

E1 PROJECT TITLE

An Analysis of Research Ethics and the Ethical Review Process as Culture and Cultural Process

E2 PROJECT DESCRIPTION AND BACKGROUND

This project, an ethnography of the ethical review process for research involving humans, involves an anthropological analysis of research ethics and the ethical review process as culture and cultural process. It does this through document reviews, case studies, key informant interviews, and observations of the ethical review process. One of its purposes is to better understand why some kinds of research, namely research involving alternative paradigms and that associated with sensitive populations, seem to present particular difficulties for ethical review committees, research gatekeepers, and the researchers involved. This research might help us better address the issues involved and allow the development of research and ethics programs, policies, applications, and educational efforts that are less problematic for all parties concerned. It is not about whether or not research and the ethical review process are ethical, but what are the cultural factors that influence ideas about ethics and the ethical assessment of research and how they may impact on contemporary research.

Background

The ethical review of research with humans was institutionalised in the 1960s. In the 1970s, Wax (1977) wrote that the precise effects of this process on the conduct of research was not yet known, but there was an impression that some types of research were being discontinued, others radically redesigned, the pace slowed, and flexibility was being curtailed by procedural constraints (see also Chambers 1980). Fitzgerald (1994) suggested a similar impression in the 1990s for Australia. In fact, there is evidence that difficulties negotiating ethics committees' review of applications, particularly those using alternative paradigm research and methods other than experimental and survey designs, have plagued researchers and ethical review committees for many years (e.g. Dodds, Albury, & Thomson 1994; Cassell & Jacobs 1987; Cassell & Wax 1980; Daly 1996; Murphy & Johannsen 1990; Pel 1999; Sieber 1992, 1982; Thomson & et al 1981; Wax 1977, 1980, 2001; Weijer, Goldsand & Emanuel 1999; Werner 1999). The difficulties appear even more problematic when the people involved are from populations commonly identified as 'sensitive' or 'vulnerable'. This includes, for example, people from culturally and linguistically diverse or aboriginal backgrounds; those who have experienced illness (in particular mental illness) or other potentially sensitive experiences; children; patients or students of the researcher; people with intellectual disabilities or cognitive impairments, etc. (e.g. Bamberger 1999; Barry 1991; Beauvais 1999; Casteel 1998; Castellucci 1998; Gil & Bob 1999; Harley, Feist-Price, & Alston 1996; Macaulay et al. 1998; Macaulay et al. 1991; Singer, Huertas, & Scott 2000; Wing 1991). When more than one of these is involved the difficulties seem to be compounded.

'The term "research with human subjects" is frequently used to describe a wide variety of biomedical, behavioural, and social investigations. Unfortunately, the phrase obscures significant differences between methods' (Cassell 1982, p.7). This research explores how cultural factors associated with some of these differences might affect the ethical review process. It does so by placing the emphasis primarily on research associated with paradigms (e.g. naturalistic, constructivist, interpretivist, multi-paradigmatic and 'blurred genre') and methods used by or borrowed from the social or behavioural sciences (ethnography, phenomenology, action research, naturalistic inquiry, participatory observation, life history, case studies, multi-method research, etc) (e.g. Denzin & Lincoln 1994) because the ethical review of this kind of research seems to be particularly problematic (e.g. Dodds, Albury, & Thomson 1994; Commonwealth of Australia 1996). As Wax and Cassell noted in 1979, with the institution of the federal regulation of research, like the process of ethical review, 'investigators are both

challenged and disconcerted, chastened and outraged' (Wax & Cassell 1979, p. 1). A review of recent publications (see examples above) and recent reviews of the ethical review process (see examples below) suggests that the same can be said more than 20 years later. As Pel (1999) notes, in the 1990s there has been a 'renewed vigor' to the discussion of ethical codes, particularly within anthropology.

