

Victorian-Specific Module



Department of
Health

IMPORTANT INFORMATION

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

All researchers are required to complete the checklist below, at a minimum, and section 1, and additionally, sections 2 and/or 3 and/or 4 of the module as applicable to individual research projects.

CHECKLIST

Please indicate whether your research involves:

1. Projects involving drugs & therapeutic devices

Yes No

If Yes, complete Section 1, questions 1.1 to 1.5

2. Recruitment of adult research participants who may be incompetent to consent:

Yes No

If Yes, complete Section 2, questions 2.1 to 2.8

3. The collection, use and/or disclosure of personal and / or health information:

Yes No

If Yes, complete Section 3, questions 3.1 to 3.8

4. The use of ionising radiation:

Yes No

If Yes, complete Section 4, questions 4.1 to 4.9

HREC Reference Number:

Project Title (in full):

Principal Investigator (please print): _____

Signature: _____ **Date:** _____

The contact details must be provided for the following (as applicable).

Trial Coordinator

Title:

First name:

Surname:

Position:

Organisation name:

Mailing address:

Suburb/Town:

State:

Post code:

Business phone number:

Email address: Generic

Personal

Fax number:

Sponsor/Contract Research Organisation

Title:

First name:

Surname:

Position:

Organisation name:

Mailing address:

Suburb/Town:

State:

Post code:

Business phone number:

Email address: Generic

Personal

Fax number:

SECTION 1 – Projects involving drugs & therapeutic devices

1.1 Type of Trial

N.B. Tick as many boxes as apply to the proposed research.

Drug \Rightarrow Phase I Phase II Phase III Phase IV

First Time in Human clinical trial

Device \Rightarrow Is this the first use in humans? Yes No

For trials involving drugs, answer question 1.2; for trials involving devices, answer question 1.3; for trials involving both drugs and devices, answer both questions 1.2 and 1.3.

1.2 Registration Status of Drugs

(a) Is the drug registered in Australia by the Therapeutic Goods Administration?

No - **Go to question 1.2 (c)**

Yes

If Yes, under what name is the drug registered?

(b) Is the dosage, administration, indications for use or age group of participants proposed for this project different from the Australian approved product information?

Yes No

If Yes, provide justification, including a summary of the most up-to-date information, to support the unapproved use in this project.

(c) Has the drug been registered/licensed/approved for marketing **for this indication** by an accepted international regulatory authority (other than the Australian Therapeutic Goods Administration)?

Yes No

If Yes, identify countries and/or regulatory authorities that have registered, licensed or approved the drug.

(d) Has the drug been registered, licensed or approved for marketing **for other indications** by an accepted international regulatory authority (other than the Australian Therapeutic Goods Administration)?

Yes No

If Yes, identify countries and/or regulatory authorities that have registered, licensed or approved the drug and give details of the other indication(s) for which the drug is registered, licensed or approved.

(e) Has the drug been reviewed for investigational or research uses by an international regulatory authority?

No – **Do not answer any further parts of question 1.2**
 Yes

If Yes, provide evidence of the review (including country and, if applicable, the regulator's drug identification number, e.g. the IND if the authority is the FDA) and answer parts (f) and (g).

(f) Did the international regulatory authority raise any objections?

Yes No

If Yes, give details

(g) Have all issues raised by the international regulatory authority been satisfied?

Yes No

Provide details

1.3 Registration Status of Devices

(a) Is the device included on the Australian Register of Therapeutic Goods?

Please note that this includes investigational and non-investigational devices. Please complete for each device, duplicating Section 1.3 (a) – (g) for each device.

No - **Go to question 1.3 (c)**

Yes

If Yes, under what name is the device registered?

(b) Is the application of the device proposed in this project different from the application(s) of the device included on the ARTG?

Yes No

If Yes, provide justification, including a summary of the most up-to-date information, to support the unregistered use in this project.

(c) Has the device been registered/licensed/approved for marketing **for this application** by an accepted international regulatory authority (other than the Australian Therapeutic Goods Administration)?

Yes No

If Yes, identify countries and/or regulatory authorities that have registered, licensed or approved the device.

(d) Has the device been registered, licensed or approved for marketing **for other applications** by an accepted international regulatory authority (other than the Australian Therapeutic Goods Administration)?

Yes No

If Yes, identify countries and/or regulatory authorities that have registered, licensed or approved the device and give details of the other application(s) for which the device is registered, licensed or approved.

