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

**Research Project Details**

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| **HREC Reference Number** |  |
| **Full Project Title** |  |
| **Principal Investigator Name** |  |

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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