

Health Records Act 2001 (Vic)

STATUTORY GUIDELINES
ON
RESEARCH

issued
for the purposes of
Health Privacy Principles
1.1(e)(iii) & 2.2(g)(iii)

Office of the Health Services Commissioner
(Victoria)

February 2002

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Decision by the Health Services Commissioner under Section 22(1) of the *Health Records Act* 2001

The *Health Records Act* 2001 (Vic) (the Act) creates a scheme to regulate the collection and handling of health information in Victoria. The Health Services Commissioner is responsible for the implementation of the Act.

The Act:

- gives individuals a legally enforceable right of access to health information about them that is contained in records held in Victoria by the private sector; and
- establishes Health Privacy Principles (HPPs) that will apply to health information collected and handled in Victoria by the Victorian public sector and the private sector.

The Act will be introduced in a two-phase process. The Health Privacy Principles will operate as voluntary standards from 1 March 2002, and become legally binding from 1 July 2002 when the rest of the Act is fully operational.

I am empowered by section 22 of the Act to “issue, approve or vary guidelines for the purposes of the Health Privacy Principles”. Section 22(6) also states that:

The guidelines may apply, adopt, or incorporate any matter contained in any document, whether

- (a) wholly or partially or as amended by the guidelines; or*
- (b) as in force at the time the guidelines are made or at any time before then; or*
- (c) as in force from time to time.*

Where these guidelines apply, adopt or incorporate any matter contained in any document, this relates to the document as in force from time to time.

Having regard to section 22 of the Act, and having satisfied the publication and comment process required by the section, and having considered the submissions received, I issue guidelines for the purposes of HPP 1.1(e)(iii) and HPP 2.2(g)(iii) under section 22(1) of the Act.

The guidelines comprise the boxed text on pages 10 to 21 and the appendices to which they refer. An introduction to the guidelines is enclosed with them.

- The guidelines concern the collection, use and disclosure of health information for the purposes of research or the compilation or analysis of statistics, in the public interest.

If you require further information about the operation of the guidelines or the Act, please contact my office on 8601 5222.



BETH WILSON
Health Services Commissioner

22 February 2002

Introduction

Statutory Guidelines issued for the purposes of Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii) of the *Health Records Act 2001 (Vic)*

The *Health Records Act 2001 (Vic)* (the Act) creates a scheme to regulate the collection and handling of health information in Victoria.

The Act:

- gives individuals a legally enforceable right of access to health information about them that is contained in records held in Victoria by the private sector; and
- establishes Health Privacy Principles (HPPs) that will apply to health information collected and handled in Victoria by the Victorian public sector and the private sector.

The access regime and the HPPs are designed to protect privacy and promote patient autonomy, while ensuring safe and effective service delivery, and the continued improvement of health services.

The Act will be introduced in a two-phase process. The HPPs will operate as voluntary standards from 1 March 2002, and become legally binding from 1 July 2002 when the rest of the Act is fully operational. From 1 July 2002, individuals will have a right of access to health information about them, and those collecting and handling health information will be obliged to comply with the HPPs.

If it is proposed that health information will be collected, used or disclosed for the purposes of research after 1 July 2002, then the project will generally need to be assessed in accordance with the Act and these guidelines. This assessment can be made by an ethics committee before 1 July, if convenient.

There are, however, special transitional arrangements in place for disclosures for the purposes of research by public and private hospitals and day procedure centres under section 141(3)(g) of the *Health Services Act 1988 (Vic)*, and also by approved mental health services under section 120A(3)(g) of the *Mental Health Act 1986 (Vic)*. For more information about these arrangements, see www.dhs.vic.gov.au/ahs/healthrecords/phasedin.htm

The Health Services Commissioner is empowered by the Act to “issue, approve or vary guidelines for the purposes of the Health Privacy Principles”. Section 22 provides that guidelines may be “issued, approved or varied” for a number of HPPs, including:

- HPP 1 in relation to paragraphs 1.1(e)(iii); and
- HPP 2 in relation to paragraphs 2.2(g)(iii).

These relate to the collection, use and disclosure of health information for the purposes of research or compilation or analysis of statistics, which is, in the public interest, where:

- (1) the purpose of the research or the compilation or analysis of statistics cannot be served by the collection, use or disclosure of information that does not identify the individual in question or from which the individual’s identity cannot be reasonably ascertained;¹ and

¹ That is, the information is “de-identified”.

- (2) where it is impracticable to seek the individual's consent to the collection, use or disclosure.

HPP 1.1(e) and HPP 2.2(g) therefore only govern the collection, use and disclosure of health information for the purposes of research or the compilation or analysis of statistics' purposes in very particular circumstances.

Collection

HPP 1 requires that personal health information must not be collected by an organisation unless the information is necessary for one or more of its functions and at least one of a series of criteria apply.

The first and most important criterion is consent. Optimally, research would be conducted with the consent of the participants, and where this is not practicable, then de-identified health information (information from which the identity of the person to whom the information relates cannot be reasonably ascertained) would be used.

Another in the list of criteria is that the information is required, authorised or permitted to be collected by or under another law.

The Act also recognises that, in some circumstances, obtaining consent may not be practicable, and other public interest priorities will need to be balanced against the public interest in maintaining an individual's privacy.

The criteria set out in HPP 1.1(e) is that such collection of health information must be:

- (1) necessary for research, or the compilation or analysis of statistics, in the public interest; and
- (2) the purpose cannot be served by collection that does not identify the individual; and
- (3) it is impracticable to seek consent; and
- (4) it complies with the Health Services Commissioner's guidelines.

Use or disclosure

HPP 2 requires that where *use* (meaning internal use within an organisation) or *disclosure* (meaning disclosure to others outside the organisation) of health information is to be for a purpose other than the primary purpose for which it was collected, then such secondary use or disclosure must be either with consent, or within one of the list of criteria set out in HPP 2.2.

Included in this list is that the information can be used or disclosed if such use or disclosure is required, authorised or permitted to be collected by or under another law. One example is the use or disclosure of health information from registries established under the *Cancer Act 1958* (Vic) (section 60).

HPP 2.2(g) allows the use and disclosure for a purpose other than the primary purpose for which it was collected where the use or disclosure is:

- (1) necessary for research or the compilation or analysis of statistics, in the public interest;
- (2) the purpose cannot be served by use/disclosure that does not identify the individual;
- (3) it is impracticable to seek consent; and
- (4) it complies with the Health Services Commissioner's guidelines.

