Health Records Act 2001 (Vic)

Proposed
Statutory Guidelines

ISSUES PAPER

Office of the Health Services Commissioner (Victoria)

October 2001

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Information

If you have any questions in relation to this issues paper and the process for making statutory guidelines process, please contact Ms Anne Mullins on 8601 5236 or Ms Sue Joseph on 8601 5235.

Further information about the *Health Records Act* 2001 is available at:

www.health.vic.gov.au/hsc and www.dhs.vic.gov.au/ahs/healthrecords

The latter site includes a link to the Second Reading speech made in the Victorian Parliament, which provides an overview of the Act.

The Act itself is available at: www.dms.dpc.vic.gov.au/sb/2001_Act/A00824.html

Copies of the Act can be purchased from:

Information Victoria
356 Collins Street
MELBOURNE VIC 3000
Tel: 1300 366 356

Anstat Customer Services
PO Box 447
SOUTH MELBOURNE VIC 3205
Tel: (03) 8278 1144
* mail order only

Copies of the issues paper

Further copies of this issues paper can be obtained by contacting the Office of the Health Services Commissioner on (03) 8601 5222.

The issues paper is also accessible via Office's Website at www.health.vic.gov.au/hsc

Submissions

If you wish to provides comments on the questions and issues raised in this issues paper, please forward them as follows:

By e-mail to: hra@dhs.vic.gov.au

By mail to: Health Records Act Implementation Group
Office of the Health Services Commissioner
Level 30, 570 Bourke Street
MELBOURNE VIC 3000

Submissions should be received by **Friday 2 November 2001** to ensure that they inform the development of the guidelines. Comments provided at any later date may, however, still be considered.

If you wish your comments to be treated in confidence, please note this on your submission.

1. *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 which is contained in records held in the private sector; and
- establishes Health Privacy Principles (HPPs) that will apply to personal health information collected and handled in both the public and private sectors.

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 commence operation on 1 March 2002. From that day, 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.

2. Guidelines

2.1 Power to issue guidelines

The Health Services Commissioner is empowered by the Act to "issue, approve or vary guidelines for the purposes of the Health Privacy Principles". Only some of the HPPs anticipate that guidelines may be made.

Section 22 provides that guidelines may be "issued, approved or varied" for the following HPPs:

- HPP 1 in relation to paragraphs 1.1(e)(iii) and (f);
- HPP 2 in relation to paragraphs 2.2(e), (f)(vi), (g)(iii), (h) and 2.5 (g);
- HPP 6 in relation to paragraphs 6.1(a) and (b); and
- HPP 10.2.

Most of the guidelines contemplated by the Act are discretionary - the HPPs refer to "guidelines, if any, issued or approved". Those referred to in HPPs 1.1(g)(iii), 2.2(g)(iii) and 10.2 are different, as these guidelines are required to be made for those HPPs to operate (see Appendix 1 for the text of these HPPs). It is these guidelines which the Commissioner intends to issue prior to the commencement of the Act. The scope of these guidelines is outlined in Table 1. It is to these mandatory guidelines that this issues paper relates.

Table 1

ACTION	PURPOSE	HPP	Scope of guidelines
Collection	Necessary for research/compilation or analysis of statistics in the public interest where the purpose cannot be served by collection that does not identify the individual & it is impracticable to seek consent	1.1 (e)(iii)	Collection is in accordance with guidelines issued/approved by the Health Services Commissioner (HSC)
Use/disclosure	Necessary for research/compilation or analysis of statistics in the public interest where the purpose cannot be served by use/disclosure that does not identify the individual & impracticable to seek consent & reasonable belief that: ▪ recipient of information will not disclose the information and ▪ disclosure will not be published in an identifying form	2.2 (g)(iii)	Use/disclosure is in accordance with guidelines issued/approved by the HSC
Notification to past service recipients about transfer/closure of practice and how the health information of recipients of services will be dealt with	Transfer/closure of health service provider's practice	10.2	Provider to take any other steps [in addition to publishing notice in newspaper] to notify recipients of health services in accordance with guidelines issued or approved by the HSC

2.2 Purpose of the guidelines

The purpose of the statutory guidelines to be issued by the Health Services Commissioner under the Act is to elaborate on the requirements of the particular HPPs. The Commissioner is empowered to issue and also to approve and vary guidelines. This suggests that such guidelines must be grounded in both accepted and best practice, and remain relevant to the needs of those who must comply with the Act.

The extent to which the Commissioner will exercise her powers to issue or approve further guidelines, or vary existing guidelines, after the Act commences will depend on how useful the HPPs and existing guidelines prove to be to those collecting or using health information. The Commissioner will continue consultations with stakeholders on the need for further guidelines after the Act commences, and monitoring the need to vary existing guidelines will be an ongoing responsibility for the Commissioner's office.

2.3 Nature of the guidelines

The guidelines contemplated by the Act are *statutory* guidelines. This means that when issued or approved, the guidelines will form part of the HPPs and therefore the Act, and will be enforceable by the Commissioner.

