

statutory guidelines

Health Records and Information Privacy Act 2002 (NSW)

Statutory guidelines on research



privacynsw

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From the NSW Privacy Commissioner

The *Health Records and Information Privacy Act 2002 (NSW)* (the HRIP Act) creates a scheme to regulate the collection and handling of health information by public and private sector organisations in New South Wales. It applies to every organisation that is a health service provider or collects, holds or uses health information.

The HRIP Act will be fully operational from 1 September 2004. It aims to promote fair and responsible handling of health information by:

- protecting the privacy of an individual's health information held in the public and private sectors
- enabling individuals to gain access to their health information
- providing an accessible framework for resolving complaints about the handling of health information.

The objects of the HRIP Act are to:

- balance the public interest in protecting the privacy of health information with the public interest in the legitimate use of that information
- enhance the ability of individuals to be informed about their health care
- promote the provision of quality health services.

The HRIP Act contains 15 Health Privacy Principles (HPPs). These HPPs are the key to the HRIP Act. They are legal obligations that describe what organisations must do when they collect, store, use or disclose health information.

This publication outlines the requirements for the use and disclosure of health information for research and statistics. It has been prepared after public consultation. You should read it in conjunction with the HRIP Act and the Privacy NSW 'User Manual: Handbook to Health Privacy'. If you are from the public health system, you should also read it in conjunction with the NSW Health Department's 'Privacy Manual'.

Part 1 explains some of the issues you need to consider when using and disclosing health information for research or statistics. It also includes a checklist and examples to help you decide what you should do in different circumstances.

Part 2 contains the statutory guidelines on research. You must comply with these statutory guidelines on research if you are seeking to use or disclose health information relying on the 'research exemption' in HPP 10(1)(f) or 11(1)(f). These statutory guidelines on research are issued under section 64 of the HRIP Act.

If you need any further information, please contact Privacy NSW on (02) 9268 5588.

JOHN DICKIE, ACTING PRIVACY COMMISSIONER **1st September 2004**

PART 1: USING AND DISCLOSING HEALTH INFORMATION FOR RESEARCH

1.1 When can I use or disclose health information for research or statistics?

This checklist will tell you when you can use and disclose health information for research or statistics, and whether you need to comply with the statutory guidelines on research (which require the research activity to be referred to a Human Research Ethics Committee for consideration). The checklist assumes that:

- the information you are proposing to use or disclose is 'personal information' – that is, information about an individual whose identity can reasonably be ascertained from the information
- the information you are proposing to use or disclose is 'health information'
- you are covered by the HRIP Act

1. Could the purpose of the research or statistics be served by using or disclosing de-identified information?

Yes	<input type="checkbox"/>	You should use or disclose de-identified information only. If you de-identify the information then you do not need to read any further, and you do not need to comply with the statutory guidelines on research [Note: although the process of de-identifying health information is a use by the organisation for the purposes of research, it does not need to be conducted in accordance with the statutory guidelines on research]
No	<input type="checkbox"/>	Go to question 2.

2. Are you proposing to use or disclose the health information with the consent of the individual(s) concerned?

Yes	<input type="checkbox"/>	You can use or disclose the health information relying on the 'consent exemption' in HPP 10(1)(a) or 11(1)(a). If you de-identify the information then you do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 3.

Best practice tip: Wherever possible, you should seek the consent of the person. Use or disclosure authorised by the person is almost always to be preferred to relying on one of the other exemptions, provided the consent is freely given and informed. It is important that the person does not feel pressured to participate.

3. Was the health information collected for the primary purpose of the research or statistics?

Yes	<input type="checkbox"/>	You can use or disclose the health information for the research or statistics relying on HPP 10(1) or 11(1). You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 4.

4. Is the research, or the compilation or analysis of statistics activity directly related to the primary purpose for which the health information was collected and would the person reasonably expect you to use or disclose their health information for the activity?

Yes	<input type="checkbox"/>	You can use or disclose the health information for the research or the compilation or analysis of statistics activity relying on the 'direct relation exemption' in HPP 10(1)(b) or 11(1)(b). You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 5.

For example: It is unlikely that many research activities will come within this exemption, however some compilation or analysis of statistics activities might come within it. Using health information to compile statistics about the number of patients treated for a particular disease within a hospital, for example, would arguably come within this exemption.

5. Is the use or disclosure for the research or statistics authorised, required, permitted or reasonably contemplated under another law?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the exemption in HPP 10(2) or 11(2). You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 6.

For example: You may be required to disclose health information involving notifiable diseases pursuant to the Public Health Act 1991 (NSW), or in accordance with another statutory direction under Commonwealth law or court order or other subpoena.

6. Can you rely on the 'research exemption' to use or disclose the health information?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the 'research exemption' in HPP 10(1)(f) or 11(1)(f) if you: <ul style="list-style-type: none"> • meet the four exemption criteria in Part 1.2 of this publication and • comply with the statutory guidelines on research in Part 2 of this publication (which require the activity to be referred to a Human Research Ethics Committee for consideration) Go to question 7.
No	<input type="checkbox"/>	You cannot use or disclose the health information for the research or statistics. (Unless you have identified another exemption in the HRIP Act that permits you to do so)

7. Are you a private sector organisation that is already covered by the NHMRC *Guidelines under section 95A of the Privacy Act 1988 (Cth)*?

