ATTACHMENT C

Submission

by the

National Health and Medical Research Council

to

The Review by the Federal Privacy Commissioner of the Private Sector Provisions of the *Privacy Act 1988*

10 December 2004

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Executive Summary

The National Health and Medical Research Council (**NHMRC**) is pleased to present this submission to the Review of the Private Sector Provisions of the *Privacy Act 1988* (the **Review**).

The NHMRC has made a substantial investment in developing this submission because of its commitment to good research and health care provision and because of its understanding of the importance of a responsible privacy regime. In order to make an informed and constructive submission, it has sponsored a process of wide consultation over the past twelve months with a comprehensive cross-section of stakeholders, and has thoroughly researched and analysed relevant material.

In preparation for this submission, seven stakeholder surveys designed to evaluate perceptions of the impact of the Privacy Act on health care as well as health and medical research were conducted, in conjunction with a comprehensive analysis of legal and operational issues associated with the Privacy Act.

The NHMRC considers that the 2001 Amendments have not achieved the objective of establishing "*a single comprehensive national scheme providing, through codes adopted by private sector organisations and National Privacy Principles, for the appropriate collection, holding, use, correction, disclosure and transfer of personal information by those organisations.*"

The Australian health care industry is uniquely complex in its structure, spanning both public and private sectors. Most individuals who access health care routinely do so across the public and private sectors. The timely transfer of their health information between those sectors in a manner that respects individual privacy is crucial to the provision of quality health care. In addition, an increasing proportion of health and medical research is conducted across sectoral and jurisdictional boundaries.

The NHMRC considers that:

- Private sector organisations that provide health care or conduct health and medical research are required to work within an overly complex Australian privacy regulatory regime; and
- It is not possible to review the private sector provisions of the Privacy Act in the areas of health care and health and medical research without considering their interaction with other elements of the Australian privacy regulatory regime.

Even if NHMRC stakeholders work solely within the private sector, many information transactions associated with the provision of health care or the conduct of health and medical research require them to understand and/or comply with multiple laws, administrative guidelines and ethical standards in different jurisdictions. Many report considerable confusion about their compliance obligations as a result of the different requirements imposed in different jurisdictions. This confusion is exacerbated by the internal complexity of the Privacy Act, with its dual sets of Privacy Principles and differing requirements for public sector agencies and private organisations.

The NHMRC believes that this complexity and confusion is causing many private sector organisations to make incorrect decisions based on a misunderstanding of the applicable law. Others appear to be adopting a highly conservative approach to privacy compliance, which is impeding unnecessarily the provision of quality health care and the conduct of important health and medical research and is not in the overall public interest.

Our recommendations therefore, are directed at simplifying and streamlining the Privacy Act across both the public and private sectors. In particular, the NHMRC believes that there is an urgent need to implement a single, simplified, national health privacy regulatory regime, and encourages the Federal Privacy Commissioner to pursue this outcome as a priority with other key decision-makers.

Recognising that such an outcome is unlikely to be achieved in the short term, however, further recommendations are directed to simplifying and streamlining the private sector provisions and clarifying their application to a number of important health care and research-related activities.

The surveys undertaken in preparation for this submission confirmed that there is significant stakeholder confusion about the Privacy Act. The different conditions under which agencies and organisations are permitted to collect, use and/or disclose health information without consent should be simplified. The NHMRC firmly believes that the present distinction in the Privacy Act between agencies and organisations creates significant unintended and detrimental effects. It recommends, therefore, that the Information Privacy Principles and the National Privacy Principles are combined into a single set of Privacy Principles that apply to all agencies and organisations; that the present distinction between the various specified types of health and medical research is removed; and that there is provision for a single set of Research Guidelines.

NHMRC stakeholders identified a number of threshold interpretation issues relating to determining whether or not health information is identified or identifiable, and the circumstances in which obtaining consent is impracticable. The NHMRC considers that these terms need to be defined more clearly and a recommendation is made to that effect.

The surveys also identified areas in which misunderstanding of the Privacy Act provisions, rather than problems with the provisions themselves, is giving rise to confusion. On this basis, the NHMRC is also interested in working with the Office of the Federal Privacy Commissioner to design and implement a structured education and communication campaign, with the objective of improving stakeholder understanding of the operation of the Privacy Act.

Clinical stakeholders expressed numerous concerns about the impact of the Privacy Act on the flow of health information for the purposes of patient care, both within single organisations or agencies and between organisations and/or agencies. Many organisations and agencies have adopted a practice of seeking blanket written consent to the future use or disclosure of health information. These consent procedures may be vulnerable to challenge because they lack specificity. In addition, they are cumbersome and costly, and many examples were provided where care was delayed or costly investigations were repeated because of delays in information flow as a result of such procedures.

Stakeholder studies suggested that most health consumers do not clearly understand the concept of health information privacy, and have a low level of awareness of the Privacy Act. Most stakeholders from the General Public and Health Consumer groups agreed that they trusted their doctors and other health professionals to keep information about their health confidential.

The NHMRC considers that the application and/or interpretation of the Privacy Act is impairing the quality, effectiveness and timeliness of management of health information, and that this outcome is not in the public interest. While strongly supporting the central role of consent, the NHMRC considers that current impediments to the flow of health information for clinical care purposes are likely to be seriously detrimental to the care of some individual patients. The NHMRC strongly submits that the enormous volume of information transactions within the health care system, the unique interrelationship between the private and public sectors and the vital impact of the timeliness of information flow on the quality of clinical care justifies the sharing of health information within the treating clinical team without explicit patient consent, provided there is no indication from the patient that such sharing is unacceptable to them.

The availability of health information without consent for quality assurance, research and related activities is crucial to the safety and quality of clinical care, now and in the future. These activities, while similar in nature and intent, are currently subject to complex and different requirements under the Privacy Act, depending on the setting in which they are conducted and whether they are characterised as quality assurance or research.

In particular, the differing requirements of Sections 95 and 95A are inconsistent and confusing. Their application to similar projects in different settings can result in different outcomes, without any apparent policy rationale.

The NHMRC wishes to emphasise the importance of such activities and considers that health information should be accessible without explicit consent for quality assurance and related activities within the organisation or agency in which it has been collected. The NHMRC reaffirms, however, that the following activities should be subject to ethical review and approval:

- The use of health information without consent for research purposes within the collecting organisation or agency; and
- All collection, use and disclosure of health information without consent for quality assurance, research or related purposes outside the organisation or agency in which it has been collected.

In addition, the Privacy Act makes a distinction between "health information relating to medical research" and "research or the compilation or analysis of statistics, relevant to public health or public safety". There is no apparent policy rationale for categorising research into "medical research" or "research relevant to public health or public safety", and the NHMRC strongly recommends that the relevant provisions are clarified and streamlined.

The NHMRC recognises that Human Research Ethics Committees are carrying the burden of privacy compliance, partly because of their need to ensure compliance by researchers with relevant provisions in the Privacy Act, which this submission will demonstrate is complex, and partly because of the annual reporting required of them by the privacy regime. The NHMRC believes that compliance monitoring could be simplified without detracting from privacy protection.

The NHMRC and its stakeholders are concerned that the information infrastructure that is essential to the conduct of quality assurance and research is being jeopardised by the Privacy Act. In particular, activities such as sample acquisition, data registries and data linkage are essential to some important quality assurance and research activities, and are likely to increase in importance in the future. The NHMRC strongly supports the maintenance of such activities provided there is appropriate protection of individual privacy. There is concern that some of these activities may not be possible under the current privacy regulatory regime. The NHMRC recommends, therefore, that the Federal Privacy Commissioner requests an appropriate national body to sponsor the development of a National Standard for the Establishment and Management of Health Information Registries and Data Linkage. Consideration could be given to approving the resulting National Standard as a Code under the Privacy Act. In the interim period, the NHMRC requests that these vital activities are recognised, through a binding determination or legislative or regulatory change, as acceptable if conducted following the scrutiny and approval of an Human Research Ethics Committee.

These recommendations are based on a thorough and well-researched analysis of the impact of the Privacy Act on health care and the conduct of health and medical research in Australia. Their implementation would have a significant positive effect on activities that are of vital interest to the community, now and in the future.

The NHMRC looks forward to continuing to work with the Office of the Federal Privacy Commissioner to ensure that an appropriate balance of individual and public interests is achieved in relation to privacy in the health care sector, through a revised Australian privacy regulatory regime.

Summary of recommendations

Recommendation 1

That the Federal Privacy Commissioner actively pursues with other key decision-makers the preferred option of implementation of a **single, simplified, national health privacy regulatory regime**, to replace rather than supplement existing regulation.

Recommendation 2

That the *Commonwealth Privacy Act 1988* is amended so that:

a) The IPPs and NPPs are combined into a single set of National Privacy Principles that apply to all relevant public sector agencies and private sector organisations;

b) The present distinction between the various specified types of health and medical research is removed;

c) There is provision for a single set of Research Guidelines that apply to the collection, use and disclosure of health information without consent, for the specific purpose of all approved health and medical research by public sector agencies and private sector organisations to which the Privacy Act applies;

d) The new Research Guidelines are applied in a consistent manner, either to exempt agencies and organisations from breach of, or as a means to enable agencies and organisations to meet, the new National Privacy Principles; and

e) The relevant section providing for the Research Guidelines is preceded by a statement highlighting the standards which apply to research involving health information and which are applied and monitored by Human Research Ethics Committees.

Recommendation 3

That the Office of the Federal Privacy Commissioner reconsiders the information it requires to have reported by Human Research Ethics Committees with a view to moving to a complaints driven, "light touch" approach.

Recommendation 4

That the Office of the Federal Privacy Commissioner, in collaboration with the NHMRC, sponsors further education of stakeholders regarding:

a) The general characteristics of data that make the identity of the subject apparent or reasonably ascertainable;

b) The fact that health information to which these characteristics do not apply is not subject to the Privacy Act;

c) The fact that even where the identity of an individual is apparent or can reasonably be ascertained from health information, an HREC, utilising the Research Guidelines, legitimately may decide on public interest grounds to approve its collection, use or disclosure for strictly confidential use by a researcher; and

d) That HREC approval is an acceptable ethical and legal basis for disclosure of health information for the specific purpose of an approved research project, including where consent of the person to whom the information relates has not been obtained.

Recommendation 5

That 'impracticability of consent' is clarified, either through legislation, regulation or a binding determination, to provide that impracticability includes but is not limited to, the following situations:

a) The procedures required to obtain consent are likely to have a serious and adverse effect on the well being of the person from whom consent would be sought;

b) The procedures required to obtain consent would prejudice the scientific value of the research; and/or

c) It is impossible in practice, due to the quantity, age or accessibility of records to be studied, and in the context of the need for scientific rigour of any relevant research, to obtain consent.

Recommendation 6

That, while recognising and supporting the central role of consent, the sharing of all necessary health information with and/or between health care professionals and support staff (the treating team) for the purposes of the current care of an individual patient is recognised as being in the overall public and individual patient interest, and is permitted so long as there is no indication from the patient that such sharing is unacceptable to them, and there are no other circumstances which could reasonably be expected to alert members of the treating team that the patient would object. Recognition should be through a binding determination, legislative or regulatory change.

Recommendation 7

That:

a) The use of health information without consent for the purposes of quality assurance and related activities (including management, funding, monitoring, policy development, planning, evaluation and cost-benefit analysis) is recognised as being in the overall public interest and is permitted (through a binding determination, legislative or regulatory change) even if it is not within the reasonable contemplation or expectation of the person to whom the information relates;

b) The disclosure of health information without consent to (and corresponding collection by) third parties for the purposes of quality assurance and related activities (including management, policy development, planning, evaluation and cost-benefit analysis) is required to be referred for appropriate ethical review, in accordance with guidelines issues by the NHMRC and approved by the Federal Privacy Commissioner (third parties means public sector agencies or private organisations other than the agency or organisation which first collected the health information);

c) All research into the provision or organisation of health care in which it is proposed that health information will be collected, used or disclosed without consent is required to be referred to an HREC for consideration and approval;

d) The definition of 'research' is consistent across all provisions of the Privacy Act and encompasses all health and medical research; and

e) The Federal Privacy Commissioner prepares guidelines on these matters in collaboration with the Australian Health Ethics Committee.