(e) Has the device been reviewed for investigational or research uses by an international regulatory authority?

Yes No

If Yes, provide evidence of the review (including country and, if applicable, the regulator's identification number) and answer parts (f) and (g).

(f) Did the international regulatory authority raise any objections?

Yes No

If Yes, give details

(g) Have all issues raised by the international regulatory authority been satisfied?

Yes No

Provide details

1.4 Drug/Device Details

Complete the following information for each **investigational drug** or **device** involved in the project. N.B. Some of the items below do not apply to devices.

| | |
|---|--|
| Approved name | |
| Trade name (if any) | |
| Manufacturer | |
| Supplier of drug/device (e.g. manufacturer/pharmacy) | |
| Approved therapeutic indication, dosage/duration in Australia | |
| Believed mode of action | |
| Dosage regimen | |
| Mode of excretion | |

| | |
|--------------------------------------|--|
| Known adverse events | |
| Known contra-indications or warnings | |

1.5 Use of Pharmacy Department

Have arrangements been made for the Pharmacy Department to receive or dispense the drugs involved in this project? (*check institutional requirements for the submission of departmental support forms*)

Yes No N/A

If No, explain how the drugs will be received and dispensed for the purposes of the research project.

| |
|--|
| |
|--|

SECTION 2 – Research Involving the Recruitment of adults who may be incompetent to consent

The *Guardianship & Administration Act 1986* information paper “*Medical research procedures involving patients under a legal incapacity*” should also be used as a reference. These can be found on the following website:

http://www.health.vic.gov.au/data/assets/word_doc/0004/324535/info-paper.doc

2.1 Consent

(a) Will there be participants who do **not** have the capacity to give voluntary and informed consent?

Yes No (Go to Section 3)

(i) If Yes, will consent be obtained from another individual? (Tick both if applicable)

Yes (go to Q 2.1 (a) (ii)) No (go to Q 2.1 (a) (iii))

(ii) If Yes, who will be asked to provide consent (tick as many as apply)?

Parent/guardian for participants under 18 years of age

‘Person Responsible’ (as defined in the *Guardianship and Administration Act 1986*)

***Note:** only applies to ‘**medical research procedures**’ (as defined in the *Guardianship and Administration Act 1986*) involving adult participants. (MUST ALSO COMPLETE Q 2.2 – 2.8)

Other (e.g. Next-of-kin acknowledgement for adult participants in research that does **not** involve any ‘medical research procedure’ (as defined in the *Guardianship and Administration Act 1986*). Give details

How will consent be obtained?

Written consent form

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

(iii) If No to Q 2.1(a)(i), identify the procedure that will be used to recruit participants.

Note: These options only apply to ‘medical research procedure’ (as defined in the Guardianship and Administration Act 1986)

Consent will not be obtained and participants will be included in the research in accordance with the “Medical Emergency” provisions of the *Guardianship and Administration Act 1986*, Section 42A).

Procedural authorisation (as defined in the *Guardianship and Administration Act 1986*)

and as detailed in Section 42T of the 'Guardianship and Administration Act 1986.'

- (b)** How will competence to give consent be determined, name of registered medical practitioner who will make this determination, and what criteria will be used?

- (c)** Describe the ongoing process for reviewing participants' capacity to consent and participate while the research is in progress.

- 2.2** Indicate which group the proposed participants, who are incapable of giving consent, fall into:

- 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 _____

- 2.3** Does the project involve a '**medical research procedure**' (see Guidelines for definition)?

Yes No

If *No*, you do not need to complete any more of Section 2.

If *Yes*, please continue to section 2.4.

Questions 2.4 – 2.8: Complete these questions if a project involves a 'medical research procedure' as defined by the Guardianship and Administration Act 1986. This may include a 'medical research procedure' performed on a forensic, involuntary or security patient as defined by the Mental Health Act 1986.

- 2.4** 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 42A the Guardianship and Administration Act 1986. 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 Guardianship & Administration Act 1986 information paper).

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?

Yes No

If yes, please provide detailed information.

If Yes to Q 2.4, you do not need to complete any more questions in Section 2.

If No to Q 2.4, Division 6 of the Guardianship & Administration Act applies. Please answer questions 2.5 – 2.8.

- 2.5** 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 Q2.6)

If Yes, wait and seek patient consent.

