Queensland Institute of
Medical Research

Submission to the Senate Legal and Constitutional References Committee's inquiry into the *Privacy Act 1988*

February 2005

1. Introduction

The Queensland Institute of Medical Research (QIMR) is an independent, not-for-profit organisation and has a world class reputation for biomedical research. The Institute accommodates over 800 scientists, students and support staff. The Institute has major research programs across the spectrum of human disease, with particular expertise in the study of immunological, biological and molecular basis of infectious diseases, cancers and other disorders. QIMR has also built a strong research stream in epidemiology, the study of the environmental, lifestyle and genetic factors that contribute to disease incidence among populations. The exceptionally high quality of research conducted at QIMR is reflected in the fact that almost all research is funded by competitive grants from Australian and international bodies.

This submission responds to matters under scrutiny by the References Committee as they bear on QIMR's research activities, in particular (a) (iii) [within our own Institute, it is clear that the privacy regulations have had a substantial and adverse impact on two groups in particular: I. epidemiological researchers and II. members of Human Research Ethics Committee…**see pages 4-7] and (a) (ii) (C).** Further information can be obtained from Prof Michael Good, Director, Queensland Institute of Medical Research, Post Office Royal Brisbane Hospital, Queensland 4029; telephone (07) 3362 0203.

2. The Privacy Act and Health and Medical Research

The *Commonwealth Privacy Act* (the Privacy Act) was originally introduced in 1988 and applied only to Commonwealth public sector agencies. Amendments passed in

2001 extended the Act to encompass the private sector throughout Australia. The effect of the *Privacy Act* (and the Privacy Principles through which the Act is codified) is that health information cannot be collected, used or disclosed without the consent of the data subject, with a small number of exceptions. These exceptions are outlined in Sections 95 and 95A of the Privacy Act, which detail the role of Human Research Ethics Committees (HREC) in allowing identifiable health information to be used without consent for the purposes of approved research activities. These parts of the Act greatly influence our conduct of health and medical research.

The National Health and Medical Research Council (NHMRC) recently conducted a comprehensive review and data collection exercise regarding the impact of Privacy regulations on health and medical research. That review was prompted by concerns of NHMRC stakeholders that the Australian privacy regulatory regime, and more particularly the 2001 Amendments, had substantial unintended effects on :

- The ability to undertake health and medical research and
- The scientific rigour of health and medical research.

The summaries of the review process have been released publicly and can be found at http://www7.health.gov.au/nhmrc/aboutus/privacy.htm.

3. Terms 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

International comparisons are complicated by Australia's fragmented structures of government (leading to privacy legislation at both State and Commonwealth level), however both New Zealand and Canada have privacy legislation which explicitly covers issues relating to health information and consent. In both countries, disclosure of health information without consent is permitted if the research cannot be done in any other way (Canada) or if an agency believes that it is neither desirable nor practicable to seek consent, and the information will not be used in an identifying way in research (New Zealand). These approaches are less stringent than the Australian approach, without any apparent loss of individual privacy.

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

…

(C) genetic testing and the potential disclosure and discriminatory use of such information

QIMR has strong interest in genetic research, particularly as it applies to the causes of disease, and QIMR researchers are keenly aware of potential misuse of genetic information. The issues relating to genes and privacy were comprehensively covered in the report issued by the Australian Law Reform Commission (ALRC) and the NHMRC entitled *Essentially Yours: the protection of human genetic information in Australia* issued in March 2003.

QIMR would seek to ensure that the term "genetic testing" is carefully defined in any amendments to the legislation, as "genetic testing" for clinical or actuarial purposes (e.g. disease risk prediction) is very different from "genetic testing" of donated blood samples for research purposes. Specifically we believe that the interests of our Genetic Epidemiology research participants are adequately covered by the current Guidelines approved under Section 95A of the *Privacy Act 1988* i.e. we are not classified as "health service provider", and again, our genotyping should not be classed as "genetic testing" as in a clinical or health service context. Therefore we should be immune to requests for disclosure of information to third parties, e.g. by life insurance companies or agencies, who otherwise do have the right to access patients' doctors and medical records with regard to medical history or any genetic test results. We usually inform research participants of this distinction. The key issues are who can be told about the results of tests, the impact that a participant's knowledge about their genotype can have on any requirement for them to disclose to a third party, and how to minimise discrimination against any individuals who have been tested.

We request participants' consent for data collection or unanticipated use of collected data whenever practicable; otherwise we seek HREC approval to waive the need for consent. We deal with genetic information in a potentially identifiable rather than an identified way. We understand that the Act allows researchers to collect personal information as long as we observe the privacy principles i.e. we tell people why the

information is being collected and why we need it (we do this, in great detail, in our information sheets); we store the information securely, and we do not pass the information on to anyone who does not have a legitimate need for it (we comply with all this).

In summary, consent after provision of adequate information is really the key factor --- the participant should know what it is they are agreeing to, why the information is being collected, who will have access to their information, how it will be dealt with etc. Providing this is adequate, the Section 95A Guidelines do not need to be invoked. The NPP on Use and Disclosure of personal information (#2) describes situations where an organisation (e.g. QIMR) might be requested disclose personal information about an individual to other third parties (e.g. re crime, court orders). QIMR needs to ensure that we have immunity from this.