Recommendation 8

That the Federal Privacy Commissioner requests an appropriate national body to sponsor the development of a National Standard for the Establishment and Management of Health Information Registries and Data Linkage which would address, amongst other issues, the collection and holding of health information without consent.

Recommendation 9

1. Background to this submission

1.1 Introduction

This submission was developed on behalf of the NHMRC following an extensive process of consultation with NHMRC stakeholders, and a technical analysis of the Privacy Act.

Dr Heather Wellington and Mr Bob Milstein were sub-contractors who were responsible for the legal analysis for the submission.

Structured stakeholder surveys were undertaken with seven NHMRC stakeholder groups:

- General public and health consumers – qualitative study;
- General public and health consumers – quantitative study;
- Medical and allied health professionals;
- Medical and health service researchers;
- Health data custodians;
- Human Research Ethics Committees; and
- Peak bodies – professional and consumer.

A summary of the survey findings and technical analysis is available on the NHMRC website.

The objective of the surveys was to provide the NHMRC with a comprehensive assessment of the key issues for consumers, researchers, health care providers and other stakeholders as a foundation upon which to develop an informed submission to the Review.

Clinical stakeholders confirmed that a particular difficulty arises when, as is common, a patient receives care from more than one provider agency or organisation. From the perspective of many health care providers, the current privacy legislation both impedes their ability to provide quality health care to individuals and raises significant medico-legal risk. They complain of significant encumbrance in the timely flow of clinical information as a result of the interpretation of consent requirements in privacy legislation. At a minimum, such encumbrance causes inconvenience and inefficiency. It can also result in costly repetition of diagnostic tests, or impaired decision-making because of inadequate information.

Likewise, health and medical researchers have reported that the application of the Australian privacy regulatory regime is an impediment to important research studies, and a large proportion of members of Human Research Ethics Committees (**HRECs**) have said that interpretation of privacy legislation has caused problems for their committees.

In fact, the range of NHMRC stakeholders have reported that the entire Australian privacy regulatory regime is imposing excessive restrictions on, or contributing to a lack of clarity in the understanding of privacy compliance obligations by, health care providers and researchers.

1.3 NHMRC approach to the Review

The NHMRC considers that the following public interests need to be taken into account in the Review:

- Protecting individuals' rights to information privacy;
- Facilitating the provision of health care to individuals;
- Protecting the rights of health care providers to practise quality medicine in a safe medico-legal environment; and
- Undertaking effective health and medical research for the benefit of individuals and the public.

This submission addresses two major issues with respect to the Review's terms of reference:

1. The first issue relates to the overall complexity of Australia's privacy regulatory regime, and the impact this has on stakeholder comprehension of and compliance with the private sector provisions; and
2. The second issue relates to the way in which the private sector provisions impact on the availability of health information for the purposes of clinical care as well as health and medical research, and whether the appropriate balance of public interests is being achieved.

The NHMRC has found it challenging to identify issues that relate exclusively to the private sector provisions. A major contributor to stakeholder difficulty in applying the Privacy Act is the complexity inherent in the Act, which is a direct consequence of the different provisions that apply to public sector agencies and private sector organisations.

> Our recommendations, therefore, are directed at simplifying and streamlining the Privacy Act across both the public and private sectors.

We consider that implementation of these recommendations will have a significant positive effect on the operation of the private sector provisions and the protection of privacy generally across the health care and health and medical research sectors.

1.4 Structure of this submission

The submission details:

- The role of the NHMRC (Section 2);
- The importance of health care, and health and medical research (Section 3);
- The complexity of Australia's privacy regulatory regime (Section 4);
- The need to simplify the Privacy Principles and Research Guidelines (Section 5);
- Threshold issues in interpreting the Privacy Act (Section 6);
- Privacy issues relevant to the sharing of health information for clinical purposes (Section 7) ;
- Privacy issues relevant to quality assurance, research and related activities (Section 8);
- Information infrastructure for research and quality assurance (Section 9); and
- Conclusions (Section 10).

Special Note

The number of respondents was relatively small and some stakeholder groups were complex in structure (eg Peak Bodies, which included professional, consumer and researcher peak bodies). The findings of this research, while indicative, may not be generalisable to the broader stakeholder population.

2. About the NHMRC

The NHMRC is an independent statutory body within the portfolio of the Commonwealth Minister for Health and Ageing. It is Australia's leading expert body promoting the development and maintenance of public and individual health standards. It has extensive links with the Australian community, national and international health research agencies and many other bodies. These bodies, together with researchers; human research and animal ethics committees; the general public and health consumers; and participants in research; form the NHMRC's key stakeholders.

The NHMRC comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission.

The functions of the NHMRC come from the statutory obligations conferred by the *National Health and Medical Research Council Act 1992* (the **NHMRC Act**). The NHMRC Act sets down four statutory obligations on the directions taken by NHMRC:

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

In addition, the *Research Involving Human Embryos Act 2002* established the NHMRC Licensing Committee, a Principal Committee of the NHMRC which is responsible for administering the national regulatory system described by the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*.

The NHMRC is an internationally unique organisation, in that it combines within the one organisation the roles and responsibilities of allocating Commonwealth funds for health and medical research, providing health advice, considering ethical issues in health and regulating sensitive medical research activities. It brings together and draws upon the resources of all components of the health care system, including governments, medical practitioners, nurses and allied health professionals, researchers, teaching and research institutions, public and private program managers, service administrators, community health organisations, social health researchers and consumers.

In 2002/03, $300 million in NHMRC grants was made available for new and continuing health and medical research in Australia. The strategic intent of all NHMRC-funded health and medical research is to improve the health status of Australians.

3. The importance of health care, and health and medical research in Australia

3.1 National investment in health care

While Australians are relatively healthy and have ready access to a health care system that is widely recognised as providing high quality care, there are many opportunities to improve the health and wellbeing of our community.

In 2002/03, expenditure on health care in Australia exceeded $72 billion, representing 9.5% of Gross Domestic Product.[2] Australia's health care expenditure is growing each year, as our population grows and ages, and as new drugs and technologies augment the range and application of available treatments.

Continuation of Australia's high standards of health and health care depends to a significant degree on the ongoing success of our national health and medical research effort.

3.2 National investment in health and medical research

Expenditure on health and medical research in Australia comes from a variety of sources. NHMRC funding of $300 million was made available for new and continuing health and medical research in 2002/03. Significant additional financial and in-kind support to research is also provided by other Commonwealth Departments, State Governments, business enterprises and the private, non-profit sector.[3]

The Australian Government's investment in health and medical research is increasing, with a commitment to double the base level of NHMRC-controlled research funding by 2004-05, representing an investment of an additional $614 million over a five year period. In 2004, the Australian Government also announced extra funding of $200 million over 7 years to support infrastructure costs of independent medical research institutes.

According to the Health and Medical Research Strategic Review (the Wills Review) there are compelling reasons why Australia should focus on health and medical research:

- We have a strong health and medical research base on which to build:
  - Australia has 0.3% of the world's population, but produces 2.5% of the world's health and medical research;
- The quality of our research is very high:
  - 1.3% of Australian publications fall in the world's top 1% most cited research;
  - Australians have received 4 Nobel Prizes for Medicine or Physiology, two others in related fields and many other prestigious awards;
  - Australia is widely recognised internationally for its strengths in health and medical research;
- The increasing cost of health care will place extreme pressure on our economy; and
- There is an unprecedented opportunity to build a strong biotechnology industry based on our accumulated knowledge in research and clinical practice, combined with a new

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[2] Australian Institute of Health and Welfare (AIHW) 2004. Health expenditure Australia 200203. AIHW Cat. No. HWE 27 (Health and Welfare Expenditure Series No. 20). Canberra: AIHW. Accessed on 18 October 2004 at http://www.aihw.gov.au/publications/hwe/hea02-03/hea02-03.pdf

[3] The Wills Review (see footnote 4) estimated that competitive funding through the NHMRC accounts for 25% of public investment in health and medical research. In addition, industry investment funds approximately 12% of overall health and medical research, and private, non-profit organisations fund approximately 16%.

understanding of the human genome and the massive information processing capabilities available through bioinformatics.[4]

Access Economics, in its report *Exceptional Returns: The Value of Investing in Health R&D in Australia,* noted:

- The likely returns from health Research and Development are so extraordinarily high that the "payoff" from a strategic portfolio of investments is enormous;
- An estimated half the historical gains in 'healthspan' are attributable to global Research and Development; and
- Australia has a comparative advantage in health Research and Development, given our levels of discovery, publications, citations and other evaluative criteria relative to our size in the global market.[5]

The NHMRC considers that a vibrant and strong health and medical research sector imparts considerable public benefit to the Australian community.

3.3 Information needs for quality health care and research

3.3.1 Introduction

The provision of high quality health care and the conduct of essential health and medical research are increasingly information-dependent, as a result of:

- A move from solo clinical practice to larger practices;
- An increasing focus on multi-disciplinary care, particularly for patients with complex or chronic conditions, with a shift in the role of the scientist and doctor from an individual contributor to a team member;
- Less reliance on institutional care, and greater reliance on community-based care;
- Increasing consumer choice and patient mobility between practitioners;
- Increasing dependence on the clinical record as the source of information for decisions, quality assurance and research; and
- Increasing technical complexity of modern science and medicine, and the accelerating pace of knowledge.

There are also growing institutional imperatives to access health information for a variety of purposes, including management, financing, education and research, all of which have a strong pubic interest imperative.

As noted by the Australian Institute of Health and Welfare:

> *In the most general terms, health information is important for the understanding of the health status of the population, the extent and nature of various health problems and their determinants and causes, the services and interventions to reduce these problems and their health outcomes. Health information and statistics are fundamental to developing effective health policies and programs, to coordinating treatment and care, and to empowering consumers.*[6]

The importance of effective health information management nationally is reflected in a recent review of governance arrangements for investment in information management and technology. Two new

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4 Commonwealth of Australia. *The virtuous cycle. Working together for health and medical research* (the Wills Review). 1999. Pages 1-11. Accessed on 23 October 2004 at http://www7.health.gov.au/nhmrc/wills/hmrsr/summary.pdf

5 Access Economics. *Exceptional returns. The value of investing in Health R&D in Australia.* September 2003. Pages 1-2. Accessed on 23 October 2004 at http://www.asmr.org.au/general/Summary.pdf.

6 Australian Institute of Health and Welfare 2004. *Australia's health 2004.* Canberra: AIHW. Page 336.

bodies – the Australian Health Information Council and the National Health Information Group – have been formed to provide leadership on information management and technology and to advise the Australian Health Ministers' Advisory Council and the Australian Health Ministers' Conference. The new arrangements recognise the need for coordinated coherent governance of information management in health care, and will be reflected in a new National Health Information Agreement.

The NHMRC is strongly committed to promoting the ethical use of health information, in a manner that complies with the law and supports the overall public interest.

The continuing provision of high quality health care and the conduct of health and medical research in Australia therefore require the creation and maintenance of a supportive regulatory scheme, including a sound, coherent and workable Australian privacy regulatory regime, operating within an overall ethical framework that protects the rights of health care recipients and research participants.

3.3.2 Information needs for quality health care

The quality of the health care provided to individuals depends on the availability to the treating health care team of all relevant information about past history, family history, present symptoms, recent treatment and investigative results.

