HUMAN RESEARCH ETHICS COMMITTEE (HREC) - ONLINE APPLICATION QUESTIONS

The Human Ethics application in IRMA has four tabs, one of which includes a questionnaire. To aid planning, this document provides the questions applicants will encounter when entering their ethics application in IRMA.

The questions are ordered as they will appear in IRMA within their sections. Depending on the response given, not all questions will be presented. The question numbers shown are system-generated and are only visible in this document to indicate the next question that would be presented online.

A range of support materials are provided at the Research Support site under both Ethics and IRMA topics.

1.0 Welcome to the University of Sydney's Human Ethics Application Questionnaire.
Please be aware that there is a limit of fifteen minutes to complete each individual question. If you exceed this time then your answer may not be saved by the system. We recommend that you prepare long answers outside of IRMA before pasting it back into the report questionnaire and/or save your answers regularly.

If you choose to edit a previous question, your responses to subsequent questions will be deleted. The restore button can be used to refill your subsequent answers if this happens.

For further information on the application procedure, please consult our website or email the Human Ethics team at ro.humanethics@sydney.edu.au

If you experience any technical difficulties, please do not hesitate to contact Research Support using the details below:
T +61 2 8627 8183
E research.support@sydney.edu.au

SECTION A
Section A is designed to identify student projects that may be eligible to be reviewed by a low-risk sub-committee of the University of Sydney HREC. In addition, this Section also seeks to identify projects that have been approved by other ethics committees.

1.0 You are about to begin the HREC application form.

Continue – directed to 120.0

120.0 Is this project a University of Sydney student project ONLY (i.e. ethics application restricted to the activities of the student research project)?

No - Go to question 130.0
Yes - Go to question 125.0

125.0 Select appropriate student classification:

- Undergraduate
- Honours
- Masters
- PhD

Go to question 130.0

130.0 Indicate whether this project has been or will be submitted to any other ethics committees

No - Go to SECTION B
Yes – Go to Q280.0

280.0 Is the responsible ethics committee Australian?

No - Go to question 305.0
Yes - Go to question 300.0

300.0 Is the responsible ethics committee registered with the National Health and Medical Research Council (NHMRC)?

No - Go to SECTION B
Yes - Go to question 325.0

305.0 Will the participants be recruited in Australia?

No - Go to question 315.0
Yes - Go to SECTION B

315.0 Is your research funded by a grant administered by the University of Sydney (this does NOT include scholarships)?

No - Go to question 325.0
Yes - Go to question 320.0

320.0 Is this HREC part of the Federal Wide Assurance?

No - Go to SECTION B
Yes - Go to SECTION B

325.0 Under the University of Sydney Procedures you do not require ethics approval from the University HREC if: - your study has already been approved by an ethics committee registered with the NHMRC and that committee has stated in writing its willingness to be responsible for ALL sites at which the research is to be conducted. Or - your study has already been approved by an overseas ethics committee AND there is no funding, or the funding is being administered by another institution. Please clarify below why you are applying for ethics approval from the University of Sydney HREC. (If you do not wish to continue please contact the Ethics Office on ro.humanethics@sydney.edu.au to unsubmit your application).
Go to SECTION B

SECTION B

Section B is designed to determine whether your study falls within the National Statement's definition of low or negligible risk. Throughout this section, you may be asked specific additional questions where you indicate that your study involves particular participant and/ or project types. In this document, these additional questions have been included in the Appendices.

Please note that the option "Possible Recruitment" with reference to specific participant populations indicates that these people MAY be recruited into your study, but are not the specific population of interest. If this population is the focus of your study, you should select "Yes".

Please answer the following questions

400.0 Does your research involve women who are pregnant and the human foetus?

Yes - see Appendix 1
No - Go to question 480.0

480.0 Does your study involve children and/or young people (i.e. younger than 18 years)?

Yes - see Appendix 2
No - Go to question 590.0

590.0 Does your study involve people in existing dependent or unequal relationships with the researcher(s)?

Yes - see Appendix 3
No - Go to question 620.0

620.0 Does your research involve people with a cognitive impairment, an intellectual disability or a mental illness?

Yes - see Appendix 4
No - Go to question 680.0
Possible Recruitment - Go to question 680.0

680.0 Does your research involve people highly dependent on medical care who may be unable to give consent?

Yes - see Appendix 5
No - Go to question 710.0

710.0 Does your study have the potential to discover illegal activity by participants or others? This includes research intending to expose illegal activity, as well as research not specifically designed to, but likely to discover, illegal activity.

Yes - see Appendix 6
No - Go to question 760.0

760.0 Does your research involve Aboriginal and/or Torres Strait Islander peoples?

Yes - see Appendix 7
No - Go to question 920.0
Possible Recruitment - Go to question 920.0

920.0 Does your research involve CALD (Culturally and Linguistically Diverse) people?

Yes
No
Possible Recruitment
Go to question 930.0

930.0 Does your research involve travel overseas?

Yes - see Appendix 8
No - Go to question 1020.0

1020.0 Is your study likely to cause or elicit distress in participants due to its subject matter, the procedures involved, information that might be revealed about the participant or related persons, or in some other way?

No
Yes
Go to question 1030.0

1030.0 Does your study involve research that could jeopardise a participant's employment?

Yes - see Appendix 9
No - Go to question 1080.0

1080.0 Is your proposed research a clinical trial? A clinical trial is a form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.

Yes - see Appendix 10
No - Go to question 1600.0

1600.0 Does your study involve the use of human tissue?

Yes - see Appendix 11
No - Go to question 2070.0

2070.0 Does your study involve human genetics or human stem cells?

No
Yes
Go to question 2080.0

2080.0 Does your study involve limited disclosure involving active concealment and/or planned deception?

Yes - see Appendix 12
No - Go to question 2130.0

2130.0 Does your study involve research that poses a risk to the physical or emotional safety or welfare of a University of Sydney student researcher (e.g. honours student or postgraduate student)?

Yes - see Appendix 13
No - Go to question 2150.0

2150.0 Does your research involve any of the following:
• Collection of biological samples (e.g. blood, saliva, bodily fluids).
• Physical screening (e.g. blood pressure, cholesterol, physical fitness, MRI scans).
• Physical exertion? (i.e. physical activity, exercise)

No
Yes

Some projects will be directed to the following extra questions

2170.0 Does the research ONLY involve existing collections of data or records about human beings (collected with appropriate ethical approval)?

No - Go to question 2230.0
Yes - Go to question 2180.0

2180.0 Indicate whether the data/records to be used in this research project will be:

- Non-identifiable - Go to question 2190.0
- Re-identifiable - Go to question 2230.0
- Individually Identifiable - Go to SECTION C

For definitions of these terms please refer to the *National Statement on Ethical Conduct in Human Research*, Chapter 3.2

2190.0 According to Sydney University guidelines you do not require HREC approval. Would you like to seek approval for publication or other reasons?

No - end of questions (negligible risk)
Yes - Go to question 2195.0

2195.0 Please outline why you are seeking ethics approval
Go to SECTION C

2230.0 Is there a foreseeable risk of more than 'discomfort'? For a useful description of the differences between harm, discomfort and inconvenience please refer to the *National Statement on Ethical Conduct in Human Research*, Chapter 2.1

No
Yes
Go to SECTION C

SECTION C
Section C is designed to determine whether there are any conflicts of interests which may compromise the research process.

2340.0 Are any "conflict of interest" issues likely to arise in relation to this research?

No - Go to question 2360.0
Yes - Go to question 2350.0

2350.0 Please provide details of the potential conflicts of interests
Go to question 2360.0

2360.0 Do the researchers have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? (Note that such benefits must be declared in the Participant Information Statement)

No - Go to question 2380.0
Yes - Go to question 2370.0

2370.0 Please provide details of this financial affiliation or involvement
Go to question 2380.0

2380.0 Do the researchers expect to obtain any direct or indirect financial or other benefits from conducting this research? (Note that such benefits must be declared in the Participant Information Statement)

No - Go to question 2400.0
Yes - Go to question 2390.0

2390.0 Please provide details of these financial or other benefits
Go to question 2400.0

2400.0 Have conditions already been imposed OR are likely to be imposed in the future, upon the use (e.g. publication), or ownership of the results (e.g. scientific presentations) or materials (e.g. audio-recordings), by any party other than the listed researchers?

No - Go to SECTION D
Yes - Go to question 2410.0

2410.0 Please provide details of the conditions imposed
Go to SECTION D

SECTION D
The questions in Section D are specifically directed at the consent process.

2540.0 Describe how you will identify and select potential participants for recruitment into the study. You should include information about how you will obtain contact details for potential participants.
Go to question 2550.0

2550.0 Describe how and where initial contact will be made with potential participants and how you will avoid real or perceived coercion. Copies of all relevant correspondence (e.g. email, letter of introduction, covering letter, circular/flyer etc.) need to be uploaded with your application. If you are using email addresses please outline how their use will not be in breach of privacy or spam legislation.
Go to question 2570.0

2570.0 If a participant, or person on behalf of a participant, chooses to withdraw from the research, what specific consequences should they be made aware of, prior to giving consent? These details should be included in the Participant Information Statement.
Go to question 2580.0

2580.0 Will participants receive any reimbursement of out-of-pocket expenses, or financial or other "rewards" as a result of participation?

