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Health Ethics Section
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Dear Dr Breen:

Thank you for the invitation to make early comments on the *National Statement on Ethical Conduct in Research Involving Humans*. My comments are based primarily on my current research on the research ethical review process as culture and cultural process, currently funded by an ARC Discovery Grant (DP0343014). This international project includes formal and informal interviews with key informants (researchers, ethics committee members, policy makers, and others), observations of ethics committees in the process of deliberation, and extensive reviews of the relevant literature and policy documents. See www.ethicsproject.com for more details on the project.

I am sure that many of my comments parallel those acquired since the current *National Statement* was released. I offer these comments to help support consideration of information you already have and that you will obtain during this review. Despite the length of this submission, it is an attempt to keep my comments succinct and I have attached copies of recent publications that expand on some of my points. Please do not hesitate to contact me if you require any clarification or I can offer any further assistance.

As part of your effort I encourage you to look at a recent document developed in relation to the review of Canada's Tri-Council Policy (Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC), 2004). Many of the comments and recommendations in that document are relevant to local concerns associated with the review of "qualitative" research.

Let me begin by acknowledging that I recognise the considerable amount of work that this review will involve and express my appreciation to the members of the joint committee for agreeing to undertake this important work. I would also like to say that I am pleased that the review involves representatives of the three bodies and assume that this means it also includes representatives from the community not directly affiliated with these groups. I make this assumption because I believe that the leaders in this area recognise the importance of lay or community involvement in the domain of the ethical review of research involving humans.

In this document I use the word "committee" as a generic term to refer to those committees that engage in the ethical review of research applications. I use "ethics officer" also as a generic term for the administrative personnel who support the work of ethics committees.

- **Length of the document.** The *Statement* should continue to be short and succinct. I think this is one of the strengths of the current document.
- **Manual or Handbook.** The succinct *Statement* could then be supplemented by more detailed information in a manual or revised handbook that might include a set of "best practice" papers written by experts for

various kinds of research and research related to particular populations. The British *Manual for Research Ethics Committees* (Eckstein, 2003) provides one of the better examples of this kind of resource. In fact, it might be one of the resources cited in the new *Statement*. Unfortunately, this book is outrageously expensive. Anything produced to support the new *Statement* needs to be affordable and accessible.

- **Availability.** The *Statement* should not only be easily accessible on the web, but hardcopies of the *Statement* and any accompanying material should be readily available and inexpensive. There should be an expectation that all members of ethics committees will have a copy and that all researchers, including students, and members of the community (potential participants in research) should be able to obtain an inexpensive copy for personal use. As NHMRC is well aware, many committee members until recently had not read the *Statement* or even knew it existed.
- **Overall tone.** One of the greatest criticisms of the *Statement* and other such documents in my data and in the literature is the overall tone of the writing, which is oriented primarily towards medical (clinical or health) research. There are obvious historical reasons for this, but now that the *Statement* is suppose to apply to “all” research, the language and emphasis in the document needs to reflect the greater range of research for which the *Statement* applies. Dot point items under a particular item should move from the general to the more specific. The *Statement* and any supporting material should make it clear that the “clinical trial” is the “gold standard” only for certain kinds of research and it is inappropriate to use it as a standard to guide the review of research based on different paradigms or have other objectives. Even in health related research, the clinical trial is not always the standard that should apply. The overall tone should include an emphasis on the need for all research with all populations to be culturally sensitive and competent, with particular attention to such issues when culture and ethnicity are a focus or key variables of the research.
- **Definitions.** One of the current strengths of the *Statement* is that it recognises the difficulties with definitions of terms such as research, particularly what constitutes research involving humans. This message needs to continue to be part of the *Statement*. Many of the difficulties encountered by researchers using alternative paradigms in the US are related to the US definition of research (i.e., the idea of “generalisable knowledge”). However, this more enlightened aspect of the current *Statement* does not help if committee members, in particular, have not read the *Statement*. On the other hand, there is a need for additional information that will help people, in particular committee members, identify what kinds of projects do require their review. I appreciate that material in the current *Statement* and the document on quality assurance projects are attempts towards this end (National Health and Medical Research Council, 2003), but this still seems to be an area of some difficulty, particularly for some people associated with the committees. Some of this information might be more appropriately placed in a manual or handbook with reference to the manual or handbook in the *Statement*.
- **Potentially vulnerable populations.** Expand the material on potentially vulnerable populations in two ways. First that these groups are “potentially” vulnerable in various ways, but not necessarily powerless, particularly in relation to some forms of research (e.g., ethnography where it may be the researcher who is in the potentially vulnerable position). Second, include a broader range of groups that are potentially vulnerable, including groups such as refugees and former refugees and people from potentially vulnerable cultural or ethnic groups. Information on best practice research with these groups — and cross-cultural research in general, should be included in supporting documentation. It might be more useful to not separate out particular groups for special attention in the *National Statement*; many of the core issues are the same for groups like children, women, prisoners, unconscious people, people with intellectual disabilities or cognitive impairment, etc. However, it would be useful to include more specific information on each group or category and the issues of particular importance in relations to them in supporting material in a manual or handbook or other supplemental documentation.
- **Purpose and what the committee should review.** My research suggests that some committees, committee members and other gatekeepers, including some I know have read the *National Statement*, are not really clear about the purpose and role of the committee and the review process,. Everyone can provide an answer that goes something like: “protection of research participants and compliance with regulations or guidelines.” How such statements get articulated in practice is one of the more interesting areas of my research. My research raises a number of questions that committees are struggling to answer that might be addressed in the new *Statement*.

