



**SUBMISSION TO
THE AUSTRALIAN LAW REFORM COMMISSION
ON REVIEW OF PRIVACY**

RESPONSE TO: ALRC ISSUES PAPER 31

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The Australian Nursing Federation (ANF) was established in 1924. The ANF is the national union for nurses, with branches in each State and Territory of Australia. The ANF is also the largest professional organisation in Australia, with a membership of over 150,000 nurses, employed in a wide range of enterprises in urban, rural and remote locations in both the public and private sectors. The ANF's core business is the industrial and professional representation of nurses and nursing.

The ANF participates in the development of policy in nursing, nursing regulation, health, community services, veteran's affairs, education, training, occupational health and safety, industrial relations, immigration and law reform.

INTRODUCTION

The ANF welcomes the opportunity to participate in the Australian Law Reform Commission's review of the *Privacy Act 1988* (Cwth). We have limited our comments to the questions that were raised in *Chapter 8 – Health Services and Research*.

The health, aged care and disability sectors of our society still have a lot to learn about privacy and the appropriate collection, use, storage, transfer and destruction of the community's personal information. Traditionally these sectors have had a relatively paternalistic approach to service provision and the management of a patient's personal information. Arising from benevolence rather than malevolence, there have been significant efforts over the past two decades to ensure there is robust policy, education and support to improve this approach. These efforts continue and the Review provides a useful opportunity to assess the current state of the culture and to identify where further improvements to the policy framework can be made.

Nurses are important players in this area. Numerically they make up the majority proportion of the health workforce and the nature of their knowledge, skills, experience and work means they are located in most practice environments in the

health system¹ where they are important cultural custodians and patient advocates as well as potential agents for change.

ISSUES:

Question 8.1

Does the regulation of health information require a different and separate set of privacy principles to those used to regulate other sensitive personal information?

The ANF considers that privacy and health information does need to be subject to a specific regulatory framework. A *National Health Privacy Code* will build consumer's confidence in the commitment of the health and related sectors to protecting consumer privacy in the health system as well as provide consistent guidance to health professionals, health researchers and other health workers, whatever their classification or venue of practice. The traditional culture within the health system has meant there has been a tendency to regard privacy as counter-intuitive to the provision of the continuity of quality and safe care. This is slowly changing with the increasing focus on privacy in health however does not always occur in a cogent and appropriate way.

The increasing focus on privacy has had four main responses in the health system:

- A diligent and competent attempt to develop workable policy and guidelines at a State (and Territory) level to assist workers in the health system to work within privacy principles, such as the *NSW Health Privacy Manual: Version 2* (NSW Department of Health 2005).
- An overzealous response by some who are not sufficiently knowledgeable of the consent, limits and exceptions principles, which does compromise consumer care because the shield that is privacy becomes a sword.
- A strong stand that there are minimal limits on information sharing as this is the foundation stone for quality and continuity of care and sound health research;

¹ In this submission, the term health system or sector also includes the aged care, community care and other associated sectors that have strong links to and arguably are part of the health system.

and that the balance has to be weighted on this side otherwise the benefits to the community are compromised.

- Those who have not considered or been exposed to the issue of privacy in any depth, in relation to the way they communicate and document in the course of their practice or other work; and in their personal life.

Hence the personal health information of health consumers has not always been treated according to fundamental privacy principles. Within the health system, there is a clear need for consistent and carefully crafted principles to assist health professionals and other health workers to achieve the very difficult balances that make up their daily decision making as they undertake consultation, assessment, treatment, care and follow-up; as well as in the associated documentation of care, research, quality improvement and administration of services.

The ANF shares the views of the Health Issues Centre when it argues that:

....the introduction of a national approach will have positive outcomes for the quality and safety of health care in Australia. These benefits depend on the Code applying to all organisations that collect health information and that it is mandatory for everyone who collects health information to comply with the Code. There also needs to be forms of redress for consumers when the Code is violated and they suffer harm because their privacy has been infringed upon. It would be beneficial for consumers and professionals if the process for resolving complaints was integrated into a quality assurance framework.