Additionally, if *disclosure* is being contemplated, the disclosing organisation must:

- (5) reasonably believe that the recipient of the information will not further disclose the information; and
- (6) that the disclosure will not be published in an identifying form.

Health Services Commissioner's Guidelines

The Health Services Commissioner's guidelines relate to the collection, use and disclosure of health information for research, or the compilation or analysis of statistics, in the public interest, in very particular circumstances: where the purposes of the research or the statistical work cannot be served by the collection, use or disclosure of de-identified² health information AND it is impracticable to seek the individual's consent to the collection, use or disclosure of that information.

The Commissioner is aware that guidelines of various levels of authority already exist to govern the use of information for research purposes. One key document is the *National Statement on Ethical Conduct in Research Involving Humans*.³

The *National Statement* was developed by the Australian Health Ethics Committee (AHEC), a principal committee of the National Health and Medical Research Council (NHMRC). AHEC advises the NHMRC on ethical issues relating to health. The *National Statement* was issued by the NHMRC in 1999 and endorsed by the Australian Vice-Chancellors' Committee, the Australian Research Council, the Australian Academy of the Humanities, the Australian Academy of Science and the Academy of Social Sciences in Australia. It provides general ethical principles that should be applied to **all** research involving humans, as well as guidelines on specific research types, participant groups and other issues. Part 18 of the *National Statement* specifically deals with privacy of information. It requires research proposals to conform to all relevant Commonwealth, State or Territory privacy legislation or codes of practice.

Guidelines Under Section 95 of the Privacy Act 1988 (Cth)

The *Guidelines Under Section 95 of the Privacy Act 1988*, issued by the NHMRC,⁴ build on the *National Statement*. The *Privacy Act 1988* applies to the Commonwealth public sector. Section 95 provides a process to resolve conflict which may arise between the public interest in privacy and the public interest in medical research, where the use or disclosure of information held by a Commonwealth agency for medical research would otherwise involve a breach of the *Privacy Act 1988*.

Section 95 permits the NHMRC, with the approval of the Federal Privacy Commissioner, to issue guidelines for the protection of privacy in the conduct of medical research.

² See Appendix 2: Glossary.

³ (Canberra: Commonwealth of Australia, 1999). The Statement applies to all disciplines of research involving or impacting on humans. It can be downloaded from the NHMRC Website at www.nhmrc.gov.au/publications/synopses/e35syn.htm. Copies can be purchased from AusInfo Government Information Bookshops (telephone 132 447 for locations and prices). If you do not have Internet access or are unable to purchase a copy, a copy will be made available on request from the Office of the Health Services Commissioner (telephone 03 8601 5222).

⁴ *Guidelines Under Section 95 of the Privacy Act 1988* (Canberra: Commonwealth of Australia, 2000) and *Guidelines approved under Section 95A of the Privacy Act 1988* (Canberra: Commonwealth of Australia, 2001) may be accessed at the NHMRC Website at: www.nhmrc.gov.au/publications/pdf/e26.pdf and www.nhmrc.gov.au/publications/pdf/e43.pdf

Guidelines Under Section 95A of the Privacy Act 1988

In 2001, the NHMRC issued guidelines under section 95A of the *Privacy Act*. The section is part of a series of amendments to the *Privacy Act* which have extended its scope to much of the private sector (all health service providers and those businesses with an annual turnover of more than \$3 million) since 21 December 2001. These guidelines apply to the collection, use or disclosure of personal health information for research or the analysis or compilation of statistics relevant to public health or public safety and to the collection of health information for the purpose of health service management where the organisation proposing to collect, use or disclose falls within the scope of the *Privacy Act*, as outlined above. These guidelines relate to National Privacy Principles 2.1(d)(ii) and 10.3(d).

Health Services Commissioner's Guidelines & NHMRC Guidelines

The HPPs of the *Health Records Act 2001* (Vic) are, like the Commonwealth's Information Privacy Principles, and their incarnation for the private sector, the National Privacy Principles, based on international privacy standards. There are obvious similarities between the two sets of principles, which both seek to balance potential competing public interests.

Conscious of these facts and the need to ensure, as far as the Act allows, a level of consistency across the requirements with which researchers and organisations must already comply, the Commissioner has, for her statutory research guidelines, drawn on those issued by the NHMRC for the purposes of sections 95 and 95A of the *Privacy Act* which, in turn, make substantial reference to the *National Statement*.

There are some inevitable differences. The section 95 guidelines must refer back to, and be grounded in, the language and the scope of the section of the *Privacy Act* under which they are made. The section 95 guidelines deal, for example, with "medical research", while the section 95A guidelines apply to research and statistical compilation and analysis which is "relevant to public health and public safety", as well as to collection of health information without consent for the purpose of the management, funding or monitoring of a health service. In contrast, Victoria's HPPs deal with research and statistical compilation and analysis "in the public interest".

The differences to be found in the Health Services Commissioner's guidelines serve only to ensure they reflect the objectives and requirements of the *Health Records Act 2001* (Vic), the legislation of which they are a part. Those who know and work with the current NHMRC guidelines will find much that is familiar in the spirit and content of these guidelines.

Human Research Ethics Committees

A cornerstone of all three sets of guidelines and of the *National Statement* is the use of human research ethics committees (HRECs) to review research proposals.

The Health Services Commissioner's guidelines allow an organisation to collect, use or disclose health information in the circumstances contemplated in HPP 1.1(e) and 2.2(g) only where the existing criteria in those sections of the HPPs are met and where the research or the compilation or analysis of statistics proposal has been approved by a properly constituted HREC, which has reviewed the proposal in accordance with the Commissioner's guidelines.

As HRECs operate in all research and teaching institutions and in the Victorian Department of Human Services, the Commissioner is confident that the need for HREC approval and monitoring required by these guidelines will not impose a burden on researchers seeking to use health information or on organisations from whom information is sought. Those organisations that hold health information but do not currently have their own HREC will very often find that the researchers seeking access to the information are either based in a teaching or research institution and so will have the proposal considered by their own HREC, or may have access through another path.

