ARTICLES

Is the Australian HREC system sustainable?

SUSAN DODDS

Chair, University Ethics Committee
Philosophy Program University of Wollongong
sdodds@uow.edu.au

ABSTRACT

In Australia, Human Research Ethics Committees (HRECs) have a vital role to play—as the primary institutional mechanism for ethical review of research—in protecting research participants, and promoting ethical research. Their ability to act effectively in this role is currently threatened by the limited support they receive and their burgeoning workloads. In this discussion paper, I trace some of the factors contributing to what I describe as a resource crisis in human research ethics. I suggest a review of the working of HRECs to canvas a range of alternatives which might serve to redress this crisis, so as to ensure the continued effectiveness of HRECs in protecting participants and promoting ethical research.

The Australian Human Research Ethics Committee (HREC) system provides excellent service for money. Millions of dollars in research funding hang on HREC approval of research. NHMRC will not grant funding to institutions that do not have HRECs duly constituted through the Australian Health Ethics Committee (AHEC), and most industrialised nations will not approve the sale of pharmaceuticals unless the research on the drugs was reviewed by an ethics committee process[1]. Nonetheless, the vast majority of HRECs in hospitals, universities and other organisations rely heavily on voluntary labour to conduct those reviews. In some cases, HREC members receive nominal sitting fees for their services, but in many cases, especially in the case of 'lay' members of HRECs, the work of HRECs is done more out of a sense that the HREC process is important and worthy of support, than because the professional and financial benefits which flow to some researchers and institutions, as a result of HREC review, will ever be enjoyed by HREC members (except as a weak, reflected glow).

It appears that most institutions with HRECs provide them with very modest resources to support the work of the HREC, including limited funds for training, workshop attendance and publication budgets—whether providing information and advisory documents for researchers, or providing members with resources needed to develop their understanding of the relevant ethical issues. HRECs have a very important role in promoting ethical research and in protecting research

participants, but their ability to act effectively in this role is hampered by their lack of support and their burgeoning workloads.

In this brief discussion piece, I'd like to articulate my growing concern that the Human Research Ethics Committee mechanism for protecting participants in research is facing a resource crisis that threatens to undermine the substantial developments in HREC processes that have improved the quality of HREC review in recent years. I argue for a system-wide review of the needs and sustainability of HRECs, reflecting the changes to HREC responsibilities, as a result of the implementation of the National Statement. I do this in the hope of stimulating debate about the current state of health of the HREC system and to encourage steps to be taken to support and protect the system from collapse.

Effects of the *National Statement*: Better processes and bigger workloads

In the shift from the *NHMRC Statement in Human Experimentation and Supplementary Notes* to the *National Statement on Ethical Conduct in Research Involving Humans*, the processes and procedures of HREC review became considerably more important in ensuring the protection of research participants. Whereas the earlier Statement emphasised the responsibility of researchers to conduct their research ethically, the current Statement requires HRECs to consider whether the researcher has provided sufficient evidence of a range of protections for participants to satisfy the HREC that the proposed research will meet the required ethical standards.[2] An immediate effect of this increased requirement for HRECs to obtain documentary evidence concerning the proposed research is an increase in the volume of paperwork associated with each HREC application, including: financial documentation, evidence of adequate insurance cover, statements of any potential financial or other conflicts of interest, copies of all documentation to be given to participants in the various languages in which it will be presented (as well as translations in English), in addition to full information relating to the rationale, design and method of the research.

At the same time that the amount of information required for each application has increased, the number of applications each HREC reviews has also increased.[3] This increase has two aspects. First, the National Statement expands the areas of research requiring HREC review. Areas of social, humanities, business and education research which might not have been reviewed by HRECs in the past, are now being reviewed by HRECs.[4] While some of this research may be appropriately addressed through a system of expedited review[5], many of these proposals are every bit as demanding for the HREC as large-scale drug trials.

In addition to a greater range of research areas being reviewed by HRECs, the number of research proposals coming before HRECs from the traditional areas of health and medicine continue to grow.

There are a number of reasons for this increase, including a greater demand in the health care sector for funding to be tied to research outcomes; greater demand for health providers to provide published (and publicly available) reports on service provision as a form of accountability; on-going emphasis, in the education sector, on publications and research grant successes as performance indicators which then form a basis for federal and internal funding; and greater emphasis on 'evidence-based practice' in health care and on clinical research in all areas of health education.