The collection, use and disclosure of health information by practitioners involves issues of great sensitivity to consumers. Consumers are vulnerable to, and dependent on, the skills, expertise and goodwill of their health practitioner and, by extension, the agency in which they practice. The need for frank and open sharing of information between consumers and their practitioner is fundamental to the building of trust in these relationships. While practitioners have a range of professional, ethical and statutory obligations relating to health information, this information is increasingly handled by people with little or no specific training in responding professionally to these particular sensitivities. So, for example, while consumers may trust their practitioner, they may not have

the same level of trust for the hospital or corporation that employs that practitioner or the government that monitors that service. Information given with confidence in a practitioner can move quickly beyond that practitioner's control. Therefore, the Code and the National Health Privacy Principles provide a framework for health information to be collected, used and disclosed in consistent and principled ways that reduces uncertainty for everyone. Consumers are also entitled to know that due attention is paid to the quality, integrity and security of their health records and what steps they can follow to obtain access to their health records (Health Issues Centre 2003: 1).

Currently there is no consistency around the legislation and guidelines for the application of the privacy principles across all health services jurisdictions. While this may not amount to inconsistency that would give rise to a Constitutional challenge, it serves to increase confusion and diversity of practices in health across the nation; across the public and private sectors; in hospitals and in community care. Hence, a *National Health Privacy Code* provides an opportunity to align these across jurisdictions in Australia at a time when there are national drives in: developing strategies to improve the quality and safety of health and aged care; consistency in the education and regulation of health professionals (Productivity Commission 2005a; 2005b; 2005d; Council of Australian Governments 2006); developing national codes of conduct and ethics, and competency standards for health professionals, eg in nursing (Australian Nursing and Midwifery Council Inc 2000; Australian Nursing and Midwifery Council 2002; Australian Nursing and Midwifery Council Inc 2002; Australian Nursing and Midwifery Council 2003; Australian Nursing and Midwifery Council Inc 2005; 2006); and ensuring that the Mutual Recognition legislation enables the easy movement of health professionals across jurisdictions with minimal or no hindrance.

Question 8.2

Should s3 of the *Privacy Act* be amended to state that the Act is intended to regulate the handling of health information in the private sector to the exclusion of state and territory legislation?

There is no doubt that there is confusion in relation to the multi-jurisdictional approaches to the handling of health information that requires some serious attention. The ANF takes the view that this should be negotiated in a rational way with a view to reaching agreement around a method of harmonisation of Commonwealth, State and Territory legislation that removes the current ambiguity and differences in approach. A Constitutional confrontation is not necessarily going to be the best means of ensuring cooperation from all jurisdictions and ultimately change in behaviours and practices on the ground.

Amendment to s3 of the *Privacy Act* is one means but by no means the only way of achieving harmonisation. The schemes outlined in the *Issues Paper* on pages 387 - 390 are some of the mechanisms available. Brian Opeskin has also done some impressive work in this area in relation to public health legislation across Australia (Opeskin BR 1998; 1999). A useful conduit for harmonisation is the *National Health Privacy Code*.

Question 8.3

Is the draft *National Health Privacy Code* an effective way to achieve a nationally consistent and appropriate regime for the regulation of health information? If so, what is the most effective model for implementing the draft *National Health Privacy Code*? If not, what other model should be adopted to achieve a nationally consistent and appropriate regime for the regulation of health information?

As outlined in the response to Question 8.1, the ANF is of the view that the *National Health Privacy Code* is the appropriate vehicle for developing a nationally consistency framework for the regulation of health information. To date there has already been considerable commitment and investment in the development of the draft *National Health Privacy Code* that deserves recognition. With the introduction of the Code there needs to be a carefully planned implementation strategy that should have two primary heads of focus – consumers; and health professionals, health workers and health researchers. The strategies following have been developed with particular acknowledgement of the Health Issues Centre's Submission on the *National Health Privacy Code* in 2003. These include (but are not exhaustive):

