Chapter 9
Human Research Ethics Guidelines in Australia

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Introduction

This chapter describes the human research ethics guidelines that have been issued by national government agencies in Australia between 1966 and the present time, the identity, authority and composition of the issuing agencies, the processes that they adopted in guideline development and promulgation together with some reflections on those processes.

In the section "Human research ethics guidelines in Australia" we present a chronological history of guidelines that address all or part of human research and identify the national agencies that issued them. In the second section, we describe those agencies, their establishment, their authority and their membership and reflect on these. In the third section, we discuss some of the processes that those agencies used in developing, issuing and promulgating guidelines and in the fourth section we reflect on the strengths and weaknesses of those processes.

We have only briefly noted the issue of ethical guidelines for special areas of research. Most important of these are the guidelines in regard to health research involving Aboriginal and Torres Strait Islander peoples. The history of their development is important and complex and deserves to be told in detail and from an indigenous perspective.

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Human Research Ethics Guidelines in Australia

Australian activity in ethical review of human research began during the 1960s and was related closely to the federal government funding of medical research. Through the passage of the *Medical Research Endowment Fund Act 1937*, the Commonwealth Parliament had established the Medical Research Endowment Fund. Responsibility for the fund was vested in the Minister for Health, who could determine its use for medical research and in the training of persons in medical research, acting on the advice of the National Health and Medical Research Council (NHMRC), constituted in 1936, by an Order-in-Council.

In 1966, the NHMRC issued the *Statement on Human Experimentation (*the *Statement)* (NHMRC 1966) that expressly drew on the 1964 *Helsinki Declaration* of the World Medical Association (WMA 2000). It was amended in 1973 on advice from a subcommittee of the Council and in 1976 by the Medical Research Advisory Committee, at which time Supplementary Note 1 was added to make the requirement for review by an institutional ethics committee (IEC) explicit. The opening paragraphs were also amended to indicate that the *Statement* was applicable to all human subject research, encompassing medical, social and behavioural research. The paragraphs of the *Statement* addressed the following matters:

Scientific design
Advantages and risks
Prior laboratory research
Duty to research subjects
Qualifications of researchers
Novel procedures
Information and consent
Withdrawal from research
Discontinuance of research
Consultation with subjects
Dependancy
Medical ethics review committee review
NHMRC grant applications to have ethics committee approval

The *Statement* was revised and Supplementary Notes added in 1982 and in following years in the manner and on the matters indicated in Table 9.1.

All of these revisions and additions were issued by the NHMRC on the advice of the Medical Research Ethics Committee that had been formed in 1982.

In 1986, the NHMRC, together with the Menzies Foundation, convened a conference on “Research Priorities in Aboriginal Health”. That conference agreed to the subsequent convening of a National Workshop on Ethics of Research in Aboriginal Health that was held in 1987 and, in 1988, the NHMRC issued *Some*

Table 9.1 Changes to the statement on human experimention 1982–1992

1982	Statement revised, adding paragraphs on: protocol to state ethical issues; children and the mentally ill; fully informed research team members; payments to volunteers
	Supplementary notes revised:
	1. Institutional ethics committees
	Supplementary notes added:
	2. Children, the mentally ill
	3. Therapeutic trials
	4. In vitro fertilization and embryo transfer
1983	Supplementary notes added:
	5. Human fetus and human fetal tissue
1985	Supplementary notes revised:
	1. Institutional ethics committees
	Supplementary notes added:
	6. Epidemiological research
1987	Supplementary notes revised:
	2. Children and the mentally ill
	3. Clinical trials
	Supplementary notes added:
	7. Somatic cell gene therapy
1992	Supplementary notes revised:
	1. Institutional ethics committees
	2. Children and the mentally ill
	4. In vitro fertilization and embryo transfer

Advisory Notes on Ethical Matters in Aborignal Research (NHMRC 1988) that were arranged under the following headings:

The Process of Consultation
Social and Gender Issues
Communication and Consent
Community Benefit and Employment of Local People
Ownership and Publication of Materials
Exploitation of Community Resources

In 1991, the NHMRC issued interim *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (Interim Guidelines)* (NHMRC 1991), which superseded the *Advisory Notes*, and were arranged under the headings of Consultation, Community Involvement and Publication of Data. It is apparent from the text of this document that the Medical Research Ethics Committee of the NHMRC contributed to their development.[1]

[1] Some published versions of this document added the word "Interim" to the title, in recognition of the need for further consultation and development.

In May 1991, the Therapeutic Goods Administration (TGA), the federal government agency responsible for the admininstration of the Therapeutic Goods Act 1989 that governs the approval of new drugs or therapeutic devices, isssued guidelines on Clinical Trials of Drugs and, in December of that year, Guidelines for Good Clinical Research Practice. These were superseded in 2000 by *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* (TGA 2000) that guides the conduct of clinical trials. In 1992, regulations under the Therapeutic Goods Act required that clinical trials of new drugs or devices could only proceed if favourable advice had been received from an institutional ethics committee that had notified its existence to the NHMRC (Therapeutic Goods Regulations 1990, 12 (1A), Schedule 5A).

In 1996, the NHMRC issued *Ethical guidelines on assisted reproductive technology* (NHMRC 1996a) which replaced Supplementary Note 4 to the *Statement*. Although these guidelines addressed the clinical use of assisted reproductive technology (ART), they also contained a section on research. They were developed by the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC established by the NHMRC Act (1992).