In Australia and elsewhere, issues and concerns regarding the ethical review of research has resulted in reviews of the ethical review process and the introduction of new policies, procedures, and information booklets (e.g. Clinton 1994; Commonwealth of Australia 1996, 1999; Dodds, Albury, & Thomson 1994; HRC New Zealand 1996a 1996b, 1997; McDonald 2000; NCPHSBBR (The Belmont Report) 1979; NHMRC 1995a, 1995b; NIH 1991; Tri-Council 1998, see also for example www.bioethics.gov; <http://ohrp.osophs.gov/polasur.html>). In the US there has been a move towards restricting applications for federal funding to only those who have official certification as the result of attending an ethics certification program, a program that does not address many of the issues associated with social science research or research that adopts its paradigms and methods and, for some, this raises serious ethical concerns (e.g. Overbey 2001; Wax 2001). Recent processes in Canada appear to have evoked similar policy changes and concerns (McDonald 2000). This has created a kind of crisis that has the potential to have a significant impact on the kinds and forms of research that will be done in the future and how they will be reviewed or controlled (e.g. AAUP 2001; McDonald 2000; Overbey 2001; Wax 1995, 2001; <http://www.aaup.org/irbdoc.htm>; www.aaanet.org/gvt/nbacresponse.htm). All of these are increased by recent scientific, political, and media attention towards such things as the Genome project, stem-cell, cloning, and unethical medical research that has raised public concerns about research ethics (McNeill 1993) that often have little relevance for most social science research.

At roughly the same time as institutional or ethics review boards were institutionalised, Nader (1972, p. 305) began to encourage anthropologists to 'study up,' to study 'institutions, organizations, bureaucracies that have broad public impact'. Like Rainwater and Pittman (1967), Nader, Galliher (1980) and others suggest that researchers have the right and, perhaps, the obligation to study publicly accountable behaviour, to make transparent the behaviour and decision-making processes of those who function in the public interest. Ethics review committees explicitly function in the public interest, they have a public impact, and they are influenced by culture.

Ethics as culture

Weisz (1990a, p. 4) states that there are 'numerous ethical visions operating in the world'. Christakis (1992), among others, states that ethics are 'local,' they are a form of 'local knowledge,' and they are enacted in local worlds. They are a product of, and a reflection of, local culture, the local moral world. They are local despite claims that they are based on universal premises or standards.

Young (1990, p. 65) describes ethics as 'a subset of moral rules'. They are about how to do the 'right' thing. Weisz (1990a, p. 8) suggests that 'defining a problem as 'ethical' may also imply that certain types of solutions implemented by particular professionals and institutions are more appropriate than others'. If ethics are based on morals, values, perceptions of right and wrong, and the social norms of particular groups, then they are obviously cultural (for relevant definitions of culture see for example: Goodenough (1981); Helman (1994); Kroeber & Kluckhohn (1963); LeVine (1982)). Morals, values, norms, beliefs and ways of conceptualising and judging human behaviour are fundamentals of culture and cultural difference. If we accept that all of these things vary across cultures, that they provide the very basis of cultural diversity, then we should expect ethics to vary across cultures and sub-cultures and that there should be diversity in the conceptualisation of ethics and what is considered ethical.

Medical ethics are, according to Weisz, ‘an extraordinarily complex cultural phenomenon’ (1990a, p. 8). As the literature on research ethics demonstrates, whether or not medical issues are involved, research ethics are an equally complex cultural phenomenon embedded in cultural values, beliefs, and norms of society and particular research paradigms; and, as such, should show variation across societies and disciplines. Thus, like medical ethics, they are worthy of further study as a cultural phenomenon.

In fact, there would seem to be a critical need to understand research ethics as a product of culture and particular cultural processes. A lack of this kind of understanding could result in misunderstandings and problems in the review of research applications by ethics committees and other gatekeepers. It could result in the imposition of inappropriate and inflexible standards that can become barriers to conducting ethically and methodologically responsible research that addresses a full range of topics and includes people from all cultural backgrounds (Fitzgerald 1994). Greater understanding in this area might lead to enhanced standards, more expeditious reviews, and better relations between researchers, ethical review committees, and the community.

The anthropology of ethics

This research will contribute to the anthropology of research ethics and the ethical review process. It will draw heavily on the work of anthropologists (among others), in particular medical anthropologists, who have explored not only medical ethics, but also various issues associated with research ethics, particularly when research crosses cultural and disciplinary boundaries and involves alternative paradigms. As Good and others have noted:

‘Anthropology’s greatest contribution to twentieth-century sociology of knowledge has been the insistence that human knowledge [and behaviour] is culturally shaped and constituted in relation to distinctive forms of life and social organization’ (Good 1994, p. 21). As Weisz (1990a, p. 3) notes, no one disputes the significance or complexities that surround research ethics or, in his work, medical or bioethics, but, in the past, the discourse on ethics (and the ethical review process) has often appeared ‘oblivious to the social and cultural context in which these occur... Nor do [people] seem very conscious of the cultural specificity of many of the values and procedures they utilize when making ethical judgements’.

