

# Guidelines for the Victorian-Specific Module

## Overview

As part of the ethics application process, a completed Victorian-Specific Module to address Victorian-specific legislation must be attached to the Human Research Ethics Application (HREA).

Completion of the Victorian-Specific Module is mandatory for all research conducted in the State of Victoria.

In Victoria there is a requirement to comply with legislation relevant to human research involving information privacy (*Information Privacy Act 2000*), health information (*Health Records Act 2001*), the use of ionising radiation (*Radiation Act 2005* and *Radiation Regulations 2007*), removal of human tissues (*Human Tissue Act 1982*) and the use of poisons or controlled substances (*Drugs, Poisons and Controlled Substances Act 1981*). In addition, consent under circumstances where the *Medical Treatment Planning and Decisions Act 2016* or the *Mental Health Act 2014* applies must meet the requirements set out in the applicable Act.

The Victorian Specific Module and these Guidelines may be modified and updated from time to time. Please access the form from the website ([www2.health.vic.gov.au/about/clinical-trials-and-research](http://www2.health.vic.gov.au/about/clinical-trials-and-research)) each time you make a new application, to ensure that you have the latest version.

For each project, the **Introduction** of the Victorian Specific Module must be completed, and Sections 1, 2 and 3 should be completed as applicable to the individual research project. The **Checklist** should be completed for all projects, and can be used to identify the necessary sections.

These guidelines provide useful information and specific instructions for completing Sections 1, 2 and 3 of the Victorian Specific Module.

## National Mutual Acceptance (NMA)

If a research project is being submitted for HREC review under the NMA initiative and there is a Victorian site participating in the trial, the Victorian-Specific Module must be submitted to the reviewing HREC.

If the Coordinating Principal Investigator (CPI) is based outside Victoria, it is recommended that the Victorian-Specific Module is completed by a Victorian Principal Investigator (PI) or delegate based at a participating Victorian site, as they will have familiarity with the relevant legislation.

The CPI should sign the completed Victorian-Specific Module in the 'Research Project Details' section on the cover page. However, if a Victorian PI has completed the VSM on behalf of an interstate CPI, the Victorian PI should sign.

## Information for Victorian Specific Module Section 1: *Research Involving the Recruitment of Participants who do not have decision making capacity to consent*

---

For further information, refer to the document “General medical health needs, annual examination, non-psychiatric treatment, special procedures and medical research procedures - Chief Psychiatrist’s Guideline” ([www2.health.vic.gov.au/about/key-staff/chief-psychiatrist/chief-psychiatrist-guidelines/general-medical-health-needs](http://www2.health.vic.gov.au/about/key-staff/chief-psychiatrist/chief-psychiatrist-guidelines/general-medical-health-needs))

### Consent and decision making capacity

Consent must be:

- Given by a person who has decision making capacity;
- Given by a person who has been adequately informed of the risks and benefits for the participant of participation; and
- Given freely.

Decision making capacity requires the person to be able to do the following:

- understand the information relevant to the decision and the effect of the decision;
- Retain that information to the extent necessary to make the decision;
- Use or weigh that information as part of the process of making that decision; and
- communicate the decision and the person’s view and needs as to the decision in some way, including by speech, gestures or other means.

A thorough assessment of a participant’s decision making capacity and capacity to make a valid informed decision is necessary prior to their recruitment into the research project. The details of this assessment should be clearly documented in a patient’s health record, where appropriate.

In those circumstances where participants do not have decision-making capacity to make a decision about a medical research procedure, the provisions of the *Medical Treatment Planning and Decisions Act 2016* will apply.

In those circumstances where participants have limited decision-making capacity to understand and provide a valid informed consent, consideration should be given to the extent of that capacity in the context of the study contemplated; for example, the stress and anxiety of an emergency department, the nature and seriousness of the participant's clinical condition. These factors may impact on the reality and capacity of a participant to peruse and digest a detailed participant information statement. In such cases, a more limited verbal process of informing participants of the proposed research may be more appropriate. In this event, accurate documentation must be included in the participant's health records. The more detailed Participant Information and Consent Form can be provided for further consideration at a later stage. This is in accordance with Section 4.4.5 of the *National Statement*.

### Dependency and consent

If the research involves participants in a dependent relationship with the researcher, for example, employees, students etc., it should be considered whether an independent person should make the initial approach and/or seek consent [*National Statement* 4.4.12].

Normally any interpreter needs to be independent. However, with low-risk research, an English-speaking relative or friend may be acceptable.

## Cognitive impairment, Intellectual disability or mental illness and issues of consent

For research involving people with cognitive impairment, intellectual disability or mental illness, researchers need to evaluate each participant's decision making capacity. If the participant has decision making capacity, researchers must obtain their valid consent. It would be wise to consult relatives or carers as part of the consent process. The HREC should be informed about how the evaluation of decision making capacity will be made, as outlined in the *National Statement* 4.5.9.

It is important to remember that the PICF for such individuals must be designed to facilitate adequate understanding of the research to which they are being invited to take part.

