Australian Government

National Health and Medical Research Council

Submission to the Senate Legal and Constitutional References Committee
Inquiry into the *Privacy Act 1988*

February 2005

Introduction

The National Health and Medical Research Council (NHMRC) is a statutory body within the health portfolio. Since 1936 it has been responsible for promoting the development and maintenance of public and individual health standards; encouraging debate on and setting standards for animal and human research ethics and health ethics issues; and managing the Government's commitment to fund health and medical research.

The NHMRC is now established under the *National Health and Medical Research Council Act 1992* which imposes four statutory obligations:

1. To raise the standard of individual and public health throughout Australia;
2. To foster development of consistent health standards between the States and Territories.
3. To foster medical research and training and public health research and training throughout Australia.
4. To foster consideration of ethical issues relating to health.

The NHMRC also has statutory obligations under the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* and corresponding State and Territory legislation.

The NHMRC pursues initiatives through a series of expert Principal and Working Committees and maintains a strong commitment to evidence-based decision making and community involvement.

This submission responds to matters raised in the Terms of Reference. The NHMRC would be pleased to discuss these matters with the Committee, if required.

Background

The NHMRC has extensive links with the Australian community, national and international health and research agencies and many other bodies. These bodies, together with researchers; human research and animal ethics committees; data custodians; the general public and health consumers; and medical and allied health professionals form NHMRC's key stakeholders.

The Commonwealth Privacy Act (the Privacy Act) was introduced in 1988. Initially applying only to Commonwealth public sector agencies, it was amended in 2001 and now also applies to the private sector throughout Australia. The Privacy Act contains two sets of principles – the Information Privacy Principles (IPPs), which guide the collection, use and disclosure of personal information by Commonwealth public sector agencies, and the National Privacy Principles (NPPs) which guide the collection, use and disclosure of personal information by private sector organisations. The effect of the Privacy Act is that, unless a limited range of exceptions applies, health information cannot be collected, used or disclosed without the consent of the data subject.

Sections 95 and 95A of the Privacy Act provide for guidelines to be developed to enable the use of identifiable health information in the conduct of specific activities (including research of various types) without the consent of the data subject. This information is made available on the proviso that an assessment is made by a Human Research Ethics Committee (HREC) that the research and other activities are, on balance, substantially in the public interest and outweigh concerns about privacy protection.

The NHMRC has developed, and received approval from the Federal Privacy Commissioner for, such guidelines:

1. *Guidelines under Section 95 of the Privacy Act 1988*[1] address aspects of the collection, use and disclosure of health information in medical research; and
2. *Guidelines approved under Section 95A of the Privacy Act 1988*[2] address research relevant to public health and public safety; compilation or analysis of statistics relevant to public health and public safety; and the management, funding or monitoring of a health service.

Copies of these guidelines are included at Attachments A and B.

Compliance with the guidelines is reported annually to NHMRC through the Australian Health Ethics Committee – a Principal Committee of NHMRC. In turn, the NHMRC reports this information to the Office of the Federal Privacy Commissioner.

The privacy protection framework has become more complex since the introduction of the private sector amendments, which now sit beside the original public sector arrangements, existing State and Territory legislation, industry codes of practice, and

[1] NHMRC, (2000) *Guidelines under Section 95 of the Privacy Act 1988*, available at: http://www.nhmrc.gov.au/publications/synopses/e26syn.htm
[2] NHMRC, (2001) *Guidelines approved under Section 95A of the Privacy Act 1988*, available at: http://www.nhmrc.gov.au/publications/synopses/e43syn.htm

other administrative decisions. Since December 2001, a range of NHMRC stakeholders have expressed concern that implementation and/or interpretation of Commonwealth and State privacy legislation is compromising research and health care that would otherwise improve outcomes for both individual and public health. It has been suggested that this is an unintended effect of the privacy legislation and, more particularly, the private sector amendments to the Privacy Act.

Given the level of concern exhibited by stakeholders and the lack of objective documentation, the NHMRC established a Privacy Working Committee late in 2003. The main role of the Working Committee was to investigate the situation further and collect information that would assist NHMRC to assess the concerns expressed.

In addition, the introduction of the *Privacy Amendment (Private Sector) Act 2000* included a stipulation that the amendments be reviewed, commencing no later than two years after their introduction. The NHMRC has made a submission to the Federal Privacy Commissioner's review of the private sector amendments. A copy of that submission is included at Attachment C to this submission. Many of the issues in that earlier submission are relevant to the current Senate Inquiry.