No - Go to question 2600.0
Yes - Go to question 2590.0

2590.0 Specify the nature and value of any proposed incentive/payment (e.g. movie tickets, food vouchers) or reimbursement (e.g. travel expenses) to participants. Explain why this offer will not impair the voluntary nature of the consent, whether by participants or persons deciding for their behalf. Payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable. (See 2.2.10 and 2.2.11 of the National Statement). Note that monetary amounts should not be specified in advertisements, but payments should be disclosed in the Participant Information Statement in accordance with 2.2.6 (j) of the National Statement.
Go to question 2600.0

2600.0 How will consent be obtained (more than one may apply)

- Written
- Oral
- Return of a Survey
- Other

Go to question 2605.0

2605.0 Please clarify your response to the question above and justify with reference to the National Statement (e.g. sections 2.2.5, 3.1.16, 5.2.16). For instance, if you indicated that consent will be written and oral, does this refer to all participants undergoing written and oral consent or does it refer to different consent processes for different participant groups? You should also justify why you have chosen these forms of consent. If you are using oral consent, explain how it will be recorded (e.g. in field notes, using tape recording).
Go to question 2610.0

2610.0 Will there be participants who are not fluent in English or who have difficulty understanding English?

No - Go to question 2670.0
Yes - Go to question 2620.0

2620.0 In what language(s) will the research be conducted?
Go to question 2630.0

2630.0 Will an interpreter be present during discussions with the participants about the research project?

No - Go to question 2640.0
Yes - Go to question 2650.0

2640.0 Why will an interpreter not be present during discussions with participants about the research project?
Go to question 2650.0

2650.0 Will participants be provided with certified translated documents (Participant Information Statement and Participant Consent Forms, questionnaires etc) in the language in which they speak?

No - Go to question 2660.0
Yes - Go to question 2685.0

2660.0 Explain why participants will not be provided with written information in the language in which they speak
Go to question 2685.0

2670.0 Will a Participant Information Statement be provided? If so, please attach this in the Documents tab.

No - Go to question 2680.0
Yes - Go to question 2685.0

2680.0 Give reasons why a Participant Information Statement will not be provided
Go to question 2685.0

2685.0 Is there an intention to recruit participants who have a physical impairment or disability that may affect the consent process (e.g. blind/vision impaired/deaf/hearing impaired/speech impaired)?

No - Go to SECTION E
Yes - Go to question 2690.0

2690.0 How will you manage your consent process to ensure that these participants are able to provide informed consent? (e.g. provision of your Participant Information Statement in Braille, the presence of an Auslan interpreter, a combination of written and recorded oral consent).
Go to SECTION E

SECTION E
The questions in Section E relate to how you will protect participants' privacy and the confidentiality of their information in your research project.

2700.0 Will you be collecting information/data directly from a participant?

No - Go to question 2715.0
Yes - Go to question 2705.0

2705.0 Which of the following recordings will be used?

- Audio Recordings
- Film/Video Recordings
- Online Surveys
- Other

Go to question 2710.0

2710.0 Outline how these recordings will be used and why they are necessary to achieve the aims of the research project. If your project involves online surveys, state where the surveys will be hosted and comment on any security, data ownership and privacy constraints associated with this survey host
Go to question 2715.0

2715.0 Will you be collecting information/data about a participant from a third party (i.e. another individual)? Please note that this DOES NOT include agencies or organisations

No - Go to question 2735.0
Yes - Go to question 2720.0

2720.0 Describe the information that will be collected from this other person
Go to question 2725.0

2725.0 Will consent be sought from the individuals concerned to obtain information about them from this other person?

No - Go to question 2730.0
Yes - Go to question 2735.0

2730.0 Please explain why consent will not be sought from the individuals concerned to obtain information about them from this other person
Go to question 2735.0

2735.0 The following questions will establish whether the HREC needs to apply federal or state/territory privacy legislation when reviewing your ethics application.

Will you use, collect or disclose information about human participants from an agency, authority or organisation? This includes Commonwealth agencies, private sector organisations, state/territory agencies and international organisations. For instance, you may be using information from a medical practice, a hospital, a university, a state or federal government department. You should say 'yes' even if it is your own organisation (e.g. your medical practice)

No - Go to question 3225.0
Yes - Go to APPENDIX 14

3225.0 Is the research project likely to produce information or results that are of personal significance to individual participants? For instance, a project may reveal that participants are at risk of developing a particular disease, provide insight into their intellectual/other abilities, or indicate that they have physical or mental health problems.

No - Go to question 3265.0
Yes - Go to question 3230.0

3230.0 Is it intended that any such information that is of potential significance to participants will be reported back to the individual concerned?

No - Go to question 3240.0
Yes - Go to question 3235.0

3235.0 Specify who will be responsible for communicating these results back to participants, and how these results will be communicated (e.g. telephone call, letter, copy of publication, consultation with clinician).
Go to question 3245.0

3240.0 Explain why these results will not be reported back to individual participants.
Go to question 3255.0

3245.0 Will results that are of personal significance to participants be reported to anyone other than the participant?

No - Go to question 3265.0
Yes - Go to question 3250.0

3250.0 To whom will the results be reported, and why?
Go to question 3255.0

3255.0 Will the participant be told that their results will be reported to this third party?

No - Go to question 3260.0
Yes - Go to question 3265.0

3260.0 Explain why the participant will not be told that their results will be reported to this third party.
Go to question 3265.0

3265.0 Is the research project likely to reveal a significant risk to the health or wellbeing of persons other than the participant (e.g. family members, colleagues, community members)?

No - Go to question 3275.0
Yes - Go to question 3270.0

3270.0 Describe what will be done with this information concerning a significant risk to the health or well-being of persons other than the participant, and explain why.
Go to question 3275.0

3275.0 Does this project involve the use of information that you or your organisation had collected previously for another purpose?

No - Go to question 3290.0
Yes - Go to question 3280.0

3280.0 When you collected this information, did the original consent cover the uses of the information that you are now proposing in this project?

No - Go to question 3285.0
Yes - Go to question 3290.0

3285.0 Please justify why the HREC should permit you to operate outside the original terms of consent.
Go to question 3290.0

3290.0 Describe how the overall results of this research project will be disseminated (e.g. journal publications and book chapters, conference presentations, student theses, creative works).
Go to question 3295.0

3295.0 Will the confidentiality of participants and privacy of their data be protected in the dissemination of overall research results? Please note that if you propose to identify individuals in publications, you should select 'no' here and obtain their consent for this. Please also note that if you have obtained personal information without individual consent under a waiver of consent, you can only publish this information in de-identified form.

No - Go to question 3305.0
Yes - Go to question 3300.0

3300.0 Explain how confidentiality of participants and privacy of their data will be protected in the dissemination of research results.
Go to question 3310.0

3305.0 Explain why confidentiality of participants and privacy of their data will not be protected in the dissemination of research results (e.g. because it is appropriate to identify/name participants), describing the measures that have been taken to respect and protect the welfare and rights of participants (e.g. they will consent to being named).
Go to question 3310.0

3310.0 Will the information generated in this research project be used for any purpose(s) other than those outlined in this application? For example, will data be retained and used in future research projects, used to establish a database/research register, provided to a third party or to a public data sharing resource? Please note that this question does not refer to the use of the data for the purposes of this project (e.g. publication of results).

No - Go to question 3320.0
Yes - Go to question 3315.0

3315.0 You have indicated that the information generated in this research project will or may be used for another purpose. Please describe this other purpose here and ensure it is outlined on the Participant Information Statement/Consent Form. If this other purpose involves data being made available to other researchers or third parties, outline the standards that will be applied to protect participants' privacy and the confidentiality of data. Please note that ethical approval will also need to be sought in future for any secondary use of the data.
Go to question 3320.0

3320.0 Outline how feedback concerning the overall results of the project will be made available to participants (e.g. via a lay summary or newsletter). If participants are not to receive feedback, please justify why not.
Go to question 3325.0

3325.0 Describe where study materials will be stored DURING the project (including electronic and hard copy files, consent forms, audio recordings, questionnaires, interview transcripts, video recordings, photographs etc). Please include building and room numbers for hard copy materials.
Go to question 3330.0

3330.0 Describe where study materials will be stored upon COMPLETION of the project (including electronic and hardcopy files, consent forms, audio recordings, questionnaires, interview transcripts, video recordings, photographs etc). Please include building and room numbers for hardcopy materials. Note that on conclusion of the project a copy of all materials must be kept in an accessible and secure location on University premises.
Go to question 3335.0

3335.0 Outline the security measures that will be used to protect study materials from misuse, loss or unauthorised access during and after the project (e.g. removal of identifiers, secure storage, restriction of access to appropriate personnel etc).
Go to question 3340.0

3340.0 Specify how long study materials will be retained for after project completion.
Please note that the options provided below are intended to facilitate compliance with relevant legislation from the State Records Authority of NSW. Data from research involving children; and from clinical trials, scanning and radioactivity studies, clinical studies, genetic manipulation, human tissue studies, and psychological research that has potential long term effects must be retained for a minimum of 20 years or until participants are 25 years of age (whichever is longer). Data from other types of studies must be retained for a minimum of 5 years. For some types of research (e.g. oral history, gene therapy) or where it is intended to reuse data in the future, it is appropriate to retain data in perpetuity (i.e. indefinitely).

- 20 yrs/until subjects are 25
- 5 years
- In perpetuity
- Other

Go to question 3345.0

3345.0 Explain why this storage period has been chosen.
Go to question 3350.0

3350.0 At the end of the project, will study materials/information be stored in individually identifiable or re-identifiable form? Please note that this does not refer to the consent forms.
Individually identifiable information is that from which the identity of a specific individual can reasonably be ascertained. Re-identifiable information has had identifiers removed and replaced by a code, so it is possible to identify individuals by using the code. Non-identifiable information has had all identifiers irreversibly removed or was never identifiable (see Chapter 3.2 of the National Statement for more information).

No - Go to question 3360.0
Yes - Go to question 3355.0

3355.0 Outline why it is necessary to store information in identifiable or re-identifiable form, given this poses a potential risk to participants' privacy and the confidentiality of data. If the data can be re-identified using a code, specify the security arrangements for the code and which research personnel will have access to the code.
Go to question 3360.0

3360.0 If they are not to be kept in perpetuity, how will project materials ultimately be disposed of?
Go to SECTION F

SECTION F
The questions in Section F concern risks to both participants and others connected with the study.