### Definition of Medical Research Procedure

With reference to the *Medical Treatment Planning and Decisions Act 2016*, "medical research procedure" means:

- a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of pharmaceuticals or the use of equipment or a device; or
- a procedure that is prescribed by the regulations to be a medical research procedure for the purposes of the *Medical Treatment Planning and Decisions Act 2016*.

However, "medical research procedure" does not include:

- any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision); or
- observing a person's activities; or
- undertaking a survey; or
- collecting or using information, including personal information (within the meaning of the *Information Privacy Act 2000*) or health information (within the meaning of the *Health Records Act 2001*); or
- any other procedure that is prescribed by the regulations not to be a medical research procedure for the purposes of this Act.

### For research that involves a "medical research procedure"

Note that if the participant(s) do not have decision-making capacity in relation to the "medical research procedure" as defined in the *Medical Treatment Planning and Decisions Act 2016* (see above) then researchers must follow the process described in the *Medical Treatment Planning and Decisions Act 2016*. In summary, the process is as follows:

- Ensure the relevant research project has been approved by the relevant HREC (section 75)
- Determine whether the person is likely to recover decision making capacity within a reasonable time (if they are, the research procedure must be delayed until the person can make their own decision) (section 72)
- If the person will not recover decision-making capacity within a reasonable time, make reasonable efforts to locate an advance care directive or medical treatment decision maker to make the decision (section 73 and 77)
- If a relevant advance care directive and medical treatment decision maker cannot be located, complete the process for providing a medical research procedure without consent (sections 80 and 81)

Section 53: If the proposed procedure is necessary as a matter of urgency to save life, prevent serious damage to health or prevent significant pain or distress, the procedure may be provided without following the above process.

It is the principal researcher's responsibility to ensure that they, and all members of the research team, are fully conversant with the requirements of the *Medical Treatment Planning and Decisions Act 2016* and, in particular, Part 5 of the Act which describes these steps in detail.

Essential Links:

- [Medical Treatment Planning and Decisions Act 2016](#)

### Consent of next-of-kin

If you anticipate that participants will not be able to consent on their own behalf, and the project does involve a medical research procedure as defined within the *Medical Treatment Planning and Decisions Act 2016*, participant information should be provided by a medical treatment decision maker as follows:

- (a) the spouse or domestic partner of the person;
- (b) the primary carer of the person;
- (c) the first of the following and, if more than one person fits the description in the subparagraph, the oldest of those persons –
  - (i) an adult child of the person;
  - (ii) a parent of the person;
  - (iii) an adult sibling of the person.

### 1.1 Consent

Before giving approval, the HREC must be satisfied as to how the researcher(s) will verify that a participant has given valid consent to participate in the project. HRECs generally require that written consent will be obtained from all participants and the signed Consent section of the PICF is evidence that valid consent has been obtained. In some circumstances, it may be ethical to rely on verbal or implied consent [*National Statement 2.2.5*]. Sometimes verbal consent may be valid and formal written consent may be unnecessary or even undesirable. In these cases, consent may be recorded by another means. Examples include video or audio taping or researcher's notes of a conversation, verbal consent given over the telephone before a telephone interview. Implied consent may be expressed by the completion and return of a questionnaire.

- (a) Indicate whether any participants will not have the capacity to give consent and if the project involves a medical research procedure.
- (b) Before a medical research practitioner administers a medical research procedure to a person who does not have decision making capacity, the medical research practitioner must make reasonable efforts to ascertain if the person has an Advance Care Directive. Outline the steps and explain how you would locate and determine the relevance of the Advance Care Directive for the research project in (i) and (ii). Indicate whether the information in the Advance Care Directive is relevant and sufficient for consent to the study's medical research procedure in (iii) and (iv).

Explain how the person who will recruit participants will determine the decision making capacity of individuals to give consent. This explanation should include information about how the decision will be made, who will make it, the criteria being used to make the determination. [NS 4.5.9 (a)-(c)]. See the discussion above for general considerations in relation to decision making capacity. This issue is particularly important when potential participants are intellectually disabled, suffering from a mental illness or another disease that may reduce the individual's ability to understand the research project.

Within certain participant groups, the capacity to consent may fluctuate and may need to be reassessed during the progress of the research. [NS 4.5.9 (d)] In such cases, a reassessment of capacity should be designed into the research procedures.

### 1.2 Group of participants unable to consent

For all proposed participants who are incapable of giving consent, indicate which group best describes them; check all that apply.

### **1.3 Emergency medical research procedure**

If a 'medical research procedure' is necessary as a matter of urgency to save life, prevent serious damage to health or prevent significant pain or distress then consent is not required, in accordance with Section 53 of the *Medical Treatment Planning and Decisions Act 2016*. The researcher must thoroughly explain that it may be necessary to perform a 'medical research procedure' in a situation that may arise (refer to the *Medical Treatment Planning and Decisions Act 2016* information paper).

### **1.4 Recovery of capacity to consent**

If patients are likely to recover capacity to consent to the 'medical research procedure' within a reasonable timeframe then you must wait and seek the patients' own consent before commencing the 'medical research procedure'.