Following the recommendation in the *Report of the review of the functioning of institutional ethics committees* (NHMRC 1996b), the *Statement* was revised between 1996 and 1999 and issued in 1999 under the new title of the *National Statement on Ethical Conduct in Research Involving Humans* (*National Statement 1999*). These guidelines were developed by the AHEC. They were issued by the NHMRC with the endorsement of the Australian Vice-Chancellors' Committee (now Universities Australia), the Australian Research Council (ARC), the Australian Academy of the Humanities, the Australian Academy of Science, and the Academy of the Social Sciences in Australia and the support of the Academy of Technological Sciences and Engineering. The *National Statement 1999* was arranged in the following sections:

Preamble

1. Principles of Ethical Conduct
2. Human Research Ethics Committees
3. Multi-centre research
4. Research Involving Children and Young People
5. Research Involving Persons with an Intellectual or Mental Impairment
6. Research Involving Persons Highly Dependent on Medical Care
7. Research Involving Persons in Dependent or Unequal Relationships
8. Research Involving Collectivities
9. Research Involving Aboriginal and Torres Strait Islander Peoples
10. Research Involving Ionising Radiation
11. Research Involving Assisted Reproductive Technology
12. Clinical Trials
13. Innovative Therapy or Intervention
14. Epidemiological Research

15. Use of Human Tissue Samples
16. Human Genetic Research
17. Research Involving Deception of Participants, Concealment of Covert Observation
18. Privacy of Information
19. Intellectual Property

Consistent with its policy of revising guidelines after 5 years, the NHMRC commenced a revision of the *Interim Guidelines* in 2000 and, in 2003, issued *Values and Ethics: Ethical Guidelines for the Conduct of Aboriginal and Torres Strait Islander Health Research (Values and Ethics)* (NHRMC 2003). These were arranged under six values: Reciprocity, Respect, Equality, Responsibility, Survival and Protection and Spirit and Integrity. In 2005, these were supplemented by the issue of *Keeping Research on Track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics (Keeping Research on Track)* (NHMRC 2005).

In 2000, the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) published *Guidelines of Ethical Research in Indigenous Studies (AIATSIS Guidelines)* (AIATSIS 2000).

In 2004, following significant legislative change in Australia concerning ART, the AHEC revised the 1996 guidelines on ART and the NHMRC issued *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines)* (NHMRC 2004).

In the exercise of its policy of guideline revision, the NHMRC commenced a revision of the *National Statement 1999* in 2005. This revision was conducted jointly by the NHMRC, the ARC and the Australian Vice-Chancellors' Committee (now Universities Australia (UA)) who together issued the *National Statement on Ethical Conduct in Human Research* in 2007 (*National Statement*) (NHMRC 2007), which contains the present primary national human human research ethics guidelines. The *National Statement* (NHMRC 2007a) is arranged as follows:

A User Guide
Preamble
Purpose, scope and limits of this document
Section 1 Values and principles of ethical conduct
Section 2 Themes in research ethics: risk and benefit, consent
Chapter 2.1 Risk and benefit
Chapter 2.2 General requirements for consent
Chapter 2.3 Qualifying or waiving conditions for consent
Section 3 Ethical considerations specific to research methods or fields
Chapter 3.1 Qualitative methods
Chapter 3.2 Databanks
Chapter 3.3 Interventions and therapies, including clinical and non-clinical trials, and innovations

Chapter 3.4 Human tissue samples
Chapter 3.5 Human genetics
Chapter 3.6 Human stem cells
Section 4 Ethical consideration specific to participants
Chapter 4.1 Women who are pregnant and the human foetus
Chapter 4.2 Children and young people
Chapter 4.3 People in dependent or unequal relationships
Chapter 4.4 People highly dependent on medical care who may be unable to give consent
Chapter 4.5 People with a cognitive impairment, an intellectual disability, or a mental illness
Chapter 4.6 People who may be involved in illegal activities
Chapter 4.7 Aboriginal and Torres Strait Islander Peoples
Chapter 4.8 People in other countries
Section 5 Processes of research governance and ethical review
Chapter 5.1 Institutional responsibilities
Chapter 5.2 Responsibilities of HRECs, other ethical review bodies, and researchers
Chapter 5.3 Minimising duplication of ethical review
Chapter 5.4 Conflicts of interest
Chapter 5.5 Monitoring approved research
Chapter 5.6 Handling complaints
Chapter 5.7 Accountability

Finally, and again in response to national legislative changes, the AHEC revised some parts of the ART guidelines and the NHMRC issued these revised guidelines as *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines)* (NHMRC 2007a).

The National Agencies that Developed the Human Research Ethics Guidelines: Their Establishment, Authority and Membership

National Health and Medical Research Council

Before 1992

Human research ethics guidelines in Australia had their origins in medical and health research. Consequently, the central agency for human research ethics guidelines since 1996 has been the NHMRC and two of its committees. The NHMRC

was initially constituted by an Order-in-Council of the Federal Government to provide advice to the Minister for Health in relation to the expenditure of the Medical Research Endowment Fund. The terms of reference of the NHMRC in 1936 were:

- To advise Commonwealth and State governments on all matters of public health legislation and administration, on matters concerning the health of the public and on medical research.
- To advise the Commonwealth government as to the expenditure of money specifically appropriated as money to be spent on the advice of this Council.
- To advise the Commonwealth government as to the expenditure of money to be spent on medical research and as to projects of medical research generally.
- To advise Commonwealth and State government on the merits or reputed cures or methods of treatment which are from time to time brought forward for recognition (Commonwealth of Australia, Order-in-Council, 24 September 1936).

The development and issue of human research ethics guidelines by the NHMRC between 1966 and 1992 appears to have been in exercise of these broad terms of reference. Unchanged for 55 years, they did not include any reference to the ethics of human research or to a requirement for public consultation.

The membership of the NHMRC then comprised:

- The Commonwealth Director-General of Health (as Chair),
- 2 officers of the Commonwealth Department of Health,
- the heads of the departments of health of the Australian States,
- representatives from the federal Council of the British Medical Association (soon to be renamed the Australian Medical Association), the Royal Australasian College of Surgeons, the Royal Australasian College of Physicians, the Australian Council of the Royal College of Obstetricians and Gynaecologists, the Australian Dental Council, the 4 Australian universities having medical schools, and
- a prominent layman and laywoman. (Commonwealth of Australia, Order-in-Council, 24 September 1936)

It seems likely that the issue of the *Statement* was influenced by events overseas, particularly the issue by the World Medical Association of the Declaration of Helsinki in 1964 (WMA 1964).