3450.0 Participation in research can involve potential harm to participants including physical, psychological, reputational, financial, spiritual, emotional and social distress. Please outline any potential harm and justify it with regard to the potential benefits of the project. What steps will the researchers take to minimise potential harm endured as a consequence of participation? (e.g. by providing access/information to counselling)
Go to question 3460.0

3460.0 Are there any other risks involved in this research? For example, to the research team, the organisation, others? What are these risks? Explain how these risks will be negated/ minimised/ managed.
Go to SECTION G

SECTION G
The questions in Section G concern details of the research study. Please answer the following questions.

3570.0 The nature of this project is most appropriately described as research involving (more than one may apply):

- Clinical Trials
- Epidemiological studies, population health and/or public health
- Participant observation (ethnography, systematic)
- Questionnaire/survey
- Interviews (including oral history)
- Focus groups
- Data linkage studies
- Psychiatric or clinical psychology studies, or psychological experiments
- Human physiological investigation(s)
- Other

Go to question 3580.0

3580.0 Are you doing research in a context which requires you to get permission from an appropriate authority e.g. a school, corporation, or similar?

No - Go to question 3590.0
Yes - Go to question 3581.0

3581.0 Please provide the name/s of the appropriate authority/ies and include any relevant correspondence or approvals as attachments to your application. Note that ethics approval may be given which is conditional on these approvals being obtained prior to research being conducted.
Go to question 3590.0

3590.0 Outline in lay language the theoretical, empirical and/or conceptual basis, background evidence for the research proposal with reference to the relevant literature (include at least four research citations). Note, that your study should be "based on a thorough study of the current literature, as well as previous studies" (NS 1.1 c).
Go to question 3600.0

3600.0 Outline in lay language the methodology for the research proposal. Note, that you study should be "designed or developed using methods appropriate for achieving the aims of the proposal" (NS 1.1 b). Your response should include:
• Aims and hypotheses/research questions
• Research plan including duration of the study and/or timeline
• Participant characteristics including sex, age range and inclusion/exclusion criteria (if relevant)
• The intended sample size with a justification, and/or the particiant sampling/selection strategy (as relevant to your study)
• Details of where the study will be undertaken (location/site/URL)
• Details of how data will be collected and analysed
• Potential significance of the study
End of Questions

APPENDIX 1
Women who are pregnant and the human foetus
You have indicated that Women who are pregnant and the human foetus would be included in your study. Please answer the following additional questions.

410.0 What steps will be taken to ensure that the well-being and care of the woman who is pregnant and her foetus takes precedence over the aims of the research?
Go to question 420.0

420.0 Provide a justification for the proposed research
Go to question 480.0

APPENDIX 2
Children and/or young people
You have indicated that Children and/or young people would be included in your study. Please answer the following additional questions.

490.0 Why is the participation of children required?
Go to question 500.0

500.0 How has this study been designed to be appropriate for children or young people?
Go to question 510.0

510.0 What is the age range of all participants involved in this study?
Go to question 520.0

520.0 Have you applied for a Working with Children check? You must complete the online form at www.newcheck.kids.nsw.gov.au and provide proof of identification with your application number to a NSW motor registry or NSW Council Agency.

No - Go to question 530.0
Yes - Go to question 540.0

530.0 Give reasons why you have not applied for a Working with Children check
Go to question 540.0

540.0 - Will consent be sought of the child/young person?

No - Go to question 560.0
Yes - Go to question 550.0

550.0 Explain how the consent of the child/young person will be sought
Go to question 570.0

560.0 Explain why the consent of the child/young person will not be sought
Go to question 570.0

570.0 Will consent be sought from the parent/guardian?

No - Go to question 580.0
Yes - Go to question 583.0

580.0 Explain why the consent of the parent/guardian will not be sought
Go to question 583.0

583.0 Will research be conducted in schools?

No - Go to question 590.0
Yes - Go to question 586.0

586.0 What type of school/s are involved? More than one may apply.

- Public schools
- Independent schools
- Catholic schools

Go to question 588.0

588.0 Please indicate what permissions will be obtained to conduct this research (more than one may apply).

- School Principal
- SERAP (State Education Research Application Process)
- CEO (Catholic Education Office)

Go to question 590.0

APPENDIX 3
Existing dependent or unequal relationship
You have indicated that an Existing dependent or unequal relationship would be included in your study. Please answer the following additional question
Go to question 600.0

600.0 Describe the existing dependent or unequal relationship
Go to question 610.0

610.0 How will the process of obtaining consent avoid perceived/actual coercion and enable persons in dependent relationships to give voluntary consent?

Go to question 620.0

APPENDIX 4
People with a cognitive impairment, an intellectual disability or a mental illness
You have indicated that People with a cognitive impairment, an intellectual disability or a mental illness would be included in your study. Please answer the following additional questions

630.0 Will there be participants who do not have capacity to give consent for themselves?

No - Go to question 670.0
Yes - Go to question 640.0

640.0 Specify why these participants do not have capacity to give consent for themselves
Go to question 650.0

650.0 Who will consent for the inclusion of these participants?
Go to question 660.0

660.0 On what basis is it believed that these people have legal authority to give consent for these participants?
Go to question 670.0

670.0 Describe the consent process
Go to question 680.0

APPENDIX 5
People highly dependent on medical care who may be unable to give consent
You have indicated that People highly dependent on medical care who may be unable to give consent would be included in your study. Please answer the following additional questions

690.0 Are you doing research on patients (i.e. subjects receiving health care)?

No - Go to question 710.0
Yes - Go to question 700.0

700.0 List the procedures/techniques which would not form part of the patient's routine clinical management
Go to question 710.0

APPENDIX 6
People who may be involved in illegal activity
You have indicated that People who may be involved in illegal activity would be included in your study. Please answer the following additional questions.

720.0 Participants may be subject to risks because of their involvement in research that uncovers illegal activity. This includes research intending to uncover illegal activity, as well as research not specifically designed to, but likely to discover, illegal activity. Please outline how these risks are justified by the benefits of the research. These risks must be specified in the PIS.
Go to question 730.0

730.0 To what extent will you keep confidential any information about illegal activity by participants or others? These details must be communicated to participants in the PIS.
Go to question 750.0

740.0 Are you aware of your legal obligations to disclose information?

No - Go to question 745.0
Yes - Go to question 750.0

745.0 You may be in a situation where there is a statutory obligation for you to disclose information revealed or discovered, or you may be subject to legal orders that compel disclosure of information obtained by a researcher. These circumstances must be clearly explained to participants. In light of this, please discuss below your response that you are not aware of your legal obligations and how you will rectify this.
Go to question 750.0

750.0 How will you respond to any legal obligation or order to disclose such information?
Go to question 760.0

APPENDIX 7
Aboriginal and/or Torres Strait Islander peoples
You have indicated that Aboriginal and/or Torres Strait Islander peoples would be included in your study. Please make sure you have read Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research and have considered the six core values of Spirit and Integrity, Reciprocity, Respect, Equality, Survival and Protection, and Responsibility in the design and implementation of your research. In addition, please note that all research involving the health of Aboriginal and Torres Strait Islander peoples undertaken in NSW must in the first instance be forwarded to the Aboriginal Health and Medical Research HREC for approval and/or comment.

770.0 Has there been appropriate representation of Aboriginal or Torres Strait Islander peoples in the development of the research protocol? If there has been no representation please state your reasons. If there has been representation please provide details below.

Go to question 780.0

780.0 Have Aboriginal or Torres Strait Islander peoples been involved from the early stages of the protocol development? If your response is "no" please discuss why this is appropriate for your study. If your response is "yes" please describe this involvement below

Go to question 790.0

790.0 All research involving Aboriginal and Torres Strait Islander peoples must demonstrate consultation with appropriate community groups, community representatives and/or community members. Please provide a brief description of the consultation process that you have undertaken for your proposed research.

Go to question 810.0

810.0 Do any of the researchers identify as Aboriginal or Torres Strait Islander peoples?

No
Yes
Go to question 820.0

820.0 Will the research be undertaken in partnership with Aboriginal and Torres Strait Islander peoples? If your response is "no" you should state why this is appropriate for your study. If your response is "yes" please describe the partnership below.

No
Yes
Go to question 830.0

830.0 Is there a research agreement between the participating communities and the researchers? If there is no research agreement, please discuss why this is appropriate for your study. If there is a research agreement please provide details of this agreement (where there is a written research agreement, either existing or proposed, this should be uploaded in the "documents" tab in IRMA).

No
Yes
Go to question 840.0

840.0 Please provide a brief description of the role of Aboriginal or Torres Strait Islander peoples in the research
Go to question 850.0

850.0 Will researchers acknowledge the cultural property rights of Aboriginal or Torres Strait Islander peoples in relation to knowledge, ideas, cultural expressions and cultural materials? If your response is "no" please discuss why this is appropriate for your study. If your response is "yes" please provide details below.

Go to question 860.0

860.0 How will researchers acknowledge the sources of information and those who have contributed to the research?

No
Yes
Go to question 870.0

870.0 Briefly describe how the contribution of Aboriginal and Torres Strait Islander peoples will be acknowledged
Go to question 880.0

880.0 How will the research provide benefits to the Aboriginal and Torres Strait Islander peoples?

No
Yes
Go to question 890.0

890.0 How does the research relate to the priority and needs of participant communities?

No
Yes
Go to question 900.0

900.0 How will the research build the capacity of Aboriginal people/organisations through participation?

No
Yes
Go to question 910.0

910.0 Briefly describe how the research will contribute to the advancement and well being of participants and their communities
Go to question 915

915.0 Describe how the outcomes of the research/feedback will be communicated to participants
Go to question 920

APPENDIX 8
Research involving travel overseas
You have indicated that your research involves travel overseas. Please answer the following additional questions.

940.0 What country/countries will you be visiting?
Go to question 950.0

950.0 What is the DFAT (Department of Foreign Affairs and Trade) alert level for the countries you will be visiting?
Go to question 960.0

960.0 Have you completed a safety protocol? Note that a safety protocol is required for all students doing research overseas. In addition a safety protocol should be provided where non-student researchers are travelling to areas with an increased DFAT (level 3 or 4) warning. This safety protocol should be attached to your application in the Documents tab.