This is in contrast to *advisory* guidelines, such as those issued by the Federal Privacy Commissioner for the private health sector in relation to the National Privacy Principles established under the *Privacy Amendment (Private Sector) Act* 2000 (Commonwealth). These are not legally binding, but aim to assist the private health sector in understanding the application of the National Privacy Principles to personal health information.

While the Health Services Commissioner does not propose to issue advisory guidelines of this type at this stage, a program of consultation, education and training for providers, consumers and other organisations has been developed as part of her educative functions under the Act.

2.4 Scope of the guidelines

Section 22 allows the guidelines to apply, adopt or incorporate any matter contained in any documents, whether wholly or partially or as amended by the guidelines.

Section 22 also allows the guidelines to be of general or limited nature and for them to differ according to differences in time, place or circumstances.

3. Purpose of the paper

Section 22 of the *Health Records Act* 2001 (Vic) (the Act) sets out a publication and comment process that must be completed prior to the making of statutory guidelines by the Health Services Commissioner under the Act:

Step 1 The Health Services Commissioner publishes a notice of intention to issue, approve or vary guidelines in the *Government Gazette* and in the newspaper.

The notice states where a copy of the guidelines in question can be obtained and calls for written submissions, with the deadline for comments being not less than 28 days from the date of publication.

Step 2 Submissions are received and considered.

Step 3 The Commissioner may then issue, approve or vary the guidelines, with whatever amendments are considered appropriate.

In addition to these statutory requirements for public consultation, the Commissioner intends to consult with stakeholders prior to Step 1, as is reflected in the publication and circulation of this issues paper. The information and comments received will assist in the formulation of the guidelines for release for public comment under Step 1.

After Step 3, the Commissioner will publish a notice advising stakeholders and the public that guidelines have been issued, approved or varied, and will ensure adequate circulation and publication of the guidelines by mail, via the Commissioner's Website and through Information Victoria.

4. Guidelines proposed to be issued

The guidelines which the Commissioner proposes to issue at this stage concern research activities which use health information, and actions which must be taken to notify service users when a health service provider's practice is sold, transferred or closed down. The Act envisages these guidelines will be in operation upon commencement of the Act on 1 March 2002.

4.1 Research: Collection, use and disclosure of health information

- **HPP 1.1(e)(iii) & HPP 2.2(g)(iii)**

Who will be subject to the research provisions and guidelines?

There are very few exemptions in the Act. Consequently it applies to virtually all private sector organisations and Victorian public sector organisations when they collect or handle identifying health information in Victoria.

The Act and guidelines will therefore apply whenever such an organisation collects, use or discloses health information for the purposes of research.

The Act permits health information about an individual to be collected, used or disclosed:

- with the consent of the individual concerned; or
- as authorised or required by another law (such the *Cancer Act* 1958); or
- in accordance with the requirements of HPP 1.1(e) or HPP 2.2(g), including the statutory guidelines.

The research will only be subject to the Act if the identity of the individual concerned is apparent, or can be reasonably ascertained from the information that is to be collected, used or disclosed.

The Act applies to "organisations". This term includes:

- bodies (such as companies, incorporated associations, unincorporated associations, Councils, Victoria Police, Government agencies and departments, public hospitals and other public bodies including courts and tribunals); and
- individuals who handle health information, such as sole practitioners, partnerships, Members of Parliament, and trustees.

- Health, disability and aged care sector organisations

The research provisions will apply whenever an organisation which provides an individual with a health, disability or aged care service collects, uses or discloses personal information for the purpose of research, if that information is "health information". All identifying personal information originally collected by the organisation *in the course of providing that service* is "health information".[1]

This will include the following health service providers:

- health professionals, including medical practitioners (general practitioners and specialists), dentists, allied health service providers (such as physiotherapists, optometrists and podiatrists), private mental health providers, pharmacists, private nursing services, and complementary health service providers (such as naturopaths and herbalists);
- private and public hospitals;
- community health centres;
- day procedure centres;
- pathology services;
- supported residential services;
- aged care providers (including nursing homes and hostels, and other service providers);
- palliative care providers;
- disability service providers; and

[1] In addition, any other "health information" held by a health sector organisation, such as that listed on p.8 in relation to "other organisations", is also subject to the Act; for example, medical details about employees.

- other organisations (such as schools, the Department of Human Services and other Government agencies or public bodies), to the extent that they provide a health, disability or aged care service.

- Other organisations

The research provisions in the Act will also apply to any other organisation, regardless of whether it is providing a health, disability or aged care service. This will be the case where it is handling the following kinds of "health information":

- information or opinion about the physical or mental health, or disability, of an individual;
- an individual's expressed preferences about the future provision of health, disability or aged care services to him or her;
- the nature of health, disability or aged care services provided to an individual;
- personal information collected in connection with the donation of human tissue;
- genetic information that is or could be predictive of the health of an individual or their descendants.