- 2.6** If patients are not likely to recover capacity within a reasonable timeframe then consent may be given by the '**person responsible**'.

- (a)** Do you anticipate obtaining consent from a 'person responsible'?

Yes (Go to Q 2.6 (b)) No

- (b)** If Yes, describe the procedures you will follow to identify and contact the 'person responsible' to determine if they will give consent for the participant to be involved in the research project.

- (c)** How will consent be obtained from the 'person responsible'?

Written consent form

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

2.7 *If the 'person responsible' for a patient can not be ascertained or contacted that patient may be included in the study if the requirements for procedural authorisation are met.*

If the situation arises and you want to include such patients in your study, you will need to initiate procedural authorisation.

(a) Do you anticipate including patients in the study using procedural authorisation?

Yes No

If *No*, you do not need to complete any more questions.

If *Yes*, please continue.

(b) Provide details regarding how this research project satisfies the requirements for procedural authorisation.

(c) Provide details of the steps to be taken to identify and contact a '**person responsible**' following, the use of procedural authorisation.

2.8 Attach relevant PICFs at the end of the Victorian Specific Module and identify which PICFs are attached below:

Note: Copy list for each site for which this HREC is responsible.

Participant Information and Consent Form – participant.

Person Responsible Participant Information and Consent Form.

Participant Information and Consent Form – patient consent to continue participation following consent by 'Person Responsible.'

Participant Information and Consent Form – patient consent to continue participation following Procedural Authorisation.

Participant Information and Consent Form – 'Person Responsible' consent to continue participation following Procedural Authorisation.

Additional PICFs (as per above and as required) for sub-studies, etc.

SECTION 3 – 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.

You may delete questions or parts of questions that you are not required to answer, in the interests of reducing paper usage.

3.1 Collection of participants' information

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

Yes - go to Question 3.2

No - answer the following questions:

(b) What type of information will be collected? (*Tick as many as apply*)

personal information

sensitive information

health information

(c) Will participants' consent be sought to use the collected information for

this research project (specific consent)

future research related to this project (extended consent)

any future research (unspecified consent)

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

Yes No

(e) Does the Participant Information and Consent Form explain the following:

| | | | |
|---|------------------------------|-----------------------------|------------------------------|
| What information is being collected? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| The purposes for which the information is being collected? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| The extent of future use of data (if you are seeking extended or unspecified consent)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| The wide-ranging implications of unspecified consent (if you are seeking unspecified consent)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| A description of the terms of the unspecified consent (if you are seeking unspecified consent)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| If permission is being sought to enter the information into a databank? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| The period for which the records relating to the participant will be kept? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| The form in which the data will be stored (i.e. whether identifiable or not)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | |

- The steps taken to ensure confidentiality and secure storage of data? Yes No
- The types of individuals or organisations to which your organisation usually discloses information of this kind? Yes No
- How privacy and confidentiality will be protected in any publication of the information? Yes No
- The fact that the individual may access that information? Yes No
- Any law that requires the particular information to be collected? Yes No
- The consequences (if any) for the individual if all or part of the information is not provided? Yes No
- The identity of the organisation collecting the information and how to contact it? Yes No

If you answered "No" to any of these questions, give the reasons why this information has not been included in the Participant Information and Consent Form.

3.2 Do other questions in this section have to be completed?

(a) Does the project involve the collection, use or disclosure of **individually identifiable or re-identifiable** information from sources other than the individual whose information it is? 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'.

- No – **Go to Question 3.7 and do not answer the remainder of question 3.2, 3.3, 3.4, 3.5 or 3.6**
- Yes – **Answer the following question**

(b) Does the project involve the collection, use or disclosure of information **without the consent** of the individual whose information it is (or their legal guardian)?

- No – **Go to Question 3.7 and do not answer questions 3.3, 3.4, 3.5 or 3.6**
- Yes – **Answer the following questions**

3.3 Type of activity proposed

Are you seeking approval from this HREC for:

(a) collection of information from a third party?

- Yes – **Answer Question 3.4**
- No – **Skip Question 3.4**

(b) use of information?

- Yes – **Answer Question 3.5**
- No – **Skip Question 3.5**

(c) disclosure of information?

Yes – **answer Question 3.6**

No – **skip Question 3.6**

If you have answered 'No' to all three parts of Question 3.3, then go directly to Question 3.7

3.4 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.