Yes	<input type="checkbox"/>	You may use or disclose health information for research or statistics in accordance with the NHMRC <i>Guidelines under section 95A of the Privacy Act 1988 (Cth)</i> . If you are bound by the Federal <i>Privacy Act 1988</i> and operate under the <i>section 95A Guidelines</i> you will be taken to have complied with the statutory guidelines on research. You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Any use or disclosure for research or statistics must be in accordance with the statutory guidelines on research in Part 2 of this publication.

1.2 When can I rely on the ‘research exemption’ and the statutory guidelines on research ?

Under the ‘research exemption’ you can use or disclose health information, without the consent of the person, for the secondary purpose of research or statistics if **all** the following four criteria are met.

Criteria 1

The use or disclosure is reasonably necessary for research, or the compilation or analysis of statistics, in the public interest.

Criteria 2

You have taken reasonable steps to de-identify the information, or the purpose of the research cannot be served by using or disclosing de-identified information and it is impracticable to seek the consent of the person to the use or disclosure.

Criteria 3

If the information could reasonably be expected to identify individuals, the information is not published in a generally available publication.

Criteria 4

The use or disclosure of the health information is in accordance with the statutory guidelines on research.

Please note that you must meet **all four** criteria to use or disclose health information relying on the ‘research exemption’. The key terms in the criteria are explained in Part 1.3.

These four criteria are a summary of the requirements of the ‘research exemption’. Please see Appendix A for the full text of the exemption.

1.3 Key terms in the ‘research exemption’ explained

To help you decide whether you can rely on the ‘research exemption’ to use or disclose information, the key terms contained in the ‘research exemption’ are explained below.

Is the use or disclosure ‘reasonably necessary’?

When deciding whether the use or disclosure is ‘reasonably necessary’, consider to what degree the health information is needed for the research. For example sometimes the research may be just as effectively carried out, without the need for the use or disclosure of personal health information.

What is meant by ‘research’?

There are many definitions of research. It can be a systematic investigation to establish facts, principles or knowledge or a study to obtain or confirm knowledge. A defining feature of research is the validity of its results. The knowledge that is generated by research is valid in the sense that what is discovered about the particular facts investigated can be justifiably claimed to be true for all like facts.

For more information, please see the ‘National Statement on Ethical Conduct in Research Involving Humans’, 1999.

What is meant by ‘the compilation or analysis of statistics’?

The compilation or analysis of statistics is the act or process of collecting numerical data, or undertaking a detailed examination of the elements or structure of numerical data, especially in or about large quantities, and inferring conclusions for the whole from conclusions reached from the whole or a representative sample.

What does ‘in the public interest’ mean?

To be ‘in the public interest’ the outcome of a research or statistical activity should have a positive impact on, or be relevant to, the community or a segment of the community as distinct from being a matter of purely private or personal interest. Some examples that could be considered to be ‘in the public interest’ include

research and statistics on communicable diseases, cancer, heart disease, mental health, injury control, diabetes and the prevention of childhood diseases.

Could de-identified information be used?

If the research or statistics could be undertaken by using or disclosing de-identified information, then you should proceed this way. This may involve you converting 'identifiable' information (information that allows identification of a specific individual) into 'de-identified' information. De-identified information is information from which identifiers have been permanently removed, or where identifiers have never been included. De-identified information cannot be re-identified.

However sometimes de-identified information cannot achieve the purpose of the research or statistical activity. This could be, for example, where a project involves linking information about individuals from two or more sources and you need identified information to correctly link records from each data source.

What are 'reasonable steps to de-identify'?

When de-identifying information, you should consider the capacity of the person or organisation receiving the information to re-identify it or re-link it to identifiable information. Removing the name and address may not always be enough, particularly if there are unusual features in the case, a small population, or there is a discussion of a rare clinical condition. Reasonable steps to de-identify might also include removing other features, such as date of birth, ethnic background, and diagnosis that could otherwise allow an individual to be identified in certain circumstances.

When is it 'impracticable to seek consent'?

The fact that seeking consent is inconvenient or would involve some effort or expense is not of itself sufficient to warrant it 'impracticable'. Some examples of where it might be impracticable to seek consent include if:

- the age and / or volume of the information is such that it would be very difficult or even impossible to track down all the individuals involved

- there are no current contact details for the individuals in question and there is insufficient information to get up-to-date contact details
- a complete sample is essential to the integrity and success of the research project and the research would not be possible if any of the subjects refused to allow their information to be used.

For a complete list of the criteria used by Human Research Ethics Committees to assess whether it is 'impracticable to seek consent', please see section 4.2 of the statutory guidelines on research in Part 2 of this publication.

What is a 'generally available publication'?

A 'generally available publication' is defined in section 4 of the HRIP Act to mean a publication that is generally available to members of the public, either in paper or electronic form.

What does 'in accordance with the statutory guidelines on research' mean ?

The statutory guidelines on research are legally binding. You must comply with them to lawfully use or disclose health information relying on the 'research exemption'. They are contained in Part 2 of this publication.

1.4 Some examples of where the ‘research exemption’ and the statutory guidelines on research might apply

You might need to rely on the ‘research exemption’ and comply with the statutory guidelines on research if:

- You have been approached by someone from outside your organisation (eg an external researcher or statistician) who asks you to disclose health information held by your organisation for a research or statistical activity. De-identified information will not serve the purpose and it is impracticable to seek the consent of the individual(s) that the health information relates to.
- You have been approached by someone from within your organisation who wants to use health information held by your organisation for a research or statistical activity. De-identified information will not serve the purpose and it is impracticable to seek the consent of the individual(s) that the health information relates to.
- You want to use health information in files held by your organisation for a research or statistical activity. De-identified information will not serve the purpose and it is impracticable to seek the consent of the individual(s) that the health information relates to.

