

## MAINTAINING COMMUNITY TRUST IN BIOMEDICAL RESEARCH INVOLVING HUMANS

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‘With the public trust, everything is possible. Without it, nothing is possible’  
Abraham Lincoln<sup>1</sup>

### I TRUST AND MISTRUST IN BIOMEDICAL RESEARCH

The Australian community has had generally little reason to mistrust its biomedical researchers.<sup>2</sup> The existing levels of trust have been well earned by researchers who have demonstrated altruism, dedication to discovery and serving the common good. A recent survey indicates that our researchers remain committed to these ideals.<sup>3</sup> Australian researchers have also enjoyed significant success in discovery but have been criticised for not sufficiently commercialising those findings.<sup>4</sup> Internationally, there have been waves of concern about medical research.<sup>5</sup> Most recently, a further wave of concern arose in the United States after the reports of two deaths of young persons enrolled in research studies.<sup>6</sup> It has been suggested that conflicts of interests relating to commercialisation pressures on researchers may have indirectly been a factor in one of these deaths.<sup>7</sup> These and other pressures and the development of research endeavours

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1 Patricia E Bauer, ‘A Few Simple Truths about your Community IRB’ (2001) 23(1) *IRB: Ethics and Human Research* 7.

2 Notable exceptions to this comment include the findings against Dr William McBride, which led to his medical deregistration in NSW, and the allegations against Professor Michael Briggs at Deakin University in Victoria. An account of both cases can be found in Lock, Wells and Farthing, below n 5.

3 Research Australia Ltd, *Health and Medical Researcher Opinion Poll* (2003) <<http://www.researchaustralia.org>> at 20 November 2003.

4 Hamilton Moses, Abbey Perumpanani and Jon Nicholson, ‘The Research Enterprise. Collaborating with Industry: Choices for Australian Medicine and Universities’ (2002) 176 *Medical Journal of Australia* 543.

5 See Stephen Lock, Frank Wells and Michael Farthing (eds), *Fraud and Misconduct in Biomedical Research* (3<sup>rd</sup> ed, 2001).

6 Kerry Breen, ‘Misconduct in Medical Research: Whose Responsibility?’ (2003) 33 *Internal Medicine Journal* 186.

7 Moses, Perumpanani and Nicholson, above n 4.

with higher risks, all of which may jeopardise community trust, need to be acknowledged (see below). In response, greater attention may need to be focussed on the systems in place to protect research participants and to promote ethical conduct by researchers.

## II THE EXISTING AUSTRALIAN SYSTEM FOR THE ETHICAL OVERSIGHT OF RESEARCH INVOLVING HUMANS

The Australian system of ethical oversight of human biomedical research is founded on two key documents: the National Statement on Ethical Conduct in Research Involving Humans issued by the National Health and Medical Research Council ('NHMRC') in 1999<sup>8</sup> and the Statement and Guidelines on Research Practice jointly issued by the NHMRC and Australian Vice-Chancellors Committee ('AVCC') in 1997.<sup>9</sup> The former document, colloquially known as the 'National Statement', is the successor of the previous NHMRC Statement on Human Experimentation first issued in 1966. The National Statement fulfils a requirement of the *National Health and Medical Research Council Act 1992* (Cth) ('*NHMRC Act*'), which in ss 8(1) and (2) provides that the Council must issue guidelines for the conduct of research involving humans and do so precisely in the form prepared by the Australian Health Ethics Committee ('AHEC'), a principal committee of the Council. The membership categories of AHEC are stipulated in the *NHMRC Act*. The Act also stipulates that AHEC must undertake public consultation in preparing ethical guidelines (the 1999 National Statement was the result of two rounds of public consultation over the period 1996–99).

The National Statement derives its status from the NHMRC policy that research funds can only be awarded to institutions which establish and maintain human research ethics committees ('HRECs') in accordance with the National Statement. The National Statement provides that no research involving humans can proceed unless the research proposal has been approved by a HREC. HRECs must provide annual reports to the NHMRC, via AHEC, verifying that the HREC has remained in compliance with the National Statement. The NHMRC has the power to withdraw all research funding if an institution and its HREC are found to be non-compliant with the National Statement.

The primary purpose of the National Statement is to protect the welfare of research participants and its secondary purpose is to 'facilitate research that is or will be of benefit to the researcher's community or to humankind'.<sup>10</sup> The Statement outlines the ethical principles which are to guide biomedical and other human research (the first being researcher integrity), provides the framework and processes to be followed by HRECs and lays down membership categories for

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8 NHMRC, National Statement on Ethical Conduct in Research Involving Humans (1999) <<http://www.health.gov.au/nhmrc/publications/humans/contents.htm>> at 20 November 2003.