The approach used in this research is based on the idea that in the arena of ethical review there appears to be the assumption that ethics are some kind of universal, unitarian, stable, unchanging phenomenon rather than a product of a particular culture with a particular cultural history at a particular time in a particular place based on a particular cultural conception of what constitutes good, moral, ethical, and worthy research (e.g. Christakis 1992; Pels 1999). In other words, ethics, including research ethics, are contextually and culturally bound and, as a result, they reflect the culture of society: its beliefs, morals, values, standards for behaviour, etc (e.g. Christakis 1992; Kleinman 1996; Weisz 1990b).

I propose that many of the real and perceived ‘problems’ commonly associated with the ethical review of research applications are, at least in part, cultural. They result when people do not view ethics as a cultural issue or understand that the research paradigms proposed are based on varying cultural assumptions, including assumptions about the nature of knowledge — its ontology and epistemology, that these different research paradigms are based on varying ideas about what constitutes important, ethical research questions and how to answer them. I propose that they are based on cultural ideas and assumptions about human beings, including ideas about personhood and the self (e.g. Kleinman 1996; Lieban 1990; Shweder 1991; Shweder & Bourne 1982/84), people’s roles in research as either researchers or participants and their ability to make decisions about their role in the research process, even whether or not they should be involved.

Research Statement

This project explores and expands on the issues and ideas presented above. It will explore some of these theories and issues through a more detailed analysis of ethical review documentation, case studies, examinations of the relevant literature, and the observation of ethical review panels in the process of deliberation. The initial focus will be on countries with similar core cultural and linguistic backgrounds: Australia, Canada, New Zealand, the United Kingdom, and the USA. This focus is important because Australian researchers are often involved in research collaborations with people in these countries, all of these countries seem to be encountering similar issues associated with the kinds of research noted above, they are all multicultural, and the ideas and policies of these countries have significant influence on international standards for the ethical conduct and review of research.

As an anthropological analysis of ethics and the ethical review process, one that expands on other work in this area (see references above, historical analyses like that by Pels (1999), and work that came out of the 1970s US NSF funded 'Program in Ethics and Values in Science and Technology' [e.g. Cassell & Wax 1980]), it offers a potential way through what often appears to many as a cultural, theoretical, and procedural impasse. It attempts to turn what is too often perceived as an adversarial situation (e.g. Commonwealth of Australia 1996) into a more positive and potentially more useful approach to the issues involved. This approach might help us better address the issues involved from an empirical rather than emotive stance and allow the development of policies and applications that are less problematic for all concerned.

The proposed research attempts to better understand the real and perceived issues involved in the ethical review of research from a cultural perspective. It explores the impact of cultural issues on contemporary research, research ethics, and the ethical review process. It asks:

- Can an understanding of ethics and the ethical review process as culture and cultural process help us understand issues raised in the ethical review process and the impact of that process on contemporary research?

To address this question it will ask a number of sub-questions, including, for example:

- What are the core issues and questions regularly raised in the ethical review of contemporary research?
 - How do they get raised, addressed, and resolved? Who raises them (researchers, committees or committee members in particular roles [e.g. doctor, ethicist/religious leader, community member])?
 - What are the cultural histories and assumptions embedded in these issues?
- Are the issues and questions associated with methods derived from the social sciences different from those associated with biomedical research? If yes, in what ways are they different?
- How do researchers react to responses from ethical review committees or other gatekeepers who use a discourse of ethics as keys to the gate? What do they do? How do review committees respond to researchers responses to their questions or recommendations?
- Does the ethics review process affect the kinds of research and methodologies proposed and conducted?

E3 SIGNIFICANCE AND INNOVATION

This project is significant in that it addresses issues of national concern: the encouragement of excellence in research that is of the highest world-class quality, research that addresses and deals

with the needs of the community in socially and culturally responsible ways. It adds to our understanding of the role of culture and research in the research process and the review of that research, and subsequently our understanding of the culture of contemporary communities, like Australia. It may help shape at least one national institution and contribute to our understanding of other regulatory institutions that play a significant role in establishing national priorities and agendas and approaches to research in contemporary societies. It will help us understand how the ethical review process influences and affects current research and may impact on the kind of research that gets done (or not done) in the future. It will add to the knowledge base of anthropology, including knowledge of contemporary societies and its institutions. It will contribute to our understanding of ethics and applied ethics in contemporary societies.