(a) From which of the following sources will information be collected? (*Tick as many as apply*)

| | Source of Information |
|--------------------------|--|
| <input type="checkbox"/> | A Victorian public health service provider |
| <input type="checkbox"/> | A Victorian private health service provider |
| <input type="checkbox"/> | An organisation other than a health service provider |
| <input type="checkbox"/> | A data set under the auspices of the Victorian DHS |
| <input type="checkbox"/> | A data set under the auspices of another Victorian government department |
| <input type="checkbox"/> | A data set from another Victorian source |
| <input type="checkbox"/> | A Commonwealth agency |
| <input type="checkbox"/> | An agency from another state |
| <input type="checkbox"/> | An "organisation" as defined in s95A of the Privacy Act |
| <input type="checkbox"/> | An individual (such as a carer) |
| <input type="checkbox"/> | 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.

| Category | Type of information or records to be collected |
|-------------------------------|---|
| <i>e.g. carers; hospitals</i> | <i>e.g. contact information; complete medical history</i> |
| | |
| | |
| | |

(b) 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.

(c) 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 – Supply a copy of the decision from the other HREC (when available)

No - A copy of any approval from this HREC will have to be forwarded to the disclosing organisation

(d) Does the person who is collecting the information routinely have access to that information?

Yes No

(e) What information will be collected? *(Tick all boxes that apply)*

| | Type of information | | Type of organisation(s) involved | Privacy Principle(s) |
|--------------------------|--|--------------------------|----------------------------------|----------------------|
| <input type="checkbox"/> | Health information | <input type="checkbox"/> | Victorian public sector | HPP 1 |
| | | <input type="checkbox"/> | Victorian private sector | HPP 1, NPP 1, NPP 10 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 1, NPP 10 |
| <input type="checkbox"/> | Personal information (other than health information) | <input type="checkbox"/> | Victorian public sector | VIPP 1 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 1 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 1 |
| <input type="checkbox"/> | Sensitive information | <input type="checkbox"/> | Victorian public sector | VIPP 10 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 10 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 10 |

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(f) Will the information be collected for deposit in a databank?

Yes No

(g) Give reasons why information will not be collected in a non-identifiable form.

(h) For what reason(s) will consent not be obtained from the individual(s) whose information will be collected? (see *Guidelines for clarification*)

(i) 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.

3.5 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 whose information it is (or their legal guardian).

(a) What information will be used? (Tick all boxes that apply)

| | Type of information | | Type of organisation(s) involved | Privacy Principle(s) |
|--------------------------|--|--------------------------|----------------------------------|----------------------|
| <input type="checkbox"/> | Health information | <input type="checkbox"/> | Victorian public sector | HPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | HPP 2, NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |
| <input type="checkbox"/> | Personal information (other than health information) | <input type="checkbox"/> | Victorian public sector | VIPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |
| <input type="checkbox"/> | Sensitive information | <input type="checkbox"/> | Victorian public sector | VIPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |

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(b) What are the specific purposes for which the information will be used?

(c) 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.

(d) Give reasons why information will not be used in a non-identifiable form. *(If the answer is the same as for Q3.4 (g), write "as above".)*

(e) 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 Q3.4 (h), write "as above".)*

(f) 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 Q3.4 (i), write "as above".)*

3.6 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 whose information it is (or their legal guardian).

(a) Will individually identifiable or re-identifiable information be disclosed by an organisation to the researcher?

- No – **Go to question 3.6(b)**
- Yes – Answer the following question

What information will be disclosed by the organisation(s) to the researcher? *(Tick all boxes that apply)*

| | Type of information | | Type of organisation(s) involved | Privacy Principle(s) |
|--------------------------|--|--------------------------|----------------------------------|----------------------|
| <input type="checkbox"/> | Health information | <input type="checkbox"/> | Victorian public sector | HPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | HPP 2, NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |
| <input type="checkbox"/> | Personal information (other than health information) | <input type="checkbox"/> | Victorian public sector | VIPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |
| <input type="checkbox"/> | Sensitive information | <input type="checkbox"/> | Victorian public sector | VIPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 2 |

| | | |
|--------------------------|----------------------------|--------|
| <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| <input type="checkbox"/> | Other | NPP 2 |

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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.

(b) Will individually identifiable or re-identifiable information be disclosed by the researcher to other organisations?