Individuals need a high level of confidence that their health information will be treated with the utmost respect and confidentiality. Without such confidence, they may not volunteer information that is vital to the provision of quality care.

Australia's health care system is substantial and complex. It is one of the largest industry sectors in the Australian economy and provides an extraordinarily high number of individual services across a wide range of primary, secondary and tertiary agencies and organisations in both the public and private sectors. In 2001/02 there were:

- 724 public acute care hospitals, 301 private hospitals other than free-standing day hospital facilities, and 236 free-standing day hospitals;[7]
- 19,464 private medical practices, and 50 private pathology laboratory businesses;[8]
- 6,398,171 separations of admitted patients from public acute, public psychiatric and private hospitals, a rate of 327 separations per 1000 population; 3,948,860 separations from public acute hospitals; 16,652 separations from public psychiatric hospitals; and 2,432,659 separations from private hospitals (including private psychiatric hospitals and private free standing day hospitals);[9] and
- 39,522,981 non-admitted patient occasions of service provided by public acute hospitals; and 1,748,000 non-admitted occasions of service provided by private hospitals.[10]

In 2002/03, 221.4 million Medicare-funded services were provided through the Australian health care system.[11] It should be noted that some individuals receive a very high number of health care services. For example, in 2002/03, 3% of the population received 51 or more Medicare-funded services.[12]

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7 Australian Institute of Health and Welfare. *Australia's health 2004.* Canberra: AIHW. Page 286. Accessed on 13 November 2004 at http://www.aihw.gov.au/publications/hse/ahs02-03/ahs02-03-c00.pdf.

8 *Ibid.* Page 293.

9 *Ibid.* Page 276.

10 *Ibid.* Page 285.

11 *Ivid.* Page 296.

12 *Ibid.* Pag e297.

The NHMRC wishes to emphasise that in practice, it is difficult to consider privacy issues in the private sector separately from privacy issues in the public sector. There are very few members of the Australian community who receive their health care from a provider, or providers, who operate solely within the private sector. Large numbers of patients are transferred between private health services and public hospitals, and, similarly, large numbers of patients are routinely discharged from public hospitals to the care of private practitioners in general or specialist community practice.

In addition, an increasing number of patients in public hospitals are electing to be treated as private patients. In 2002-03, there were 371,000 private patients (9.1 per cent of all patients) admitted to public hospitals compared with 318,000 private patients (8.3 per cent of all patients) in 1998-99. This represents nearly a 17 per cent growth in the proportion of private patients admitted to public hospitals over the five-year period.[13]

Within the community sector, many patients move between privately and publicly owned and/or funded organisations including general practices and community health services.

> The NHMRC considers that the uniquely complex structure of the Australian health care system and the way in which service provision routinely crosses public and private boundaries requires special consideration of how to manage health information privacy most effectively.

Above all, the privacy regime within which health information is managed must ensure that the provision of quality health care is not hindered unnecessarily by impediments to the transfer of important clinical information in a timely manner between the public and private sectors.

3.3.3 Information needs for health and medical research

The ethical conduct of research is a key priority for the NHMRC. The NHMRC has resolved that only institutions that observe the standards and procedures set out in its *National Statement on Ethical Conduct in Research Involving Humans* (the **National Statement**) will be eligible for NHMRC research grants. The National Statement sets out the minimum acceptable standards for conducting research involving humans. Importantly, it also describes the role and responsibilities of HRECs in reviewing research proposals involving humans.

The National Statement is endorsed by the Australian Vice-Chancellors' Committee, the Australian Research Council, the Australian Academy of Humanities, the Australian Academy of Science and the Academy of Social Sciences in Australia, and is supported by the Academy of Technological Sciences and Engineering. This means that the vast majority of human research conducted in the Australian health care system is reviewed by an HREC, the primary role of which is to protect the welfare and the rights of participants in research.

Consistent with patterns of the provision of clinical care, the conduct of health and medical research in the Australian health care system frequently spans the public and private sectors.

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[13] Australian Government Department of Health and Ageing. *Public versus private. Do you know the difference?* Accessed on 23 October 2004 at http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-ahca-sooph-where_public.htm

Much health and medical research is multi-site or multi-jurisdictional, involving participants who move between the public and private health sectors.

Privacy legislation needs to take into account the public interest in effective research being conducted regardless of jurisdictional or sectoral boundaries.

4. The complexity of Australia's privacy regulatory regime

4.1 Introduction

The NHMRC notes that the Australian privacy regulatory regime is not confined to Commonwealth privacy legislation. There are relevant common law principles, administrative guidelines and ethical standards, and in addition, the Privacy Act operates in conjunction with other Commonwealth, State and Territory laws. The consequence is a remarkable level of complexity.

At **Attachment 1** we provide, as an example, a description of the privacy regulatory regime as it applies to Victoria.

The majority of episodes of health care provision, and a significant proportion of health and medical research projects, are conducted in multiple settings that cross sectoral and jurisdictional boundaries.

The jurisdictional and sectoral differences inherent in Australia's privacy regulatory regime do not rest easily with the everyday realities of information flow for both clinical care and health and medical research in Australia. The challenge for all NHMRC stakeholders is to protect the privacy of individuals' health information in circumstances where timely transfer of that information between agencies and organisations operating in both the public and private sectors may be crucial to the individual's and/or the public's interest.

In any setting, for every disclosure there is a corresponding 'collection'. Even if the private sector provisions of the Privacy Act apply to a stakeholder, it is almost inevitable that in the ebb and flow of information exchange they will encounter stakeholders whose legal obligations differ. Stakeholders often, therefore, have to answer two fundamental questions:

1. Which laws apply to me?
2. Which laws must I apply?

To be confident of compliance with their privacy obligations, those to whom the private sector provisions of the Privacy Act apply may need to be aware of and/or comply with co-existing obligations of privacy and confidentiality, as established by:

- Privacy legislation or regulation applying to all public sector bodies. The Commonwealth, Australian Capital Territory, New South Wales, the Northern Territory and Victoria all have legislation of this type;
- Other privacy legislation or regulation applying to private sector bodies. Currently, this exists in New South Wales and Victoria where state legislation regulates private sector health services in the collection, storage, access, use and disclosure of health information;
- Administrative guidelines applying to public sector bodies in Tasmania, Queensland and South Australia. These would generally be treated as subject to other legislation, a status that is explicit in Queensland;
- Legislative privacy provisions contained within other statutes;
- Legislative confidentiality or secrecy provisions contained within other statutes; and
- Common law obligations of privacy and confidentiality.

It is clear that, even for stakeholders who work within a single jurisdiction, identification of and compliance with the relevant legislation can be a daunting task (see Attachment 1). In some jurisdictions that have their own private sector legislation, affected persons are obliged to comply with two sets of privacy statutes – their own jurisdiction's and the Commonwealth's. Given the multiplicity of laws, it is very difficult for individual stakeholders, most of whom are strongly committed to the ethical conduct of health care delivery and research but are not experts in privacy law, to determine with certainty which laws apply in a relevant information exchange.

The NHMRC firmly believes that the high volume of complex interactions between the public and private sectors in the delivery of health care, as well as in the conduct of health and medical research, means that the private sector provisions of the Privacy Act cannot and should not be considered in isolation from other elements of the Australian privacy regulatory regime.

4.2 The consequences of the complexity

Stakeholders have advised the NHMRC that the complexity inherent in Australia's privacy regulatory regime is leading to:

- Clinical care, quality assurance and related activities being compromised because access to essential health information is impaired;
- Significant research not being approved; and/or
- Additional requirements being imposed on some research that reduce its scientific rigour.

The stakeholder surveys conducted in preparation for the development of this submission confirmed that there is only a modest level of awareness of many of the relevant elements of the Australian privacy regulatory regime. The survey of health care professionals confirmed that almost half of all respondents did not know which privacy legislation applied to them in their capacity as health care professionals. Other stakeholders have a relatively high level of awareness of the broad concepts underpinning the Privacy Act, but the level of awareness falls with more detailed aspects of the legislation (Table 1).

Table 1: Awareness of aspects of the Federal privacy regulatory regime[14]

Specific aspect of the Federal privacy regime	Researchers n=112 (%)	Data Custodians n=37 (%)	HRECs n=80 (%)	Peak Bodies n=51 (%)
The role of HRECs	98	97	97	79
The Commonwealth Privacy Act that applies to public agencies	76	94	92	90
The Amendment (2001) to the Commonwealth Privacy Act	59	82	77	80
The 10 National Privacy Principles for the private sector	44	81	62	74
The 11 Information Privacy Principles for Commonwealth agencies	40	68	68	67

[14] Note that proportions are indicative but not necessarily representative of the entire population from which the samples were recruited.

Table 1: Awareness of aspects of the Federal privacy regulatory regime[14]				
Specific aspect of the Federal privacy regime	Researchers n=112 (%)	Data Custodians n=37 (%)	HRECs n=80 (%)	Peak Bodies n=51 (%)
The use of Section 95 Guidelines (Commonwealth)	39	71	63	30
The use of Section 95A Guidelines (private sector)	31	78	57	41
The difference between Section 95 and Section 95A Guidelines	24	57	53	24
The difference between the Information and National Privacy Principles	20	53	55	43

Overall, the NHMRC believes that the current complexity of the Australian privacy regulatory regime is generating confusion for stakeholders for whom privacy is an important but not frequently encountered aspect of their work. As a result stakeholders appear to be:

- Ignoring the legislation (with the well-intentioned but incorrect assumption that by working according to the confidentiality prescripts of ethical professional practice they are working within the law);
- Working according to their intuition of what the law probably requires of them;
- Conducting their affairs based on a superficial reading of the legislation that they believe probably applies to them; and/or
- Adopting an unnecessarily conservative approach to the handling of information due to misinterpretation of the legislation.

The NHMRC believes that such responses are hindering the provision of quality health care as well as the conduct of effective health and medical research. There is evidence that legitimate and ethical activities (which in some cases are vital to the quality provision of health care or the conduct of important health and medical research) are being delayed or proscribed because some key decision-making bodies are unable to determine, with sufficient confidence, whether specific collections, uses and/or disclosures of information accord with legislative requirements. The adoption of a highly conservative approach is resulting in excessive administrative effort and a reluctance to approve the legitimate use and disclosure of health information for the purposes of health care, as well as health and medical research.

> The NHMRC considers that an appropriate balance between individual privacy and the public interest in the provision of quality health care and the conduct of effective health and medical research is not being achieved within the current federal privacy framework.

The NHMRC considers, therefore, that:

- There is an urgent need to simplify Australia's privacy regulatory scheme and create a single, simplified national scheme; and
- In the absence of a single, simplified, national scheme, there are, nevertheless, opportunities to simplify the Privacy Act to improve consistency of its application and to remove significant barriers to the provision of quality health care and the conduct of important health and medical research.

The NHMRC notes that the Australian Health Ministers' Advisory Council (**AHMAC**) draft National Health Privacy Code:

- Represents a significant advance in privacy regulation with respect to health information; and
- Could form the basis of a uniform regulatory approach applicable in all jurisdictions, replacing rather than supplementing existing regulation.

The NHMRC urges the Federal Privacy Commissioner, as well as considering amendments to the Privacy Act, to pursue as a priority with other key decision-makers the acceptance and implementation of a single, simplified national health privacy regulatory regime.

Recommendation 1

That the Federal Privacy Commissioner actively pursues with other key decision-makers the preferred option of implementation of a **single, simplified, national health privacy regulatory regime**, to replace rather than supplement existing regulation.

Recognising, however, that:

- The terms of reference for the Review focus on the operation of the private sector provisions of the Privacy Act;
- It is difficult to separate privacy issues in the private sector from privacy issues in the public sector; and
- The progress of the draft National Health Privacy Code has been slow;

the remainder of this submission focuses on opportunities to promote the appropriate balance of public interests through simplification, clarification and reform of the existing private sector provisions of the Privacy Act.