Any organisation wishing to collect, use or disclose this kind of identifying health information for the purposes of research will be subject to the guidelines. This means any of the following organisations could be affected, if they participate in research projects:

- Victorian Government Departments and public bodies established under Victorian law;
- blood and tissue banks;
- employers (in relation to their employees' personnel records);
- kindergartens and crèches;
- counsellors;
- insurers and superannuation organisations;
- gymnasiums;
- any other organisations that hold health information or health reports concerning their clients or customers.

This paper seeks information to enable a draft of the research guidelines to be prepared for public comment. The guidelines would apply whenever an organisation collects, uses or discloses health information without consent of the individual concerned, and where a more specific law does not authorise the activity.

HPP 1.1(e) and HPP 2.2(g) only permit the collection, use and disclosure of heath information for research purposes in very particular circumstances.

HPP 1 requires that personal health information must not be collected 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. The Act recognises that, in some circumstances, obtaining consent may not be possible or 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 must be:

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

HPP 2.2(g) is its parallel in terms of use (meaning internal use within an organisation) and disclosure (meaning disclosure to others outside the organisation) of health information for research purposes. Where use or disclosure is to be for a purpose other than the primary purpose for which it was collected, then such secondary use or disclosure must be (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 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.

Relationship between the two sets of requirements

Where research is being conducted by the organisation that originally collected the information, the research will involve the use of health information by that organisation. It will therefore be covered exclusively by HPP 1.1(e), including the statutory guidelines.

In contrast, whenever the information is being obtained by an organisation that did not originally collect the information, it will be 'collecting' the information. The collector will be subject to HPP 1.1(e) and the disclosing organisation will be subject to HPP 2.2(g), including the statutory guidelines.

It is proposed that the one set of guidelines would deal comprehensively with the collection, use and disclosure of information without consent for the purposes of research, and set consistent standards. This will ensure that both the giver and the recipient of the information will generally need to comply with the same tests under the guidelines.

Relationship between the guidelines and other standards

In developing the draft guidelines for public comment, the Commissioner will have regard to the requirements of the Act, principally section 22.

The Commissioner is also mindful that many organisations subject to the Act and guidelines will also be obliged to operate under other State and Commonwealth laws, and to comply with standards set by funding bodies. To the extent authorised by the Act, regard will therefore be had to these other standards, where appropriate. This would ensure that the collection, use and disclosure of health information in Victoria can proceed as permitted by the Act, in a manner that protects privacy while not creating unnecessary duplication of effort by organisations or researchers.

What do the HPPs already require organisations to do?

HPP 1.1(e) already sets three criteria to be met in addition to the Commissioner's guideline. HPP 2.2(g) sets five criteria to be met in addition to the Commissioner's guideline. To satisfy these criteria, what must be in contemplation is 'research', which is 'in the public interest' and where obtaining consent to collection, use of disclosure of the information is 'impracticable'.

- What is "research"?

As defined by the *National Statement on Ethical Conduct in Research Involving Humans*[2], 'research' involves systematic investigation to establish facts, principles and knowledge. It is important to distinguish it from quality assurance (QA) activities. QA can be characterised as a monitoring activity performed to assess the effectiveness and appropriateness of a service, and to determine whether the outcome was satisfactory. These activities are a necessary component of providing health, disability or aged care services. Any organisation that provides these services should be monitoring the quality of those services, and taking appropriate steps to ensure the services it provides are safe, effective and meet the needs of consumers.

The distinction is important, because certain privileges are given by law to QA activities. For example, section 139 of the *Health Services Act* 1988 (Vic) grants immunity from use in court proceedings to the information prepared for QA bodies approved by the Victorian Minister for Health.

The *Health Records Act* 2001 separately regulates the way in which health information may be collected, used or disclosed for the purposes of funding, management, planning, monitoring, improvement or evaluation of health, disability or aged care services. It will therefore not be necessary for these activities to be carried out under the research provisions (and guidelines) under the Act. Separate information will be made available for organisations about these standards.

- Research in the "public interest"

For a research activity to be in the "public interest", it must be for the good of the community as a whole, even if it may directly benefit only a particular group. While such an activity may also have commercial potential, it is unlikely to be in the public interest if its sole purpose was commercial.

[2] Issued by the National Health and Medical Research Council (NHMRC) in 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

- "Impracticability" of obtaining consent

For something to be 'impracticable' means to be impracticable in any particular set of circumstances. In relation to obtaining consent to the use of health information, for example, it may refer to physical impracticability in gaining consent, ie the age or the volume of the records may be such that while it may be possible to track down all the individuals involved and seek their consent, it may not be practicable. This would need to amount to more than mere inconvenience or involving some expense. The level of inconvenience and the amount of the expense would, however, be part of the circumstances in which the impracticability would need to be judged.