Should committees be dealing with privacy, legal, and occupation health and safety issues? Do they have the right or responsibility to tell a researcher that he or she cannot do a particular kind of research with a particular population in a particular place because it might be dangerous? Should the committee review involve a review of methodology or not? If it should, then should all projects be reviewed in relation to their methodology? If not, when should methodology be considered? Should the committee require changes in protocols when they may not have the methodological expertise to do so or such a directive results in a project that at best is useless and at worst unethical? Should committee members decide if the research is worthwhile or not? On what basis should a committee decide? Do they have the expertise to make such decisions? When do committee decisions result in an infringement on academic freedom and how can this be avoided? Some committees have made informed decisions in these areas; others use broad umbrella statements, including statements from the National Statement, to suggest that a project one or more members does not like for personal reasons is unethical and should not be approved.

Issues related to the purpose of review are seemingly simply, yet complex in practice. Ethics are personal and cultural. There are limits to the guidance that can be offered in this area, but some additional guidance seems necessary for researchers, committee members and others who might be approached to provide information for a study, such as health professionals. As I note in one of my publications, the lack of guidance in this important area can result in committees taking on things that do not belong in the ethics committee's "basket" (Fitzgerald, 2004, see attached). In addition, some people in the health care community will not provide any information or support without the inquirer having first obtained ethics approval, even for information that has no direct link to any individual and may be of a more general nature. A lack of general guidance in this area is important because ethics committees often make up the rules as they go along. As they do they too often develop standards that are applied to all research in a blanket manner without necessarily considering how those standards apply to the case being considered. I can provide multiple examples of this from my research. This is the source of many problems related to the ethical review process. What might be appropriate for medical research, a drug trial, can be totally inappropriate for another kind of research in another population using a totally different paradigm. Ethics committees need guidance, education and need to have the necessary expertise to make reasonable, rational and ethically sound decisions. They need such information to lighten their workload.

Another result is that there is a kind of moral panic or confusion about ethical review being generated that is having an impact not only on the research process (sometimes unnecessarily increasing levels of anxiety, particularly among health professionals), but on relations between professional colleagues. This is again related to the idea that any kind of information collection exercise must have ethical approval, including quite innocuous student research. (See also student research and the rhetoric of ethics.)

One of the areas that epitomize the issues above is the consent process. Many committees can now deal with the idea of verbal consent, but still often within very narrow parameters. Many have "standard statements" for information sheets that are often inappropriate for some research. And some spend inordinate amounts of time on information sheets, mainly dealing with wording, punctuation, and grammar. Greater explication of consent and the consent process that takes into consideration: the population involved, the methodology, and the potential sensitivity of the research topic and data is needed. If editorial assistance is required, then this should be accomplished in other ways, not during committee meetings. Things like the consent process cannot be universally based on what is appropriate for medical research or research with literate, educated, Western populations. The literature on consent and all the problems involved is one of the largest bodies of literature available in relation to research ethics and the ethical review process — and this is just in the medical literature. The literature from other disciplines is equally rich, if not quite so abundant. (See also the point on workload.)

Today ethics committees have tremendous power! They have become the final arbitrators of whether or not a research project can be conducted and the manner in which it will be conducted. It does not matter how many reviews a project has undergone, how expert the researchers, or how much support it has from the population to be involved. This is too much power in the hands of a few. In relation to multisite research this power gets compounded. Thus it is imperative that it be clear just what are the parameters of their power and responsibility. (See also the point on appeals.)

The purpose of the review and the extent of the power of ethics committees need to be clear if we are to move from an adversarial situation to one of facilitation, a position long supported by NHMRC. Currently many researchers still see ethics committees as adversaries. As a result, some researchers are choosing to not engage in research, a tragedy when this involves bright young people who could make major contributions to society and our bodies of knowledge and understanding through their research, or to engage in “safe” research, such as library or secondary data based research. (See also monitoring)