(iii) any legislative changes that may help to ….improve the current regime in any way

Within our own Institute, it is clear that the privacy regulations have had a substantial and adverse impact on two groups in particular:

(I) epidemiological researchers

(II) members of Human Research Ethics Committee

(I) Impact upon epidemiological researchers

Epidemiological researchers investigate inter alia the causes of major diseases affecting Australians (eg cardiovascular disease, cancer). They typically undertake large-scale studies involving many hundreds or thousands of people. Often their research involves ascertaining people affected by the disease under investigation, and comparing them with healthy "controls" randomly selected from the general population. In this way, epidemiologists can identify those environmental or genetic or constitutional factors that cause a disease, with the aim of applying this knowledge to disease prevention. Major health advances have occurred through this type of research ranging, for example, from insights into the predominant role of cigarette smoking in the present and future global burden of disease, to understanding the causes of congenital malformations or cot-deaths.

For epidemiological studies to have scientific validity, it is essential that the sample of patients in a study truly represents ALL patients with that disease. (If the sample of patients is *not* representative, then the researchers are highly likely to draw erroneous conclusions about the causes of a disease, potentially leading to misguided attempts at disease prevention). It is therefore critical that epidemiologists monitor the representativeness of patients enrolled in their studies. This can only be done by collecting relevant information about those enrolled and those not enrolled.

In the past, epidemiologists were permitted (under strict supervision and guarantees of confidentiality) to screen hospital admissions lists for eligible patients. Researchers were then permitted to contact the treating doctor for permission to approach the patient. This activity ("screening") ensured that all potentially eligible patients were identified and accounted for, even if they (or their doctors) elected not to participate. In this way, the researcher was able to monitor the representativeness of the sample and thereby maintain the scientific quality of their research.

Under the myriad changes resulting from implementation of the Privacy Act, epidemiologists are now faced with the situation where this previously acceptable activity is no longer permitted. The logistical challenges in recruiting scientifically valid samples of patients due to changes in the process are demonstrated by the experience of one QIMR researcher:

"*Whereas previously, we were permitted to screen lists of patients to identify eligible cases, we now have to negotiate a complicated and expensive procedure with institutions to identify patients simply to invite them into one of our studies. Briefly, the process is as follows. Patients who meet the eligibility criteria are identified and "flagged" by the institution. Because of the new privacy laws, patients must first grant permission to the institution for the release of any identifying information to a third party, including approved research groups. Thus all initial contacts with patients are through the institution. The institution writes to each patient requesting their permission to release their details to the researchers. Patients are invited to respond by reply-paid mail, fax, email or telephone. Each institution is requested to log mail-outs and returns to monitor the representativeness of the sample. A de-identified record of refusals and non-responses is then provided to permit calculation of response rates and to identify any biases in the recruitment procedure. The*

considerable administrative costs incurred by the institution in obtaining permission and maintaining records to epidemiological standards are now passed on to the researchers."

The end result is that the already sizeable costs involved in recruiting patients are now twice as much as previously (because each patient has to be contacted twice, once by the institution to get permission to release their details by the researcher, and then again by the researcher to obtain formal written consent to be in the study). Moreover, a third party (in this example, the institution) with no particular interest in the quality of the research is now primarily responsible for identifying and contacting patients. Inevitably, recruitment rates have declined, and hence the research is of poorer quality. Finally, the researchers are ***not*** permitted to know anything about the people who did not enrol (or did not reply to the letter from the institution), thus there is no way of establishing that the patient group sampled is truly representative of patients.

In short, as a direct consequence of the Privacy Act, epidemiological research costs considerably more, but is likely to be of substantially poorer quality. These issues were explored more fully in the NHMRC reports from the review of the Privacy Act.

(II) Impact upon members of Human Research Ethics Committees

Under Sections 95 and 95A of the Privacy Act, Human Research Ethics Committees (HRECs) are charged with the responsibility of deciding on the legal status of research proposals involving consent and privacy issues. This places a considerable burden of responsibility upon the members of ethics committees, all of whom are volunteers. Members are not experts in privacy law and thus the decision making process can be fraught with difficulty and be an extremely taxing undertaking for the committee and researchers alike. It is the opinion of many that the Privacy Act has led to ethically acceptable research being halted or modified on the basis of concerns about interpretation of the privacy legislation. Researchers on multi-centre projects have also reported instances of considerable inconsistencies in decisions made by committees in different jurisdictions, presumably due to complex piece of legislation being administered by untrained volunteers.

Moreover, HRECs are required to submit annual reports to the NHMRC regarding their application of guidelines issued under sections 95 and 95A of the *Privacy Act 1988*. The NHMRC then forwards this information to the Federal Privacy Commissioner. This reporting requires collection of considerable amounts of data, an expensive and time-consuming undertaking which is at odds with the proposed "light touch" approach to privacy.

(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

The fragmented approach to privacy regulation in Australia is a major impediment to efficient multi-centre research. Research teams must deal with multiple different pieces of legislation, all with the same intent, but with subtly different wording that can have considerable impact upon the conduct of research. A single, unified approach to privacy would be a step forward.

(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.

It appears that many of the difficulties experienced by health and medical researchers and members of HRECs in working within the provisions of the Privacy Act stem from inadequate training in this rapidly evolving area are due as much to lack of knowledge or awareness as to actual deficiencies in the legislation. A national education program and rapid access to advice from a well-resourced Federal Privacy Commissioner would be an extremely valuable service to groups in the health research sector. In particular, members of HRECs whose role is to administer important aspects of this legislation should receive training in this area. Finally, a searchable electronic archive of decisions made by HRECs under Section 95/95A of the Privacy Act would be useful resource and would be expected to lead to more efficient and consistent deliberations.