The statutory guidelines on research are also relevant for:

- Researchers, statisticians and other organisations proposing to undertake research or statistical activities. The statutory guidelines explain when and how organisations can disclose health information to them for these purposes.
- Human Research Ethics Committees who have to assess proposals in accordance with the statutory guidelines.

1.5 How do the statutory guidelines on research relate to other regulation?

Guidelines already exist to regulate the use and disclosure of information for research under the Federal *Privacy Act 1988*. The *Guidelines under section 95 and 95A of the Privacy Act 1988* were issued by the National Health and Medical Research Council (NHMRC), and have been approved by the Federal Privacy Commissioner. The *Guidelines under section 95* apply to Commonwealth agencies. The *Guidelines under section 95A* apply to private sector organisations.

The NSW Privacy Commissioner's statutory guidelines on research under the HRIP Act generally replicate the NHMRC *Guidelines under section 95 and 95A*. This is to ensure a level of consistency across the requirements with which organisations must already comply. There are some differences, due to the fact that each set of guidelines must reflect the language and scope of the Act under which they were written. However those of you who know and work with the current NHMRC guidelines will find much that is familiar in spirit and content in these statutory guidelines on research.

The approach of the NSW Privacy Commissioner mirrors the approach taken in Victoria by the Health Service Commissioner in the Statutory Guidelines on Research under the *Health Records Act 2001 (Vic)*.

In addition, you should note that if you are a private sector organisation that already complies with the *Guidelines under section 95A*, then you may continue to do so. As long as the research project has been approved in accordance with the *Guidelines under section 95A*, then there is no need for it to also be approved in accordance the statutory guidelines on research under the HRIP Act. If you comply with the *section 95A Guidelines* you will be taken to have complied with the statutory guidelines on research. This is so as to prevent an unnecessary impost on organisations, researchers and Human Research Ethics Committees.

Comparison between the Guidelines under Section 95A of the Privacy Act 1988 (Cth) and NSW Privacy Commissioner’s statutory guidelines on research

	<i>Guidelines under Section 95A of the Privacy Act 1988 (Cth)</i>	Statutory guidelines on research under the HRIP Act 2002 (NSW)
Proposed action	Collection, use or disclosure of health information	Use or disclosure of health information in NSW
Proposed activity	Research relevant to public health or public safety, and the compilation or analysis of statistics, relevant to public health or public safety	Research, or the compilation or analysis of statistics, in the public interest
Organisations bound	Private sector health service providers and other private sector organisations.	NSW public and private sector organisations that are health service providers or that collect, hold or use health information.
Process to be followed	Substantially the same: ensure proposal fits within relevant criteria then submit proposal to HREC for approval; content of proposal	
Content of guidelines	Substantially the same	
	Has separate sections for ‘research’ and ‘compilation or analysis of statistics’.	Same section deals with ‘research’ and ‘compilation or analysis of statistics’. Does not cover ‘collection’.
Reporting annually by HREC	Report to AHEC	Report to NSW Privacy Commissioner

PART 2: STATUTORY GUIDELINES ON RESEARCH

1. *Application of the statutory guidelines*

- 1.1 These statutory guidelines define the scope and applicability of the ‘research exemption’ in Health Privacy Principle 10(1)(f) and 11(1)(f). These statutory guidelines require research proposals to be submitted to a Human Research Ethics Committee for approval, and provide a mechanism for Human Research Ethics Committees to weigh the public interest in the research or the compilation or analysis of statistics against the public interest in the protection of privacy. In order for the proposal to be approved, the public interest in the research or the compilation or analysis of statistics activity must substantially outweigh the public interest in maintaining the level of privacy otherwise afforded by the Health Privacy Principles.

Failure to comply with statutory guidelines constitutes a breach of the Act

- 1.2 An organisation proposing to use or disclose health information relying on the ‘research exemption’ in Health Privacy Principles 10(1)(f) or 11(1)(f), must comply with these statutory guidelines in order for the health information to be lawfully used or disclosed. Failure to comply with these statutory guidelines constitutes a breach of the Health Privacy Principles and the *Health Records and Information Privacy Act 2002 (NSW)*.

Prerequisites to applying the statutory guidelines

- 1.3 (a) It must be **reasonably necessary** to use or disclose health information for the purpose of research or the compilation or analysis of statistics, in the public interest; and
(b) the conduct and/or outcome of the research or the compilation or analysis of statistics activity must be in the **public interest**; and
(c) the relevant purpose of research or the compilation or analysis of statistics activity cannot be achieved by the use or disclosure of **de-identified** information¹; and
(d) it must be **impracticable to seek consent**² from the individual(s) to use or disclose their health information for the purpose of research or the compilation or analysis of statistics, in the public interest.

Conditions for organisations seeking to use or disclose

- 1.4 Where an organisation seeks to rely on these statutory guidelines to lawfully use or disclose health information it must:
- (a) be satisfied that the research or the compilation or analysis of statistics activity in which the health information is to be used or disclosed has been

¹ Note that if you have taken reasonable steps to de-identify the information before using or disclosing it, then these statutory guidelines on research do not apply. The statutory guidelines on research only apply where the purpose cannot be served by the use or disclosure of de-identified information.

