# Victorian-Specific Module

OFFICIAL

## Introduction

### What is the Victorian-Specific Module (VSM)?

The Victorian-Specific Module (VSM) forms part of the ethics application for a research project conducted in Victoria. This form assists the reviewing Human Research Ethics Committee (HREC) to assess whether the project meets relevant Victorian legislative requirements. The questions help researchers demonstrate that they have considered relevant Victorian legislative requirements. Each section of the form relates to a different piece of Victorian legislation:

- **Section 1** relates to the *Medical Treatment Planning and Decisions Act 2016 (Vic)* and is relevant for research projects that involve recruitment of participants who may not have decision-making capacity to consent.
- **Section 2** relates to the *Health Records Act 2001 (Vic)* and the *Privacy Act 1988 (Cth)* and is relevant for research projects that involve the collection, use and/or disclosure of personal and/or health information.
- **Section 3** relates to the *Human Tissue Act 1982 (Vic)* and is relevant for research projects that involve the removal of tissue or blood from a living or deceased adult or child, or performance of a post-mortem.

### When does the VSM need to be completed?

Researchers must complete and submit the VSM with the initial ethics application to the reviewing HREC whenever a Victorian site is involved. If researchers add a Victorian site after initial ethics approval, they must submit the VSM as part of the ethics amendment.

### Who should complete the VSM?

If the Coordinating Principal Investigator (CPI) is based in Victoria, they should complete and sign the VSM. If the Coordinating Principal Investigator (CPI) is based outside Victoria, a **Victorian Principal Investigator** (PI) from a participating Victorian site should complete the VSM, as they are expected to be familiar with the relevant legislation.

### How do I complete the VSM?

**For Ethical Review Manager (ERM) users**, complete and submit the VSM using the ERM online application system. The VSM is available as a sub-form of the Human Research Ethics Application (HREA).

**For non-ERM users**, complete the checklist below and Sections 1, 2 and 3 as applicable to the research project. Contact the reviewing HREC office for further information on how to submit this form.

## What if my research project is under National Mutual Acceptance (NMA)?

If a research project is reviewed under NMA and a Victorian site is participating in the research project, researchers **must submit the VSM to the reviewing HREC** as part of the ethics application regardless of which state/territory hosts the reviewing HREC.