This project is innovative in that it takes an anthropological approach to understanding an area of concern for the community, ethical review committees, researchers, and the nation. It does so by researching the issue as a research and cultural issue: it uses the research process, in particular ethnography, to address a research and social issue. In doing so, it uses a particular disciplinary perspective that has not been widely applied to this topic in recent years. It takes an empirical rather than strictly theoretical or emotive approach to addressing a controversial topic. It is innovative in that it focuses on specific approaches to research and, as a result, adds a counterbalance to current discussions on bio- and medical research ethics.

Reyes (2000, p. 59) states that most of the literature on research involving humans is 'descriptive and does not delve into the ways in which research ethics is engendered, but rather is concerned with the existence of research policies and procedures as a result of research misconduct'. Although cultural, historical, and political issues and anthropological analyses have been brought into discussions about research ethics (see in particular works by Cassell, Christakis, Pels, Sieber, Wax, Weisz, and others noted above) and culture is increasingly addressed in ethical guidelines, much of the literature deals with biomedical research and advised consent (see for example the bibliography in Weisz (1990b)). Thus much of the literature focuses on the ethical conduct of research; there are few cultural or anthropological analyses of the culture in research or the ethical review process. In addition much of the literature on research ethics and ethical review addresses specific cases or potential problems, but few involve the systematic study of the actual process. To date the only somewhat similar study that I am aware of for Australia is the collection of studies by McNeill (1993) and his colleagues, who studied the ethical review of human experimentation and biomedical research from a socio-political perspective. The other major project with some similarities took place in the USA in the 1970s (e.g. Cassell & Wax 1980; Wax & Cassell 1979).

This work is particularly important at this time because of the increased international professional and public attention being given to research ethics. Much of this attention is directed towards biomedical research, but the outcomes of the ethical debates will have a significant impact on the development of standards and expectations for all research involving humans and this will affect and influence the ethical review process. This work provides a counterbalance to the discussions and debates surrounding such research and specifically addresses the other research paradigms, paradigms that are increasingly being used in health research.

This research addresses an issue of international concern. To adapt a comment by Weisz (1990a, p. 6), who spoke primarily of medical and bioethics: 'the development and international diffusion of [research] ethics is itself a social phenomenon of considerable importance with consequences for our understanding of the entire [research] enterprise'. Thus this research takes a scholarly and empirical approach to something that has internationally become a highly emotive and often controversial topic. Its intention, like McNeill's (1993) work, is to encourage critical reflection on research ethics and the ethical review process.

It also provides a way to give some ‘transparency’ to the ethical review process, much of which occurs informally (Reyes 2000) and ‘beyond the sight’ or experience of most researchers and the people involved in research (McNeill 1993). The use of ethnography provides the opportunity to provide both an emic and etic perspective. As noted above, Nader (1972) and others have suggested that it is important to study institutions, etc that have broad public impact, that researchers have both a right and responsibility to do so. This research addresses the ethical review process as a public and research concern.

E4 APPROACH

This ethnographic study involves an anthropological analysis of research ethics, and the ethical review process as culture and cultural process through four overlapping activities: 1) a review and analytical critique of the national and international documentation on ethical review and other relevant literature, including that associated with the themes and issues raised in the analyses; 2) the collection and analysis of ‘instrument’ cases (Stake 1994); 3) discussions and interviews with national and international key informants, experts and policy developers; and 4) observation of ethical review panels in the process of deliberation.

Analysis of forms, documents, and relevant literature. There is an international body of literature and a new and rapidly developing body of forms, information booklets, and policy documents on this topic. This phase of the project will focus on the systematic collection and in-depth analysis of these materials. It will use a cultural schema approach to coding the documents and sections of the documents. This schema will be developed and refined in the first stage of the project using the initial analysis of core documents and analyses related to other aspects of the project.

Collection and analysis of case studies. As Stake (1994, p. 245) points out, ‘case studies are of value in refining theory and suggesting complexities for further investigation’. The project will use what Stake calls ‘instrumental cases’ or Fitzgerald calls ‘critical incidents’ (e.g. Fitzgerald 2000, 2001; Fitzgerald, et al 1997, see also Arthur 2001) because they can provide insight into an issue. In this approach, the unit of analysis is the ethical review case, not specific individuals or committees. This approach uses ethnographic style interviews (e.g. Spradley 1979) to get people to present, discuss or respond to a case. In this approach instrument cases or critical incidents are ‘neither inherently negative nor positive, they are merely distinct occurrences or events which require some attention, action, or explanation; they are situations for which there is a need to attach meaning’ (Fitzgerald 2000, p. 190). Cases may include sets of documentation on an application (e.g. correspondence between an ethics committee and a researcher). The analysis of these cases will allow the development, application and testing of theories and hypotheses generated from other phases of the research in a recursive fashion.

