**Victorian-Specific Module**

**INTRODUCTION**

**Important Information**

If the **Human Research Ethics Application (HREA)** is used for an ethics application, the Victorian Specific Module (VSM) must be submitted to the reviewing Human Research Ethics Committee (HREC) as part of the ethics application. Complete the checklist below, and Sections 1, 2 and 3 as applicable to the research project. Sections that are not relevant to the research project may be deleted.

If the **Victorian Low and Negligible Risk (LNR VIC)** application form is used for an ethics application, the VSM is not required. *Please note that some reviewing HRECs may not accept the LNR VIC; always discuss the research project with the reviewing organisation’s research office before creating an ethics application for a low risk research project.*

**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 research project, the VSM **must be submitted to the reviewing HREC** as part of the ethics application regardless of which state/territory hosts the reviewing HREC.

If the Coordinating Principal Investigator (CPI) is based outside Victoria, it is recommended that the VSM 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 VSM in the ‘Research Project Details’ section below. However, if a Victorian PI has completed the VSM on behalf of an interstate CPI, the Victorian PI should sign.

**Checklist**

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| Does the research involve recruitment of adult research participants who do not have decision making capacity to consent? | [ ]  Yes 🠊 complete **Section 1**[ ]  No |
| Does the research involve the collection, use and/or disclosure of personal and/or health information? | [ ]  Yes 🠊 complete **Section 2**[ ]  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**[ ]  No |

If you have answered ‘No’ to all of the above questions, delete Sections 1, 2 & 3 and submit only the VSM Introduction (pages 1 and 2) as part of the ethics application.

**Research Project Details**

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| --- | --- |
| **HREC Reference Number** |  |
| **Full Project Title** |  |
| **Principal Investigator Name** |  |
| **Signature** |  | **Date** |  |

**Contact Details**

Provide details as applicable.

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| **Study Coordinator** |
| **Name** |  |
| **Position** |  |
| **Organisation** |  |
| **Address** |  |
| **Email** |  |
| **Phone** |  |

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| **Sponsor/Contract Research Organisation** |
| **Name** |  |
| **Position** |  |
| **Organisation** |  |
| **Address** |  |
| **Email** |  |
| **Phone** |  |

**SECTION 1: Research Involving the Recruitment of Adults who do not have decision making capacity to consent**

* 1. **Consent**
1. Will there be participants who do **not** have the capacity to give consent?
2. [ ]  Yes [ ]  No (Do not complete any more of Section 1)
3. Does the project involve a ‘medical research procedure’ (see Guidelines for definition)?

*Complete these questions if a project involves a ‘medical research procedure’ as defined by the Medical Treatment Planning and Decisions Act 2016. This includes a ‘medical research procedure’ performed on a forensic, compulsory or security patient as defined by the Mental Health Act 2014.*

[ ]  Yes [ ]  No (Do not complete any more of Section 1)

1. There may be participants in this project that have an Advance Care Directive containing an instructional directive.
2. Outline the steps you will take to know of and locate an Advance Care Directiveincluding an instructional directive for all participants who do not have decision making capacity (refer to the *Medical Treatment and Planning Decisions Act,* Part 5 **Section 73**).

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1. Give a full explanation of the following steps and how you will determine whether there is sufficient information regarding consent in that patient’s Advance Care Directive (refer to the *Medical Treatment and Planning Decisions Act*, Part 5 **Section 75**).

Steps:

• Explain how you would determine the relevance of the Advance Care Directive to the medical research procedure in the research project (refer to the *Medical Treatment and Planning Decisions Act*, **Part 1**).

• Explain how you believe the Advance Care Directive would be sufficient for consent

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1. Is the medical research procedure in the Advance Care Directive relevant to this research project?

[ ]  Yes, go to the next question

[ ]  No, go to Question 1.1 (b)( v )

1. Is the information in the Advance Care Directive sufficient for consent to this study’s medical research procedure?

[ ]  Yes - If Yes, provide in detail information in the Advance Care Directive relating to consent. Complete Question 1.2 only

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[ ]  No - If No, proceed to Question 1.1 (b) (v)

1. Will consent be obtained from another individual? *Tick both if applicable.*

 [ ]  Yes - Complete Question 1.1 (b) (vi) and 1.1 (b)(vii) only

 [ ]  No - to Question 1.1 (b) (viii)

1. Who will be asked to provide consent? *Tick all that apply.*

[ ]  Parent/guardian for participants under 18 years of age

[ ]  ‘Medical treatment decision maker’(as defined in the *Medical Treatment Planning and Decisions Act 2016*)

**Note:** only applies to ‘**medical research procedures**’ (as defined in the *Medical Treatment Planning and Decisions Act 2016*) involving adult participants.

