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| Human Research Ethics Committee Ethics Approval for Research Involving Humans APPLICATION FORM - EXPEDITED REVIEW |

The Human Research Ethics Committee (HREC) at the University of New England applies a hierarchical level of review to applications for ethics approval. This reflects the ethical issues and possible risks to research participants or researchers presented by the research protocol. Risk is the potential for harm, whether it is physical, psychological, social, economic, or legal, or the potential to cause people to think they have been treated disrespectfully.

* E1 expedited review = Negligible or no appreciable risks or ethical issues
* E2 expedited review = Low risk and ethical issues can be addressed by the research design
* Greater than low risk = Full HREC review = Potential for significant risk/ more than low risk, i.e., does not qualify for E1 or E2 review

Further details about the levels of review and response times are available from the [Human Research Ethics website](http://www.une.edu.au/research/res-services/rdi/human-research-ethics). HREC believes that research, especially those involving human participants is a planned process which requires foresight and proper planning. Researchers are advised to consider allocating an adequate time frame for the ethics review process as the Committee may ask for more details or raise questions where the researchers will have to answer/respond and that may take additional time. Researchers can contact the Human Research Ethics Office for any advice or support in completing this form via the contact details or the Zoom link on the HRE webpage, or by telephone on 6773 1115.

NOTE: Human research is to be informed by and comply with the [*National Statement on Ethical Conduct in Human Research, 2023*](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) and the [*Australian Code for the Responsible Conduct of Research*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)

General Information

It is the responsibility of the researchers to ensure that all facets of human research meet the requirements of the National Statement on Ethical Conduct in Human Research 2023.

It is important to consider these principles when designing and carrying out projects.

In assessing applications, it is often difficult for the HREC to obtain a clear picture of what happens to participants from the beginning to the end of the project unless the applicant provides adequate detail. The HREC must assess the impact on participants as well as the project as a whole.

The application should therefore focus on what is happening to and expected of participants and what is in place to ensure their well-being. It is important that this information is presented in a way that clearly shows what is required of participants from the beginning to the completion of a project, and that the impact of these requirements is clearly detailed. The researchers should provide a step-by-step explanation of all requirements. In addition, factors that will impact on participants, researchers and the society in general should be considered. A risk management plan in accordance with the UNE WHS guidelines and supported by the WHS team or the Head of School is desirable.

It is important for applicants to remember the composition of the HREC. Applications must be written primarily for an interested, intelligent person without a scientific background, and not for a specialist. The use of specialist language is not helpful to the Committee and may delay the processing of an application while explanations are sought.

To submit an application to the University of New England’s HREC for approval to undertake research, you are requested to answer all questions clearly and concisely. Questions requiring a Yes/No answer should be answered by checking the appropriate box. This document contains hidden text which will assist you in completing some of the questions by giving you more information. You will notice some questions have blue numbers at the end, these relate to the relevant sections in the National Statement as they relate to that question. As part of this process you should ensure that you are familiar with, and comply with, the [National Statement on Ethical Conduct in Human Research 2023](C://Users/bayers2/Downloads/national-statement-2018-updated%20(2).pdf). The completed and signed application along with all the supplementary documents should be submitted via email to [humanethics@une.edu.au](mailto:humanethics@une.edu.au). The closing date for expedited applications is every Tuesday at 12 noon.

If you require assistance to complete the application or to respond to the request for further information, you are welcome to contact the Human Research Ethics Officer on 02 6773 1115 or by email [humanethics@une.edu.au](mailto:humanethics@une.edu.au) . Further you can meet with the Chair and/or the Human Research Ethics Officer via the [Zoom link](https://www.une.edu.au/research/research-ethics-integrity/human-research-ethics/hrec) shown on the HREC website.

How to use this application form

Commence at Part A. Answer the questions, ending with Part D, and follow the instructions to determine the level of review required for your research. If your project qualifies for expedited review (E1 – Negligible Risk or E2 – Low Risk) you will complete all this form. If your research is greater than low risk you will be directed to complete the HREA (Human Research Ethics Application).

Guidelines to help you respond to the questions in this form are included as **blue hidden text**.

To view the hidden text on a **windows** computer, select  from your toolbar, or go to your toolbar and select the paragraph option and then select ‘show/hide’. If this is not visible please contact IT Help on x5000 for assistance to locate this functionality..

The hidden text will not be seen on the printed version

**DO NOT** submit applications with hidden text showing.

**Sections of the application form**

[Part A Eligibility check for expedited ethical review](#_PART_A_–)

[Part B1 Project title and summary](#_PART_B1_–)

[Part B2 Chief Investigator or Project Supervisor (if student research)](#_PART_B2_–)

[Part C Identification of ethical issues and eligibility for expedited review E1](#_PART_C_–)

[Part D Eligibility for expedited review E2](#_PART_D_–)

[Part E Project details](#_PART_E_–)

Part F1 Declaration by applicants

Part F2 Peer review and Head of School declaration

[Appendix How to submit your application](#_APPENDIX_–_How)

***DO NOT submit this page with your application***

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| --- | --- | --- | --- | --- | --- |
|  | **Reference Number** |  | **Date Received** |  | E1  E2 |

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| Human Research Ethics Committee Ethics Approval for Research Involving Humans APPLICATION FORM - EXPEDITED REVIEW |

Throughout the application [National S](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)tatement (NS) hyperlinks refer to relevant sections of the *National Statement on Ethical Conduct in Human Research, 2015*.

#### PART A – ELIGIBILITY FOR EXPEDITED ETHICAL REVIEW

Does your research involve? *(insert X in box)*

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| --- | --- | --- | --- | --- | --- |
| A1 | Exposure of participants to ionising radiation |  | Yes |  | No |

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| --- | --- | --- | --- | --- | --- |
| A2 | Accessing personally identifiable information or records without specific consent from the individuals to whom the information or records relate |  | Yes |  | No |

Either in the course of identifying/selecting people for recruitment or during data collection. Excludes material in the public domain

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| A3 | Use of drugs; alternative or complementary therapies or care; or surgical or other therapeutic or diagnostic procedures and devices |  | Yes |  | No |

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| A4 | An innovation or intervention which is not standard practice in the study population |  | Yes |  | No |

This is the systematic testing of a novel technique or method which is different to established practice. It normally involves a comparison between the new and the existing using research methods like randomisation to avoid or reduce bias. For example, the trialling of new educational teaching and learning strategies outside those adopted by the governing educational authority, the testing of a new safety protocol aimed to reduce workplace injuries, or a comparison of new diagnostic or therapeutic methods against established techniques or best practice guidelines. The ethical issue is whether participants might be disadvantaged or harmed by the intervention as opposed to participants who are exposed to the established and accepted set of conditions.

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| A5 | Accessing human tissue samples without specific consent from the individuals from whom the tissue was collected (this includes cell lines other than those acquired commercially) |  | Yes |  | No |

Either in the course of identifying/selecting people for recruitment or during data collection.