Where neither the researcher seeking to collect health information nor the organisation holding health information has an obvious avenue to a HREC, the *National Statement* provides clear direction on the establishment and functions of HRECs.

These guidelines therefore provide an additional measure of scrutiny for the collection, use and disclosure of health information for research and statistical compilation and analysis where identifying information may be involved and where consent from the individuals concerned is not obtained. This is by providing a mechanism for the weighing of the public interest in the research or statistical work being undertaken against the public interest in the protection of privacy.

These statutory guidelines are part of the HPPs and so form part of the *Health Records Act 2001 (Vic)*. Researchers, statisticians, HRECS and other organisations using these guidelines should be aware they must be read in conjunction with the HPPs and the rest of the Act.

Complaint Mechanisms

Under section 45 of the *Health Records Act 2001 (Vic)*, an individual may complain to the Health Services Commissioner about an act or practice that may be an interference with the privacy of the individual.

Where an organisation seeks to rely on these guidelines to lawfully collect, use, or disclose health information for the purpose of research and the compilation or analysis of statistics pursuant to HPPs 1.1(e) and 2.2(g), an individual may complain to the Health Services Commissioner if the procedures set out in these guidelines are not followed.

In addition, complaints may be made to the organisation conducting the research or the compilation or analysis of statistics, in the public interest, and/or the HREC which has approved the research or the compilation or analysis of statistics activity by the person whose information is being used, where it is believed that the conduct of the approved activity may interfere with that person's privacy.

Compliance Reporting

The *National Statement* obliges HRECs to report annually to the NHMRC information relevant to its procedures. The NHMRC, through AHEC, audits the activities of HRECs to ensure compliance with the *National Statement*.

Additional reporting on privacy issues to AHEC & Health Services Commissioner

Where the nature of research or compilation or analysis of statistics' proposals raises the privacy issues discussed in this introduction, HRECS must provide additional compliance reports to the relevant authorities.

If Victorian HRECs apply either the section 95 or section 95A guidelines issued by NHMRC, they are required under the *Privacy Act* to submit similar reports to AHEC. Whether the section 95 or section 95A guidelines apply will depend on the type of organisation proposing to collect, use or disclose the information.

Where Victorian HRECs consider proposals relevant to the guidelines issued by the Health Services Commissioner and apply those guidelines, then those HRECs must submit additional reports to the Health Services Commissioner, giving details about the way in which they reached their decision. This is outlined in sections 4.8 and 4.9 of the guidelines.

The Health Services Commissioner's guidelines will only apply where-

- the proposal involves research or compilation or analysis of statistics in Victoria; and
- the proposal requires the collection, use or disclosure of personal health information; and
- it is impracticable to seek the individual's consent to the collection, use or disclosure; and
- the purpose of the research cannot be served by using de-identified information.

The report submitted to the Health Services Commissioner in such a case will be similar to the report required to be submitted to AHEC by those HRECs which have applied the section 95 or section 95A guidelines in assessing proposals.

There will be some organisations which will need to submit a proposal for approval to collect, use or disclose health information under the *Health Records Act 2001 (Vic)* and guidelines, and the *Privacy Act 1988 (Cwlth)* and guidelines. In these circumstances, a HREC may elect to accept one application which addresses the requirements of both. Further information will be provided about such a process in due course.

Comparison between the NHMRC and Health Services Commissioner's Guidelines

	Section 95 Guidelines	Section 95A Guidelines	Health Services Commissioner's Guidelines
Nature of proposed activity	medical research	research and statistical compilation and analysis relevant to public health and public safety	research and statistical compilation and analysis, in the public interest
Type of organisation proposing to collect, use or disclose	any organisation wanting to use personal information held by a Commonwealth agency; Commonwealth agency wanting to release personal information	any private sector health service provider; private sector organisations with annual turnover of more than \$3 million	any Victorian public sector organisation; any private sector organisation collecting, using or disclosing health information in Victoria
Tasks for proposers	Substantially the same: ensure proposal fits within relevant criteria, then submit proposal to HREC for approval; content of proposal, including matters to be addressed, substantially the same.		
Tasks for HREC	Substantially the same: must determine whether the public interest in maintaining the level of privacy substantially outweighs the public interest in maintaining the level of privacy; minor differences reflect differences in State and Cwlth privacy laws		
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
Reporting annually by HREC	Report to AHEC	Report to AHEC	Report to Health Services Commissioner

STATUTORY GUIDELINES

issued for the purposes of

Health Privacy Principles

1.1(e)(iii) & 2.2(g)(iii)

Health Records Act 2001 (Vic)

1. Application of the guidelines

1.1 These guidelines apply to Health Privacy Principle (HPP) 1.1(e) for the collection of health information¹ and HPP 2.2(g) for the use and disclosure of health information, for the purpose of research² or compilation or analysis of statistics, in the public interest. The HPPs are established under the *Health Records Act 2001* (Vic) (the Act). These guidelines provide a mechanism for weighing the public interest in research and compilation or analysis of statistics against the public interest in the protection of privacy. The public interest in the research activity must substantially outweigh the public interest in maintaining the level of privacy protection afforded by the HPPs other than HPP 1.1(e) and HPP 2.2(g).

Prerequisites to applying the guidelines

1.2 It must be **necessary** to collect, use or disclose health information for the purposes of research or compilation or analysis of statistics, in the public interest. It must be determined that:

- (a) the conduct and/or the outcome of the research or compilation or analysis of statistics activity would be, in the public interest; **and**
- (b) the relevant purpose of the research or the compilation or analysis of statistics activity cannot be achieved by the collection, use or disclosure of de-identified information;³

1.3 It must be **impracticable**⁴ to seek consent from the individual(s) to collect, use or disclose their health information for the purpose of research or the compilation or analysis of statistics, in the public interest.

1.4 Where an organisation⁵ seeks to rely on these guidelines to lawfully collect, use or disclose health information for the purpose of research or the compilation or analysis of statistics, in the public interest, **under HPP 1.1(e)(iii) or HPP 2.2(g)(iii)**, the organisation must:

- (a) be satisfied that the research or the compilation or analysis of statistics activity in which the health information is to be used has been approved by a human research ethics committee (HREC) under these guidelines; and
- (b) be satisfied that the HREC granting the approval satisfies the conditions in section 1.5 of these guidelines; and
- (c) comply with other duties imposed on it by these guidelines.

