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Review of National Statement
NHMRC (MDP 24)
GPO Box 9848
Canberra ACT 2601

To the Committee:

I would like to commend the committee on the work they have done with the revision of the *National Statement*. This is a huge task. There are many added strengths in several sections and many changes are consistent with some of the suggestions in my July 2004 response to the committee (although I am sure I was not the only one who made them). The move away from a “medical tone” or emphasis is a very positive step.

I have again drawn on my research on *Research Ethics and the Ethical Review Process as Culture and Cultural Process* (ARC Discovery Grant DP0343014) in making my suggestions and comments. Details on the project are available on the Project website (www.ethicsproject.com).

I would also like to acknowledge the contribution of my Project Assistant, Paul Phillips, who commented on my draft and, where noted, added some comments. However, I take full responsibility for the comments and suggestions presented here.

I have copies of all the references cited here if you do not already have them. Please let me know if you want me to provide copies of any of this material.

Note: Material in **bold** is a suggested insert; a strikethrough suggests a deletion. The section of the draft statement referenced is in *italics* with my comments in regular font.

Comments

Research Governance — I think the point that this is part of a larger governance structure is important and needs to be highlighted to overcome issue related to “mission creep” and the “big basket” phenomena (Bruner, 2004; Fitzgerald, 2004; Gunsalus, 2003; Haggerty, 2004).

I wonder if more could be said about institutional responsibilities within the document? I appreciate the emphasis in the document that the committee is to focus on ethical issues and that the idea of institutional responsibilities is noted, but I am not sure that many members are clear about what falls within which domain. Obviously education and training, like that already being done by NHMRC, should help in this regard, but I think there are still problems to be addressed in this area not only because of what is happening in Australia, but what is also occurring in other countries. The idea of mission creep has been gaining increasing attention in the literature and in the talk of the people I interview in all the countries where my research has occurred. Some committees have really stepped outside the boundaries of their remit, but they are very good at using a “rhetoric of ethics” to justify what they are doing.

Page 3. Statement on research. The term “widely available” could be a problem when the research is being conducted primarily for educational purposes. One of the issues that does not seem to have been addressed in the document is research where the objective is research education or education and training in relation to research skills (e.g., interviewing skills for research and clinical applications) or the use of small research projects primarily as a teaching strategy. This is an area that requires some general guidance on whether or not such work requires ethics committee review. The level of variability across the country would suggest some guidance at the national level would be very helpful. If it does not get included in this document, might it be possible to develop a position paper like that developed for quality assurance projects (National Health and Medical Research Council, 2003)?

Would it be useful in this section to make reference to the document: *When does quality assurance in health care require independent ethical review?* (National Health and Medical Research Council, 2003)?

the invention and generation of new ideas, images, performances and artefacts including design, where one of the primary purposes is that these lead to new insights; and — The change here was suggested by my Project Assistant, because he felt that the original version required an *a priori* assumption about the outcome. He also asks if the concept of “new insights” is in reference to the researcher/s or the wider community? He noted that the rewording might also be relevant in relation to the issue of research type activities that are conducted primarily for educational purposes. Such work might not require review or might be better addressed with another process when the primary purpose is not to lead to new insights for the instructor or the broader community, but serve an educational purpose for students. There is an additional issue that Paul’s comments raise, that is what if an activity is undertaken and an unexpected consequence is that new insights are gained? How should such situations be addressed? Most committees will not do *post hoc* reviews.

Page 4. “HRECs need to be satisfied that the conduct foreshadowed in the research proposals they approve is lawful.” This statement addresses the point that it is not the responsibility of the HREC to make this determination, but I am not sure the statement is strong enough to make this point clear to those who will continue to feel that they must make the determination as they do not believe others are doing it or where they are not willing to accept the institution’s or the researchers’ assurance that they have addressed the legal issues.

*1.1.1 The essential value for researchers is integrity, which is expressed in a commitment to the search for knowledge **and understanding**,...* Again, my Project Assistant noted that knowledge and understanding are not the same thing and that the inclusion of the word understanding makes the statement more applicable to a wider range of paradigms.