- The development of a comprehensive communication strategy for both consumers and health professionals and workers in the health system.
- Consumer and health workers input being sought on the development and implementation of the communication strategy, and the development of information products, to educate consumers and health workers about the *National Health Privacy Code*.
- Consultation and cooperation with the professional and industrial organisations representing health professionals and other workers who have a key role in the development of codes and policy, in ensuring that there is agreement and consistency in approach to matters relating to health information and privacy.
- A plan for qualitative research to describe and evaluate the effect of the *National Health Privacy Code* on the protection of consumer privacy to be undertaken within three years of the introduction of the Code.
- A plan for qualitative research to describe and evaluate the effect of the *National Health Privacy Code* on the conduct of health professionals, workers and researchers in relation to the handling of health information.
- Various media (print, audio-visual, web based technology etc) being used to promulgate accessible consumer focused information about the *National Health Privacy Code* and the *National Health Privacy Principles*. These should be in 'plain English' as well as community languages, and include scenarios and examples to ensure that consumers understand the ways that the new privacy Code will be applied to their health information. These products need to be widely advertised and distributed through consumer networks.
- Various media (print, audio-visual, web based technology etc) being used to provide accessible information for health professionals, health workers and health researchers that is widely advertised and distributed through the conduits of professional and industrial networks.
- The Federal Privacy Commissioner clearly sponsoring the *National Health Privacy Principles*, writing articles and updates about the *Code* for publication in consumer and health worker newsletters, journals and bulletins – both print and electronic.
- Workshops and presentations about the *Code* being conducted for consumers and health service providers and researchers, targeting specific groups such as:

- different groupings of health workers - by professions, venues of work, type of work (eg clinical practice, management, research, administration etc);
 - people in regional and rural areas;
 - people from migrant and refugee communities;
 - people from Indigenous communities;
 - people from marginalised and vulnerable populations;
 - people in custody; and
 - people with chronic illness, young people and people affected by substance misuse.
- These educational sessions being developed through consultation with consumers and health service providers that include representatives from the target community and groups.
 - Messages promoting consumer protections being provided by the National Health Privacy Code across mainstream, community and alternative media.
 - The language, content and tone of the information in the documents being positive, encouraging, and giving examples of best practice in protecting the privacy of consumer's health information and the importance of the appropriate conduct and practice of health professionals, health workers and health researchers.
 - The Communication Strategy emphasising to health service providers the benefits for enhanced trust and communication in providing consumers with access to their records, as part of good quality care; and encouraging service providers to incorporate information about their willingness to provide access free of charge or to waive the fee in appropriate circumstances into their information policies.
 - Developing mechanisms by which all individuals or organisations collecting personal health information are encouraged to seek advice and guidance from an appropriate source, such as the Office of the Privacy Commissioner, in an effort to enable the development of local health privacy information policy and guidelines that are both accurate and reflecting the consumer-oriented spirit of the *Code* (Health Issues Centre 2003: 2-3).

The ANF is of the view that the *National Health Privacy Code* should apply to the handling of all health information, no matter: by whom it is collected; where it is collected, used and held; or for whatever purpose it is collected.

Question 8.4

If the draft *National Health Privacy Code* is not implemented nationally, should the Australian Government adopt the Code as a schedule to the *Privacy Act*?

See comments in 8.2. The inclusion of the *Code* as a Schedule to the Act may be a useful first step while negotiations for other harmonisation strategies are occurring. However, the preference of the ANF for the long term is national implementation of the *Code*.

Question 8.5

Do electronic health information systems require specific privacy controls over and above those provided in the *Privacy Act* or the draft *National Health Privacy Code*?

The ANF shares the view of Privacy NSW, citing Carter, in its Submission on the *National Health Privacy Code* in 2003:

The development of electronic health records (HER) will enhance and expand the scope of both primary and secondary uses of health records including care, legal, research and educational activities. EHR will make it increasingly easier to store, access and disseminate personal health information. However, the application of such technology may not yet be sufficiently sophisticated to meet the needs of health care administration while at the same time adequately protecting patient data. The mere fact of ready availability increases the pressures on health custodians to allow secondary use of health information. Examples of information security breaches illustrate that, like other technologies, health information security systems are also susceptible to technological or human errors (Carter M 2000; Privacy NSW 2003).

Therefore, there is a need to ensure that there are appropriate controls in place to reduce the risks of information security breaches. Specific principles in the *Code* are a means to address this issue specifically, including the particular risks identified by

the ALRC in its 2005 Report *Essentially Yours - The Protection of Human Genetic Information in Australia* (Australian Law Reform Commission and Australian Health Ethics Committee 2005).