[ ]  Other (e.g. Next-of-kin for adult participants in research that does **not** involve any ‘medical research procedure’ (as defined in the *Medical Treatment Planning and Decisions Act 2016*). Give details.

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1. How will consent be obtained?

[ ]  Written consent form

[ ]  Verbal – explain below, in detail, how consent will be obtained and recorded

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**(viii)** Identify the procedures that will be used to recruit participants without consent

*Note: Complete both options if applicable. These options only apply to ‘medical research procedure’ (as defined in the* Medical *Treatment Planning and Decisions Act 2016)*

[ ]  Consent will not be obtained and participants will be included in the research in accordance with the ‘medical research procedures in an emergency’ provisions of the *Medical Treatment Planning and Decisions Act 2016,* **Section 53**.

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[ ]  Administering medical research procedures without consent where a person without decision making capacity does not have an Advance Care Directive or a medical treatment decision maker.

 How would you identify a person’s preferences and values whether expressed or inferred from the person’s life or from the personal and social wellbeing of the person (refer to the *Medical Treatment Planning and Decisions Act 2016*, **Section 81**)

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1. Name the registered medical research practitioner who will make this determination, and what criteria will be used

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1. Describe the ongoing process for reviewing participants’ capacity to consent and participate while the research is in progress.

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* 1. Indicate which group the proposed participants, who do not have decision making capacity, fall into:

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| [ ]  Intellectual impairment | [ ]  Brain injury |
| [ ]  Physical disability | [ ]  Dementia |
| [ ]  Highly dependent on medical care | [ ]  Impaired capacity for communication |
| [ ]  Unconscious | [ ]  Mental illness |
| [ ]  A forensic patient | [ ]  An involuntary patient |
| [ ]  A security patient | [ ]  Other: please specify |
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* 1. Does the research project involve a ‘medical research procedure’ that will be necessary as a matter of urgency to save life, prevent serious damage to health or prevent significant pain or distress?

*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*** *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).*

 [ ]  Yes [ ]  No(**Part 5** of the *Medical Treatment and Planning and Decisions Act 2016* applies Continue to Questions 1.4 – 1.7))

If Yes, provide detailed information.

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

Do you anticipate that patients will be likely to recover capacity to consent within a reasonable timeframe?

[ ]  Yes [ ]  No (Go to Question 1.5)

If Yes, wait and seek patient consent.

* 1. *If patients are not likely to recover capacity within a reasonable timeframe then consent may be given by the ‘****medical treatment decision maker’.***
1. Do you anticipate obtaining consent from a ‘medical treatment decision maker’?

[ ]  Yes [ ]  No

If Yes, describe the procedures you will follow to identify and contact the ‘medical treatment decision maker’ to determine if they will give consent for the participant to be involved in the research project.

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1. How will consent be obtained from the ‘medical treatment decision maker’?

[ ]  Written Consent Form

[ ]  Oral – explain below, in detail, how consent will be obtained and recorded

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* 1. *If the ‘medical treatment decision maker’ for a patient cannot be ascertained or contacted that patient may be included in the study if the requirements for medical research procedures without consent are met as detailed in the Medical Treatment Planning and Decisions Act 2016,* **Section 80***.*

*If the situation arises and you want to include such patients in your research project, you will need to initiate the medical research procedures without consent.*

1. Do you anticipate including patients in the study using medical research procedures without consent?

[ ]  Yes

[ ]  No (Do not complete any more of Section 1)

1. Provide details regarding how this research project satisfies the requirements for medical research procedures without consent.

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1. Provide details of the steps to be taken to identify and contact a ‘medical treatment decision maker’ following a medical research procedure without consent.

