

Model for a single ethical and scientific review of multicentre research in New South Wales

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A welcome alternative to the current cumbersome and inefficient system

Australia's system of ethical review of human research is based on a National Health and Medical Research Council (NHMRC) publication, the *National statement on ethical conduct in research involving humans*.¹ This statement requires all research involving humans to be reviewed by an appropriately constituted human research ethics committee (HREC), whose primary role is to protect the welfare, rights and dignity of human research participants. It is also a requirement of Australian therapeutic goods legislation that all clinical trials that use unapproved therapeutic goods obtain approval from an HREC.²

There are currently 59 HRECs in New South Wales registered with the NHMRC, of which 23 are within the public health sector. Historically, HRECs were established by institutions or organisations to review research proposals conducted solely within their facilities, or involving only their researchers (single-site research).

The ethical and scientific review of multicentre research, whereby a single research protocol is conducted at numerous sites, presents unique difficulties for HRECs, researchers, industry and governments.³⁻⁵ Under the current system, multicentre research projects are reviewed regularly by the HREC at each site where the research will be conducted, resulting in multiple reviews of the same project. As multicentre research grows, this process is becoming increasingly untenable.

In 2005, the NSW Department of Health undertook a review of all research projects submitted to HRECs within the public health sector. In 2003, 148 multicentre research projects were reviewed 491 times, and in 2004, 196 projects were reviewed 607 times. It is clear that the current system has resulted in a number of inefficiencies, including the duplication of effort for HRECs and researchers, an increased burden on HRECs to provide reviews of adequate quality in a timely manner, and increased time from conception of a project to completion of recruitment of participants. In addition, the system is expensive to administer and hinders Australia's international competitiveness in attracting quality research activities. Researchers, industry and HRECs have been calling for reform of the current system for many years.^{6,7}

In response to these observations and after exhaustive consultation, at the end of 2006, the NSW Department of Health finalised a model for single ethical and scientific review of multicentre research, which will be implemented in July 2007. Further information can be found at: http://www.health.nsw.gov.au/healthethics/multicentre_research.html. The aim of the model is to provide for a single review of multicentre research projects within the NSW public health system, so that every research project is ethically and scientifically reviewed once only.

There are three key points which underpin the model:

- the separation of research governance from the scientific and ethical review of a research project;
- the notion of a lead HREC; and
- the concept of a coordinating investigator.

Research governance refers to the administrative aspects of research, including: support of department managers; the financial and human resources required to undertake the research project; and ensuring appropriate levels of insurance and indemnity. As many of these issues are site-specific, each site where the research is to be conducted will undertake their own site-specific assessment. A standardised six-page site-specific assessment form will need to be completed by the principal investigator at each site and assessed by a Research Governance Officer at the site.

Lead HRECs will be accredited by the NSW Department of Health to conduct a single ethical and scientific review on behalf of all sites within the NSW public health system at which a research project is to be conducted. The actual process used by a lead HREC to undertake the ethical and scientific review remains the decision of each committee. The lead HREC will be responsible for overseeing the research project at all sites, including handling complaints from research participants. An HREC may be a lead HREC in relation to all types of research or in specific research areas only. These areas of research include clinical trials and interventional clinical research and general research including epidemiology, population health, health services, and qualitative and clinical research of a non-interventional nature. In line with the European Directive on the implementation of good clinical practice in the conduct of clinical trials on medical products for human use,⁸ lead HRECs should take no more than 60 days to reach a decision and communicate that decision to the coordinating investigator. The 60 days does not include time during which the HREC is awaiting a response from the investigator.

Lead HRECs will retain the right to limit the number of applications reviewed at each meeting. However, as a number of lead HRECs will be accredited to conduct single ethical and scientific reviews, there will always be more than one lead HREC available to consider a multicentre research project.

Under the new model, the research team will appoint a coordinating investigator. This person will be responsible for submitting the research project to the lead HREC. He or she will be able to choose the lead HREC to which to submit the ethics application, provided the HREC is accredited to review that area of research. Use of the NHMRC's National Ethics Application Form (NEAF) will be mandatory for submission of all multicentre projects.

While the site-specific assessment and lead HREC review may occur in parallel, the decision to authorise or not authorise the commencement of a research project at a particular site will only be made by the chief executive or delegate of the public health organisation when the lead HREC has granted approval and the site-specific assessment has been satisfactorily completed.

This new model will be effective within NSW Health facilities only. Similar models to streamline ethical and scientific review by HRECs are being developed for the public health sector in Victoria and Queensland.⁹ The health departments in these states and in

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NSW have been cooperating to standardise the mechanisms that will be used in their various systems. This is in preparation for the introduction of a national system of single review, currently being examined by the NHMRC, and having been allocated \$5.6 million in the 2007–08 federal budget.¹⁰

It is hoped that the new NSW model will achieve its goals of efficiency, effectiveness, timeliness, cost-effectiveness, reduction in workloads and transparency.

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