9 NHMRC and AVCC, *Statement and Guidelines on Research Practice* (1997) <<http://www.health.gov.au/nhmrc/research/general/nhmrcavc.htm>> at 20 November 2003.

10 NHMRC, above n 8, preamble.

the HRECs. In addition the document has separate chapters which provide more specific ethical guidance for research involving certain groups of persons and research in specific fields, such as genetics and clinical trials. The National Statement is to be reviewed every five years.

Since the introduction of ethical review of research proposals by ethics committees, the committees have been predominantly based within institutions. As a result Australia now has over 200 HRECs which have notified their existence to AHEC. The minimum membership of a HREC is seven persons and over 2000 people serve as members, the vast majority on an honorary basis. In addition to the guidelines provided via the NHMRC, AHEC supports the work of HRECs in a number of practical ways.<sup>11</sup>

The second document, the joint 1997 NHMRC and AVCC statement is directed at researchers and provides clear standards of what good research practice entails. This document also indicates the steps an institution is to follow if allegations of scientific misconduct are made against an individual researcher.

The existing system for the oversight of research has been examined recently by the joint inquiry conducted by the Australian Law Reform Commission ('ALRC') and the AHEC into the protection of human genetic information. The final report of the enquiry entitled '*Essentially Yours*' canvasses the strengths and weaknesses of the system of oversight for genetic research and makes a number of recommendations for improvement.<sup>12</sup>

In addition to the role of these two key national documents issued by the NHMRC, there are other powerful influences on the ethical conduct of researchers. These include peer review which accompanies presentation of findings at scientific meetings and when reports are submitted for publication,<sup>13</sup> as well as institutional oversight. Biomedical scientists are very aware of the risks of loss of reputation, position, peer approval and research grants should they be found to have engaged in scientific misconduct.

In addition, research involving therapeutic goods (such as pharmaceuticals and medical devices) is closely regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* (Cth). This legislation provides a range of controls, some of which have implications for HRECs.<sup>14</sup>

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11 A term of reference for AHEC is to 'advise, support and facilitate the work of HRECs'. Support provided includes national and regional training workshops, a handbook, a regular bulletin and an advice 'hotline'.

12 ALRC and AHEC, *Essentially Yours: The Protection of Human Genetic Information in Australia*, Report No 96 (2003) ('ALRC and AHEC Final Report').

13 International Committee of Medical Journal Editors, 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals' (1997) 277 *Journal of the American Medical Association* 927.

14 Therapeutic Goods Administration, *Human Research Ethics Committees and the Therapeutic Goods Legislation* (2001).

### III THE STRENGTHS AND WEAKNESSES OF THE EXISTING ETHICAL REVIEW PROCESSES

The strengths and weaknesses of the Australian system have been identified by many commentators<sup>15</sup> and are recognised by AHEC and NHMRC. The strengths include the following:

- (1) The HREC system has to date served the community and researchers very well;
- (2) The system is based on the mainly voluntary and dedicated contributions of over 2000 members from a broad range of community backgrounds and is thus not costly;
- (3) The institutional structure locates responsibility close to the conduct of the research;
- (4) The balance of community and institutional members of HRECs provides an appropriate level of oversight of human research; and
- (5) As the ethical guidelines are not embedded in legislation, there is both flexibility of application and an emphasis on ethical principles, not on simply following the letter of the law.

The weaknesses are seen to be more numerous and include:

- (1) The system was designed for an era when most research was undertaken on a small scale at a single institution and creates unnecessary obstacles for modern multi-centre research;
- (2) The voluntary nature of the system and its dependence on public research funding for sanctions means that private researchers have little incentive to comply;
- (3) The system is under resourced and over loaded;
- (4) HRECs are not sufficiently skilled and as a result outcomes of ethical review at times vary unpredictably (such differences are readily highlighted to those researchers who submit multi-centre research proposals to the HRECs of several institutions);
- (5) HRECs lack transparency and accountability;
- (6) Resources for ongoing monitoring of research are minimal and monitoring relies predominantly upon self reporting by researchers;
- (7) The annual self reporting of HREC compliance with the National Statement does not sufficiently assure the community of the quality of the ethical review by any HREC; and
- (8) There are difficulties in recruiting new members to HRECs, partly related to significant increases in HREC workloads.

To these weaknesses could be added the lack of any systematic requirement for, or approach to, the provision of training in research ethics to young researchers.