Question 8.6

The National Health Act 1953 (Cwth) requires the Privacy Commissioner to issue guidelines in relation to the handling of personal information collected in connection with claims under the Medicare Benefits Program and the Pharmaceutical Benefits Program. Is this an appropriate and effective role for the Privacy Commissioner?

There should not be specific constraints on the Privacy Commissioner in relation to the privacy considerations in the handling of personal information collected in connection with claims under the Medicare Benefits Program and the Pharmaceutical Benefits Program. The Commissioner, whose primary focus is privacy, has an important oversight and consumer protection role that should not be constrained, and this role should include the capacity to advise and review the policy and activities of other Government agencies in relation to privacy and personal health information.

Question 8.7

Are the definitions of: (a) 'health information'; and (b) 'health service' in the draft National Health Privacy Code appropriate and effective? Should the *Privacy Act* be amended to adopt these definitions?

Yes – they are certainly more comprehensive than those currently in the *Privacy Act* and do give credence to the issues relating to genetic information which are becoming increasingly important with modern technology, current and planned research, insurance interest and evolving knowledge and understanding of the issues.

Question 8.8

Should the Privacy Act be amended to ensure that all agencies and organisations that collect, hold or use health information are required to comply with the Act?

Yes. A consumer's right to have their personal health information dealt with appropriately is the underpinning ethic for this area and therefore the same principles should apply no matter: by whom it is collected; where it is collected, used and held; or for whatever purpose it is collected.

Question 8.9

Is guidance by the Office of the Privacy Commissioner to clarify that organisations can disclose health information for the management, funding and monitoring of a health service an appropriate and effective response to concerns in this area? If not, what is an appropriate and effective response?

In the answer to Question 8.3 the ANF recommends in the development of roll-out strategies for the *Code* that there be investment in developing mechanisms by which all individuals, Government agencies or other organisations collecting personal health information are encouraged to seek advice from an appropriate source such as the Office of the Privacy Commissioner, in an effort to enable the development of local health privacy information policy and guidelines that are both accurate and reflecting the consumer-oriented spirit of the *Code* (Health Issues Centre 2003: 2 -3).

The ANF views the guidance of the Commissioner as an important component in a suite of mechanisms such as the *Privacy Act*, the Privacy Principles, the *Code* and other strategies, some of which were suggested in 8.3 above. The guidance from the Commissioner may be at a cross jurisdictional level or indeed, at a local level to a specific organisation.

Question 8.10

Is there evidence that the regulation of personal health information impedes the provision of appropriate health services to individuals? If so, what changes are necessary to facilitate the provision of appropriate health services?

The ANF is of the view that while the notion that regulation of personal health information may impede the provision of services prevails across some areas of the health system, this generally represents a lack of understanding of the principles and the means by which such personal health information can be collected, used,

transferred and stored, primarily by having the consent of the individual whose information it is, and by fully informing that person of the implications of this. The notion of a more partnership style relationship between health service provider and health consumer is not new, and use of sound, ethical information management techniques can ensure that regulation of personal health information does not impede the provision of health services.

Question 8.11

Does the *Privacy Act* provide an appropriate and effective regime for handling health information in those circumstances where an individual has limited capacity to give consent? Does the draft *National Health Privacy Code* provide a more appropriate and effective framework for handling health information in these circumstances?

This is a particular difficulty across a number of areas in the health, disability and aged care sectors where there are many situations where a person has limited capacity to give consent, be it temporarily or permanently, due to their injury, illness or disability. It is therefore imperative that there is clear and consistent guidance for all service providers. The ANF is of the view that the *Code* provides much clearer and specific guidance than the Act. That said, it may be useful for such guidance to be available across the commercial and other sectors where personal information is gathered and used – it is one of the higher risk areas for people unaware or ignorant of their privacy responsibilities.

Question 8.12

Are there any other issues relating to consent to deal with health information in the health services context that the ALRC should consider?