5. Simplifying the Privacy Principles and Research Guidelines

5.1 The relationship between Privacy Principles and Research Guidelines

One of the most readily identifiable aspects of the Privacy Act that is creating confusion for NHMRC stakeholders is the existence of two sets of Privacy Principles – the Information Privacy Principles (**IPPs**) and the National Privacy Principles (**NPPs**) – and the related Section 95 Guidelines and Section 95A Guidelines (the **Research Guidelines**).

The NHMRC notes that the IPPs apply to agencies (which are, essentially, Commonwealth Government entities and entities that represent the Commonwealth Government) and the NPPs apply to organisations (which are, essentially, private sector entities[15]). Although the IPPs and NPPs are similar in content, they differ in some important respects, and have potentially very different effects on some information-based activities in health care as well as in health and medical research.

Section 95 enables the NHMRC, with the approval of the Federal Privacy Commissioner, to issue guidelines for the protection of privacy in the conduct of medical research by agencies. Where an activity undertaken in an agency would otherwise breach an IPP, and the activity is done in the course of medical research and in accordance with the Section 95 Guidelines, the activity is regarded as not breaching the IPP.

Section 95A relates to the collection, use and disclosure of health information by organisations, and provides that:

- For the purposes of subparagraph 2.1(d)(ii) of the NPPs, the Federal Privacy Commissioner may, by notice in the *Gazette*, approve guidelines that relate to the use and disclosure of health information for the purposes of research, or the compilation or analysis of statistics, relevant to public health or public safety; and
- For the purposes of subparagraph 10.3(d)(iii) of the NPPs, the Commissioner may, by notice in the *Gazette*, approve guidelines that relate to the collection of health information for the purposes of:
  - Research, or the compilation or analysis of statistics, relevant to public health or public safety; or
  - The management, funding or monitoring of a health service.

The Research Guidelines, therefore, establish conditions under which either agencies (Section 95) or organisations (Section 95A) are permitted to collect, use and/or disclose health information *without consent* for specific activities.

The activities which can be referred to an HREC for consideration under the Research Guidelines differ, depending on the particular setting in which they are to be conducted:

- Proposals by an agency for the collection, use and disclosure of health information for the purposes of medical research (a term which is not defined) can be referred to an HREC;
- Proposals by an organisation for the collection, use and disclosure of health information for the purposes of research, or the compilation or analysis of statistics, relevant to public health or public safety (terms that also are not defined) can be referred to an HREC; and
- Proposals by an organisation for the collection of health information for the purposes of management, funding or monitoring of a health service can be referred to an HREC.

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15 Note that the definition of 'organisations' includes non-government organisations, community groups and individuals.

It is clear to the NHMRC that the varying conditions associated with the collection, use and/or disclosure of health information for specific purposes are creating considerable confusion for all NHMRC stakeholders, public and private alike. The surveys conducted by Campbell Research & Consulting in preparation for this submission confirm that it is a challenging task indeed for a stakeholder who is not trained in the law to discern from the Privacy Act which principles apply to their specific activities, or the detail of the differences between the IPPs and the NPPs and the relevant Research Guidelines. In fact, of the 80 members of HRECs who responded to the relevant survey, only 55% were aware of the difference between the IPPs and the NPPs and only 53% were aware of the difference between the Section 95 and Section 95A Guidelines.

This group of stakeholders is relatively well-educated about privacy compliance issues. Its members are informed and motivated. Most have been exposed to significant training in relation to the Privacy Act, but many remain confused about its proper application, including the proper application of the private sector provisions.

The NHMRC considers that:

- It is extremely challenging to establish and maintain an acceptable level of stakeholder awareness about the application of the private sector provisions of the Privacy Act to the collection, use and/or disclosure of health information by agencies, when compared with the way in which the Privacy Act addresses the same issues for organisations. Such an objective may never fully be achieved;
- There is no obvious rationale that requires health information to be managed differently by agencies and organisations, and the existence of these differences is creating confusion and resulting in incorrect interpretation of the Privacy Act in all sectors;
- There is no obvious rationale for the Section 95 Guidelines operating to exempt agencies from breach, while the Section 95A Guidelines operate to facilitate organisations meeting the NPPs;
- There is no obvious rationale for the present distinction in the Privacy Act between "health information relating to medical research" and "health information relating to research, or the compilation or analysis of statistics, relevant to public health or public safety, or the management, funding or monitoring of a health service". The distinction results in significant detriment to research and related activities that can provide substantial benefit to the health of the Australian population, because it excludes non-medical health research by agencies from consideration under the Section 95 guidelines, and medical research that is not relevant to public health or public safety from consideration under the Section 95A Guidelines;
- Combining the IPPs and the NPPs into a single set of Privacy Principles, associated with a single set of Guidelines for the collection use and/or disclosure of health information for research purposes would substantially facilitate stakeholder comprehension and compliance; and
- There is a pressing need to expand and improve resources, education and training for stakeholders, both in relation to their specific privacy compliance obligations with respect to the Privacy Act and the interaction between those and other existing and expanding privacy compliance obligations.

5.2 Impact on Human Research Ethics Committees

Chapter 18 of the *National Statement on Ethical Conduct in Research Involving Humans* sets out the responsibilities of HRECs, when reviewing research proposals, in regard to the researcher's conformity with relevant privacy regulation and the protection of individual privacy. The review by HRECs of the privacy issues related to research protocols is a significant responsibility because the environment, as described above, is complex.. The differences in the requirements of the *Guidelines under Section 95 of the*

Privacy Act 1988 and the *Guidelines approved under Section 95A of the Privacy Act 1988* are small, but confusing. The lack of awareness revealed in Table 1 (Section 4) means that HRECs devote additional time and resources to identifying and deliberating over the application of privacy regulation to research proposals. This is reinforced by, and in turn contributes to, the conservative approach revealed by the stakeholder survey undertaken.

Added to the complexity of the review process by HRECs is the requirement for reporting their application of the Research Guidelines. This requirement to report to AHEC is enshrined in the Research Guidelines and is undertaken on an annual basis. The aim of the reporting is to provide information to AHEC to determine HREC compliance with the Research Guidelines. The information requested by AHEC is based on information required by the OFPC as determined when the Research Guidelines were developed. The most recent annual report form contained thirty questions relating to the Research Guidelines.

The result of this current reporting approach has been a significant increase in both HREC and AHEC Secretariat workloads in order to meet external (OFPC) reporting requirements. HRECs find it somewhat difficult to report retrospectively on their application of the Research Guidelines and always need prior warning if the reporting requirements are to change to allow them to commence data capture. In turn, AHEC has had to commit significant staff resources to analyse the responses from approximately 220 HRECs and undertake follow up action on those responses to the 30 privacy questions that suggest some misinterpretation of the questions and hence doubts about these HRECs' compliance status. Other costs incurred by AHEC include the initial development and dissemination of the Research Guidelines and the annual cost of compiling, printing and distributing the annual report form.

In order to facilitate compliance, in 2002, NHMRC, through AHEC, conducted national workshops to assist HRECs and researchers in understanding the requirements of the Research Guidelines. The workshops were developed and run collaboratively with OFPC and were attended by approximately 1110 people at a cost to NHMRC of approximately $230 000.

In addition, AHEC is currently working on mechanisms and models to facilitate the more efficient review of research that is undertaken at multiple sites. In cases where such research raises issues around privacy, the need for reform of the current approach is heightened: as noted earlier in this submission, multi-site research often involves both the public and private health sector, compounding the difficulties encountered with the current need to have regard to two sets of Privacy Principles.

Given that AHEC's monitoring of the Research Guidelines to date indicates that adherence is satisfactory, it may be useful to consider alternative monitoring mechanisms. It is worth noting that alleged breaches of privacy in clinical practice are monitored by a complaints-based approach; such an approach could be adequate in the research context and may be more cost-effective, better aligned with risk management principles and in keeping with the original spirit and intent of the "light touch" legislation.

The NHMRC considers that:

- With the experience of reporting over the past four years, it has been demonstrated that breaches of privacy in research are not occurring and that the current annual process of collecting and analysing information from HRECs does not, of itself, contribute to privacy protection.
- However, it is appropriate that HRECs should continue to report to either AHEC or the OFPC on their application of the Research Guidelines.
- The current approach to reporting privacy compliance is onerous for both HRECs and AHEC and it is timely to consider both the purpose of the reporting and therefore the optimal type and amount of information to be collected.

- Having reviewed what information it requires relating to privacy, should the OFPC determine that it wishes to retain the current reporting arrangements, then the OFPC and AHEC should discuss and agree on appropriate mechanisms and relative responsibilities for the collection and analysis of the data required.
- As indicated in Recommendation 4 (Section 6) of the submission, NHMRC is open to assisting OFPC in any educational endeavours relating to revision of the legislation. However, such activities would require the allocation of resources for this specific purpose.

Recommendation 2

That the *Commonwealth Privacy Act 1988* is amended so that:

a) The IPPs and NPPs are combined into a single set of National Privacy Principles that apply to all relevant public sector agencies and private sector organisations;

b) The present distinction between the various specified types of health and medical research is removed

c) There is provision for a single set of Research Guidelines that apply to the collection, use and disclosure of health information without consent, for the specific purpose of all approved health and medical research by public sector agencies and private sector organisations to which the Privacy Act applies;

d) The new Research Guidelines are applied in a consistent manner, either to exempt agencies and organisations from breach of, or as a means to enable agencies and organisations to meet, the new National Privacy Principles; and

e) The relevant section providing for the Research Guidelines is preceded by a statement highlighting the standards which apply to research involving health information and which are applied and monitored by Human Research Ethics Committees.

Recommendation 3

That the Office of the Federal Privacy Commissioner reconsiders the information it requires to have reported by Human Research Ethics Committees with a view to moving to a complaints driven, "light touch" approach.

Implementation of Recommendation 2 will provide the opportunity to address a number of inconsistencies and interpretative difficulties in the private sector provisions of the Privacy Act.

The NHMRC is willing to work with the Office of the Federal Privacy Commissioner to design and conduct a long term, structured education and communication campaign, to improve understanding by all key stakeholders of the operation of privacy legislation with respect to the management of health information in health care, health and medical research, quality assurance and related activities.

In the remainder of this submission, we describe and make recommendations about a number of issues that have created difficulties for NHMRC stakeholders in their efforts to comply with the private sector provisions of the Privacy Act.

6. Threshold interpretation issues

6.1 Introduction

The Privacy Act only imposes obligations with respect to information where the identity of the person to whom the information relates is apparent or can reasonably be ascertained. In addition, if valid consent for collection, use or disclosure of health information is obtained, no further obligations are imposed.

'*Impracticability of consent*' is one of three prerequisites to the operation of the Section 95A Guidelines, as set out in NPP 2(1)(d)(i) and NPP 10.3(c).

NHMRC stakeholders are, however, experiencing difficulty in determining whether a person's identity is 'apparent or can reasonably be ascertained' and in which circumstances consent is 'impractical'.

Further threshold issues relate to the management of health information relating to individuals who are dead, and the management of identifiable genetic samples. The NHMRC notes that the management of genetic information is outside the terms of reference of the Review. Nevertheless, the NHMRC wishes to draw to the Privacy Commissioner's attention its support for recommendation 8-2 of Australian Law Reform Commission Report *Essentially Yours: The Protection of Human Genetic Information in Australia*, which recommends that the Privacy Act should be amended to extend the coverage of the IPPs and NPPs (or similar privacy principles) to identifiable genetic samples.[16]

The NHMRC also notes and supports recommendation 7-6 of that report, which proposes that the Privacy Act should be amended to provide that health information includes information about an individual who has been dead for 30 years or less, and that such amendments should include provision to enable decision making by next-of-kin or an authorised person in relation to the handling of a deceased individual's health information. This is an additional area in which significant jurisdictional differences add to the confusion of health care professionals and administrators as they attempt to meet their compliance obligations. Clear and consistent requirements at a national level would be welcomed by those charged with administering Australia's privacy regulatory regime, as well as by those who seek to access information relating to deceased individuals.