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| A6 | Human genetic studies |  | Yes |  | No |

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| --- | --- | --- | --- | --- | --- |
| A7 | Human stem cells |  | Yes |  | No |

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| A8 | Focusing on women who are pregnant, and/or research involving the human foetus |  | Yes |  | No |

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| --- | --- | --- | --- | --- | --- |
| A9 | People who are highly dependent on medical care and who may be unable to give consent, e.g. unconscious or too ill |  | Yes |  | No |

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| A10 | Focusing on people with a cognitive impairment, an intellectual disability, or a mental illness |  | Yes |  | No |

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| A11 | Focusing on illegal activity or the likelihood of discovering an illegal activity |  | Yes |  | No |

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| --- | --- | --- | --- | --- | --- |
| A12 | The intentional recruitment of Aboriginal and Torres Strait Islander (ATSI) peoples, groups, communities; the investigation of issues focussing on ATSI peoples; or the identification of any ATSI peoples recruited as a separate subgroup of participants. or issues |  | Yes |  | No |

The research involves the intentional recruitment of Aboriginal and Torres Strait Islander persons, a significant coincidental recruitment of Aboriginal and Torres Strait Islander persons, and / or issues likely to be considered significant to the Aboriginal and Torres Strait Islander peoples.

If you have answered YES to any of the above questions do not continue completing this form. Your research is not eligible for the expedited review process, and you must submit a HREA form. Please go directly to https://hrea.gov.au where you will need to create a login to complete you greater than low risk application (HREA).

If you have answered NO to all of A1 – A12, please continue onto PART B. Please note, depending on your answers to the following sections you may still be directed to the HREA form.

#### PART B1 – PROJECT

|  |  |  |
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|  |  | |
| **Project Title**  This title will be used in all correspondence relating to this project **150 character limit.**  This title will be recorded on the human ethics database and used in all correspondence in relation to this project. |  |  |
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| **Project Summary**  Provide a brief plain English snapshot of the project including, the background of the project, a justification, aims of the project and methods. (max. 200 words). Provide a lay persons snapshot of the project. Include central aims, study population, method and technique (eg surveys, interviews, observations, etc). |  |  |
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#### PART B2 – PRINCIPAL INVESTIGATOR, PRINCIPAL SUPERVISOR or PROJECT SUPERVISOR (this is not the student)

This is the person whom the research team wishes the HREC to correspond with in relation to this project. Only UNE researchers can be listed as contact persons for an ethical clearance application. In the case of student research, a member of the student’s supervisory team must be listed.

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|  |  | |
| **Name** *(eg. Dr James Nightly)*  **(one name only)** |  |  |
|  |  | |
| **UNE Staff Number** |  |  |
|  |  |  |
| **Position/Role (*e.g. Lecturer, etc*)** |  |  |
|  |  |  |
| **Qualifications** |  |  |
|  |  | |
| **School** |  |  |
|  |  | |
| **Mailing Address** |  |  |
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| **Phone No.** |  |  |
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| **Email Address** |  |  |
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#### PART B3 – CO-INVESTIGATOR, CO-SUPERVISOR or CO-RESEARCHERS other than student researchers

Please list all Co-Investigators, Co-Supervisors & Co-Researchers on the project. **However,** if students of the University are working on the project, e.g. as research assistants, but not using the research for their studies, they should be listed here.

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|  |  | |
| **Name** *(eg. A/Prof Larry Brown)* |  |  |
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| **UNE Staff/Student Number** |  |  |
|  |  |  |
| **Qualifications** |  |  |
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| **Role** | Choose a role |  |
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| **School /Affiliation** |  |  |
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| **Mailing Address** |  |  |
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| **Phone No.** |  |  |
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| **Email** |  |  |
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| **Name** *(eg. A/Prof Larry Brown)* |  |  |
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| **UNE Staff/Student Number** |  |  |
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| **Qualifications** |  |  |
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| **Role** | Choose a role |  |
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| **Name** *(eg. A/Prof Larry Brown)* |  |  |
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| **UNE Staff/Student Number** |  |  |
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| **Qualifications** |  |  |
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| **Role** | Choose a role |  |
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| **School /Affiliation** |  |  |
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| **Mailing Address** |  |  |
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| **Phone No.** |  |  |
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| **Email** |  |  |
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*Copy this table and repeat for any additional co-investigators.*

#### PART B4 – STUDENT RESEARCHERS

List all students working on the project who **are** conducting the research as a component of their studies.

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| **Name** *(eg. Ms Beth Schmidt)* |  | | | | | | | | | |  |
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| **UNE Student Number** |  | | | | | | | | | |  |
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| **Qualifications** |  | | | | | | | | | |  |
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| **School** |  | | | | | | | | | |  |
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| **Mailing Address** |  | | | | | | | | | |  |
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| **Phone No.** |  | | | | | | | | | |  |
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| **Email (**please use UNE email**)** |  | | | | | | | | | |  |
|  |  | | | | | | | | | | |
| **Name of degree program** |  | | | | | | | | | |  |
|  |  | | | | | | | | | | |
|  | Undergraduate | | |  | Honours |  | Postgraduate  Coursework |  | Postgraduate  Research |  |  |
|  |  | | | | | | | | | | |
| **University of New England?** | Yes |  |  | | Other *(please specify)*: | | | | | |  |
|  |  | | | | | | | | | | |
| **Principal supervisor** |  | | | | | | | | | |  |
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*Copy this table and repeat for each additional student.*

#### PART C – IDENTIFYING ETHICAL ISSUES

Your responses to the questions in this section serves two purposes: identifying the ethical issues associated with the proposed research; and to help you determine which level of ethical review applies to your project.

Where relevant there are **hyperlinks** to corresponding questions in Part D. (Ctrl + click to follow the link.)

*(insert X in box)*

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| C1 | Will participants of this research be quoted either directly or using a pseudonym, in the reporting? |  | Yes  Go to **D1** |  | No  Go to **C2** |

Will participants be quoted verbatim in reports?

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| --- | --- | --- | --- | --- | --- |
| C2 | Will participants of this research be identifiable in the reporting? |  | Yes  Go to **D2** |  | No  Go to **C3** |

Will it be possible for third parties to identify the research participants or others either directly, e.g. by name, or indirectly, e.g. by association or other unique characteristic such as CEO of a prominent organisation?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C3 | Will the research involve physically invasive procedures? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to [**D17**](#D17)then **C4** |  | No  Go to **C4** |

Invasive procedures include, but are not limited to, any introduction of products or devices into the body, piercing of the skin (e.g. the taking of blood, skin prick tests), x-rays, MRIs, or any other procedure that could be considered invasive of a participant’s body. This question relates to risks which are inherent in the procedure, i.e. those that exist prior to the application of any strategies to negate, minimise or manage them.

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| --- | --- | --- | --- | --- | --- |
| C4 | Could the research expose participants to economic loss or damage to their reputation? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D12** |  | No  Go to **C5** |

Could the research expose participants to financial loss or potential loss of reputation, market standing, or employability? Some research can have a negative economic impact on participants if the results or data from the research become known are reported, or it becomes known to third parties through other means that they participated.