- **“Historical context.”** There seems to be a cultural expectation that an obligatory history should be provided in documents like the *Statement*. Thus, the historical information in the *Statement* addresses this expectation, but I think it is important for people to also realise that much of what is involved in the ethical review of research is more often a product of contemporary issues and concerns, the moral dilemmas of contemporary societies, mainly Western societies. It might be useful to provide greater explication of the kinds of things that influence ethical review and decision-making processes, including cultural, sociopolitical, economic, educational and personal influences and the need for members (and applicants) to be aware of these influences on their decision-making
- **Composition of committees.**
 - **Lay or community members.** My data suggest that there is general agreement that committees should be made up of a balance of lay or community members and researchers and other specialists. Many are already attempting to achieve such a balance. My data also suggest that these lay or community members are often people with prior research experience or affiliation with the institution involved. Thus they are not always strictly independent lay or community members. This is just a statement and not a suggestion about the characteristics of such members. At this point I have no specific suggestion in relation to these members, although it is clear that lay members, like all members of the committees, need some relevant background to function well on a committee and that all members of the committee require some preparation to become effective members of committees (see education and training of committee members). A number of people advocate the inclusion of one or more people who have been “subjects” in research projects. There is, however, no general agreement on this point. The idea of someone who could represent the interests of “subjects” on committees that review primarily medical research seems worthy of some consideration, but at this point only as a suggestion rather than a requirement.
 - **Lawyers.** Lawyers often make good committee members, but my research suggests that the requirement for a lawyer on the committee presents some concerns and confusion. First, some of these lawyers seem to take on or be asked to make legal judgements during the review of applications. Second, a strong lawyer on a committee can turn the focus of the review from ethical issues towards legal issues. In addition, some lawyers are not sure what their role is on the committee. Thus, although committees should continue to recruit lawyers to committees, it may be appropriate that they sit as either lay members or specialist members depending on the nature of the applications the committee reviews. As I have suggested in one of my publications (see attached), it might be better if there are potential legal issues that the institution, not the ethics committee, addresses these. I understand that a move towards removing lawyers as required members of committees is happening in the UK.
 - **Member with knowledge of, and current experience in, the professional care, counselling or treatment of people.** This change in the last *Statement* was appropriate as people other than doctors are often more appropriate on committees not involved in medical research. However, these people need to be aware of how the concerns they are meant to consider are related to and are addressed in various kinds of research, particularly “qualitative,” international, rural/remote, and cross-cultural research. The standards and expectations vary across contexts. What might be appropriate in an urban centre in Australia may be quite inappropriate in other contexts. What is appropriate for medical or psychology research may be inappropriate for other kinds of research, particularly that based on long-term relationships. The background of the researchers can also be an important consideration, thus, for example, interview research by health professionals might not require referral to other parties and such referrals may be inappropriate for some issues for cultural, psychological, and safety reasons.
 - **Minister or person who performs a similar function in a community.** I am still trying to figure out why this person is required on a committee and some committee members, including some of the people on committees under this category, are also generally unclear about why they are there. If

anything, it seems to be an artefact of a cultural past of Australian society when, in terms of religion, it was viewed as predominately Christian. Again, as with lawyers, some of the people in this role are exceptional committee members, but their effectiveness seems to have little to do with this aspect of their identity. I can see why an Aboriginal elder should be on a committee that reviews many applications associated with work in Aboriginal communities or with Aboriginal people. Cultural experts should most certainly be encouraged for committees dealing with culturally unique populations. In fact, this point suggests that the makeup of the committee should reflect the required expertise required for appropriate review of applications common for that committee. This point is covered already in the *Statement* under point 2.6(c). This point could be expanded to include other domains.

- There needs to be more explicit statements that encourage committees to consider issues related to membership of committees so that the membership better addresses the range of topics, methodologies and populations involved. This might also include explicit statements that institutions might have more than one committee to address the institution's, its researchers' and the community's needs (see also structure) and a reminder that the committee can use the services of outside experts.
- **Appointment of members.** At this point the process for appointing members of the committees varies across institutions and the process is often unclear. Committees are increasingly advertising for members and then using a selection process that may involve interviews with potential candidates. At the very least, the process of appointing members needs to be more transparent and open.
- **Administrative support for committees.** The ethics officers (by whatever name) are critical and essential to the work of the committees and the quality of the review process and experience for all involved. They are often the "face" of the committee. In my research there is an almost universal identification of the importance of these people and the fact that resources available are insufficient for adequate administrative support. The *Statement* already refers to the need for adequate support but, at the very least, this statement must be stronger. Money is not going to resolve all the problems. In some cases things like a restructuring of the review process, including greater use of simple, expedited review processes can address some of the workload and resource issues.
- **Qualifications of members and administrative personnel.** In addition to identifying the kind of expertise required for membership on a committee or as a support person for a committee, there needs to be some consideration of necessary qualifications. Thus, either within the *Statement* or in the supporting documentation, there needs to be greater explication or identification of the qualifications for: ethics committee members, particularly Chairs, and ethics officers. Some participants in my research have suggested that more experienced, rather than new, researchers should be members of committees. Others suggest that there needs to be a range of research experience and knowledge. There should also be some consideration of the possibility of developing an expectation of the level of training for particular positions, such as ethics officers. This might include the expectation of them having a research background and qualifying degree and/or certification. Several institutions are already moving in this direction.
- **Education and training of members.** At this time many people join committees with no preparation relevant to research ethics or the ethical review requirements or processes. Until very recently many were not even aware that there was a *National Statement*. There needs to be greater emphasis on the education and training of committee members prior to being appointed to a committee and regular training throughout their tenure. This might include nationally recognised training programs and formal and independent learning programs. This will require the allocation of resources at the national and local level to support such efforts.
- **Compensation of members.** This is a topic that regularly comes up in my research. All committees recognise that committee members put in considerable effort to carry out their responsibilities. Each year the workload is increasing dramatically. More and more institutions are compensating lay/community members in one or more ways (e.g., pay expenses, sitting fees, pay for related educational and conference fees). Some institutions compensate Chairs, and on rare occasions institutional members, with funding for attendance at conferences and educational forums and less often teaching release or some adjustment to other work responsibilities. Discussion around compensating members are ethical and legal discussions related to such things as ideas about conflict of interest and the idea that membership should be voluntary and yet so much is being asked of these people. One result of the voluntary nature of committee