Discussions/interviews with key scholars and informants. Key scholars and informants will include national and international experts on research ethics and the ethical review process (e.g. scholars who have written on or have a particular interest in this area, people involved in research ethics policy development, past and present members of ethics review committees). Some discussions, again using the ethnographic interview approach, will be by telephone or email, but most will be conducted in face-to-face contexts. De-identified critical incidents collected as part of this research may be used as stimuli for discussion. This portion of the research requires national and overseas travel and, where possible, will be combined with interviews to collect case studies and observations of ethics committee in that region.

Observation of ethical review panels and documentation review. Observations of ethical review panels in the process of deliberation and review will be guided by the work of Spradley (1980) and others on participant observation. It will draw on the Chief Investigator’s more than 20 years of experience doing ethnography. These observations are important for identifying key

ethical issues and contextualising information collected in other aspects of the project. For example, the documentation researchers receive from ethics committees generally does not provide in-depth information on the underlying concern or the discussion that resulted in asking the researcher to respond to the committee on particular points in the application. The focus will be on the deliberations and the nature of the deliberations or discourse involved, not particular applications. Application deliberations will be categorised by type of research and issues raised. No information that will allow the identification of the researchers involved or the project will be recorded. Data will be collected using fieldnotes. Data collection sheets to facilitate the collection of regularly occurring information (e.g. type of research – biomedical, social science, etc; general topic area, methods involved – drug trial, interviews, etc; type of population involved – patients, general population, potentially sensitive, etc.) will be developed following the initial observations and refined as necessary. Where allowed, proceedings will be tape-recorded. The tape will be transcribed for in-depth analysis removing all information that might allow the identification of researchers or research projects. All fieldnotes will use de-identified information. Tapes and transcripts will be given a unique identifying number. Chairs and Secretaries of ethics committees will be the first point of contact for gaining permission to observe. Committees may chose to allow only observation, only review of documentation, or both.

Analysis. This research uses an ethnographic approach to data collection and analysis (e.g. Fitzgerald 1997). This work requires various forms of on-going, iterative, and comparative analyses (textual, content, discourse, narrative, etc) that focus on explicit and implicit meaning. It involves, for example, the comparative analyses of data from all the sources from all the sites to look for patterns and significant breaks in patterns. As Lieban (1990, p. 233) notes, ethnography and ‘comparative studies in the social sciences are concerned with description and analysis of social and cultural differences and similarities’ even if it appears that culturally we are dealing with ‘one case writ large’. All of the methods that will be used are derived from the social sciences, in particular anthropology (for reviews of these approaches see for example: Denzin and Lincoln (1994) and Emerson (1983)). The use of multiple methods provides opportunities to view the data from various perspectives. This requires the researcher to regularly become immersed in data collection and analysis.

Most of the data will be textual and includes documents, transcripts, and fieldnotes. Where appropriate, data will be acquired or converted to computerised text files to facilitate analyses using various computer programs.

E5 NATIONAL BENEFIT

This research contributes to Australia’s recognition of the importance of research, using a variety of approaches, in addressing issues of national and international cultural, social, economic, and political importance. It addresses issues related to the relationship of researchers with the community and the need for transparency in its research related policies and procedures. It is in the national interest to better understand the cultural issues associated with contemporary research ethics and the ethical review process. This knowledge can enhance the quality of research and Australia’s place as a leader in research ethics and the ethical conduct of research. It can be used to develop policies and procedures that support and encourage research, particularly that involving alternative paradigms, using the most supportive and expeditious processes, thus encouraging people to participate in research, in particular new and innovative types of research. The information will provide culturally based information for the education and training of researchers and members of ethics committees and assist in the development appropriate policy. Furthermore, as noted earlier, many researchers in Australia collaborate with researchers in the countries to be included in the investigation. The international information

from this research may help researchers develop applications that are more likely to be received favourably in all these countries.

E6 COMMUNICATION OF RESULTS

The results will be communicated in national and international presentations, workshops, and publications. In addition to peer reviewed journal articles, the results will be developed into a book-length monograph and an information booklet for researchers and ethics committee members. The material will also be incorporated into my teaching on ethics, particularly with the research students I supervise.