No
Yes
Go to question 970.0

970.0 Have you obtained formal permission from relevant authorities for entry to the area to carry out the research (e.g. national or local government bodies; organisations of local communities)?

No - Go to question 990.0
Yes - Go to question 980.0

980.0 Name the relevant authorities and attach the relevant correspondence

Go to question 993.0

990.0 Please outline why you have not obtained formal permission from relevant authorities
Go to question 993.0

993.0 In the country/ies where research is intended to be conducted are there ethics approval processes that are relevant to the research and are such processes mandatory or voluntary in relation to the proposed research?
Go to question 996.0

996.0 In the country/ies where research is intended to be conducted is the proposed research lawful? Please discuss.
Go to question 998.0

998.0 Outline the experience or access to expertise that will enable researchers to engage with participants in a manner that accords them respect and protection. Where research is to be conducted overseas by a researcher who is subject to academic supervision researchers should explain how that supervision is to be effected so that due respect and protection will be accorded to participants.
Go to question 1000.0

1000.0 Outline how the researchers / investigators have taken into account the opinions and expectations of participants and their communities on:
(a) the way the research will be conducted;
(b) participants' post-research welfare;
(c) application of the results of the research;
(d) access to culturally sensitive artefacts or matters;
(e) known issues affecting a local cultural norm;
(f) any cultural, religious or political differences you may encounter.
Go to question 1010.0

1010.0 Please outline any local factors that make it problematic to comply with the ethical standards expressed in the National Statement on Ethical Conduct in Human Research (NHMRC 2007)?
Go to question 1013.0

1013.0 Has a local contact for the receipt of complaints been provided in the Participant Information Statement in accordance with 4.8.16 of the National Statement?

No - Go to question 1016.0
Yes - Go to question 1020.0

1016.0 Please explain why you have not provided a local contact for receipt of complaints in the Participant Information Statement.
Go to question 1020.0

APPENDIX 9
Research that could jeopardise a participant's employment
You have indicated that your study involves research that could jeopardise a participant's employment. Please answer the following additional questions.

1040.0 Indicate at whose workplace the research is to be conducted?
Go to question 1050.0

1050.0 What is the relationship of the researcher / investigator to the workplace (e.g. proprietor, student, consultant, employee - past or present)?
Go to question 1060.0

1060.0 What is the status in the workplace of all of the proposed participants (e.g. Employee, client, consultant)?
Go to question 1070.0

1070.0 What measures will be taken to minimise the risk to workplace relationships?
Go to question 1080.0

APPENDIX 10
Interventions and therapies, including clinical and non-clinical trials
You have indicated that your study involves interventions and therapies, including clinical and non-clinical trials. Please answer the following additional questions

1090.0 Will genetically modified organisms or other gene modification techniques be used in the research?

No - Go to question 1110.0
Yes - Go to question 1100.0

1100.0 Provide details of the genetically modified organisms or other gene modification techniques. Describe the procedures, which are in place to minimise the risks to participants and researchers.

Go to question 1110.0

1110.0 Will toxins, mutagens, teratogens or carcinogens be used?

No - Go to question 1130.0
Yes - Go to question 1120.0

1120.0 Provide details of the toxins, mutagens, teratogens or carcinogens. Describe the procedures, which are in place to minimise the risks to participants and researchers.

Go to question 1130.0

1130.0 Will biohazardous materials be used?

No - Go to question 1150.0
Yes - Go to question 1140.0

1140.0 Provide details of the biohazardous materials. Describe the procedures, which are in place to minimise the risks to participants and researchers.

Go to question 1150.0

1150.0 Does your study involve the administration of a drug / medicine (includes a complementary / alternative medicine)?

No - Go to question 1250.0
Yes - Go to question 1154.0

1154.0 Is the study using only approved drug(s) in accordance with Therapeutic Goods Administration (TGA) product information? This information is contained on the Australian Register of Therapeutic Goods (ARTG), which is available on the TGA's website.

No - Go to question 1160.0
Yes - Go to question 1157.0

1157.0 What is the approved therapeutic indication (including dose and duration) in Australia? Please note that you must upload the public ARTG summary in the Documents tab as evidence that the drug is being used in accordance with this approved therapeutic indication.
Go to question 1160.0

1160.0 How many drugs will be used in this research project?
Go to question 1170.0

1170.0 What are the Trade name/s of the drugs to be used in this research project?
Go to question 1180.0

1180.0 What is the dosage regimen?
Go to question 1190.0

1190.0 What are the known adverse effects?
Go to question 1200.0

1200.0 What are the known contra-indications/warnings?
Go to question 1210.0

1210.0 What concurrent drugs should be avoided?
Go to question 1220.0

1220.0 Describe briefly the type of study to be conducted
Go to question 1230.0

1230.0 How many participants are projected to be enrolled into the trial at this site and in total? (Please give a single figure for each, not a range)
Go to question 1240.0

1240.0 What is the projected duration of the trial, from first enrolment to the last protocol interaction with the last enrolled subject (in years)?
Go to question 1250.0

1250.0 Does your study involve the trial of a medical device?

No - Go to question 1410.0
Yes - Go to question 1254.0

1254.0 Is the study using only approved medical devices in accordance with Therapeutic Goods Administration (TGA) product information? This information is contained on the Australian Register of Therapeutic Goods (ARTG), which is available on the TGA's website.

No - Go to question 1260.0
Yes - Go to question 1257.0

1257.0 What is the approved therapeutic indication for the device in Australia? Please note that you must upload the public ARTG summary in the Documents tab as evidence that the device is being used in accordance with this approved therapeutic indication.
Go to question 1260.0

1260.0 Describe the trial phase for the medical device.
Go to question 1270.0

1270.0 How many devices, including comparators, are being tested in the trial?
Go to question 1280.0

1280.0 What are the Trade name/s of the devices?
Go to question 1290.0

1290.0 Is the device implantable?

No
Yes
Go to question 1300.0

1300.0 What are the known adverse effects?
Go to question 1310.0

1310.0 What are the known contra-indications/warnings?
Go to question 1320.0

1320.0 What is the length of time participants will be monitored for adverse reactions?
Go to question 1330.0

1330.0 Has the sponsor or manufacturer agreed to supply the device free of charge for the duration of the trial?

No
Yes
Go to question 1340.0

1340.0 Describe what arrangements have been made for the supply of the device
Go to question 1350.0

1350.0 Describe procedures for tracking participants for the life time of the device on the completion of the trial.
Go to question 1360.0

1360.0 Will the trial device/treatment be made available to participants after the completion of the trial?

No - Go to question 1380.0
Yes - Go to question 1370.0

1370.0 Explain who will have access to the trial device, under what conditions, for how long and who will pay for the device/treatment
Go to question 1390.0

1380.0 Explain why participants will not have post trial access to the device
Go to question 1390.0

1390.0 How many participants are projected to be enrolled into the trial at this site and in total? (Please give a single figure for each, not a range)
Go to question 1400.0

1400.0 What is the projected duration of the trial, from first enrolment to the last protocol interaction with the last enrolled subject (in years)?
Go to question 1410.0

1410.0 Does your study involve the administration of a therapeutic treatment (e.g. exercise intervention, speech therapy, psychotherapy etc)?

No - Go to question 1450.0
Yes - Go to question 1420.0

1420.0 Describe briefly the type of study to be conducted
Go to question 1430.0

1430.0 How many participants are projected to be enrolled into the trial at this site and in total? (Please give a single figure for each, not a range)
Go to question 1440.0

1440.0 What is the projected duration of the trial, from first enrolment to the last protocol interaction with the last enrolled subject (in years)?
Go to question 1450.0

1450.0 Is the research being conducted under the Clinical Trial Notification Scheme (CTN)? Please note that all Clinical Trials involving a CTN will be forwarded for consideration by the Clinical Trials Sub-Committee at the Sydney Local Health District Network

No
Yes
Go to question 1460.0

1460.0 Is the research being conducted under the Clinical Trial Exemption Scheme (CTX)? Please note that all Clinical Trials involving a CTX will be forwarded for consideration by the Clinical Trials Sub-Committee at the Sydney Local Health District Network

No
Yes
Go to question 1470.0

1490.0 Will this research be undertaken on behalf of (or at the request of) a company (e.g. Medical Device company)?

No - Go to question 1600.0
Yes - Go to question 1500.0

1500.0 Provide details of the name of the sponsor (and co-sponsors if any)? This information should be included in the Participant Information Statement and Consent Form. Please note that projects supported by a commercial sponsor may incur an administrative fee.
Go to question 1510.0

1510.0 Will the sponsor(s) provide any support in money or kind? Provide details
Go to question 1520.0

1520.0 Will the sponsor(s) undertake in writing to abide by either the Medicines Australia Guidelines for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (www.medicinesaustralia.com.au) or the ABPI Clinical Trial Compensation Guidelines?

No - Go to question 1540.0
Yes - Go to question 1530.0

1530.0 **Provide details**
Go to question 1540.0

1540.0 Will the sponsor(s) undertake in writing to indemnify the institution, the HREC(s) and the researchers?

No - Go to question 1560.0
Yes - Go to question 1550.0

1550.0 Provide details
Go to question 1560.0

1560.0 Does the sponsor(s) hold a current insurance policy to cover this project?

No - Go to question 1580.0
Yes - Go to question 1570.0

1570.0 Provide details
Go to question 1580.0

1580.0 If all projected participants complete the protocol, what total payment will be received from the sponsoring company? (Please give a single figure, not a range)
Go to question 1590.0

1590.0 If all projected participants complete the protocol, what additional "in kind" support (ie. free drug, equipment, etc), if any, will be provided by the sponsoring company?
(NB: after answering this question, you will be directed back to Section B)
Go to question 1600.0

APPENDIX 11
Human tissue samples
You have indicated that your study involves human tissue samples. Please answer the following additional questions.