membership, according to some who have participated in my research, is that it skews membership towards retired people, particularly for lay/community positions. Institutional membership may also be skewed towards those who have the time or (more often) are committed to research ethics and the ethical review process. Although committed members are important to the process, there are many who would like to contribute but simply cannot add to already heavy workloads. Thus there might be some consideration of including some suggestions on how committee members might reasonably be recognised for their work. This might include a suggestion/support for teaching or other work release for institutional members, identifying committee work as service to the community and institution, and other kinds of compensation, including established sitting fees for non-institutional expert members.

- **Types of committees.** This point covers two issues: 1) committees to deal with multisite research and 2) specialist committees.
- **Multisite research.** This is an issue I know members of the joint committee are already familiar with. It has been a topic of concern for some time and has been raised in earlier reviews. The issue is how to best address this issue. The use of regional committees for multisite research has been used with some success in places like New Zealand. Another option is for there to be reciprocity across committees, with one committee being identified as the primary committee. Both options are contentious, mostly because local committees do not want to give up their power and control over the research in their area, although this is generally expressed as a need to address local issues, often using a cultural rhetoric. Based on my work to date, I am more inclined towards a regional committee approach for multisite research, supported by ideas about reciprocity. My one concern here is that because most multisite research is medical, other kinds of research might again be confronted by problems that currently exist when a committee with a medical focus reviews these other applications. There is a potential solution to this problem that is similar to the one proposed in the next section: different kinds of regional committees.
- **Specialist committees.** This point is again related to several issues. The most common is associated with medical (clinical, health) vs other kinds of research. Many institutions in Australia already have specialist committees in place. Most commonly these are a “medical” committee and a “social and behavioural science” committee. Although not without their own set of problems, this separation seems to work reasonably well in those institutions that have made this adjustment. This approach is already allowed within the *Statement*, but some committees/institutions use a very narrow reading of the *Statement* and claim that this cannot be done. In my research I have identified at least five structures for committees, all of which would be in line with the *Statement* (some seem more functional than others). Thus I think the *Statement* needs to make it clear that the guidelines do allow different organisational structures so that the needs of the researchers, the institutions and the community can be met in a way that allows the best review of applications.

There is a second related issue. This is related to research in specialist research or population areas, often areas where a particular committee or institution would not have the required expertise. The *Statement* allows the use of outside expertise, although only a small number of committees seem to use this option. (I am not sure some committees even know they can use outside experts). Committees should receive greater encouragement to seek outside advice, but this does have resource and other implications. On the other hand, there are a number of research areas that might be well served by specialist committees, a model for which already exists within medicine and in Australia (e.g., the Cancer Council, Veterans’ Affairs). This could include committees to review research with special (often potentially vulnerable) populations: people living with HIV/AIDS, refugees, cross-cultural research or research with specific cultural or ethnic populations, research related to death and dying, such as research with people living in a hospice. Potentially such specialist committees could address issues related to multisite research because much of this research crosses sites. Obviously, even if this approach is adopted, people will have to still go through local gatekeepers, but this does not necessarily have to be an ethics committee. Currently many people use local ethics committees as local gatekeepers (or assume they must be used for this purpose), when this role might be more appropriately assigned to others in the institution.
- There is one more option to deal with some of these issues: private committees. People I have talked to in my research are not generally inclined towards this kind of an approach.