1.1.5 Every research proposal should be based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of proposing to conduct novel research for which there is little or no literature available. — Not sure about the use of the word “thorough.” This is applicable to some kinds of research, but not others. For all research there needs to be an appropriate background section that utilises the appropriate literature, but a “thorough” review is more applicable to some kinds of research, like clinical research and drug trials, where there have been problems related to insufficient reviews of the literature (e.g., Savulescu, 2002). Thus there are projects where there may be a body of literature, but a thorough review is not applicable or cannot be done at this stage of the work because it is not possible yet to identify what is relevant (e.g., emergent paradigm research). The other problem, which may not be a problem if we go to a national form, is that many application forms do not provide sufficient space for any kind of in-depth review or presentation of an analysis of the relevant literature.

1.2.6 Evidence of consent. Change the word “must” to “should.” It is these “must” words that tend to create a narrowing of vision in some committee members. There are many instances, particularly in relation to ethnographic research and informal “everyday” talk that can be part of many kinds of research, where the standard consent procedure is not appropriate or feasible. See also the comment with *2.1.16* re “action consent.”

*1.2.8 A guiding aim for researchers should be to seek and obtain consent from participants in ways appropriate to their **age**, culture and the circumstances.* Again, this is an important statement, one that allows some flexibility in the consent process. Given its importance as a guiding principle, I wonder if it should be moved forward in this section.

1.2.9 Might it be useful to include ethnography with the examples?

Respect for human beings (p. 8) — Thank you for including the material in this section and others relevant to culture.

Methods commonly used in qualitative research — Oral History (p 12) — given the position taken in the US (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/exprev.htm>) (see also American Anthropological Association, 2003) and often followed in Canada, I wonder if there needs to be more information here, including perhaps the distinction between such things as life history, narrative and oral history. Oral history has a specific purpose and there are clear professional codes on how to do oral history research and deal with the resulting information. The issues in relation to oral history, particularly in regards to confidentiality and anonymity, are very different compared to other kinds of research that may use similar methods or data collection techniques. Another possibility is to simply leave out the material on oral history.

Institutions and Human Research Ethics Committee (HRECs) will need to determine the kinds of qualitative research activities that require review by an HREC (p. 13) — Bit unclear. Does this mean that there is now (or can be) an exempt category? This is a good idea. However, given my research I have

mixed feelings about leaving this item too open. It might be good to note some of the kinds of work that would not necessarily have to be reviewed. Some committees already have lists to guide researchers and committee members in helping them determine if review is required, although many committees are loath to allow researchers to make such determinations, even with good, clear guidelines. This generally means people still have to do basically the same amount of paperwork whether or not someone finally decides it does not require formal review. One result is the kind of frustration and sense of denigration identified by some researchers. It might also be useful to make a cross-reference to the section on minimal risk research.

2.1 • *Key informant interviews, which are conducted with individuals **or groups** with special expertise or knowledge about the issue being investigated.* Again, as my assistant points out, key informant interviews may also be group interviews without meeting the criteria or assumptions associated with focus groups. Such interviews are common in ethnographic and other community-based research.

2.1.4 *Some studies do not rely on any formal sampling strategies, for example ethnographic studies of communities **or groups**.* — Thank you, thank you, thank you! Unfortunately, the next couple of sections go back to statements on sampling that undo the good in this statement.

2.1.5 *The rigour of a qualitative study should not be judged on sample size ~~alone~~. The objectives and theoretical basis of the research should determine the size of the sample and the sampling strategy **when sampling is appropriate**.* — delete the word alone and add the material in bold.

2.1.6 **Again, when sampling is appropriate**, *research proposals should clearly describe the sampling strategy and state the criteria for selecting cases.*

2.1.8 *Research proposals should provide information about **the** systematic research design, with relevant data collection and analysis methods **outlined**.* — Move this to before sampling. This is the more important issue, not sampling.