¹ See Appendix 2: Glossary.

² See Appendix 2: Glossary.

³ Information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained.

⁴ Assessing whether it is 'impracticable' to seek consent requires consideration of what is impracticable in any particular set of circumstances. It may refer to physical impracticability in gaining consent; the age or the volume of the information may be such that it may not be practicable to track down all the individuals involved and seek their consent. This would need to amount to more than mere inconvenience or involving some expense. It may also refer to the impracticability of obtaining consent in terms of the nature of the research or statistical analysis or compilation or analysis proposed; a complete sample may be essential to the integrity and success of some research and so the research would not be possible if any of the subjects refused to allow their information to be used.

⁵ See Appendix 2: Glossary.

Conditions relating to the approval of research or the compilation or analysis of statistics, in the public interest given by a HREC

1.5 A HREC must:

- (a) only give approval under the Act for the collection, use or disclosure of health information for the purpose of research or compilation or analysis of statistics, in the public interest, in accordance with these guidelines;
- (b) be constituted in accordance with the *National Statement on Ethical Conduct in Research Involving Humans* (2: Human Research Ethics Committees);⁶ and
- (c) comply with sections 4.5 – 4.9 of these guidelines.

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

2. Procedures to be followed in the collection of health information pursuant to Health Privacy Principle 1.1(e)(iii)

Collection

2.1 This section of the guidelines applies to the collection of health information under HPP 1.1(e)(iii), for the purpose of research or compilation or analysis of statistics, in the public interest. A research proposal must be submitted to a HREC for approval. The research proposal must follow the procedures set out in this section and will be considered by a HREC only if the proposal also satisfies the requirements in section 1 of these guidelines.

Respect for dignity and personal privacy

2.2 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 a HREC

2.3 An organisation or individual who proposes to collect information for the purposes of research or the compilation or analysis of statistics, in the public interest, pursuant to HPP 1.1(e), must give a written proposal for the research or the statistical analysis or compilation to a HREC:

- (a) under this section; or
- (b) under sections 3.5 and 3.6 of these guidelines, where a joint proposal is to be made with the organisation proposing to disclose the information.

The information to be included in a written proposal under paragraph (a) is set out in section 2.4 of these guidelines.

⁶ (Canberra: Commonwealth of Australia, 1999). It can be downloaded from the NHMRC Website at www.nhmrc.gov.au/publications/synopses/e35syn.htm Copies can be purchased from AusInfo Government Information Bookshops (telephone 132 447 for locations and prices). If you do not have Internet access or are unable to purchase a copy, a copy will be made available on request from the Office of the Health Services Commissioner (telephone 03 8601 5222).

What must be in the proposal submitted to a HREC

- 2.4 A proposal which is required by section 2.3 of these guidelines to be submitted to a HREC for approval must:
- 2.4.1 contain a reference to HPP 1.1(e);
 - 2.4.2 state reasons for believing the criteria set out in section 1.2-1.4 of these guidelines have been met;
 - 2.4.3 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;
 - 2.4.4 provide the HREC with necessary information to enable the HREC to weigh the public interest considerations in accordance with section 4.4 of these guidelines;
 - 2.4.5 state:
 - (a) the aims or purpose of the research or statistical compilation or analysis;
 - (b) the credentials and technical competence of the collector(s) of the data;
 - (c) the data needed;
 - (d) the study period;
 - (e) the target population;
 - (f) the reasons why de-identified information cannot achieve the relevant purpose of the research or the compilation or analysis of statistics activity;
 - (g) the reasons why it is impracticable to seek consent from the individual for the collection of the health information.⁷ Any genetic research should be conducted in accordance with the principles in '16. Human Genetic Research' of the *National Statement on Ethical Conduct in Research Involving Humans* (1999); these principles should be considered in the context of collection of health information and genetic testing;
 - (h) the estimated time of retention of the health information. Standards must be in accordance with HPP 4;
 - (i) the proposed method of publication (if any) of the results of the research or the compilation or analysis of statistics, and a statement that this will not be in a form that identifies particular individuals or from which an individual's identity can reasonably be ascertained;
 - (j) the identity of the custodian(s) of the health information to be collected;
 - (k) the security standards to be applied to the health information.

⁷ 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' of the *National Statement* for further information.

Standards must be in accordance with HPP 4 and either the Joint NHMRC/AVCC Statement and Guidelines on Research Practice (Appendix 3), or the Australian Standard *Personal privacy protection in health care information systems*.⁸ Health information should be retained in a form that complies with HPP 4 and is at least as secure as it was in the sources from which it was obtained (unless more stringent legislative or contractual provisions apply);

- (l) a list of personnel within the collecting organisation or organisations with access to the health information collected;
- (m) the level of protection that will be applied by the collector(s) to protect health information disclosed to the collector(s) by the disclosing organisation. These should include the:
 - (i) terms of any release agreement between the disclosing organisation and the collector(s) to govern the limits on use and disclosure of collected health information [see section 2.8 of these guidelines] and, for disclosure, such agreement must comply with HPP 2.2(g)(iv)(A); and
 - (ii) proposed methods of disposal of the health information on the completion of the research or statistical activity as required by HPP 4 or the *Public Records Act 1973* (Vic) for those agencies bound by that Act, and any other legislative requirements.

Providing written notification of a HREC's decision

2.5 The collector(s) of health information for the purpose of research or compilation or analysis of statistics, in the public interest, 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 guidelines.

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 3.4 of these guidelines).

A disclosing organisation may still decide to submit a written proposal to a HREC in accordance with section 3 of these guidelines even if that disclosing organisation receives written notification of HREC approval from the collector(s).

Using collected information to contact individuals⁹

2.6 If a collector uses health information about an individual, which has been obtained from an organisation in accordance with these guidelines, to contact that individual, the collector must inform the individual:

- (a) that health information has been provided by that organisation in accordance with these guidelines; and
- (b) how that information will be used;

⁸ AS 4400-1995 (Standards Australia, 1995).

⁹ The requirements of sections 2.6 - 2.9 of these guidelines apply to a collector under this section and to a collector making a joint proposal under section 3.6 of these guidelines.