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| C5 | Will the research involve collection, extraction, or use of human tissue (including cell lines), blood or other body fluids? [**NS3.2**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D6** then[**D17**](#D17) then **C6** |  | No  Go to **C6** |

This extends to any organ, tissue or fluid, eg skin, blood, urine, saliva, hair, bones, tumour and biopsy specimens. This question relates to inherent risks in the procedure, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

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| C6 | Might the research have a negative impact on personal relationships? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D13** |  | No  Go to **C7** |

Some research can have a negative impact upon a participant’s personal relationships, eg damage the relationship between a participant and their partner, family member, friend, associate, etc.

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| --- | --- | --- | --- | --- | --- |
| C7 | Does the research involve children, or people younger than 18 years who are not University students? [**NS4.2**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D4** |  | No  Go to **C8** |

If potential participants are currently enrolled University students aged 16 or 17 years, answer ‘No’. For all other young people or children aged <18, answer ‘Yes’.

If University students aged 16 or 17 may be involved, the information statement for participants must detail the educational or other benefits they will obtain from their involvement in the research project.

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| C8 | Is there a risk of physical injury to participants? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D7** |  | No  Go to **C9** |

This question relates to inherent risks in the research procedures, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

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| C9 | Are participants, 18 years or older, who are not competent to give consent, expected to be recruited? [**NS2.2.12**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D3** |  | No  Go to **C10** |

Might the capacity of adult participants to give voluntary and informed legal consent for their participation in research be compromised, ie, will participants be people who are unable to communicate or whose judgement might be impaired.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C10 | Will the research involve pain or discomfort for participants? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D8** |  | No  Go to **C11** |

This question relates to inherent risks in the research procedures, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

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| --- | --- | --- | --- | --- | --- |
| C11 | Will the potential participants be offered payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks? [**NS2.2.10 & NS2.2.11**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to [**D17**](#D17) then **C12** |  | No  Go to **C12** |

It is accepted ethical practice to offer potential participants reimbursements for any expenses associated with their participation. Depending on the research, it may also be appropriate to offer payment, in money or kind, to encourage participation. However, the researcher must consider whether such payments would be considered coercive inducements posing a risk to participants, ie, the inducement is so significant or attractive that a potential participant might feel they cannot afford not to participate, or it would cause a person to agree to participate and expose themselves to risks that they would otherwise not take. No inducement that is likely to encourage participants to take undue risks is acceptable. Decisions on these matters are on a case-by-case basis depending on the specifics of the participant pool, the context and the inducement.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C12 | Are potential participants in a dependent or unequal relationship with the researcher/s? eg lecturer/student, doctor/patient, teacher/pupil, employer/employee, prisoner/warden [**NS4.**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)**3** |  | Yes  Go to **D5** |  | No  Go to **C13** |

Unequal relationships can include: students as participants, when the researcher is their lecturer or tutor; employees as participants, when the researchers include their employer or supervisor; and patients as participants, when the researcher is part of their clinical care team. Unequal relationships also exist where the party with power over the potential participants could be perceived to have significant interest in the research or is a significant stakeholder in it. When potential participants are in an unequal relationship there is the potential for this situation to compromise the voluntary nature of their consent, and to expose them to heightened risks. It might also impact, or be perceived to impact, upon the recruitment process, or the risks associated with the research.

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| C13 | Could the research cause participants psychological or emotional stress? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D9** |  | No  Go to **C14** |

This question relates to inherent risks in the research procedures, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

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| --- | --- | --- | --- | --- | --- |
| C14 | Will the research involve deception or limited disclosure to participants? [**NS2.3.1**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#download) |  | Yes  Go to **D15** |  | No  Go to **C15** |
| C15 | Will the research involve the collection of sensitive personal information? |  | Yes  Go to **D11** |  | No  Go to **C16** |

Sensitive personal information about individuals who are identifiable directly or indirectly includes that which relates to their sexual identity or behaviour, substance abuse, illegal behaviour, membership of a disadvantaged group, attitudes on contentious issues, religious or some other personal beliefs and feelings such as grief, etc.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C16 | Will existing databases, datasets, databanks or human tissue banks be accessed for this research? **NS3.1.51 &** [**NS3.2**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D6** |  | No  Go to **C17** |
| C17 | Might the research expose participants to civil, criminal or other proceedings? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D10** |  | No  Go to **C18** |

If the results or data from this research become known, or are reported, to third parties, could the data and disclosure expose participants to potential civil, criminal or other proceedings?

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| C18 | Will the research involve covert observation? [**NS2.3.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D14** |  | No  Go to **C19** |

This is observation of others without their knowledge.

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| --- | --- | --- | --- | --- | --- |
| C19 | Is this research being conducted outside Australia? (This does not include the recruitment of participants via an online survey/questionnaire/Zoom.) [**NS4.8**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes  Go to **D16** |  | No  Go to **C20** |

Research conducted overseas by researchers from an Australian institution is considered overseas research. Also, If participants are being sourced from overseas, but the researcher is not going over, then this is still overseas research.

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| --- | --- |
| **C20** | **If you answered No to all C1-18, the project appears to qualify for Expedited Review E1. Please proceed to** [**Part E**](#PartE)**.**  **If you answered Yes to any questions numbered C1-18 but were not advised that an HREA application was required by the corresponding questions in Part D, then your project appears to qualify for Expedited Review E2. Please proceed to** [**Part E**](#PartE)**. However, the Committee may refer your application for a HREA based on the information provided in this application.** |

This question relates to inherent risks in the research procedures, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

This question relates to inherent risks in the research procedures, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

If the results or data from this research become known, or are reported, to third parties, could the data and disclosure expose participants to potential civil, criminal or other proceedings?

Could the research expose participants to financial loss or potential loss of reputation, market standing, or employability? Some research can have a negative economic impact on participants if the results or data from the research become known are reported, or it becomes known to third parties through other means that they participated.

Some research can have a negative impact upon a participant’s personal relationships, eg damage the relationship between a participant and their partner, family member, friend, associate, etc.

Might the capacity of adult participants to give voluntary and informed legal consent for their participation in research be compromised, ie, will participants be people who are unable to communicate or whose judgement might be impaired.

It is accepted ethical practice to offer potential participants reimbursements for any expenses associated with their participation. Depending on the research, it may also be appropriate to offer payment, in money or kind, to encourage participation. However, the researcher must consider whether such payments would be considered coercive inducements posing a risk to participants, ie, the inducement is so significant or attractive that a potential participant might feel they cannot afford not to participate, or it would cause a person to agree to participate and expose themselves to risks that they would otherwise not take. No inducement that is likely to encourage participants to take undue risks is acceptable. Decisions on these matters are on a case-by-case basis depending on the specifics of the participant pool, the context and the inducement.

Will the participants be deceived or given limited disclosure about the true purpose of the research or of what is involved? The researcher will need to present a compelling argument to the HREC for the need and ethical justification for the deception. Refer to Chapter 2.3 of the [*National Statement*](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) for guidance.

This is observation of others without their knowledge.