² Please see footnote 7 for a list of the factors that HRECS should consider in assessing whether it is impracticable to seek consent.

- approved by a Human Research Ethics Committee (HREC) under these statutory guidelines; and
- (b) be satisfied that the HREC granting the approval satisfies the conditions in section 1.5 of these statutory guidelines; and
 - (c) comply with other duties imposed upon it by these statutory guidelines.

Conditions for HRECs

1.5 An HREC must:

- (a) only give approval under the Act for the collection, use or disclosure of health information for the purpose of research or the compilation or analysis of statistics, in the public interest, in accordance with these statutory guidelines;
- (b) be constituted and functioning in accordance with the *National Statement on Ethical Conduct in Research Involving Humans*³ (2: Human Research Ethics Committees); and
- (c) comply with sections 4.1-4.10 of these statutory guidelines.

Organisation being asked to use or disclose health information may decline to do so

- 1.6 An organisation from which health information is sought for the purpose of research or the compilation or analysis of statistics, in the public interest, may decline to agree to the use or disclosure of health information it holds, even where the use or disclosure of that health information has been approved by an HREC in accordance with these statutory guidelines.

2. *Procedures to be followed in the use or disclosure of health information pursuant to Health Privacy Principles 10(1)(f)(iii) and 11(1)(f)(iii)*

Use or disclosure

- 2.1 Where an organisation proposes to use or disclose health information under the 'research exemption' in Health Privacy Principle 10(1)(f) or 11(1)(f), a research proposal must be submitted to an HREC for approval. The research proposal must follow the procedures set out in this section and will be considered by an HREC only if the proposal also satisfies the requirements in section 1 of these statutory guidelines.

Respect for dignity and personal privacy

- 2.2 An overriding obligation for those who seek to use or disclose health information is at all times to respect the dignity and privacy of the individual.

Proposal to use health information

Written proposal to be submitted to HREC

³ (Canberra: Commonwealth of Australia, 1999). It can be downloaded from the NHMRC website at www.nhmrc.gov.au/publications/synopses/e35syn.htm

- 2.3 An organisation proposing to use health information for the purpose of research or the compilation or analysis of statistics, in the public interest, pursuant to Health Privacy Principle 10(1)(f), must submit a written proposal for that activity to an HREC. The information to be included in such a written proposal is set out in section 2.9 of these statutory guidelines.

Proposal to disclose health information

Collection and disclosure inextricably linked

- 2.4 Collection and disclosure are inextricably linked. All research proposals involving the collection of health information about an individual from a source other than the individual, will also involve disclosure. Wherever a collector proposes to *collect* health information from the organisation that holds it, the organisation holding the health information is being asked to *disclose* the information. A collector cannot *collect* health information from the organisation that holds it, unless the organisation from which the information is sought agrees to *disclose* that information to the collector.

Written proposal to be submitted to HREC

- 2.5 An organisation proposing to disclose health information for the purpose of research or the compilation or analysis of statistics, in the public interest, pursuant to Health Privacy Principle 10(1)(f), must submit a written proposal for that activity to an HREC. The information to be included in such a written proposal is set out in section 2.9 of these statutory guidelines.

Where written notification of HREC decision is provided by collector

- 2.6 An organisation may disclose health information to a collector for the purpose of research or the compilation or analysis of statistics, in the public interest without submitting a written proposal to an HREC if it receives written notification of the HREC approval for health information to be collected from it by the collector as set out in section 3.4 of these statutory guidelines. The written notification must include a copy of the collector's proposal to the HREC and the HREC's response. However, the disclosing organisation may still choose to submit the proposal to an HREC.

Option of submitting a joint proposal

- 2.7 An organisation seeking or approached to disclose health information may submit a joint written proposal in conjunction with the collector to an HREC for approval to disclose (and approval for the collector to collect) the health information. The joint written proposal may be submitted to an HREC selected by the collector or by the disclosing organisation, as negotiated by the collector and the disclosing organisation.
- 2.8 Where a proposal is submitted jointly to an HREC by the collector and disclosing organisation pursuant to section 2.7 of these statutory guidelines,

the collector as well as the disclosing organisation must state the matters listed in section 2.9 of these statutory guidelines.

Guidance for preparing a proposal to an HREC

- 2.9 A proposal that is required by these statutory guidelines to be submitted to an HREC for approval must:
- 2.9.1 contain a reference to Health Privacy Principles 10(1)(f) or 11(1)(f), and, if the proposal seeks approval for collection of health information, a reference to Health Privacy Principles 1 and 2;
 - 2.9.2 state reasons for believing the criteria set out in section 1.5 of these statutory guidelines have been met;
 - 2.9.3 state reasons why the public interest in the research or the compilation or analysis of statistics substantially outweighs the public interest in the protection of privacy;
 - 2.9.4 provide the HREC with the necessary information to enable the HREC to weigh the public interest considerations in accordance with section 4.4 of these statutory guidelines;
 - 2.9.5 state:
 - (a) the aims or purpose of the research or the compilation or analysis of statistics activity;
 - (b) the credentials and technical competence of those involved in the research or the compilation or analysis of statistics activity;
 - (c) the data needed;
 - (d) the study period;
 - (e) the target population;
 - (f) the reason(s) why de-identified information cannot achieve the relevant purpose of the research or the compilation or analysis of statistics activity;
 - (g) the reason(s) why it is impracticable to seek consent from the individual for the collection, use or disclosure of the health information.⁴
 - (h) the estimated time of retention of the health information (standards must be in accordance with HPP5);
 - (i) the specific uses to which the health information will be put during the research or the compilation or analysis of statistics activity;
 - (j) whether the collector, user or discloser proposes to use the information to contact an individual;
 - (k) the proposed method of publication (if any) of the results of the research or the compilation or analysis of statistics, and, if the information is in a form that could reasonably be expected to identify individuals, a statement that it will not be published in a generally available publication⁵;
 - (l) the identity of the custodian(s) of the health information to be collected, used or disclosed;