E7 DESCRIPTION OF PERSONNEL

Chief Investigator. The chief investigator, a US trained medical anthropologist who has worked in a Faculty of Health Sciences for ten years, is the primary researcher for this project. She has been involved in research for nearly 20 years and has conducted research in several countries. She has more than ten years of research student supervision experience. This work requires an experienced anthropologist to be involved in data collection and analysis because it builds on anthropological theory, method, and literature and uses a variety of analytical techniques. Data analyses require 'first hand' in-depth knowledge of and experience with the data. She will be the project director, engage in all aspects of data collection, and take the key role in data analysis and the production of research products. In conducting the research she can call on an international pool of scholars for advice and assistance. In fact, this opportunity is written into the methodology.

Postgraduate and Honours Students. These students will be key members of the research team. Although each will identify a specific focus within the project to concentrate on, all will work across all the datasets and engage in all aspects of the project to some degree. This will provide experience in both a variety of research activities and the ethical conduct of research. Thus each will work in parallel with the Chief Investigator in terms of data collection, data management, and analysis and allow the project to maintain continuity across the life of the project. For the project, one advantage of having students involved is that some people and committees, particularly in Australia – the home site of the research, may be more comfortable working with a student, rather than an experienced member of the local research community. The work the students do on this project is expected to have a direct impact on the student's own work for his or her thesis and any subsequent professional activities. This approach has demonstrated success. The research scholarship student from a 1995 NHMRC PHRDG completed her Masters degree as a result of the scholarship, is now completing her PhD, has already received NHMRC grants in her name, and has published in international peer reviewed journals.

E8 REFERENCES

- AAUP. (2001) *Protecting human beings: Institutional review boards and social science research*. Washington, DC: American Association of University Professors.
- Arthur, N. (2001) Using critical incidents to investigate cross-cultural transitions. *International Journal of Intercultural Interactions*, 25, 41-53.
- Bamberger, M. (1999) Ethical issues in conducting evaluation in international settings. In J. L. Fitzpatrick & M. Morris & e. al. (Eds.), *Current and emerging ethical challenges in evaluation. New directions for evaluation: A publication of the American Evaluation Association* (pp. 103). San Francisco: Jossey-Bass.
- Barry, M. (1991) Ethical dilemmas with economic studies in less-developed countries: AIDS research trials. *IRB*, 13(4), 8-9.
- Beauvais, F. (1999) Obtaining consent and other ethical issues in the conduct of research in American Indian communities. *Drugs & Society*, 14(1-2), 167-184.
- Cassell, J. (1982) Harms, benefits, wrongs, and rights in fieldwork. In J. E. Sieber (Ed.), *The ethics of social research: Fieldwork, regulation, and publication* (pp. 7-31). New York: Springer-Verlag.