- **Structure.** This point reiterates that the *Statement* is not prescriptive in relation to how the ethical review process is structured within a particular institution. I think the *Statement* should continue its non-prescriptive stance in this and other areas. As already noted, I have identified several structures already in place. Some structures are more effective than others, but no one structure would be appropriate for every institution. One particularly useful structure for educational institutions, like universities, is a general committee, primarily for policy development, oversight, and difficult applications, supported by subcommittees (e.g., medical, social science/behavioural science or departmental or Faculty committees). There are various models that could be presented as possible structures.
- **Openness and transparency.** My research supports the need for openness and transparency of the ethical review and decision-making process and highlights the benefits of this openness. There is a growing body of literature on this point and I have presented information relevant to it in a recent publication (Fitzgerald & Yule, 2004, see attached). Greater openness and transparency might include greater encouragement for open meetings, possibly including the opportunity for students and researchers to observe in the name of transparency and as part of a comprehensive educational process. Greater openness should make the ethical review process more effective and help it better achieve its aim of encouraging more ethically responsible research. If the process is to move towards a more open and transparent model, there should be information in the *Statement* that makes it clear this is allowed and appropriate. The current wording is ambiguous at best. As noted in one of the attached papers, rhetoric about “confidentiality” is often used to keep meetings and their processes closed or secret. As noted in the paper, this issue can easily be addressed by providing researchers with the option of closed or open review.
- **Communication.** Enhanced communication has become a standard for every set of recommendations. Here I would like to highlight specifically the need for clearer, more transparent, more open communication between ethics committees and researchers. Encouraging more open committees will help in this. Communications from ethics committees need to provide some foundation or context for their requests or comments. References to the *National Statement* can be helpful, but often the issue is not directly related to something that is in the *Statement*. Good communication from the committee is often difficult in a written form when that communication is just one of many the ethics officer and/or the Chair must produce after every meeting. Many problems are or could have been addressed with little angst with a more open system that includes the possibility of members of committees and researchers talking to one another. Often a problem that would take months of written communications to solve can be solved in just a few minutes if people talk to one another. The emphasis on email and paper trails does an injustice to the kind of communication that is often required. Give committees permission (and encouragement) to talk to people. Encourage researchers to seek advice if they are not sure about something or think something might present a problem. Give them resources (a manual, reading lists, etc) that are readily accessible and easy to use. (I am constantly amazed at how unfamiliar researchers and ethics committee members are of the resources available to them — including the *National Statement* and the *Handbook*. Many of the issues raised by committees during their deliberations and discussed at length are addressed in the literature. Then again, many of the members have had little or no preparation to be members of committees. They learn to be members by being one. As a result, they keep reinventing the wheel.)
- **Expedited review.** The *Statement* already allows for expedited review, but many institutions do not use this option, although there seems to be an increase in this area. Considering the workload of the committees and that much of the research that is the most contentious and gets bogged down in the review process is associated with low risk research, there should be greater encouragement for the use of this approach. This has to be done by clearly defining what expedited review means. In my research the term is used in two ways: 1) simply “fast-tracking” the standard review process and 2) having a different and abbreviated process. The latter is more consistent with the way the term is used elsewhere. Encouraging the greater use of expedited review needs to be accompanied by clearer ideas about what it means, what is appropriate for expedited review, and how this can be done in a way that decreases both the workload of researchers and reviewers and the time involved for review. Another contentious issue in this area is who decides what can be reviewed under an expedited review process. Some opt for the “put in the full application and the committee decides — absolutely do not let the researcher decide,” which is no more efficient or less problematic than the full review process. Others suggest that there should be clear statements about what fits within this category and that questions about whether or not a project meets the criteria can be addressed to someone associated with the ethics committee (chair, ethics officers, or a

member of the committee) before a full application is prepared. If the guidelines are clear, for example with clear definitions about what constitutes low risk research as are available in the US, then there should be few problems. In this case the onus of responsibility is on the researcher, which is consistent with the current *Statement*.

- **Workload.** The workload of committees is incredible! It increases every year and is likely to continue to increase. Committee members report to me that the workload associated with ethics committees is far greater than with any other committee they have been on. The workload for chairs and ethics officers is even greater. Two things need to be addressed: the provision of appropriate resources to support committees and streamlining processes and structures. Good guidance in the new *Statement* may be helpful. Things like expedited review and delegating student education research activities to other groups could be useful. Some administrative structures are more effective and efficient than others. As noted above, there also need to be clear guidelines about what kinds of projects need review by the ethics committee. Members of committees need to be supported in a number of ways, including providing time to engage in the work of the committee unencumbered by other responsibilities. This issue has to be addressed because it affects the quality of the ethical review. Meetings that regularly last 5-7 hours cannot be effective.
- **Research as part of the educational process.** Much of the research reviewed by committees associated with educational institutions relates to student research and research as part of the educational process. Much of this research is low risk and its primary purpose is the education and training of students in research or as a teaching strategy. As much of this research is low risk, educational in purpose, and often the focus develops or emerges over the course of the teaching unit, there should be different mechanisms for the review of such work, if required. In some places responsibility for such research and review, when necessary, has been placed within departments or the educational domain (e.g., teaching and learning committees). A different, less onerous and time consuming process for the review or responsibility for the conduct of such research will serve the needs of students, educators and committees. Moving responsibility for such work away from the ethics review committee would in many cases substantially decrease the workload of ethics committees. A second option, but one that would not significantly decrease workload, is to encourage expedited review of such projects. It should be clear in any recommendation in this regard that the person with the greatest responsibility is the supervisor for such work. This is consistent with statements in the current version of the *Statement*.
- **Turn around time.** One of the greatest complaints of researchers is the length of time it takes to get through the review process. It is common in Australia for the process to take from 2 months to 1 year. One result is that some research does not get done. Sometimes researchers' funding and students' candidatures run out. Mechanisms need to be put in place to shorten the turn around time for review. Suggestions throughout this submission may help in this regard.
- **Timing of review.** The ethical review process currently takes place at a particular point in the research process, a point in the process most relevant to certain kinds of research, including medical research. For such projects this is appropriate, as this kind of research should not be conducted without a clear plan of action. However, other kinds of research have different kinds of ethical issues, these may occur at different points in the research process, and many cannot be foreseen until the researcher is "in the field." Some kinds of research begin with a broad question and the specific question and the specific data collection methods emerge out of the research process. There is often no opportunity to turn to an ethics committee that may be thousands of miles away to obtain approval for a change in protocol. For such research it is important to know that the researcher is aware of such things and is well grounded in knowledge about the ethical issues related to his or her field of practice. Thus the current ethical review process is out of sync with this kind of research and artificially imposes a structure, often an inappropriate structure, on the research. The new *Statement* needs to help committees deal with the ethical concerns of such research in a meaningful and useful way. In many cases this kind of research involves no risk greater than everyday risk and could potentially be addressed through expedited review, if review is required.