2.1.11 *By its nature, qualitative research often requires deep enquiry into sensitive topics ~~which~~ **that may** result in emotional and other risks to both participant and researcher.* — The operative word here is **may**. This needs to be emphasised. My research suggests that there are problems in this area that include over assessment of the potential risks (developing elaborate, improbable worst cases scenarios) (see also Israel, 2004) and the fact that many participants in what committee members assume to be potentially sensitive research do not necessarily see participating in such research as a problem. Talking about things some consider sensitive can also be beneficial and does not necessarily require any further action on the part of the researchers, even if the interview was distressful (e.g., Scott, Valery, Boyle, & Bain, 2002). Sometimes life is tough — and sometimes it is good to talk about it to someone who actually wants to listen. In addition to interview data from key informants, I have documents from a community consultation on this issue from the UK, but do not yet have permission to share the documents with you. In that work people made some of the points I just made, that even when the research might cause a bit of distress that is not a reason to not do or to construct barriers to doing what is for these people important research that addresses issues in their lives. In my research, based on both observations and key informant interviews, there can be “knee-jerk” reactions to particular topics, which are automatically assumed to be sensitive when considered using the values and sensitivities of the committee members, not the members of the target community. One example is research with those using illegal drugs or at risk for diseases associated with injection drug use. As one key informant reported, a representative of the target population told members of a committee (and I summarise in polite words here) to put aside (or make themselves aware of) their middle class values

when they make decisions about research involving injection drug users who live in a very different world. In other words, there was a major disparity in the values of the two groups (the committee members and people from the target population). (See also Israel, 2004)

2.1.12 ... *Researchers and HRECs should be aware that such relationships may raise methodological issues (often referred to as 'reflexivity') and issues about the potential risk of harm to either researchers or participants.* — Sorry, lost me with this one. Why is 'reflexivity' an "issue"? Reflexivity is a necessary part of many, maybe all, kinds of qualitative research. In fact it is the core component of many kinds of research, e.g., reflexive ethnography (e.g., Davies, 1999), phenomenology. The wording here suggests it is a problem. I cannot really see it as ever really being a problem; it could be a solution. Given the wording of this point I think the wrong word got inserted. Not sure what the word might be, but I think the issue is related to a lack of objectivity that can result from becoming too involved.

2.1.15 *Qualitative research by its nature allows for an interpretive framework. Researchers should assume a non-judgemental stance* — I appreciate the sentiment and concern behind this statement. In many kinds of research a non-judgmental stance is appropriate. However, as presented, this statement would disallow any research based on critical social theory. I can foresee many problems arising for researchers in a number of fields, particularly historians, biographers, criminologists, and anthropologists. Researchers who see social activism as an essential aspect of their role as researchers are going to have problems obtaining approval for their research because it is based on a particular — often judgmental — position. A statement like this could be used to argue a potential infringement on academic freedom. The statement would also seem to assume that research participants are always in the less powerful position, which is not always the case, for example, in research such as that described by Nader (1972) as "studying up." Researchers should attempt to control bias, but there are occasions when a judgemental stance is appropriate and socially and ethically justifiable. I think the point in 2.1.14 on presenting findings in "sensitive ways" is more in line with the intention here and the term is better than "non-judgemental."

2.1.16 *Although in qualitative research consent is normally given in writing, there are justifiable exceptions. Sometimes verbal consent is more appropriate, for example, when the research topic is particularly sensitive, or the participant feels vulnerable, or when it is culturally inappropriate, including situations where participants may be illiterate.*

2.1.16 *In other circumstances, consent may be implied by participation.* — One of my informants calls this "action consent," i.e., the person is informed about the research and begins to talk in relation to the research, thus consent is active or implied. (I was introduced to this term by Janice Dicken (University of Calgary) and use it with her written permission via an email dated 29.12.2004.)

2.1.17 *In on-going, long-term research participants must be given the opportunity to withdraw consent at later stages of the research (See: paragraphs 1.2.13-1.2.14).* As my Project Assistant noted, this is a very open statement. Does this mean indefinitely? What if the results have already been disseminated through publication? Is there a point that should be considered "too late" in terms of methodology or time frame? There are relevant comments on this in other parts of the document, for example in relation to when data have been de-identified, but these do not deal with time frames. We have witnessed committees debating this issue.

2.1.18 *Consent from children and young people to participation in qualitative research should be obtained in accordance with 3.2 Research involving children and young people.* — This really depends on the type

of participation and the type of research. Children are a normal, and important, part of the daily scene or the daily life that is the subject of many ethnographic studies. I am not sure there is enough information here, despite the reference to the section on children and young people, to allow some committee members to understand this type of situation. When it comes to children, many committee members develop tunnel vision and find it difficult to engage in the kind of decision making that is context specific (See also Israel, 2004).