### **1.5 Medical treatment decision maker**

The *Medical Treatment Planning and Decisions Act 2016* is quite specific about who the medical treatment decision maker may be and researchers need to consider how the appropriate person will be identified. Careful consideration should be given to how the medical treatment decision maker will be approached, bearing in mind that this may in some situations also be when the medical treatment decision maker first learns of a relative's accident or health condition. In some cases, when the research is time-critical and the medical treatment decision maker is not present, they may need to be informed and provide consent by telephone. Details of how this will be done and recorded should also be included, if relevant.

### **1.6 Administration of a medical research procedure without consent**

This should be based on the criteria set out in Section 80 of the *Medical Treatment Planning and Decisions Act 2016*.

If the medical research procedure is to continue after a medical treatment decision maker has been located or after the participant themselves regains the capacity to consent, 'continuing consent' must be obtained. If the procedure is already over, researchers should check whether their HREC requires information to be given to the medical treatment decision maker and/or participant after the event.

### **Submitting a Section 81 Certificate**

Before, or as soon as practicable after the research procedure is carried out, the practitioner supervising the conduct of the procedure must sign a Section 81 certificate ('Medical research procedure on a patient who is unable to consent and there is no person responsible to provide consent'). The certificate is available from the Office of the Public Advocate website.

Copies of this certificate must be forwarded to both the Office of the Public Advocate and the relevant HREC within a maximum of 2 working days of the medical procedure being carried out. The original certificate should be filed in the patient's medical record. A separate Section 81 certificate must be submitted for each patient recruited under procedural authorisation. If the procedure extends over more than one month, and it is still not possible to obtain person responsible or participant consent, a further Section 81 certificate must be submitted (and resubmitted every month for the duration of the procedure) as above.

### **1.7 Participant Information and Consent Form**

Refer to the following links:

- [Clinical Trials](#)
- [Health and medical research](#)

## **Children and consent**

Part 5 of the *Medical Treatment Planning and Decisions Act 2016*, is not applicable to children i.e. medical research provision.

## Information for Victorian Specific Module Section 2: *Research Involving the Collection/Use/Disclosure of Information*

---

This section covers those aspects of the project proposal to which the various pieces of State and Commonwealth privacy legislation relate. It is expected that all researchers will have to complete at least some of the questions in this section, since every project will involve the collection, use or disclosure of some piece of information.

It is hoped that the process of completing this section of the application form will be educative for researchers, as well as providing information that assists the HREC in assessing the project from the perspective of privacy issues. While privacy legislation may seem complex, the underlying principles are actually quite straightforward. Moreover, the principles are consistent between State and Commonwealth legislation, so if the project is compliant with the privacy principles in Victoria, in most cases, it will also be compliant with the Commonwealth legislation.

The first time researchers complete the questions in Section 2, they will be faced with issues that they may not have considered in previous research projects. It is hoped that, once they are aware of the issues that must be addressed, researchers will take these issues into account when they are developing future research projects. Some of these issues include the source of the information and the purpose for which the information will be used and how this relates to the purpose for which the information was collected in the first instance. Researchers should also consider the nature of the information (see definitions below) and why the collection, use or disclosure of that information is justified.

The following is an overview of the State and Commonwealth privacy legislation that may impact upon a project. Note that Table 1 helps the researcher identify which pieces of legislation (and which Privacy Principles within that legislation) are relevant to the project.

Note: Most of the advice given in these Guidelines only relates to the Privacy Principles concerned with collection, use or disclosure of information, since these are the Privacy Principles to which the various sets of Statutory Guidelines apply. There are other Privacy Principles that deal with data quality, data security, access to data, identifiers, trans-border data flows and other issues. Researchers should review ALL Privacy Principles in the relevant legislation to ensure that their project is fully compliant with all aspects of the law. Legislation and any relevant guidelines can be downloaded from the websites listed below.

Researchers should be aware that HRECs have a statutory reporting requirement in relation to information that is provided in this section of the application. Failure by the researcher to provide all this information will delay the review of the application.

### Victorian Law

#### **Health information – where the collection, use or disclosure is by an organisation in Victoria**

The *Health Records Act 2001* (Victoria) applies to all health information (see definitions below) handled by the Victorian public sector and private sector. There are eleven Health Privacy Principles (HPPs). HPP 1 and 2 govern the collection, use and disclosure of health information, including for the purposes of research. This Act is administered by the Victorian Health Complaints Commissioner, who may issue or approve Guidelines in relation to the HPPs. The Guidelines in relation to research can be obtained from the Health Complaints Commissioner's website: <https://hcc.vic.gov.au>. Any researcher who considers that the HPPs might apply to their research should read these guidelines.

It is important to note that this Victorian Act applies generally to private sector organisations when they handle health information in Victoria. Unlike the Commonwealth Privacy Act (see below), it does not contain any exemptions for “small business”.

## Other laws

Other more specific laws may apply to particular categories of research. For instance, section 60 of the Cancer Act 1958 regulates the disclosure of information from registries established under that Act.