Based on anecdotal evidence, it seems that HREC members are now routinely asked read and consider well over 500 pages of information for each monthly HREC meeting.

Thus, while the *National Statement* considerably tightened-up the *process* of HREC review in a manner that has decreased the likelihood that unethical research will be approved, it has also vastly increased the workload of HRECs. It appears that many HRECs are straining under the pressure. Here are three examples that are not far from reality. At one HREC, the monthly lunchtime meetings have become four to five hour marathons so that the Committee can properly consider 15-20 applications each month (excluding those that the Committee ratifies after a process of expedited review). At a larger institution meetings also run for four hours (starting at six, when the members are finished with their paid work); this committee considers forty applications. It is hard for me to believe that each of those applications receives the careful consideration expected by the spirit of the *National Statement*, as each would presumably receive an average of six minutes' deliberation. Yet another HREC considers a maximum of eighteen applications each meeting, to protect the committee against overload. Those applications that are not considered in one month's meeting are held over until the next meeting. While this approach allows for adequate deliberation, it must surely test the patience of researchers and funding bodies!

I doubt that these three examples are entirely abnormal. While some HRECs may well have small workloads, the bulk of those associated with universities, teaching hospitals and large institutions are wilting under the mountains of paper, despite valiant efforts to meet their increased responsibilities.

HREC support: Publications and training

The increased demands placed on HRECs have been met in a limited way with support from the Australian Health Ethics Committee of the NHMRC (AHEC). The staff and members of AHEC are very helpful (most AHEC members also have 'day jobs'). Sometimes, however, what HRECs really need are material resources (publications), detailed advice about processes and training (attendance at workshops relevant to HRECs). AHEC lacks a sufficient budget to provide detailed advice to HRECs, to provide substantive training or to identify and address the substantive needs of HRECs. The current AHEC has been landed with a wide array of responsibilities, in addition to support for the work of

HRECs. AHEC is involved in a project with the Law Reform Commission into genetic privacy, has considered the issue of stem cell research (and the effect of changes in policy or legislation regarding stem cell and cloning research on Supplementary Notes 5 and 7 of the old *NHMRC Statement* which remain in force), has responsibility for developing guidelines for research involving Aboriginal and Torres Strait Islander participants, to name just three areas.

Given the heavy workload and limited resources of AHEC, the publications produced by AHEC (and those currently under development) must be recognised as providing useful support to HRECs. It has produced a number of information sheets and specific guidelines to assist HRECs. In March, AHEC released the *Research Ethics Handbook: Commentary on the National Statement on Ethical Conduct in Research Involving Humans.*[6] It currently has a working party, which includes HREC secretaries and members, developing a common HREC application form. AHEC holds well-attended annual workshops for HRECs in each of Australia's capital cities.

A further support for HRECs comes from a network of HRECs, originally set up through New South Wales Health, that uses an email list to raise questions, share expertise and pass on suggestions. That list is administered and supported by the NSW Department of Health and has now extended well-beyond that state, with some list members based in the United States.

Compliance and review of HRECs

Although the volume and quality of written information assisting HRECs has increased in recent years, there is still no effective mechanism for reviewing individual HREC processes, providing training and ensuring compliance with the *National Statement* and applicable commonwealth and state legislation. For its monitoring of HREC practices and processes, AHEC relies almost exclusively on self-reporting by HRECs through the annual review report process.[7] While it is certain that HRECs strive to meet the requirements of the *National Statement*, if an HREC is not aware that its processes are inadequate, it is not going to report its lack of compliance in the annual report. This is another area in which the aspirations of the *National Statement* could easily fail to be met.

By way of contrast, research conducted involving non-human animals is subject to NHMRC guidelines and State legislation[8] which provides for regular and extensive review of Animal Care and Ethics Committee processes, site-visits of facilities used in animal research and animal housing, as well as paper-based monitoring of Animal Care and Ethics Committee compliance. Researchers and Animal Ethics Committee members are encouraged to attend a range of regular workshops and training sessions (in some cases participation is a requirement for accreditation allowing some kinds of research to be conducted). While the methods used to check compliance with the guidelines and legislation relating to animal research are not directly applicable to research involving human participants (e.g. site visits by

the regulators could well be a greater privacy intrusion than the intrusion risked by the research being assessed for compliance), the difference between the resources devoted to ensuring that Animal Care and Ethics Committees meet the requirements of federal and state policy and those available for similar activities in research involving human participants is noticeable.