- Cassell, J., & Jacobs, S.-E. (Eds.) (1987) *Handbook on ethical issues in anthropology*. Washington, DC: American Anthropological Association.
- Cassell, J., & Wax, M. L. (Eds.) (1980) Ethical problems of fieldwork. *Social Problems*, 27(4).
- Casteel, J. K. (1998) The ethics of informed consent among storyteller cultures. *International Journal of Circumpolar Health*, 57 Suppl.(1), 41-42.
- Castellucci, L. (1998) Culturally identifiable populations raise thorny issues for researchers. *Journal of the National Cancer Institute*, 90(20), 1508-1509.
- Chambers, E. (1980). Fieldwork and the law: New contexts for ethical decision making. *Social Problems*, 27(3), 330-341.
- Christakis, N. A. (1992) Ethics are local: Engaging cross-cultural variation in the ethics for clinical research. *Social Science & Medicine*, 35(9), 1079-1091.
- Clinton, W. J. (1994) Memorandum for the Vice President, the Heads of Executive Departments and Agencies: Review of federal policy for the protection of human subjects. Washington, DC: U. S. Government.
- Commonwealth of Australia. (1999) National statement on ethical conduct in research involving humans. Canberra: Commonwealth of Australia.
- Commonwealth of Australia. (1996). *Report of the review of the role and functioning of Institutional Ethics Committees*. Canberra: Commonwealth of Australia.
- Daly, J. (Ed.) (1996) *Ethical intersections: Health research, methods and researcher responsibility*. Sydney: Allen and Unwin.
- Denzin, N. K., & Lincoln, Y. S. (Eds.) (1994) *Handbook of qualitative research*. Thousand Oaks, CA: Sage.
- Dodds, S., Albury, R., & Thomson, C. (1994) *Ethical research and ethics committee review of social and behavioural research proposals*. Canberra: Australian Government Publishing Service.
- Emerson, R. (1983) *Contemporary field research: A collection of readings*. Prospect Heights, IL: Waveland Press.
- Fitzgerald, M. H. (1994) Negotiating human ethics committees in Australia. *Society for Applied Anthropology Newsletter*, 5(4), 3-5.
- Fitzgerald, M. H. (1997) Ethnography. In J. Higgs (Ed.), *Qualitative research: Discourse on methodologies* (pp. 48-60). Sydney: Hampden Press and The Centre for Professional Education Advancement, The University of Sydney.
- Fitzgerald, M. H. (2000) Establishing cultural competency for health professionals. In V. Skultans & J. Cox (Eds.), *Anthropological approaches to psychological medicine* (pp. 184-200). London: Jessica Kingsley.
- Fitzgerald, M. H. (2001) Gaining knowledge of culture during professional education. In J. Higgs & A. Titchen (Eds.), *Practice knowledge and expertise in the health professions* (pp. 149-156). Oxford: Butterworth Heinemann.
- Fitzgerald, M. H., Beltran, R., Pennock, J., Williamson, P., & Mullavey-O'Byrne, C. (1997) *Occupational therapy, culture and mental health*. Sydney: Transcultural Mental Health Centre.
- Galliher, J. F. (1980) Social scientists' ethical responsibilities to superordinates: Looking upward meekly. *Social Problems*, 27(3), 298-308.
- Gil, E. F., & Bob, S. (1999) Culturally competent research: An ethical perspective. *Clinical Psychology Review*, 19(1), 45-55.
- Good, B. J. (1994) *Medicine, rationality, and experience: An anthropological perspective*. Cambridge: Cambridge University Press.
- Goodenough, W. (1981) *Culture, Language, and Society* (2nd ed.) Menlo Park, CA: Benjamin/Cummings.
- Harley, D. A., Feist-Price, S., & Alston, R. J. (1996) Cultural diversity and ethics: Expanding the definition to be inclusive. *Rehabilitation Education*, 10(2&3), 201-210.
- HRC New Zealand. (1996a) *HRC guidelines for ethics accreditation*. Auckland: Health Research Council of New Zealand.
- HRC New Zealand. (1996b) *National standards for ethics committees*. Auckland: Health Research Council of New Zealand.
- HRC New Zealand. (1997) *HRC guidelines on ethics in health research*. Auckland: Health Research Council of New Zealand.
- Helman, C. G. (1994) *Culture, health and illness* (4th ed.) Oxford: Butterworth-Heinemann.
- Kleinman, A. (1996) Chapter 3: Anthropology of Bioethics, *Writing at the margin: Discourse between anthropology and medicine*. Berkeley: University of California Press.
- Kroeber, A. L., & Kluckhohn, C. (1963) *Culture: A critical review of concepts and definitions*. Cambridge, MA: Harvard University Press.
- LeVine, R. A. (1982) *Culture, behavior and personality: An introduction to the comparative study of psychological adaptation* (2nd ed.) New York: Aldine Publishing.
- Lieban, R. W. (1990) Medical anthropology and the comparative study of medical ethics. In G. Weisz (Ed.), *Social science perspectives on medical ethics* (pp. 221-239). Dordrecht: Kluwer Academic Publishers.
- Macaulay, A. C., Cross, E. J., Delormier, T., Potvin, L., Paradis, G., & McComber, A. (1998) Developing a Code of Research Ethics for research with a Native community in Canada: a report from the Kahnawake Schools Diabetes Prevention Project. *International Journal of Circumpolar Health*, 57 Suppl.(1), 38-40.