This extends to any organ, tissue or fluid, eg skin, blood, urine, saliva, hair, bones, tumour and biopsy specimens. This question relates to inherent risks in the procedure, ie those that exist prior to the application of any strategies to negate, minimise or manage them.

If potential participants are currently enrolled University students aged 16 or 17 years, answer ‘No’. For all other young people or children aged <18, answer ‘Yes’.

If University students aged 16 or 17 may be involved, the information statement for participants must detail the educational or other benefits they will obtain from their involvement in the research project.

Unequal relationships can include: students as participants, when the researcher is their lecturer or tutor; employees as participants, when the researchers include their employer or supervisor; and patients as participants, when the researcher is part of their clinical care team. Unequal relationships also exist where the party with power over the potential participants could be perceived to have significant interest in the research or is a significant stakeholder in it. When potential participants are in an unequal relationship there is the potential for this situation to compromise the voluntary nature of their consent, and to expose them to heightened risks. It might also impact, or be perceived to impact, upon the recruitment process, or the risks associated with the research.

Research conducted overseas by researchers from an Australian institution is considered overseas research. Also, If participants are being sourced from overseas, but the researcher is not going over, then this is still overseas research.

Sensitive personal information about individuals who are identifiable directly or indirectly includes that which relates to their sexual identity or behaviour, substance abuse, illegal behaviour, membership of a disadvantaged group, attitudes on contentious issues, religious or some other personal beliefs and feelings such as grief, etc.

#### PART D – ELIGIBILITY FOR EXPEDITED REVIEW E2

**Only complete the questions in this part if instructed to do so in response to a question in Part C**.

*(insert X in box)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D1 | D1a | Will prior warning be given to potential participants that they may be quoted? |  | Yes  Go to D1b |  | No  Go to [**D19**](#D19) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D1b | Will the potential participants be quoted for the purpose of reporting, presenting at conferences & publishing? |  | Yes  Go to D1c |  | No  Go to D1c |
|  | D1c | Will specific consent for quoting be obtained? |  | Yes  Go to D1d |  | No  Go to [**D19**](#D19) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D1d | Are there strategies in place for participants to confirm their consent to be quoted? |  | Yes Go to [**D17**](#D17)then  Go to D1e |  | No  Go to [**D19**](#D19) |
|  | D1e | Will participants be allocated a pseudonym? |  | Yes Go to [**D17**](#D17)then  Go to [C2](#C2) |  | No  Go to [C2](#C2) |

Participants should be given an opportunity to sight the sections of the report where they are being quoted verbatim and asked to confirm their consent for the material to be used in that form.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D2 | D2a | Will prior warning be given to potential participants that they may be identifiable? |  | Yes  Go to D2b |  | No  Go to [**D19**](#D19) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D2b | Will the potential participants be identifiable for the purpose of reporting, presenting at conferences & publishing? |  | Yes  Go to D2c |  | No  Go to D2c |
|  | D2c | Will specific consent for identification be obtained? |  | Yes  Go to D2d |  | No  Go to [**D19**](#D19) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D2d | Are there strategies in place for participants to confirm their consent to be identified and the benefits of being identified? |  | Yes Go to [**D17**](#D17)then  Go to [D2e](#C3) |  | No  Go to [**D19**](#D19) |
|  | D2e | Are there strategies in place for participants to be informed about the benefits/disadvantages of being identified? |  | Yes Go to [D17](#D17) then  Go to [C3](#C3) |  | No  Go to [D19](#D19) |

Participants should be given an opportunity to sight the sections of the report where they are identifiable and asked to confirm their consent for the material to be used in that form.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D3 | D3a | Will consent be obtained from a ‘person with authority? |  | Yes  Go to [**C4**](#C4) |  | No  Go to [**D17**](#D17) then [**C4**](#C4) |

Appropriate consent from a ‘person with authority’ may be required if the participant’s capacity to assess the risks, including loss of privacy, may be impaired.

A 'person with authority' is one of the following (in hierarchical order) and is not necessarily the next of kin:

* a guardian (including an enduring guardian);

or, if there is no guardian:

* the most recent spouse or de facto spouse with whom the person has a close, continuing relationship. 'De facto spouse' includes same sex partners;

or, if there is no spouse or de facto spouse:

* an unpaid carer who is now providing support to the person or provided this support before the person entered residential care;

or, if there is no carer:

* a relative or friend who has a close personal relationship with the person.

A ‘person responsible’ cannot consent to special or experimental medical procedures, or consent to treatment if the patient objects.

*(Source: The NSW Guardianship Tribunal)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D4 | D4a | Will parental or carer consent be obtained? |  | Yes  Go to D4b |  | No  Go to [**D17**](#D17)then D4b |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D4b | Will assent of the children be obtained? |  | Yes  Go to D4c |  | No  Go to [**D17**](#D17) then D4c |

At a minimum it should be ensured that, where at all possible, children are given an assent form for which they can either agree or not to participating in the research. The Information Sheet for Parents/carers should advise them to discuss the research with their children before they agree to consent to their child’s involvement.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D4c | Are children a focus of this research? |  | Yes  Go to D4d |  | No  Go to D4d |

Is it intended to recruit children, or will their recruitment be coincidental, ie the age of participants is not necessarily dictated by the study topic.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D4d | Will the researcher be alone with the children? |  | Yes  Go to [**D17**](#D17)then D4e |  | No  Go to [D4e](#C5) |
|  | D4e | Is the research contrary to the best interests of the children? |  | Yes  Go to [**D19**](#D19) |  | No  Go to [**C5**](#C5) |

Could the research present risks to the physical, emotional or psychological safety of the children?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D5 | D5a | Does the recruitment process address the issues relating to the dependent relationship? |  | Yes  Go to [**D17**](#D17) then D5b |  | No  Go to [**D19**](#D19) |

Can the issues in relation to the dependent relationship be managed through ensuring participant anonymity or special recruitment processes, e.g. an independent third party issuing the invitation to participate - care needed to ensure there would be no breach of the potential participants’ privacy?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D5b | Is the recruitment of people in a dependent relationship essential for the purposes of this research? |  | Yes  Go to [**D17**](#D17) then D5c |  | No  Go to [**D17**](#D17) then D5c |

When the unequal relationship is incidental to the purposes of the research, ie the research is not designed to improve understanding of dependent or unequal relationships, a specific case must be made for including people in dependent or unequal relationships as participants.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D5c | Is this a captive relationship? |  | Yes  Go to [**D19**](#D19) |  | No  Go to [**C6**](#C6) |

A captive relationship is a situation where the participant is under the control of another, and this control may extend to their being instructed to participate against their will (e.g. prisoners or members of the defence forces), or tacitly coerced into doing so (e.g. members of an organisation who have been ‘strongly encouraged’ to participate).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D6 | D6a | Are you using tissue samples? |  | Yes  Go to D6b |  | No  Go to D6e |
|  | D6b | Is the tissue retained in an identifiable or potentially re-identifiable form? |  | Yes  Go to D6c |  | No  Go to [**C7**](#C7) |
|  | D6c | Is there existing consent from the individuals involved, which will cover this research? |  | Yes  Go to [**C7**](#C7) |  | No  Go to D6d |
|  | D6d | Will consent be obtained from the individuals involved, which will cover this research? |  | Yes  Go to [**C7**](#C7) |  | No  Go to [**D19**](#D19) |
|  | D6e | Are you using a database, dataset or databank? |  | Yes  Go to D6f |  | No  Go to [**C7**](#C7) |

Identifiable: the data/tissue is held with the individual’s identity which may include name, image, date of birth or address.