Response to Terms of Reference

Term of Reference: (a) The overall effectiveness and appropriateness of the *Privacy Act 1988* as a means by which to protect the privacy of Australians with particular reference to: (i) international comparisons

As part of its 2003-2004 investigations, the NHMRC prepared a description and comment of the existing privacy regulation framework as it relates to health information. The report entitled *The Regulation of Health Information Privacy in Australia. A description and comment*[3] is included at Attachment D and contains information about privacy frameworks of the European Parliament and the Council of Europe, Canada, the United States, and New Zealand.

The report notes that it is difficult to undertake a direct comparison between overseas privacy frameworks and the Australian framework because of the different environments, government structures, and terminology. However, there are provisions in international legislation, notably the *Privacy Act 1980* (Canada) and the New Zealand *Privacy Act 1993* and Health Information Privacy Code relating to use of information for research that are comparable. In the former instance, the Canadian legislation permits agencies to disclose personal information without the individual's consent, for research, if it is satisfied that the research cannot be achieved with non-identifying information and the researcher obtains an undertaking that the information will not be disclosed in an identifying way. Equally, the New Zealand Act and Code permit such disclosure if an agency believes on reasonable grounds that it is neither desirable nor practicable to seek consent and the information will not be used in an

[3]NHMRC (2004) *The Regulation of health information privacy in Australia. A description and comment*, available at: http://www.nhmrc.gov.au/publications/synopses/nh53syn.htm.

identifying way in research. By contrast, the Australian NPPs only permit use or disclosure of personal information for research if it is impracticable to seek consent and an HREC has approved the use or disclosure using the privacy guidelines. Both Canadian and New Zealand legislation appear to be more relaxed than comparable Australian provisions.

Part seven of the report at Attachment D is relevant.

Term of Reference:
(a) The overall effectiveness and appropriateness of the *Privacy Act 1988* as a means by which to protect the privacy of Australians with particular reference to:

(ii) the capacity of the current legislative regime to respond to new and emerging technologies which have implications for privacy including:

(A) "Smart Card" technology and the potential for this to be used to establish a national identification regime;
(B) biometric imaging data;
(C) genetic testing and the potential disclosure and discriminatory use of such information; and
(D) microchips which can be implanted in human beings (for example, as recently authorised by the United States Food and Drug Administration)

The NHMRC has not specifically addressed items (ii) (A), (B) and (D) in its work program to date. However, there are thought to be a number of significant ethical issues associated with each of these matters, most importantly the potential for loss of freedom and misuse of information, for example through hacking. There are also issues around compulsory use, such as that enforced in Iceland for the contribution of information to a national data bank, which are also relevant. The NHMRC believes that these issues would benefit from public consultation and this Inquiry may provide such an opportunity. Some additional comments specific to the individual criteria are provided below.

A – 'Smart card' technology

The NHMRC acknowledges that smart card technology can be applied to a range of personal information, not exclusively health information. Some of the ethical issues in health are similar to the ethical issues of 'smart card' technology more generally, for example the storage of personal information linked to either finance records or health records are equally sensitive. However, some health issues are more sensitive and arise in more contexts such as an individual's history of mental illness or sexually transmitted diseases.

A particular issue of concern is the storage of and access to data. Information will need to be housed in secure conditions with appropriate facilities, equipment and qualified staff to ensure the integrity of the data. There is no difference in terms of

ethical issues between storage of general health information and information contained on genetic registers (see for example *Guidelines for Genetic Register and Associated Genetic Material*, NHMRC, 1999).

Additional security questions arise if the holder of a 'smart card' loses the card. How can the holder be reassured that his or her information cannot be accessed by others? Is there a means of protecting the card, for example with a personal identification number, to reduce the risk of unauthorised access? How does the holder go about obtaining a replacement card? However, it should also be noted that some levels of security could make the 'smart card' inaccessible in emergency situations, for example if the holder is unconscious.

The NHMRC also believes that there are issues around segmenting information held on a 'smart card' in order to restrict access. Not every health care provider needs to access all information about a patient, for example in the case of a person attending for an ophthalmological consultation it would be irrelevant to the specialist concerned that the individual suffers from a sexually transmitted disease or that the individual was the victim of sexual abuse as a child. The NHMRC understands that the Australian Government Department of Health and Ageing has considered this issue through its (former) National Health Information Management Group.

Recommendation:
The NHMRC recommends that the community's views on the use of 'smart card' technology across a range of health services/applications should be sought through extensive public consultation in order to identify and consider specific ethical as well as other issues of concern.

B – biometric imaging data

The ethical issues associated with biometric imaging data are similar to those surrounding the use of 'smart card' technology and for the management of genetic information. The risk of inappropriate and unauthorised access to health information as a result of the biometric 'code' being corrupted, broken or mischievously duplicated is one such issue. The uniquely sensitive nature of such data would merit the highest security and access protection.

In addition, the question of compulsory use of biometric imaging is one that needs to be examined especially in view of the fact that such information could be used for a variety of purposes beyond health care, for example law enforcement.