Review of HRECs?

In 1994 the Federal Minister for Health and Family Services announced a review of the institutional ethics committee system in Australia (Institutional Ethics Committees were the precursors of HRECs). The report of that review, published in 1996, made a wide range of recommendations, including the review of the NHMRC *Statement on Human Experimentation and Supplementary Notes (1992)* which lead to the drafting of the *National Statement on Ethical Conduct in Research Involving Humans*. I believe that the time has come for a further review of the HREC system to assess the effects of the National Statement, to determine HREC needs and to recommend structural and material support for the HREC system, before the system disintegrates or is found to be inadequate. In light of the matters raised above, I believe the three key areas that need addressing are:

- HREC workloads and institutional support
- Training and guidance for HRECs through individual review of HRECs
- A system of compliance auditing which is not entirely based on self-reporting and written compliance reviews.

While much will need to be discussed about all three areas, I will conclude by simply raising some considerations in relation to the first of these.

- Should there be some level of centralised review of multi-centre research?
- In the case of research being conducted through the Clinical Trial Notification (CTN) or the Clinical Trial Exemption (CTX) schemes of the Therapeutic Goods Administration (TGA), should there be a *national* body that reviews the drugs and their pharmacological/toxicological effects? Such a national review body could relieve HRECs of the complex (and often expensive) task of assessing the rationale and scientific method of those trials, while preserving for local HRECs the responsibility for determining whether the method of recruitment, information provided to participants, indemnity, back-up support is appropriate given the local factors affecting the local participant population and the local institutions participating in the research.
- Should institutions be encouraged, or discouraged from having multiple HRECs covering different kinds of research or different

research topics (and what effect would this have on intra- and inter- institutional consistency)? For example, in a University, should there be social science and humanities HRECs operating in parallel with health and behavioural HRECs or committees that focus on drug trials as opposed to committees addressing non-drug research?

- Should institutions supporting HRECs be required to make specific funding support available for *all* HREC members to have opportunities to obtain publications and to participate in AHEC workshops? If so, how should such levels of support be determined—e.g. as a proportion of research funding received?; how would HRECs outside of educational and medical institutions meet that obligation?

ENDNOTES

1 "National Statement on Ethical Conduct in Research Involving Humans", *Commonwealth of Australia,* 1999, p. 2; *Therapeutic Goods Administration,* "Human Research Ethics Committees and the Therapeutic Goods Legislation", *Commonwealth Department of Health and Aged Care,* June 2001: 4-5; US Food and Drug Administration/International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guidance for Industry: E6 Good Clinical Practice, Consolidated Guidance. *US Department of Health and Human Services, Food and Drug Administration,* April 1996: 8-9.

2 S. Dodds, 'Human Research Ethics in Australia: Ethical Regulation and Public Policy', *Monash Bioethics Review*, vol. 19, no. 2 (April, 2000) Ethics Committee Supplement: 4-21

3 *According to the* HREC Bulletin of the Australian Health Ethics Committee *(No 4. October 2001): 2* there were 210 HRECs active in Australia at the end of 2001. Those HRECs reviewed 15.5 thousand research proposals. On average, each HREC approved 70 applications, the highest number of approvals for a single committee being 764.

4 *National Statement on Ethical Conduct in Research Involving Humans, Commonwealth of Australia,* 1999: 6-8.

5 *National Statement on Ethical Conduct in Research Involving Humans, Commonwealth of Australia,* 1999: 19.

6 As I was a member of the editorial team contracted to develop the Handbook—with Paul Komesaroff, Paul McNeill and Loane Skene—I am particularly pleased that it has been released.

7 *National Statement on Ethical Conduct in Research Involving Humans*, 1999: 21-22. The *HREC Bulletin of the Australian Health Ethics Committee* (No 4. October 2001):2 includes a report on the 2000-2001 HREC annual compliance reporting process.

8 NHMRC Australian code of practice for the care and use of animals for scientific purposes, 6th edition. Canberra: Commonwealth of Australia (1997). NSW Animal Research Act (1985) No 123. I assume that the other Australian states have similar legislation and compliance processes.