In 1972, the NHMRC appointed the Ethics in Clinical Research Subcommittee to examine the need to revise the existing *Statement* and in 1976 this subcommittee reported to the Council recommending revisions.

The revision of the *Statement* in 1976 that stated that "institutions undertaking medical research on human subjects should have a medical ethics review committee" seems likely, again, to have been influenced by events overseas, including the enactment of the National Research Act of the United States in 1974 and the 1975 revision of the Declaration of Helsinki with its explicit requirement for prior ethics committee review of research.

In October 1982, the NHMRC adopted a report from a Working Party on Ethics in Medical Research and, in accordance with its recommendation, established the

Medical Research Ethics Committee (MREC) as a subcommittee of its Research Committee and gave to it the functions:

- to assist the Council by keeping under review and making recommendations to Council on ethical principles in human experimentation and
- to facilitate, keep under review and report to the Council on the work of institutional ethics committees and respond to questions raised by them.

The nine members of this committee comprised:

- A chair – in practice a professor of medicine
- 3 medical scientists
- 2 laywomen
- A non-medical scientist, and
- 2 lawyers. (NHMRC 1987)

The MREC was the source of advice to the NHMRC on changes and additions to the *Statement* between 1982 and 1992. It is also apparent from the text of the *Interim Guidelines* (NHMRC 1991), referred to above, that the MREC contributed to their development. The committee was disbanded in 1992 as a result of the passage of the *National Health and Medical Research Council Act 1992* (NHMRC Act) and the formation of the AHEC.

Between 1992 and 2006

In 1992, the Commonwealth Parliament passed the NHMRC Act which established the NHMRC as a statutory agency and also established the AHEC as a principal committee of the Council.

The NHMRC's general functions were identified in the legislation as:

(a) to inquire into, issue guidelines on, and advise the community on matters relating to:

  (i) The improvement of health; and
  (ii) the prevention, diagnosis and treatment of disease; and
  (iii) the provision of health care; and
  (iv) public health research and medical research; and
  (v) ethical issues relating to health; and

(b) to advise, and make recommendations to, the Commonwealth, the States and Territories on the matters referred to in paragraph (a); and
(c) to make recommendations to the Commonwealth on expenditure:

  (i) on public health research and training; and
  (ii) on medical research and training; including recommendations on the application of the Fund; and

(d) any functions incidental to any of the foregoing.

(2) Subject to the direction of the Minister, the Council has the general administration of this Act.

The specific function in relation to human research ethics guidelines was in section 8 of the Act, which provided:

> 8 (1) Without limiting any of the matters on which the Council may issue guidelines under subparagraph 7(1)(a)(v), the Council must issue guidelines under that subparagraph for the conduct of medical research involving humans.
> (2) The guidelines for the conduct of medical research involving humans must be issued precisely as developed by the Principal Committee known as the Australian Health Ethics Committee and provided to the Council for the purpose. (National Health and Medical Research Council Act. (Cwth) 1992, s. 8(2) (since amended))

Medical research was defined as "including the laboratory-based or clinical study, or group or community-based study of the causes, treatment and prevention of human diseases and also includes dental research" (NHMRC Act 1992, s. 4).

In this way, the Act contained the first formal grant of authority for any national agency to issue human research ethics guidelines, limited to those relating to medical research.

The functions of the Australian Health Ethics Committee were stated in the Act to be:

(a) to advise the Council on ethical issues relating to health; and
(b) to develop and give the Council guidelines for the conduct of medical research involving humans; and
(c) such other functions as the Minister from time to time determines. (NHMRC Act 1992 s. 35 (3))

The membership of the NHMRC during this period was prescribed as:

(a) the Chairperson;
(b) the Secretary to the Council;
(c) each person who is, or is acting as, the Chairperson of a Principal Committee and who is not a member of the Council because of the operation of any other paragraph;
(d) an officer of each State or Territory health instrumentality nominated by the Minister having administrative responsibility for the instrumentality concerned;
(e) an officer of the Department nominated by the Minister;
(f) a person:
    (i) nominated by the Aboriginal and Torres Strait Islander Commission; and
    (ii) having knowledge of the health needs of Aboriginal persons or Torres Strait Islanders;
(g) a person with expertise in health care training;

(h) a person with knowledge of professional medical standards and expertise in post-graduate medical training;
(i) a person with a background in, and knowledge of, the medical profession;
(j) a person with a background in, and knowledge of, the nursing profession;
(k) an eminent scientist:

  (i) who has knowledge of public health research and medical research issues; and
  (ii) who has no current connection with the Council;

(l) a person with a background in, and knowledge of, the trade union movement;
(m) a person with a background in, and knowledge of, business;
(n) a person with a background in, and knowledge of, consumer issues;
(o) a person with knowledge of the needs of users of social welfare services;
(p) a person with knowledge of environmental issues;
(q) a person with a background in, and knowledge of, public health issues;
(r) no more than 2 other persons with expertise relevant to the functions of the Council. (NHMRC Act 1992, s.20)

Although the Council had a formal role in the issuing of human research ethics guidelines, its membership is relevant because, while the Council could only issue research ethics guidelines precisely as developed by the AHEC, it was not prevented from refusing to issue guidelines. If, for example, the Council disagreed with such guidelines, it could decline to issue them and request AHEC to re-consider them. However, it is clear that the intention of the Act was that the primary work was to be done by the AHEC.