Recommendation:
The NHMRC recommends that the community's views on the use of biometric imaging should be sought through extensive public consultation in order to identify and consider specific ethical as well as other issues of concern.

C – genetic testing

The NHMRC notes that it is likely to be difficult to enact a legislative regime to protect the privacy of genetic information because the field of genetics is rapidly evolving. Thus, what is not possible today is likely to be feasible tomorrow and hence privacy protection measures will need to be sufficiently flexible to permit levels of protection to be amended and upgraded (or downgraded) as necessary.

The NHMRC also believes that, in terms of genetics-based knowledge, the definition of an individual's privacy needs to be considered in the context that DNA is shared by all family members, ie privacy is a more complex issue in this field and there is a need to be cognisant of shared genetic information. The NHMRC is aware that this raises the dilemma of the individual's right to privacy versus the right of others to know certain information. A recent report of a court decision in Iceland that recognises a daughter's privacy rights in her father's genetic information is an early legal recognition of this scientific reality[4].

The NHMRC commends to the Committee of Inquiry the report *Essentially Yours: the protection of human genetic information in Australia*[5], jointly released by the Australian Law Reform Commission and the NHMRC in March 2003. The consultations and subsequent report extensively reviewed matters relating to genetic privacy. The report identified issues and put forward potential solutions including recommendations for amendments to the *Privacy Act 1988*.

Of particular interest to this current Inquiry is Volume One of the report which addresses ethical considerations of genetic material, anti-discrimination, privacy of genetic samples, genetic testing including matters of consent, and the establishment and management of human genetic databases and tissue collections. As noted above, the recommendations set out in this Volume address proposals for amendments to the *Privacy Act 1988* including:

- Clarifying definitions of 'health information' to include genetic information, including information about people who have been deceased for less than 30 years (R7-4 and 7-6), and 'sensitive information' to include genetic test information (R7-5);

- Extending coverage of the Act to include all small business operators who hold genetic information (R7-7) and extending the coverage of the IPPs and NPPs to include identifiable genetic samples (R8-2);

- Including provisions to permit access to genetic information by individuals (R8-3) and by first-degree genetic relatives (R8-4 and R21-3);

Whilst the NHMRC does not need to reiterate those issues as they were well canvassed and addressed at the time, with recommendations, we do believe that implementation of the recommendations in *Essentially Yours* is important and should take place without further delay.

[4] Guomundsdottir v. Iceland, No 151/2003 (27 November 2003), Ice., cited in *Harvard Law Review*, 118 Harv.L.Rev. 810, 378 (December 2004).
[5] Available at http://www.austlii.edu.au/au/other/alrc/publications/reports/96/.

D – implanted microchips

The NHMRC is aware that the United States Food and Drug Administration recently approved the implantation of microchips in humans for release of medication or therapy. Despite this, and without further consultation and discussion, the NHMRC remains unconvinced at this stage that there is merit in this approach.

If the use of implanted microchips involves tailoring the information to specific individuals as an extension of pharmacogenetics, for example full identification which could be useful in certain circumstances such as disaster victim identification, ethical issues including loss of freedom; compulsion or coercion of the individual to accept a microchip (especially minors); access to information contained on the microchip beyond health applications; and the individual's ability to update or change information as needed would arise. The NHMRC believes there needs to be a thorough and full examination of all the issues before such a proposal is considered further in Australia.

Recommendation: The NHMRC recommends that the community's views on the use of microchips in health care delivery should be sought through extensive public consultation in order to identify and consider specific ethical as well as other issues of concern.

Term of Reference: (a) The overall effectiveness and appropriateness of the *Privacy Act 1988* as a means by which to protect the privacy of Australians with particular reference to: (iii) any legislative changes that may help to provide more comprehensive protection or improve the current regime in any way;

The NHMRC undertook a series of consultations in early 2004 to identify and document the experiences of, and attitudes towards, health information privacy regulation in Australia by NHMRC stakeholders. A copy of the summary report of those consultations is included at Attachment E[6]. The consultations were conducted to assist the NHMRC to answer questions about health information privacy generally and specifically about the changes brought about by introduction of the *Privacy Amendment (Private Sector) Act 2000*.

During those consultations it became clear to the NHMRC that the existing privacy framework, as it relates to health, is fragmented and complex. Not only do health care practitioners and researchers need to contend with Commonwealth legislation, but also with a plethora of State and Territory legislation and administrative rules, as well as industry codes of practice. This fragmentation is counterproductive in the health care setting because it creates confusion and uncertainty and can act as a barrier to

[6] NHMRC (2004) *The Impact of Privacy Regulation in Australia: a comparative stakeholder analysis*, available at: http://www.nhmrc.gov.au/aboutus/privacy.htm.

optimal health care and a disincentive to the undertaking of research of potential health benefit to Australians.