# Research Project Information

## Research Project Details

| | |
|---|---|
| **HREC Reference Number** | |
| **Full Project Title** | |

## VSM Checklist

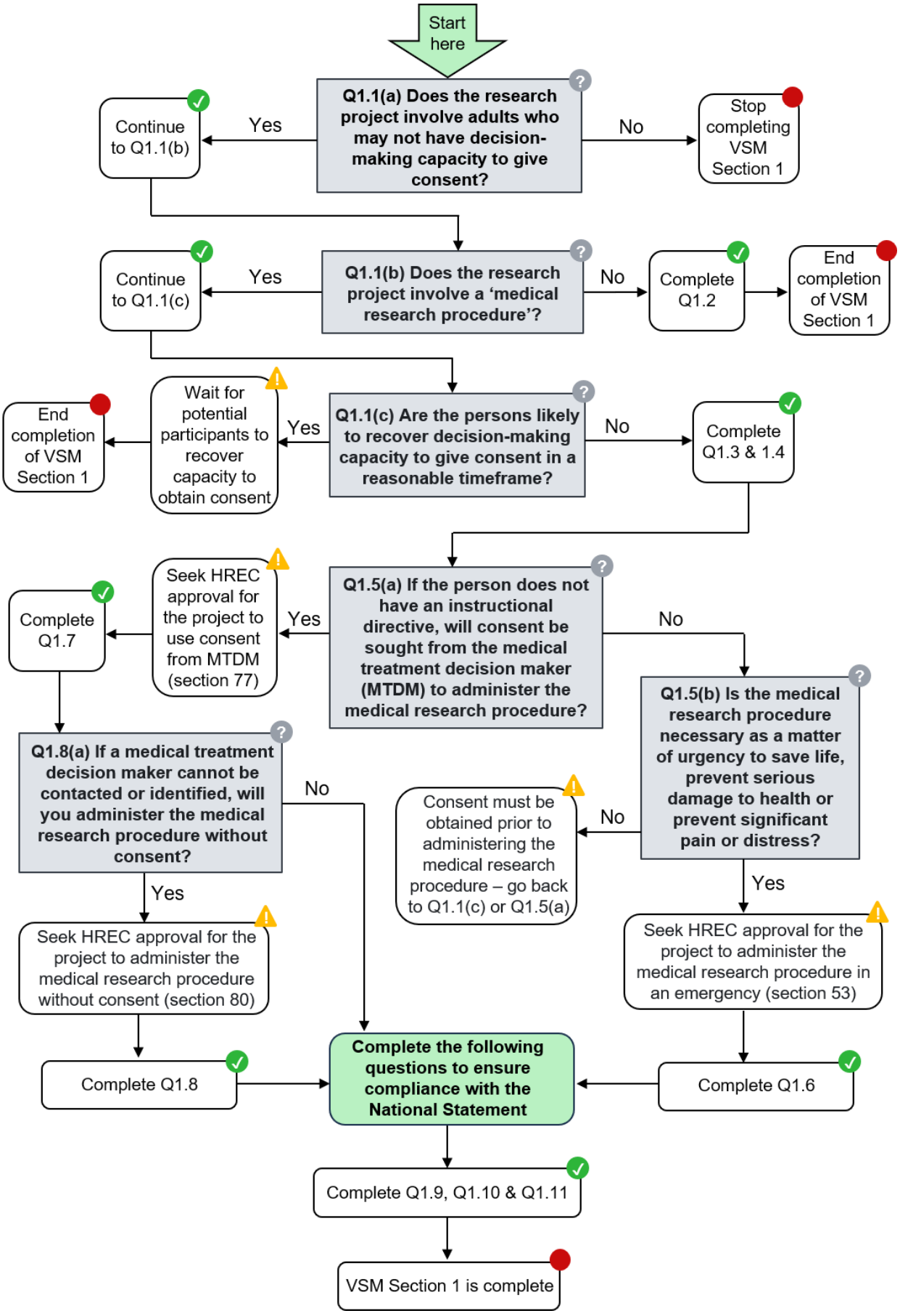
| | |
|---|---|
| Does the research involve recruitment of adult participants who may not have decision-making capacity to consent? | ☐ Yes ➔ complete **Section 1**<br>☐ No |
| Does the research involve the collection, use and/or disclosure of personal and/or health information? | ☐ Yes ➔ complete **Section 2**<br>☐ No |
| Does the research involve the removal of tissue or blood from a living or deceased adult or child, or performance of a post-mortem? | ☐ Yes ➔ complete **Section 3**<br>☐ No |

If you have answered 'no' to all the above questions, sign the section below and submit only **this Research Project Information section** to the HREC as part of your ethics application.

## Investigator Signature

| | | | |
|---|---|---|---|
| **Coordinating Principal Investigator (CPI) Name** | | | |
| **CPI Signature** | | **Date** | |
| **Victorian PI (if not CPI) Name** | | | |
| **Victorian PI Signature** | | **Date** | |

## Question and decision map to guide researchers in completing section 1 of the VSM.



# Section 1: Research projects involving adults (aged 18 years and over) who may not have decision-making capacity to consent to a medical research procedure

Please refer to the *Medical Treatment Planning and Decisions Act 2016* and the *National Statement on Ethical Conduct in Human Research 2025* in this section.

## 1.1 Applying the *Medical Treatment Planning and Decisions Act 2016*

### (a) Does the research project involve adults who may not have decision-making capacity to consent to a medical research procedure?

Section 4 of the *Medical Treatment Planning and Decisions Act 2016* states that a person has decision-making capacity if they can do the following:
(i) understand the information relevant to the decision and the effect of the decision;
(ii) retain the information to the extent necessary to make the decision;
(iii) use or weigh that information as part of the process of making the decision; and
(iv) communicate the decision and the person's views and needs as to the decision in some way.