6.2 Identity of the person to whom the information relates

The issues for health researchers and HREC members are:

- Identifying whether it is from the perspective of the discloser or the collector that data are de-identified;
- Distinguishing between the meaning of terms used in the National Statement and the Privacy Act. The National Statement uses the terms 'identified data', 'potentially identifiable data' and 'de-identified data'. This categorisation applies a higher protection to coded data, because in combination with the code, identity can be discovered. The Privacy Act, on the other hand, uses the test of reasonable ascertainability from the information itself;
- The implications of permanent severance where, for clinical reasons, the person to whom the information relates may need to be contacted for their own benefit;
- The implications of permanent severance where identification may be required for research that may benefit public health (either for recruitment of research subjects or data linkage); and

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16 Australian Law Reform Commission 2003. *Essentially yours. The protection of human genetic information in Australia.* Canberra: ALRC. Accessed on 22 November 2004 at http://www.austlii.edu.au/au/other/alrc/publications/reports/96/_6_List_of_Recommendations.doc.html

- Disclosure of information between members of a research team.

The NHMRC recognises that stakeholders require further education, with a focus on the following:

- That the Privacy Act does not apply to information where the risk of identification has been reduced to a level where the identity of the individual could not reasonably be ascertained by a researcher to whom the data were disclosed;
- Only where there is a reasonable possibility that a researcher may be able to ascertain the identity of a person to whom the information relates does the Privacy Act come into play; and
- In that circumstance, following an assessment based on the balance of public interests and acting in accordance with approved guidelines, an HREC may nevertheless conclude that it is reasonable for health information to be collected, used or disclosed.

Recommendation 4

That the Office of the Federal Privacy Commissioner, in collaboration with the NHMRC, sponsors further education of stakeholders regarding:

a) The general characteristics of data that make the identity of the subject apparent or reasonably ascertainable;

b) The fact that health information to which these characteristics do not apply is not subject to the Privacy Act;

c) The fact that even where the identity of an individual is apparent or can reasonably be ascertained from health information, an HREC, utilising the Research Guidelines, legitimately may decide on public interest grounds to approve its collection, use or disclosure for strictly confidential use by a researcher; and

d) That HREC approval is an acceptable ethical and legal basis for disclosure of health information for the specific purpose of an approved research project, including where consent of the person to whom the information relates has not been obtained.

6.3 Impracticability of consent

The *Guidelines on privacy in the private health sector* (the **Health Guidelines**) and the Office of the Federal Privacy Commissioner's Information Sheet 9 provide guidance concerning 'impracticability'.

The Health Guidelines provide that 'impracticability' may arise where there are no current contact details for an individual and there is insufficient information to get up-to-date contact details. Information Sheet 9 suggests that in some circumstances, invalidation of a research methodology may constitute 'impracticability'.

The National Statement, in its discussion of epidemiological research, at 14.4(a) identifies the following criteria as generally relevant to the release of identified or potentially identifiable data:

- The procedures required to obtain consent are likely either to cause unnecessary anxiety for those whose consent would be sought or to prejudice the scientific value of the research and there will be no disadvantage to the participants or their relatives or to any collectivity involved; or
- It is impossible in practice, due to the quantity, age or accessibility of records to be studied, to obtain consent.

The key issues in relation to impracticability of consent were summarised by one Research respondent to stakeholder survey:

> *"Many of my epidemiological studies are based on the linked statistical collections maintained by the Department of Health of [state], supplemented by additional clinical information abstracted from hospital medical records or questionnaires to doctors and occasionally to patients (for example about continuation on medications prescribed while in hospital). These are generally large retrospective studies involving several hundred (sic) or thousands of patients, for whom it would not be possible to obtain informed consent, particularly for those who had died or suffered other adverse outcomes that are the end points for the research. Ethics approval for these studies are often based on the provisions of Paragraph 14.4 of the NHMRC National Statement on Ethical Conduct of Research Involving Humans, that permit epidemiological research without informed consent where the procedures to obtain this could cause unnecessary anxiety, where the scientific value would be prejudiced and there would be disadvantage to participants or their families or to collectivities, or it would be impossible in practice to gain consent AND the public interest in the research outweighs to a substantial degree the public interest in privacy."*

Some health researchers who responded to the stakeholder survey considered that the privacy framework is a step in the right direction, although more consistent guidelines on impracticability of consent would be welcomed:

> *"However, the future direction of research in my own field will be towards larger, multicentre trials, enrolling many more patients than has formerly been the case. I think, and I believe the rest of the Intensive Care community would agree, that, because of the absence of informed consent in intensive care research, the existing guidelines and legislation need to consider intensive care specifically, and spell out what is and what is not, permissible. Existing legislation is often unclear, and there is an absence of legislation in some jurisdictions, which leaves the researcher in an uncomfortable position. The privacy legislation is better than the legislation, for example, on informed consent; but nevertheless, the absence of informed consent in our particular field merits specific consideration."*

The NHMRC considers that:

- The consent provisions of the National Statement and the Privacy Act should be consistent; and
- The creation of adverse psychological or treatment outcomes for a person from whom consent is sought, or the creation of prejudice to the scientific value of health and medical research, are both relevant circumstances that justify waiving the requirement for consent to the collection, use and/or disclosure of health information for the purposes of health and medical research.

In line with contemporary legal approaches to the concept of therapeutic privilege, however, the NHMRC considers that the concept of 'unnecessary anxiety' should be further defined to only encompass circumstances in which the procedures necessary to obtain consent are likely to seriously and adversely affect the well being (which includes the psychological health) of the person from whom consent would be sought.

Recommendation 5

That 'impracticability of consent' is clarified, either through legislation, regulation or a binding determination, to provide that impracticability includes but is not limited to, the following situations:

a) The procedures required to obtain consent are likely to have a serious and adverse effect on the well being of the person from whom consent would be sought;

b) The procedures required to obtain consent would prejudice the scientific value of the research; and/or

c) It is impossible in practice, due to the quantity, age or accessibility of records to be studied, and in the context of the need for scientific rigour of any relevant research, to obtain consent.

7. Sharing health information for clinical purposes

7.1 Introduction

Health care professionals have a long history of respecting the confidentiality of health care information. They did so before the introduction of legislative obligations and continue to do so notwithstanding those obligations. The multi-disciplinary nature of health care necessitates prompt and effective communication between health care professionals, some of whom work within and some of whom work outside the entity that is primarily responsible for a patient's care.

The Privacy Act provides that health information may only be used for the primary purpose for which it was collected, unless specific circumstances apply. Both the IPPs and the NPPs, rightly, give consent a central place in privacy protection. Both demand that individuals are informed about, or consent to, collection of information, and consent is also an important condition for use and disclosure of information for purposes other than the primary purpose.

Many health consumers do not appear to clearly understand the concepts of health information privacy. Health Consumer[17] respondents (70%) to the stakeholder study were more aware of 'special privacy laws' than the General Public (52%). Specific awareness of 'Commonwealth privacy laws' was lower for both Health Consumer respondents (45%) and the General Public (43%). Many members of the General Public and Health Consumers, however, identify privacy only with confidentiality, and many are unable to articulate the specific confidentiality protections in privacy legislation. For example, when the 52% of the General Public and 70% of Health Consumer respondents who stated they were aware of privacy laws were asked what they knew about the laws, two main responses were received:

- *"Information about me must be kept confidential/secret".* In total 44% of those who claimed to be aware of privacy laws gave this response – 47% of the General Public and 33% of Health Consumer respondents; and
- *"Doctors must keep information confidential unless they have [written/signed] permission".* In total 39% gave this response – 36% of the General Public and 50% of Health Consumer respondents.

Thus only 35% of all the stakeholder respondents who considered themselves to be aware of privacy laws were able to identify (without prompting) this specific aspect of Privacy legislation.

Discussion with clinical stakeholders suggests that there is considerable confusion about how privacy legislation impacts on the exchange of clinical information. One stakeholder reflected these views as follows:

> *"The privacy legislation either seemingly or directly inhibits or prohibits the exchange of information about a given patient between clinicians who are involved in care of that patient but who may be 'located' in different departments, institutions or states or territories of Australia. This free exchange of information is critical to the provision of optimal care to patients and is unnecessarily complicated by privacy requirements."*

The challenge, clearly, is to achieve an acceptable balance between ensuring that the health care of some individuals is not jeopardised by the administrative difficulties associated with processes to protect their personal privacy, for which they may or may not see a need, while addressing simultaneously the needs of those individuals who seek rigorous protection of the privacy of their health information.

7.2 Current practice

Current practice, in some cases, is to seek a 'blanket' written consent to use or disclose health information for a range of future purposes. Such consent processes are vulnerable to legal challenge,

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[17] 'Health Consumers' were defined as those consumers who have a serious infectious, life threatening or chronic health conditions who are likely to attend a GP once a week or a specialist once a month.

on the basis that they may be uninformed and lack specificity. The alternative of seeking explicit consent on each occasion in which health information is proposed to be used or disclosed for the purposes of clinical care is likely, however, to generate considerable costly administrative effort. Particularly in large health organisations and in the context of an increasing system-wide emphasis on multi-disciplinary care, ascertaining individually with each patient whether it is acceptable for health information to be shared between various health care professionals and support staff involved with their care is unworkable and, arguably, unnecessary in most circumstances.

7.3 Stakeholder attitudes

The telephone survey of the General Public and Health Consumers found that:

- Few (6% of the General Public and 17% of Health Consumer) respondents had ever felt that *information about their health was not treated in confidence*;
- Nearly all (99% of the General Public and 93% of Health Consumer) respondents had never made a complaint about a perceived breach of their personal health information;
- Most (89% of the General Public and 84% of Health Consumer) respondents agreed that *I trust the doctors and other health professionals I deal with to keep information about my health confidential*;
- The majority (74%) of the General Public respondents agreed that *unless an individual chooses to opt out, health professionals who provide them with treatment should have automatic access to their health information*, although only 53% of Health Consumers supported this concept.

Agreement with health professionals having automatic access to health information was consistent across the stakeholder groups except the HREC member respondents where only a minority (26%) agreed.

Of the 203 health professionals interviewed by telephone:

- 40% had changed the way in which they share health information with other professionals outside their practice;
- 29% had made changes affecting the way in which they share health information with other professionals in their own practice;
- 65% are now more likely to ask patients to sign a consent form to allow release of their health information to others outside the organisation than for any other purpose. 33% seek a signed consent from all patients. 32% seek consent only when needed;
- 53% seek signed consent for release of patient information to others within the organisation; and
- 47% seek signed consent for access to the patient's records for research purposes.

In terms of the impact of the Commonwealth Privacy Act on the provision of health care:

- 33% of health professional respondents felt the impact had been *mixed*;
- 15% perceived it to have had *no* impact;
- 12% answered *don't know*;
- 30% thought the impact had been positive; and
- 10% considered the impact had been negative.

Medical specialist respondents were more likely than other health professional respondents to say they did not know what the impact of the legislation had been on the provision of health care – 22% compared to 9% of other health professional respondents. Nurse respondents were more inclined to believe the legislation had been positive – 49% compared to 23% of other respondents.

Overall, health professional respondents were more readily able to identify difficulties arising from Commonwealth privacy legislation than benefits (Table 2).

