

Strengthening Australia's framework for research oversight

All stakeholders should contribute to enhancing Australia's guidelines for ethical research

Health and medical research involving human participants in Australia has been subject to guidelines promulgated by the National Health and Medical Research Council (NHMRC) since 1966. Currently, the key documents are the *National statement on ethical conduct in research involving humans* (1999)¹ and the *Joint NHMRC/AVCC statement and guidelines on research practice* (1997).² The former, better known as the "National Statement", is endorsed by a number of peak national bodies, including the Australian Research Council (ARC) and the Australian Vice Chancellors' Committee (AVCC). The "Joint Statement" is issued under the aegis of the NHMRC and the AVCC. The National Statement encompasses the ethical principles to be followed in proposing research involving humans, and advises institutions on the requirements for establishing human research ethics committees (HRECs). The Joint Statement provides guidance on good research practice, including details related to data collection, authorship and publication, supervision and mentoring and like matters, as well as providing the framework by which institutions should handle allegations of research misconduct.

The system of oversight of human research based on these documents has been updated and modified from time to time and has served the nation reasonably well. However, the guidance provided in the documents has not been without its critics, and weaknesses in relation to the National Statement have been identified. These include under-resourcing of overworked HRECs,³ deficiencies in transparency and accountability of

HRECs,³ absence of explicit application of the guidelines to the private sector,³ the failure of institutions and their HRECs to accommodate the vast increase in multicentre research⁴ and the "one size fits all" process of ethical review.⁵ The provisions of the Joint Statement for handling research misconduct allegations were severely tested and found wanting in a high profile case in 2004;⁶ furthermore, compared with Scandinavian countries,⁷ the education of new researchers in research ethics is patchy, especially outside our universities.

As health and medical research has expanded in our teaching hospitals, there have been accusations that these institutions have not paid sufficient attention to the important task of research governance.⁸ In some instances, this has led to HRECs playing research governance roles for which they are neither equipped nor authorised — a development termed "mission creep".⁹ The National Statement was extended by agreement to cover human research beyond the health and medical field, such as sociology, criminology and the humanities.¹ However, this extension has led to criticisms of "ethics creep"; that is, the ethical review by HRECs of research of very low risk, thereby discouraging and frustrating some researchers and at the same time creating unnecessary work for HRECs.¹⁰

NHMRC guidelines are subject to regular review and any review includes obligatory public consultation. In addition, the Commonwealth *National Health and Medical Research Council Act 1992* requires that the NHMRC, its principal committees and any

1 Research governance

Research governance is the framework by which institutions support, monitor and attest to the safety, ethical acceptability and quality of the research they undertake. Standards which underpin effective research governance exist in the domains of ethics and law, science, information protection, health and safety, intellectual property and commercialisation, financial management and public relations.

For a more detailed discussion see reference.⁸ ◆

2 Education, training and induction*

"To maintain a culture of responsible research conduct, it is important that institutions provide induction, formal training and continuing education for all research staff, including students and research trainees. Training should cover research methods, ethics, principles of confidentiality, data storage and records retention, as well as regulation and governance. Training should also include the institution's policies and procedures regarding responsible research conduct, all aspects of this code, and the other sources of guidance that are available.

Smaller institutions may make joint arrangements for induction and training with other institutions."

* Extracted from reference.¹² ◆

working parties must "have regard" to any submissions received. Currently, both the National Statement and the Joint Statement are under active review by separate working parties of the NHMRC, the ARC and the AVCC. The two documents have already had an initial round of public consultation, and second draft revisions incorporating the responses to those consultations are now available for comment.^{11,12}

Both documents contain important new sections. The necessity for institutions which support research to have solid policies and practices of good research governance (Box 1) is emphasised in both documents. For most institutions, this requirement should not have significant cost implications; rather, it will be a matter of more formally identifying and allocating existing responsibilities and reporting lines.⁸

The draft revised National Statement¹¹ has been significantly modified. Researchers in fields beyond health and medical research should find it more responsive to their specific needs, and institutions should find it a more flexible document to use when deciding the level of independent review required for any research proposal. For health and medical researchers, interest will focus on several areas of new guidance, including risk in research and research with human stem cells, as well as extensively rewritten chapters such as those on data banks, clinical trials, genetics and tissue. Institutions and their HRECs should carefully consider the new final section on "Processes for research governance and ethical review", which proposes significant alterations to matters including complaints handling, annual compliance reporting and monitoring of research.

The draft revised Joint Statement, now to be known as the *Australian code for the responsible conduct of research*¹² makes the roles and responsibilities of institutions and researchers much clearer. It calls for institutions to be much more active in providing education and induction of researchers in the realms of research ethics, research methods and research governance (Box 2). It spells out the conditions under which authorship of research publica-

tions is legitimate. It covers general principles for good research practices, data and records management, supervisory responsibilities, publication and dissemination of findings, peer review and conflicts of interest.