It may also refer to the impracticability of obtaining consent in terms of the nature of the research proposed. It is arguable that the HPP may permit research where the information is essential to the integrity of the research and to it achieving its aims, and a complete rather than a random or controlled sample must therefore be used. Seeking consent from the subjects would contemplate that some may not give that consent, and this may compromise the integrity of the research.

Current safeguards

- Medical research

Institutional and government-funded research is already a well-regulated field. What is understood as medical research would be a significant user of health information for research purposes, and there are a number of guidelines governing its conduct. These include:

- *Guidelines for Good Clinical Research Practice in Australia* (Therapeutic Goods Administration, Commonwealth Department of Health and Family Services, 1991);
- *Joint NHMRC/Australian Vice-Chancellors Committee Statement and Guidelines on Research Practice* (1997);
- *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 1999).

In addition, section 95 of the *Privacy Act* 1988 (Commonwealth) empowers the NHMRC, with the approval of the Federal Privacy Commissioner, to issue guidelines for the Commonwealth public sector for the protection of privacy in the conduct of medical research.[3]

Under the recent amendments extending the *Privacy Act* 1988 to the private sector, the Federal Privacy Commissioner may approve further guidelines issued by the NHMRC (under section 95A) that will apply to research involving health information collected, used or disclosed by private sector organisations.

[3] The Guidelines can be downloaded from the Federal Privacy Commissioner's Website: www.privacy.gov.au/act/index.html - 2.9.1.

- Ethics committees

Ethics committees play a key role in approving and managing medical and other research. The *National Statement on Ethical Conduct in Research Involving Humans* requires "all institutions or organisations that receive NHMRC funding for research to establish a Human Research Ethics Committee (HREC) and to subject all research involving humans, whether relating to health or not, and whether funded by the NHMRC or not, to ethical review by that committee" (p.3).

The task of HRECs is to review proposals for research involving humans and to ensure such research is soundly designed and conducted according to high ethical standards. The Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC, provides support for the work of HRECs, including developing guidelines for the conduct of medical research involving humans.

Public and private hospitals, multi-purpose services, day procedure centres and community health centres are subject to strict confidentiality laws (section 141 of the *Health Services Act* 1988 (Vic)). However, that Act allows the giving of information concerning a person's medical treatment for the purposes of medical or social research if, among other criteria, the use to which the information is to be put and the research methodology have been approved by an ethics committee established under the by-laws of the agency. That Act has been amended by the *Health Records Act* 2001 to require, in addition to such approval, that it also satisfy the requirements of HPP 2.2(g)(iii), ie one of the paragraphs under discussion. (This amendment will come into effect on 1 March 2002).

A similar amendment to section 120A of the *Mental Health Act* 1986 (Vic) will come into force at the same time as the *Health Records Act* 2001. The guidelines will therefore apply whenever identifying information about persons who receive mental health services is to be disclosed for the purposes of research by approved mental health services and other mental health providers subject to section 120A.

The *Heath Records Act* 2001 and guidelines will also apply to government agencies when collecting, using and disclosing identifying health information for the purposes of research. This will build on the current administrative practice of submitting research proposals to the Department of Human Service's Ethics Committee, where identifying information held by the Department is to be used in research.

Paragraph 2.4 of the NHMRC's *Guidelines under Section 95 of the Privacy Act 1988* sets out what a research proposal must provide to a HREC (see Appendix 2). In summary, it requires statements concerning:

- the aims of the research;
- the credentials and technical competence of the researcher;
- the data needed and how it will be analysed;
- the source of the data;
- the study period;
- the target population;

- the reasons why identified information is needed rather than de-identified information and why it is not proposed to seek consent to the use of the information;
- the specific uses to which personal information used in the study will be applied;
- the proposed method of publication of the results of the research;
- the estimated time the information will be retained;
- the identity of the custodians of the personal information used during the research;
- security standards to be applied to the personal information;
- a list of personnel with access to the personal information;
- the standards to be applied to protect personal information disclosed including details of any disclosure agreements between the disclosing agency and the researcher and the proposed methods of disposal of the information on completion of the research and the standards that will be applied to protect privacy of personal information where it is made available to other researchers or third parities if that is proposed.

HRECs are then required to assess whether they have enough information, expertise and understanding of privacy issues to make a decision that takes proper account of privacy. They must assess whether it is necessary to use identified data and whether it is reasonable to proceed without the consent of the people to whom the information relates. They must ensure that the Committee has the competence to determine if the public interest in the proposed research outweighs or does not outweigh, to a substantial degree, the public interest in the protection of privacy. If it does not outweigh that interest, then the research should not be carried out. The guidelines then require the HREC to consider a series of matters in undertaking that weighing exercise (see Appendix 2).

- Other research activities and settings

Not all research activities or requests for access to information for research purposes will occur in large, research-oriented institutions with an established system for considering ethical issues relating to research. Schools, for example, can be a popular choice for researchers on a wide range of issues. The Department of Employment and Education requires external researchers seeking access to student populations or information to seek permission to conduct their research, and to ensure that there is always active, informed consent and that confidentiality is maintained.