2.2 Ethical considerations specific to research involving deception of participants, concealment or covert observation — I appreciate the reasons for such strong language in this section, but it seems out of character with the kind of more tempered statements in the document so far. The document should give guidance, but at this point it has moved from guidance to more forceful language — and then hedges the bet with 2.2.6, which seem like a bit of a “tag on.” Such research does not always imply disrespect and, in fact, may be respectful, particularly when no one can or will be identifiable, as often occurs in research in public places. In some cases, debriefing can produce harm. Furthermore, my research suggests, “unobtrusive observation” can be (and in many cases is) interpreted as covert observation, thus this more stringent section might be applied when the earlier section is more applicable. On a separate, but related note, perhaps it might be useful to consider including some discussion of public vs private behaviour as this is often one of the defining points in whether “covert” observation is considered acceptable. This section also does not seem to support reasonable consideration of covert observation, which is essential in some kinds of research, e.g., that associated with some studies by psychologists, criminologists, sociologists and others.

2.2.7 Participants must be able to withdraw from the research any data obtained from them during the research. The same caveats apply here as noted in other parts of the draft statement about what data, if any, can actually be withdrawn, mainly in regards to covert observation where no identifying information has been recorded. This statement is more applicable to research involving deception and concealment, particularly if the person is identifiable.

*2.4.3 Researchers must demonstrate, and an HREC must be satisfied that, there is ~~a scientifically~~ an acceptable process for the disclosure of information and communication of research results and, where there is to be selective disclosure of information, that there are scientifically, **ethically and culturally** justifiable reasons for so doing.* As my Project Assistant points out, the criteria should not only be “scientifically” acceptable, but it also should be culturally and ethically acceptable. This issue is more complex than the original wording would suggest.

2.4.8 Information arising from both long and short term epidemiological research must be securely stored. — Why is this only mentioned in relation to epidemiological research? Shouldn’t all data be stored in the most secure manner possible? And this does not necessarily mean in locked files in the researcher’s office, which may be one of the most unsafe places to store data. There is also the issue that much data today is maintained electronically, including on laptop computers. As noted elsewhere in the draft, the issue is appropriate storage of data to maintain confidentiality and anonymity (see for example 2.3.7, 2.6.3), and this may take many forms.

2.4.12 If identified data or coded data are to be used for any research purposes or by any persons other than those specified in the approved proposal, a new proposal must be presented to an HREC for approval. — I understand the new purpose part, but why should you need a whole new proposal to add a new person/s? Given the wording here, every time you add a new person to the research team you would need

to submit a new proposal. I can see obtaining a written agreement if the data is shared with another group, but I am not sure why a new proposal would be required if it is for the same purpose. Couldn't this be done with an amendment to the proposal?

Section 2.5 — This whole section seems to have some redundancies that make this section seem repetitive or even more complex than necessary.

2.5.1 Counselling and provision of information arising from the research must be provided to participants by ~~health~~ professionals with appropriate training, skills and experience. — Why is this under research merit and integrity? It would seem better placed under benefits/risks or even respect or justice. There are far more important issues in relation to merit and integrity, like justification for the research. This is an area where data storage and future use might be mentioned as it seems that a number of studies that include the collection of blood samples are now asking to store the data for future, but indeterminate, use.

2.5.2 ... that researchers have adopted measures to prevent mis-use or misrepresentation of the results of research that might otherwise lead to prejudice, disrespect or other harm to the participants or communities to which they belong. — A wonderful ideal, if only this was humanly possible. The absolutist language is the problem, not the ideal. Once the data have been made public (i.e., published) the researchers no longer have control over how it might be used and it is unlikely that any human I know could predict all the possible ways that others might mis-use data that is in the public domain (i.e., published). What might seem unimportant today might be important in another time and the opposite can also be true. Controversies over anthropological data provide many instances where values, beliefs, etc change and thus change the significance or meaning of the information. Again, the issue here is not the underlying ideal, but the absolutist language. This is the kind of thing that committee members, particularly those who lack or feel they lack, the necessary expertise seize on because it seems so “black and white” and easy to deal with, when it is really so socially, morally and ethically complex.

2.5.4 b ~~If this occurs, the other research group must undertake to hold the material and related information in such a manner that there is no reduction in the protection of the privacy of the participants or of the confidentiality of the information.~~ Long, awkward sentence. How about something like: If this occurs, the other researcher group should also store and handle the material and information in a manner that protects privacy and confidentiality.