The membership of AHEC at this time was prescribed as:

(a) the Chairperson;
(b) a person with knowledge of the ethics of medical research;
(c) a person who has expertise in law;
(d) a person who has expertise in philosophy;
(e) a person who has expertise in religion;
(f) a person who has experience in medical research;
(g) a person who has experience in public health research;
(h) a person who has experience in social science research;
(i) a person who has experience in clinical medical practice;
(j) a person who has experience in nursing or allied health practices;
(k) a person with knowledge of the regulation of the medical profession;
(l) a person with understanding of health consumer issues;
(m) a person with understanding of the concerns of people with a disability;
(n) no more than 2 other persons with expertise relevant to the functions of the Committee. (NHMRC Act 1992, s.36)

The Act further required that the membership must include people who were members of the other principal committees. The appointments were to be made by the Minister who was required to consult with members of the Australian Health

Ministers Conference in relation to appointment of the Chair and of the category (b) member and, in relation to all the other categories, consider nominations from the following relevant professional bodies specified in regulations under the Act: Law Council of Australia; Academy of the Social Sciences in Australia; Australian Academy of Science; Australian Academy of the Humanities; Australian Catholic Bishops Conference; Australian Council of Churches; Australian Federation of Islamic Councils Inc.; Jewish Board of Deputies; Public Health Association of Australia Inc.; The Australian Medical Association Ltd; The Committee of Presidents of Medical Colleges; Australian Nursing Federation; Australian Council of Deans of Health Sciences; Royal College of Nursing, Australia; Australian Medical Council; The Committee of Presidents of Medical Colleges; Consumers' Health Forum of Australia Inc.; Disabled Peoples International (Australia) Limited; and National Council on Intellectual Disability Inc.

From 2006 to the Present

Amendments to the NHMRC Act in 2006 made by the *National Health and Medical Research Council Amendment Act, (Cwth) 2006* gave the Chief Executive Officer (CEO) the obligation to issue human research guidelines when they are provided to the CEO for that purpose by the Council. Although these amendments retain the requirement that the Council may only provide such guidelines precisely as developed by AHEC, they also state that "the Council is not obliged to provide particular guidelines referred to in subsection (2) to the CEO merely because the Australian Health Ethics Committee has provided the guidelines to it in accordance with this Division" (National Health and Medical Research Council Act. (Cwth) 1992, s.10(3)). Accordingly, although AHEC is given responsibility to "develop and give to the Council" (NHMRC Act 1992, s. 35(3)(b)) such guidelines, the Council may decide not to give those guidelines to the CEO to be issued.

Since 2006, according to its establishing statute, the NHMRC is formally comprised of the CEO, the Council, the committees and the staff.

The Act does not contain any qualifications for the CEO, only that the appointment is to be by the Minister. The membership of the Council is now prescribed as:

(a) the Chair;
(b) the chief medical officer for the Commonwealth;
(c) the chief medical officer for each State and Territory;
(d) a person with expertise in the health needs of Aboriginal persons and Torres Strait Islanders;
(e) a person with expertise in consumer issues;
(f) a person with expertise in business;
(g) at least 6, but no more than 11, persons with expertise in one or more of the following:

    (i) health care training;
    (ii) professional medical standards;

(iii) the medical profession and post-graduate medical training;
(iv) the nursing profession;
(v) public health research and medical research issues;
(vi) public health;
(vii) ethics relating to research involving humans; other appropriate expertise. (NHMRC Act 1992, s. 20(2))

The definition of medical research is unchanged and that of "public health research" is:

> *"public health research"* includes the study of the health of a community or population for purposes directed at improving or protecting the health of that community or population. (NHMRC Act 1992, s. 4)

Although the membership of AHEC is unchanged, the previous requirement for consultation and consideration of nominations from identified bodies before appointment have been replaced with the requirement that those appointments are to be made by the Minister "after consulting appropriately". (NHMRC Act 1992, s. 41(1))

National Bioethics Consultative Committee

For a short period of time, Australia had a separate National Bioethics Consultative Committee (NBCC). It was established in 1988 by the Australian Health Ministers Conference and given the following terms of reference:

To provide advice and undertake studies on matters as requested by the Australian Health Ministers Conference (AHMC) on the ethical, legal and social issues arising from:

- reproductive technology including human embryo experimentation and the bearing of children;
- biomedical and health related research;
- the application of scientific and medical technology; and
- the provision and delivery of health services.

This body did not issue any guidelines about ethics in human research. It was disbanded in 1992 and its work was assumed by AHEC under the 1992 NHMRC Act. In practical terms, AHEC can be seen to be a pragmatic merging of the roles and membership of the NBCC and the MREC.

Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS)

In 1989, the Commonwealth Parliament passed the *Australian Institute of Aboriginal and Torres Strait Islander Studies Act*, establishing the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS). This agency replaced the

Australian Institute of Aboriginal Studies formed by legislation in 1964. The functions of AIATSIS include "to assist in training persons, particularly Aboriginal persons and Torres Strait Islanders, as research workers in fields relevant to Aboriginal and Torres Strait Islander studies" (*Australian Institute of Aboriginal and Torres Strait Islander Studies Act* 1989, s.5(d)). It appears that it is this function that has been used to develop and publish guidelines on the ethics of indigenous research.

Australian Research Council (ARC)

Although it had operated as an agency in earlier years, in 2001, the Commonwealth Parliament passed the *Australian Research Council Act*, establishing the current ARC. The Act provides that the functions of the Chief Executive Officer (CEO), as assisted by the Council are:

(a) to make recommendations to the Minister under section 52 in relation to which proposals should be approved as deserving financial assistance under Division 1 of Part 7;
(b) to administer the regimes of financial assistance provided for in Divisions 1 and 2 of Part 7;
(c) to provide advice to the Minister on research matters;
(d) any other functions conferred on the CEO by this or any other Act. (*Australian Research Council Act* 2001, s.33B)

The ARC is comprised of the CEO, designated committees and the staff. There is no specification of any personnel qualifications in the Act establishing the ARC.

Universities Australia (UA)

Universities Australia (UA) was established in 2007 as the industry peak body representing the university sector. It represents Australia's 39 universities in the public interest, both nationally and internationally and succeeds the organisation previously known as the Australian Vice-Chancellors' Committee (AVCC) that was formed in May 1920 of Australia's then six universities. The aims of UA are to:

- advance and promote the benefits of Australian Universities to the nation;
- support Australian Universities in the performance of their roles;
- develop policy positions on higher education matters through discussing higher education issues, including teaching, research and research training;
- advance internationalisation of Australian Universities;
- provide information for and about Australian Universities;
- provide services and programs to Australian Universities including the negotiation of common purchasing arrangements;
- promote the welfare of students, staff and graduates of Australian Universities;

- facilitate opportunities for Australian Universities (in particular, their students, staff and graduates) to develop their knowledge and skills;
- study the problems and needs of Australian Universities and their relations with other education institutions, organisations and the community and to encourage and sponsor their study; and
- assist in the further development of Australian Universities.[2]

The UA is comprised of Australian universities represented by their vice-chancellors.