Table 2:	**Difficulties arising from the Commonwealth privacy legislation**	
Q24.	*What do you personally believe are the most important difficulties arising from the Commonwealth privacy legislation?*	
		Total Sample (203) %
Difficult to access and exchange patient information		40
More work for the health professional		32
Making professionals and consumers aware of/ understand the Privacy Act		8
More time consuming for patients		5
Other		13
Don't Know		5
No difficulties reported		11
Not familiar with the legislation/can't comment		7

Note: Figures add to more than 100% due to multiple responses to the question.

The NHMRC considers that the application and/or interpretation of the Privacy Act is impairing the quality, effectiveness and timeliness of management of health information. In their efforts to ensure compliance with the law, health care professionals and administrators are experiencing considerable difficulty in developing and implementing practical policies that do not 'over-interpret' their obligations and do not impair the legitimate flow of information between providers for patient care purposes.

The NHMRC also considers that the overall public interest and the interests of the majority of individual patients are served by the efficient transfer of all necessary clinical information between health care providers for the purposes of the current care of an individual patient. There is, in fact, considerable potential for individual harm as a result of a privacy regime which results in individual health care providers being uncertain about their legal obligations, afraid of breaking the law by transferring health information without explicit consent, and implementing ineffective and inefficient procedures in their efforts to comply with the law.

Recommendation 6

That, while recognising and supporting the central role of consent, the sharing of all necessary health information with and/or between health care professionals and support staff (the treating team) for the purposes of the current care of an individual patient is recognised as being in the overall public and individual patient interest, and is permitted so long as there is no indication from the patient that such sharing is unacceptable to them, and there are no other circumstances which could reasonably be expected to alert members of the treating team that the patient would object. Recognition should be through a binding determination, legislative or regulatory change.

8. Quality assurance, research and related activities

8.1 Introduction

Apart from its central role in clinical care, health information is also vitally important to the conduct of various research and management activities in health care. These activities include but are not limited to health and medical research, quality assurance, quality improvement, policy development, planning, evaluation and cost-benefit analysis.

Quality assurance, research and related activities are currently subject to different requirements under the Privacy Act, depending on:

- Whether they are conducted by a public sector agency (to which the IPPs apply) or a private organisation (to which the NPPs apply); and
- Whether they are characterised as quality assurance or research.

The IPPs permit the *use* of health information without consent for a purpose *directly related to the purpose for which the information was obtained.* They also permit *disclosure* if the individual concerned is reasonably likely to have been aware that information of that kind is usually passed to that person, body or agency.

The NPPs permit the *use* and *disclosure* of health information without consent for a secondary purpose if the secondary purpose is *directly related to the primary purpose of collection* and the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose.

With respect to activities such as research, quality assurance, quality improvement, policy development, planning, evaluation or cost-benefit analysis, it is, therefore, currently necessary to decide whether, in the absence of consent:

- Any proposed use or disclosure of health information is a use or disclosure for a directly related purpose or directly related secondary purpose, as relevant;
- Such use or disclosure would be within the reasonable expectation of the person to whom the information relates, or the person would be reasonably likely to be aware, as relevant; and/or
- If these conditions do not apply, whether the proposed activity can be characterised as either 'medical research' or 'research, or the compilation or analysis of statistics, relevant to public health or public safety' or 'the management, funding or monitoring of a health service', thereby enabling referral of the activity to an HREC for consideration under the Research Guidelines.

The IPPs and NPPs specify different requirements and definitions of 'related purposes'. For both sets of Privacy Principles, directly related primary and secondary purposes are critical to the way in which decisions about privacy are made.

8.2 Related purposes within the reasonable expectation or awareness of the person to whom the information relates

The terms 'directly related purpose' and 'directly related secondary purpose' are not defined in the Privacy Act.

With respect to quality assurance, the Health Guidelines identify "*an organisation's quality assurance or clinical audit activities, where they evaluate and seek to improve the delivery of a particular treatment or service*" as a 'directly related secondary purpose'.

With respect to research, the Federal Privacy Commissioner, in the Health Guidelines, has suggested that:

It is advisable to include some information in the health service provider's information handling policies or patient brochures if the provider is regularly involved in [these kinds of] research projects. This may assist in advising individuals who use the service about how their data may be used or disclosed for research activities.

The provision of such advice has caused some confusion, however, because it does not clarify:

- Whether such action will assist in the obtaining of implied consent to the relevant collection, use or disclosure;
- Whether such action will enhance the prospect that the research thereby constitutes a purpose directly related to the purpose for which the information was obtained, or a directly related secondary purpose that is now within the reasonable expectation of the person to whom the information relates; and
- To what extent, if at all, the undertaking of this practice will obviate or minimise the need to undertake additional steps in order to discharge the relevant legal obligations.

The NHMRC is firmly committed to HREC review of all relevant research. The National Statement provides that review by an HREC is required for all activities that involve human participation or definable human involvement and that have:

- A purpose of establishing facts, principles or knowledge or of obtaining or confirming knowledge; and
- The potential for infringing basic ethical principles, including respect for humans, beneficence and justice.

> The NHMRC considers that the Federal Privacy Commissioner should express support for the review by an HREC of all relevant research.

Consistent with this NHMRC position, most stakeholders who were surveyed did not believe that there should be automatic access to health information for research purposes, and there is a general view that collection, use or disclosure of health information without patient consent for the purposes of research (even if individuals are advised that their data may be used or disclosed for research activities) without approval by an HREC according to the Research Guidelines is not permitted by the Privacy Act. Referral to an HREC for consideration according to the Research Guidelines, where the requested use or disclosure of health information for the purposes of the research may or may not be approved by the HREC depending on the assessed balance of public interests, appears to be accepted standard practice.

The NHMRC considers that all research involving humans should be referred to an HREC for ethical consideration. The implication in the Health Guidelines that such research may be permissible without ethical review, either:

- As a result of implied consent; or
- As either a directly related purpose or a directly related secondary purpose within the reasonable expectation of the person to whom the information relates;

should be clarified to ensure consistency with the National Statement.

The practice of reviewing health information without consent for the purposes of identifying relevant quality assurance or research activities, recruiting patients into established quality assurance or research studies, or establishing health information databases and registries is, however, an important preliminary activity which should be permitted under certain circumstances. This issue is addressed further in section 9.2 of this report.

8.3 Quality assurance or research?

There is a widely acknowledged difficulty in distinguishing quality assurance from research in health care. The difficulties in making this distinction are addressed in detail in the NHMRC's publication: *When does quality assurance in health care require independent ethical review?*[18]

The NHMRC defines quality assurance as an activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation). It has noted that terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably.[19]

Previously, the NHMRC has observed that quality assurance and research are activities that form a continuum, and that attempts to clearly separate quality assurance from research are difficult, and can be artificial and unhelpful.[20]

Whilst the need to make a clear distinction between these terms may appear academic in many circumstances, in the context of the application of the Privacy Act, classification of an activity as either 'research' or 'quality assurance' is important, and may determine whether:

- The use or disclosure of health information can occur without specific consent, within the provisions of the IPPs/NPPs;
- Referral of the activity to an HREC is necessary, for consideration under the Research Guidelines; or
- In some circumstances, whether the activity can be conducted at all.

8.4 Implications for quality assurance

If a 'research-like' activity is characterised as quality assurance, health information may be able to be used and/or disclosed without consent and without recourse to the Research Guidelines.

The IPPs and NPPs create different provisions for agencies and organisations in relation to the use and disclosure of health information for the purposes of quality assurance. Again, the rationale for these differences is unclear.

The IPPs appear to set a lower threshold than the NPPs for the *use* of health information for the purposes of quality assurance, but a higher threshold for the *disclosure* of health information for the same purpose. If the relevant conditions established by the IPPs for both use and/or disclosure without consent cannot be met, however, an agency cannot refer a proposed quality assurance activity to an HREC for consideration under the Section 95 Guidelines, as the Section 95 Guidelines apply only to medical research, not quality assurance.

Similarly, an HREC may not be in a position to consider under the Section 95A Guidelines a proposal by an organisation to use or disclose health information without consent for the purposes of quality assurance (in circumstances where the quality assurance is not a secondary purpose directly related to the primary purpose of collection and the individual would not reasonably expect the organisation to use of disclose the information for that secondary purpose) because a quality assurance activity may not fall within the categories of activities to which the Section 95A Guidelines apply for the purposes of use and disclosure.

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18 National Health & Medical Research Council (NHMRC) 2003. *When does quality assurance in health care require independent ethical review? Advice to institutions, human research and ethics committees and health care professionals.* Canberra: NHMRC. Accessed on 18 October 2004 at http://www.nhmrc.gov.au/publications/pdf/e46.pdf

19 *Ibid.* Page 3

20 *Ibid.*

In some circumstances, these provisions may directly impede the conduct of important quality assurance activities. For example, in the following situation, it is unlikely that information could be disclosed for apparently useful quality assurance purposes:

> *An agency wishes to disclose health information for quality assurance purposes to a new national body auspiced by an Australian medical college. The body is compiling and analysing information about every case of a health care intervention that has been undertaken over the past 5 years in Australia, to determine complication rates associated with the type of intervention amongst different health care providers. The data need to be identifiable, because the national body needs to follow up some patients to determine their outcomes. It is impracticable to obtain consent because of the large volume of patients.*
>
> *The patients are not aware that information of that kind is usually disclosed to that specific body, because when the information was collected the body did not exist. The health information cannot, therefore, be disclosed without consent, unless approved by an HREC following consideration under the Section 95 Guidelines. As the activity is a quality assurance activity rather than medical research, it is not, however, referable to an HREC.*

If, however, a private sector organisation (to which the NPPs apply) rather than a public sector agency wished to disclose the same information, it may be permissible without referral to an HREC if the disclosure were assessed as being a directly related secondary purpose within the reasonable expectation of the person to whom the information relates.

8.5 Implications for research

Currently, as noted in **Section 5** above, the Privacy Act creates different pathways for consideration of different types of research activities:

- Proposals for the collection, use and disclosure of health information for the purposes of medical research (a term which is not defined) *can be referred* by an agency to an HREC for consideration under the Section 95 Guidelines on public interest grounds;
- Proposals for the collection, use and disclosure of health information for any research purposes other than medical research *cannot be referred* by an agency to an HREC for consideration under the Section 95 Guidelines on public interest grounds. There is, in fact, no provision within the Privacy Act for health information to be collected, used or disclosed without consent by an agency for research other than medical research, unless the activity can alternatively be classified as quality assurance and it also fulfils the specific requirements of the Privacy Act that apply to use and disclosure without consent (that is, use for a purpose directly related to the purpose for which the information was obtained, or disclosure if the individual is reasonably likely to have been aware or made aware that information of that kind is usually passed to that person, body or agency);
- Proposals for the collection, use and disclosure of health information for the purposes of research, or the compilation or analysis of statistics, relevant to public health or public safety (terms that are not defined) *can be referred* by an organisation to an HREC for consideration under the Section 95A Guidelines on public interest grounds; and
- Proposals for the collection of health information for the purposes of the management, funding or monitoring of a health service *can be referred* by an organisation to an HREC for consideration under the Section 95A Guidelines on public interest grounds.

It is unclear whether the term 'medical research' includes, for example, nursing, psychological, sociological or health services research, all of which are extremely important to the ongoing efficiency and effectiveness of our health care system. One view expressed in the consultation with HREC members was that the wider interpretation should be used, but there is some concern that currently there is no apparent pathway by which agencies can use or disclose health information without consent for these types of research.

There is also no readily available legislative definition of the term 'public health and public safety' which is critical to the operation of Section 95A. The term suggests a requirement of relevance to a sector of the community which is broader than a few individuals. It is possible that organisations may seek to conduct research that involves the collection, use or disclosure of health information which is relevant only to a few individuals, rather than to a broad sector of the community, but nevertheless is of scientific importance and ethically robust. The Privacy Act does not appear to enable such research by organisations, even if it is strongly in the public interest, if its conduct requires the collection, use or disclose health information without consent.