2.5.8 consent should be sought from appropriate community representatives. — Easier said than done in some populations, as most anthropologists and geneticists who have done fieldwork in complex communities can attest. Who counts as the appropriate community representatives? This presents the same kind of problems the term collectivities raised. Again, there just needs to be some tempering of the language to allow some flexibility to deal with the real world.

2.5.13 Institutions wishing to conduct research on genetic material and information collected for non-research purposes, should develop and disseminate a general policy ~~which~~ that informs patients that such material and information may be used for future research following HREC approval, subject to the issues raised in paragraphs 2.5.6 and 2.5.12. — Still a rather awkward sentence.

Section 3 Individuals and communities — Thank you for including this. It may help some committees better deal with cultural issues that actually take culture into consideration. I think this terminology is

better than the use of the term “collectivities,” which has produced a number of problems in the countries that have used the term.

3.1 It is not possible to define exhaustively all types of dependent or unequal relationships, but they include situations where unequal power relationships exist between participants and researchers or where participants occupy junior or subordinate positions in hierarchically structured groups. — Is the word “or” required here? In some cases (e.g., some ethnographic research and “studying up”) it is the researcher who is in the subordinate position. So the issue is really when the researcher is in the superordinate position.

3.3.1 a — Thank you for acknowledging that people with intellectual disabilities and mental impairments are often capable of giving consent. This is a move in the right direction (i.e., away from an overly paternalistic stance).

3.1.2 Where the dependence or unequal nature of the relationship is incidental to the purpose of the research, researchers must make a special case for including people in dependent or unequal relationships as participants. Is this a potential infringement of autonomy? What if people in such relationships want to participate or ask to be included? Must the researcher return to the committee to justify their inclusion?

*3.1.3 Researchers must seek to ensure that a participant’s refusal **or acceptance** to participate in, or a decision to withdraw from, research will not result in any negative consequences, such as discrimination, reduction in the level of care, or any other penalty. This issue is addressed in other parts of the document, but, as my Project Assistant notes, it also seems relevant here. For example, the choice to participate in some research may have the potential to result in such negative consequences. One example that comes to mind is people who would effectively function as “whistle blowers” if they participated in the research and this could result in negative consequences, particularly in small organisations or groups.*

3.2.6 Consent of a child or young person — I agree that in many cases the child or young person can consent and should be allowed to do so on their own behalf. I am also happy to see this being acknowledged as a respect issue. However, I do have a question: I wonder if this deals with the distinction many of my research participants make relative to assent vs consent? I think the distinction has some legal foundation, but I am not certain of this. I wonder also if it might be useful to remind readers that consent should be obtained in a manner appropriate to the participant and thus a signed written consent form is not always the preferable method?

3.4.8 The distinguishing feature of research involving unconscious people is that, due to their incapacity for cognition and communication, it is impossible for them to be informed about the research or to determine their wishes about it. — Actually we do not know if unconscious people are always incapable of understanding (cognition) even though they may be incapable of communicating that understanding. I have had too many years as a critical care nurse to make this assumption.

3.5.1 Other researchers also, in applying paragraph 1.1.13 of this Statement, may find the Values and Ethics guidelines informative. — Yes. Nice inclusion, even if there are still some problems with parts of the document researchers should be aware of this document.

4.1 Institutional responsibilities — I wonder if this section should be expanded to delineate further the responsibilities of the institution as a way to deal with issues like the “mission creep/big basket” phenomena (Fitzgerald, 2004). (See also the earlier comment on governance.)

4.1.3 *An institution and its HREC; must put in place mechanisms to ensure good ethical review of research involving humans; so that: — delete commas. Nice list. Addresses many essential issues, many of which are currently the source of problems with the review process.*

4.1.5 (c) **at least one member with current experience in each of the areas of research regularly considered by the HREC and not less than two members in total with research knowledge and expertise;**

4.1.5 (e) *at least one member who performs a pastoral care role in a community, for example, a minister of religion; and —* I still do not understand the justification for this person. I have no problem with a minister being on a committee, they often make good members, but I still do not understand why this is a required member.

4.1.5 (f) *at least one member who is a lawyer. —* Again, I think lawyers often make good members of committees, but I do not know why a lawyer should be a required member if the institution carries out its role in relation to the legal issues associated with any particular project. These members often do not have the full range of legal expertise required or alluded to in the Statement. At the very least, I think there needs to be some statement about this person's role so that they do not, and are not asked to, make legal judgments within the context of the ethics review.