Some Reflections on Functions and Membership of National Agencies

This account of the functions and memberships of the national agencies that have been involved in the issue of human research ethics guidelines shows that the clarity of functions of the NHMRC have contributed to its being the leading agency in the activity. The only other body with comparable formal commitment to the subject appears to be AIATSIS.

In the functions of the ARC, there is no explicit function that relates to the ethics of human research. However, the function in paragraph (c) above appears to be broad enough to include advice in the form of guidelines.

For UA, there is no clear recognition of a role in relation to the ethics of human research. However, the breadth of its functions could support its involvement in the provision of guidelines on the subject.

The memberships of the NHMRC Council and the AHEC provide for some relevant expertise for the development of human research ethics guidelines. However, it is apparent that the scope of that expertise is confined (appropriately) to health and medical research. There is no assurance from the specified expertise that there will be adequate knowledge of the traditions and practices of human research in wider arenas such as social and behavioural research (Dodds et al. 1994).

What Processes Did Agencies Adopt for the Task of Developing Ethical Guidelines?

Prior to the 1992 NHMRC Act, there were no formal responsibilities relevant to the development and issuing of human research ethics guidelines. It appears from the report of the NHMRC Working Party on Ethics in Medical Research adopted by the Council in October 1982 that the NHMRC *Statement* had "wide acceptance" so that

[2] Universities Australia website, http://www.universititesaustralia.edu.au/content.asp?page=/about/index.htm. Accessed 3 Nov 2009.

the working party recommended retaining its format and making changes by the use of supplementary notes. There is no reference in the description of the revision to any consultation. Nonetheless, the recommended changes were prefaced with the following insightful observations:

In revising the NH & MRC Statement on Human Experimentation and preparing the Supplementary Notes we thought it important to strive for consistency. On the one hand we sought to avoid violating philosophical values which we thought were widely accepted in the Australian community, and on the other to avoid contradicting demonstrable biological facts. Throughout our discussions we tried to remember that ethics is not an exact science, that there are many issues to which the question "right or wrong?" cannot be given a simple answer, and that there are some matters that cannot be settled by consensus. When, therefore, our statements have indicated a belief that some activity is acceptable from an ethical standpoint, this will frequently mean not that it is clearly ethically right, rather that it is ethically defensible but may still be legitimately controverted. We recognised that judgments in these matters must always permit dissent. (NHMRC 1983, 5)

The work of the MREC between its establishment in 1982 and its replacement by the AHEC in 1992 drew mainly on the expertise of the members. However, it was the practice during those years to conduct annual 1 day workshops for institutional ethics committees and these provided opportunites for information and feedback about the *Statement* and its use. The reports of these workshops were drawn on when revisons of the *Statement* or Supplementary Notes were being conducted.

Statutory Consultation

Since the passing of the 1992 NHMRC Act, there have been statutory constraints on the process of developing and issuing guidelines, especially as to public consultation. Section 12 provided that before the NHMRC issued guidelines, it must consult "persons or bodies" in accordance with the steps set out in the section. Those steps were to publish a notice, in the specified manner and form, of the intention to issue guidelines, that invited persons or bodies to make submissions relating to the guidelines, in accordance with the procedures, and within the period, specified in the notice. The section required the Council to "have regard to any submissions received" and prepare a draft of the proposed guidelines and publish a second notice in the specified form, containing the draft and inviting persons or bodies to make submissions relating to it. The regulations specified a form for the notice and specified a minimum consultation period of 30 days.

These requirements were followed thoroughly in the revision of the *Statement* between 1996 and 1999. There were in fact three "rounds" of public consultation, the first to explore the opinions of users of the *Statemen*t as to the general form and style that a revision should take and the second and third that followed the required statutory sequence.

Late in the 1996–1999 process of revising the original *Statement*, AHEC invited a number of peak agencies to examine and thus possibly endorse or support the new *National Statement*, with the intent of legitimising its relevance to human research unrelated to medicine or health. One of these agencies was the ARC which at the time was part way through the process of developing its own ethical guidelines for researchers and institutions in receipt of ARC funding. These negotiations were successful to the extent that when issued, the *National Statement 1999* was "endorsed" by the ARC, the Australian Vice-Chancellors Committee (now Universities Australia), the Australian Academy of the Humanities, the Australian Academy of Science and the Academy of the Social Sciences in Australia, and "supported" by the Academy of Technological Sciences and Engineering.

This attempt to seek to establish a single national ethical guideline for all research involving humans was not without its difficulties. Tensions arose between members of AHEC who were concerned that negotiations with these peak agencies and academies could lead to a "watering down" of protections deemed essential in health research. The *National Statement 1999* had been subjected to two rounds of public and stakeholder consultation but neither round of consultation had deliberately included, as stakeholders, the general researcher membership of the peak agencies and academies that endorsed and supported the new document. This lack of consultation, together with a continuing clear primary focus on health research (by way of content and language), had the effect of creating considerable antipathy to the *National Statement* on the part of the large community of "non-health" researchers.

The statutory requirement for consultation was amended in 2000[3] and is now contained in section 13 of the NHMRC Act which, in relation to human research guidelines, provides:

Before:

(a) ….
(b) the Australian Health Ethics Committee provides human research guidelines to the Council for the purposes of subsection 10(2); the…Committee must:
(c) prepare a draft of the guidelines; and
(d) publish a notice, in the manner and form specified in the regulations:

    (i) containing a summary of the draft guidelines; and
    (ii) stating where copies of the draft guidelines can be obtained; and
    (iii) inviting persons or bodies to make submissions relating to the draft guidelines in accordance with the procedures, and within the period, specified in the notice; and

(e) have regard to any submissions received as a result of the invitation referred to in subparagraph (d)(iii). (NHMRC Act 1992, s.13)

[3] By the *Health Legislation Amendment Act (No. 2)* 2000, No. 6, Schedule 1.