Some health service providers may wish to conduct research using their own patient or client information and/or those of colleagues. Professional associations or educational colleges provide some level of peer review on research proposals. The Royal Australian College of General Practitioners National Research and Evaluation Ethics Committee, for example, conducts ethical reviews of research proposals. Its primary task is to assess the ethical propriety of research submissions and, where appropriate, to take account of scientific, methodological, legal and human rights aspects of the proposal. In doing so, the Committee follows the guideline set down for institutional ethics committees by the NHMRC. The Committee is also constituted according to NHMRC requirements.

The Australian Psychological Society's Code of Ethics (Section E) requires members to comply with guidelines and requirements for ethical accountability in research within their settings, such as the NHMRC Guidelines, and sets out eighteen requirements to be met. These cover a range of issues including consent and confidentiality. In particular, the Code states that "[b]efore deciding that research does not require written informed consent of research participants, members must consult with colleagues or gatekeepers and ethics committees as appropriate" (paragraph 8).

In most instances, it will be unlikely that many research requests or proposals would require identifying information to be used or be unable to obtain consent from the individuals concerned. Although the number of such research proposals might be small, it is critical they are dealt with in the way that best balances competing interests and ensures the appropriate protection of personal health privacy.

The following questions are asked as part of the consultation process to enable the Commissioner to ascertain the likely scope of the research guidelines and the variety of situations in which they might apply.

Q1 **What research activities does your organisation undertake that involves the collection, use or disclosure of identifying health information (including health, disability or aged care information)?**

Q2 **If your organisation does not undertake research itself, does it disclose the information for the purpose of research (by allowing outside researchers access to the health information held by it)?**

Q3 **What processes are in place for approval of research or research requests?**

Q4 **What processes do you currently adopt to determine whether to collect, use or disclose health information for the purposes of research?**

Q5 **What aspects, if any, of the practices outlined in this paper would be appropriate for your organisation?**

Q6 **For those organisations which do not currently have access to an ethics committee process for review of research proposals, would access to such a committee be appropriate? If not, what other mechanisms might be appropriate?**

Q7 **Would the criteria listed on pp.12-13 and in Appendix 2 provide a sufficient basis for guidelines for the purposes of HPP 1.1(e)(iii) and 2.2(g)(iii)? (Note that the criteria would also need to reflect the current statutory requirements of these two HPPs, as outlined at p.9.)**

Q8 **What changes would be needed to adapt them for use:**

- **in non-institutional settings?**
- **by organisations that do not provide health, disability or aged care services?**

Q9 **From a consumer perspective, what mechanisms would be appropriate to ensure that the privacy of health information is safeguarded when research of the type discussed above is being contemplated?**

Q10 **Are there particular categories of information or consumers which would warrant additional or different standards being set?**

4.2 Notification to past service users about transfer/closure of a health service provider's practice

- **HPP 10.2**

Context

HPP 10 regulates what a health service provider must do with its records when the practice or business is:

- sold, transferred or amalgamated (and the provider will not be providing health services at the new practice or business); or
- closed down (including as a result of the death of the health service provider).

This should be contrasted to situations where a health service provider practice or business is subsumed into a larger one, and the health service provider will continue to provide health services at the larger concern.

The purpose of HPP 10 is to encourage individuals to apply for their health information while it is still readily available, before it has been transferred following closure or sale of a practice, or before an estate has been wound up in the event of the death of a practitioner. This enables individuals to provide their current treating practitioner with their existing health information. This is critical in terms of maintaining quality and continuity of care.

Existing notice requirements and subsequent responsibilities

HPP 10 requires a notice to be published in a newspaper, available in the relevant locality, which advises current and former patients or clients that the practice is transferring or closing, so those patient or clients can apply for their information before the practice closes or changes hands. The health service provider can indicate whether or not they propose to retain the health information or transfer it to the health service provider who has taken over the practice or business (in the case of it being sold) or to the patient or client, or to a new practitioner nominated by them.

In the case of the sale of a business or practice, the transfer of health information in an original record to the buyer of the business in accordance with HPP 10 would not contravene other HPPs. This makes it clear individual consent is not needed for such a transfer.

If the provider decides to retain the information, and an individual requests the information be given to him or her, the provider may keep the information but must treat the request as an application for access under the Act. If the individual has asked

that the information be made available to another health service provider, then the information (not the actual records themselves) must be made available to the new health service provider in accordance with HPP 11 (see Appendix 1).

Public bodies, such as public hospitals, should note this HPP operates subject to the *Public Records Act* 1973. On closure of a practice conducted by a public body, original records required to be retained under the Public Records Act cannot be provided to the individual.

HPP 10 also applies when a health service provider dies and their practice closes. The duties regarding notification and providing access apply to a legal representative of the deceased health service provider, such as an executor.

Who will be subject to the guidelines?