1610.0 Describe the nature of the tissue samples to be used in your research study (i.e. blood, saliva, heart, brain, bone etc)?
Go to question 1620.0

1620.0 Will your tissues be collected from participants who will be recruited to this research project?

No - Go to question 1640.0
Yes - Go to question 1630.0

1630.0 By whom will the sample/s be collected? Please detail the process of collection
Go to question 1640.0

1640.0 Will your tissues be obtained from a tissue bank?

No - Go to question 1670.0
Yes - Go to question 1650.0

1650.0 Name the tissue bank from which the tissue samples are being obtained
Go to question 1660.0

1660.0 At the time of collection of the samples in the tissue bank, for which purposed was consent obtained?
Go to question 1670.0

1670.0 Will your tissue samples be sourced/obtained from overseas?

No - Go to question 1690.0
Yes - Go to question 1680.0

1680.0 Name the overseas organisation/s from which the sample/s is being obtained and outline the approval process obtained in that country
Go to question 1690.0

1690.0 Will your tissue samples be sourced from another source not mentioned above?

No - Go to question 2030.0
Yes - Go to question 1700.0

1700.0 Please describe the "other" source of tissue to be used in this research study
Go to question 1710.0

1710.0 In 2003, there were amendments to the Human Tissue Act 1983 relating to the legal requirement for consent to the use of human tissue for research purposes.
The amendments are not retrospective. That means there are different consent requirements for tissue removed before and after the commencement of the amendments.
The amendments commenced on 1 November 2003.

Were any of your samples collected before 1 November 2003?

No - Go to question 1860.0
Yes - Go to question 1720.0

1720.0 Were any of your samples removed for the purposes of a post mortem examination?

No - Go to question 1750.0
Yes - Go to question 1730.0

1730.0 Was consent obtained for use of the samples removed for the purpose of a post mortem examination for research (from the deceased person before death or their next of kin after death)?

No - Go to question 1740.0
Yes - Go to question 1750.0

1740.0 The National Statement indicates that consent should usually be obtained, unless it is suitable to waive consent. Please outline why you are seeking a waiver of consent
Go to question 1750.0

1750.0 Were any of your samples removed from a deceased person other than for the purpose of a post mortem examination?

No - Go to question 1800.0
Yes - Go to question 1760.0

1760.0 Was consent obtained for the use of samples removed from a deceased person other than for the purpose of a post mortem examination for research (from the deceased person before death or their next of kin after death)?

No - Go to question 1770.0
Yes - Go to question 1780.0

1770.0 The law does not allow consent to be waived even if the requirements of the National Statement are met. The law overrides the ability in the NS to waive consent. Consent must be obtained from the person, or in the event that the person is now deceased from their next of kin. Please comment
Go to question 1780.0

1780.0 Have you obtained the written authorisation of a designated officer of a hospital?

No - Go to question 1790.0
Yes - Go to question 1800.0

1790.0 The law requires that you obtain the written authorisation of a designated officer of a hospital. Please comment.
Go to question 1800.0

1800.0 Were any of the tissue samples removed in the course of a medical, dental or surgical procedure?

No - Go to question 1830.0
Yes - Go to question 1810.0

1810.0 Was consent obtained for the use of the tissue samples removed in the course of a medical, dental or surgical procedure for research?

No - Go to question 1820.0
Yes - Go to question 1830.0

1820.0 The National Statement indicates that consent should usually be obtained, unless it is suitable to waive consent. Please outline why you are seeking a waiver of consent
Go to question 1830.0

1830.0 Were any of the tissue samples removed for the purposes of research?

No - Go to question 1860.0
Yes - Go to question 1840.0

1840.0 Was consent obtained for the use of the tissue samples removed for the purposes of research?

No - Go to question 1850.0
Yes - Go to question 1860.0

1850.0 The common law requires the person's consent to the removal, otherwise the removal would be a battery. The law does not allow consent to be waived. Please comment.
Go to question 1860.0

1860.0 Were any of your samples collected after 1 November 2003?

No - Go to question 2030.0
Yes - Go to question 1870.0

1870.0 Were any of the tissue samples held in a block or tissue slide?

No - Go to question 1900.0
Yes - Go to question 1880.0

1880.0 Was consent obtained for the use of the tissue samples held in a block or tissue slide for research?

No - Go to question 1890.0
Yes - Go to question 1900.0

1890.0 Were tissues removed from a deceased body (either for the purposes of a post mortem examination or otherwise)?
Go to question 1900.0

1900.0 Were tissues removed from a deceased body (either for the purposes of a post mortem examination or otherwise)?

No - Go to question 1950.0
Yes - Go to question 1910.0

1910.0 Was consent obtained for use of the samples removed for the purpose of a post mortem examination for research (from the deceased person before death or their next of kin after death)?

No - Go to question 1920.0
Yes - Go to question 1930.0

1920.0 The law does not allow consent to be waived even if the requirements of the National Statement are met. The law overrides the ability in the NS to waive consent. Consent must be obtained from the person, or in the event that the person is now deceased from their next of kin. Please comment
Go to question 1930.0

1930.0 Have you obtained the written authorisation of a designated officer of a hospital?

No - Go to question 1940.0
Yes - Go to question 1950.0

1940.0 The law requires that you obtain the written authorisation of a designated officer of a hospital. Please comment.
Go to question 1950.0

1950.0 Were any of the tissue samples removed in the course of a medical, dental or surgical procedure?

No - Go to question 1980.0
Yes - Go to question 1960.0

1960.0 Was consent obtained for the use of the tissue samples removed in the course of a medical, dental or surgical procedure for research?

No - Go to question 1970.0
Yes - Go to question 1980.0

1970.0 The law does not allow consent to be waived even if the requirements of the National Statement are met. The law overrides the ability in the NS to waive consent. Consent must be obtained from the person, or in the event that the person is now deceased from their next of kin. Please comment
Go to question 1980.0

1980.0 Were any of the tissue samples removed for the purposes of research?

No - Go to question 2010.0
Yes - Go to question 1990.0

1990.0 Was consent obtained for the use of the tissue samples removed for the purposes of research?

No - Go to question 2000.0
Yes - Go to question 2010.0

2000.0 The common law requires the person's consent to the removal, otherwise the removal would be a battery. The law does not allow consent to be waived. Please comment.
Go to question 2010.0

2010.0 Were any tissue samples removed from the body of a deceased child who is or was a ward of the state for research purposes?

No - Go to question 2030.0
Yes - Go to question 2020.0

2020.0 In no circumstances is tissue to be removed from the body of a deceased child who is or was a ward of the state for research purposes, either with or without consent from any person. Please comment.
Go to question 2030.0

2030.0 Will the tissue sample(s) used for this project be destroyed once the project is completed?

No
Yes
Go to question 2040.0

2040.0 Does this research involve the development of a cell line?

No
Yes
Go to question 2050.0

2050.0 Does your study involve the creation of a human tissue bank or repository?

No
Yes
Go to question 2060.0

2060.0 Describe how you will ensure that all sample/s used in this project will be stored securely and describe how you will monitor this as well as the use of the sample/s . Note that the creation of a tissue bank requires consultation with the Tissue Bank Reference Group

Go to question 2070.0

APPENDIX 12
Limited disclosure involving active concealment and/or planned deception
You have indicated that your study involves limited disclosure involving active concealment and/or planned deception. Please answer the following additional questions

2090.0 The National Statement states that where research involves active concealment or explicit deception, researchers should provide an explanation of both the real aims and/ or methods and also of why the concealment or deception was necessary after participant involvement in the study has ended. Will a full explanation of the aims and methods of the research and why concealment was necessary be provided?

No - Go to question 2100.0
Yes - Go to question 2095.0

2095.0 What form of explanation will be provided regarding the aims and method of the research and why concealment was necessary (e.g. a written debrief statement)?
Go to question 2110.0

2100.0 Explain why a full explanation will not be given.
Go to question 2110.0

2110.0 Does the proposal involve the secretive use of photographs, tape-recordings, or any other form of record-taking?

No - Go to question 2130.0
Yes - Go to question 2120.0

2120.0 Please provide details and a justification for the secrecy
Go to question 2130.0

APPENDIX 13

Research that poses a risk to the welfare of a University of Sydney student

You have indicated that your study involves research that poses a risk to the welfare of a University of Sydney student. Please answer the following additional questions.

2140.0 There is a requirement of a duty of care for students. Please detail below the risk to the student and how this risk is being addressed/managed (e.g. providing a safety protocol, briefing/debriefing, providing specific training, provision of counselling).

Go to question 2150.0

APPENDIX 14
The following questions allow the HREC to determine what privacy laws apply to the data you are using in your research.

2740.0 Will you obtain consent from individual participants for the use/collection/disclosure of their information (or has consent already been obtained for this purpose)?

No - Go to question 2745.0
Yes - Go to question 3225.0

2745.0 Will this information be individually identifiable or re-identifiable? Please note this refers to the nature of the information as you initially access it, not the nature in which you will store or publish it. Individually identifiable information is that from which the identity of a specific individual can reasonably be ascertained. Re-identifiable information has had identifiers removed and replaced by a code, so it is possible to identify individuals by using the code. Non-identifiable information has had all identifiers irreversibly removed or was never identifiable (see Chapter 3.2 of the National Statement for more information).

No - Go to question 3225.0
Yes - Go to question 2750.0

2750.0 Are any of the agencies, authorities or organisations from which this personal information will be used/collected/disclosed Australian?

No - Go to question 3135.0
Yes - Go to question 2755.0

Australian agencies, authorities or organisations
2755.0 You have indicated that you will use/collect/disclose personal information without individual participant consent. Will any of this information be from Australian Commonwealth agencies?