No – **Go to question 3.7**

Yes – answer the following questions

What information will be disclosed by the researcher? (*Tick all boxes that apply*)

| | Type of information | | Type of organisation(s) involved | Privacy Principle(s) |
|--------------------------|--|--------------------------|----------------------------------|----------------------|
| <input type="checkbox"/> | Health information | <input type="checkbox"/> | Victorian public sector | HPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | HPP 2, NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |
| <input type="checkbox"/> | Personal information (other than health information) | <input type="checkbox"/> | Victorian public sector | VIPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |
| <input type="checkbox"/> | Sensitive information | <input type="checkbox"/> | Victorian public sector | VIPP 2 |
| | | <input type="checkbox"/> | Victorian private sector | NPP 2 |
| | | <input type="checkbox"/> | Commonwealth public sector | IPP 11 |
| | | <input type="checkbox"/> | Other | NPP 2 |

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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.

(c) Give reasons why information will not be disclosed in a non-identifiable form. (*If the answer is the same as for Q3.4 (g) or Q3.5 (d), write "as above".*)

(d) 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 Q3.4 (h) or Q3.5 (e), write "as above".)*

(e) 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 Q3.4 (i) or Q3.5 (f), write "as above".)*

3.7 General issues

(a) 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)*

Source:

Number of records:

Type of information:

(b) 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. HPP 7, VIPP 7 or NPP 7).

(c) 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. HPP 9, VIPP 9 or NPP 9).

(d) For what period of time will the information be retained? How will the information be disposed of at the end of this period?

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

(f) If data are to be stored in a databank for future research, provide details of the following:

- (i) the name of the databank;
- (ii) the form in which the data will be stored (identifiable, re-identifiable or non-identifiable) [NS 3.2.9(a)];
- (iii) what the purpose of future use will be [NS 3.2.9(b)];
- (iv) how any restrictions on the use of the data will be recorded to ensure future adherence [NS 3.2.11 & 3.2.12];
- (v) who the custodian of the data will be (include name, position, department and organisation) [NS 3.2.7].

(g) How will the privacy of individuals be respected in any publication arising from this project?

3.8 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.

SECTION 4 – Use of Ionising Radiation

Glossary

| | |
|----------------------------------|--|
| <i>Medical physicist:</i> | <i>A person qualified to perform radiation dosimetric calculations, measurements and monitoring and that has been approved by a regulatory authority to make estimates in a speciality relevant to the research project. This person must be approved and listed by the Radiation Safety Section of the Department of Human Services</i> |
| <i>Participant:</i> | <i>A person taking part in a research project.</i> |
| <i>Radiation Safety Officer:</i> | <i>Is the responsible person at an institution for safety of radiation materials, apparatus or conduct relating to use of radiation.</i> |
| <i>Volunteer:</i> | <i>A participant that receives no benefit from radiation exposure and/or it does not form part of their standard clinical care (ARPANSA Code).</i> |

Definitions

| | |
|--------------|---|
| <i>DEXA:</i> | <i>Dual Energy xray Absorptiometry</i> |
| <i>PET:</i> | <i>Positron Emission Tomography</i> |
| <i>PICF:</i> | <i>Participant Information and Consent Form</i> |

Requirements in Victoria

| | |
|--------------------------------------|--|
| <i>Institution licensing:</i> | <i>An institution that administers ionising radiation to humans for research purposes must be licensed with the Department of Human Services (DHS). Prior to commencement, Human Research Ethics Committee approved research projects involving ionising radiation must be added to the licence and notified to DHS using the standard proforma addressed to: Ingrid Cardillo, Radiation Safety Section, DHS, 15 floor, 50 Lonsdale Street, Melbourne, VIC 3000.</i> |
| <i>Medical physicist assessment:</i> | <i>A written assessment from an approved medical physicist of the total effective radiation dose that the participant is likely to receive as a result of being part of a research project.</i> |

Classification of radiation exposure that participants (including volunteers) will receive.

A. Standard clinical care

*Standard clinical care is defined as the typical or routine management of the patient with a recognised medical condition. When considering whether the management is 'standard clinical care' the following items need to be taken into account:

- The number of radiation procedures being performed;
- The frequency or time interval between the radiation procedures;
- The body part region being exposed to radiation.

B. Additional to standard clinical care

Any exposure to ionising radiation beyond that considered normal care of the condition being treated.

Radiation exposure that is requested for research purposes only, for example screening for osteoporosis.