Please refer to section 4 of the *Medical Treatment Planning and Decisions Act 2016* for the requirements when determining whether a person has decision-making capacity.

☐ **Yes → continue to 1.1(b)**

☐ **No → do not complete section 1 of the VSM**

### (b) Does the research project involve a 'medical research procedure'?

Section 3 of the *Medical Treatment Planning and Decisions Act 2016* defines a 'medical research procedure' as 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. It **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, collecting or using personal or health information.

☐ **Yes → continue to 1.1(c)**

☐ **No → skip to 1.2**

### (c) Are the persons likely to recover decision-making capacity within a reasonable time to give consent for the medical research procedure?

Section 72(3) of the *Medical Treatment Planning and Decisions Act 2016* defines a 'reasonable time' as 'the time by which, given the nature of the relevant research project, the procedure would need to be administered to the person, having regard to the following:
(a) the medical or physical condition of the person;
(b) the stage of medical treatment or care;
(c) other circumstances specific to the person'.

☐ **Yes → you must wait for potential participants to recover to obtain consent. Do not complete section 1 of the VSM.**

☐ **No → skip to 1.3**

## 1.2 Research projects not involving a medical research procedure

If a research project does not involve a medical research procedure, the *Medical Treatment Planning and Decisions Act 2016* does not apply. Researchers should refer to the *National Statement on Ethical Conduct in Human Research 2025,* section 4.5 for guidance in this situation.

**(a) Please explain why the examinations and observations in this research project do not meet the definition of a 'medical research procedure'.**

**(b) Who will provide consent for participation in the research?**

**(c) How will you obtain and record consent? Explain how you will obtain and record written and/or verbal consent.**

**Stop completing section 1. Continue to other sections that apply.**

## 1.3 Assessing decision-making capacity

**(a) Who will determine that the person does not have decision-making capacity? Include their qualifications and role(s) in the research project.**

**(b) Please describe the criteria for assessing decision-making capacity.**

**(c)** **Indicate which group the persons who may not have decision-making capacity fall into (select all that apply). Note:** A diagnosis, disability, communication difficulty or legal status does not, by itself, mean that a person lacks decision-making capacity. Capacity must be assessed individually in relation to the particular decision.

- ☐ **Intellectual impairment**
- ☐ **Physical disability**
- ☐ **Highly dependent on medical care**
- ☐ **Unconscious**
- ☐ **A forensic patient**
- ☐ **A security patient**
- ☐ **Brain injury**
- ☐ **Dementia**
- ☐ **Impaired capacity for communication**
- ☐ **Mental illness**
- ☐ **An involuntary patient**
- ☐ **Other: _____**

## 1.4 Ascertaining if a person has an advance care directive

Some people may have an advance care directive containing an instructional directive consenting to a medical research procedure. Before administering a medical research procedure, researchers must make reasonable efforts in the circumstances to ascertain if the person has an advance care directive (section 73 of the *Medical Treatment Planning and Decisions Act 2016*).

**(a)** **Describe the steps you will take to find out if a person without decision-making capacity has an advance care directive, locate it and determine if there is a relevant instructional directive.**

**(b)** **Please explain:**

- how you would determine the relevance of an instructional directive to the medical research procedure in the research project
- how you believe the instructional directive would be sufficient for consent
- how you will determine whether there is sufficient information regarding consent in a person's instructional directive

Refer to section 75(b)(i) of the *Medical Treatment Planning and Decisions Act 2016*.

## 1.5 Options to administer a medical research procedure if there is no instructional directive

**(a) If the person does not have an instructional directive, will you seek consent from the medical treatment decision maker to administer the medical research procedure?**

☐ **Yes → skip to 1.7**

☐ **No → continue to 1.5(b)**

**(b) Is the medical research procedure necessary as a matter of urgency to save life, prevent serious damage to health or prevent significant pain or distress?**

☐ **Yes → continue to 1.6**

☐ **No → you cannot administer the medical research procedure without consent under section 53 of the *Medical Treatment Planning and Decisions Act* 2016. The person or the medical treatment decision maker must provide consent. Review question 1.1(c) and 1.5(a).**