4.1.6 *The institution must ensure that the membership of the HREC includes a member or members with experience in the ethics of research involving humans. —* This is a good idea and one the Canadians have tried to use. However, given my knowledge of the Canadian experience this requirement will present some problems. My research in Canada, where this has been a requirement under the Tri-Council policy (Tri-Council, 1998), suggests that there are problems fulfilling this requirement. There are not enough ethicists to fill this position on all committees and the ethicists do not want to spend all of their time sitting on ethics committees. The result is that the requirement gets loosely defined and people with questionable qualifications in this regard (i.e., no formal background or training in ethics) are identified to fill this position. This includes using someone who has been a member of a committee for some time as the person with experience. I do not think this is the intention here as it was not the intention with the Tri-Council document. It might be more appropriate to require some training for all members in research ethics. At the very least, if you keep this statement, I think there needs to be some explanation of what "experience in the ethics of research involving humans" means.

4.1.12 *...communicating with researchers, including face to face, by telephone and in writing —* This is good. Hopefully it will help in relation to communication with researchers, which is a core issue raised in my research.

confidentiality of the content of applications and of committee proceedings. — Is this a place where there might be some mention of committee meeting observers? I think this is an issue that does need to be addressed as outline in one of the papers that came out of my research (Fitzgerald & Yule, 2004). Observing committee meetings is an excellent strategy to be included in the educational process and provides some transparency of the decision making process. The use of confidentiality agreements, if necessary, can deal with some of the concerns committee members have raised in this area. In addition, application forms can include an item where the researcher can request a closed meeting with an explanation. Obviously committees can also choose to review some applications in closed sessions, but there should be some reasonable reason for choosing to do so.

4.1 *Review of minimal risk research* — Hopefully this expanded section will encourage more committees to use this form of review. The one concern is with the statement: “Minimal risk research should involve no greater risks than those ~~which~~ **that** occur in normal life.” This phrase has resulted in some problems in other places. Charles Weijer (Weijer, 2000; Weijer & Miller, 2004) has published some interesting analyses that are relevant here. The 2000 document is particularly informative.

4.1.16 *and a statement of how their proposals meet the ethical principles of justice, beneficence and respect* — I think this is a good statement, but I can see some committees having a problem with it as it will require them to change their forms. Unfortunately, many of these committees will probably just add more questions to their forms. For others this will not be a problem as they already use forms that deal with these issues reasonably well. Again, if (or when) a national form becomes available, this should resolve this issue.

4.1.25 *An HREC should consider whether to consult an advocate for any participant or group of participants to inform the HREC about how best to enable informed decision making and understanding by these participants.* — This is a nice inclusion. Might it be expanded to include that researchers can nominate or bring with them to a meeting they attend someone from the participant group to help address the committee’s questions? I have some reports in my data where researchers did this to good effect. See, for example, my earlier reference to research involving injection drug users.

4.1.26 *Where research involves the participation of people unfamiliar with English (or the language in which the research is to be conducted) an HREC must ensure that the participant information statement (whether or not a written form is used) has been translated into the potential participants’ language.* — This addition might help remind committee members that the information should be presented in a format that is appropriate to the research and the population involved. Without an addition like this, I fear committees will “forget” that a written information sheet is not always required and will continue to require written forms even when they are inappropriate. I have data where this has happened, i.e., the committee agreed to a verbal consent process and then asked for a formal, written, translated information sheet.

4.1.27 *For participants unfamiliar with English, and ~~also~~ for those with hearing impairment, an HREC must ensure that an appropriate interpreter is present during discussions with the participants about the project.* — Three concerns with this statement. The first is that not all people with hearing impairments require an interpreter and some people, even those who are profoundly deaf, do not sign and cannot understand sign language. So the statement requires some qualification in relation to people with hearing impairments. Second, this seems to be referring to the consent process — or at least I think this is what it is referring to. I assume this comes out of the needs related to medical and interventionist research. But for any talk about the project? This is not always necessary or feasible for some kinds of research, for example research that involves long-term interaction where the project is regularly discussed and consent is regularly formally and informally renegotiated (e.g., ethnographic, life history, action research). Third, this seems to assume that the language for all research is first and foremost English and that researchers (and their assistants) never have the appropriate language skills to work in another language. Just because another language is involved does not necessarily mean an interpreter is required, particularly when the researchers are fluent in the language involved in the research. Again, it is the absolutist language (i.e., must) that has caused the potential problem.