Re-identifiable or potentially re-identifiable: identifiers have been removed and replaced with a code from which it remains possible to re-identify the individual, eg by using the code or linking different data sets.

Non-identifiable: never held with individual identifiers or codes, or identifiers/codes have been permanently removed or did not exist.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D6f | Is the data retained in an identifiable or potentially re-identifiable form to the researchers? |  | Yes  Go to D6g |  | No  Go to [**C7**](#C7) |
|  | D6g | Is there existing consent from the individuals involved, which will cover this research? |  | Yes  Go to [**C7**](#C7) |  | No  Go to [**D19**](#D19) |

At E6 you will need to explain the nature of the existing consent and provide evidence of how it was obtained, e.g. a copy of the consent form template (not copies of individual consent forms).

Note: The *Human Tissue Act 1983 (NSW)* has very specific consent requirements regarding the use of human tissue for research purposes. Refer to http://nswmoh-search.clients.funnelback.com/s/search.html?collection=nsw\_health&query=human%20tissue%20act%201983

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D7 | D7a | Will prior warning be given to potential participants? |  | Yes  Go to D7b |  | No  Go to [**D19**](#D19) |

Is information about the risk – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D7b | Will there be an appropriate screening process of the potential participants to identify those at a higher risk? |  | Yes  Go to D7c |  | No  Go to [**D19**](#D19) |

If appropriate, will potential participants be screened for possible complicating health issues? If Yes, ensure you provide a copy of the screening document

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D7c | Will procedures be conducted by experienced and appropriately licensed or accredited person(s)? |  | Yes  Go to D7d |  | No  Go to [**D19**](#D19) |

If Yes, explain who and what qualifications they have to perform the screening.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D7d | Will they be compliant with the relevant safety procedures? |  | Yes  Go to [**D17**](#D17) then [**C10**](#C10) |  | No  Go to [**D19**](#D19) |

For example, infection control, resuscitation equipment and trained personnel present.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D8 | D8a | Will prior warning be given to potential participants? |  | Yes  Go to D8b |  | No  Go to [**D19**](#D19) |

Is information about any risks – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D8b | Is there a reasonable possibility that exposure will have a significant adverse impact on the participants? |  | Yes  Go to D8c |  | No  Go to [**C11**](#C11) |
|  | D8c | Will there be an appropriate screening process of the potential participants to identify those at a higher risk? |  | Yes  Go to D8d |  | No  Go to [**D19**](#D19) |

If appropriate, will potential participants be screened for possible complicating health factors? If Yes, ensure you provide a copy of the screening document.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D8d | Is the exposure likely to be life threatening? |  | Yes  Go to [**D19**](#D19) |  | No  Go to [**D17**](#D17) then [**C11**](#C11) |

Would a reasonable person attach significance to exposure to the pain or discomfort?

The question of significance should be based upon the severity, probability of it occurring, duration and nature of the pain / discomfort.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D9 | D9a | Will prior warning be given to potential participants? |  | Yes  Go to D9b |  | No  Go to [**D19**](#D19) |

Is information about the risk – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D9b | Is there a reasonable possibility that exposure will have a significant adverse impact on the participants? |  | Yes  Go to D9c |  | No  Go to [**D17**](#D17) then [**C12**](#C12) |
|  | D9c | Will there be an appropriate screening process of the potential participants to identify those at a higher risk? |  | Yes  Go to [**D17**](#D17) then D9d |  | No  Go to [**D19**](#D19) |

If appropriate, will potential participants be screened for possible complicating mental health factors? If Yes, ensure you provide a copy of the screening document.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D9d | Is the exposure likely to be life threatening? |  | Yes  Go to [**D19**](#D19) |  | No  Go to [**D17**](#D17) then [**C12**](#C12) |

Would a reasonable person attach significance to exposure to the stress?

The question of significance should be based upon severity, probability of it occurring, duration, impact upon quality of life, enduring implications and stigma.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D10 | D10a | Will prior warning be given to potential participants? |  | Yes  Go to D10b |  | No  Go to [**D19**](#D19) |

Is information about any risks – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D10b | Do researchers have a duty of care or a duty of disclosure? |  | Yes  Go to [**D17**](#D17) then [**C13**](#C13) |  | No  Go to [**C13**](#C13) |

Are there any duty of disclosure issues, or mandatory reporting requirements, which might necessitate reporting identified data to the authorities?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D11 | D11a | Will prior warning be given to potential participants? |  | Yes  Go to D11b |  | No  Go to [**D19**](#D19) |

Is information about any risks – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D11b | Will the information be identified or re-identifiable? |  | Yes  Go to [**D17**](#D17) then [**C14**](#C14) |  | No  Go to [**C14**](#C14) |

Information should be considered identified or re-identifiable if the researcher can identify individual respondents directly or via a code.

Identifiable: the data/tissue is held with the individual’s identity which may include name, image, date of birth or address.

Re-identifiable or potentially re-identifiable: identifiers have been removed and replaced with a code from which it remains possible to re-identify the individual, eg by using the code or linking different data sets.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D12 | D12a | Will prior warning be given to potential participants? |  | Yes  Go to [**C15**](#C15) |  | No  Go to [**D17**](#D17) then [**C15**](#C15) |

Is information about any risks – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D13 | D13a | Will prior warning be given to potential participants? |  | Yes  Go to [**C16**](#C16) |  | No  Go to [**D17**](#D17) then [**C16**](#C16) |

Is information about any risks – in plain language – included in the Information/Consent materials)?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D14 | D14a | Is the observed activity something which would generally occur in public? |  | Yes  Go to D14b |  | No  Go to [**D17**](#D17)then D14b |

Is the activity something which generally occurs in public and that a reasonable person is unlikely to be concerned about having observed?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D14b | Will ‘participants’ be identifiable? |  | Yes  Go to [**D17**](#D17)then [**C18**](#C18) |  | No  Go to [**C18**](#C18) |

Will the information recorded have the potential to identify individuals, eg notes/photographs/recordings of people/places/events? If so, it represents a breach of the participants’ privacy.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D15 | D15a | Is the deception or limited disclosure likely to harm the participants or compound the risks associated with this research? |  | Yes  Go to [**D19**](#D19) |  | No  Go to D15b |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D15b | Have any alternatives involving full disclosure been considered? |  | Yes  Go to D15c |  | No  Go to [**D19**](#D19) |

Have alternatives to the deception or limited disclosure been considered, and rejected because they would compromise the scientific validity of the research?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D15c | Will the participants be given a full and prompt debriefing after their participation? |  | Yes  Go to [**D17**](#D17) then D15d |  | No  Go to [**D19**](#D19) |