## Commonwealth Law

The *Privacy Act 1988* (Cth) applies to Commonwealth and ACT government agencies, and to certain private sector organisations. It applies to private sector health service providers, and to private and ACT universities. It does not apply to State or Northern Territory government agencies, including state and territory public hospitals and health care facilities except in relation to Personally Controlled Electronic Health Records and Individual Healthcare Identifiers in certain circumstances. It does not cover ACT Government agencies handling health information or health records, nor does it cover universities (other than private and ACT universities). It does not apply to public schools (except ACT public schools) but does apply to private schools that have an annual turnover of \$3 million, or that provide a health service.

The *Privacy Act 1988* (Cth) outlines thirteen Australian Privacy Principles, which establish requirements for the collection, storage, use and disclosure of personal information and health information. Sections 16A and 16B of the Privacy Act set out certain circumstances in which it is permissible to collect, use and disclose personal information and health information for the purposes of research.

Sections 95, 95A and 95A of the *Privacy Act 1988* (Cth) provide for the NHMRC to issue guidelines for the protection of personal information, health information and genetic information in research the Guidelines, and establish that, if the Guidelines are approved by the Privacy Commissioner, research that is carried out in accordance with the guidelines will not be in breach of the APPs.

Any researcher wishing to obtain information from a Commonwealth agency, and any researcher who considers that that the APPs might apply to their research, should read the Guidelines under Section 95, 95A and 95AA of the *Privacy Act 1988*, issued by the NHMRC (see [www.nhmrc.gov.au/publications/synopses/e26syn.htm](http://www.nhmrc.gov.au/publications/synopses/e26syn.htm)).

## General Considerations

All of the Guidelines described above provide very clear instructions as to the information that researchers must include in their application.

Researchers are responsible for identifying the relevant Act and guidelines under which an application for approval of a project is made.

If more than one Act (or set of guidelines) applies, all relevant legislative requirements will need to be met, including the obtaining of any necessary approvals from a Human Research Ethics Committee. The statutory guidelines referred to above are not identical, as they must reflect the various statutes under which they are made and any different requirements must be adhered to. There is nonetheless a high level of concordance in relation to the key requirements.

**Researchers should note that this discussion about privacy laws is general information intended to provide a starting point to assist them in understanding how the legislative regimes may apply to their research activities. It does not constitute legal advice.** If in doubt as to their legal obligations, researchers should seek their own advice, or contact the responsible Commissioner:



- Health Records Act: Victorian Health Complaints Commissioner (1300 582 113);
- Victorian Commissioner for Privacy and Data Protection: <https://www.cpdp.vic.gov.au>;
- Privacy Act: Office of the Australian Information Commissioner (1300 363 992).

## Definitions

**Collection:** an organisation or individual collects information if it gathers, acquires or obtains information from any source and by any means, whether that information has been requested or not. Questionnaires, surveys, interviews, focus groups and requests for information held in databases, data sets or institutional records are all examples of how information may be collected.

**Use:** an organisation or individual uses information if it handles the information in any way. Use of information includes any form of quantitative or qualitative analysis and any inclusion of the information in any form of publication. Note that contacting a person based on contact details is considered to be use of that information.

**Disclosure:** an organisation or individual discloses information when it releases information to other organisations or individuals (that is, outside of those who collected the information in the first instance). Giving individuals information about themselves does not constitute disclosure.

**Personal Information:** generally<sup>1</sup> means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

**Health Information:** under the Victorian *Health Records Act 2001* means:

- a. information or an opinion about:
  - i. the physical, mental or psychological health or a disability (at any time) of an individual; or
  - ii. an individual's expressed wishes about the future provision of health, disability or aged care services to him or her; or
  - iii. a health, disability or aged care service provided, or to be provided, to an individual;
- b. other personal information collected to provide, or in providing, a health, disability or aged care 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. 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 any of his or her descendants.

Sensitive Information: means information or an opinion about an individual's:

- racial or ethnic origin; or
- political opinions; or
- membership of a political association; or
- religious beliefs or affiliations; or
- philosophical beliefs; or
- membership of a professional or trade association; or
- membership of a trade union; or
- sexual preferences or practices; or
- criminal record;

that is also personal information; or (in the *Commonwealth Privacy Act* only): health information about an individual.



## Other Relevant Information

Other relevant Federal and State Government legislation includes:-

- The Public Records Act 1973 and Amendments (Victoria)
- Disposal Schedule for Public Health Services Patient Information Records “PROS 99/94” the Health Services Act 1988 Victoria

Recommendations/Guidelines of national bodies include:

- The *National Statement on Ethical Conduct in Human Research* (2007), produced by the National Health and Medical Research Council (NHMRC) under the *National Health and Medical Research Council Act 1992*.
- The Australian Code for the Responsible Conduct of Research (2007)
- Guidelines for the Protection of Privacy in the Conduct of Medical Research Aspects of Privacy in Medical Research (1995)

Note: The National Health & Medical Research Council requires original data to be kept at least seven years for clinical research, 15 years for clinical trials and 23 years for clinical trials involving children.

## General Advice For Completion Of Section 2

There may be projects that involve more than one set of information, with each set being collected, used or disclosed in a different manner. In these cases, researchers may find it difficult to answer questions in this section unambiguously.