Importantly, the new "Australian Code" presents a new look at dealing with research misconduct and fraud, including a proposed new framework for institutional responsibilities in handling allegations of research misconduct. This section was not available in the first round of public consultation, but incorporates material discussed at a stakeholder workshop on research misconduct held in Canberra in October 2005. It provides a more encompassing definition of research misconduct and calls for institutions to appoint "advisers on research integrity" as well as a senior "designated person" to take responsibility for the preliminary investigation of research misconduct allegations. For allegations of a serious nature, the inquiry established by an institution must be made up of people independent of the institution and must follow procedural fairness principles.

We believe that these two draft documents herald a new era in the governance of research involving humans in Australia. At a time when commercial and other pressures on researchers may be increasing the risk of fraud and misconduct,¹³ it is crucial that our system for the oversight of research be sufficiently robust to protect participants and maintain community confidence in research. By emphasising the importance of research governance, reasserting the important roles that researchers and institutions have in the system of oversight, insisting on mechanisms for handling allegations of misconduct that are independent, prompt, fair and just, and making the processes of ethical review more responsive to the needs of different fields of research, the revised documents should be welcomed by all stakeholders.

It is important that these stakeholders, including researchers, institutional leaders, sponsors of research, potential research participants, federal, state and territory governments and interested members of the community, consider and comment on the two draft documents. Input from as many stakeholders as possible in this second public consultation will enhance the guidelines and bring a greater sense of shared ownership.

Warwick P Anderson

Head, School of Physiology, Monash University, Melbourne, VIC

Christopher D Cordner

Head, Department of Philosophy, University of Melbourne
Melbourne, VIC

Kerry J Breen

Chair, Australian Health Ethics Committee, Melbourne, VIC
kerrybreen@access.net.au

1 National statement on ethical conduct in research involving humans. Canberra: National Health and Medical Research Council, 1999. Available at: <http://www.nhmrc.gov.au/publications/synopses/e35syn.htm> (accessed Jan 2006).

2 Joint NHMRC/AVCC statement and guidelines on research practice. Canberra: National Health and Medical Research Council, 1997. Available at: <http://www.nhmrc.gov.au/funding/policy/researchprac.htm> (accessed Jan 2006).

3 Essentially yours: the protection of human genetic information in Australia. Canberra: Australian Law Reform Commission and Australian Health Ethics Committee, 2003. (Report ALRC96.) Available at: <http://www.alrc.gov.au/publications/finalreps.htm> (accessed Jan 2006).

4 Roberts LM, Bowyer L, Homer CS, Brown MA. Multicentre research: negotiating the ethics approval obstacle course [letter]. *Med J Aust* 2004; 180: 139.

EDITORIALS

- 5 Israel M. Ethics and the governance of criminological research in Australia. Sydney: NSW Bureau of Crime Statistics and Research, 2004. Available at: [http://www.lawlink.nsw.gov.au/bocsar1.nsf/files/r55.pdf/\\$file/r55.pdf](http://www.lawlink.nsw.gov.au/bocsar1.nsf/files/r55.pdf/$file/r55.pdf) (accessed Jan 2006).
- 6 Van Der Weyden MB. Managing allegations of scientific misconduct and fraud: lessons from the "Hall affair" [editorial]. *Med J Aust* 2004; 180: 149-150.
- 7 Riis P. Misconduct in clinical research — the Scandinavian experience and actions for prevention. *Acta Oncol* 1999; 38: 89-92.
- 8 Walsh MH, McNeil JJ, Breen KJ. Improving the governance of health research. *Med J Aust* 2005; 182: 468-471.
- 9 Improving the system for protecting human subjects: counteracting IRB "mission creep". The Illinois white paper. Urbana: Center for Advanced Study, University of Illinois, 2005. Available at: <http://www.law.uiuc.edu/conferences/whitepaper/> (accessed Dec 2005).
- 10 Haggerty KD. Ethics creep: governing social science research in the name of ethics. *Qual Sociol* 2004; 27: 391-414.
- 11 National statement on ethical conduct in human research — second consultation draft. Canberra; National Health and Medical Research Council, 2006. Available at: <http://www.nhmrc.gov.au/ethics/human/ahec/projects/statementssec.htm> (accessed Feb 2006).
- 12 Australian code for conducting research — consultation draft #1. Canberra: National Health and Medical Research Council, 2004. Available at: <http://www.nhmrc.gov.au/funding/policy/code.htm> (accessed Feb 2006).
- 13 Breen KJ. Misconduct in medical research: whose responsibility? *Intern Med J* 2003; 33: 186-191. □