Prompt disclosure is as soon as possible after the participants complete the research procedures.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D15d | Do participants have the option of withdrawing their data once the deception has been disclosed |  | Yes  Go to [**D17**](#D17) then [**C19**](#C19) |  | No  Go to [**D19**](#D19) |

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Can it be reasonably anticipated that, following debriefing, the research participants will regard the research as justified and acceptable conduct and not risk corrupting the relationship between the community and researchers and research in general?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| D16 | D16a | Are there any ethical or other approval processes in the overseas country? |  | Yes  Go to [**D17**](#D17)then D16b |  | No  Go to D16b |

Researchers must ascertain whether they are required to obtain ethics or some other form of approval from a body or committee in the country before they may conduct the research. The HREC needs to know if these are mandatory or voluntary, who grants the approval, and they will require evidence of approval from this authority. For research conducted overseas compliance with the *National Statement on Ethical Conduct in Human Research, 2007(updated May 2015),* is the minimum standard.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D16b | Will you recruit co-researchers in the overseas country? |  | Yes  Go to D16c |  | No  Go to D16c |

Co-researchers recruited must have the capacity and expertise to conduct that part of the research assigned to them. This person must be added to the project and approved, prior to commencing any part of the research

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D16c | Are the proposed recruitment, consent methods, and remuneration (where used) acceptable to the local culture and its beliefs and practices? |  | Yes  Go to D16d |  | No  Go to [**D19**](#D19) |

The processes to be followed in recruiting participants and through which they choose whether to be involved must be respectful of their different cultural context and likely to lead to participation that is freely chosen and adequately informed.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D16d | Are there social, educational, or other factors that may compromise free and informed consent? |  | Yes  Go to [**D17**](#D17)then D16e |  | No  Go to D16e |

For example, in some cultures it might be considered impolite to say ‘No’, poor literacy standards can impede free and informed consent and, depending on the focus of the research, if conducted in politically unstable countries can increase the risks for participants, particularly where perceived criticism of the government or institutions could attract punitive action.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | D16e | Are participants given a local contact for complaints? |  | Yes  Go to [**D17**](#D17) then D16f |  | No  Go to [**D19**](#D19) |
|  | D16f | Will you be applying for, or have you applied for a UNE travel grant? |  | Yes  Go to D16g |  | No  Go to D16g then [**D17**](#D17) then [**D18**](#D18) |
|  | D16g | What is the current DFAT warning and Smart Traveller status? (Answer this question then Go to [**D17**](#D17) then [**D18**](#D18)). **Please note** that the HREC will not assess suitability of overseas travel. You must seek advice from the appropriate UNE department. | | | | |

Are participants given details in the Information Statement of a local person independent of the researchers who can receive complaints about its conduct and advise the University of New England Human Research Ethics Officer of any complaints received? In some countries, without a local contact participants may feel inhibited or be unable to communicate any of their concerns or adverse experiences to the researchers or UNE.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| D17 | Can the risks be easily negated, minimised or managed? You are required to explain each relevant item identified with the question number where specified below. |  | Yes  Provide details below |  | No  Go to [**D19**](#D19) |

Are the risks to participants associated with the research easily negated, minimised or managed? If yes, provide details (maximum of 500 words per question).

Explain how each risk will be negated, minimised or managed. Failure to adopt and explain adequate procedures to address the risks may result in your application being referred to E3 review.

Your answer should include clear details of what action will be taken, such as emergency procedures or referrals to appropriate sources of assistance, should participants be adversely affected / stressed / harmed by the research procedures.

|  |  |
| --- | --- |
| **Details**  Provide the details for each question that directed you here. Then return to that question and continue. | **Question [insert number]:**  (max 500 words)  **Question [insert number]:**  (max 500 words) |

|  |  |
| --- | --- |
| **D18** | **If you have completed questions in Part D but were not advised that an HREA application was required, then your project appears to qualify for Expedited Review E2. Proceed to** [**Part E**](#PartE)**.** |

|  |  |
| --- | --- |
| **D19** | Your project requires full HREA ethical review. You should stop completing this form and go to the [HREA](https://hrea.gov.au/) (Human Research Ethics Application). |

#### PART E – PROJECT DETAILS – Answer all questions.

|  |  |
| --- | --- |
| **E1** | **Give a brief ‘plain English’ description of the project NS1** |

Expanding on Part B1, provide a brief and simple description of your project. The description must be in plain English suitable for a lay person as the HREC has a wide representation of members.

Using the following headings: *Background*; *Aims / hypotheses / questions*; *Research design*; , and *Potential value and significance of the research*. Include relevant references.

|  |  |
| --- | --- |
| **Details**  (Max 500 words exclusive of references) |  |

|  |  |
| --- | --- |
| **E2** | **List the experience and skills of each researcher for this and similar research NS1.1** |

For each applicant named in this application, list the relevant experience and /or skills that equips them to conduct or supervise this research.

|  |  |
| --- | --- |
| **Details**  (Max 100 words per researcher) |  |

|  |  |
| --- | --- |
| **E3** | **Participants**  . |

‘Participant’ has a broad definition in the [*National Statement*](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) and includes the involvement of people through:

* taking part in surveys, interviews or focus groups;
* undergoing psychological, physiological or medical testing or treatment;
* being observed by researchers;
* researchers having access to their personal records, documents or other materials (eg employment, university or medical records, electoral roll, personal collections of documents/photographs, etc);
* the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
* access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database (databanks or unpublished human research data, eg analysis of existing unpublished data obtained by someone other than you or obtained for a different research project.

|  |  |  |  |
| --- | --- | --- | --- |
| **E3.1** | Does the research specifically target participants from any of the following groups? (*select all that apply)* | | |
|  | Children less than 18 years |  |  |
|  | The general public |  |  |
|  | Students or staff of the University of New England |  |  |
|  | Students or staff of other universities or colleges |  |  |
|  | School children, i.e., obtained through schools |  |  |
|  | Employees of schools |  |  |
|  | Registers or databases |  |  |
|  | Members of community groups or organisations |  |  |
|  | Employees of organisations |  |  |
|  | Patients or clients of health service providers |  |  |
|  | Hospital patients |  |  |
|  | Clients of organisations or community services |  |  |
|  | Prisoners or persons held in detention |  |  |
|  | People who have a sight or hearing impairment |  |  |
|  | People with a specific health condition |  |  |
|  | People in a dependent or unequal relationship with the researchers |  |  |
|  | Records or information about people without approval from those people |  |  |
|  | Human tissue collections without approval from the donors |  |  |
|  | Other *(please specify your target participants below in no more than 50 words)* |  |  |
|  |  |  |  |

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| --- | --- |
| **E3.2** | Identify where participants will be sourced from and the locations, i.e., the name of the schools, hospitals, organisations etc, and the town they are located in. |
| *Site(s)* If more than 10, give number and type, eg “12 NSW government primary schools” |
|  |
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| --- | --- | --- |
| **E3.3** | How, and by whom, will potential participants be selected, initially contacted and recruited? This should explain how participants contact details were obtained. **NS1.4 & NS3.1** | |
|  | **Details**  (Max 300 words) |  |

Care needs to be taken not to breach the privacy of potential participants, or create a coercive situation, in the course of selecting and inviting people to participate in your research.