It is recommended in these situations that researchers duplicate Section 2 and distinguish each repeated section with a number (e.g. Section 3-Part I, Section 3-Part II, etc.) or title (e.g. Information from Case Workers, Information from Department of Health and Human Services datasets, etc.). In this way, it will be clear which answers apply to each set of information.

An example of circumstances when this approach might be useful is if one set of information is to be handled with the consent of the individual, while another set of information is to be individually identifiable (or re-identifiable) but handled without consent. Another example is when the researcher is handling more than one set of individually identifiable information without consent, but the reasons for needing identifiable information or for not obtaining consent are different for each set of information.

### Individually identifiable, re-identifiable and non-identifiable information

The *National Statement* identifies three mutually exclusive forms of data identifiability, as follows [NS 3.2]:

**Individually identifiable data** where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual’s name, image, date of birth or address; Identifying information can include other information, if that information is unique in some way or highly specific. For example, “employee of the Victorian Department of Health and Human Services” is not sufficient information to identify a person. However, “employee of organisation X” which only employs three people may be sufficient information to identify someone, particularly in conjunction with other information;

**Re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets;

**Non-identifiable data**, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person’s identity remains unknown.

Consider the situation where health information is disclosed to a researcher without information that could identify the individual, but coded so that it may be re-identified if necessary. If it would be impossible for the researcher to access the link, then the information collected and subsequently used by the researcher is **non-identifiable**. If the researcher is given the code, as well as the information, then the information is **re-identifiable**, as long as the code remains associated with the information. Potentially identifiable information is treated in the legislation in the same way as **identifiable information**.

## 2.1 Collection of participants' information

(a) If participants will not be aware of their inclusion in the research and are not being asked for consent, do not answer any other parts of this question and move directly to question 2.2. If the project does involve collection of information about individuals (either directly from the individual or from a source other than the individual) **with their knowledge and consent** indicate which categories of information will be collected in part (b).

(c) Indicate whether you are seeking consent from participants to use their data for this specific research project ('specific' consent), future research that is closely related to the original project or in the same general area of research e.g. cancer research ('extended' consent), or unspecified future research ('unspecified' consent). Refer to the *National Statement* 2.2.14 for further information about consent to future use of data.

(d) The *National Statement* defines databanks (which includes databases) as "[A] systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable." (see definitions above). If data are being collected, aggregated and stored with a view to use for future related or as yet unspecified research, this may involve 'banking' the participants' data. For more information, refer to the *National Statement* Chapter 3.2.

(e) If information is being collected with the consent of the individual, the researcher is responsible for informing the participants about how the information will be used, disclosed, stored and published and how the individual may access the information concerning them. If the participants will not be informed about these matters in the Participant Information and Consent Form, give reasons why this is the case.

(f) Failure to provide this information to the individual may be a breach of the applicable privacy legislation.

## 2.2 Do other questions in this section have to be completed?

(a) If the project does not involve the collection or use or disclosure of individually identifiable or re-identifiable (potentially identifiable) information (see definitions above), then you do not need to answer most of the questions in this section. Go directly to question 2.7 and do not answer questions 2.2(b), 2.3, 2.4, 2.5 or 2.6. Please remember that access to identifiable records for the purpose of extracting non-identifiable data constitutes 'use' and 'disclosure' of identifiable data, even if such data will not be 'collected' by the researcher. Therefore, the correct answer to this question is "yes" and further questions in this section must be answered. That is, the answer to part (a) is "yes" if **any one** of the possible activities (collection/use/disclosure) involves individually identifiable or re-identifiable information.

(b) If the project does not involve collection or use or disclosure of information without the consent of the person to whom the information relates, then you do not need to answer most of the questions in this section. Go directly to question 2.7 and do not answer questions 2.3, 2.4, 2.5 or 2.6. Please note that the answer to part (b) is "yes" if any one of the possible activities (collection/use/disclosure) will be conducted without consent.

## 2.3 Type of activity proposed

Indicate all types of activity for which this proposal is seeking approval. You may be seeking approval for more than one type of activity, for example, collection and use of information. Note that disclosure may occur in two directions: an organisation may disclose information to a researcher (which the researcher, in

turn, collects from that organisation) and/or the researcher may disclose information to other organisations or in the form of a publication.

If you are collecting information about individuals from a third party (i.e. not directly from the individuals themselves), then you should consider whether this application for ethical approval is to cover the disclosure of the information from the third party, as well as the collection and use of the information by yourself and your colleagues. (Note: You will be asked about this issue specifically in Question 2.4(c)) There is no legal requirement for a separate application to be made by the disclosing organisation providing the application covers disclosure, if applicable. Therefore, it is important for the application to cover **disclosure, collection and use** of information. This issue is most relevant in cases where the disclosing organisation does not have its own HREC. In such situations, the disclosing organisation would probably prefer to have its disclosure activities reviewed as part of the application to collect and use the information.

## **2.4 Collection of information about individuals from a third party**

The italicised instruction at the start of this question is a reminder to researchers that if they answered “no” to either part (a) or part (b) of question 2.2, then they should not be answering this question.