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* 1. List the type of PICFs for the research project. Refer to the links to locate the PICFs.
* [Clinical Trials](https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials)
* [Health and medical research](https://www2.health.vic.gov.au/about/clinical-trials-and-research/health-and-medical-research/how-to-make-an-hrec-application-and-reporting)

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**SECTION 2: Research Involving the Collection/Use/Disclosure of Information**

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

Table 1: Privacy Principles

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| --- | --- | --- |
| **Type of Information** | **Type of Organisation(s) Involved** | **Privacy Principle Codes** |
| **Data Collection** | **Data Use & Disclosure** |
| Health information | Victorian public sector | HPP 1 | HPP 2 |
| Victorian private sector | HPP 1, APP 2, APP 3, APP 5 | HPP 2, APP 6Where 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

1. Does the project involve collection of information about individuals without their knowledge or consent?

[ ]  Yes (Go to Question 2.2) [ ]  No (Answer the following questions)

1. What type of information will be collected? (Tick all that apply)

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| [ ]  Personal information  |
| [ ]  Sensitive information |
| [ ]  Health information |

1. Will participants’ consent be sought to use the collected information for

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| [ ]  This research project (specific consent) |
| [ ]  Future research related to this project (extended consent) |
| [ ]  Any future research (unspecified consent) |

1. Does the project involve the establishment of a databank?

 [ ]  Yes [ ]  No

1. Does the Participant Information and Consent Form explain the following:

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| --- | --- | --- | --- |
|  | Yes | No | N/A |
| What information is being collected? |[ ] [ ]   |
| The purposes for which the information is being collected? |[ ] [ ]   |
| The extent of future use of data (if you are seeking extended or unspecified consent)? |[ ] [ ] [ ]
| The wide-ranging implications of unspecified consent (if you are seeking unspecified consent)?  |[ ] [ ] [ ]
| A description of the terms of the unspecified consent (if you are seeking unspecified consent)? |[ ] [ ] [ ]
| If permission is being sought to enter the information into a databank? |[ ] [ ] [ ]
| The period for which the records relating to the participant will be kept? |[ ] [ ]   |
| The form in which the data will be stored (i.e. whether identifiable or not)? |[ ] [ ]   |
| The steps taken to ensure confidentiality and secure storage of data? |[ ] [ ]   |
| The types of individuals or organisations to which your organisation usually discloses information of this kind? |[ ] [ ]   |
| How privacy and confidentiality will be protected in any publication of the information? |[ ] [ ]   |
| The fact that the individual may access that information? |[ ] [ ]   |
| Any law that requires the particular information to be collected? |[ ] [ ]   |
| The consequences (if any) for the individual if all or part of the information is not provided? |[ ] [ ]   |
| The identity of the organisation collecting the information and how to contact it? |[ ] [ ]   |

1. If you answered *No* to any of the questions in (e), give the reasons why this information has not been included in the Participant Information and Consent Form.

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

1. Does the project involve the collection, use or disclosure of **individually identifiable or re-identifiable** information from sources other than the individual 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’.*

[ ]  (Answer the following questions) [ ]  No (Go to Question 2.7)

1. Does the project involve the collection, use or disclosure of information **without the consent** of the individual to whom the information relates (or their legal guardian)?

[ ]  Yes (Answer the following questions) [ ]  No (Go to Question 2.7)

**2.3 Type of activity proposed**

*Answer all three parts of Question 2.3 (a), (b) and (c).*

1. Are you seeking approval from this HREC for collection of information from a third party?

[ ]  Yes (Answer Question 2.4) [ ]  No (Do not answer Question 2.4)

1. Are you seeking approval from this HREC for use of information?

[ ]  Yes (Answer Question 2.5) [ ]  No (Do not answer Question 2.5)

1. Are you seeking approval from this HREC for disclosure of information?

 [ ]  Yes (Answer Question 2.6) [ ]  No (Do not answer Question 2.6)

If you have answered *No* to all three parts of Question 2.3, go directly to Question 2.7

**2.4 Collection of information from a third party**

*Only answer this question if the project involves the collection of individually identifiable or re-identifiable information from a source other than the individual (or their legal guardian) without the consent of the individual or their legal guardian.*

1. From which of the following sources will information be collected? *Tick all that apply.*

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| [ ]  A Victorian public health service provider |
| [ ]  A Victorian private health service provider |
| [ ]  An organisation other than a health service provider |
| [ ]  A data set under the auspices of the Victorian Department of Health and Human Services |
| [ ]  A data set under the auspices of another Victorian government department |
| [ ]  A data set 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 |

List the categories of individuals or organisations from which individually identifiable or re-identifiable information will be collected. If information will be collected from more than one category, indicate clearly what information or records will be collected from each category.