Information identifying potential participants cannot be accessed unless it is in the public domain. Eg, while it is quite acceptable to randomly select people from the telephone directory, it is not acceptable to ask an organisation or other custodian of identifying information to provide a list of people without the prior consent of those people. Instead, the organisation or custodian of the list should be asked to distribute the study invitation on your behalf. The Information Sheet for Participants is to explain the process used so recipients can be assured their privacy has not been breached.

To avoid coercion or making people feel uncomfortable or obligated to participate, the invitation to participate must be distributed in a manner that allows potential participants to consider their decision at leisure and independent of the researcher if they wish. This is particularly important where there might be a dependent relationship between the researcher and potential participant, eg lecturer/student, employer/employee. In those cases it must be stressed to potential participants, and ensured, that whatever decision they make their assessment or treatment will not be affected and they will not be disadvantaged in any way. The invitation should be distributed either by a third party who would normally have access to the study population, or via a general distribution, eg poster or letter, and those interested can then make contact with the researcher.

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| **E3.4** | How many participants will be recruited and what is the rationale for that number? | | |
| *Total number of participants to be recruited:* | |  |
| *Rationale:*  (Max 300 words) |  | |

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| --- | --- | --- |
| **E3.5** | List the inclusion and exclusion criteria **NS1.4** | |
|  | **Details** | Inclusion:        Exclusion: |

|  |  |  |
| --- | --- | --- |
| **E3.6** | What will be required of the participants? This should explain everything that is expected of the participants from start to finish. If there are multiple phases/stages, please include a heading and details for each phase/stage. | |
|  | **Details**  (Max 300 words) |  |

This must include a full and clear explanation of exactly what all participants/groups will be required to do in this project. This should also include how much time participants will need to put aside to take part in this research.

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| **E3.7** | What, if any, are the benefits of this research for participants, the wider community or both? **NS1.6** | |
|  | **Details**  (Max 300 words) |  |

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| --- | --- | --- | --- |
| **E3.8** | Will participants receive reimbursement, payment, or rewards for participating in this research? **NS2.2.10** | Yes | No |

If Yes, provide details of the reward and the amount, when it will be given to the participants, and how the customs and practices in the community/group in which the research is to be conducted have been taken into account, ie why it would not be considered unacceptable or inappropriate in that community/group.

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|  | **Details**  (Max 300 words) |  |

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| **E3.9** | Will participants be proficient in the English language?  *If No, certified translations must be attached to the application.* | Yes | No |

If participants are not proficient in the English language the Information and Consent documents, and any other study documents they receive, must be presented in their respective language. If ‘No’, in which language will the material be presented and will interpreters be used. Submit an English version of all documents with this application, plus a certified translation in the relevant language. The documents should be certified by someone that can read both the English version and the translation and is willing to state that what they read are the same.

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|  | **Details if required.**  (Max 300 words) |  |

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| **E3.10** | If participants are under the age of 18 years, please advise whether a teacher or parent/guardian will be present. Also please attach a copy of working with children’s check or police clearances. |

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|  | **Details**  (Max 300 words) |  |

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| **E4** | **Analysis** |

Provide details of how the information you receive will be analysed/interpreted. What specific approaches or techniques (statistical or qualitative) will be employed.

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| **Details–** Explain how the data will be analysed.  (Max 300 words) |  |

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| **E5** | **Research methods and techniques** | | | | |
| **E5.1** | The research methods and techniques to be used in this research are: (*X all that apply)* | | | |
|  | Computer based tests |  |  |
|  | Data linkage |  |  |
|  | Focus groups |  |  |
|  | Face-to-face interviews (via Zoom/Teams/etc) |  |  |
|  | Face-to-face interviews (in person) |  |  |
|  | Telephone Interviews (have you read the protocol? Yes/No) |  |  |
|  | Internet or web based research This is the practice of using internet information, especially free information on the world wide web, in research |  |  |
|  | Observation |  |  |
|  | Covert observation |  |  |
|  | Photographs of people |  |  |
|  | Physical activities, tests or exercises |  |  |
|  | Psychological tests |  |  |
|  | Anonymous **online** questionnaires/surveys, or diaries |  |  |
|  | Anonymous **paper-based** questionnaires/surveys, or diaries |  |  |
|  | Identifying **online** questionnaires/surveys, or diaries |  |  |
|  | Identifying **paper-based** questionnaires/surveys, or diaries |  |  |
|  | Record or document analysis |  |  |
|  | Recording – audio or video |  |  |
|  | Case studies |  |  |
|  | Case-control studies Is a study that compares patients who have a disease or outcome of interest (**cases**) with patients who do not have the disease or outcome (**controls**), and looks back retrospectively to compare how frequently the exposure to a risk factor is present in each group to determine the relationship between the risk factor and the disease. |  |  |
|  | Epidemiological research |  |  |
|  | Intervention study |  |  |
|  | Qualitative research |  |  |
|  | Randomised controlled trial A study in which people are allocated at random (by chance alone) to receive one of several clinical interventions. One of these interventions is the standard of comparison or **control**. The **control** may be a standard practice, a placebo or no intervention at all. |  |  |
|  | Physiological & Body Function Measurements |  |  |
|  | Clinical or Medical Trial |  |  |
|  | Other *(please specify below in no more than 300 words)* |  |  |
|  |  |  |  |

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| **E5.2** | Any of the procedures or tests you intend to use should be provided indicating the title and risk level (if known). You should also, provide details and ***attach*** a copy of questionnaires, surveys, interview scripts, tests, instruments or procedures that will be used. | |
|  | **Details**  (Max 300 words) |  |

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| **E6** | **Informed consent NS2.2** |

Select the method of consent to be used.

**Existing consent:** Explain the nature of the existing consent and provide evidence of how it was obtained, e.g. a copy of the consent form template (not copies of individual consent forms). Otherwise, detail the procedure to be used to ensure voluntary and informed consent.

**Written informed consent** is required when participants are identifiable, ie when the research method used is Face-to Face interviews or the participants are completing identifying questionnaires or surveys. It should be written to the readers level of comprehension and written in the first person ie “I have read the information”.

**Recorded informed consent** is required for telephone interviews or when a person is illiterate and can be used when participants are video or audio recorded.