The time of review also presents problems for certain kinds of research, in particular community collaborative, participatory or action research. In this case there is a "Catch 22" situation. Researchers are told to not begin research until they have approval, but much preliminary research has to be done as part of the developmental process. Then the project may move in various directions as the research is

conducted. Some committees suggest putting in a series of applications, but this often does not resolve problems, particularly given the time required for review. The greater problem with this approach is that a complex project can appear to be fragmented when it is presented as a series of decontextualised studies when they need to be seen as parts of a complex whole. This sense of fragmentation can then result in a form of decontextualisation that encourages some committee members to view a project as “unethical” in some way. With the current emphasis on multi-methodology and cross-disciplinary research, this is an area that is likely to become increasingly problematic for many committee members, particularly as the various components cannot be treated as though they are a series of separate studies.

Thus, the current model for review is not always appropriate for many types of research. As many of these projects are low risk, some could be addressed by expedited review. Other, more sensitive research, may require other approaches. Thus flexibility in structure and process might encourage the development of models of review or oversight that are more appropriate for various kinds of research.

- **Referencing Codes of Practice.** References to professional codes of practice can be useful in relation to reviewing alternative forms of research. Students and graduates of most professions and disciplines are guided in all their work, including research, by professional codes of practice. Thus it might be useful to expand the early mention of codes of practice in the *Statement* to reinforce the fact that researchers are not only guided by the *National Statement* and those of any other countries involved, but they are also expected to conform to their professional code of practice. Furthermore, a committee’s response that the researcher is expected to conduct research conforming to their code of practice might help committees deal with some of the applications that do not fit the research model inherent to the current review process. This approach fits with the emphasis on researcher integrity that is in the current *Statement*.
- **Appeals process.** Researchers report difficulties when they have problems with a committee. Many will not take appeals to a committee for fear of long-term repercussions when they submit later applications. Based on my research I can report this is not an unfounded fear in some cases. In institutions with open and accessible committees this issue seems to be less of a problem. Nevertheless, there needs to be a re-examination of the appeals process (or a secondary review process), possibly including a process at the regional or national level, one that does not have the local ethics committee as the primary site for appeal.
- **Education and training.** Education and training of researchers, students, and committee members is regularly raised in my research. Education and training have to become a priority and the new *Statement* and any accompanying materials, like a manual, can help. There is clearly a need for greater support for research ethics education and debate, not only by ethics committees and NHMRC/ARC, but in teaching and learning contexts and university or institution-wide or cross-institutional programs. I would like to suggest the possibility of considering the institution of competitive teaching grants to facilitate the development and presentation of educational programs at the local, state and national level. Such programs should be directed towards research ethics (broadly defined) and the issues and concerns in contemporary research in many fields and not how to fill out forms properly. Many of the people involved in my research see education and support as the defining quality of an ethics committee and the review process; others see it as all about monitoring and control. A stronger emphasis on education and support as a purpose of the whole process might help deal with many issues related to the review process and, once again, move it away from being seen as adversarial or simply a hoop researchers have to jump through.
- **Monitoring.** The monitoring of research is often mentioned in my research. In some cases it is not clear just what people mean by this and most suggest that they do not have the resources to engage in any kind of monitoring. Some are not sure monitoring should be the responsibility of ethics committees. There is within this kind of talk two implied assumptions: 1) that researchers do not follow their protocols (are untrustworthy) and 2) that there must be some easy way to monitor the conduct of research, in particular the consent process. The latter is based on concepts best related to medical research. Various suggestions have been offered for such monitoring programs beyond the now common regular report by researchers to the committee. These include “following paper trails” and including in the research and consent process the option for the committee to contact “subjects” in the future to investigate the conduct of the research. Although these are possible in relation to some kinds of research, in particular medical research, they are problematic ethically and nearly impossible in relation to many kinds of research. Two good examples are in relation to ethnographic research and potentially vulnerable populations, where often even the consent process places people at risk. The first assumption may have some basis. There are unethical

researchers, but I do not believe they are the majority and there is no evidence to suggest they are. Sometimes ethics committees make requirements that simply cannot be followed in the field, and in some kinds of research the project emerges during the research process and thus any protocol developed before entering the field is “best guess.” For these kinds of projects the ethical issues are different when compared to medical research and at best the ethical review process can only deal with core principles. Thus the monitoring issue is going to arise in this review, but I ask that the joint committee be cautious in putting forward anything specific in relation to monitoring research. Any model for monitoring must take into consideration the potential logistical and ethical problems in relation to particular kinds of research.