There are hidden traps in health for the unwary. There needs to be ongoing and accessible guidance and advice for policy makers and individuals, as well as all efforts to heighten awareness of possible risk areas. For example, visitor access to health services can pose challenges in ensuring the confidentiality of information when documentation of therapeutic orders, treatment, care and progress is undertaken in a timely way near the point of care, and is available for health service providers delivering ongoing care. Ensuring that the right person is having the right

procedure on the right organ or limb creates a need for operating lists, check lists, ward lists and accessible information that can be challenging when balancing the need to protect information from those not entitled to have that information.

Question 8.13

Should the Privacy Act be amended to allow health service providers to collect information about third parties without their consent in line with Public Interest Determinations 9 and 9A? Does NHPP 1 of the draft *National Health Privacy Code* provide a more appropriate and effective framework for collection of such information than the current provisions of the Privacy Act?

The ANF is of the view that formal codification of issues such as the collection of information about third parties without their consent by health service providers should be clearly articulated as part of a comprehensive code such as the *National Health Privacy Code* with a clear, consistent and identifiable philosophical platform upon which the reasoning can be understood for making such decisions.

Question 8.14

Should the *Privacy Act* be amended to allow insurance companies to collect health information about third parties without their consent in similar circumstances to those set out in Public Interest Determinations 9 and 9A?

NO. This is a commercial arrangement and there are means for insurance companies to obtain information by consent and they have remedies when it is either not provided or falsely provided.

Question 8.15

Should NPP 10 of the *Privacy Act* be amended to clarify when health information may be collected without consent? Does NHPP 1 of the draft *National Health Privacy Code* provide a more appropriate and effective framework for collection of health information without consent?

NHPP 1 of the draft *National Health Privacy Code* provides greater guidance. However the ANF considers that the principle could also be articulated in NPP 10 in

the *Privacy Act* for broader application of the principle outside the traditional area of health service provision.

Question 8.16

Are there any other issues relating to the collection of health information that the ALRC should consider?

The collection and use of health information by employers for the use in determining the ongoing suitability of an employee remains a fraught but important area and one where members of the ANF have observed many abuses over time. While informed consent should be the primary means by which this occurs there are many instances where an employee is not fully informed of the intent, purpose and possible ramifications of providing consent to an employer to collect, obtain, store or transfer such information.

Even ethical employers are currently confused about their obligations and the requirements under the *Privacy Act*.

Question 8.17

Is guidance by the Office of the Privacy Commissioner an appropriate and effective response to concerns that the phrases in NPP 2, 'primary purpose of collection' and 'directly related to the primary purpose', might impede the appropriate management of an individual's health? If not, what is an appropriate and effective response?

Guidance by the Office of the Privacy Commissioner is one appropriate and effective response to concerns that the phrases in NPP 2, 'primary purpose of collection' and 'directly related to the primary purpose'. However other means are important also, such as the codification of the notion in a *National Health Privacy Code* (which currently recognises the need for ongoing guidance and advice); as well as educational and embedded policy advice being available through other Government agencies, organisations and professional groups to ensure that the principles are well understood and applied.

The ANF is of the view that if the information is collected with appropriate information being provided and the person's consent obtained then there should be little impediment to the appropriate management of the individual's health.

Question 8.18

Does NHPP 2 of the draft *National Health Privacy Code* provide a more appropriate and effective framework for the use and disclosure of health information than the current provisions of the *Privacy Act*?

As suggested above, codification in a *National Health Privacy Code* provides a central point of guidance. However the ANF is not averse to the consistent reiteration of the principles for application outside the direct provision of health services.

Question 8.19

Are there any other issues relating to the use and disclosure of health information that the ALRC should consider?

Not at this stage.

Question 8.20

Is the exception in NPP 6.1(b) in relation to providing access to health information (that is, that access may be denied if it would pose a serious threat to the life or health of any person) appropriate and effective? Should the exception be extended to allow a health service provider to deny access to health information if providing access to the information would pose a threat to the therapeutic relationship between the health service provider and the health consumer?

The ANF is of the view that the exception in NPP 6.1(b) in relation to providing access to health information (that is, that access may be denied if it would pose a serious threat to the life or health of any person) is appropriate and effective, but it must be reiterated that it is indeed an exception that should only be exercised in the most extraordinary of therapeutic situations where there is indeed the potential to pose a serious threat to the life or health of any person.