## 1.6 Medical research procedures in an emergency

*Medical Treatment Planning and Decisions Act 2016, section 53*

**(a) Explain why administering the medical research procedure is necessary as an emergency measure (to save life, prevent serious damage to health or prevent significant pain or distress) and why it is appropriate in the circumstances.**

**(b) While consent to administer the medical research procedure is not required, please explain if you will inform the medical treatment decision maker of the person's enrolment in the research project and how you will convey this information.**

**Skip to 1.9 – Consent for continued participation**

## 1.7 Obtaining consent from the medical treatment decision maker

*Medical Treatment Planning and Decisions Act 2016*, section 77

**(a) Describe the procedures you will follow to identify and contact the medical treatment decision maker to determine whether they will give consent for the person to be involved in the research project.**

**(b) How will you obtain consent from the medical treatment decision maker? Explain in detail below how you will obtain and record written and/or verbal consent.**

## 1.8 Administering a medical research procedure if the person has no medical treatment decision maker

*Medical Treatment Planning and Decisions Act 2016*, section 80

There may be circumstances in which researchers are unable to identify or contact a medical treatment decision maker. If researchers cannot locate an instructional directive and cannot identify or contact a medical treatment decision maker, they can only administer the medical research procedure if the Human Research Ethics Committee (HREC) has granted approval for enrolment under section 80 of the *Medical Treatment Planning and Decisions Act 2016*.

**(a) If you cannot contact or identify a medical treatment decision maker, will you administer the medical research procedure without consent?**

☐ **Yes → continue to 1.8(b)**

☐ **No → skip to 1.9**

**(b) Describe how you would identify the following:**

- a person's values, whether expressed by way of a values directive or inferred from the person's life;
- any other relevant preferences that the person has expressed; and
- the personal and social wellbeing of the person, having regard to the need to respect the person's individuality.

Refer to section 80(1)(b) of the *Medical Treatment Planning and Decisions Act 2016*

**(c) Describe the following:**

- how one of the purposes of the research project is to assess the effectiveness of the research procedure; and
- that the research procedure poses no more of a risk to the person than the risk inherent in their condition and alternate medical treatment

Refer to section 80(1)(c) of the *Medical Treatment Planning and Decisions Act 2016.*

**(d) Describe how the research project is based on a valid scientific hypothesis that supports a reasonable possibility of benefit for the person as compared with standard treatment.**

Refer to section 80(1)(d) of the *Medical Treatment Planning and Decisions Act 2016.*

**(e) Describe the process for completing and submitting the medical research practitioner's certificate to the Office of the Public Advocate and the reviewing Human Research Ethics Committee (HREC), and for including the certificate in the person's medical record.**

Refer to section 81 of the *Medical Treatment Planning and Decisions Act 2016.*

## 1.9 Consent for continued participation

Following administration of the medical research procedure, it may be necessary to obtain consent from the person or the medical treatment decision maker for continued participation in the research project. In this situation, the medical researcher should continue to assess the person's capacity to consent and/or make attempts to identify and contact the medical treatment decision maker. The medical researcher should give the person or the medical treatment decision maker the option to continue in the research project or withdraw. Refer to the *Medical Treatment Planning and Decisions Act 2016*, section 81 and *National Statement on Ethical Conduct in Human Research 2025*, sections 4.5.23, 4.5.24 and 4.5.34.

**(a) Will you seek agreement for continued participation from the participant and/or the medical treatment decision maker?**

☐ **Yes → skip to 1.9(c)**

☐ **No → continue to 1.9(b)**

**(b) Please explain why you will not seek agreement for continued participation.**

**(c) Describe the ongoing process for reviewing a person's capacity to agree while the research project is in progress.**

**(d) Describe the steps that you will take to identify and contact the medical treatment decision maker after a medical research procedure has been administered without consent.**

If you will always obtain consent prior to administering the medical research procedure, please write "not applicable".