4.1.31 *All documents and other material used to inform potential research participants should **normally** be approved by the HREC including ..., questionnaires, ...* — I have some concerns with including the word

questionnaires — and strictly speaking the intention of a questionnaire is not to inform participants about the research. I am well aware that there are far too many poorly designed and worded questionnaires and most probably should not see the light of day. However, in my research it is common for committees to not approve a questionnaire simply because a member does not like it. But, more important, committees often nit-pick over wording. Not only does this take up an inordinate amount of time at a meeting, but some committees have even tried to change the wording of “standardised” questionnaires that would result in making them invalid. They may also try to take out items that they do not particularly like when, again, these items may be there for a very sound reason and be necessary for the validity of the instrument. The second problem is that in some kinds of research the questionnaire may arise out of a stage of the research and time may be an issue when the committee has to review all “questionnaires.” The two primary examples that come to mind are procedures that use the Delphi technique where a questionnaire is developed in response to the panel’s responses and needs to be returned to the panel quite quickly. The second situation involves action research, which involves similar issues. In regards to questionnaires, some committees confound methodological issues with ethical issues. Perhaps this issue could be addressed in part by including something like “introductions to questionnaire,” as I think the issue in this section is about informing potential participants and the introduction to a questionnaire may serve this function.

4.1.34 ... ethical approval or non-approval — What exactly does “approval” mean? This is somewhat of a rhetorical question, but the issue of what this means has come up in my research and has been discussed in some depth by some key informants. Because of concerns about this word, some committees use alternative phrasing, none of which I have yet found less problematic. I know that this cannot be included here, but for many researchers non-approval or rejection means anything other than outright acceptance or acceptance with minor amendments. Thus the understanding of this concept can differ between committee members and many researchers.

4.1.35... proposed date of completion of the approved proposal for those with a clear endpoint — This idea that all projects have a “completion” date is a problem for many long-term studies, particularly those conducted by social scientists, like anthropologists. Alternatively, the wording might be changed to deal with the length or conditions of the “approval”.

4.1.35 ... whether approval was by expedited review; — Earlier in the document the term minimal risk was used. I assume that minimal risk and expedited review mean the same thing in relation to the form of the review. Some of my key informants find the term “expedited” a problem as it implies that the review will be quicker than a full review. (There are two understandings of the term “expedited review”: 1) a more rapid version of full review and 2) a different process, like the one suggested earlier under minimal risk — and in many cases it is understood as going through a different process and thus is also quicker.) In some institutions, depending on how they have organised this process, this kind of review can take as long, if not longer, than a full review. For example, some committees have identified people for expedited review. If these people are not available (e.g., during summer holidays or other periods of leave) then the applications sit waiting for them. In some cases in my research (including cases in Canada and Australia) expedited in the sense of “quicker” is inaccurate.

Good communication between HRECs and researchers. — Thank you, thank you. This is a really important section. Let’s hope it helps, as this is one of the most important issues to come out in my research.

4.2 *Multiple ethical review of research Unjustified repetition or duplication of HREC review is an ethically unacceptable use of research resources.* — I absolutely agree. Has there been any progress towards the development of committees for multi-site research or regional committees? The regional systems in the UK and New Zealand (now a national system) have many good points to recommend the system. Although these countries are still working out some of the details, the early indications are that they deal with many of the issues related to multisite review and there are reasonable ways to deal with local issues. The main problem is getting local committees to let go.

4.2.2 (d) *adoption of any other administrative procedures to accelerate timely consideration and avoid unnecessary duplication, including, where appropriate, a form of expedited review.*

4.3.4 ... *progress to date or outcome in the case of completed research;* — Does this imply a report on the findings of the research? I am sure some people will understand this statement in this way, while others will not.

4.3.5 *An HREC shall, as a condition of approval of each research proposal, require that researchers immediately report anything ~~which~~ that might warrant review of ethical approval of the research, including: ... • proposed changes in the conduct of the approved research;* — This point raises some issues for some committees. Does this mean any change? The qualifying phrase in the statement: “which might warrant review of ethical approval” is important, but I wonder if this statement is strong enough for some committees. Some committees currently expect any change, even of minor consequence, be reported to the committee and the research discontinued until the change is approved. This is a particular problem for researchers using certain methodologies (research that is often referred to as “emergent”) and those conducting research in rural or remote contexts where correspondence with the committee is difficult. I wonder if the qualifying phrase could be enhanced in some way.