- **Application forms.** This is again a contentious issue. Few committees really want to give up their form for a national form over which they have little control. Every committee I have talked to thinks their form is the best. Furthermore, I do not think the “perfect” form is within the realm of possibility. I think complaints about “forms” have become a way for people to express frustrations with the process when they do not really know what the problem is or do not know how to articulate it. Nevertheless, there is a need for some consistency in the forms, particularly for multisite research. Despite the opposition to a national form, I would encourage its continued development. It will have to be a flexible form, however. Given the current state of computer technology this is not beyond the possible. Thus if a particular section of a form is not required for a project, the computer program will drop out any subsequent questions. This will allow researchers to feel more comfortable with the form when they do not have to fill in questions that are totally irrelevant to their work or are worded in ways that are difficult to answer. As they become accustomed to one format they can better anticipate the questions to be addressed when they are developing their original research protocols (it might more consistently become part of the mindset when developing a proposal). Thus the form has to be constructed, in format and language, with a wide range of research paradigms in mind. The medical orientation of many forms is a problem for many researchers for at least two reasons. First, many of the questions are irrelevant or inappropriate for some research. Second, the medical orientation to the form gives these researchers a message that either their work is not considered as important as medical research or that they will be judged using a medical research paradigm, which may or may not be the case. Thus the form is a source of irritation, particularly for many non-medical researchers. One of the benefits of a national, computerized form is the potential for better record keeping, tracking of the status of applications, and more consistency in administrative activities. Some institutions already have good tracking procedures in place, but many do not. The lack of a good tracking system can result in problems, including delays in the review process.
- **Qualitative/alternative paradigm research and cross-cultural research.** These are areas the panel knows are particularly contentious. Many of the issues that come up in my research, the literature, and in the comments above apply to all kinds of research: medical/clinical, social and behavioural science, humanities, etc. More and more often health related research draws its methods from a broad range of research paradigms. Some research crosses disciplinary boundaries and some involve multiple methodologies. Some are relevant to some populations, but not to others. Committees are now confronted with the need to review research in areas and for communities with which they have no familiarity. Even the best behavioural/social science committee is not likely to possess the expertise to review existing paradigms and fields of study, let alone some of the emerging areas of research or the new paradigms and methods. The field is too big for any one person to possess all the necessary knowledge. Few committees as a group possess the methodological or cultural knowledge to judge the ethical issues related to research with particular groups in Australia, let alone in parts of the world they have never even heard of or have only heard about by watching television. Some argue that the principles are the same no matter what the topic, the paradigm, methodology, or population. Others say they cannot be the same. They may be similar, but not the same. At every stage in the review process and the development of the new *Statement*, the panel needs to consider each point in relation to a broad range of questions. For example, how does this fit in relation to genetic research, ethnographic research, potentially vulnerable populations (I intentionally use potentially here, because we cannot make assumptions about vulnerability), etc. Some of the points raised earlier will help address some of the issues raised in this point, but some may compound the error. This is why I think each point in the new *Statement* must be subjected to the “what about ...” question. A broadly applicable *Statement* needs broad thinking.
- **International research.** Increasingly medical research is becoming international research. The work of people like anthropologists has long been international and cross-cultural. Much can be learned from the writings on ethics by anthropologists and others who commonly worked in other countries and cultures. (I

would be happy to provide a relevant reference list.) The *Statement* needs to deal with this kind of research, without being too prescriptive. As much of the literature on cross-cultural and international research demonstrates, a too prescriptive approach creates, rather than avoids, ethical dilemmas. My early comment on the need for cultural sensitivity and competency in all research is a move towards the development of research that is always conscious of ethical issues within a cultural context, whether that research is conducted locally or overseas. There is also a need to be sure that committees have or have access to the necessary expertise to evaluate the potential ethical issues in such research. Some committees deal with this by consulting outside experts or include people with the appropriate expertise on their committee, but too many others seem to approach such applications as though there is and must be a universal ethical standard. The literature in this area is mixed. Some believe that ethics are universal, but many believe that there can be no universal standard, that even the principalism that guides the ethical review of research in places like Australia is culturally biased. The debate in this area needs to be acknowledged in the *Statement*.

- **A rhetoric of ethics.** Although this is not something that can necessarily be addressed in the new *Statement*, it is part of the context in which the *Statement* will be applied. On the other hand, clear statements in the *Statement* might help address the issue. Today most people, particularly in health contexts, are aware of ethical issues and the need for ethics review. Particularly in these contexts people are beginning to use a rhetoric of ethics as a way to control the kind of research and quality assurance projects that are done. They are using successful ethical review as a key to the gate. Here is another “Catch 22.” Some groups and individuals will not provide support for the research until you have ethical approval, but you cannot obtain ethical approval without evidence of their support.