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| **Category** | **Type of information or records to be collected** |
| *e.g. carers, hospitals* | *e.g. contact information, complete medical history* |
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1. Have all organisations from which the information is to be collected agreed to provide the information or to allow access to the information?

[ ]  Yes [ ]  No

If Yes, provide evidence of this agreement. Provide details of any conditions imposed by the organisation(s) concerning the release of the information.

If *No*, explain how and when the agreement of the disclosing organisation will be obtained.

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1. Is any organisation from which the information will be collected seeking separate HREC approval for disclosure of the information? *Note: The organisation(s) disclosing the information is not required by law to obtain separate HREC approval to disclose the information.*

[ ]  Yes [ ]  No

If *Yes*, supply a copy of the decision from the other HREC (when available).

If *No*, a copy of any approval from this HREC will have to be forwarded to the disclosing organisation.

1. Does the person who is collecting the information routinely have access to that information?

[ ]  Yes [ ]  No

1. For the information that will be collected, list the relevant Privacy Principle Codes (Refer to Table 1: Privacy Principles) e.g. HPP1, APP 3

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1. Will the information be collected for deposit in a databank?

[ ]  Yes [ ]  No

1. Give reasons why information will not be collected in a non-identifiable form.

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1. For what reason(s) will consent not be obtained from the individual(s) whose information will be collected? (For clarification, refer to *Statutory Guidelines on Research of the Health Records Act 2001* (Vic) at [www2.health.vic.gov.au/about/clinical-trials-and-research](https://www2.health.vic.gov.au/about/clinical-trials-and-research)).

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1. Give reasons why the proposed collection of information is in the public interest. Note that the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy.

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**2.5 Use of information**

*Only answer this question if the project involves the use of individually identifiable or re-identifiable information without the consent of the individual to whom the information relates (or their legal guardian).*

1. For the information that will be used, list the relevant Privacy Principle codes (Refer to Table 1: Privacy Principles) e.g. HPP2, APP 6

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1. What are the specific purposes for which the information will be used?

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1. Is the purpose for which the information will be used (the secondary purpose) related to the purpose for which the information was **originally** collected (the primary purpose)?

[ ]  Yes [ ]  No

Give details

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1. Give reasons why information will not be used in a non-identifiable form. If the answer is the same as for Q2.4(g), record “as above”.

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1. For what reason(s) will consent not be obtained from the individual(s) whose information will be used? If the answer is the same as for Q2.4(h), record “as above”.

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1. Give reasons why the proposed use of information is in the public interest. Note that the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy. If the answer is the same as for Q2.4(i), record “as above”.

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**2.6 Disclosure of information**

*Only answer this question if the project involves the disclosure of individually identifiable or re-identifiable information without the consent of the individual to whom the information relates (or their legal guardian).*

1. Will individually identifiable or re-identifiable information be disclosed by an organisation to the researcher?

[ ]  Yes (Answer the following questions) [ ]  No (Go to Question 2.6(b))

For the information that will be disclosed by the organisation(s) to the researcher, list the relevant Privacy Principle Codes (Refer to Table 1: Privacy Principles) e.g. HPP2, APP6

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List the organisations that will disclose information to the researcher. If more than one organisation is involved, indicate clearly what information or records will be disclosed by each organisation to the researcher.

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1. Will individually identifiable or re-identifiable information be disclosed by the researcher to other organisations?

[ ]  Yes (Answer the following questions) [ ]  No (Go to Question 2.7)

For the information that will be disclosed by the researcher, list the relevant Privacy Principle Codes (Refer to Table 1: Privacy Principles) e.g. HPP2, APP6

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List the organisations to which information will be disclosed. If information will be disclosed to more than one organisation, indicate clearly what information or records will be disclosed in each case.

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1. Give reasons why information will not be disclosed in a non-identifiable form. If the answer is the same as for Q2.4(g) or Q2.5(d), record “as above”.

