

## new developments

### *New Zealand's Ethics Committees*

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In May 2004, New Zealand's Minister of Health made the following key decisions regarding the country's system of health and disability ethics committee review. A standard of 'one review per study' will be established. For multi-centre and national proposals, the review body will be a new national ethics committee, with 'locality assessment' provided by the 'host organisations' in which the study is conducted. For single-centre studies, the review body will be a regional ethics committee. The workload and consequently the number of regional committees will be reduced, because no study will be multiply reviewed. The fifteen current regional ethics committees will be disestablished, and six new committees established in larger regions. All the new ethics committees will be established under section 11 of the New Zealand Public Health and Disability Act 2000 ('the Act'). An applicant right of appeal will be established, with the appeal body a sub-committee of the National Ethics Advisory Committee (NEAC), an independent committee established by section 16 of the Act. Appeal will be accessible only when all other avenues for resolution have been exhausted, and will be by 're-hearing' rather than *de novo*.

The Ministry of Health is implementing the Minister's decisions, and is currently consulting stakeholders on aspects of this. The new arrangements will be operational early in 2005. Further information on the Minister's decisions and their implementation is available at: <http://www.moh.govt.nz/media.htm>.

The Minister also decided that NEAC should do further work as a matter of priority on 'locality assessment'; complete its work on ethical guidelines for observational studies; continue its work on a Maori framework for research ethics; and do scoping work on a 'governance framework' for research ethics that identifies and clearly matches key parties in the research process with key accountabilities, such as assessment of legal issues, consultation with Maori, and scientific assessment.

The Minister's decisions were informed by advice from NEAC in December 2003, arising from its review of ethics committee operation (full report available at: <http://www.newhealth.govt.nz/neac.htm>), and by substantial further work and advice from the Ministry of Health. NEAC's review took more than a year, and was shaped by many stakeholders, through an inclusive and robust process. This included a survey of ethics committee members and researchers; interviews; group meetings; submissions on discussion documents, one of which contained a Crown Law Office opinion as an Appendix; and cross-sectoral workshops. In its review, NEAC strove to identify and build on convergences of opinion where possible, to acknowledge divergences where these remained, and to base its recommendations on the most persuasive arguments.

The Minister's decisions will retain important virtues of the current system. Protection of participants will remain the primary focus of ethics committee review; the system will remain primarily regional, with some national elements; strong lay membership will continue; and consultation with Maori will remain an important researcher responsibility. The Minister's decisions will also strengthen the public authority, accountability, and independence of ethics committee review. Public authority and accountability will be conferred and constrained by statute, rather than by administrative decision of the Ministry, as at present. The independence of ethics committee review is a matter of freedom from undue influence by the researcher and research sponsor of each study (Declaration of Helsinki, paragraph 13). New Zealand health and disability ethics committees will in future be established by actions of Parliament and the Minister of Health, neither of whom is a researcher or research sponsor. Finally, the Minister's decisions will streamline processes, with each proposal to receive just one ethics committee review (c.f., up to thirteen reviews currently) to ensure proposal consistency with the country's one national set of review standards.