No - Go to question 2865.0
Yes - Go to question 2765.0

Australian Commonwealth agencies, authorities or organisations
2765.0 Is this a health/medical research project? This includes epidemiological studies, interventions aiming to improve health, clinical/medical record audits that will be published, etc. Please note that your project may be a medical research project even if the personal information you are using/collecting/disclosing is not health information (e.g. if you are collecting demographic information for the purposes of a medical research project).

No - Go to question 3135.0
Yes - Go to question 2770.0

2700.0 You have indicated that you will use/collect/disclose personal information from a Commonwealth agency without individual participants' consent, for the purposes of medical research. The HREC can only approve such a request if it meets certain criteria set out in the Guidelines Under Section 95 of the Privacy Act 1988. Unless these criteria are met, carrying out the project would result in infringement of the Australian Privacy Principles (APPs), which may lead to prosecution or other serious action. Therefore please answer the following questions as honestly and accurately as possible, as they seek to determine whether your project meets the relevant criteria.
Indicate why it is necessary to use/collect/disclose this information in identifiable or re-identifiable (coded) form. More than one may apply

- The project involves linkage of data
- Use of non-identifiable data would compromise the research merit of the project/result in scientific deficiencies
- Other

Go to question 2775.0

2775.0 Please explain your response to the question above. That is, justify why information needs to be collected in identifiable or re-identifiable form, and why the purpose of this project could not be achieved with non-identifiable information
Go to question 2780.0

2780.0 Please indicate why it is impracticable to seek consent from the individuals concerned to collect, use or disclose their personal information. More than one may apply.

- The size of the population involved in the research (i.e. the number of records)
- The risk of introducing bias into the research, affecting the generalisability and validity of the results
- The risk of creating additional threats to privacy by having to link information in order to locate and contact subjects to seek their consent of the results
- The risk of inflicting psychological, social or other harm by contacting participants.
- The difficulty of contacting individuals (i.e. difficulties associated with the age of records or lack of up to date contact details)
- The nature of any existing consent from this population concerning the collection, use or disclosure of their personal information
- The fact that the proposed research is minimally intrusive on the privacy and wellbeing of the individuals involved
- The fact that this research project is an extension of, or closely related to, a previously approved research project
- Other

Go to question 2785.0

2785.0 Provide details regarding your response to the question above. That is, justify why it is impracticable to seek consent from the individuals concerned and reasonable to proceed without consent.
Go to question 2790.0

2790.0 List the Australian Privacy Principles (APPs) that would be infringed as a result of carrying out this project, if the HREC did not apply the S95 Guidelines. All 13 APPs are outlined in the fact sheets on the website of the Office of the Australian Information Commissioner (OAIC).
Go to question 2795.0

2995.0 Indicate which of the following your project involves. More than one may apply. Please note that collection refers to gathering, acquiring or obtaining personal information from any source and by any means. This includes when an agency keeps personal information it has come across by accident or has not requested. Disclosure refers to the release of personal information to others outside an agency. It does not include giving individuals information about themselves. Use refers to the handling and management of information within an agency including the inclusion of information in a publication.

- Collection of personal health information by an agency
- Use/disclosure of personal health information from an agency

Go to question 2800.0

2800.0 If your project involves the COLLECTION of personal health information for research, the Australian Privacy Principles (see APP 3) state that this information must be reasonably necessary for one or more of the agency's functions or activities. If applicable to your project, please comment on how this criterion is satisfied in relation to the information and agency(ies) involved in your project. If not applicable because your project involves use/disclosure only, please write n/a.
Go to question 2805.0

2805.0 Provide the name and a description of the Commonwealth agency(ies) from which information will be collected/used/disclosed. Please note that you will also need to obtain permission from the agency(ies).
Go to question 2810.0

2810.0 Provide a description of the information to be collected/used/disclosed. Please be specific in your answer. For example, instead of simply stating 'demographic and health information', list the specific

types of information such as 'gender, date of birth, physical and mental health diagnoses, number of hospital visits per year'.
Go to question 2815.0

2815.0 Indicate the number of records you are requesting access to.
Go to question 2820.0

2820.0 Describe how the personal information will be used to achieve the aims of the research project. In your answer please explain why the aims of your project cannot be achieved without the collection, use or disclosure of this particular personal information.
Go to question 2825.0

2825.0 List by name and position all research personnel and others (e.g. supervisors, research monitors) who, for the purposes of this research, will have authority to use or access the personal information involved in this project. Please also describe the nature of each person's use of, or access to, the information.
Go to question 2830.0

2830.0 Describe the qualifications, credentials and experience of the research investigators as relevant to this project. Please note that the HREC is required to consider this information under relevant privacy legislation.
Go to question 2835.0

2835.0 Outline the standards that will be applied to protect the personal health information. This should include the terms of any disclosure agreement between the organisation and the researcher to govern the limits on use and disclosure of that information. Please note that relevant privacy guidelines require that you do not disclose this information to anyone else, that you store it securely, that you destroy or de-identify it after project completion and an appropriate retention period, and that this information is not published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained.
Go to question 2840.0

2840.0 Indicate whether the personal information will be disclosed to an overseas recipient (e.g. an overseas cloud storage provider, an overseas research collaborator).

No - Go to question 2850.0
Yes - Go to question 2845.0

2845.0 You have indicated that your project involves the disclosure of personal information overseas. Please list by name all countries to which the information will be sent, and explain how you will comply with APP 8 of the Privacy Act.
Go to question 2850.0

2850.0 In order to approve your proposal, the HREC needs to determine that the public interest in the proposed research substantially outweighs the public interest in the protection of privacy. The following questions will guide you through various criteria that are relevant in this regard. For each question, please indicate which of the criteria listed are specifically relevant to your project.

Please indicate which of the following seven criteria related to risk and potential benefits are relevant when weighing the public interest involved in your project (more than one may apply).

- Any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from this medical research project being undertaken in the manner proposed.
- The fact that the research design cannot be satisfied without risking infringement of privacy and that scientific defects would arise in the medical research if it was not conducted in the manner proposed
- The financial costs of not undertaking this medical research project (to the government, the public, the health care system etc
- The public importance of this medical research project
- The extent to which the data being sought are ordinarily available to the public for a similar purpose to that proposed in this project

- The fact that the project does not require an alteration of the format of the data that would constitute a breach of privacy if it were carried out by the Commonwealth agency
- The fact that the risk of harm to the people whose personal information is to be used in the proposed research is minimal, based on the criteria in section 2.4 of the S95 Guidelines

Go to question 2855.0

2855.0 Indicate which of the following specific research outcomes are relevant when weighing the public interest involved in your project. That is, the fact that this medical research project is likely to contribute to (more than one may apply):

- The identification, prevention or treatment of illness or disease.
- Scientific understanding relating to health
- The protection of the health of individuals and/or communities
- The improved delivery of health services
- Scientific understanding or knowledge.

Go to question 2860.0

2860.0 Indicate which of the following risk management strategies/standards of conduct will be employed in your project to minimise risk and maximise public benefit (more than one may apply).

- Rigorous study design and credentials of the researchers
- If the research involves contact with participants, there are protocols in place to ensure that they are treated with integrity and sensitivity. This includes careful consideration of the degree of intrusiveness of proposed questions/procedures.
- Access to information will be restricted to appropriate researchers.
- The risk of identification of a person or group in the published results will be minimal.
- Specific procedures will followed upon project completion to ensure that all personal information is at least as secure as it was in the original data source, and there is a designated date for data destruction.

Go to question 2865.0

2865.0 You have indicated that you will use/collect/disclose personal information without individual participant consent. Will any of this information be from Australian private sector organisations?

No - Go to question 2990.0
Yes - Go to question 2870.0

Australian private sector organisations

2870.0 Is the information to be used/collected/disclosed personal HEALTH information? For this purpose, health information is defined as a sub-set of personal information (as defined by the Privacy Act 1988) which pertains to a person's health or disability, their use or desired use of health services, the donation of their body parts, or genetic information in a form that is or could be predictive of the health of the individual or their genetic relatives. It includes any personal information collected by a health service provider during the course of providing treatment and care to an individual. See the Privacy Act 1988 for a full definition.

No - Go to question 3135.0
Yes - Go to question 2875.0

2875.0 You have indicated that you will use/collect/disclose personal health information from a private sector organisation without individual participants' consent. The HREC can only approve such a request if it meets certain criteria set out in the Guidelines Under Section 95A of the Privacy Act 1988. Unless these criteria are met, carrying out the project would result in infringement of the Australian Privacy Principles (APPs), which may lead to prosecution or other serious action. Therefore please answer the following questions as honestly and accurately as possible, as they seek to determine whether your project meets the relevant criteria.
Indicate why it is necessary to use/collect/disclose information in identifiable or re-identifiable (coded) form. More than one may apply.

- The project involves linkage of data.

- Use of non-identifiable data would compromise the research merit of the project/result in scientific deficiencies.
- Other

Go to question 2880.0

2880.0 Provide details regarding your response to the question above. That is, justify why information needs to be used/collected/disclosed in identifiable or re-identifiable form, and why the purpose of this project could not be achieved with non-identifiable information.

Go to question 2885.0

2885.0 Indicate why it is impracticable to seek consent from the individuals concerned to collect, use or disclose their personal information. More than one may apply.

- The size of the population involved in the research (i.e. the number of records).
- The proportion of individuals who are likely to have moved or died since the information was originally collected.
- The risk of introducing bias into the research, affecting the generalisability and validity of the results.
- The risk of creating additional threats to privacy by having to link information in order to locate and contact participants to seek their consent.
- The risk of inflicting psychological, social or other harm by contacting participants.
- The difficulty of contacting individuals directly when there is no existing or continuing relationship between the agency and the individuals (i.e. difficulties associated with the age of records or lack of up to date contact details).
- The difficulty of contacting individuals indirectly through public means, such as advertisements and notices.
- The fact that the additional resources needed to obtain consent would impose an undue hardship on the agency.
- Other

Go to question 2890.0

2890.0 Please elaborate on your response to the question above. That is, justify why it is impracticable to seek consent from the individuals concerned.

Go to question 2895.0

2895.0 List the Australian Privacy Principles (APPs) that would be infringed as a result of carrying out this project, if the HREC did not apply the S95A Guidelines. All 13 APPs are outlined in the fact sheets on the website of the Office of the Australian Information Commissioner (OAIC).

Go to question 2900.0

2900.0 Indicate which of the following your project involves. More than one may apply. Please note that collection refers to gathering, acquiring or obtaining personal information from any source and by any means. This includes when an agency keeps personal information it has come across by accident or has not requested. Disclosure refers to the release of personal information to others outside an agency. It does not include giving individuals information about themselves. Use refers to the handling and management of information within an agency including the inclusion of information in a publication.

- Collection of personal health information by an agency
- Use/disclosure of personal health information from an agency

Go to question 2905.0

2905.0 If your project involves the COLLECTION of personal health information for research, the Australian Privacy Principles (see APP 3) state that this information must be reasonably necessary for one or more of the agency's functions or activities. If applicable to your project, please comment on how this criterion is satisfied in relation to the information and agency(ies) involved in your project. If not applicable because your project involves use/disclosure only, please write n/a.

Go to question 2910.0

2910.0 Provide the name(s) and a description of the private sector organisation(s) from which information will be used/collected/disclosed. Please note that you will also need to obtain permission from the organisation(s).

Go to question 2915.0

2915.0 Provide a description of the information to be collected/used/disclosed. Please be specific in your answer. For example, instead of simply stating 'demographic and health information', list the specific types of information such as 'gender, date of birth, physical and mental health diagnoses, number of hospital visits per year'.
Go to question 2920.0

2920.0 Indicate the number of records you are requesting access to.
Go to question 2925.0

2925.0 Describe how the personal information will be used to achieve the aims of the research project. In your answer please explain why the aims of your project cannot be achieved without the collection, use or disclosure of this particular personal information.
Go to question 2930.0

2930.0 List by name and position all research personnel and others (e.g. supervisors, research monitors) who, for the purposes of this research, will have authority to use or access the personal information involved in this project. Please also describe the nature of each person's use of, or access to, the information.
Go to question 2935.0

2935.0 Describe the qualifications, credentials and experience of the research investigators as relevant to this project. Please note that the HREC is required to consider this information under relevant privacy legislation.
Go to question 2940.0

2940.0 Outline the standards that will be applied to protect the personal health information. This should include the terms of any disclosure agreement between the organisation and the researcher to govern the limits on use and disclosure of that information. Please note that relevant privacy guidelines require that you do not disclose this information to anyone else, that you store it securely, that you destroy or de-identify it after project completion and an appropriate retention period, and that this information is not published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained.
Go to question 2945.0

2945.0 Do you plan to use the personal health information to contact an individual?

No - Go to question 2955.0
Yes - Go to question 2950.0

2950.0 You have indicated that you plan to use the personal health information collected or disclosed for the purposes of this project to contact an individual. Relevant privacy guidelines require that you inform that individual of the information below (e.g. on the Participant Information Sheet). Please check the boxes to indicate that you will provide the individual with this information.

- That the health information is being used or disclosed in accordance with the Privacy Act 1988 and the S95A Guidelines.
- How their health information will be used or disclosed.
- That they are free to withdraw their consent at any time.
- Of the standards that will apply to protect their privacy
- Of the complaint mechanisms available to them.

Go to question 2955.0

2955.0 Indicate whether the personal information will be disclosed to an overseas recipient (e.g. an overseas cloud storage provider, an overseas research collaborator).

No - Go to question 2965.0
Yes - Go to question 2960.0

2960.0 You have indicated that your project involves the disclosure of personal information overseas. Please list by name all countries to which the information will be sent, and explain how you will comply with APP 8 of the Privacy Act.

Go to question 2965.0

2965.0 Indicate the nature of your project (please select one):

- Research relevant to public health or safety
- The compilation or analysis of statistics relevant to public health or safety
- The management, funding or monitoring of a health service

Go to question 2970.0

2970.0 In order to approve your proposal, the HREC needs to determine that the public interest in the proposed research substantially outweighs the public interest in the protection of privacy. The following questions will guide you through various criteria that are relevant in this regard. For each question, please indicate which of the criteria listed are specifically relevant to your project.
Indicate which of the following general criteria related to risk and potential benefits are relevant when weighing the public interest involved in your project. More than one may apply.

- The degree to which the proposed collection, use or disclosure of health information is necessary to the functions or activities of the organisation.
- The degree to which the project is relevant to public health or public safety.
- Any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from this project being undertaken in the manner proposed.
- The fact that the research design cannot be satisfied without risking infringement of privacy and scientific defects would arise if the project was not conducted in the manner proposed.
- The costs of not undertaking this project (to the government, the public, the health care system etc).
- The public importance of this project.
- The extent to which the data being sought are ordinarily available to the public for a similar purpose to that proposed in this project.
- The fact that the project does not require an alteration of the format of the data that would constitute a breach of privacy if it were carried out by the organisation.
- The fact that the risk of harm to the people whose personal information is to be used in the proposed research is minimal, based on the criteria in the relevant section(s) of the S95A Guidelines (A.2.6, A.3.6, B.2.6, B.3.6 or C.2.6).

Go to question 2975.0

2975.0 Indicate which of the following research outcomes are relevant when weighing the public interest involved in your project. That is, the fact that this project is likely to contribute to (more than one may apply):

- The identification, prevention or treatment of injury, illness or disease.
- Scientific understanding relating to public health or safety.
- The protection of the health of individuals and/or communities.
- The improved delivery of health services.
- Scientific understanding or knowledge.
- Knowledge of issues within the fields of social science and the humanities relating to public health or public safety.

Go to question 2980.0

2980.0 Indicate which of the following risk management strategies/standards of conduct will be employed in your project to minimise risk and maximise public benefit (more than one may apply).

- Rigorous study design and credentials of the researchers.
- If the research involves contact with participants, there are protocols in place to ensure that they are treated with integrity and sensitivity. This includes careful consideration of the degree of intrusiveness of proposed questions/procedures.
- Access to information will be restricted to appropriate researchers.
- The risk of identification of a person or group in the published results will be minimal.

- Specific procedures will followed upon project completion to ensure that all personal information is at least as secure as it was in the original data source, and there is a designated date for data destruction.

Go to question 2985.0

2985.0 Does your project have any likely benefits to individuals from one or more of the following groups?

- Children and young people.
- Persons with intellectual or psychiatric disability.
- Persons highly dependent on medical care.
- Persons in dependent or unequal relationships.
- Persons who are members of collectivities
- Aboriginal and Torres Strait Islander peoples
- Persons whose information relates to their mental or sexual health
- Persons who are incarcerated
- None of the above.

Go to question 2990.0

2990.0 You have indicated that you will use/collect/disclose personal information without individual participant consent. Will any of this information be from Australian state/territory agencies?

No - Go to question 3130.0
Yes - Go to question 2995.0

Australian state/ territory agencies
2995.0 Where is/are the agency(ies) located. More than one may apply.

- New South Wales
- Australian Capital Territory
- Northern Territory
- Western Australia
- South Australia
- Queensland
- Victoria
- Tasmania

Go to question 3000.0

3000.0 Is the information to be used/collected/disclosed personal HEALTH information? For this purpose (under the Privacy Act 1988), health information is defined as a sub-set of personal information which pertains to a person's health or disability, use or desired use of health services, or relating to donation of body parts and includes information collected by a health service provider during the course of providing treatment and care to an individual.

No - Go to question 3005.0
Yes - Go to question 3005.0

3005.0 You have indicated that you will use, collect or disclose personal information from an Australian state/territory agency without individual participants' consent. The HREC can only approve such a request if it meets certain criteria set out in relevant state/territory privacy guidelines. Unless these criteria are met, carrying out the project would infringe privacy principles, which may lead to prosecution or other serious action. Therefore please answer the following questions as honestly and accurately as possible, as they seek to determine whether your project meets the relevant criteria. Indicate why it is necessary to collect information in identifiable or re-identifiable (coded) form. More than one may apply.

- The project involves linkage of data.
- Use of non-identifiable data would compromise the research merit of the project/result in scientific deficiencies.
- Other

Go to question 3010.0

3010.0 Provide details regarding your response to the question above. That is, justify why information needs to be used/collected/disclosed in identifiable or re-identifiable form, and why the purpose of this project could not be achieved with non-identifiable information.
Go to question 3015.0

3015.0 Indicate why it is impracticable to seek consent from the individuals concerned to collect, use or disclose their personal information. More than one may apply.

- The size of the population involved in the research (i.e. the number of records).
- The proportion of individuals who are likely to have moved or died since the information was originally collected.
- The risk of introducing bias into the research, affecting the generalisability and validity of the results.
- The risk of creating additional threats to privacy by having to link information in order to locate and contact participants to seek their consent.
- The risk of inflicting psychological, social or other harm by contacting participants.
- The difficulty of contacting individuals directly when there is no existing or continuing relationship between the agency and the individuals (i.e. difficulties associated with the age of records or lack of up to date contact details).
- The difficulty of contacting individuals indirectly through public means, such as advertisements and notices.
- The fact that the additional resources needed to obtain consent would impose an undue hardship on the agency.
- Other

Go to question 3020.0

3020.0 Please elaborate on your response to the question above. That is, justify why it is impracticable to seek consent from the individuals concerned.
Go to question 3025.0

3025.0 Indicate which of the following your project involves (more than one may apply); so that the HREC is able to determine which privacy principles are relevant to this project.
Please note that collection refers to gathering, acquiring or obtaining personal information from any source and by any means. This includes when an agency keeps personal information it has come across by accident or has not requested. Disclosure refers to the release of personal information to others outside an agency. It does not include giving individuals information about themselves. Use refers to the handling of information within an agency including the inclusion of information in a publication.

- Collection of personal information about individuals.
- Use of personal information about individuals.
- Disclosure of personal information about individuals.