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15 See, eg, ALRC and AHEC Final Report, above n 12; Volume 21(3) of the *Monash Bioethics Review* (2001), which contains a range of views on the Australian system of ethical review of research.

#### **IV NEWLY EMERGING PRESSURES ON BOTH RESEARCHERS AND THE ETHICAL REVIEW SYSTEM**

It should be clear to the community that our society now places even greater expectations upon our researchers. Not only are researchers to be concerned about advancing science and winning research grants, but they are encouraged by governments and employing public institutions to seek to patent their discoveries, commercialise their findings and become entrepreneurs who are prepared to establish or participate in venture capital 'start-up biotech' companies. They live in a world of 'publish or perish' when viewed from the perspective of career advancement and yet the institutional demands for seeking to patent discoveries can inhibit publication and sharing of research data (the traditional manner in which science collectively makes progress on our behalf) before those patents are granted.

Internationalisation and international competition in research also compounds the difficulties for researchers and HRECs. This is most obvious for research into new drugs sponsored by pharmaceutical companies. Companies are attracted to conduct segments of international drug trials in Australia for reasons of the quality of our health care system, our clinical scientists and our sound ethical review, but those same companies closely monitor the performance of such trials and make it very clear that the trials can be taken elsewhere if more favourable circumstances arise. There is, in effect, international competition for the resource of suitable patients for clinical trials and for the funds such trials bring into a country.

Quite recently HRECs in Australia have had to learn to work with the new privacy laws which are not aligned between state and federal jurisdictions, adding another pressure to an overtaxed system. Another area of pressure on the ethical oversight and monitoring of research is the apparent increase in the complexity and/or risks of certain types of research. These areas include gene therapy, genetic research generally (complex because of the family and privacy dimensions) and xenotransplantation.<sup>16</sup>

#### **V WAYS FORWARD TO ENHANCE AND SIMPLIFY THE ETHICAL REVIEW PROCESS**

Several means of enhancing the HREC system and responding to identified weaknesses have been under consideration or already acted upon by AHEC and the NHMRC. In the last three years, much more has been done to provide support and training for HREC members. These initiatives have included regional and national training workshops for HRECs, the publication of the *Human Research Ethics Handbook*, the publication of a regular *Bulletin* and the issuing of advice

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16 NHMRC, *Draft Guidelines and Discussion Paper on Xenotransplantation*, Public Consultation Document (2002).

on problematic topics such as quality assurance studies.<sup>17</sup> AHEC has actively supported several state initiatives to foster more efficient ethical review of multi-centre research. Considerable work has been done towards the creation of an electronically based national common application form for submitting proposals to HRECs.

Arising in part from the ALRC and AHEC Final Report and now incorporated into the NHMRC Strategic Plan for 2003–2006 tabled recently in federal Parliament,<sup>18</sup> the following new initiatives will be developed and publicly consulted upon by AHEC:

- (1) The introduction of a quality assurance framework for HRECs with the potential in the longer term to be translated into a system of external accreditation of HRECs;
- (2) Processes for centralising the review of multi-centre research;
- (3) Further strengthening of the training opportunities provided for HREC members; and
- (4) A revision of the National Statement during this triennium.

In addition, AHEC plans to work closely with another principal committee of the NHMRC, the Research Committee, in regard to researcher training in ethics, institutional responsibilities for the governance of research and in the planned revision of the joint NHMRC and AVCC Statement and Guidelines for Research Practice.

## VI SO ON WHAT DOES COMMUNITY TRUST DEPEND?

Lincoln's recognition of the importance of public trust to achievement prompts the question: on what does public trust in biotechnological research depend? In Australia, at present, it could be said that this trust depends upon the generally good reputation of our researchers, the absence of any persistent reasons for distrusting them, and the success of the mostly voluntary system of ethical oversight. The challenge presented by newly emerging pressures upon our researchers will be to ensure that this trust is maintained. I believe that this can be achieved but will require several steps to strengthen the existing system of ethical oversight while maintaining its flexibility and quality. The alternate approach involving a statutory system with strictly policed controls, and greatly increased costs, may seem attractive to regulators, but can we predict what benefits or drawbacks this might have on the quality, creativity and productivity of Australian research?

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17 NHMRC, *When Does Quality Assurance in Health Care Require Independent Ethical Review?* (2003).

18 NHMRC, *Strategic Plan 2003–2006*, <<http://www.nhmrc.gov.au/publications/pdf/nh46.pdf>> at 20 November 2003.