HPP 10 applies only to "health service providers". These are organisations and persons that provide a "health service" as defined by the Act. The definition includes activities performed that are intended or claimed to assess, maintain or improve an individual's health. It includes diagnosis or treatment of illness, injury or disability, as well as the provision of disability, aged care or palliative care services and the dispensing of prescriptions. "Health service providers" include those organisations included in, or similar to, those listed as part of the 'health, disability or aged care sector' on pp.7-8.

However, other organisations may also be covered in relation to some of their activities. The definition of "health service provider" does not require an organisation to provide such a service exclusively; an organisation is regarded by the Act to be a health service provider "to the extent that it provides such a service" (section 3). This may include the bodies listed on p.8 to the extent they provide any health, disability or aged care services.

A school, for example, may provide health services to its students, in the form of counselling or medical services, and so would be considered a health service provider to the extent of the provision of those services. This means when there is a turnover of staff providing such services, counsellors or nurses, for example, the 'practice' or 'business' would not be regarded as itself closing down. This can be contrasted with schools which may refer students to external counsellors or psychologists in private practice, where it is clear a different 'practice' is being attended. A closing down or sale of such a practice would require such a provider to satisfy HPP 10.

Scope of guidelines

Health service providers are already required under the Act to put a notice in a newspaper advising of the change or closure of the practice, and advising patients or clients what they propose to do with the information they currently hold (HPP 10.2(a)).

HPP 10.2(b) then requires health service providers to:

> "take any other steps to notify individuals who have received a health service from the provider in accordance with the guidelines issued or approved by the Health Services Commissioner."

This paper seeks information to enable a draft of such notification guidelines to be prepared for public comment. The guidelines would apply whenever the practice of a health service provider is sold, transferred or amalgamated (and the provider would not be providing health services at the new practice or business), or closed down (including as a result of the death of the health service provider).

Current practice

For many health, disability and aged care service providers, it makes good clinical, professional and business sense to ensure patients and clients are made aware promptly of changes which will affect their health service provision in the future and their access to past health, disability or aged care information.

This is reflected in current advice given to health service providers by their professional or educational associations. In its *RACGP Health Record Operating Manual* (1996), for example, the Royal Australian College of General Practitioners (RACGP) advises its members that '[t]he patient's right to continuity of health care recording must be preserved. People should be given a positive choice on future medical care" (p.59). In the case of a patient transferring to another dentist, the Dental Board of Victoria expects sufficient information to be given to the new dentist to enable proper and adequate treatment to be provided (*Standards for Dental Records*, 1998).

In relation to the sale or closure of a practice, the RACGP advises its members to put a notice in the Public Notices section of an "appropriate newspaper" and a suitable announcement be displayed in the reception area.

Issues

Putting a notice in a newspaper assumes first, that all people read, and secondly, that people read newspapers, and thirdly, that such newspaper reading includes reading the Public Notices section. Such assumptions cannot always be made with confidence. More individualised notification would seem preferable. Just how individual and extensive that notification might be could be plotted on a spectrum, from least personally directed to most. The level of burden on the health, disability or aged care service provider would also increase with an increased level of individualisation.

(1) Notice in daily paper [current statutory requirement]

PLUS

(2) Notice in local paper
- If a practice has a number of culturally and linguistically diverse patients or clients, should a non-English language newspaper also be included?

AND/OR

(3) Notice in reception area
- May reach current patients who read notices.
- How long should such a notice remain?

AND/OR

(4) Notice handed to each patient during a set notice period
- Will reach all patients receiving services during the notice period.
- How many languages should the notice be in?
- What about patients or clients who can't read?
- For what period of time should a provider be required to distribute such a notice?

AND/OR

(5) Verbal advice
- This would enable patients or clients with low levels of literacy to be reached.

AND/OR

(6) Letter sent to patients

Written notification raises a number of issues.
- Which patients should receive written notification? The options include requiring a notice to be given to all patients (except past patients where the organisation knows that the patient has died) or only 'current' patients or clients.
- If the duty were to apply to 'current' patients or clients, then this term would need to be defined. There are a number of possible options. Should this be determined by the length of time since their last visit? Should this be six months, twelve months or two years? Should it include someone with an appointment scheduled for sometime within the next three months, six months, twelve months?
- It may be appropriate to take into account the nature or state of the person's condition. A number of patients or clients may have regular follow-ups or check-ups in the post-initial treatment monitoring phase. The expectations of these patients or clients need to be considered as they may regard themselves as in the care of that provider even if they see them only every two or three years.

Another issue is whether any efforts should be made to follow-up patients or clients if written notification is returned to sender. A patient may not update their records with a provider at the time of a change of address, but may plan to do so when they next make an appointment.

In determining what are appropriate notification efforts, it may be useful to consider what steps a provider would currently take to advise patients or clients when the practice or business moves premises.

Additional notice requirements must ensure a balance between:

- the need for patients and clients to be advised of what is happening to their information and their service provision and to have continuity of record keeping despite across organisational change; and
- the need for health, disability and aged care providers not to be unreasonably burdened.