HREC requirements

A. Standard clinical care

- Complete sections 4.1 and 4.2 only
- A copy of the research protocol
- A copy of the PICF
- A copy of the ethics application form
- Confer and confirm with your HREC Co-ordinator and/or RSO in accordance with your site policy and then submit this form.

B. Additional to standard clinical care

- A research project cannot commence until a letter is received confirming that the project has been added to the Institution's licence.
- ALL sections of this form must be completed
- A copy of the research protocol
- A copy of the PICF
- A copy of the ethics application form

4.1 Participants

(a) Are all radiation examinations and /or therapies part of 'standard clinical care'?

Yes No

If Yes, only Sections 4.1 & 4.2 should be completed. If No, complete all questions.

(b) How many participants will be included in this research proposal?

(c) What is the minimum age of participants irradiated?

If the study does involve juveniles under the age of 18, please justify:

(d) Will women who are pregnant or breastfeeding be irradiated in this research?

Yes No

If the study does involve pregnant or breastfeeding women, please justify:

(e) Will babies, infants or foetuses be irradiated in this research?

Yes No

If Yes, provide a detailed justification. Note that research projects involving irradiation of babies, infants or foetuses are generally not justified unless the information sought is essential and cannot be obtained by other means.

(f) Is the life expectancy of the participants less than five years?

Yes No

4.2 Procedures involving the use of ionising radiation

List **all** procedures involving ionising radiation in your project. Include and identify procedures deemed to be 'standard care' and those procedures that are 'additional to standard care' and are required because of the participant's inclusion in the research. *Add rows for projects involving more than eight different types of ionising radiation.*

| Detail the type, number and frequency of ionising investigations | (Please mark one box) | |
|--|----------------------------|-------------------------------------|
| | Deemed to be Standard Care | Additional to Standard Care |
| <i>eg. CT exam of chest, (x 3), every 10 weeks over study period</i> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 1 | <input type="checkbox"/> | <input type="checkbox"/> |
| 2 | <input type="checkbox"/> | <input type="checkbox"/> |
| 3 | <input type="checkbox"/> | <input type="checkbox"/> |
| 4 | <input type="checkbox"/> | <input type="checkbox"/> |
| 5 | <input type="checkbox"/> | <input type="checkbox"/> |
| 6 | <input type="checkbox"/> | <input type="checkbox"/> |
| 7 | <input type="checkbox"/> | <input type="checkbox"/> |
| 8 | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>Additional comments (if necessary):</i> | | |

4.3 Radiation Assessment

(a) Has an approved Medical Physicist assessed the application and written a report on the doses and risks involved?

Yes No

If Yes, provide the medical physicist's details and attach a copy of the written report:

Medical Physicist:

Institution:

| |
|--|
| |
| |

If No, please organise to have an assessment carried out in order for it to be forwarded to the HREC Secretariat and the Department of Human Services – Radiation Safety Section (*if required*).

Note: RPS8 - the ARPANSA Code of Practice – Exposure of Humans to Ionising Radiation for Research Purposes Radiation Protection Series Publication No. 8 (May 2005) requires that:

- The investigators submit to HREC's calculations for the total effective dose, relevant organ doses and associated risk information provided to participants;
- Dose calculations and risk assessments submitted to HREC's must be independently verified by a medical physicist, approved to perform that type of assessment by the Department of Human Services Radiation Safety Section;
- In the case of doses in excess of the dose constraints listed in the guideline document, verification by a second medical physicist must also be obtained. If the dose exceeds the dose constraint and the HREC deems there is no benefit to the participant or is unsure whether there is a benefit or not, then the research will require review and approval from the Radiation Safety Section (RSS).
- Once approved by the HREC, the RSS will require notification so that the research project can be listed on the Institution licence. A standard proforma listing the information required by the RSS must be completed and sent or emailed back to the RSS. On receipt of this information the RSS will send out a letter confirming that the project has been added to the licence. **The project can start as soon as the confirmation letter from the RSS has been received by the researcher.**

(b) Have the dose constraints been exceeded?

Yes No

If Yes, provide the details of the second medical physicist that has verified the initial dosimetry calculations performed:

Second Medical Physicist:

Institution:

| |
|--|
| |
| |

Certification by an approved Medical Physicist

I have reviewed the information in **Section 4.3 "Radiation Assessment"** and I am satisfied that the information is accurate and that it complies with the recommendations of:

- (ARPANSA) *RPS 8. Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes* Radiation Protection Series Publication No. 8 (May 2005).