**(e) If the person or the medical treatment decision maker does not agree to continued participation in the research project, explain:**

- how you will end the person's participation in the research project as soon as safely practicable
- how you will manage the data you have already collected and whether you will destroy or retain the data

## 1.10 Waiver of the requirement for consent to keep and use data

There may be a situation where the person does not recover capacity, the medical treatment decision maker cannot be contacted, or it would be inappropriate to contact the medical treatment decision maker. Consider if you will seek a waiver of the requirement for consent for this research project. If approved by the Human Research Ethics Committee (HREC), a waiver may permit the retention **and use of data following administration of the medical research procedure**. You can find the conditions that a research project must meet for the HREC to approve a waiver in section 2.3.10 of the *National Statement on Ethical Conduct in Human Research 2025*.

**(a) Are you requesting a waiver for the requirement for consent for the collection, use and disclosure of data?**

☐ **Yes → continue to 1.10(b)**

☐ **No → skip to 1.11**

**(b) Please explain how the research project meets the requirements of section 2.3.10 of the *National Statement on Ethical Conduct in Human Research 2025* if not already detailed in the human research ethics application (HREA).**

## 1.11 Participant Information and Consent Forms

The design of a research project and how researchers will obtain consent determines the types of participant information and consent forms (PICFs) researchers need to develop. One research project might require different consent forms for before and after administering a medical research procedure.

**(a) Indicate the types of participant information and consent forms you will use to obtain consent prior to administering the medical research procedure:**

☐ **Consent to administer a medical research procedure - medical treatment decision maker**

☐ **Other:** _____

**(b) Indicate the types of participant information and consent forms you will use to obtain consent following administration of the medical research procedure:**

☐ **Consent for continued participation – participant**

☐ **Consent for continued participation – medical treatment decision maker**

☐ **Other:** _____

**You have completed section 1 of the VSM.**

# Section 2: Research projects involving the collection, use and/or disclosure of information

Please refer to *Privacy Act 1988 (Cth)* and *Health Records Act 2001 (Vic)* in this section.

Researchers have a legal as well as an ethical obligation to consider privacy issues. The following questions assist researchers, the HREC and the institution to fulfil their obligations under State and Commonwealth privacy legislation.

**Table 1: Privacy Principles.**

Use this table to identify relevant privacy principles for the type of information and organisation involved in your research project. List the relevant codes in the response fields below.

| Type of information | Type of organisation(s) involved | Privacy Principle Codes – Data Collection | Privacy Principle Codes – Data Use and Disclosure |
|---|---|---|---|
| Health information | Victorian public sector | HPP1 | HPP2 |
| | Victorian private sector | HPP 1, APP 2, APP 3, APP 5 | HPP 2, APP 6<br>Where disclosure is cross-border: APP 8, HPP 9 |
| | Commonwealth public sector | APP 2, APP 3, APP 5 | APP 6 |
| | Other | APP 3, APP 5 | APP 6 |
| Personal information (other than health information) | Victorian public sector | APP 2, APP 3, APP 5 | APP 6 |
| | Victorian private sector | APP 2, APP 3, APP 5 | APP 3, APP 5 |
| | Commonwealth public sector | APP 2, APP 3, APP 5 | APP 6 |
| | Other | APP 3, APP 5 | APP 6 |
| Sensitive information | Victorian public sector | APP 3 | APP 6 |
| | Victorian private sector | APP 3 | APP 3, APP 6 |
| | Commonwealth public sector | APP 3 | APP 3, APP 6 |
| | Other | APP 3 | APP 3, APP 6 |

APP - Australian Privacy Principle, *Privacy Act 1988 (Cth)*
HPP - Health Privacy Principle, *Health Records Act 2001 (Vic)*

## 2.1 Collection of participants' information

**(a) Does the research project involve collection of information about persons without their knowledge or consent?**

☐ **Yes → skip to 2.2**

☐ **No → continue to 2.1(b)**

**(b) What type of information will you collect? (select all that apply)**

☐ **Personal information**

☐ **Sensitive information**

☐ **Health information**

**(c) Will you seek participants' consent to use the collected information for:**

☐ **This research project (specific consent)**

☐ **Future research projects related to this project (extended consent)**

☐ **Any future research projects (unspecified consent)**

**(d) Does the research project involve the establishment of a databank?**

☐ **Yes**

☐ **No**

**(e) Please indicate whether the participant information and consent form explains each of the following items:**

| | Yes | No | N/A |
|---|---|---|---|
| What information will researchers collect? | ☐ | ☐ | ☐ |
| Why will researchers collect the information? | ☐ | ☐ | ☐ |
| How will researchers use the information in the future (if seeking extended or unspecified consent)? | ☐ | ☐ | ☐ |
| What unspecified consent may mean for participants (if seeking unspecified consent)? | ☐ | ☐ | ☐ |
| What terms apply to unspecified consent (if seeking unspecified consent)? | ☐ | ☐ | ☐ |
| Whether researchers are seeking permission to enter the information into a databank? | ☐ | ☐ | ☐ |
| How long will researchers keep records relating to participants? | ☐ | ☐ | ☐ |
| How will researchers store information (including whether it will be identifiable)? | ☐ | ☐ | ☐ |
| What steps will researchers take to ensure information is kept confidential and stored securely? | ☐ | ☐ | ☐ |
| The types of people or organisations to which the organisation conducting the research usually discloses this kind of information. | ☐ | ☐ | ☐ |
| How will researchers protect privacy and confidentiality when publishing information? | ☐ | ☐ | ☐ |
| The possibility that participants may access their information | ☐ | ☐ | ☐ |
| Any law that requires researchers to collect the information? | ☐ | ☐ | ☐ |
| Any consequences for participants if they do not provide all or part of the information? | ☐ | ☐ | ☐ |
| The identity of the organisation conducting the research and how participants can contact it? | ☐ | ☐ | ☐ |

**(f) If you answered 'no' to any of the questions in 2.1(e), provide the reasons why you have not included this information in the participant information and consent form.**

## 2.2 Collection, use or disclosure of identifiable information

**(a) Does the research project involve the collection, use or disclosure of individually identifiable or re-identifiable information from sources other than the person to whom the information relates?**

Note 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'.

☐ **Yes → continue to 2.2(b)**

☐ **No → skip to 2.6**

**(b) Does the research project involve the collection, use or disclosure of information without the consent of the person to whom the information relates (or their legal guardian)?**

☐ **Yes → continue to 2.3**

☐ **No → skip to 2.6**

## 2.3 Collection of information from a third party

**(a) Are you requesting approval from this HREC for the collection of information from a third party?**

Answer 'yes' if this research project involves collection of **individually identifiable or re-identifiable information** from a source other than the individual (or their legal guardian) without the individual's or legal guardian's consent.

☐ **Yes → continue to 2.3(b)**

☐ **No → skip to 2.4**

**(b) From which of the following sources will you collect information? Select all that apply.**

☐ **A Victorian public health service provider**

☐ **A Victorian private health service provider**

☐ **An organisation other than a health service provider**

☐ **A dataset under the auspices of the Victorian Department of Health**

☐ **A dataset under the auspices of another Victorian government department**

☐ **A dataset from another Victorian source**

☐ **A Commonwealth agency**

☐ **An agency from another state**

☐ **An 'organisation' as defined in the *Privacy Act 1988 (Cth)***

☐ **An individual such as a carer**

☐ **Other: _____**

**For each source of information selected above, indicate clearly what information you will collect from each one in the table below.**

| Source of information | Type of information you will collect |
|---|---|
| *Example: public hospital, carers* | *Example: contact information, complete medical history* |
| | |
| | |
| | |
| | |
| | |

**(c) Have you obtained agreement from all organisations to collect this information?**

☐ **Yes – provide evidence of this agreement and details of any conditions imposed by the organisation(s) concerning the release of the information.**

☐ **No – explain below how and when you will obtain agreement from the disclosing organisation.**

**(d) Have any organisations from which you are collecting information sought separate HREC approval to disclose that information?**

Note: The organisation(s) disclosing the information do not need to obtain separate HREC approval to disclose the information by law.