Q11 What additional steps should a health service provider be required to take to notify users of the service of the sale or closure of the practice or business?

Closure as a result of a health, disability or aged care provider's death

It is arguable that some of the additional notification tools outlined above may not be appropriate when a practice or business closes as a result of a provider's death, particularly if they were a sole practitioner. In most instances of a sale or transfer, there would be a reasonable amount of time in which to carry out any notice requirements, and the personnel to do it. When a provider dies, all notice requirements must be carried out by their legal representative, and neither time nor personnel may be available.

In 1999, the Medical Practitioners Board of Victoria offered a number of options to guide an executor in dealing with the medical records of a deceased practitioner. These included:

- obtaining assistance from another medical practitioner who agrees to take care of the records and to notify patients of this arrangement;
- inviting patients to accept their own records and make use of them (within a reasonable time frame); and
- inviting patients to nominate another doctor to whom the medical records may be forwarded.[4]

Such advice reflects the practice now required under the HPPs. In terms of notification, it does not specify in detail how patients should be notified, but clearly contemplates that they should be notified. The question is in what manner?

Q12 Should different notification requirements apply when a practice or business closes down due to the death of a health, disability or aged care service provider? What would they be?

'Secondary' providers & single-event providers

Some providers will not necessarily have an on-going or primary-care relationship with their patients or clients.

Sometimes this will result from the nature of the service provided. Pathologists and radiologists, for example, essentially provide services to other medical practitioners. They see patients, but are unlikely to have an ongoing relationship with them, and patients would not necessarily have the expectation of future care being provided to

[4] *Bulletin of the Medical Practitioners Board of Victoria* (Spring 1999).

them by such specialists. Similarly, patients of public or private hospitals who are admitted only once or twice for different procedures over their lifetime would not necessarily regard themselves as being in the continuing care of the particular hospital. This can be contrasted with patients whose conditions are such that they are regular in-patients or out-patients to particular wards or clinics within a hospital, which clearly provide on-going, primary care to these patients during that time.

Consideration of the nature of such relationships should inform any characterisation of what a 'current' patient would be, as discussed above, but it is possible that different notification standards may need to be considered in these cases.

Q13 Would the notice requirements appropriate for patients or clients with on-going and primary care relationships with their health service provider be appropriate for situations where the relationship is of a different order, such as with pathologists and radiologists? If not, what notice requirements should apply?

Appendix 1

Health Privacy Principles 1, 2, 10 & 11

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.

10. ***Principle 10--Transfer or closure of the practice of a health service provider***

10.1 This Principle applies if the practice or business of a health service provider (**"the provider"**) is to be--

(a) sold or otherwise transferred and the provider will not be providing health services in the new practice or business; or

(b) closed down.

10.2 The provider or, if the provider is deceased, the legal representatives of the provider, must--

(a) publish a notice in a newspaper circulating in the locality of the practice or business stating--

(i) that the practice or business has been, or is about to be, sold, transferred or closed down, as the case may be; and

(ii) the manner in which the provider proposes to deal with the health information held by the practice or business about individuals who have received health services from the provider, including whether the provider proposes to retain the information or make it available for transfer to those individuals or their health service providers; and

(b) take any other steps to notify individuals who have received a health service from the provider in accordance with guidelines issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph.

10.3 Not earlier than 21 days after giving notice in accordance with HPP 10.2, the person giving the notice must, in relation to health information about an individual held by, or on behalf of, the practice or business, elect to retain that information or transfer it to--

(a) the health service provider, if any, who takes over the practice or business; or

(b) the individual or a health service provider nominated by him or her.

10.4 A person who elects to retain health information must continue to hold it or transfer it to a competent organisation for safe storage in Victoria, until the time, if any, when the health information is destroyed in accordance with HPP 4.

10.5 Subject to HPP 10.2, a person must comply with the requirements of this Principle as soon as practicable.

10.6 Despite any other provision of the Health Privacy Principles, a person who transfers health information in accordance with this Principle does not, by so doing, contravene the Health Privacy Principles.

10.7 If—

(a) an individual, in response to a notice published under HPP 10.2, requests that health information be transferred to him or her or to a health service provider nominated by him or her; and

(b) the person who published the notice elects to retain the health information-

the request must be taken to be--

(c) in the case of a request that the health information be transferred to him or her, a request for access to that health information in accordance with Part 5 or HPP 6; and

(d) in the case of a request that the health information be transferred to a health service provider nominated by him or her, a request for the transfer of that health information in accordance with HPP 11--

and it must be dealt with in accordance with this Act.

10.8 This Principle operates subject to any other law, including the Public Records Act 1973.

10.9 For the purposes of HPP 10.1(a), a business or practice of a provider is transferred if--

(a) it is amalgamated with another organisation; and

(b) the successor organisation which is the result of the amalgamation is a private sector organisation.