Go to question 3030.0

3030.0 In some states/territories, different privacy legislation applies for public sector health agencies versus other public sector agencies. Please indicate whether the agency is a health agency or some other public sector agency.

- Yes, it is a health agency
- No, it isn't a health agency

Go to question 3035.0

3035.0 In some states/territories, different privacy legislation applies when personal information is transferred outside of the state/territory where it was collected (to another state/territory in Australia or overseas). Does your project involve the transfer of personal information outside the state/territory in which it was collected (e.g. to a cloud storage provider, a research collaborator)?

No - Go to question 3050.0
Yes - Go to question 3040.0

3040.0 You have indicated that your project involves the transfer of personal information outside the state/territory in which it was collected. Please indicate whether information will be transferred within Australia or overseas. More than one may apply.

- Transfer to another state/territory within Australia
- Transfer outside of Australia

Go to question 3045.0

3045.0 Please justify the transfer of this personal information outside the state/territory in which it was collected, in light of the fact that this will remove it from the legislative protections of that state/territory. Reasons in your justification could include the privacy obligations that the recipient is subject to, and/or the steps that have been taken to protect the information (e.g. disclosure agreements).
Go to question 3050.0

3050.0 Provide the name and a description of the state/territory agency(ies) from which information will be collected. Please note that you will also need to obtain permission from the agency(ies).
Go to question 3055.0

3055.0 Provide a description of the personal information. Please be specific in your answer. For example, instead of simply stating 'demographic and academic information', list the specific types of demographic and academic information such as 'gender, date of birth, postcode, semester 1 unit of study grades'.
Go to question 3060.0

3060.0 Indicate the number of records you are requesting access to.
Go to question 3065.0

3065.0 Describe how the personal information will be used to achieve the aims of the research project. In your answer please explain why the aims of your project cannot be achieved without the collection, use or disclosure of this particular personal information.
Go to question 3070.0

3070.0 List by name and position all research personnel and others (e.g. supervisors, research monitors) who, for the purposes of this research, will have authority to use or access the personal information involved in this project. Please also describe the nature of each person's use of, or access to, the information.
Go to question 3075.0

3075.0 Describe the qualifications, credentials and experience of the research investigators as relevant to this project. Please note that the HREC is required to consider this information under relevant privacy legislation.
Go to question 3080.0

3080.0 Outline the standards that will be applied to protect the personal information. This should include the terms of any disclosure agreement between the agency and the researcher to govern the limits on use and disclosure of that information, and the proposed methods of disposal of the personal information on completion of the research. Please note that relevant privacy guidelines require that you do not disclose this information to anyone else, that you store it securely, that you destroy or de-identify it after project completion and an appropriate retention period, and that this information is not published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained.
Go to question 3085.0

3085.0 Do you plan to use the personal information to contact an individual?

No - Go to question 3095.0
Yes - Go to question 3090.0

3090.0 You have indicated that you plan to use the personal health information collected or disclosed for the purposes of this project to contact an individual. Relevant privacy guidelines require that you inform that individual of the information below (e.g. on the Participant Information Sheet). Please check the boxes to indicate that you will provide the individual with this information.

- That the health information is being used or disclosed in accordance with the Privacy Act 1988 and the S95A Guidelines.
- How their health information will be used or disclosed.
- That they are free to withdraw their consent at any time.
- Of the standards that will apply to protect their privacy.
- Of the complaint mechanisms available to them.

Go to question 3095.0

3095.0 Indicate the nature of your project (please select one):

- Research relevant to public health or safety.
- The compilation or analysis of statistics relevant to public health or safety.

Go to question 3100.0

3100.0 In order to approve your proposal, the HREC needs to determine that the public interest in the proposed research substantially outweighs the public interest in the protection of privacy. The following questions will guide you through various criteria that are relevant in this regard. For each question, please indicate which of the criteria listed are specifically relevant to your project.
Indicate which of the following five criteria related to risk and potential benefits are relevant when weighing the public interest involved in your project (more than one may apply).

- Any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from this medical research project being undertaken in the manner proposed.
- The fact that the research design cannot be satisfied without risking infringement of privacy and scientific defects would arise if the project was not conducted in the manner proposed.
- The costs of not undertaking this project (to the government, the public, the health care system etc).
- The public importance of this project.
- The fact that the risk of harm to the people whose personal information is to be used in the proposed research is minimal, based on the criteria in the relevant state/territory privacy legislation guidelines.

Go to question 3105.0

3105.0 Indicate which of the following research outcomes are relevant when weighing the public interest involved in your project. That is, the fact that this project is likely to contribute to (more than one may apply):

- The identification, prevention or treatment of injury, illness or disease.
- Scientific understanding relating to public health or safety.
- The protection of the health of individuals and/or communities.
- The improved delivery of health services.
- Scientific understanding or knowledge.
- Knowledge of issues within the fields of social science and the humanities relating to public health or public safety.

Go to question 3110.0

3110.0 Indicate which of the following risk management strategies/standards of conduct will be employed in your project to minimise risk and maximise public benefit (more than one may apply).

- Rigorous study design and credentials of the researchers.
- If the research involves contact with participants, there are protocols in place to ensure that they are treated with integrity and sensitivity. This includes careful consideration of the degree of intrusiveness of proposed questions/procedures.
- Access to information will be restricted to appropriate researchers.
- Specific procedures will be followed to ensure that the information will not be published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained.

- Specific procedures will be followed upon project completion to ensure that all personal information is at least as secure as it was in the original source, and there is a designated date of destruction for data.

Go to question 3115.0

3115.0 Does your project have any likely benefits to individuals from one or more of the following groups?

- Children and young people.
- Persons with intellectual or psychiatric disability.
- Persons highly dependent on medical care.
- Persons in dependent or unequal relationships.
- Persons who are members of collectivities.
- Aboriginal and Torres Strait Islander peoples.
- Persons whose information relates to their mental or sexual health.
- Persons who are incarcerated.
- None of the above.

Go to question 3130.0

3130.0 Thank you for responding to the questions about personal information from Australian agencies, authorities and organisations. Will you also use/collect/disclose personal information from an international agency, authority or organisation without individual participants' consent?

No - Go to question 3275.0
Yes - Go to question 3135.0

International agencies, authorities or organisations

3135.0 You have indicated that your project involves the use of identifiable or re-identifiable information about participants without their consent. This needs to be justified with reference to the criteria outlined in the National Statement Section 2.3.6/2.3.7. The following questions will gather relevant information about your project and guide you through these criteria. If you have already provided details on your use of information from one agency, authority or organisation earlier in the form and are now declaring a different source of information, please just provide details for the new agency, authority or organisation. Provide the name and a description of the agency(ies), authority(ies) or organisation(s) from which the information will be collected. Please note that you will also need to obtain permission from them.

Go to question 3140.0

3140.0 Which best describes the agency(ies), authority(ies) or organisation(s)?

- International agency, authority or organisation
- Australian private sector organisation
- Australian state/territory agency
- Australian Commonwealth agency

3145.0 Provide a description of the information to be collected from each agency, authority or organisation. Please be specific in your answer (e.g. instead of simply stating 'demographic information', list the specific types of demographic information such as 'gender, date of birth, level of education').

Go to question 3150.0

3150.0 Indicate the number of records you are requesting access to for each agency, authority or organisation.

Go to question 3155.0

3155.0 Describe the specific uses to which the personal information involved in this project will be applied.

Go to question 3160.0

3160.0 Explain why it is necessary to collect information in identified or potentially identifiable (coded) form. For example, the project involves data linkage; or use of non-identifiable data would result in scientific deficiencies in the project.
Go to question 3165.0

3165.0 Explain why it is impracticable to seek consent from the individuals concerned. For example, the number of records involved makes it impracticable to seek consent; or there is a risk of harm/distress to participants in raising the matters about which the research is concerned; or seeking consent would alert participants in a way which would affect the behavior being researched.
Go to question 3170.0

3170.0 Explain why the collection, use or disclosure of this information is in the public interest, and why the public interest in the project substantially outweighs the public interest in the protection of privacy. That is, how do the potential benefits of this research outweigh the risks associated with not seeking consent? In responding to this question applicants should refer to the ethical framework of the National Statement on Ethical Conduct in Human Research, specifically Section 1 on values and principles and Section 2 on risk and benefits.
Go to question 3175.0

3175.0 Describe the measures that will be taken to protect participants' privacy throughout the course of the project, and the measures that will be taken to protect the confidentiality of data. Please note that it is not permissible to publish or disclose information in identifiable or potentially identifiable form without participants' consent.
Go to question 3180.0

3180.0 The NHMRC requires that the waiver of consent is not prohibited by state, federal or international law. Please confirm this using the check box below. If the waiver is prohibited by law, your application cannot be granted approval.

- I can confirm that the waiver is not prohibited by law.
- The waiver is prohibited by law.

Go to question 3185.0

3185.0 Does your research intend to expose illegal activity? Please note this does not refer to research that does not specifically intend to discover illegal activity, but may or is likely to do so. Rather, it refers to research where the specific purpose is to study and expose illegal activity.

No - Go to question 3195.0
Yes - Go to question 3190.0

3190.0 Outline why the value of exposing the illegal activity justifies any potential adverse effects on the people involved.
Go to question 3275.0

3195.0 Explain how your research project carries no more than 'negligible risk' or 'low risk' to participants, as defined in section 2.1.6 and 2.1.7 of the National Statement.
Go to question 3200.0

3200.0 Is there any reason why participants would not have consented to this use of their information if they had been asked? Please give details.
Go to question 3205.0

3205.0 If the results have significance for participants' welfare, please describe the plan for making information from the research available to them (e.g. via regional news media), if practicable.
Go to question 3210.0

3210.0 If relevant, please confirm that the possibility of commercial exploitation of derivatives of the data or tissue involved in the project will not deprive the participants of any financial benefits to which they would be entitled.
Go to question 3275.0