- (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 ‘1. Principles for Ethical Conduct’; subheading ‘Consent’. *National Statement on Ethical Conduct in Research Involving Humans* (1999).]; and
- (d) of the standards that will apply to protect the privacy of that person; and
- (e) of existing complaint mechanisms to the organisation and to the Health Services Commissioner.

Matters warranting review of ethical approval

- 2.7 The collector of health information for the purposes of research or 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 ‘2. Human Research Ethics Committees’; subheading ‘Monitoring’, paragraph 2.37 *National Statement on Ethical Conduct in Research Involving Humans* (1999)].
- 2.8 Where health information is collected in accordance with these guidelines, the collector must take all reasonable steps to de-identify the information before disclosing it.

Secondary use or disclosure

- 2.9 Any use or disclosure of health information for a purpose other than the purpose for which it was collected under these guidelines must be in accordance with HPP 2.2.

Role of a HREC

- 2.10 Once a proposal is submitted to a HREC pursuant to section 2.3 of these 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 use or disclosure of health information pursuant to Health Privacy Principle 2.2(g)(iii)

Use or disclosure

- 3.1 This section of the guidelines applies to the use or disclosure of health information under HPP 2.2(g) for the purpose of research or compilation or analysis of statistics, in the public interest. A research proposal must be submitted to a HREC for approval. The research proposal must follow the procedures set out in this section and will be considered by a HREC only if the proposal also satisfies the requirements in section 1 of these guidelines.

Respect for dignity and personal privacy

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

Proposal to use health information

Written proposal to be submitted to HREC

- 3.3 An organisation that proposes to use health information for the purposes of research or the compilation or analysis of statistics, in the public interest, pursuant to HPP 2.2(g), must give a written proposal for the research or the statistical analysis or compilation to a HREC. The information to be included in such a written proposal is set out in section 3.7 of these guidelines.

Proposal to disclose health information

Where written notification of HREC decision is provided by collecting organisation

- 3.4 An organisation may disclose health information to a collecting organisation for the purposes of research or compilation or analysis of statistics, in the public interest without giving a written proposal to a HREC if the disclosing organisation receives written notification of HREC approval for the health information to be collected as set out in section 2.5 of these guidelines. However, the disclosing organisation may still choose to submit the proposal to a HREC.

Where written notification of HREC decision is not provided by collecting organisation

- 3.5 An organisation seeking or approached to disclose health information for the purposes of research or compilation or analysis of statistics, in the public interest, where notification from the collector is not given under section 2.5 of these guidelines, must give a joint written proposal in conjunction with the collector to a HREC for approval to disclose the health information.
- 3.6 Where a proposal is submitted jointly to a HREC by the organisation seeking to collect health information and the organisation seeking to disclose health information pursuant to section 3.5 of these guidelines, the collector as well as the discloser must state the matters listed in section 3.7 of these guidelines.

What must be in a proposal given to a HREC?

- 3.7 A proposal which is required by sections 3.3 or 3.5 of these guidelines to be given to a HREC for approval must:
- 3.7.1 contain a reference to HPP 2.2(g), and, if a joint proposal is being made pursuant to section 3.5 of these guidelines, a reference to HPP 1.1(e);
 - 3.7.2 state reasons for believing the criteria set out in sections 1.2 - 1.4 of these guidelines have been met;
 - 3.7.3 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;
 - 3.7.4 provide the HREC with necessary information to enable the HREC to weigh the public interest considerations in accordance with section 4.4 of these guidelines;

3.7.5 state:

- (a) the aims or purpose of the research or the compilation or analysis of statistics;
- (b) the credentials and technical competence of the collector(s) of the data;
- (c) the data needed;
- (d) the study period;
- (e) the target population;
- (f) the reasons 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 of the health information.¹⁰ Any genetic research should be conducted in accordance with the principles in '16. Human Genetic Research' of the *National Statement on Ethical Conduct in Research Involving Humans* (1999); these principles should be considered in the context of collection of health information and genetic testing;
- (h) the specific uses to which the health information used during the research or statistical analysis will be applied;
- (i) the proposed method of publication (if any) of the results of the research or the compilation or analysis of statistics, and a statement that this will not be in a form that identifies particular individuals or from which an individual's identity can reasonably be ascertained;
- (j) the estimated time of retention of the health information. Standards must be in accordance with HPP 4;
- (k) the identity of the custodian(s) of the health information to be collected;
- (l) the security standards to be applied to the health information. Standards must be in accordance with HPP 4 and either the Joint NHMRC/AVCC Statement and Guidelines on Research Practice (Appendix 3), or with the Australian Standard *Personal privacy protection in health care information systems*.¹¹ Health information should be retained in a form that complies with HPP 4 and is at least as secure as it was in the sources from which it was obtained (unless more stringent legislative or contractual provisions apply);
- (m) a list of personnel within the collecting organisation or organisations with access to the health information collected;

¹⁰ 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' of the *National Statement* for further information.

¹¹ AS 4400-1995 (Standards Australia, 1995).

- (n) the level of protection that will be applied by the collector(s) to protect health information disclosed to the collector(s) by the disclosing organisation. These should include the:
 - (i) terms of any release agreement between the disclosing organisation and the collector(s) to govern the limits on use and disclosure of collected health information [see section 2.8 of these guidelines] and, for disclosure, such agreement must comply with HPP 2.2(g)(iv)(A); and
 - (ii) proposed methods of disposal of the health information on the completion of the research or statistical activity as required by HPP 4 or the *Public Records Act 1973* (Vic) for those agencies bound by that Act, and any other legislative requirements.

Using information to contact individuals

3.8 If those seeking to use or disclose health information propose to use or disclose 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 Act 2001* (Vic) and these guidelines; and
- (b) how that information will be used; 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 '1. Principles for Ethical Conduct'; subheading 'Consent'. *National Statement on Ethical Conduct in Research Involving Humans* (1999).]; and
- (d) of the standards that will apply to protect the privacy of that person; and
- (e) of existing complaint mechanisms to the organisation and to the Health Services Commissioner.

Matters warranting review of ethical approval

3.9 Those who seek to use or disclose health information for the purposes of research or 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 on Ethical Conduct in Research Involving Humans* (1999).]

Role of a HREC

3.10 Once a proposal is submitted to a HREC pursuant to sections 3.3 or 3.5 of these guidelines, the HREC must then weigh the public interest considerations set out in section 4 of these 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 guidelines, a 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.