Signature of Medical Physicist

Medical Physicist name:

Date

4.4 Procedure Description

List all procedures involving radiation that are additional to 'standard care' in your project. *Please copy tables (a) & (b) below, for projects involving more than two types of procedures.*

(a) Radiology & DEXA

| | Procedure 1 | Procedure 2 |
|--|--------------------|--------------------|
| 1. Type of Investigation | | |
| 2. Will all participants undergo this investigation? | | |
| 3. Institution at which the procedure will be performed | | |
| 4. Effective Dose [mSv] per investigation | | |
| 5. Number of Investigations | | |
| 6. Effective Dose (total) in addition to standard care (per participant) [mSv] | | |
| 7. Relevant organ dose [mSv] (state organs) | | |

(b) Nuclear Medicine & PET

| | Procedure 1 | Procedure 2 |
|--|--------------------|--------------------|
| 1. Type of Investigation | | |
| 2. Institution at which the procedure will be performed | | |
| 3. Radionuclide | | |
| 4. Chemical / Pharmaceutical Form | | |
| 5. Activity to be administered [MBq] | | |
| 6. Number of Investigations | | |
| 7. Effective Dose (total) in addition to standard care (per participant) [mSv] | | |

| | | |
|---|--|--|
| 8. Relevant organ dose [mSv] (state organs) | | |
|---|--|--|

Note: The medical physicist will be able to assist you with determination of the effective dose for the above procedures.

(c) Procedures other than in (a) and/or (b)* (Please specify)

** Attach all dosimetry calculations and/or dosimetry references used to estimate the radiation exposure. In addition, the name and qualifications of the person(s) who performed these calculations must be included.*

4.5 Categories of Risk & Dose

For ionising radiation 'additional to standard care' only.

Choose the level of dose and risk from the table below. The medical physicist will provide advice.

| Level of Risk | Risk Category | Effective Dose Range (adults) (mSv) | Level of Societal Benefit Expected | Total Radiation Risk (Please tick one box) |
|---------------|---|-------------------------------------|------------------------------------|--|
| Minimal | Category I (~10 ⁻⁵ or less) | < 0.2 | Minor | <input type="checkbox"/> |
| Very Low | Category IIa (~10 ⁻⁵ or 10 ⁻⁴) | ≥ 0.2 and < 2 | Intermediate | <input type="checkbox"/> |
| Low | Category IIb (~10 ⁻⁴ or 10 ⁻³) | ≥ 2 and ≤ 20 | Moderate | <input type="checkbox"/> |
| Moderate | Category III (~10 ⁻³ or more) | > 20 | Substantial | <input type="checkbox"/> |

4.6 Expected Societal Benefit

Please explain the benefit(s) for the individual and society that can be expected to accrue from this research.

4.7 Participant Information Risk Statements

An appropriate radiation risk statement must be included in all Participant Information sheets except where radiation exposure is part of 'standard care'.

In cases where a participants' life expectancy is less than five years, an appropriate risk statement is NOT required.

For a participant with a life expectancy greater than five years a different statement should be used.

The Medical Physicist who reviews the research project will provide you with an appropriate risk statement.

4.8 Regulatory Authorisations

(a) Does the institution(s) hold a valid licence to conduct research approved under the Institution's management licence involving the radiation exposure of human volunteers?

Yes No

(b) Is the irradiation apparatus approved under the Institution's management licence for the purpose?

Yes No

(c) Are all staff appropriately licensed by the Radiation Safety Section to perform the ionising radiation procedures in this study?

Yes No

4.9 Certification

HREC Reference number:

Project Title (in full):

Principal Investigator:

Certification By Principal Investigator

I accept responsibility for the conduct of this research project according to the principles of the *National Statement on Ethical Conduct in Human Research* published by the National Health & Medical Research Council (March 2007), the requirements of the (ARPANSA) *RPS 8. Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes* Radiation Protection Series Publication No. 8 (May 2005) and the recommendations of the Medical Physicist.

Signature of Principal Investigator:

Print Principal Investigator name: Date:

Certification by Radiation Safety Officer

I have reviewed the information and authorise for it to be submitted to the relevant Human Research Ethics Committee for consideration, as the proposal complies with the recommendations of:

- (ARPANSA) *RPS 8. Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes* Radiation Protection Series Publication No. 8 (May 2005).

Signature of Radiation Safety Officer:

Radiation Safety Officer name: Date: