (researcher and participant) is involved (Larkin, 2008). Within the NZEC process, an application involving a community photo-voice project, for example, is something that would be discussed and understood with the applicant to negotiate the most helpful solution for researcher and participants (especially, perhaps, regarding the information documents and informed consent forms). Such a project might require a number of drafts, until a final iteration of the consent form occurs. Some of this drafting and revision may occur verbally. Anecdotal evidence suggests the experience for many researchers, in settings where research-governance dominates an ethics committee’s functioning, is to respond to a rule-based system of completing a template form, and signing and submitting it without an opportunity to discuss the content with a member of the ethics committee. NZEC recognises a meaningful dependency on context for the ‘performance’ of ethical practice within any given project.

Another point of difference between the NZEC and some committees within New Zealand is the review of methodology/scientific validity. HDECs used to include review of scientific validity, but that has since been specifically separated from ethical review within the HEDC process (Marlowe and Tolich, 2015; Tolich and Smith, 2015). There is ongoing debate in the research ethics community regarding ethics committees’ scope in reviewing scientific validity or the methodologies of social science research projects (Bond, 2012; Emanuel, 2000; Freedman, 1987; Gunsalus, et al., 2006; Ozdemir, 2009 – to name a few). Some authors describe expansion of scope in this area as mission creep (Bond, 2012; Hammersley, 2010; Schrag, 2010). NZEC handles this issue in the following way: it not only explicitly reviews scientific validity as a factor of ethical practice (see Emanuel, 2000), but also provides supplementary research methodology advice to applicants who sit outside the academy. This contributes to supporting the protection of participants and also provides applicants with the means of improving skills and producing rigorous work. It has to be noted that the pressures on community groups and government organisations to produce evidence of their efficacy in line with evidence-based policy decision-making (Black, 2001; Gray, 2004) has created a greater degree of research activity in the sector, in the form of evaluations and intervention studies. This has not been accompanied by any form of research activity support for these groups.

The NZEC committee discusses the methodology of projects with applicants where these are potentially mismatched with the stated aims or unlikely to provide adequate data. Any project that is methodologically unsound is unethical in that it either wastes participants’ time or exposes them to risks that are unnecessary. Where other committees would agree with this as a premise, in practice they are divorced from this review through their Standard Operating Procedures6 or are implicitly removed from it, insofar as methodological input is unwelcome and contested. NZEC advice to applicants is not provided as a distinct or additional service (i.e. groups cannot seek only methodological input for example), but rather as an essential part of the fundamental service of ethical review, which (as discussed below) has been found to be valuable (Marlowe and Tolich, 2015).

**Community Response to NZEC**

The NZEC has been reviewing applications since 2013. In that time, applications have been received from government entities and Non-Government Organisations (NGOs) (see Table 2).

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A research project exploring the experiences of those accessing the committee (Marlowe and Tolich, 2015) found that applicants experienced the process to be supportive and worthwhile. Those Marlowe and Tolich spoke with described their exclusion from other avenues of ethical review. Not only did they value being able to maintain control of their own projects (i.e. not having to sacrifice control to other researchers in order to gain access to an institutional committee), but also the process was described as being less onerous, while more helpful (Marlowe and Tolich, 2015). Applicants had the opportunity to refine or balance methodology and discuss options, and felt that they had gone through a process that showed respect for their participants, who were often clients of their services.

What stands out here is the perception of applicants that their projects were improved by the ethical review process. This perception stands in stark relief to the experiences reported in the literature and in submissions to a government enquiry11 of those going through traditional IRBs or RECs, who describe ethics committees as gate-keepers (Getz, 2011; Heimer and Petty, 2010), and the changes they require as bureaucratic for the purposes of compliance (Coe, 2007; Gunsalus, 2004) rather than the purposes of improving ethical conduct or honouring participants. This perception is also evidenced by the fact that over the years NZEC has been in operation, some of the organisations with regular research activity have repeatedly applied to NZEC.12 It must be remembered that none of these groups are obligated at present under New Zealand legislation/regulation to seek any ethical approval whatsoever.

One area the committee has debated amongst members is whether, when reviewing applications from government agencies, there is potential for political and ethical tension. As a committee that has transparently informed applicants that responses will cover not only ethical issues, but also research design and methodology, the committee also openly critiques projects where the committee is concerned about the potential effects for participants during the research process, as well as potential effects of the outcomes of the research for participants. However, as an advisory committee, NZEC accepts that responsibility for the research and what advice is taken (or not) remains with the government agency (Ministry or Department). Nonetheless, we recognise that NZEC offers a unique contribution as an independent and non-governmental committee, in providing critique of these research projects.