⁴ Any genetic research should be conducted in accordance with the principles in '16. Human Genetic Research' of the *National Statement in Research Involving Humans* (1999). The impracticability of obtaining consent for research involving identified genetic information may extend beyond the individual to include relatives of the individual. See '16. Human Genetic Research' on the National Statement for further information.

⁵ The 'research exemption' in Health Privacy Principles 10(1)(f) and 11(1)(f) can only be relied upon on the basis that 'if the information is in a form that could reasonably be expected to identify individuals, the information is not published in a generally available publication' (HPP 10(1)(f)(ii) and 11(1)(f)(ii)).

- (m) the security standards to be applied to the health information⁶.
- (n) a list of personnel within the organisation(s) with access to the health information to be collected, used or disclosed;
- (o) the level of protection that will be applied by those seeking to collect, use and/or disclose health information to protect that health information. These should include the:
 - (i) terms of any agreement between the organisation that holds the health information and the collector(s) or user(s) to govern limits on the use and disclosure of the health information; and
 - (ii) proposed methods of disposal of health information on the completion of the research or compilation or analysis of statistics as required by HPP 5.

Using information to contact individuals

- 2.10 Where an organisation seeking to use or disclose health information proposes to use the information to contact an individual, they must inform that individual:
- (a) that the health information is being used or disclosed in accordance with the *Health Records and Information Privacy Act 2002 (NSW)* and these statutory guidelines; and
 - (b) how that information will be used or disclosed; and
 - (c) that he or she is free at any time to refuse consent for further involvement in the research or the compilation or analysis of statistics [see paragraph 1.12 'Principles of Ethical Conduct', *National Statement (1999)*] and
 - (d) of the standards that will apply to protect the privacy of that individual; and
 - (e) of existing complaint mechanisms.

Matters warranting review of ethical approval

- 2.11 Those who seek to use or disclose health information for the purposes of research or the compilation or analysis of statistics, in the public interest must immediately report to the HREC anything that might warrant review of ethical approval of the research or the compilation or analysis of statistics proposal. [See: paragraph 2.37, 'Human Research Ethics Committees', *National Statement (1999)*].

Role of an HREC

- 2.12 Once a proposal is submitted to an HREC that satisfies the procedural requirements of these statutory guidelines, the HREC must then weigh the public interest considerations set out in section 4 of these guidelines.

3. Procedures to be followed in the collection of health information

⁶ Standards must be in accordance with HPP 5 and the joint NHMRC/AVCC Statement and Guidelines on Research Practice (contained in Appendix B of this publication) or with the Australian Standard *Personal privacy protection in health care information systems*. The health information should be retained in a form that is at least as secure as it was in the sources from which the health information was obtained unless more stringent legislative or contractual provisions apply.

Collection and disclosure inextricably linked

- 3.1 Collection and disclosure are inextricably linked. All research proposals involving the collection of health information about an individual from a source other than the individual, will also involve disclosure. Wherever a collector proposes to *collect* health information from the organisation that holds it, the organisation holding the health information is being asked to *disclose* the information. A collector cannot *collect* health information from the organisation that holds it, unless the organisation from which the information is sought agrees to *disclose* that information to the collector.

In order for the organisation from which the health information is being sought, to lawfully disclose the information under HPP 11(1)(f), it is necessary for the collector to operate in compliance with this section of the statutory guidelines.

Respect for dignity and personal privacy

- 3.2 An overriding obligation for those who seek to collect health information is at all times to respect the dignity and personal privacy of the individual.

Written proposal to be submitted to an HREC

- 3.3 Where a collector proposes to collect health information from an organisation that holds it, the collector must submit a written proposal for the research or the compilation or analysis of statistics to an HREC:
- (a) under this section; or
 - (b) under section 2.7 of these guidelines, in the form of a joint proposal prepared in conjunction with the organisation being asked to disclose the health information.

The information to be included in written proposals to HRECs is set out in section 2.9 of these statutory guidelines.

Collector to provide written notification of an HREC's decision

- 3.4 Where a collector submits a written proposal to an HREC under section 3.3 (a) of these statutory guidelines, and has obtained approval from the HREC to collect health information from an organisation for the specific research or compilation or analysis of statistics activity, the collector must give to the organisation(s) from which the health information is sought written notification of the decision of the HREC made in accordance with these statutory guidelines. The written notification must include a copy of the collector's proposal to the HREC and the HREC's response.

This written notification removes the obligation for the disclosing organisation(s) to submit a written proposal for the disclosure of health information for the same research or compilation or analysis of statistics activity (see section 2.6 of these statutory guidelines)

A disclosing organisation may still decide to submit a written proposal to an HREC in accordance with section 2 of these statutory guidelines even if that disclosing organisation receives written notification of HREC approval from the collector(s).