In other situations it is simply a lack of understanding of the ethical review process and its purpose that is involved. This is too often an issue of a little knowledge can be a “dangerous” thing. A little knowledge results in unnecessary delays and application procedures, which is particularly problematic in relation to very low risk research or information collection exercises or quality assurance exercises. There are cases in my data where gatekeepers in potential research settings use a little knowledge about research and then a rhetoric of ethics to criticise or block research, including, sometimes, research that has ethical approval. Inherent in this is also fear. Fear that if an ethical or difficult situation might arise that they will have to bear responsibility for it. There is within this not only a moral panic, but a fear, not so much of litigation, but some kind of institutional repercussions.

All this suggests that in some contexts the awareness of ethical issues has been raised, but a solid understanding of research ethics, particularly those related to alternative paradigms, is not there. Thus, this once again raises the issue of a broad based educational program on research ethics that not only addresses the information needs of committee members and researchers, but the more general community as well.

Recommendations

- ◆ Maintain the short, succinct, generally non-prescriptive form for the *Statement* and supplement it with a manual or handbook or set of “best practice” position papers.
- ◆ Widely distribute and market the *Statement* and make it readily accessible and inexpensive.
- ◆ Modify the language of the document to be more inclusive and not so medically oriented.
- ◆ Include in the special populations categories groups like refugees and potentially vulnerable ethnic or cultural populations. Include in supporting documentation information on best practice in culture-based, cross-cultural, and refugee-oriented research. Encourage a culturally sensitive and competent approach to all research.
- ◆ Further delineate the role and responsibilities of ethics committees and the review process.
- ◆ Give clearer recommendations on what kinds of research the committees need to review.
- ◆ Provide a slightly expanded introduction on the historical and contemporary context in which ethical review occurs.

- ◆ Encourage an equal balance between lay/committee members and specialists in relation to committee membership.
- ◆ Reassess the required makeup of committees to present the inclusion of people like lawyers or ministers as suggestions, not requirements.
- ◆ Make it clearer that institutions have some flexibility in how they structure the review process.
- ◆ Reinforce the need to proper resource committees and offer appropriate support and recognition for committee members.
- ◆ Move towards requiring education and training for members and ethics officers that includes a preparation program for new members.
- ◆ Provide statements that permit the development of ethical review structures that address the needs of particular institutions, researchers and communities.
- ◆ Provide recommendations that would allow more options for the review and oversight of research activities with primarily a student educational agenda (delegate responsibility to departments or expedited review for low risk projects).
- ◆ Consider the development of regional and/or specialist committees for multisite and/or particular kinds of research.
- ◆ Make the statement on seeking outside advice (para 2.19) stronger.
- ◆ Encourage openness and transparency of the ethical review and decision-making process.
- ◆ Encourage greater use of expedited review and provide clear guidelines on the kinds of projects for which expedited review might be appropriate.
- ◆ Encourage mechanisms that will allow shorter “turn around” times for review.
- ◆ Consider whether the current model for review (pre-research review) is the most appropriate or if there should be more than one model.
- ◆ Continue to emphasise primacy of integrity among researchers and encourage committees to recognise that professional codes of practice already include an emphasis on research ethics, that this is not the sole responsibility of the committee.
- ◆ Consider the development of a more open appeals process.
- ◆ Encourage and promote a wide range of educational endeavours directed towards committee members, researchers, students, and the community. Encourage a “life long” learning ethos.
- ◆ Consider the possibility of developing a funding program to support local and national ethics education programs.
- ◆ Move cautiously in the development of monitory programs. Is this the role of the ethics committee? Where monitoring programs are deemed appropriate or particularly important, namely in clinical trials, provide reasonable guidelines.
- ◆ Develop a statement and supporting documentation that deals with the many contentious issues related to alternative paradigm, including qualitative, research, not as problems but important considerations. Avoid being prescriptive, as there is so much variation within this domain.
- ◆ Address the issues related to international and cross-cultural research with an informed perspective that acknowledges the debate about the universal nature of research ethics.
- ◆ Continue to work towards a national form that allows better and more consistent application preparation processes, tracking and administrative activities.
- ◆ As the new document is develop keep in mind the resource and workload implications of each point.
- ◆ In the process of writing the new statement subject each point to the “what about” question.

Thank you for allowing me to make this submission. I realise that it seems overlong, but it only begins to address some of the issues that have come up in my research that are related to the kind of guidance required in a *National Statement*. I hope some of my comments will prove useful. Again, please do not hesitate to contact me if I can offer any further assistance.

In the end, there will never be a document that addresses all the issues and all the concerns. I am hopeful, however, that the next *Statement* will address some of the more contentious issues. In the end, we can only raise people's consciousness about what constitutes good, ethical research and encourage them to think critically about what they do and its implications for others. If the only thing the new *Statement* does is enhance this consciousness in relation to the ethical review process so all aspects of it can become a more positive aspect of research then it will be a good thing.

Sincerely,

Maureen H. Fitzgerald, PhD

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