☐ **Yes – supply a copy of the decision from the other HREC (when available)**

☐ **No – you will have to forward a copy of any approval from this HREC to the disclosing organisation**

**(e) Do you (or researchers in your team) have routine access to the information you are collecting from organisations?**

☐ **Yes**

☐ **No**

**(f) For the information that you will collect, list the relevant Privacy Principle Codes.**

Refer to Table 1: Privacy Principles (e.g. HPP1, APP 3)

**(g) Will you collect the information for deposit in a databank?**

☐ **Yes**

☐ **No**

**(h) Please explain why you will not collect information in a non-identifiable form.**

**(i) Please explain why you will not obtain consent from the individual(s) whose information you will collect.**

Refer to the *Health Records Act 2001 (Vic) Statutory Guidelines on Research*.

**(j) Please explain why collecting this information is in the public interest. Note that the public interest in the proposed research project must substantially outweigh the public interest in respecting individual privacy.**

## 2.4 Use of information

**(a) Are you seeking approval from this HREC for use of information?**

Answer 'yes' if this research project involves use of **individually identifiable or re-identifiable information** without the consent of the individual to whom the information relates (or their legal guardian).

☐ **Yes → continue to 2.4(b)**

☐ **No → skip to 2.5**

**(b) For the information that you will use, list the relevant Privacy Principle Codes.**

Refer to Table 1: Privacy Principles (e.g. HPP1, APP 3)

**(c) Please explain the specific purposes for which you will use the information.**

**(d) Is the purpose for which you are using the information in this research project (the secondary purpose) related to the purpose for which the information was originally collected (the primary purpose)?**

☐ **Yes → complete the field below for 2.4(d)**

☐ **No → skip to 2.4(e)**

**Please explain how the secondary purpose is related to the primary purpose.**

**(e) Please explain why you will not use information in a non-identifiable form.**

If your answer is the same as for Q2.3(h), record “as above”.

**(f) Please explain why you will not obtain consent from the individual(s) whose information you will use.**

If your answer is the same as for Q2.3(i), record “as above”.

**(g) Please explain why using this information is in the public interest. Note that the public interest in the proposed research project must substantially outweigh the public interest in respecting individual privacy.**

If your answer is the same as for Q2.3(j), record “as above”.

## 2.5 Disclosure of information

### (a) Are you seeking approval from this HREC for disclosure of information?

Answer 'yes' if this research project involves disclosure of **individually identifiable or re-identifiable information** without the consent of the individual to whom the information relates (or their legal guardian).

☐ **Yes → continue to 2.5(b)**

☐ **No → skip to 2.6**

### (b) Will an organisation disclose individually identifiable or re-identifiable information to you as part of this research project?

☐ **Yes → complete the fields below for 2.5(b)**

☐ **No → skip to 2.5(c)**

**For the information that the organisation(s) will disclose to you, list the relevant Privacy Principle Codes.**

Refer to Table 1: Privacy Principles (e.g. HPP1, APP 3)

**List the organisations that will disclose information to you as part of this research project. If there is more than one organisation involved, indicate clearly what information or records each organisation will disclose.**

### (c) Will you disclose individually identifiable or re-identifiable information to other organisations?

☐ **Yes → complete the fields below for 2.5(c)**

☐ **No → skip to 2.6**

**For the information you will disclose to other organisations, list the relevant Privacy Principle Codes.**

Refer to Table 1: Privacy Principles (e.g. HPP2, APP 6)

**List the organisations to which you will disclose information. If you will disclose information to more than one organisation, indicate clearly what information or records you will disclose to each.**

**(d) Please explain why you will not disclose information in a non-identifiable form.**

If your answer is the same as for Q2.3(h) or Q2.4(e), record “as above”.

**(e) Please explain why you will not obtain consent from the individual(s) whose information you will disclose.**

If your answer is the same as for Q2.3(i) or Q2.4(f), record “as above”.

**(f) Please explain why disclosing this information is in the public interest. Note that the public interest in the proposed research project must substantially outweigh the public interest in respecting individual privacy.**

If your answer is the same as for Q2.3(j) or Q2.4(g), record “as above”.