The effect of the change to this section is to only require one round of consultation before guidelines are issued.

The current regulations referred to in this section provide:

6 Consultation about guidelines – manner and form of notice

(1) A notice under paragraph 13 (d) of the Act must be published:
  (a) in a daily newspaper that circulates throughout Australia; and
  (b) on an NHMRC website.

(2) A notice under paragraph 13 (d) must include the following:
  (a) the subject matter of the draft guidelines;
  (b) the last day, being a day at least 30 days after the notice is first published under sub-regulation (1), on which the Council or the Australian Health Ethics Committee will accept submissions relating to the draft guidelines;
  (c) the manner in which a submission is to be made.

Note A notice under paragraph 13 (d) of the Act must also include the information mentioned in that paragraph.

These provisions are a minimum standard and mere compliance can lead to a passive consultation process. Further, the requirement in section 13 that consultation about guidelines is consultation about a draft can lead to a perception that the consultation will exclude opinions that could have led to a fundamentally different draft.

In practice, in relation to human research guidelines, these risks have been addressed by a number of strategies. The first of these is to establish working parties that include members drawn from beyond the membership of the AHEC who can bring to the task a suitably wide range of perspectives. In the 2005–2007 revision of the *National Statement 1999* (NHMRC 1999), the primary working party established by the AHEC included representatives from the ARC and UA, and subcommittees were established in areas in which additional expertise was needed, such as qualitative methods research and the use of databases. Second, by the commencement of that process, the NHMRC had accumulated an extensive contact list of organisations that had an interest in human research and copies of the draft guidelines were specifically directed to those organisation with a request that a submission be provided. Thirdly, in relation to the methods that institutions used to address ethical review of research involving low risk, a workshop was convened to which representatives of a number of institutions were invited.

In some circumstances, the formality of the procedures prescribed in the legislation has been preceded by more informal but suitable processes. One example was in the development of the *Values and Ethics* (NHMRC 2003) guidelines between 2000 and 2003. The formal processes were preceded by extensive consultation with key individuals and organisations by a member of the AHEC who had extensive experience with and was respected by these people and their communities. Following that process, a meeting was convened of most of the key people who had been consulted in order to reach agreement on the revision process. The agreed process

included, in addition to the formal steps required under the Act, a 2 day workshop to clarify the key values that were to underpin the guidelines.

Having Regard to Submissions

The NHMRC's consideration of submissions was directly affected by the outcome and opinion of the 1996 Federal Court decision in *Tobacco Institute of Australia Ltd & Ors* v *National Health & Medical Research Council & Ors* ([1996] FCA 1150), in which the NHMRC was found not to have fulfilled its statutory duty to have regard to submissions related to guidelines about passive smoking. The judge said that:

> the obligation to have regard to submissions received required the NH&MRC, in preparing the draft recommendation, to take them into account and to give positive consideration to their contents as a fundamental element in its decision making. ([1996] FCA 1150 at 1161)

This obligation was clearly applicable to all the expert working parties that the NHMRC established and to the principal committees responsible for recommending guidelines to the Council. The process now followed is that all submissions are copied and copies provided to all working party members with the expectation that all members will read all submissions. In addition, staff and/or volunteer working party members summarize all submissions and strive to extract all of the key points and suggestions from each submission. Face to face meetings of working party members are held at which time the draft ethical guidelines are considered paragraph by paragraph and relevant comments made in submissions are debated by the working party. At times, a subgroup of a working party (colloquially called a "writing group") may undertake this detailed work but only on the understanding that the full working party will discuss the outcome of the subgroup's work and the submissions. The AHEC regularly reviews the progress of any working party it has established and members of the AHEC are also provided with copies of all public submissions. Guideline documents prepared by working parties are debated at AHEC meetings before being agreed to by the AHEC. The positive benefits and the significant impact of this public consultation process should not be underestimated. Analysis of the first draft of any proposed guideline and comparison with the final product will confirm this.

In the revision of the *Statement* between 1996 and 1999, all submissions were provided to members of the working parties and of the AHEC, with the expectation that they would all be read. Further, minutes were kept of the manner in which each submission was dealt with: whether the working party agreed or disagreed with it and how those decisions were reflected in the developing draft.

In the most recent revision process, between 2005 and 2007, in addition to following the same procedure as in 1996–1999, all submissions that were not confidential were published on the NHMRC website.

Promoting the Use of Guidelines

From 1982, the *Statement* (and succeeding NHMRC guidelines) required institutions conducting medical research involving human subjects to establish an institutional ethics committee (IEC). This establishment came to be one of the conditions for research funding eligibility for human research and, as a result, the practice of institutions notifying the existence of their IECs to the NHMRC developed. This was later formalized and is now referred to as registration of Human Research Ethics Committees (HRECs) and, at least since the *National Statement 1999*, these HRECs provide annual "compliance" reports to the NHMRC. These reports helped to maintain the relevance of the *National Statement 1999* and its successor guidelines, although the reports themselves did not collect data about the use of the guidelines.

Since the development of the *National Statement 1999*, the AHEC has undertaken considerable work to promulgate new or revised ethical guidelines through workshops in all capital cities and has held three bi-annual national conferences – in 2003, 2005 and 2007 – on health research ethics for researchers and members of HRECs. Both processes represent an opportunity for stakeholders to provide feedback to the AHEC on existing and proposed guidelines. This feedback then informs the subsequent work of the AHEC.

For the ethical review of clinical trials (which forms a large part of the workload of many HRECs), awareness of and compliance with ethical guidelines was reinforced for researchers and institutions in 1992 when new regulations under the Therapeutic Goods Act were issued. These required that clinical trials of new drugs or devices could only proceed if favourable advice had been received from an institutional ethics committee that had notified its existence to the NHMRC. Those regulations under the Therapeutic Goods Act were amended in 2000 to require that trials of new therapeutic goods were to be conducted in accordance with the *National Statement 1999*.[4]

Strategic Drafting

In its experience of working on the development of guidelines, the AHEC adopted some strategic responses to contested issues, of which two, accommodating differences and postponing determinations, we note here.