In summary, the requirements of Sections 95 and 95A are inconsistent and confusing. Their application may result in different outcomes for similar projects, without any apparent policy rationale, depending on whether the projects are characterised as quality assurance, research or related activities.

8.6 The management, funding or monitoring of a health service

NPP 10.3 enables the collection of health information for the purposes of the management, funding or monitoring of a health service in accordance with the Section 95A Guidelines.

The phrase 'necessary for the management, funding or monitoring of a health service' is not defined in the Privacy Act. According to the Federal Privacy Commissioner, the 'management, funding or monitoring of a health service' may include some quality assurance and audit activities:

> *"An example of collection for these purposes might be an incident monitoring body collecting information about dangerous incidents occurring in a private hospital."*

There is no directly corresponding use or disclosure provision in the Privacy Act, suggesting that the use or disclosure of health information for these purposes may be achieved without recourse to the Section 95A Guidelines – perhaps, as suggested above, as a directly related secondary purpose within the reasonable expectation of the person to whom the information relates. This appears to create an anomaly, in that health information may be disclosed by an organisation in circumstances where compliance with the Privacy Act can be achieved without recourse to the Section 95A Guidelines, yet the legality of collection by the receiving organisation of the same health information depends on approval by an HREC under the Section 95A Guidelines.

The rationale for these differing requirements for organisations that use and/or disclose health information necessary for the management, funding or monitoring of a health service, compared with those that collect the same health information, is unclear.

A summary of the various ways in which health information may currently be used or disclosed without consent, depending on the type of entity and the characterisation of the specific activity, is presented below (Table 3).

Table 3: Use and disclosure of health information without consent for quality assurance and research

	Quality Assurance		Research	
	IPPs	**NPPs**	**IPPs**	**NPPs**
Use without consent	**Permitted**, provided the quality assurance use is a purpose "*directly related to the purpose for which the information was obtained*".	**Permitted**, provided the quality assurance use is a secondary purpose "*directly related to the primary purpose of collection*" and the individual would reasonably expect the organisation to use the information for the secondary purpose.	**Not permitted**[12] unless approved under Section 95 Guidelines (must be "*medical research*").	**Not permitted**[21] unless approved under Section 95A Guidelines (must be "*research, or the compilation or analysis of statistics, relevant to public health or public safety*").
Disclosure without consent	**Permitted** provided the individual is reasonably likely to have been aware or made aware that information of that kind is usually passed to that person, body or agency.	**Permitted**, provided the quality assurance disclosure is a secondary purpose "*directly related to the primary purpose of collection*" and the individual would reasonably expect the organisation to disclose the information for the secondary purpose.	**Not permitted**[12] unless approved under Section 95 Guidelines (must be "*medical research*").	**Not permitted**[12] unless approved under Section 95A Guidelines (must be "*research, or the compilation or analysis of statistics, relevant to public health or public safety*").
Consideration +/- approval by an HREC under Research Guidelines if above conditions not met?	**Not applicable,** because the Section 95 Guidelines only relate to the protection of privacy in the conduct of medical research, not quality assurance.	**Not applicable,** unless quality assurance is considered to be "*compilation or analysis of statistics relevant to public health or public safety*".	**Applicable**, provided it is "*medical research*".	**Applicable,** provided it is "*research, or the compilation or analysis of statistics, relevant to public health or public safety.*"

8.7 Recommended reforms

The NHMRC wishes to emphasise the important public benefits derived from effective quality assurance in health care. The incidence of adverse events in health care is recognised, nationally and internationally, as unacceptably high. The Australian Council for Safety and Quality in Health Care was established in the year 2000, with the support of all health ministers, to progress national efforts and to stimulate measurable improvement in the safety and quality of care. There is additional significant public investment being made through national organisations such as the National Institute of Clinical Studies and the Australian Council on Healthcare Standards, each of which has a charter to contribute to improving the safety and/or quality of health care. In addition, considerable investment is being made at all levels of the health care system to develop and implement strategies and tools to improve the safety and quality of care. The further development of appropriate strategies will be impaired and

[21] Unless other specific exceptions apply, for example, as required by law.

the value of this public investment will be unable to be ascertained, however, if essential health information is not readily accessible for the purpose of evaluating the outcomes of clinical care.

Under the current Privacy Act:

- There are definitional issues and inconsistencies that can result in inconsistent outcomes, depending on the type of entity in which an activity is proposed to be conducted and the way in which a particular activity is characterised;
- Health information may not be available for quality assurance because the need to access it for that purpose was not predicted when the information was collected, or because use or disclosure for quality assurance purposes is not within the reasonable expectation of the person to whom the information relates; and
- Health information may not be available for research activities because the research is not of the type that is specified within the Act.

The NHMRC also wishes to emphasise that, apart from the inconsistencies and apparent omissions in the Privacy Act, its stakeholders are encountering considerable difficulties interpreting the Act in relation to these activities. At a minimum, there is need for much greater clarity of the status of important activities such as quality assurance.

The consequence of these inconsistencies and difficulties in interpretation is that opportunities to undertake important quality assurance and research activities may be lost. The NHMRC considers that this outcome is not in the public interest.

The NHMRC considers it likely that the vast majority of patients would consider quality assurance and related activities to be an acceptable use of their health information. The conduct of properly designed quality assurance represents an unqualified public good and agencies and organisations should be free to use health information for properly designed quality assurance and related activities without undue administrative burden or fear of non-compliance with the Privacy Act.

The NHMRC proposes, therefore, that the use of all health information, within the agency or organisation in which it has been collected, for the purposes of quality assurance and related activities[22] should be independently recognised and facilitated by the Privacy Act. Such use should be permitted by both staff of and contractors to organisations and agencies in which health information has been collected, provided appropriate confidentiality arrangements are in place, and even if such use is not within the reasonable contemplation of the person to whom the information relates.

Increasingly, however, quality assurance and related activities are becoming multi-site or multi-jurisdictional. The disclosure of health information to (and its corresponding collection and use by) other people, agencies or organisations for such purposes is almost certainly not within the contemplation of some patients, may not be acceptable to some patients, and raises a significantly greater potential for infringement of individual privacy. The current practice is for most agencies and organisations to refer such proposals to an HREC for review, although, as noted above, they may not actually fall within the category of 'research' activities which the Privacy Act identifies as appropriate for such referral.

The NHMRC also considers that it remains difficult to precisely define 'research' and there appears to be little benefit derived from further categorising research into 'medical research' or 'research relevant to public health or public safety'. It is quite possible, for example, that the first definition may exclude valuable non-medical sociological or nursing research, and that the second definition may exclude valuable research relevant to a small group of patients but not to the public as a whole.

The NHMRC strongly recommends, therefore, clarification and streamlining of provisions for the use of health information for quality assurance and related purposes, as follows:

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[22] Including quality improvement, policy development, planning, evaluation and cost-benefit analysis.

- Where it is proposed that quality assurance and related activities will be conducted[23] *within* the entity in which the health information was collected, the NHMRC considers that neither consent by the person to whom the information relates, nor referral to an HREC, should be required by the Privacy Act;
- Where it is proposed that health information will be *disclosed to an external agency or organisation* for their independent conduct of quality assurance or related activities, the NHMRC considers that HREC scrutiny is necessary and should be required by the Privacy Act; and
- In accordance with the requirements of the National Statement, all research that utilises health information, regardless of its type, should be scrutinised by an HREC.

The NHMRC recommends that a statement is inserted into the Privacy Act before the amended sections 95 and 95A (as proposed earlier in this submission) highlighting the standards which are applied and monitored by HRECs. Such a statement would assist community understanding and confidence.

Recommendation 7

That:

a) The use of health information without consent for the purposes of quality assurance and related activities (including management, funding, monitoring, policy development, planning, evaluation and cost-benefit analysis) is recognised as being in the overall public interest and is permitted (through a binding determination, legislative or regulatory change) even if it is not within the reasonable contemplation or expectation of the person to whom the information relates;

b) The disclosure of health information without consent to (and corresponding collection by) third parties for the purposes of quality assurance and related activities (including management, policy development, planning, evaluation and cost-benefit analysis) is required to be referred for appropriate ethical review, in accordance with guidelines issues by the NHMRC and approved by the Federal Privacy Commissioner (third parties means public sector agencies or private organisations other than the agency or organisation which first collected the health information);

c) All research into the provision or organisation of health care in which it is proposed that health information will be collected, used or disclosed without consent is required to be referred to an HREC for consideration and approval;

d) The definition of 'research' is consistent across all provisions of the Privacy Act and encompasses all health and medical research; and

e) The Federal Privacy Commissioner prepares guidelines on these matters in collaboration with the Australian Health Ethics Committee.

[23] Either by contractors on behalf of an entity, or by internal staff.

9. Information infrastructure for research and quality assurance

9.1 Introduction

The conduct of quality assurance and research in health care is facilitated by ready access by health care professionals and researchers to individual patients or cohorts of patients with specific characteristics.

It has been a longstanding and productive practice for health care professionals to undertake preliminary review of data sets (eg hospital admission lists) to determine the presence of patients with specific characteristics relevant to quality assurance or research. This activity is broadly described as '**sample acquisition**'. It can precede the development of a formal quality assurance or research proposal, or it may enable recruitment of patients into established quality assurance or research activities.

In addition, in some circumstances, collections of information relating to specific patients have been established, for the purposes of:

- Enabling ongoing review and identification of important quality assurance processes or research hypotheses; or
- Establishing a repository of information which can be accessed in the future, as relevant quality assurance or research questions become apparent.

Such collections often reside within hospital specialty units. For example, a respiratory unit may establish a data collection of all patients with asbestos-related diseases, and may undertake intermittent review of that collection or may review it for the purpose of determining whether there are sufficient patients with specific characteristics to support the development of a detailed quality assurance or research proposal addressing a particular issue.

There is a strong tradition of confidentiality associated with such practices.

The NHMRC considers that there is an ethical imperative for these activities to be undertaken to ensure the feasibility of quality assurance and research, avoiding unnecessary expenditure of scarce resources on activities that ultimately prove to be impractical or not viable. Proper consideration should always be given, however, to the benefit of these activities and appropriate confidentiality safeguards must always be in place.

9.2 Sample acquisition

The review of health information without consent for the purposes of:

- Identifying relevant quality assurance or research activities;
- Recruiting patients into established quality assurance or research studies; and/or
- Establishing health information databases and registries for the purposes of identifying a pool of patients to participate in future quality assurance or health and medical research studies;

is an extremely important preliminary activity which is potentially jeopardised by the Privacy Act (both the private sector provisions and the provisions that apply to public sector agencies) in its current form.

As noted above, the NPPs permit the use or disclosure of health information for a purpose directly related to the purpose for which it was collected and that is within the reasonable expectation of the person to whom the information relates. The IPPs permit the use of health information without consent for a purpose directly related to the purpose for which the information was obtained. They also permit disclosure if the individual concerned is reasonably likely to have been aware or made aware that information of that kind is usually passed to that person, body of agency.

The practice of sample acquisition (for example, perusing, without consent, weekly hospital admission records to identify persons who may be eligible for an invitation to join a future research project) would not be consistent, in most cases, with either the IPPs or the NPPs, because generally it would not be a directly related purpose and would not be within the reasonable expectation of the person to whom the information relates. Because of its preliminary, unsystematic nature, it would arguably also not fulfil the definitions of 'medical research' or 'research, or the compilation or analysis of statistics, relevant to public health or public safety' and therefore would not be referable to an HREC for consideration of approval under the Section 95 or 95A Guidelines. The consequences appear to be that such preliminary activities may not be permitted under the Privacy Act at all.