The NHMRC holds a strong view that a single, national, health information privacy protection framework applicable to both clinical care and research is a priority. This would have the effect of producing one set of national privacy principles (to replace the current Information Privacy Principles and National Privacy Principles) and one set of research guidelines (to replace the existing separate guidelines under sections 95 and 95A of the *Privacy Act 1988*).

In addition, in the field of health research the current obligations on human research ethics committees (HRECs) to weigh the balance of the public interest in the protection of privacy against the public interest in proposed research, is onerous for two reasons. Firstly, members of HRECs are by and large volunteers or institutional staff members taking on additional responsibilities. The guidelines under sections 95 and 95A of the *Privacy Act 1988* require HRECs to assess whether they have sufficient information, expertise and understanding of privacy issues from among their members or otherwise available. Committee members are not experts in privacy law and, as demonstrated by the NHMRC's consultations, even the lawyer members of HRECs are not appointed or approached as experts in privacy law. Thus the decision making process, even if informed by someone with sufficient understanding, is as difficult for the HREC as it was for the researcher in developing the proposal.

Secondly, the current arrangements in privacy require all HRECs to report to the NHMRC on an annual basis on their application of guidelines issued under sections 95 and 95A of the *Privacy Act 1988*. In turn, the NHMRC reports this information to the Federal Privacy Commissioner. The reporting is onerous because it requires considerable data capture and transmission on numerous aspects of the HREC's deliberations and decisions. The Australian Health Ethics Committee (a principal committee of NHMRC and responsible for this activity), is of the view that this level of detailed reporting is unhelpful and is certainly not in line with the intended 'light touch' nature of the privacy regime, and particularly the private sector arrangements. The NHMRC, which supports this view, has no evidence that privacy breaches in health research are common or even regular events. The NHMRC appreciates that any new system may require higher levels of monitoring than would occur in a 'maintenance' phase. For this reason the NHMRC believes that it is timely to review the reporting arrangements.

These issues are addressed in detail in the submission to the Federal Privacy Commissioner (Attachment C).

Recommendations:
The NHMRC recommends that the Committee note the issues raised in the NHMRC's submission to the Federal Privacy Commissioner's review of the private sector arrangements of the *Privacy Act 1988.*
The NHMRC further recommends that the Committee consider NHMRC's recommendations, especially those relating to the operations and effectiveness of the *Privacy Act 1988* generally and the private sector provisions specifically.

The NHMRC also recommends that the Committee agree that current HREC reporting arrangements should be reviewed with a view to simplifying reporting.

Term of Reference:

(b) the effectiveness of the *Privacy Amendment (Private Sector) Act 2000* in extending the privacy scheme to the private sector, and any changes which may enhance its effectiveness; and

In its submission to the Federal Privacy Commissioner's review of the private sector arrangements, the NHMRC highlighted the complexity of the current situation. As noted above, the NHMRC believes there is room for improvement and suggestions were made in its submission.

The NHMRC commends the recommendations in that submission to the Committee of Inquiry and asks that the Committee consider NHMRC's recommendations relating to matters that could streamline and improve the health information privacy regime in Australia.

The NHMRC questions whether it is, in fact, effective to have one privacy regulation framework covering all types of information. It is noted that several States and Territories have enacted separate health privacy legislation as a means of giving special attention to the issues that health information privacy raises.

Term of Reference:

(c) the resourcing of the Office of the Federal Privacy Commissioner and whether current levels of funding and the powers available to the Federal Privacy Commissioner enable her to properly fulfil her mandate.

In order to facilitate compliance with the *Privacy Act 1988* generally, and with the private sector arrangements specifically, in 2002 the Australian Health Ethics Committee worked in collaboration with the Office of the Federal Privacy Commissioner to develop, organise and conduct a series of training workshops. The workshops, held in every capital city, were intended to assist HRECs and researchers in understanding the requirements of the guidelines issued under sections 95 and 95A of the *Privacy Act 1988*. Approximately 1110 people attended the workshops at a cost to the NHMRC of approximately $230,000. No other funding was provided for this activity.

The NHMRC agrees with AHEC that the cost of such training should not be a charge only to the NHMRC. The NHMRC believes that such activities should be collaborative, but that training in the area of privacy, especially when it occurs as a result of legislative change, should be funded largely if not exclusively by the Federal Privacy Commissioner, as the responsible agency.

Further, if reporting by HRECs of their use of privacy guidelines is to continue, that reporting could be direct to the Office of the Federal Privacy Commissioner which should be sufficiently resourced to conduct the necessary analysis.

Recommendation:
The NHMRC recommends that the Federal Privacy Commissioner be given sufficient resources to ensure that education and awareness programs can follow any legislative change as well as continuing education and awareness.