In the development of chapter 15 on use of Human Tissue Samples in the *National Statement 1999* (NHMRC 1999), the AHEC received widely competing submissions on the circumstances in which consent should be sought for the research use of human tissue previously collected from clinical investigations or held in tissue banks. There was strong research interest in reducing the need for consent so as

[4] Australian Government 1990. Therapeutic Goods Regulations 1990, 12 AD.

to facilitate research and, on the opposite side, forceful submissions asserting the right of individuals to control the use of "their" tissue as a protection against harm they may ensue or as a way of exercising their rights to any benefits, whether health or financial, that might flow from the research. The AHEC adopted an accommodating differences approach and drafted a provision (NHMRC 1999, 15.7) that required that consent should normally be obtained where the research use of such tissue "may lead to harm, benefit or injustice to a donor". It could be said that while this achieved a conceptual resolution of the differences, its expression left a wide scope for interpretation, rather than offering a helpful guideline.

The other approach of postponing a decision was adopted in two different ways in the guidelines on ART (NHMRC 1996a). In 1996, there was deep division within the Australian community about the status of the human embryo such that the guidelines, in addressing the questions of embryo research, stated that "At the present time these differences cannot be resolved" (NHMRC 1996a, 10). When these guidelines were revised in 2004, questions of the use of genetic technology associated with ART, sex selection and surrogacy were regarded as matters that, in the AHEC's opinion, required "further community debate and consideration by elected governments" (NHMRC 2004, 59). They were included in an Appendix to the 2004 guidelines with a summary of the contesting arguments.

Reflections on the Strengths and Weaknesses of the Australian System for Development and Issue of Human Research Ethics Guidelines

We readily admit that the following comments are likely to be biased as they come from people who have been deeply involved at a national level in the Australian system for ethical review of human research. Nevertheless, we have tried to be objective and reflect as honestly as we can on the strengths and weaknesses of the system as it has evolved.

Roles and Resources

The AHEC has made considerable efforts over time to keep itself informed of relevant developments of systems in other countries, most noticeably in Canada, the United Kingdom, the United States, and several European countries. It has participated actively in international conferences, including hosting the Fifth International Conference of National Bioethics Committees in Canberra in 2004 and has invited international experts to visit Australia. This has allowed the AHEC and NHMRC to compare Australia's processes with those of other nations.

Such comparison reveals that Canada is most similar to Australia in having issued national human research ethics guidelines designed to apply to all human

research and depending for their effect on federal research funding. The US research regulations have a clear focus on health and medical research, although they do govern other federally funded research. In most other developed countries, more attention has been directed to health and medical research than social and behavioural research.

An important difference from other nations emerges when the roles of national bodies other than those related to ethical guideline development are examined. The AHEC has responsibilities related to human research ethics and to the provision of advice to NHMRC, the Federal Health Minister and government on matters generally in health ethics. By contrast, most developed nations have established national bioethics committees but few have given those committees both the broad roles that the AHEC plays. Those national committees that do not have a role in relation to human research ethics, but only in bioethics, are frequently composed of persons with expertise in bioethics and not all such committees are bound to consult with the broader community in developing advice.

One view of the Australian position is that the national committee (AHEC) that emerged in 1992 out of the merger of NBCC and MREC has two important strengths: the breadth of backgrounds of its membership and the statutory requirement for consultation in guideline development. These facets make it more likely that positions developed by the AHEC will reflect a broad community consensus and will be better accepted by the Australian community. Another view is that the combination of responsibilities about human research ethics guidelines and health ethics advice in a part-time committee stretches available resources so that neither role is filled as well as it should be. The AHEC budget often cannot stretch to provide adequate resources for an engaged and pro-active consultation or for promulgating research ethics guidelines as well as resourcing adequate time to research and develop health ethics advice in sufficient depth.

Registration, Compliance and Complaints

The NHMRC administers a registration process for HRECs. Institutions intending to seek research funds from the NHMRC must undertake to have any human research reviewed by an HREC that is registered with the NHMRC. Legislation that governs the research use of unregistered therapeutic goods imposes a similar requirement.

To maintain registration, institutions and their HRECs submit an annual return assuring the NHMRC that they have adhered to the requirements of the *National Statement*. These returns are examined by NHMRC staff and the NHMRC Research Committee, responsible for recommendations of grants to institutions, is advised of the "compliance status" of each institution. This system creates the following potential problems. First, it makes the NHMRC both the issuer/creator of guidelines as well as the "policing body". Second, it raises but does not answer the question of whether the NHMRC has the power to take remedial action if non-compliance is

identified. Whether NHMRC has such power has never been tested, although refusing to pay research grant funds to non-compliant institutions would appear to have a contractual basis.

In our view, the enforcement role sits uncomfortably with NHMRC's and AHEC's role in promoting ethically good human research. The *National Statement* was purposefully developed as a document to promote deliberation and not an instrument to enforce compliance. In contrast to the regulations in the United States, the *National Statement* does not provide the precision necessary as a basis for formal and fair compliance interventions. These considerations expose the uncertainty in the scope of NHMRC's and the AHEC's responsibility in human research ethics beyond developing and issuing guidelines. However, to date, this uncertainty has not unduly influenced the form and expression of these guidelines.

The existence of a registration system of HRECs with the NHMRC has another consequence. It has at times raised the expectation that where institutional processes have failed to resolve a complaint about research conduct or review, the NHMRC might exercise a supervisory role and receive, investigate and resolve such matters. Such a function raises the same uncertainty about the scope of the human research ethics role and, at the same time, the questions about how available resources should be used.