- Macaulay, A. C., Delormier, T., McComber, A. M., Cross, E. J., Potvin, L. P., Paradis, G., Kirby, R. L., Saad-Haddad, C., & S., D. (1991) Participatory research with native community of Kahnawake creates innovative Code of Research Ethics. *Canadian Journal of Public Health*, 89(2), 105-108.
- McDonald, M. (Ed.) (2000) *The governance of health research involving human subjects (HRIHS)*. Ottawa, Ontario: Law Commission of Canada.
- McNeill, P. M. (1993). *The ethics and politics of human experimentation*. Cambridge: Cambridge University Press.
- Murphy, M. D., & Johannsen, A. (1990) Ethical obligations and federal regulations in ethnographic research and anthropological education. *Human Organization*, 49(2), 127-134.
- Nader, L. (1972) Up the anthropologist: Perspectives gained from studying up. In D. Hymes (Ed.), *Reinventing anthropology* (pp. 284-311). New York: Pantheon.
- NCPHSBBR. (1979) *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Washington, DC: Department of Health, Education, and Welfare.
- NHMRC. (1995a) *Ethical aspects of qualitative methods in health research -- An information paper for institutional ethics committees*. Canberra: National Health and Medical Research Council.
- NHMRC. (1995b) *Report of 1995 ethics workshops*. Canberra: Commonwealth of Australia.
- NIH. (1991) *Part 46: Protection of human subjects, Code of Federal Regulations*. Washington, DC.
- Overbey, M. M. (2001) AAA responds to human research oversight proposals. *Anthropology News*, 42(4), 9-10.
- Pels, P. (1999) Professions of duplexity. *Current Anthropology*, 40(12), 101-136.
- Rainwater, L., & Pittwater, D. J. (1967) Ethical problems in studying a politically sensitive and deviant community. *Social Problems*, 14, 357-366.
- Reyes, J. A. (2000) The construction of research ethics involving human subjects: A preliminary analysis. *Michigan Academician*, 32(2), 59-69.
- Shweder, R. A. (1991) *Thinking through cultures: Expeditions in cultural psychology*. Cambridge: Harvard University Press.
- Shweder, R. A., & Bourne, E. J. (1982/84) Does the concept of person vary cross-culturally? In A. J. Marsella & G. M. White (Eds.), *Cultural conceptions of mental health and therapy* (pp. 97-137). Dordrecht, Holland: D. Reidel.
- Sieber, J. (1992) *Planning ethically responsible research: A guide for students and internal review boards*. Newbury Park, CA: Sage.
- Sieber, J. E. (Ed.) (1982) *The ethics of social research: Fieldwork, regulation, and publication*. New York: Springer-Verlag.
- Singer, M., Huertas, E., & Scott, G. (2000) Am I my brother's keeper?: A case study of the responsibilities of research. *Human Organization*, 59(4), 389-400.
- Spradley, J. P. (1979) *The ethnographic interview*. New York: Holt, Rinehart, Winston.
- Spradley, J. P. (1980) *Participant observation*. Fort Worth: Harcourt Brace Jovanovich College Publishers.
- Stake, R. E. (1994) Case studies. In N. K. Denzin & Y. S. Lincoln (Eds.), *Handbook of qualitative research* (pp. 236-247). Thousand Oaks, CA: Sage.
- Thomson, J., & et al. (1981) Regulations governing research on human subjects: Academic freedom and the institutional review board. *Academe*, 67, 358-370.
- Tri-Council. (1998) *Tri-council policy statement: Ethical conduct for research involving humans*. Ottawa, Canada: Medical Research Council of Canada.
- Wax, M. L. (1977) On fieldworkers and those exposed to fieldwork: Federal regulations and moral issues. *Human Organization*, 36(3), 321-328.
- Wax, M. L. (1980) Paradoxes of 'consent' to the practice of fieldwork. *Social Problems*, 27(3), 272-283.
- Wax, M. L. (1995) Informed consent in applied research: A comment. *Human Organization*, 54(3), 330-331.
- Wax, M. L. (2001) When the Feds are uninformed, researchers cannot consent. *Society for Applied Anthropology Newsletter*, 12(1), 3-4.
- Wax, M. L., & Cassell, J. (Eds.) (1979) *Federal regulations: Ethical issues and social research*. Boulder, CO: Westview Press.
- Weijer, C., Goldsand, G., & Emanuel, E. J. (1999) Protecting communities in research: Current guidelines and limits of extrapolation. *Nature Genetics*, 23(3), 275-280.
- Weisz, G. (1990a) Introduction. In G. Weisz (Ed.), *Social science perspectives on medical ethics* (pp. 3-15). Dordrecht: Kluwer Academic Publishers.
- Weisz, G. (Ed.) (1990b) *Social science perspectives on medical ethics*. Dordrecht: Kluwer Academic Publishers.
- Werner, D. L. (1999). Comment: Imperialism, research ethics and global health. *Journal of Medical Ethics*, 25(1), 62.
- Wing, J. (1991) Ethics and psychiatric research. In S. Bloch & P. Chodoff (Eds.), *Psychiatric ethics* (pp. 415-434). New York: Oxford University Press.
- Young, A. (1990) Moral conflicts in a psychiatric hospital treating combat-related posttraumatic stress disorder (PTSD). In G. Weisz (Ed.), *Social science perspectives on medical ethics* (pp. 65-82). Dordrecht: Kluwer Academic Publishers.