11. ***Principle 11--Making information available to another health service provider***

11.1 If an individual--

> (a) requests a health service provider to make health information relating to the individual held by the provider available to another health service provider; or
>
> (b) authorises another health service provider to request a health service provider to make health information relating to the individual held by that provider available to the requesting health service provider--

a health service provider to whom the request is made and who holds health information about the individual must, on payment of a fee not exceeding the prescribed maximum fee and subject to the regulations, provide a copy or written summary of that health information to that other health service provider.

11.2 A health service provider must comply with the requirements of this Principle as soon as practicable.

11.3 Nothing in Part 5 or HPP 6 limits the operation of this Principle.

11.4 For the purposes of HPP 10.7, this Principle applies to a legal representative of a deceased health service provider in the same way that it applies to a health service provider.

Appendix 2:

Extracts from *Guidelines under Section 95 of the Privacy Act*, National Health and Medical Research Council (Commonwealth of Australia, 2000), paragraphs 2.4, 3.1, 3.2 and 3.3[5]

2.4 In the proposal for the conduct of each such research project, the researcher should state:

(a) the aims of the research;
(b) the credentials and the technical competence of the researcher;
(c) the data needed and how it will be analysed;
(d) the source of the data;
(e) the study period;
(f) the target population;
(g) the reason why identified* or potentially identifiable* information is needed rather that de-identified* information, and the reason why it is not proposed to seek consent to the use of personal information.

[Note: 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) when considering the release of personal information, and genetic testing.]

(h) the specific uses to which the personal information used during the study will be applied;
(i) the proposed method of publication of results of the research;
(j) the estimated time of retention of the personal information;
(k) the identity of the custodian(s) of the personal information used during the research;
(l) security standards to be applied to the personal information. In particular, that personal information will be retained in accordance with the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (Appendix 3), and in a form that is at least as secure as it was in the sources from which the personal information was obtained unless more stringent legislative or contractual provisions apply;
(m) a list of personnel with access to the personal information;
(n) the standards that will be applied to protect personal information disclosed by a Commonwealth agency. These should include:
    (i) terms of any disclosure agreement between the agency and the researcher to govern the limits on use and disclosure of that personal information; and
    (ii) proposed methods of disposal of the personal information on the completion of the research, and that these are in accordance with the *Archives Act*, 1983 for the Commonwealth records and legislative requirements of a State or Territory; and

[5] Available in full at www.privacy.gov.au/act/index.html - 2.9.1.
* See Appendix 4: Glossary

(iii) standards that will be applied to protect privacy of personal information where it is made available to other researchers or third parties if that is proposed.

* * * * * *

3. Consideration by Human Research Ethics Committees (HREC)

3.1 Before making a decision under these guidelines, an HREC must assess whether it has 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. [See '2. Human Research Ethics Committees' and 18. 'Privacy and Information', *National Statement on Ethical Conduct in Research Involving Humans* (1999)].

3.2 In making a decision under these guidelines, HREC must consider the following matters:

(a) identify and consider the IPP or IPPs that might be breached in the course of the proposed research, including whether it is necessary for the research to use identified or potentially identifiable data, and whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates, and

(b) ensure that the committee has the competence to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy. If the public interest in the proposed research does not outweigh, to a substantial degree, in public interest in the protection of privacy then the research should not be carried out.

Weighing the public interest

3.3 In reaching a decision under 3.2 (b) an HREC should consider the following matters:

(a) the degree to which the medical research is likely to contribute to:
- the identification, prevention or treatment of illness or disease; or
- scientific understanding relating to health; or
- the protection of the health of individuals and/or communities; or
- the improved delivery of health services; or
- scientific understanding or knowledge.

(b) any likely benefit to individuals, to the category of persons to which they belong, or the wider community that will arise from the medical research being undertaken in the manner proposed;

(c) whether the medical research design can be satisfied without risking infringement of an IPP and the scientific defects in the medical research that might arise if the medical research was not conducted in the manner proposed;

(d) the financial costs of not undertaking the medical research (to government, the public, the health care system, etc);

(e) the public importance of the medical research;

(f) the extent to which the data being sought are ordinarily available to the public from that Commonwealth agency; and

(i) whether the medical research involves use of the data in a way which is inconsistent with the purpose for which the data were made public; and

(ii) whether the medical research requires an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an IPP.

(g) whether the risk of harm to a person whose personal information is to be used in proposed research is minimal, having regard to the elements of that research provided in response to paragraph 2.3 of these guidelines;

(h) the standards of conduct that are to be observed in medical research, including:

(i) the study design and the scientific credentials of the researchers;

(ii) if the research involves contact with participants, the procedure or controls which will apply to ensure that participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be employed are intrusive;

(iii) whether access to personal information is restricted to appropriate researchers;

(iv) the risk that a person or group could be identified in the published results; and

(v) the procedures that are to be followed at the completion of the research to ensure that all data containing personal 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.