What a HREC must consider and ensure in making a decision

- 4.2 In making a decision under these guidelines, a 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 data; and
 - (b) consider whether it is impracticable for the organisation seeking to collect, use or disclose the information to seek the consent of the individual to whom the information relates; and
 - (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 a HREC must 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 to proceed by a 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, a 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 understanding or knowledge; or
 - (vi) enhanced knowledge within the fields of social science and the humanities;
 - (c) any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from the research, or the compilation or analysis of statistics being undertaken in the manner proposed;

- (d) whether the research or the compilation or analysis of statistics design can be satisfied without relying on HPP 1.1(e) or HPP 2.2(g) and the defects in the activity that might arise if the research or the compilation or analysis of statistics was not conducted in the manner proposed;
- (e) 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 dependent 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;
- (f) the cost of not undertaking the research or the compilation or analysis of statistics (to government, the public, the health care system, etc);
- (g) the public importance of the research or the compilation or analysis of statistics;
- (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 is minimal, based on the information provided in response to sections 2.4 and/or 3.7 of these guidelines;
- (i) the standards of conduct to be observed in the research or the compilation or analysis of statistics, including:
 - (i) the study design and the scientific or other credentials of those involved in conducting that study;
 - (ii) if the study 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 to be followed to ensure 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 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 were obtained, including the date when the data will be destroyed or returned. These procedures must be in accordance with HPP 4.

Recording, notification and monitoring of decisions made by a HREC

4.5 Details of the decision made by a HREC regarding proposals to conduct research or 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 details of the following:

- (a) the organisation(s) proposing to collect, use or disclose the health information, as applicable, is sought;
- (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) considerations involved in weighing the public interest in the proposed research or the compilation or analysis of statistics against the public interest in privacy, including why the purpose cannot be served by the collection, use or disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained, and why it is impracticable to seek the consent from the individual(s) involved.

4.6 When a HREC approves a proposal for research or 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 a HREC to monitor proposals approved in accordance with these guidelines for the purposes of research or compilation or analysis of statistics, in the public interest in accordance with paragraphs 2.33 - 2.38, 'Human Research Ethics Committees', *National Statement on Ethical Conduct in Research Involving Humans* (1999).

Reporting to the Health Services Commissioner

4.8 A HREC must provide a report on an annual basis to the Health Services Commissioner on those decisions it has made in each financial year where it has applied the Health Services Commissioner's guidelines. The report will consist of:

- (a) the information required to be recorded by paragraphs (a) – (f) of section 4.5 of these guidelines;
- (b) the information specified in Appendix 4; such information must be provided in the form and within the time specified in Appendix 4.

4.9 A HREC must provide information in relation to sections 4.5, 4.6 and 4.7 of these guidelines to the Health Services Commissioner on request, at any time.

4.10 In these guidelines and Appendix 4, 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 1:

Health Privacy Principles 1, 2 & 4

The following Health Privacy Principles are extracted from the *Health Records Act 2001* (Vic).

SCHEDULE 1
Section 19

THE HEALTH PRIVACY PRINCIPLES

1. *Principle 1--Collection*

When health information may be collected

- 1.1 An organisation must not collect health information about an individual unless the information is necessary for one or more of its functions or activities and at least one of the following applies--
- (a) the individual has consented;
 - (b) the collection is required, authorised or permitted, whether expressly or impliedly, by or under law (other than a prescribed law);
 - (c) the information is necessary to provide a health service to the individual and the individual is incapable of giving consent within the meaning of section 85(3) and--
 - (i) it is not reasonably practicable to obtain the consent of an authorised representative of the individual within the meaning of section 85; or
 - (ii) the individual does not have such an authorised representative;
 - (d) the information is disclosed to the organisation in accordance with HPP 2.2(a), (f), (i) or (l) or HPP 2.5;
 - (e) if the collection is necessary for research, or the compilation or analysis of statistics,, in the public interest--
 - (i) that purpose cannot be served by the collection of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained; and
 - (ii) it is impracticable for the organisation to seek the individual's consent to the collection; and
 - (iii) the information is collected in accordance with guidelines issued or approved by the Health Services Commissioner under section 22 for the purposes of this sub-paragraph;
 - (f) the collection is necessary to prevent or lessen--
 - (i) a serious and imminent threat to the life, health, safety or welfare of any individual; or
 - (ii) a serious threat to public health, public safety or public welfare--
and the information is collected in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph;

- (g) the collection is by or on behalf of a law enforcement agency and the organisation reasonably believes that the collection is necessary for a law enforcement function;
- (h) the collection is necessary for the establishment, exercise or defence of a legal or equitable claim;
- (i) the collection is in the prescribed circumstances.

How health information is to be collected

- 1.2 An organisation must collect health information only by lawful and fair means and not in an unreasonably intrusive way.
- 1.3 If it is reasonable and practicable to do so, an organisation must collect health information about an individual only from that individual.
- 1.4 At or before the time (or, if that is not practicable, as soon as practicable thereafter) an organisation collects health information about an individual from the individual, the organisation must take steps that are reasonable in the circumstances to ensure that the individual is generally aware of--
 - (a) the identity of the organisation and how to contact it; and
 - (b) the fact that he or she is able to gain access to the information; and
 - (c) the purposes for which the information is collected; and
 - (d) to whom (or the types of individuals or organisations to which) the organisation usually discloses information of that kind; and
 - (e) any law that requires the particular information to be collected; and
 - (f) the main consequences (if any) for the individual if all or part of the information is not provided.
- 1.5 If an organisation collects health information about an individual from someone else, it must take any steps that are reasonable in the circumstances to ensure that the individual is or has been made aware of the matters listed in HPP 1.4 except to the extent that making the individual aware of the matters would pose a serious threat to the life or health of any individual or would involve the disclosure of information given in confidence.
- 1.6 An organisation is not required to notify the individual of the identity of persons, or classes of persons, to whom health information may be disclosed in accordance with HPP 2.2(f).