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1. For what reason(s) will consent not be obtained from the individual(s) whose information will be disclosed? If the answer is the same as for Q2.4(h) or Q2.5(e), record “as above”.

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1. Give reasons why the proposed disclosure of information is in the public interest. Note that the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy. If the answer is the same as for Q2.4(i) or Q2.5(f), record “as above”.

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**2.7 General issues**

1. How many records will be sourced and what is the source (e.g. medical record, participant in person) and the type of information that will be collected, used or disclosed (e.g. date of birth, medical history, number of convictions, etc.). *Repeat for each source.*

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| **Source** |  | **Number of records** |  |
| **Type of information** |  |

1. Does the project involve the adoption of unique identifiers assigned to individuals by **other** agencies or organisations?

[ ]  Yes [ ]  No

If *Yes*, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP7, APP 9).

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1. Does the project involve trans-border (i.e. interstate or overseas) data flow?

[ ]  Yes [ ]  No

If *Yes*, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP9, APP 8).

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1. For what period of time will the information be retained? How will the information be disposed of at the end of this period?

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1. Describe the security arrangements for storage of the information. Where will the information be stored? Who will have access to the information?

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1. If data are to be stored in a databank for future research, provide the following (see *National Statement* Chapter 3.2):

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| --- | --- |
| **Name of databank** |  |
| **Form in which data will be stored** | [ ]  Identifiable | [ ]  Re-identifiable | [ ]  Non-identifiable |
| **Purpose of future use** |  |
| **How will restrictions on use of data be recorded to ensure future adherence?** |  |

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| --- | --- |
| **Data Custodian’s Name** |  |
| **Position** |  |
| **Department** |  |
| **Organisation** |  |

Refer to the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) Chapters 3.2.7, 3.2.9(a), 3.2.9(b), 3.2.11 and 3.2.12.

1. How will the privacy of individuals be respected in any publication arising from this project?

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**2.8 Other ethical issues**

Discuss any other ethical issues **relevant to the collection, use or disclosure of information** proposed in this project. Explain how these issues have been addressed.

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**SECTION 3: Research Involving the Use of Human Tissues or Blood, or Performance of Post Mortem**

**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.*

1. Will the research involve removing regenerative tissue from an adult?

[ ]  Yes (Answer the following questions) [ ]  No (Go to Question 3.1(b))

**(i)** Provide details of the arrangements that will be in place for obtaining consent from the donor for the removal of the tissue

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**(ii)** Provide details of the arrangements that will be in place for arranging a medical practitioner to issue a certificate of consent

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**(ii)** Provide details of the arrangements that will be in place for receiving and recording any withdrawal of consent

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1. Will the research involve removing tissue from a child (a ‘child’ is defined as a person who is under the age of 18 and is not married (*Human Tissue Act 1982*))?

[ ]  Yes [ ]  No

*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 parental consent has been obtained*.

*However 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*.

**3.2 Blood**

1. Will the research involve the collection of blood from an adult?

[ ]  Yes (Answer the following questions) [ ]  No (Go to Question 3.2(b))

**(i)** Provide details of the arrangements that will be in place for obtaining consent from the donor for the removal of blood

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**(ii)** Provide details of the arrangements that will be in place for receiving and recording any withdrawal of consent

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1. Will the research involve the removal of blood from a child (a ‘child’ is defined as a person who has not attained the age of 16 years (Section 20A, *Human Tissue Act 1982*))?

[ ]  Yes (Answer the following questions) [ ]  No (Go to Question 3.3)

**(i)** Provide details of the arrangements that will be in place for obtaining consent from the child’s parent(s) for the removal of blood

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**(ii)** Provide details of the arrangements that will be in place for receiving and recording any withdrawal of consent

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**3.3 Post mortem**

1. Will the research involve a post mortem?

[ ]  Yes [ ]  No

If *Yes*, provide details of how necessary consents will be obtained or verified.

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**3.4 Removal of tissue from a deceased person**

1. Will the research involve removal of tissue from a deceased person?

[ ]  Yes [ ]  No

If *Yes*, provide details of how necessary consents will be obtained or verified.

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**3.5 Fees**

1. Will the research 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 [ ]  No

If *Yes*, provide details.

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