Sample acquisition has been a common activity within health care settings, and is considered vital to enable researchers to reach a preliminary conclusion as to the potential availability of suitable patients before developing a completed research proposal. Indeed, there is an ethical imperative to determine the feasibility of research proposals. Researchers who are denied the opportunity to undertake sample acquisition are in a "Catch 22" situation. The NHMRC considers that this activity, provided it is conducted ethically and with appropriate regard for confidentiality, should be enabled by the Privacy Act.

9.3 Data registries

The NHMRC is also concerned that the Privacy Act directly impairs the establishment of registries (or databases), either within the organisation in which the data are collected or by an external body, in the absence of a statutorily-created right or power.

The NHMRC considers that access to health information through properly designed and maintained registries is absolutely essential for the conduct of effective quality assurance and related activities, as well as for research into health outcomes. In particular, access to complete episode of care and outcome information is necessary to properly understand the cost-benefit of various interventions and the safety and quality of care that is provided in the Australian health care system. Optimal value for money for national health expenditure, and the highest quality health care for individuals, will only be assured through thorough evaluation of the inputs to and outcomes of care. As demand for health care increases, the need for access to quality information to enable effective evaluation becomes even more critical.

Health information registries should only be established and used for purposes that further the overall public benefit, and with due regard for privacy. Gaining consent from all patients for their health information to be used in this way is likely to be impracticable, however, and incomplete data sets will substantially impair the utility of registries. The NHMRC submits that it is vital that the Australian privacy regulatory regime permits the establishment of properly designed and complete health information registries. For the following reasons, we do not consider that this is currently the case.

The use or disclosure of health information for the purposes of establishing or maintaining a registry (either internal to the organisation or external) without consent is unlikely to meet the definition of a directly related secondary purpose and also would be unlikely to be within the reasonable expectation of all people from whom health information has been collected. In the absence of an appropriate legislative base, the only potential avenue for these activities is via approval by an HREC according to the Research Guidelines.

It is open to question, however, whether such activities, of themselves, constitute either 'medical research' or 'research, or the compilation or analysis of statistics, relevant to public health or public safety'. Arguably, they are preliminary to research, rather than constituting research of themselves, and therefore would not be reviewable under the Research Guidelines. It may be possible to argue that they represent 'the compilation or analysis of statistics, relevant to public health or public safety' and therefore are available to organisations covered by the Section 95A Guidelines, but this is not entirely clear and it could be considered that until the proposed use of the health information is clear, it is not possible to determine whether the activity is relevant to public health or public safety.

It would also be extremely difficult for an HREC to reach a definitive conclusion about whether the balance of public interests is served by the maintenance of any individual collection, in the absence of specific information about the proposed use of the health information.

The consequences of such an interpretation are that health information registries may not be permitted under the Privacy Act in the absence of consent or a direct legislative base. While it may be argued that this is not an unreasonable consequence of the Privacy Act, given the difficulty in determining the balance of public interests where a health information registry is maintained for undefined future purposes, the implications for quality assurance and research may be significant. Prospective data collection is much more likely than retrospective data collection to yield meaningful information. It is not always apparent which questions need to be investigated. By the time the questions are obvious, the opportunity to identify the person to whom the information relates or to gain consent to use the health information may be lost.

The privacy concerns surrounding health information registries are not insignificant. The NHMRC considers, however, that these registries need to be facilitated and should be permitted within a rigorous ethical and privacy framework that appropriately protects the public interest.

The development of, and rigorous enforcement of compliance with, national health registry standards would ensure that these data are available for future use, subject to adequate privacy and other ethical controls. The NHMRC believes it would be useful for the Federal Privacy Commissioner to consult with organisations such as the Australian Institute of Health and Welfare to determine the most appropriate and expert body to auspice such an activity and that a national standard could be approved as a Code under the Privacy Act to ensure its status. The NHMRC also considers that clear, public statements from the Office of the Federal Privacy Commissioner about the role of data registries – accompanied by clear national standards – would allay community anxieties.

9.4 Data linkage

The ability to combine data from various sources for research or public health purposes is increasing, with improvements in technological applications.

Privacy concerns about the linkage of health information from various sources relate to the potential for the combined information to be much more personally sensitive than each individual component. Some researchers have advised that some HRECs appear to have discounted completely the potential for the conduct of projects involving linkage of health information without consent, and have rejected such applications out of hand, apparently in the mistaken belief that such linkage is not ethically or legally acceptable.

On the other hand, researchers consider that in many circumstances the power of linked data can substantially contribute to the public benefit.

In responses to the survey conducted in preparation for the development of this submission, 66% of the General Public and 64% of Health Consumer respondents reported that it was acceptable or very acceptable for *approved researchers to match information from different databases.* 26% of the General Public and 32% of Health Consumer respondents considered this was unacceptable. 82% of the General Public and 86% of Health Consumer respondents reported that it was acceptable or very acceptable for *approved researchers to access health information from databases where records are identified by a unique number rather than a name.*

The qualitative consumer focus groups conducted in parallel with the quantitative survey suggested that consumers are less concerned about the use of their information for the purposes of data linking when it is de-identified using codes or numbers, if such usage would contribute to improvements in health care through research. The importance of data linkage in improving effectiveness of treatment (and consequently public health) was acknowledged by nearly all health providers, data custodians, HREC members and peak body representatives who participated in the stakeholder surveys.

9.5 Recommended reforms

The NHMRC considers that the development of a national standard addressing, *inter alia*, subject acquisition, data registries and data linkage, would assist health care organisations to understand the circumstances in which the development and application of such information infrastructure is appropriate and not unnecessarily intrusive to individual privacy.

In the interim, the NHMRC considers that the maintenance of such activities is crucial to the safety and quality of health care and the conduct of effective health and medical research, and recommends that they are recognised, through a binding determination, legislative or regulatory change, as acceptable activities if conducted with the scrutiny and approval of an HREC.

Recommendation 8

That the Federal Privacy Commissioner requests an appropriate national body to sponsor the development of a National Standard for the Establishment and Management of Health Information Registries and Data Linkage which would address, amongst other issues, the collection and holding of health information without consent.

Recommendation 9

That the Federal Privacy Commissioner considers approving the resulting National Standard as a Code under the *Commonwealth Privacy Act 1988*.

Recommendation 10

That in the interim period before such a National Standard is available, the activities of subject acquisition, the development of data registries and data linking are recognised, through a binding determination or legislative or regulatory change, as acceptable activities if conducted following the scrutiny and approval of an HREC.

Recommendation 11

That the Office of the Federal Privacy Commissioner, in consultation with the NHMRC and other relevant bodies, undertakes awareness raising activities to educate the community on the existence and role of comprehensive health information registries and data linkage and their contribution to health and medical research.

10. Conclusion

For some time, the NHMRC has been concerned about representations from many of its stakeholder groups that the Australian privacy regulatory regime is hindering unnecessarily:

- The transfer of health information essential for effective clinical care; and
- The availability of health information for important health and medical research purposes.

In preparation for this Review, the NHMRC's Privacy Working Group supervised the conduct of an extensive body of work, incorporating comprehensive surveys of each of the NHMRC's stakeholder groups and a legal analysis of the application of privacy legislation to the provision of health care and the conduct of health and medical research in Australia.

The NHMRC is highly cognisant of the need to achieve an appropriate balance between:

- Protecting the privacy of individuals; and
- Ensuring that vital health care and important health and medical research can proceed without unnecessary obstruction, in the overall public interest.

The results of this work have convinced the NHMRC that the complexity of Australia's privacy regulatory regime, as well as the internal complexity of the Privacy Act, are causing considerable compliance problems for most stakeholder groups, and interfering unnecessarily with both of these activities.

The complex structure of the Australian health care sector and the fact that many episodes of health care involve a mix of public and private providers means that the private sector provisions cannot be reviewed in isolation from the other components of the Australian privacy regulatory regime. Many stakeholders are unable to identify the privacy legislative provisions with which they must comply, and most are adopting various compensatory strategies that are either ineffective in meeting their compliance obligations or are resulting in excessive conservatism in the management of health information.

In addition, the Privacy Act creates a confusing and unclear regulatory regime relating to the transfer of health information within clinical teams, the conduct of quality assurance activities and the availability of health information for research purposes.

The NHMRC firmly believes that the appropriate balance of public interests is not being met at present, and recommends the adoption of a single, simplified, national health privacy regulatory regime, replacing rather than supplementing existing regulation. Recognising, however, that achieving such an outcome is likely to take some time, a number of recommendations are made that are designed to simplify and clarify the application of the Privacy Act.

In particular, the NHMRC makes a number of recommendations directed at:

- Clarifying threshold issues relevant to whether or not health information enables the identification of the individual to whom it relates, and what constitutes impracticability of consent;
- Clarifying and streamlining the circumstances in which:
  - information relevant to current treatment can be shared within and/or between the treating health care team for the purposes of current treatment; and
  - information can be collected, used or disclosed, for the purposes of quality assurance and health and medical research, and for associated information infrastructure.

Attachment 1: The Victorian privacy regulatory regime

Table 4: The Victorian privacy regulatory regime

	Public Sector (inc Vic – Funded Services)	Public and Private Sector (inc Vic – Funded Services)	Private Sector
What is Covered?	**"Personal Information" other than "Health Information"**	**"Health Information"**	**"Personal Information" including "sensitive information" (which includes "health information").**
Regulator	Office of the Victorian Privacy Commissioner	Health Services Commissioner	Office of the Federal Privacy Commissioner
Legislation	Information Privacy Act 2000	Health Records Act 2001	Privacy Act 1988 (2000 Amending Act)
Commencement date (fully operational)	1 September 2002	1 July 2002	21 December 2001
Privacy Principles **(the bracketed words "(yes)" and "(no)" indicate whether the Principles in the legislation apply to relevant information collected before the legislation came into existence)**	Information Privacy Principles[24]	Health Privacy Principles[15]	National Privacy Principles
	1 Collection (no)	1 Collection (no)	1 Collection (no)
	2 Use & Disclosure (yes)	2 Use & Disclosure (yes)	2 Use & Disclosure (no)
	3 Data Quality (yes)	3 Data Quality: (yes - use/holding/disclosure; no - collection)	3 Data Quality: (yes - use/disclosure; no – collection;
	4 Data Security (yes)	4 Data Security and Data Attention (yes)	4 Data Security (yes)
	5 Openness (yes)	5 Openness (yes)	5 Openness (yes)
	6 Access & Correction (yes)	6 Access & Correction (Subject to specific provisions of s.25)	6 Access & Correction (yes, subject to ongoing use/disclosure and reasonableness considerations)
	7 Unique Identifiers (yes)	7 Identifiers (yes)	7 Identifiers (yes)
	8 Anonymity (yes)	8 Anonymity (no)	8 Anonymity (no)
	9 Transborder Data Flows (yes)	9 Transborder Data Flows (yes)	9 Transborder Data Flows (yes)
	10 Sensitive Information (but **not** health information) (no)	10 Transfer or closure of the practice of a health service provider (yes)	10 Sensitive Information (**including** health information) (no)
		11 Making information available to another health service provider (yes)	
Health-specific provisions?	None	All	"Sensitive information" (NPP 10 and NPP 2.1(d))
Access to records provisions?	No (see Freedom of Information Act 1982)	Public sector – no (see Freedom of Information Act 1982), Private sector – yes.	Yes
Exemptions relevant to Health Providers?	None	None	Employee information (including employee health information)
Web address	www.privacy.vic.gov.au	www.health.vic.gov.au/hsc/	www.privacy.gov.au
Health-specific provisions?	None	healthrecords.health.vic.gov.au	"Sensitive information" (NPP 10 and NPP 2.1(d))

[24] NB: Victorian (the Victorian Information Privacy Principles differ from the Commonwealth IPPs)