Matters warranting review of ethical approval

- 3.5 The collector of health information for the purposes of research or the compilation or analysis of statistics, in the public interest, must immediately report to the HREC anything that might warrant review of ethical approval of the research or the compilation or analysis of statistics [see paragraph 2.37, 'Human Research Ethics Committees, *National Statement on Ethical Conduct in Research Involving Humans (1999)*]

Role of an HREC

- 3.6 Once a proposal is submitted to an HREC that satisfies the procedural requirements of these statutory guidelines, the HREC must then weigh the public interest considerations set out in section 4 of these statutory guidelines.

4. Consideration by Human Research Ethics Committee (HREC)

HREC to have sufficient information, expertise and understanding of privacy issues

- 4.1 Before making a decision under these statutory guidelines, an HREC must assess whether it has sufficient information, expertise and understanding of privacy issues, either among the members of the HREC or otherwise available to it, to make a decision that takes proper account of privacy matters.
- 4.2 In making a decision under these statutory guidelines, an HREC must:
- (a) consider whether the purpose of the research or the compilation or analysis of statistics can be achieved by the collection, use or disclosure of de-identified information;
 - (b) consider whether it is impracticable⁷ for the organisation seeking to collect, use or disclose the information to seek the consent of the individual to whom the information relates; and

⁷ HRECs should consider the following factors in assessing whether it is impracticable to seek consent for the proposed collection, use or disclosure:

- The size of the population involved in the research;
- The proportion of individuals who are likely to have moved or died since the health information was originally collected;
- The risk of introducing potential bias into the research, thereby affecting the generalisability and validity of the results;
- The risk of creating additional threats to privacy by having to link information in order to locate and contact individuals to seek their consent;
- The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances;
- The difficulty of contacting individuals directly when there is no existing or continual relationship between the organisation and the individuals;
- The difficulty of containing individuals indirectly through public means, such as advertisement and notices;

- (c) ensure that the HREC has the competence to determine if the public interest in the proposed activity substantially outweighs, or does not substantially outweigh the public interest in the protection of privacy.

When an HREC should not approve a proposed activity

- 4.3 If the public interest in the research or the compilation or analysis of statistics does not substantially outweigh the public interest in the protection of privacy then the activity should not be approved by an HREC.

Weighing the public interest

- 4.4 In determining whether or not the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy, an HREC should consider the following matters:
 - (a) the degree to which the research or the compilation or analysis of statistics is in the public interest;
 - (b) the degree to which the research or the compilation or analysis of statistics is likely to contribute to:
 - (i) the identification, prevention or treatment of illness, injury or disease; or
 - (ii) scientific understanding relating to health; or
 - (iii) the protection of the health of individuals and / or communities; or
 - (iv) the improved delivery of health, disability or aged care services; or
 - (v) enhanced scientific knowledge or understanding; or
 - (vi) enhanced knowledge within the fields of social science and the humanities relating to health;
 - (c) any likely benefits to individuals, to the category of persons to which the individual(s) belong, or the wider community that will arise from the research or the compilation or analysis of statistics activity being undertaken in the manner proposed;
 - (d) in considering benefits to the category of persons to which the individual(s) belong, specific consideration should be given to any likely benefits to individuals that belong to certain categories where the information may be of a particularly personal or sensitive nature; for example:
 - (i) children and young people; or
 - (ii) persons with intellectual or psychiatric disability; or
 - (iii) persons highly dependant on medical care; or
 - (iv) persons in dependent or unequal relationships; or
 - (v) persons who are members of collectivities; or
 - (vi) Aboriginal and Torres Strait Islander peoples; or
 - (vii) persons whose information relates to their mental or sexual health
 - (viii) persons who are incarcerated.
 - (e) whether the research or the compilation or analysis of statistics activity design can be satisfied without needing to apply HPP 10(1)(f) or 11(1)(f) and the defects in the activity that might arise if the research or

-
- Whether the additional resources needed to obtain consent will impose an undue hardship on the organisation.

- the compilation or analysis of statistics activity was not conducted in the manner proposed;
- (f) the cost of not undertaking the research or the compilation or analysis of statistics activity (to government, the public, the health care system, etc.);
 - (g) the public importance of the research or the compilation or analysis of statistics activity;
 - (h) whether the risk of harm to an individual whose health information is to be collected, used or disclosed in the proposed research or the compilation or analysis of statistics activity is minimal, based on the information provided in response to sections 2.9 of these guidelines;
 - (i) the standards of conduct to be observed in the research or the compilation or analysis of statistics activity, including:
 - (i) the study design and the scientific or other credentials of those involved in conducting that study;
 - (ii) if the activity involves contact with participants, the procedures or controls that will apply to ensure participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be employed are intrusive;
 - (iii) whether access to health information is restricted to appropriate personnel involved in conducting the proposed study;
 - (iv) the procedures that are to be followed to ensure that the information will not be published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained; and
 - (v) the procedures that are to be followed at the completion of the proposed study to ensure that all data containing health information are at least as secure as they were in the sources from which the data was obtained, including the date when the data will be destroyed or returned. These procedures must be in accordance with HPP 5.

Recording, notification and monitoring of decisions made by an HREC

- 4.5 Details of the decision made by the HREC regarding proposals for research or the compilation or analysis of statistics, in the public interest, under these guidelines must be recorded in accordance with paragraph 2.30 of the *National Statement on Ethical Conduct in Research Involving Humans (1999)*. The HREC must also record the following:
- (a) the organisation(s) proposing to collect, use and/or disclose health information under the proposal;
 - (b) the data items sought from the organisation(s) or to be used by the organisation(s), and approved by the HREC;
 - (c) the aims and purposes of the project;
 - (d) the number of records involved;
 - (e) how and on what grounds the HREC came to the conclusion that it had sufficient information, expertise and understanding of privacy issues, either amongst the members of the HREC or otherwise available to it, to make a decision that takes proper account of privacy; and
 - (f) the considerations identified in section 4.4.