This exception should **NOT** be extended to a health service provider to deny access to health information if providing access to the information would pose a threat to the therapeutic relationship between the health service provider and the health consumer. If the therapeutic relationship is so fragile then it is not going to be improved if the health service provider refuses to provide access. There is also the potential for a person to deny access for an improper purpose eg the information reveals an adverse event, inappropriate care or treatment or other information that a person may be entitled to have.

The provisions around alternative decision making where a person does not have the capacity to understand and communicate their consent, along with the current exception, are sufficient safeguards for health service providers.

Question 8.21

Do NHPP 6 and Part 5 of the draft *National Health Privacy Code* provide a more appropriate and effective framework for access to health information than the current provisions of the *Privacy Act*?

The ANF is of the view that a *National Health Privacy Code* should be comprehensive and cover the field in relation to personal health information to reduce the potential for confusion and having to inquire of multiple sources. The consistency between the *Privacy Act* and such a *Code* is essential but not mutually exclusive, therefore both could mirror the same principles.

Question 8.22

Should the *Privacy Act* be amended to deal expressly with the situation in which a health service provider ceases to operate? Does NHPP 10 of the draft *National Health Privacy Code* provide an appropriate and effective framework to deal with this situation?

Universal adoption of the *Code* would be adequate for this purpose. It is an area that does require specific and detailed guidance. Health complaint agencies in each of the jurisdictions are recipients of multiple complaints when a health service provider ceases to operate and has not made adequate provision for appropriate transfer and

long-term storage of a person's personal health information. This is particularly so if the provider is a sole or small trader. This is also an area where investment in targeted education and information through professional and industrial organisations will have significant rewards.

Question 8.23

Are there any other issues the ALRC should consider in relation to access to health information?

There remains significant resistance across the health system in granting access to health consumers to their personal health information that will require major culture change. Whether it is in relation to fear of revealing litigable conduct or health professional censure; or is part of the characteristic paternalism that is linked to benevolence that has been a feature of the provision of health services over many years, is neither here nor there. It does, however indicate that there needs to be significant efforts made to inform and actively assist that culture to change.

Question 8.24

Does NHPP 11 of the draft *National Health Privacy Code* provide a more appropriate and effective framework to deal with the transfer of health information from one health service provider to another than the current provisions of the *Privacy Act*?

The transfer of information is not specifically addressed in the *Privacy Act* yet it is an area of high risk in the health system where there is considerable unevenness in knowledge and practice across the jurisdictions, health service providers and researchers. Often, little thought is given to acquiring the consent of the individual who is the subject of the personal health information, and yet this information is faxed, posted, emailed and relayed orally via telephone as an everyday part of a therapeutic relationship. This occurs whether the health service provider is: seeking expert advice; referring a person for other services; chatting informally about an interesting 'case'; speaking more formally in a clinical review, peer review or morbidity and mortality meeting; and on many other occasions in the course of the therapeutic relationship.

Therefore NHPP 11 of the draft *National Health Privacy Code* does provide a more appropriate and effective framework to deal with the transfer of health information from one health service provider to another than currently exists, plus it sits as part of a cogent whole set of principles for information management in the health system.

Question 8.25

Is the current public interest test in the *Privacy Act* and Section 95 and Section 95A Guidelines (that the public interest in promoting research substantially outweighs the public interest in maintaining the level of protection of health information provided by the Act) appropriate and effective? If not, what is an appropriate and effective test?

As with the use and management of personal health information for the purposes of therapy and associated activities, the appropriate collection, use, storage and disposal of health information for research has not always been a key criterion in the development of research proposals and the conduct of research.

The National Health and Medical Research Council (NHMRC) has played an important role in distilling the privacy requirements into a health research domain through their work including the 1999 *National Statement on Ethical Conduct in Research Involving Humans* (National Health and Medical Research Council 1999), and the improvements being made under the review process currently underway with the Australian Research Council (ARC) (National Health and Medical Research Council, Australian Research Council *et al* 2004; 2006). Also impressive is the work being done around research governance by many of the universities, other health research institutes and other organisations conducting health research. That said, the public interest test in the *Privacy Act* and Section 95 and Section 95A Guidelines remains a foundational principle upon which each of those organisations should test the appropriateness of their protection arrangements for the health information that they wish to collect.