The importance of NZEC independence from institutional research governance, and its responsiveness to the social science audience it serves, are keys to its success. Positive word-of-mouth, recognition through funding, and increasing use of the committee’s services may prove to be forms of credibility that are as important as formal accreditation for this committee.

**IMPROVED RESEARCH QUALITY**

Scientific merit is a key factor for the assessment of the ethical nature of any given research project (Freedman, 1987) – if the research rationale or methodology is unsound, the project cannot be ethical. As noted above, the evaluation of scientific merit by an ethics committee can be unwelcome (see Ministry of Health, 2012); NZEC however provides methodological input to those applicants who may need it, in order to support community-based research and develop research quality in the sector. It bears repeating that the

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7 Government ministries, agencies, organisations, departments, etc.
8 NGOs – charities, trusts providing services.
9 Other applicants include private research companies and education providers (both national and international, etc.).
10 Categories represent the number of different organisations applying, and totals represent the total number of applications received; therefore totals are higher since some organisations have submitted more than one application.
11 Submissions can be found at http://www.parliament.nz/en-nz/pb/sc/documents/evidence?custom=00dbsch_ing_9752_1
12 To date in 2015, there are eight groups who have submitted more than one application to NZEC, and three who have made more than two submissions – voluntarily.
demand for evidence of support services efficacy has meant a rise in the NGO sector of research and evaluation to justify activities. Groups conducting this work are highly skilled practitioners, with expert knowledge of their settings, but less experience of the specifics of question framing in surveys, or statistical methods, for example. The NZEC provides a mentoring role to applicants who are conducting work in this manner. Marlowe and Tolich’s (2015) study, which interviewed NZEC applicants about their experiences of NZEC in general, found that the methodological input specifically had been very helpful. Applicants commented: ‘The review itself gave us a few good ideas in terms of tweaking the survey to become more balanced … So it definitely enhanced the design of the study.’ (p. 8), and ‘… that’s actually where we got most of our help around the questions and how they were framed up. The convener gave quite a bit of really good advice around that and made quite a few changes as a result of that ….’ (p. 9).

One applicant in the study specifically explained how important going through this voluntary process was and what benefits there were in terms of ensuring both ethical and scientific robustness:

We wanted to do this right. We needed to know that our project was sound and we needed to know that it was ethically valid I suppose. …There is an enormous amount of information in there and I think for me it was just about making absolutely sure that our process was right, you know, none of us are researchers and I guess it was to make sure we had followed the process along the way. I would hate for there to be any questions in the future surrounding the validity of what we had done so I guess it was another step towards making sure that was addressed (p. 6).

The NZEC takes the time to address project design in a meaningful way to ensure that applicants achieve what they set out to achieve for their organisation and the participants in the project. Without this review and help provided by NZEC, NGOs especially have little in the way of support or resources to generate the evidence required of them.

Voluntary Review – Perceptions and Power

The authors, two members of the NZEC committee, find what is most interesting about the NZEC is the relationship between applicants and the committee. Both authors have been or are currently members of other committees, both institutional and accredited, and have found anecdotally that those applying to these more ‘formal’ committees are less likely to perceive the process as one that is valuable and has improved their work, an impression that is supported in the literature (see Tolich and Smith, 2015). This difference in perception of the ethics review process can be explored from a number of perspectives.

The Committee

The committee’s membership is much like other committees, insofar as there is a high level of research expertise and experience, there are a number of demographic variables included and all members are members voluntarily while also having other workloads (i.e. there is no difference in workload/commitments). One thing that is different is the inclusion of three previous chairs of HDECs.

The committee’s governance of its ethical review procedures is self-directed. It meets once annually in person to review the year’s operation, to evaluate its procedural items, to engage in professional development, and to discuss ethical issues and standards. The committee is therefore independent and self-governing. This independence provides what was previously discussed as a double-edged sword. It cannot provide its applicants with the same approval and related safety that is provided by ethics committees that are formally accredited (i.e. accredited committees can, for example, provide access for participants to the ACC insurance structure for approved applications), but it can also be more supportive of applicants given there are no external restraints on the committee. As an independent entity, NZEC has the freedom to make decisions and set standards solely in line with ethical practice and participants’ (as well as researchers’) safety, rather than enforcing any form of research governance.

Since the inception of NZEC, members of the committee have been aware that it is something new and radical; it offers a service to those who cannot access review in any other way. Not only that, but the freedoms discussed above and the members’ experiences of research and ethics in the past meant the committee had a sense that they had an opportunity to provide ethics review to an underserved population in a way that was positive and productive with room for innovation. This space to reimagine ethics review outside of the academy is exciting for many members and creates a strong drive to make ethics review work, and work well.