- 4.6 When an HREC approves a proposal for research or the compilation or analysis of statistics, in the public interest, it must decide whether the proposed activity should commence within a defined period from the date of approval and whether the project should be completed within a set period, and notify those conducting the activity of that decision.
- 4.7 It is an obligation of the HREC to monitor proposals approved in accordance with these guidelines for the purposes of research or the compilation or analysis of statistics, in the public interest in accordance with paragraphs 2.33-2.38 'Human Research Ethics Committees', *National Statement (1999)*.

Reporting to the NSW Privacy Commissioner

- 4.8 An HREC must provide a report (a template is attached as Appendix C) on an annual basis to the NSW Privacy Commissioner on those decisions it has made in each financial year where it has applied the statutory guidelines on research. The report will consist of:
- (a) the information required to be recorded by paragraphs (a) - (f) of section 4.5 of these guidelines;
 - (b) an evaluation of the operation of these guidelines for the year of reporting.
- 4.9 An HREC must provide information in relation to sections 4.5, 4.6 and 4.7 of these statutory guidelines to the NSW Privacy Commissioner upon request, at any time.
- 4.10 For the purposes of section 4.9, a reference to a 'financial year' shall be construed as a reference to the period of twelve months ending at midnight on 30 June.

APPENDIX A

HEALTH PRIVACY PRINCIPLE 10

Limits on use of health information

(1) An organisation that holds health information must not use the information for a purpose (a "secondary purpose") other than the purpose (the "primary purpose") for which it was collected unless:

(f) Research

the use of the information for the secondary purpose is reasonably necessary for research, or the compilation or analysis of statistics, in the public interest and:

(i) either:

(A) that purpose cannot be served by the use of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the use, or

(B) reasonable steps are taken to de-identify the information, and

(ii) if the information could reasonably be expected to identify individuals, the information is not published in a generally available publication, and

(iii) the use of the information is in accordance with guidelines, if any, issued by the Privacy Commissioner for the purposes of this paragraph, or ...

HEALTH PRIVACY PRINCIPLE 11

Limits on disclosure of health information

(1) An organisation that holds health information must not disclose the information for a purpose (a "secondary purpose") other than the purpose (the "primary purpose") for which it was collected unless:

(f) Research

the disclosure of the information for the secondary purpose is reasonably necessary for research, or the compilation or analysis of statistics, in the public interest and:

(i) either:

(A) that purpose cannot be served by the disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the disclosure, or

(B) reasonable steps are taken to de-identify the information, and

(ii) the disclosure will not be published in a form that identifies particular individuals or from which an individual's identity can reasonably be ascertained, and

(iii) the disclosure of the information is in accordance with guidelines, if any, issued by the Privacy Commissioner for the purposes of this paragraph, or

APPENDIX B

Joint NHMRC/AVCC Statement and Guidelines on Research Practice, Section 2

Data storage and retention

- 2.1 Data (including electronic data) must be recorded in a durable and appropriately referenced form. Data management should comply with relevant privacy protocols, such as the Australian Standard on Personal Privacy Protection.⁸
- 2.2 The department or research unit must establish procedures for the retention of data and for the keeping of records of data held.
- 2.3 Data must be held for sufficient time to allow reference. For data that is published this may be for as long as interest and discussion persists following publication. It is recommended that the minimum period for retention is at least five years from the date of publication but for specific types of research, such as clinical research, fifteen years may be more appropriate.⁹
- 2.4 Wherever possible, original data must be retained in the department or research unit in which they were generated. Individual researchers should be able to hold copies of the data for their own use. Retention solely by the individual researcher provides little protection to the researcher or the institution in the event of an allegation of falsification of data.
- 2.5 Data related to publications must be available for discussion with other researchers. Where confidentiality provisions apply (for example, where the researchers or institution have given undertakings to third parties, such as the subjects of the research), it is desirable for data to be kept in a way that reference to them by third parties can occur without breaching such confidentiality.
- 2.6 Confidentiality agreements to protect intellectual property rights may be agreed between the institution, the researcher and a sponsor of the research. Where such agreements limit free publication and discussion, limitations and restrictions must be explicitly agreed.
- 2.7 It is the obligation of the researcher to enquire whether confidentiality agreements apply and of the Head of the Department or research unit to inform researchers of their obligations with respect to these provisions.
- 2.8 All confidentiality agreements should be made known at an early stage to the head of the research institution, or nominated representative.
- 2.9 The procedures formulated by institutions must include guidelines on the establishment and ownership of and access to databases containing confidential information, and any limits on this.

⁸ *Personal Privacy Protection in Health Care Information Systems*, Australian Standard AS 4400-1995.

⁹ The December 1991 *Guidelines for Good Clinical Research Practice in Australia*. Published by the Therapeutic Goods Administration of the Commonwealth Department of Health and Family Services, recommends retention of data for at least 15 years.