(a) Specify the source of the information that is to be collected. Check as many boxes as are relevant (i.e. if information will be collected from multiple sources).

In the case of health information, researchers should note that some organisations that are not health service providers (such as the YMCA or child care centres) (see definition below) do collect and hold health information. If such an organisation is the source of the health information to be used in the research project, researchers should check the box corresponding to “An organisation other than a health service provider”.

Carers are sometimes used as the source of information about an individual they are caring for. If the carer is managed representative (whether as paid or unpaid worker) of an organisation that provides services to assess, maintain or improve a person’s health, or to treat or diagnose a person’s illness, injury or disability, they are a health service provider for the purposes of the *Health Records Act 2001*. If the carer is providing care in a private capacity (for example as a family member or friend), then the carer is not a health service provider and the researcher should check the box for “Others”.

### **Definition of “Health Service Provider”**

For the purposes of the *Health Records Act 2001*, a health service provider means a person or an organisation that provides a health service in Victoria. A health service means an activity that is intended or claimed to assess, maintain or improve a person’s health, or to diagnose or treat illness, injury or disability, and includes a disability, palliative care or aged care service.

### **Definition of “Commonwealth Agency”**

For the purposes of the Privacy Act 1988, a Commonwealth agency is a minister, department, statutory corporation or other body established for a public purpose by Commonwealth legislation. This covers virtually all Commonwealth departments. The main exceptions are companies, incorporated societies, intelligence organisations and trade unions. Some of the organisations and government departments defined as Commonwealth record keepers are listed below. This list is a guide to the agencies most commonly approached by researchers (from the AHEC Report on Use of Section 95 Guidelines)

- Aboriginal and Torres Strait Islander Commission (ATSIC)
- Australian Archives
- Australian Bureau of Statistics
- Australian Electoral Commission (not State Electoral Offices)
- Australian Institute of Health and Welfare
- Australian National University
- Australian Sports Commission
- Health Insurance Commission

In the table at the end of part (a), list the categories of individuals or organisations from which information will be collected and clearly indicate precisely what information will be obtained from each source.

(b) Indicate whether the organisations from which you intend to collect information have agreed to provide that information. Please supply written evidence of the agreement to disclose information. If the agreement of the disclosing organisation has not yet been obtained, explain why not and how/when the agreement will be obtained.

(c) As discussed above in Question 2.3, indicate whether the organisation(s) from which information will be collected will be seeking separate HREC approval for disclosure of the information. If separate approval is sought by the disclosing organisation, researchers should supply a copy of that approval when it is available. If separate approval will not be sought by that organisation, then the researcher should supply a copy of this HREC's approval (and any conditions associated with it) to the organisation disclosing the information.

(d) Indicate whether the person collecting the information routinely has access to the information. An example would be a psychiatrist who routinely accesses the RAPID database (a Department of Health and Human Services database) for clinical purposes, but wishes to use the database for a research purpose.

(e) If you are answering this question, it is because individually identifiable (or re-identifiable) information will be collected without the consent of the individual to whom the information relates. In this case, Guidelines may have to be applied, depending upon which Privacy Principles apply. This part of Question 2.4 assists researchers to identify which Privacy Principles apply to the collection of information. This will be determined by:

- The type of information being collected;
- The type of organisation that will be collecting the information (i.e. the researcher's organisation or institution).

List all of the Privacy Principle Codes (from Table 3) that apply. Remember that health information includes personal information (such as name, address, date of birth, Medicare number, etc) that is contained within the health record. Therefore, if health information is being collected, it is not necessary to record "personal information" codes as well in relation to that information. "Personal Information" codes only need to be recorded if personal information that is not part of a health record is being collected. **Remember that these Privacy Principles only relate to the collection of information and other Privacy Principles in that Act may also apply.**

The relevant Guidelines are:

- For Health Privacy Principles (HPPs) – Statutory Guidelines on Research issued for the purposes of Health privacy principles 1.1 (e)(iii) & 2.2(g)(iii).
- Download from the Health Complaints Commissioner's website: <https://hcc.vic.gov.au>
- For Australian Privacy Principles (APPs) – Guidelines Approved under Section 95A of the Privacy Act 1988. Download from: [www.nhmrc.gov.au/publications/synopses/e43syn.htm](http://www.nhmrc.gov.au/publications/synopses/e43syn.htm)

(f) Identifiable data may not be collected for deposit in a databank without participants' consent unless an HREC gives permission. By ticking the 'yes' box here, you are asking the HREC to waive the need to seek consent from participants to 'bank' their data for possible use in future research *National Statement 3.29* (c)(ii).

Parts (g), (h) and (i) are key issues. The answers provided by the researcher to these questions will in large part determine whether the HREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals.

In answering part (g), researchers are asked to explain why the information will not be collected in a non-identifiable form, e.g. because identifiers are required for data linkage, etc. This question is not requesting an explanation of why the information is considered to be individually identifiable or re-identifiable (e.g. because names and birth dates will be included).

