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REVIEW OF NATIONAL STATEMENT ON ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS (1999) (NATIONAL STATEMENT)

**Submission from
the National Association of People Living with HIV/AIDS (NAPWA)**

Who we are

NAPWA is the peak, community-based organisation advocating for and providing policy advice on behalf of the 14,000 Australians currently living with HIV/AIDS. In partnership with the Australian Federation of AIDS Organisations (AFAO), NAPWA works to ensure a national continuum of community-based advocacy and service delivery, from prevention, to care and support. Our 20 years of engagement, aligned with the singular challenge that HIV has offered, has given us a significant depth of experience in and with health delivery in Australia, and also with the full range of stakeholder interests engaged in its provision.

General comments

Overall, NAPWA welcomes and endorses the content and direction of the First Consultation Draft (December 2004) of the National Statement.

We believe it provides a clear, coherent, sensible and balanced overview of the ethical issues involved in conducting social, clinical and other kinds of research involving humans, and would like to congratulate the drafting committee for their very thorough and considered first draft.

Specific comments

We would like to raise a few further issues for the consideration of the committee, which we hope will add constructively to these Guidelines.

1. Research participants or research subjects?

We note that the Guidelines (p. 34) explains that the terms “participants” and “research participants” are used to refer to people recruited for involvement in research. This is helpful, in that it emphasises the agency and autonomy of participants, in a way different to terms such as “subject”.

It would be useful to highlight this particularly with regard to clinical research and the terms commonly used when researchers develop and design research, and when research results are written up and disseminated in journals and by other methods. Often, researchers use the term 'subjects' in this context: it would be useful if the Guidelines could therefore be part of a culture shift, by encouraging researchers to consider the term 'participants' rather than 'subjects'. This may seem semantic, but we believe that the term 'trial participants' is preferable, in that it avoids the 'dehumanising' connotations which participants in research often attribute to the more neutral, but clinical, "subject".

2. Human Research Ethics Committees

The Guidelines pay welcome and useful attention to the roles, responsibilities and makeup of Human Research Ethics Committees. NAPWA would like to raise a couple of additional points, which we believe it would be helpful to see reflected in this document.

Community and consumer involvement

For many research participants, the processes of human research ethics approval appear as somewhat of a mystery. While we acknowledge it's impractical and in other ways problematic for HRECs to conduct their business publicly, we believe there are ways in which greater participation by health consumers in this process could be considered. These might include:

- The possibility that HRECs may seek, from time to time, independent opinion or advice from particular consumer or community groups that represent the population of intended research participants, particularly in research areas where lay members may not have great familiarity with specific issues.
- That there also be clear mechanisms for consumer and community to independently provide comment or input on particular proposals, where this might be of particular relevance or interest to consumer or community advocates.

Accountability

In a similar vein, it would be helpful if the Guidelines could provide clear information and direction as to who is ultimately responsible, and where people can go, if they have concerns or issues about the conduct of the HREC process in relation to particular projects or research proposals.

While we believe that most HRECs conduct their business with integrity and with the best of intentions, nonetheless, from time to time, NAPWA is aware of research protocols which have received ethics approval, but which have presented significant concerns to people living with HIV or AIDS, the intended participants of the studies.

We therefore believe the Guidelines should stress:

- What bodies, authorities or accountability mechanisms there are if people wish, for example, to query a process or raise concerns about the ethics approval process;
- How health consumers can go about raising concerns during these deliberations.

Chairing

It may be useful to provide some specific comments about the particular responsibilities of HREC Chairs, as the driving force behind most committees.

In particular, two issues may be worth noting:

- The responsibilities of Chairs to provide detailed information about their research involvements, including conflicts of interest, or perceptions of same.
- The duties of HRECs and Chairs to ensure that all projects are given thorough scrutiny, particularly when they may come from researchers and investigators who may have longstanding relationships and put high volumes of research through particular HRECs. While HRECs and their chairs may understandably come to expect only high standards and ethically appropriate research from those who “do it all the time”, it may be worth noting that familiarity with a particular researcher, their institution and approaches, and past record, should not lead to the effective ‘rubber-stamping’ of research proposals, a concern which has been raised with NAPWA on occasions in the past several years.

3. Importance of feedback to research participants

It’s common for NAPWA to hear, through its membership, that participants in social or clinical research are often not made aware of the outcomes or results of research projects in a timely or appropriate way.

We have raised this issue at various times with research institutions and individuals working in the HIV area, but it’s not an issue which is particular to people with HIV.

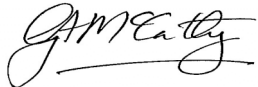
The Guidelines do note that researchers have “an obligation to make the results of their research available to research participants in appropriate ways” (p. 7), and we agree this is fundamental to the notion of “Justice in Research”.

What’s less clear, however, is how this applies in practice, and the many and varied interpretations of “appropriate ways”. An article published in a peer reviewed medical or social research journal does, of course, constitute feedback of a sort – but such articles are rarely fully accessible to people (e.g. the article or journal fee is exorbitant), and such

articles are generally written for peers, utilising professional and technical language and assumptions of knowledge which a significant number of research participants cannot be expected to have mastered.

It would be helpful, therefore, if the Guidelines could provide some further comment or detail on this important matter, and suggest ways in which researchers may be able to more fully discharge this important, often neglected, responsibility.

We hope that these points will be of use in the re-draft of this document. We are pleased to have had the opportunity to participate in the consultation process, and look forward to the final version of what we believe will be a very thorough and comprehensive National Statement.

A handwritten signature in black ink, appearing to read 'G. McCarthy', with a horizontal line underneath.

Gabe McCarthy
President
16 March 2005