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International Perspectives of Ethical Approval: The New Zealand scene

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## **International Perspectives of Ethical Approval: The New Zealand scene**

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### **Introduction**

The paper "Navigating the process of ethical approval" (Carey, 2010) raises many issues about the influence Institutional Ethics Committees have on research methodology and what can or cannot take place in research. Carey draws attention to the ethical challenges classic grounded theory researchers face when an ethical proposal that follows the principles of the methodology is presented to an Ethics Committee, whose main responsibility is the protection of participants. Ethics committees not only guide researchers on acceptable ethical practice, but are charged with monitoring ethical standards and ensuring researchers act in accordance with professional expectations for researchers within the jurisdiction. These committees aim to ensure consistency of ethical practice in research. While there is generally some flexibility in the review process researchers often find ethical requirements constraining, as guidelines are primarily prescriptive and are designed to ensure consistency in the application of universal ethical principles in research. In New Zealand, consistency includes paying attention to broader socio-cultural responsibilities to society that includes promoting awareness of the Code of Health and Disability Services Consumer Rights 1996, the Health Information Privacy Code 1994, and promoting ethical practices which involve Maori (the local indigenous people) in research proposals as much as possible (Ministry of Health, 2006). So while researchers in training assume that their prime interest concerns the management of a research topic and methodology, they quickly find out that ethical guidelines influence research design. Even though there is an international code of ethics (Universal Declaration of Human Rights, 2005) that defines ethical standards for researchers around the world, each country has its own specific requirements depending on the context. In this paper, ethical drivers in the New Zealand context are outlined and considered in relation to Irish issues. This is followed by a consideration of methodological rules and managing the practical realities that emerge when

working with a specialist methodology such as grounded theory.

### **Ethical drivers: New Zealand and Ireland**

There are two major drivers that have influenced ethics and research in New Zealand. The first was a public inquiry into medical research conducted on women who had major cervical abnormalities (Cartwright Report, 1988). The Cartwright Inquiry found that women with cervical abnormality were entered into a randomised control trial without informed consent. Some were treated while others were not. Many subjects developed cervical cancer. Some women died. This inquiry, which was known as "the unfortunate experiment," raised critical issues about consumer rights and informed consent in research. The Cartwright Report recommended the establishment of the Office of the Health and Disability Commissioner that developed the Code of Health and Disability Services Consumer Rights (1996) and established the Health Information Privacy Code (1994) mentioned previously. Cartwright also recommended that Ethics Committees improve their systems and review processes. Much progress has been made since in that Ethics Committees operate independently from researchers. There is though some tension in balancing individual rights and safety with the increasing pressure for research development in New Zealand (Women's Health Action Trust, 2010). The Women's Health Action Trust for example, questions researcher compliance in relation to consumer protection. Nonetheless, the primary purpose of Ethics Committees in New Zealand is to protect and safeguard research participants, and to respect the dignity of persons (Ministry of Health, 2006).

The second critical factor influencing research in New Zealand is the Treaty of Waitangi, a document determining the relationship between the indigenous people (Maori) and the Crown. The central focus of this Treaty is the individual rights of Maori and their ownership of land. The Treaty is enshrined in New Zealand legislation and compensation for past land grievances is negotiated and settled. By law, all New Zealanders are expected to honour the Treaty principles of partnership, participation and protection. These principles affect health researchers, who are expected to include them in all health research proposals (Health Research Council of New Zealand, 2005). Partnership is about working together with Maori communities in order to achieve health gain. Participation

requires researchers to involve Maori in research design, governance, management, and analysis, in order to reduce health inequalities. Protection requires researchers to safeguard cultural rights to promote health gain (Ministry of Health, 2006). Thus, the Treaty is a fundamental component of research ethics in New Zealand and health researchers expect to design research proposals in ways that go beyond topic and methodology. Not surprisingly, novice researchers find the ethics emphasis on cultural issues challenging.

By comparison, the Irish context for ethical approval sounds simpler. Fortunately, Ireland has not had to contend with an "unfortunate experiment" or managing the rights of the indigenous people, hence the lack of a central office for ethics committee management. The Irish National Disability Authority's guidelines for research practice likely reflect internationally accepted criteria to protect vulnerable people in research. There are some similarities between Ireland and New Zealand in that the person-centred emphasis in the Irish National Standards for Disability emphasise what is important for the person. This is in keeping with the Code of Health and Disability Services Consumer Rights and the Treaty principles. Both countries focus on a fundamental respect for persons. The assumption is made, in New Zealand at least, that people have rights and if there is a lack of respect for these rights, "benefits to some do not justify burdens to others" (Wilkinson, 2001, p. 15). This notion challenges researchers who are keen to generate new knowledge. Although research may generate knowledge for a community (scientific or cultural) it may burden participants because privacy is invaded and participation is inconvenient. In the area of intellectual disabilities in New Zealand, Ethics Committees are responsible for ensuring that research enhances the interests and well-being of the researched:

- Research must be well designed and focus on an issue of significant importance to people with intellectual disabilities;
- Research must respect the rights of people with intellectual disabilities to make their own choices and give informed consent; and
- Research must protect people with intellectual disabilities from undue risks, exploitation and abuse (Ministry of Health, 2006, p. 56).