Similarly for part (h), the researcher should explain why consent will not be obtained, e.g. because the number of records is so large that obtaining consent is not practicable, or because not obtaining consent from all relevant individuals would impact on the scientific rigour of the research, or because of the negative impact that an attempt to obtain consent might have on individuals. This question is not seeking an explanation of why the researcher's actions constitute 'not seeking consent' (e.g. because the researcher won't be contacting the individuals).

## 2.5 Use of information about individuals

The italicised instruction at the start of this question is a reminder to researchers that if they answered "no" to either part (a) or part (b) of question 2.2, then they should not be answering this question.

(a) If you are answering this question, it is because individually identifiable (or re-identifiable) information will be used without the consent of the individual to whom the information relates. In this case, Guidelines may have to be applied, depending upon which Privacy Principles apply. This part of Question 2.5 assists researchers to identify which Privacy Principles apply to the use of information. This will be determined by:

- The type of information being used;
- The type of organisation that is using the information.

List all of the Privacy Principle Codes (from Table 3) that apply. For example, if health information and other non-health personal information are being used, record all relevant codes. **Remember that these Privacy Principles only relate to the use (and disclosure) of information and other Privacy Principles in that Act may also apply.**

The relevant Guidelines are as listed above for question 2.4(e).

(b) Specify how the information is to be used.

(c) If the information is to be used for a purpose (the "secondary purpose") other than the primary purpose for which the information was collected, the secondary purpose may be directly related to the primary purpose and the individual might reasonably expect that their information would be used for that purpose. If this is the case, state how the secondary purpose is related to the primary purpose.

Parts (d), (e) and (f) are key issues. The answers provided by the researcher to these questions will in large part determine whether the HREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals. Please refer to Question 2.4 parts (g) and (h) for guidance about the information sought from researchers in response to these questions. Researchers who have already answered similar questions in Question 2.4 (g), (h) and (i) may refer to their earlier answers, if those answers are relevant.

## 2.6 Disclosure of information

The italicised instruction at the start of this question is a reminder to researchers that if they answered "no" to either part (a) or part (b) of question 2.2, then they should not be answering this question.

Question 2.6 examines "disclosure" from two different perspectives, since disclosure may occur at the start of the process (i.e. an organisation discloses information to the researcher) and/or at the end of the process (i.e. the researcher discloses information to another organisation), but does not include publication (which is considered to be a "use" of information, not a "disclosure").

(a) If you answer “yes” to this question, it is because individually identifiable (or re-identifiable) information will be disclosed by an organisation to the researcher without the consent of the individual to whom the information relates. In this case, Guidelines may have to be applied, depending upon which Privacy Principles apply. This part of Question 2.6 assists researchers to identify which Privacy Principles apply to the disclosure of information. This will be determined by:

- The type of information being disclosed;
- The type of organisation that is disclosing the information.

List all of the Privacy Principle Codes (from Table 3) that apply. For example, if health information and other non-health personal information are being disclosed, record all relevant codes. **Remember that these Privacy Principles only relate to the disclosure (and use) of information and other Privacy Principles in that Act may also apply.**

The relevant Guidelines are as listed above for question 2.4(e).

(b) If you answer “yes” to this question, it is because individually identifiable (or re-identifiable) information will be disclosed by the researcher to another organisation without the consent of the individual whose information it is. As for part (a) above, Guidelines may have to be applied, depending upon which Privacy Principles apply. This will be determined by:

- The type of information being disclosed;
- The type of organisation that is disclosing the information (i.e. the researcher’s organisation).

List all of the Privacy Principle Codes (from Table 3) that apply. For example, if health information and other non-health personal information are being disclosed, record all relevant codes. **Remember that these Privacy Principles only relate to the disclosure (and use) of information and other Privacy Principles in that Act may also apply.**

Identify the individuals or organisations to which the information will be disclosed, if applicable. List the organisations by name (or by category if there are a large number, e.g. “child care centres”) and clearly indicate what information will be disclosed to each one.

Parts (c), (d) and (e) are key issues. The answers provided by the researcher to these questions will in large part determine whether the HREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals. Please refer to the guidelines for Question 2.4 parts (f) and (g) for guidance about the information sought from researchers in response to these questions. Researchers who have already answered similar questions in Questions 2.4 or 2.5 may refer to their earlier answers, if those answers are relevant.

## 2.7 General issues

These questions assist the HREC to determine whether other Privacy Principles have been adhered to.

(a) Provide an indication of the number of records that will be collected, used or disclosed in this project. A record is a set of information about an individual. If the information is only to be collected directly from the person to whom the information relates, then the number of records will be equal to the total number of participants in the project. If the information is to be collected from a hospital or a Department of Health and Human Services held dataset, then the number of records will be equal to the number of separate individuals, whether identifiable or non-identifiable, whose information is collected. If information is to be collected from participants and from datasets, then the number of records will be the sum total of the two. Provide approximate numbers if exact numbers are not known. Also specify the type of information that will be collected. Note that this question is part of the mandatory reporting requirement for HRECs.

(b) The use of unique identifiers and the adoption of identifiers assigned by another agency or organisation is dealt with in privacy legislation. Researchers should ensure that the use of identifiers is done in accordance with Privacy Principle dealing with Identifiers in any relevant privacy legislation.

