

## EDITORIAL

# HUMAN RESEARCH ETHICS COMMITTEES – WHAT’S NEEDED NEXT TO PROTECT PARTICIPANTS AND ADVANCE HEALTH?

Over the last half century all countries that have a developed health and medical research effort have established human research ethics review systems. These vary between comprehensive centralised governmental systems (e.g. in New Zealand and Scandinavia) to more localised systems such as Australia and the USA.

Australia’s system of human ethics review is well regarded internationally. National standards were first developed and promulgated by the National Health and Medical Research Council (NHMRC) in 1966 and there have been two major revisions and several updates to the guidelines in the ensuing 40 years, to take account of international ethical and scientific developments. The most recent version has just been released by the NHMRC (*National Statement on Ethical Conduct in Human Research*). As previously, it sets the overall parameters for Human Research Ethics Committees (HRECs) (e.g. membership, operations, special considerations for specific populations, clinical trials, privacy).

This publication outlines how several HRECs addressed a wide range of research questions. The dilemmas vary from concerns about whether consent to involvement in research is informed and voluntary, to the privacy implications of new technologies such as gene therapies which involve collection of genetic information now for use and disclosure in the future. Each HREC consists not only of researchers and people with expertise in ethics, law and counselling, but also a person who performs pastoral care and at least two lay people (a man and a woman) not currently engaged in medical, scientific, legal or academic work. This range of membership ensures that a variety of views are taken into account for every research proposal reviewed. The dedication of HREC members to this task, many hundreds of people who donate their time, is very impressive. Without their commitment the system would not work!

There are currently 230 HRECs registered with the NHMRC. The establishment and proper support of a HREC requires considerable resources from a research institution (hospital, University, medical research institute, company). The amount of work involved can be huge, with some of our larger Universities examining around 1000 applications per year. As this document shows, there is little doubt that considerable care and attention is given to the initial consideration and approval/rejection processes by the HREC. But, as we move into this century, a number of questions have been raised about the system that should be examined. Is it adequate for the complexities of research, the size of the community’s investment in medical research, and the community’s expectation that all HRECs will continue to have the capacity and resources to protect the interest and safety of participants in research?

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1. Monitoring of the conduct of research? Are all HRECs aware of deviations from the approved protocols or of problems that might arise during the conduct of the approved research (e.g. unexpected problems with recruitment, complaints or concerns of the research subjects). An exception is that larger clinical trials have independent monitoring in place so that as soon as it becomes clear that the “treatment” being trialled is significantly effective, or significantly harmful, the trial is stopped. NHMRC sponsors the Australian Clinical Trials Registry at its University of Sydney Clinical Trials Centre. This allows anyone to see what trials are being conducted in Australia.

2. Are HRECs adequately resourced? HRECs may be overloaded and under supported as they may be sometimes required to take on other functions (e.g. clinical or professional

ethics, grant administration, research governance generally).

3. Who monitors the HRECs? The only formal reporting of the operations and functioning of HRECs is by the NHMRC and this only applies to those HRECs that have registered with the NHMRC. These committees are asked to complete an annual questionnaire about compliance with the provisions of the *National Statement on Ethical Conduct in Human Research*. Compliance with provisions of the *Privacy Act 1988* is also checked and reported to the Federal Privacy Commissioner. These questionnaires give a snap-shot of compliance but beyond this there is no other external audit or inspection of the work of HRECs.

4. Do we need a formal complaints mechanism? Currently, there is no formal complaint system at either the State/Territory or national levels. The *National Statement* requires institutions to investigate complaints, but such a system of self regulation may have served its time. NHMRC receives complaints about researcher and research conduct or HRECs from time to time. The NHMRC's legislation does not provide a statutory capacity to investigate complaints. However if the research is funded by NHMRC, we can suspend or cancel the research if there is evidence that research, even if approved by an HREC, is not in accord with the conditions under which it was funded, or with NHMRCs, *National Statement on Ethical Conduct in Human Research*.

5. More and more, research is collaborative and conducted with multiple investigators and across multiple centres, across State and Territory boundaries, and also across international boundaries. Is there a better system for multi-institutional research, and can the current excessive time that is sometimes taken to review such research be reduced? Whilst the NHMRC has been encouraging mutual recognition of the ethics approval granted by one HREC, institutions and HRECs have been slow to take up the opportunities this affords. Most cite concerns about insurance, indemnity, and monitoring as their reasons for seeking to give individual approval. This situation is becoming untenable, creating inefficiency in the system, delays in approving and commencing research, and most of all increased work for researchers and HRECs alike.

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To help, NHMRC has worked with jurisdictions to introduce the National Ethics Application Form (NEAF) as a means of creating comprehensive and consistent information for HRECs. We are now also working to gain agreement from all jurisdictions for a national system of single ethics review based on mutual recognition. An implementation plan will be developed over the coming months and implementation is planned from late 2007.

## WHERE TO FROM HERE?

First, it is essential to ensure that the diligent work of many hundreds of Australians that serve on HRECs is maintained and acknowledged. No system will work without their energetic contributions. The current system has evolved to suit Australian circumstances and in general has worked well to protect research participants under local conditions.

However, improvements are needed. These might include:

1. Mandatory registration and accreditation or credentialing of HRECs.
2. A reliable method of monitoring compliance by researchers and HRECs with the *National Statement* and related guidelines.
3. A formal complaints process.

As ever, the promotion of best practice and awareness of the ethical implications of research, by researchers, HREC's and research institutions, remains the cornerstone of any ethical review system. NHMRC is proud of the system of human research ethics that it has nurtured, with its

partners (ARC, AVCC) over the last half century. We are keen to continue its development to ensure that the system is suited to the 21st century, and that it protects those who selflessly contribute to the better health of humankind through participation in research projects. It is time to take the next steps in the evolution of the Australian System.

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