## 2.6 General issues

**(a) Please complete the table below to record:**

- the source of information that you will collect, use and/or disclose
- the number of records from each source
- the type of information (e.g. date of birth, medical history)

| Source | Number of records | Type of information |
|---|---|---|
| *Example: medical record* | *Example: 100* | *Example: Medical history* |
| | | |
| | | |
| | | |

**(b) Will you use unique identifiers that other agencies or organisations have assigned to individuals?**

☐ **Yes → complete the field below for 2.6(b)**

☐ **No → skip to 2.6(c)**

**Please explain how you will do this in accordance with relevant Privacy Principles (e.g. HPP7, APP 9).**

**(c) Will data move interstate or overseas as part of this research project?**

☐ **Yes → complete the field below for 2.6(c)**

☐ **No → skip to 2.6(d)**

**Please explain how you will do this in accordance with relevant Privacy Principles (e.g. HPP9, APP 8).**

**(d) For how long will you retain the information? How will you dispose of the information at the end of this period?**

**(e) Please explain the following:**

- **How will you securely store the information?**
- **Where will you store the information?**
- **Who will have access to the information?**

**(f) If you will store data in a databank for future research, complete the following information:**

Refer to National Statement, chapter 3.1

| Information required | Response |
|---|---|
| Name of databank | |
| Form in which you will store data | |
| Purpose of future use | |
| How will you record restrictions on the use of data to ensure future adherence? | |
| Data custodian's name | |
| Position | |
| Department | |
| Organisation | |

**(g) How will you respect the privacy of individuals in any publication arising from this project?**

**(h) Discuss any other ethical issues relevant to the collection, use or disclosure of information proposed in this project. Explain how you will address these issues.**

**You have completed section 2 of the VSM.**

# Section 3: Research involving the use of human tissues or blood, or performance of post-mortem

Please refer to *Human Tissue Act 1982* in this section.

## 3.1 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) Will the research involve removing regenerative tissue from an adult?**

☐ **Yes → complete the fields below for 3.1(a)**

☐ **No → skip to 3.1(b)**

**Please explain how you will obtain consent from the donor for the removal of tissue.**

**Please explain how you will arrange for a medical practitioner to issue a certificate of consent.**

**Please explain how you will receive and record any withdrawal of consent.**

**(b) Will the research project involve removing tissue from a child?**

The *Human Tissue Act 1982* defines a child as a person who is **under the age of 18** and is not married.

Under the *Human Tissue Act 1982*, it is not lawful to remove regenerative tissue or non-regenerative tissue from a child, for research purposes, irrespective of whether a parent has given consent. 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.

☐ **Yes**

☐ **No**

## 3.2 Blood

### (a) Will the research project involve collecting blood from an adult?

☐ **Yes → complete the fields below for 3.2(a)**

☐ **No → skip to 3.2(b)**

**Please explain how you will obtain consent from the adult for the collection of blood.**

**Please explain how you will receive and record any withdrawal of consent.**

### (b) Will the research project involve the collection of blood from a child?

Section 20A of the *Human Tissue Act 1982* defines a child as a person who has **not attained the age of 16 years.**

☐ **Yes → complete the fields below for 3.2(b)**

☐ **No → skip to 3.3**

**Please explain how you will obtain consent from the child's parent(s) for the removal of blood.**

**Please explain how you will receive and record any withdrawal of consent.**

## 3.3 Post-mortem

### (a) Will the research project involve a post-mortem?

☐ **Yes → complete the field below for 3.3(a)**

☐ **No → skip to 3.3(b)**

**Please explain how you will obtain or verify necessary consent.**

**(b) Will the research project involve removal of tissue from a deceased person?**

☐ **Yes → complete the field below for 3.3(b)**

☐ **No → skip to 3.3(c)**

**Please explain how you will obtain or verify necessary consent.**

**(c) Will the research project involve any fee being paid or offered in exchange for human tissue, or in exchange for the right to take human tissue from a body?**

☐ **Yes → complete the field below for 3.3(c)**

☐ **No → you have completed section 3 of the VSM.**

**Provide details.**

## You have completed section 3 of the VSM.

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