Consultation, Deliberation and Promulgation

As described above, the issue of human research ethics guidelines has been preceded by consultation processes that, as a minimum, conform to the statutory design. This design is characteristic of its time – the 1990's – when a passive form of public engagement was regarded as sufficient, especially in relation to scientific or clinical practice guidelines where the community to be engaged was expert, articulate, organised, informed and accustomed to this type of communication. The use of the same passive methods for ethics guidelines can be questioned. Here, the community to be engaged frequently lacks, or believes it lacks, all the characteristics of a scientific community and, as a result is unlikely to see itself as equipped to initiate a submission. More pro-active methods have been used with effect in other countries and in Australia by other agencies, such as the Australian Law Reform Commission. These would better suit the development of ethics guidelines, but the resources needed to support them may not be available because they are needed to support the other roles of the AHEC.

The process of assessing, deliberating on and incorporating submissions into developing versions of guidelines is, we recognise, a complex and intricate interchange of opinion and experience. The wide range of AHEC membership means that its work is informed but not confined by the content of submissions, because individual committee members respond to each submission from their own perspective. The deliberation thus blends differing expert assessments of the relative weight and importance of the submissions with the content of the submissions themselves.

This process that depends on and uses the variety of committee opinion is as much an expression of community opinion as are the submissions.

The NHMRC, on the AHEC's initiative, has taken steps to inform HREC members and researchers when guidelines are issued or revised. This has been seen to be a natural and desirable initiative and valued by recipients. In the absence of other providers, the AHEC in the years from 2003 to 2007 (but not since) took on the role of providing training and education for HREC members. For this reason, advice was given to the appointing Minister of the value of appointing some AHEC members with HREC experience. However, since 2007,, these activities have largely ceased, for budgetary reasons, and the task of training HREC members and researchers in the application of ethical guidelines hopefully will be taken up by other agencies or entities. This is perhaps ironic because both the NHMRC *National Statement* and the *Australian Code for the Responsible Conduct of Research* (NHMRC/ARC/UA 2007b) require institutions to ensure that their researchers are adequately trained in research ethics.

Ownership of Guidelines

There is no doubt that a key task of the AHEC is to develop, revise and issue guidelines for the ethical conduct of health and medical research. The application of these guidelines to other types of human research has been deliberate and at times supported by other agencies that have seen the desirability of a single national document.

Through the broad membership of the joint agency working party and the wide stakeholder consultations, the *National Statement* appears to have been reasonably well received by researchers in disciplines outside of health and medicine. However, when questions arise during the life of this edition – as to interpretation or application – it is by no means clear whether such questions should be directed to and responded to by the AHEC or the NHMRC. These bodies simply lack the expertise and experience that would generate the confidence of a social or humanities researcher that meaningful advice was likely on inquiry.

Research Governance

Institutional establishment or use of HRECs is a condition for their receipt of NHMRC research funding and forms part of deeds of agreement that institutions sign to receive those funds. The membership requirements and responsibilities of those HRECs are provided in the *National Statement*. Until the latest revision of the *National Statement* and the revision of the complementary NHMRC document entitled the *Australian Code for the Responsible Conduct of Research* (NHMRC/ARC/UA 2007b), the importance of not only having effective human research ethics review in place but also an effective system of research governance in place had

been largely overlooked in Australia, especially in those hospitals that undertook research. This has been exposed starkly as recent initiatives to remove duplication of ethics review compel institutions to decide how to govern research when the ethical review is conducted elsewhere. Here again, as with research ethics, the NHMRC may not appear to be the best informed source of advice about how to establish such structures, even though its issued guidelines have promoted the need.

Some Historical Reflections and Changes to NHMRC Act in 2006

In the years since the formation of the AHEC in 1992, the committee appears to have achieved a perhaps enviable reputation as the national authority on both the principles and the practice of human research ethics. Although the AHEC was never a separate entity, but always only a principal committee of the NHMRC with obligations only to the Council of the NHMRC and to the federal Minister, it was referred to in the research community as if it was its own master.

One difficulty of this perception for the AHEC (and for the NHMRC) has been the expectation that the AHEC can (and should) not only issue guidelines, but also train researchers and HREC members in their use, assess annual institutional compliance with human research ethics standards, receive, investigate and resolve complaints about research ethics review and provide prompt, informal and expert advice about research ethics issues. To its credit and that of the staff who supported the committee, sufficient of this was in fact done so that the perception was maintained.

Changes to the NHMRC Act in 2006 have led to a more corporate vision of the NHMRC and to a more internally cohesive role for the AHEC. Issues of institutional research ethics compliance are now likely to be combined with financial accountability for research funding and, as noted above, the AHEC is likely to significantly confine its roles in promulgation and education. This appears to leave a space, perhaps even a vacuum, of activity in the promotion of human research ethics that is likely to be filled by other players. The significance of these changes for the nation is yet to be realised.

One of the strengths of the AHEC that we believe has been of great importance has been the statutory guarantee of a degree of independence from the NHMRC in the work of developing ethical guidelines for research. Another means of ensuring its independence (from politicisation) has been the need until 2006 for the Federal Minister of Health to consult with members of the Australian Health Ministers Conference in relation to appointment of the Chair and the member with knowledge of the ethics of medical research, and in relation to all the other categories, consider nominations from relevant professional bodies. The 2006 amendment to the *NHMRC Act 1992,* requiring, as it does, only that those appointments be made by the Minister " after consulting appropriately" appears to weaken this independence

from political considerations in appointments. Further, the specific powers given to the CEO appear to place the agenda and the public outcome of the work of the AHEC substantially within the CEO's power. While these constraints may have a sound organisational and accountability basis in government agencies that administer policy, they appear inappropriate for an entity charged with the development of ethical guidelines intended to reflect community opinion. It is concerning also that these changes were accepted without wide debate by key stakeholders. It is too early to determine if these changes will alter the broad community acceptance of the AHEC's status or alter the workings of the AHEC or the nature of the output of the AHEC's work, current and future.

Competing Interests The authors of the chapter have all had direct involvement in the development and issue of some of the guidelines and have drawn on their personal engagement as well as official records of this work.[5]

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[5] Nor have we have discussed our thoughts with Justice Robyn Layton QC who was the first chair of the Australian Health Ethics Committee.

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