The Applicants

Applicants apply to this committee voluntarily and in this voluntariness alone there is a difference in the dynamic between committee and applicant. Where ethics review has been described as pejorative by those
within the academy (Israel and Hay, 2006; Johnsson et al., 2015; Schrag, 2010), those seeking review voluntarily are asking for input to ensure they are doing things in a manner that they think is worthwhile. Anecdotally, this changes the perception the committee has of applicants – mistakes are viewed more favourably. Where information is missing or a process is in and of itself poor or described poorly, NZEC members tend to consider these mistakes as indicating a lack of experience rather than as a sign of either deception or laziness on the part of the applicant. This may be quite different than what occurs in institutional settings where the relationship between committees and applicants has been marked as one of ‘institutionalised distrust’ (Johnsson et al., 2015). One aspect of institutional and HDEC committees is their role as representatives for their respective organisations (i.e. Ministry of Health or individual tertiary institutions). Through acting representatively on behalf of those organisations, such committees include considerations beyond those of ethical practice, protecting also against possible business and legal risk to their organisation. In contrast, the NZEC as an independent body acts on its own conscience to promote ethically and methodologically sound research practice.

In addition, applicants to the NZEC range from the research-experienced to those new to the process, but their setting is always one where their primary skills are professionally-based not research-based, i.e. their professional esteem is based outside of research practice. It is the authors’ opinion that, unlike in the academy where applicants to committees are partly judged on their research performance continually, in this setting applicants are less likely to feel affronted when questioned on their ethical practice as set out in an application. Those in the community see that research ethics is something to be learned along with research methodology/practice. It is our experience that sometimes those in the academy find the questioning of their ethics in research as a direct questioning of their research practice. One potential result is that they might be less open to input from the committee, which they perceive as less knowledgeable, which may be true of their speciality, but not necessarily of reviewing ethical research practice.

All of this speaks to the difference in power relations between the NZEC and its applicants and the traditional IRB/REC and its applicants. As Boser (2007) describes, the power relation between committee and applicant is parallel to that which is often perceived between applicants and their research participants: that is, IRBs/RECs adopt a power-as-dominance model with applicants (reviewing applications through that lens). The NZEC, however, has no power given it is not accredited. Applicants apply voluntarily, so the relationships between NZEC and its applicants are, by their very nature, relational and more equal. Applicants tend to consider the relationships between themselves and their participants quite differently also.

LIMITATIONS FOR NZEC

The number of applications to NZEC has increased over the years, as the work of the committee becomes known, and its processes and quality is tested. In response, the committee has created a secretariat, invited and welcomed new members, and sourced interim funding for its growth. In contrast to HDECs (which are funded by the Ministry of Health) and institutional RECs (funded by their institutions), NZEC is voluntary and funded by donors and two one-off grants (from the Ministry of Social Development (MSD) and Tindall). NZEC finds itself currently at a crossroads in the sustainable development of its vision, and the directors are focusing on potential revenue sources (including donations) that will not negatively affect community projects that cannot pay (or pay much) for ethical review. There is goodwill from committee members – and a view that this work is worthwhile and useful, as evidenced by applicants’ feedback and Marlowe and Tolich’s (2015) survey. Members of NZEC are not seeking recompense for their time, but do want to know that this project is sustainable, well-founded and sufficiently funded for its future. The time spent with applicants, as numbers of applications increase, is sustainable only if the committee adapts.

CONCLUSION

This article has described the development and function of the NZEC. This community-focused organisation currently remains a viable ethics committee without accreditation, providing a valuable service to those doing important work, both in government and community sectors. This development is interesting in and of itself, as an innovative project in a neo-liberal political research environment, and useful learning from this committee may also apply to other ethics committees. Specifically, joining with applicants relationally and fostering engagement on broader (methodological) matters related to research projects has contributed greatly to the success of NZEC as credible and helpful.

Irrespective of the future of the NZEC within the New Zealand accreditation environment, the applicants’ perception of the process of review by NZEC is worth considering further in ensuring the ongoing development of the current accredited committees and the regulations that govern them. In 2015, the National Ethics Advisory Committee (NEAC) in New Zealand initiated a process of consultation around ethical review in New Zealand and one of the topics about which input is sought is alternative forms of ethical
review. One would hope that this consultation indicates a potential broadening of the ethical review environment in New Zealand, while recognising the need to address ethical review with applicants as a partnered process rather than a paternalistic one.

Ethics committees accredited by the Health Research Council Ethics Committee are limited – not only in the groups they serve, but in the standards they apply (i.e. guidelines cover only interventional and observational health studies). The assumption that all research revolves around health is problematic on a number of counts. Moreover, too many New Zealand researchers fall outside either health or the tertiary sector and are therefore excluded from participating in ethics review within these committees. The NZEC goes some distance towards filling these gaps.

Acknowledgements

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References


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**APPENDIX 1.**

**APPLICATION FORM**