(c) Trans-border data flow occurs if, for example, a researcher in Victoria sends data to a colleague interstate or overseas. Researchers should ensure that such data transfers of personal and/or health information are carried out in accordance with the Privacy Principle dealing with Trans-border Data Flows in any relevant privacy legislation.

(d) Indicate the period of time for which the information will be retained. Note that the Australian Code for the Responsible Conduct of Research (2007) recommends that data should be retained for at least 5 years from the date of publication, but in the case of clinical research, 15 years may be more appropriate. (see Australian Code 2.1.1). Note also that certain organisations in Victoria are subject to the Public Records Act 1973 (Vic).

(e) Describe the security arrangements for storage of the information, including who will have access to the information.

(f) If the research data will be 'banked' in a databank for possible use in future research, this additional information about how data will be stored and made available for future use should be provided. Researchers should be familiar with the requirements in the *National Statement* - Chapter 3.2: Databanks.

(g) Explain how the publication of results from this project will be handled in terms of the privacy of the individuals whose information has been used.

## **2.8 Other ethical issues**

Provide details of any other ethical issues (with respect to the collection, use or disclosure of information) not described above and how these issues will be addressed. Issues may include:

- Identification and reporting of illegal activities;
- Consequences of the findings of the project for indigenous or other special community or cultural groups (see *National Statement* Chapters 4.7 and 4.8).



## Information for Victorian Specific Module Section 3: *Research Involving the Use of Human Tissues or Blood, or Performance of Post Mortem*

---

The *Human Tissue Act 1982* (Vic) contains specific requirements about the consent for the removal of tissue or blood and the donation of human tissue after death, where the removal or donation is for medical and scientific purposes.

It is an offence to remove tissue from a person without the consent or authorisation that is required under the *Human Tissue Act 1982* (Vic).

### 3.1 Regenerative tissue

#### Definition of 'regenerative tissue'

"Regenerative tissue" means tissue that, after injury or removal, is replaced in the body of a living person by natural processes.

"Non-regenerative tissue" means tissue other than regenerative tissue.

(a) An adult may consent in writing to the removal of regenerative tissue for the purposes of transfer to another living person or for therapeutic, scientific or medical purposes. A medical practitioner may then issue a certificate of consent. The certificate will be sufficient authority to allow another medical practitioner to remove the tissue.

A consent or agreement given under the *Human Tissue Act 1982* (Vic) may be revoked. A certificate will not be sufficient authority for the removal of the tissue or blood if the consent has been revoked or if the medical practitioner who is removing the blood or tissue has reason to believe that the certificate of consent contains a false statement.

(b) A parent may give written consent for the removal of regenerative tissue from a child but only for the purposes of transplanting the tissue to a sibling or parent of the child. It is not lawful to remove non-regenerative tissue from the body of a living child for the purpose of the transplantation of the tissue to the body of another living person. Note that 'parent' does not include reference to any other guardian of a child.

#### Definition of 'child'

For the purposes of regenerative tissue removal, a 'child' is a person who has not attained the age of 18 years and is not married (see Section 2, *Human Tissue Act 1982* (Vic)).

### 3.2 Removal of blood

(a) As detailed in the *Human Tissue Act 1982* (Vic), an adult may consent to the removal of blood:

- for the purpose of a blood transfusion to another person; or
- for the purpose of using the blood or any of its constituents for other therapeutic purposes or for medical or scientific purposes.

(b) A parent of a child under 16 may consent to removal of blood from the child for the above purposes, provided the child agrees and a medical practitioner advises that the removal will not be prejudicial to the health of the child.

#### Definition of 'child'

For the purposes of blood removal, a 'child' is a person who has not attained the age of 16 years (see Section 20, *Human Tissue Act 1982* (Vic)).

### 3.4 Removal of tissue from a deceased person

Where a body is in a hospital, tissue may be removed from it for the purposes of the transplantation of the tissue to the body of a living person, or for use of the tissue for other therapeutic purposes or for medical or scientific purposes, on the authority of a designated officer of the hospital. That authority is only given if:

- certain consents have been obtained from the deceased or their senior available next of kin; or
- the designated officer cannot locate the senior available next of kin after reasonable enquiries, and has no reason to believe that the deceased expressed an objection to the removal of the tissue for the proposed purpose.

Where a body is in a place other than a hospital, a registered medical practitioner may remove tissue from the body if:

- the deceased consented or;
- the senior available next of kin have consented; or
- the registered medical practitioner cannot locate the senior available next of kin after reasonable enquiries, and has no reason to believe that the deceased expressed an objection to the removal of the tissue for the proposed purpose.

Authority shall not be given and tissue shall not be removed if the designated officer or registered medical practitioner has reason to believe that the deceased expressed an objection to tissue being removed.

When tissue is removed the senior available next of kin must be notified.

### **3.5 Fees**

Unauthorised sale or purchase of tissue is prohibited. The Minister may in writing authorise a person to buy tissue or take tissue from the body of another person, subject to conditions set out in the permit.