Information given in confidence

- 1.7 If personal information is given in confidence to a health service provider about an individual by a person other than--
 - (a) the individual; or
 - (b) a health service provider in the course of, or otherwise in relation to, the provision of health services to the individual--
 with a request that the information not be communicated to the individual to whom it relates, the provider must--
 - (c) confirm with the person that the information is to remain confidential; and

- (d) if the information remains confidential--
 - (i) record the information only if it is relevant to the provision of health services to, or the care of, the individual; and
 - (ii) take reasonable steps to ensure that the information is accurate and not misleading; and
 - (e) take reasonable steps to record that the information is given in confidence and is to remain confidential.

2. Principle 2--Use and Disclosure

- 2.1 An organisation may use or disclose health information about an individual for the primary purpose for which the information was collected in accordance with HPP 1.1.
- 2.2 An organisation must not use or disclose health information about an individual for a purpose (the "**secondary purpose**") other than the primary purpose for which the information was collected unless at least one of the following paragraphs applies:
 - (a) both of the following apply--
 - (i) the secondary purpose is directly related to the primary purpose; and
 - (ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose; or
 - (b) the individual has consented to the use or disclosure; or
 - (c) the use or disclosure is required, authorised or permitted, whether expressly or impliedly, by or under law (other than a prescribed law); or
 - (d) all of the following apply--
 - (i) the organisation is a health service provider providing a health service to the individual; and
 - (ii) the use or disclosure for the secondary purpose is reasonably necessary for the provision of the health service; and
 - (iii) the individual is incapable of giving consent within the meaning of section 85(3) and--
 - (A) it is not reasonably practicable to obtain the consent of an authorised representative of the individual within the meaning of section 85; or
 - (B) the individual does not have such an authorised representative; or
 - (e) all of the following apply--
 - (i) the organisation is a health service provider providing a health service to the individual; and
 - (ii) the use is for the purpose of the provision of further health services to the individual by the organisation; and
 - (iii) the organisation reasonably believes that the use is necessary to ensure that the further health services are provided safely and effectively; and
 - (iv) the information is used in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph; or

- (f) the use or disclosure is for the purpose of—
 - (i) funding, management, planning, monitoring, improvement or evaluation of health services; or
 - (ii) training provided by a health service provider to employees or persons working with the organisation--
 and--
 - (iii) that purpose cannot be served by the use or 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 individual's consent to the use or disclosure; or
 - (iv) reasonable steps are taken to de-identify the information—
 and--
 - (v) 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; and
 - (vi) the information is used or disclosed in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this sub-paragraph; or
- (g) if the use or disclosure is necessary for research, or the compilation or analysis of statistics,, in the public interest--
 - (i) it is impracticable for the organisation to seek the individual's consent before the use or disclosure; and
 - (ii) that purpose cannot be served by the use or disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained; and
 - (iii) the use or disclosure is in accordance with guidelines issued or approved by the Health Services Commissioner under section 22 for the purposes of this sub-paragraph; and
 - (iv) in the case of disclosure—
 - (A) the organisation reasonably believes that the recipient of the health information will not disclose the health information; and
 - (B) the disclosure will not be published in a form that identifies particular individuals or from which an individual's identity can reasonably be ascertained; or
- (h) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent--
 - (i) a serious and imminent threat to an individual's life, health, safety or welfare; or
 - (ii) a serious threat to public health, public safety or public welfare--
 and the information is used or disclosed in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph; or

- (i) the organisation has reason to suspect that unlawful activity has been, is being or may be engaged in, and uses or discloses the health information as a necessary part of its investigation of the matter or in reporting its concerns to relevant persons or authorities and, if the organisation is a registered health service provider, the use or disclosure would not be a breach of confidence; or
- (j) the organisation reasonably believes that the use or disclosure is reasonably necessary for a law enforcement function by or on behalf of a law enforcement agency and, if the organisation is a registered health service provider, the use or disclosure would not be a breach of confidence; or
- (k) the use or disclosure is necessary for the establishment, exercise or defence of a legal or equitable claim; or
- (l) the use or disclosure is in the prescribed circumstances.

Note: Nothing in HPP 2 requires an organisation to disclose health information about an individual. An organisation is always entitled not to disclose health information in the absence of a legal obligation to disclose it.

2.3 If an organisation discloses health information under paragraph (i) or (j) of HPP 2.2, it must make a written note of the disclosure.

2.4 Despite HPP 2.2, a health service provider may disclose health information about an individual to an immediate family member of the individual if--

- (a) either--
 - (i) the disclosure is necessary to provide appropriate health services to or care of the individual; or
 - (ii) the disclosure is made for compassionate reasons; and
- (b) the disclosure is limited to the extent reasonable and necessary for the purposes mentioned in paragraph (a); and
- (c) the individual is incapable of giving consent to the disclosure within the meaning of section 85(3); and
- (d) the disclosure is not contrary to any wish--
 - (i) expressed by the individual before the individual became incapable of giving consent and not changed or withdrawn by the individual before then; and
 - (ii) of which the organisation is aware or could be made aware by taking reasonable steps; and
- (e) in the case of an immediate family member who is under the age of 18 years, considering the circumstances of the disclosure, the immediate family member has sufficient maturity to receive the information.

2.5 Despite HPP 2.2, an organisation may use or disclose health information about an individual where—

- (a) it is known or suspected that the individual is dead; or
- (b) it is known or suspected that the individual is missing; or
- (c) the individual has been involved in an accident or other misadventure and is incapable of consenting to the use or disclosure--

and the use or disclosure is to the extent reasonably necessary--

- (d) to identify the individual; or
 - (e) to ascertain the identity and location of an immediate family member or other relative of the individual for the purpose of--
 - (i) enabling a member of the police force, a coroner or other prescribed organisation to contact the immediate family member or other relative for compassionate reasons; or
 - (ii) to assist in the identification of the individual--
- and, in the circumstances referred to in paragraph (b) or (c)--
- (f) the use or disclosure is not contrary to any wish--
 - (i) expressed by the individual before he or she went missing or became incapable of consenting and not withdrawn by the individual; and
 - (ii) of which the organisation is aware or could have become aware by taking reasonable steps; and
 - (g) the information is used or disclosed in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph.