The ANF is of the view that the balance should not shift in order to enable greater access to health information without the subject individual's consent.

Question 8.26

Should the term 'research' be defined for the purposes of the *Privacy Act*? If so, how should the term be defined?

The 2006 Draft of the *National Statement on Ethical Conduct in Research Involving Humans - 2nd consultation* definition of research which will possibly form the basis of the final *National Statement* may be sufficient for needs as the *National Statement* is regarded as a key source document for the conduct of research in the health system and increasingly in other areas where some form of research may involve human participants (National Health and Medical Research Council, Australian Research Council *et al* 2006).

Question 8.27

Should the *Privacy Act* be amended to include definitions of 'identifiable'; 're-identifiable'; and 'non-identifiable' personal information?

Yes. This is an area where there is much confusion. A clear definition of each would assist understanding and enable participants in health research to understand the potential risks inherent in any research that they may be recruited to participate. Also, many researchers and members of human research ethics committees are not always clear on the sometimes subtle differences between the three levels of identifiability.

Question 8.28

Should the *Privacy Act* draw a distinction between 'identifiable' and 're-identifiable' health information in the context of health and medical research?

The ANF is not sure that such a distinction should be made - it seems to be a relatively universal principle.

Question 8.29

What provision should be made for the use of health information without consent in health and medical research?

This is a challenging legal and ethical issue and does not easily lead to a slick legislated response. As noted in the Issues Paper the most recent draft of the *National Statement on Ethical Conduct in Research Involving Humans* has a section of consent that includes guidance on when and how researchers may proceed with research when participants consent is not warranted (National Health and Medical Research Council, Australian Research Council *et al* 2006).

This is a useful decision making framework but may require some further strengthening as there is definitely a need to ensure that appropriate safeguards are in place to prevent abuse in this area. There does need to be further guidance provided, especially around the notion of 'impracticability' which is a very subjective notion. One person's view of difficulty may be regarded very differently by another. This is particularly so in the area of genetic research. There is also a need to ensure that the *Privacy Act* and the *National Statement* are consistent.

For health researchers who are registered health professionals, abuse could be dealt with as a disciplinary matter through their respective professional disciplinary processes eg as a breach of a code of conduct. When the offender is not a health professional but, for example a multi-national pharmaceutical corporation - there may be a need for a more robust response to breaches with remedies such as criminal penalties required.

Question 8.30

Does NPP 2 provide an appropriate and effective framework for the use, without consent, of health information in health and medical research?

The framework is probably adequate. As with many of the requirements set out in the principles and codes it is the incorporation of these into the day to day practice of individuals and organisations that requires intense investment.

Question 8.31

Are Human Research Ethics Committees the most appropriate bodies to make decisions about the collection, use and disclosure, without consent, of health information in the context of health and medical research?

As the primary review instrument for any health research being conducted, practically HRECs provide the logical mechanisms to at least identify that this is an issue in research they may be over sighting. Layering other review mechanisms onto research over and above the governance responsibilities of host organisations and HRECS will be an unnecessary burden and bind any research initiatives in too much restrictive red tape that is likely to significantly constrain health research.

However, the ANF is of the view that many HRECs are not constituted with a membership that is adequately prepared to undertake this and many other tasks that they are required or choose to undertake. The ANF supports the ALRC and AHEC recommendations from the *Essentially Yours Report* that substantial investment is made to educate and support HRECs to improve their decision making processes in undertaking their role, including in the area of the examination of the handling of participants personal information, including the waiver of consent.

Question 8.32

Are the requirements imposed on Human Research Ethics Committees by the Section 95 and Section 95A Guidelines issued under the *Privacy Act* appropriate and effective?

If the HRECs: had a better understanding of their roles and the legal and ethical frameworks that they were working in; were well supported in their roles; and had robust administrative systems and decision making algorithms to assist them in undertaking routine review and decision making, there should be no need to amend the current Guidelines. Removing some of the safeguards has the potential to place participants in research at risk.

Question 8.33

Does the *Privacy Act* provide an appropriate and effective regime for: (a) the establishment of health data registers; and (b) the inclusion and linkage of health information in data registers?

This is outside the ANF's current capacity to comment.

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