Therefore, researchers expect an Ethics Committee to review methodology (Gauld, 2001). Typical questions asked are 'Will methods induce harm or poor results?'; 'Would an alternative methodological design eradicate the problem?'; 'Is the method ethically questionable, or will it generate dubious results?' (Gauld, 2001, p. 115).

When these questions are situated under a general philosophy whereby researchers work "with" participants, rather than "on" participants, there are differences in the Irish and New Zealand approaches to research. However, if a specific methodology like grounded theory is introduced into the mix, it is argued that the two countries move closer together because this methodology tends to emphasise "working for" participants.

### **Methodology: Integrating rules and realities**

Clearly, New Zealand researcher responsibilities go beyond methodology. Observation suggests that many health researchers begin a project wanting to research in a way that they know is "right" for participants. A sample is proposed, a context selected, methods are clarified. In the case of grounded theory, the researcher has an initial idea of how to proceed which must also meet ethical guidelines. Long-standing involvement with numerous ethics applications plus membership of a university ethics committee suggests that there are some basic rules that ensure an ethics application will be passed at the first meeting. The rules are: read the guidelines; seek advice from a committee member who will advise about requirements; and, above all, do what is required. A researcher is always free to challenge or to be non-responsive to ethical questions, but the research will not be signed off until a full ethical clearance is given.

This does not mean that there is no room for movement, because while an Ethics Committee is responsible for maintaining consistency, there is always some degree of flexibility, as long as participants are protected. For example, in a grounded theory study researchers do not know how many participants they will interview. The rule of thumb is that poorly articulated sampling strategies will always raise questions for a committee charged with ensuring the issues of privacy, consent and harm are addressed. The reality for grounded theory researchers is that the researcher does not yet know who needs to be interviewed. Not knowing may well be intrinsic to grounded theory methodology, but the Ethics Committee still cannot give

an open mandate to proceed wherever for a student researcher who is learning methodology and the research process. If a researcher states that study numbers are unknown and does not offer any explanation of the reasons why, the Ethics Committee will seek further clarification. Does the researcher intend to interview 10 people or 50 people? Where will they come from? Who will be included? Who will be excluded? Is there discrimination in recruitment and selection? The questions are not unreasonable. In contrast, the grounded theory researcher who states that anticipated numbers will be 20-30 seldom has a problem. Even if a researcher wants to go beyond the original number, an email stating the situation and the number of extra interviews required (usually three of four at most) gets an immediate clearance as a minor amendment.

All the same, there is some tension between ethical rules and the reality of theoretical sampling. Because consent may not be individual, and some individuals may need to consult with their community, the ethics committee will require detail of intention. People with disability are part of a community for instance. Depending on the disability, members of the group may be vulnerable in terms of their capability for understanding what the research is about and what will be required of them. The onus is on the researcher to explain clearly and in simple language what is required. An immediate sample is proposed, and alternatives are put forward. For example, research into nursing practice in end-of-life care is designed to begin with interviews of nurses in hospices and rest homes. In order to give the researcher room to move for theoretical sampling the researcher anticipates where else participants might be found e.g. acute care adults and/or paediatric care, or in a community service. While the latter choices are pre-emptive selective sampling that is contrary to emergent theoretical explanation, access request to multiple areas is not problematic for an Ethics Committee in New Zealand. If, on the other hand theoretical development moved into a very different context (such as an intensive care unit) that had not been identified previously, a minor ethical amendment would be required. The issue for the committee is that a researcher's need to talk to a new group of people in a different area, to develop theoretical explanation, may put potential participants at risk. As long as the issues of privacy (anonymity and confidentiality), consent (information provision), and harm (physical, social or psychological) have been addressed problems

would not be anticipated. To date such a challenge remains hypothetical, as the nature of student research projects is such that most grounded theory researchers in training stay in their area of interest and are reluctant to move across disciplines or into completely different contexts. The one message the researcher needs to convey to an Ethics Committee is that he or she shows a clear respect for the rights of participants and that participants will be safeguarded at all times. These underpinning values are conveyed to a committee by the attitude inherent in the writing of the proposal, the language used and the consideration shown towards others.

### **Conclusion**

So, while we do not know the full story behind some of the difficulties encountered by Carey, her firm stance on methodology raises tensions for a researcher learning a new methodology. Part of the problem for new researchers is that they are learning the research process, and learning how to manage an Ethics Committee is one aspect of the process. Appreciating that an Ethics Committee is not there to defend methodology but rather defend potential participants, goes some way to alerting an enthusiastic methodologist of probable ethical priorities. The challenge for a grounded theory researcher is to maintain methodological rigour as well as protecting participants at one and the same time. This also draws attention to the fact that research seldom occurs in isolation and methodological ideals and the aims of knowledge generation need to be considered in relation to the broader socio-cultural context.

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