4. Principle 4--Data Security and Data Retention

- 4.1 An organisation must take reasonable steps to protect the health information it holds from misuse and loss and from unauthorised access, modification or disclosure.
- 4.2 A health service provider must not delete health information relating to an individual, even if it is later found or claimed to be inaccurate, unless--
 - (a) the deletion is permitted, authorised or required by the regulations or any other law; or
 - (b) the deletion is not contrary to the regulations or any other law and occurs--
 - (i) in the case of health information collected while the individual was a child, after the individual attains the age of 25 years; or
 - (ii) in any case, more than 7 years after the last occasion on which a health service was provided to the individual by the provider--

whichever is the later.
- 4.3 A health service provider who deletes health information in accordance with HPP 4.2 must make a written note of the name of the individual to whom the health information related, the period covered by it and the date on which it was deleted.
- 4.4 A health service provider who transfers health information to another individual or organisation and does not continue to hold a record of that information must make a written note of the name and address of the individual or organisation to whom it was transferred.
- 4.5 An organisation other than a health service provider must take reasonable steps to destroy or permanently de-identify health information if it is no longer needed for the purpose for which it was collected or any other purpose authorised by this Act, the regulations made under this Act or any other law.

Appendix 2: Glossary

NOTE: Reference in this glossary to “this Act” refers to the *Health Records Act 2001* (Vic).

“de-identified information” means, for the purposes of these guidelines, information that does not identify the individual or from which the individual’s identity cannot reasonably be ascertained.

“health information”¹ means

- (a) information or an opinion about--
 - (i) the physical, mental or psychological health (at any time) of an individual; or
 - (ii) a disability (at any time) of an individual; or
 - (iii) an individual's expressed wishes about the future provision of health services to him or her; or
 - (iv) a health service provided, or to be provided, to an individual-- that is also personal information; or
- (b) other personal information collected to provide, or in providing, a health service; or
- (c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or
- (d) other personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or of any of his or her descendants—

but does not include health information, or a class of health information or health information contained in a class of documents, that is prescribed as exempt health information for the purposes of this Act generally or for the purposes of specified provisions of this Act;

“organisation”² means a person or body that is an organisation to which this Act applies by force of Division 1 or 2 of Part 2. Further information on who is subject to this Act is available at: www.dhs.vic.gov.au/ahs/healthrecords/overview.htm

“research”

As discussed in the *National Statement on Ethical Conduct in Research Involving Humans*,³ “research” involves systematic investigation to establish facts, principles and knowledge. For further discussion, see pages 6-7 of the *National Statement*.

¹ See section 3, *Health Records Act 2001* (Vic).

² See section 3, *Health Records Act 2001* (Vic).

³ Issued by the National Health and Medical Research Council (NHMRC) in 1999. The *National Statement* applies to all disciplines of research involving or impacting on humans. It can be downloaded from the NHMRC Website at www.nhmrc.gov.au/publications/synopses/e35syn.htm

Appendix 3: 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.¹
- 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.²
- 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.

¹ *Personal Privacy Protection in Health Care Information Systems*, Australian Standard AS 4400-1995.

² 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 4:

Human Research Ethics Committee Report on the use of the Health Services Commissioner's guidelines issued for the purposes of Health Privacy Principle 1.1(e)(iii) & 2.2(g)(iii) of the *Health Records Act 2001 (Vic)*

Health Services Commissioner

Human Research Ethics Committee Report
on the use of the
Health Services Commissioner's guidelines
issued for the purposes of
Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii),
Health Records Act 2001 (Vic)

1 July ____ to 30 June ____
(insert relevant years)

Please complete and return form to:
Health Services Commissioner
Level 30, 570 Bourke Street
Melbourne Vic 3000
or to: hra@dhs.vic.gov.au
by
1 August
for the year ending 30 June

The *Health Records Act 2001* (Vic) (the Act) creates a scheme to regulate the collection and handling of health information in Victoria. The Health Services Commissioner is responsible for the implementation of the Act.

The Act:

- gives individuals a legally enforceable right of access to health information about them that is contained in records held in Victoria by the private sector; and
- establishes Health Privacy Principles (HPPs) that will apply to health information collected and handled in Victoria by the Victorian public sector and the private sector.

The Act takes effect on 1 July 2002.

The Commissioner is empowered by section 22 of the Act to “issue, approve or vary guidelines for the purposes of the Health Privacy Principles”. In February 2002, the Commissioner issued guidelines for the purposes of HPP 1.1(e)(iii) and HPP 2.2(g)(iii).

These guidelines concern the collection, use and disclosure of health information for the purposes of research or the compilation or analysis of statistics, in the public interest, where consent to the use of the information is not obtained, and where the information could identify the individuals concerned.

The guidelines are available at: www.health.vic.gov.au/hsc or from the Office of the Health Services Commissioner.

This form should be submitted to the Health Services Commissioner by 1 August of each financial year in conjunction with the information required by section 4.8(a) of the guidelines. Should you have any queries, please contact the Office of the Health Services Commissioner on (03) 8601 5222.

HREC Report to Health Services Commissioner

1 July _____ to 30 June _____ (insert relevant years)

Name of your Institution or Organisation

1	
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Name of your Human Research Ethics Committee (HREC)

2	
---	--

If the name of your HREC has changed since last year, what was the old name?
(write n/a if name is unchanged)

3	
---	--

Contact person

4	
---	--

Position of contact person

5	
---	--

Contact details for HREC

Postal address (street number and name, suburb, city and postcode)

6	
---	--

Telephone number

7	
---	--

Fax number

8	
---	--

E-mail address

9	
---	--

Chairperson's name in full (please print)

10	
----	--

Chairperson's telephone number

11	
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Chairperson's signature

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**Statutory Guidelines issued for the purposes of
Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii)
*Health Records Act 2001 (Vic)***

12	During the financial year to which this report applies, how many proposals for research or statistical compilation or analysis that involved the collection, use or disclosure of health information in the circumstances set out in Health Privacy Principles 1.1(e) or 2.2(g) and which involved application of the Health Service Commissioner's statutory guidelines did your Committee consider?	
13	How many of these proposals were approved?	
14	How many of these proposals were <u>not</u> approved?	
15	How many of these proposals are awaiting a decision by your Committee?	

For each proposal about which a decision has been made by your Committee, attach to this form a copy of the relevant record required to be made by paragraphs (a) – (f) of section 4.5 of the Health Services Guidelines issued for the purposes of Health Privacy Principles 1.1(e)(iii) and 2.2(g)(iii) of the *Health Records Act 2001 (Vic)*.