4.4 *Complaints handling procedures* — Another important section with important additions, including the appointment of an independent person or body to deal with complaints, particularly by researchers, and the reference to other institutional processes. Although there is the potential for the latter to be misused (researchers inappropriately accused of misconduct in the name of ethics has occurred with serious implications for the researchers involved), this statement places this whole process within the institutional framework, a point that needs reiteration on a regular basis. It is interesting that I considered this to be an appeals process (or an equivalent), but one of my participants does not see this as outlining an appeals process. Wonder how others will read it.

(d) *the appointment of an independent person or group to receive, handle and resolve complaints described in 4.4.3.(c); and* — Some organisations have put a committee in place for this purpose, particularly to deal with or mediate complaints from researchers. I have been told that such committees rarely meet, but the fact that such a committee exists still has important effects.

4.5 ... *These responsibilities are arranged in a hierarchy* — There is an interesting reading related to this by McDonald (2001).

4.5.4 ... *the number of proposals presented, the number approved, and the number rejected;* — I wonder if it would be possible to consider including another category, something like: “approved after clarification or something more than minor modification.” Data on this category, which seems to be the most common, are difficult to find. My data suggest that this may represent 70-80% of all applications with most going on to

full approval (albeit after a process that can take months to complete). Information on this category would be very informative about the review process, including issues like workload (because all of these applications have to come back to the committee or a member of the committee for review before the final decision is made). I would also like to suggest including something that would indicate “turn around” time. Some committees already collect this information. In the UK there is now a requirement for a 60-day turn around time. This is not without problems, but the more problematic part of the requirement is what committee members call the “one bite of the cherry” requirement. They only get one opportunity to raise issues. I think the collection of information on “turn around” times could serve two purposes: 1) remind committees that this aspect of review is important, and 2) provide information on what the time frames actually are. As you know, complaints about the time it takes to get through the review process are among the most common complaints. There are many reports of reviews taking too long, many months, even a year or more, but general figures on actual times are difficult to find. Any information on this needs to include those situations where final approval was contingent on some, perhaps, minor change being completed and accepted. So turn around time might be defined as something like: from the date of formal submission of an application to the date the final decision is communicated to the applicant.

Additional Comments

Multi-site research is addressed in the document in ways that could be reasonably used by reasonable committees to overcome some of the issues associated with multi-site research. But, I think this is still going to be a problem. There is no real mention of the possibility of developing regional committees, or even a consortium of institutions. It seems more that committees can choose to accept the decision of another committee — or not. This is basically the current situation and few committees seem to accept the decision of other committees even though this is currently possible. Is it likely that there will be some kind of a regional committee system in the future?

Two of the most important people on the committees are the Chair and the Ethics Officer (by whatever title). My research indicates that the quality of the leadership of the committee is a critical factor in how effective it is, how smoothly meetings and the system run, and how accepting researchers are in relation to participating in the system. In other words, there is an effect on the quality of the review and the review experience. One of the initiatives taken in the UK with the introduction of their new system is to require that Chairs and Associate Chairs undergo training on how to chair an ethics committee in light of their new policy. My recent observations in the UK indicate that this training makes a difference. One effect is that there was greater consistency in how the meetings were run and how the guidelines were applied. The chairs I spoke to, despite years of experience as chairs of various kinds of committees, generally reported that they found the training sessions useful. It is interesting that there appeared to be little significant resistance to being involved in the training, but then again they were not really given a choice. The implementation of the new National Statement provides an opportunity to put a similar system in place. In Australia this could also mean greater consistency across committees even if we do not go to a regional system. This suggestion is not in place of the kinds of training that is already occurring for all committee members and that for ethics officers. This would be something in addition that specifically addresses issues related to chairing a committee, a role that can be particularly challenging.

There are some minor editorial things, which I assume will be addressed in the final version. Things like missing or misplaced commas and a fairly consistent misuse of the word “which” when the word “that” is the appropriate word.

Thank you again for the invitation and opportunity to contribute to the review of the *National Statement*. I hope my comments are useful. Please do not hesitate to contact me if I can be of further assistance.

Sincerely,

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