- 2.10 When the data are obtained from limited access databases, or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which it was collected, must be retained by the researcher or research unit.
- 2.11 Researchers must be responsible for ensuring the appropriate security for any confidential material, including that held in computing systems. Where computing systems are accessible through networks, particular attention to security of confidential data is required. Security and confidentiality must be assured in a way that copes with multiple researchers and the departure of individual researchers.

APPENDIX C

HREC REPORT TO THE NSW PRIVACY COMMISSIONER

1 JULY _____ [insert year] TO 30 JUNE _____ [insert year]

Compliance with Statutory guidelines on research under the Health Records and Information Privacy Act 2002

1. Name of HREC

Please include previous name of HREC in brackets if name has changed in last 12 months.

Name of HREC:

2. Details of Chairperson

Name of HREC Chairperson: (include title)

Phone:

Fax:

Email:

3. HREC Contact Officer Details

The mailing address for the Contact Officer will be used for HREC correspondence whether addressed to the Contact Officer or addressed to the Chairperson. This address must be a business address.

Name of HREC Contact Officer: (include title)

Position:

Mailing address:

Phone:

Fax:

Email:

4. Organisation Details

Name of Organisation:

Head of Organisation:

Mailing address for Organisation:

Type of Organisation: (please indicate which category best describes your organisation, tick one box only)

Hospital / health service – public

Government department

Hospital / health service – private

Government statutory agency

University/ education institution – public

Other organisation – not for profit

University/ education institution – private

Other organisation –for profit

-
5. During the financial year to which this report applies, did your HREC review any proposals which involved the use or disclosure of health information **without** the consent of those individuals for:

- a. Research or the compilation or analysis of statistics in the public interest or
- b. the management of health services

[ie. proposals seeking to rely on the exemptions in Health Privacy Principle 10(1)(d), 11(1)(d), and / or 10(1)(f), 11(1)(f) of the Health Records and Information Privacy Act 2002]

YES

NO Thank you for completing this form. Please go to final page to complete declarations.

-
6. When considering these proposals did your HREC apply the NSW Privacy Commissioner's Statutory guidelines on research?

(Both boxes may be ticked)

YES If Yes, for how many proposals did your HREC apply the Statutory guidelines on research? _____

NO If No, for how many proposals did your HREC **not** apply the Statutory guidelines on research? If No, what are the reasons for not applying the Statutory guidelines on research?

7. Did your HREC assess whether it had sufficient information, expertise and understanding available to it of privacy issues to make a decision that takes proper account of privacy (see Part 2, paragraph 4.1)?

YES Please tick one or more of the following to indicate the information, expertise and understanding of privacy issues available to your HREC:

- Members are familiar with the Health Privacy Principles (HPPs) set out in Schedule 1 of the Health Records and Information Privacy Act 2002 and the Statutory guidelines on research.
- One or more member attended an information session/ seminar or workshop on privacy
- Lawyer or other member had knowledge of privacy issues
- One or more member had experience or qualifications relevant to privacy issues
- One or more member accessed written guidance about privacy issues
- HREC sought additional advice or information from someone who is not a regular member of the committee
- Other (please outline)

NO Please provide reasons for not making this assessment.

8. Did your HREC consider whether the purpose of the proposed activity could be achieved using de-identified information (see Part 2, paragraph 4.2(a))?

(Both boxes may be ticked)

YES Please tick one or more of the following to indicate if your HREC considered:

- that scientific defects in the proposed activity would result if that activity was conducted using de-identified information
- that the proposed activity involved linkage of data
- Other (please outline)

NO If No, please provide reasons why this was not considered.

9. Did your HREC consider whether it was impracticable to obtain consent to collect, use or disclose an individual's health information (see paragraph Part 2, 4.2 (b))?

(Both boxes may be ticked)

YES Please tick one or more of the following to indicate if your HREC considered:

- The size of the population involved in the research;
- The proportion of individuals who are likely to have moved or died since the health information was originally collected;
- The risk of introducing potential bias into the research, thereby affecting the generalisability and validity of the results;
- The risk of creating additional threats to privacy by having to link information in order to locate and contact individuals to seek their consent;
- The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances;
- The difficulty of contacting individuals directly when there is no existing or continual relationship between the organisation and the individuals;
- The difficulty of containing individuals indirectly through public means, such as advertisement and notices;
- Other (please outline)

NO Provide reasons why this was not considered

10.

In reaching a decision under the Statutory guidelines on research (see Part 2, paragraph 4.4), for how many proposals did your HREC determine that:

- the public interest in the proposed research, statistical or management of health services activity substantially outweighed the public interest in the protection of privacy?

Number of proposals:

11.

Do you have any comments or feedback on the NSW Privacy Commissioner's Statutory guidelines on research?

Thank you for completing this form.

Please complete the declarations on the final page.

Declaration of the organisation with responsibility for the HREC.

This declaration must be completed and signed by the CEO or equivalent officer who exercises the authority of the organisation/ institution for HREC activities.

HREC Name:

Organisation Name:

I confirm:

- that I am duly authorised to sign this declaration;
- that the information supplied on this form and any other attachment is true and correct;
- that, for the period to which this form relates, the above HREC has operated in accordance with the Statutory guidelines on research pursuant to the Health Records and Information Privacy Act 2002.

Name:

Position:

Date:

Signature:

When completed, please return this form to:

The NSW Privacy Commissioner
Privacy NSW
GPO Box 6
SYDNEY NSW 2001

If you have any queries, please contact the Office of the Privacy Commissioner on telephone (02) 9228 8585, or email privacy_nsw@agd.nsw.gov.au