**Implied consent** is appropriate for anonymous surveys, ie consent is assumed if they return the survey and may be appropriate for some discussion groups depending on the sensitivity of the research topic and the mechanisms in place to protect the identity of participants.

|  |  |
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| Written informed consent |  |
| Recorded informed consent |  |
| Parent, Guardian or Carer consent |  |
| Child’s assent with parent or guardian consent |  |
| Young persons (16-17 years) consent |  |
| Implied consent |  |
| Retrospective consent |  |
| Waiver of informed consent obtained |  |
| Waiver of parent or guardian consent obtained |  |
| Existing consent *(provide details below & add a copy of the document used)* |  |
| Other *(please specify)* |  |
| **Please provide details of the consent process/es as listed above.**  (Max 300 words) | |

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| **E7** | **Communication of results or reporting. NS3.1 (Element 5) & NS3.1 (Element 6)** |

Provide details of how the results of the research will be reported / disseminated, including the appropriate provision of results to participants. If relevant / required, please also provide details of any planned debriefing of participants.

|  |  |
| --- | --- |
| Thesis |  |
| Published in future journal articles |  |
| Presented at conferences |  |
| Other *(please specify below)* |  |
| **Please provide details for ‘Other’.** (Max 300 words) | |

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| **E8** | **Duration of data collection for research.** (‘Start date’ will be the approval date unless specified below and the proposed end date should include the writing up phase of the project) |

What is the anticipated duration of the data collection / human research phase of the project? This is to include the time where there is to be any contact with participants or their personally identifiable information, eg follow-up, access to records/tissue held by third parties, feedback of results etc. This date should not be prior to the meeting date where this application will be assessed, unless retrospective consent is being sought.

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| --- | --- | --- | --- |
| **Start** (if not approval date) | **dd/mm/yyyy** | **End:** | **dd/mm/yyyy** |

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| **E9** | **Has the research been approved, or is under consideration, by another Human Research Ethics Committee (HREC)?**  *If Yes, and approved, attach a copy of the approval(s).* | Yes Give Details | No Go to E10 |
| *Name of other HREC:* |  | |
| Yes  Give details |  | |

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| **E10** | **Is the research or researcher receiving any financial support/funding from any internal or external entity? Eg, School/Faculty funding, grant, etc?** | | Yes Give Details | No Go to E11 |
| *Organisation or Funding Body* |  | | |
| *Project title on contract or funding application* |  | | |
| *First named investigator* |  | | |
| *Administering institution* |  | | |
| *Does the funding body have ownership of or control over the dissemination of results? If yes give details.* |  | | |

*Copy this table and repeat for each contract or grant.*

|  |  |  |  |
| --- | --- | --- | --- |
| **E10.1** | **Does the funding constitute a conflict of interest for either the researcher(s) or provider(s) of the funding?** **NS5.4** | Yes Give Details | No Go to E11 |

For example:

* does the provider(s) of the support have a financial interest in the outcome of the research;
* will there be any commercialisation of the outcomes of the research;
* does any member of the research team have an affiliation with the provider(s) of support?

If yes, provide details, including an outline of how this potential conflict of interest is to be disclosed to research participants.

|  |  |
| --- | --- |
| **Details**  (Max 300 words) |  |

|  |  |  |
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| **E11** | The National Statement (**NS3.1.44**) suggests all researchers should develop a Research Data Management Plan (RDMP). University of New England (UNE) researchers are required to comply with the UNE [Research Data Management policy](http://www.une.edu.au/research/digital-research-support/research-data-management).  Please confirm that all researchers understand these data management obligations. |  |

#### PART F1 – DECLARATION BY APPLICANTS

All the required signatures in this part must be provided before this application can be processed. (Refer to *Special Circumstances* in the *Appendix – How to submit your application*.)

* I declare that the information provided in this application is truthful and as complete as possible.
* In signing this application, I declare that the research protocol conforms to the *National Statement on Ethical Conduct in Human Research, 2023,* which I have read and understood.
* I undertake to conduct the research in accordance with the approved protocol, the *National Statement*, Australian Code for the Responsible Conduct of Research and other relevant legislation and the policies and procedures of the University of New England.
* I have read, completed and agree to comply with the University of New England’s Research Data Management Policy, pursuant policies and procedures and have a plan for managing and/or sharing Research Data securely.
* I have read, completed and agree to comply with the University of New England’s Risk Management Policy, pursuant policies and procedures and have a plan for managing Research Risk.
* I understand and agree that project files, documents, sites, research records, and data may be subject to inspection by the University of New England’s, HREC, the Research Ethics Officer, the sponsor or an independent body for auditing and monitoring purposes.
* Where I am the project supervisor for the research described herein which will be conducted by a student of the University of New England, I declare that I have provided guidance to the student in the design, methodology and consideration of ethical issues of the proposed research. And that I will supervise the student during the conduct of this research.
* I make this application on the basis that the information it contains is confidential and will be used by the University of New England for the purposes of ethical review and monitoring of the research project described herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.
* I agree to submit progress reports annually, if approval is more than 12 months, and a final report on the completion of the project (NS 5.4.3).

**All researchers named, in sections** [**B2**](#B2) **,** [**B3**](#_PART_B3_–) **and** [**B4**](#_PART_B4_–) **are required to sign this declaration.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Name* | *Signature* | *Date* |
| Chief investigator or project supervisor |  |  |  |
| Co-Investigator or Student Researcher |  |  |  |
| Co-Investigator or Student Researcher |  |  |  |
| Co-Investigator or Student Researcher |  |  |  |
| Co-Investigator or Student Researcher |  |  |  |

#### PART F2 – HEAD OF SCHOOL DECLARATION

**Head of School Declaration (or their delegate)**

*Where the Head of School, Dean or their delegate has a conflict of interest with the proposed research, e.g., an investigator on the project, a member of the research group, or a personal relationship to any member of the research team, this Declaration is to be completed by another suitable nominated delegate.*

* I have considered this application and the ethical implications of the proposed research and recommend it for consideration by the HREC. I confirm that the qualifications and experience of all investigators is appropriate to the study to be undertaken, and the necessary resources are available to enable this research to be conducted.
* I confirm that I have reviewed the risk management proposal for this project, and I am satisfied that the researchers have considered all safety measures.
* I confirm that that this research project has scientific and/or research merit.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title |  | First Name |  | Last Name |  |
| Position |  | | | | |
| Signature |  | | | Date |  |

***To be completed by the Chief Investigator or Project Supervisor***

**Level of Review**

*Having completed this application, and as indicated from my answers to the ‘C’ and ‘D’ questions I believe that this project qualifies for (X one box):*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Expedited Review E1** |  | or | **Expedited Review E2** |  |

**Attachments:** (Please complete)

I have attached the required documents as follows: *(please check all boxes that are relevant to your project)*

|  |  |
| --- | --- |
| * [Information Sheets for Participants](https://www.une.edu.au/research/research-services/rdi/ethics/hre/hrec-forms) (ISP) (templates found [here](https://www.une.edu.au/research/research-ethics-integrity/human-research-ethics/hrec-forms)) |  |
| * [Consent Form(s)](https://www.une.edu.au/research/research-services/rdi/ethics/hre/hrec-forms) (templates found [here](https://www.une.edu.au/research/research-ethics-integrity/human-research-ethics/hrec-forms)) |  |
| * All recruitment material, e.g., emails, advertisements, posters, social media posts |  |
| * Surveys and questionnaires (if online exactly as they will appear) |  |
| * Focus group and Interview questions |  |
| * Telephone script (template found [here](https://www.une.edu.au/research/research-ethics-integrity/human-research-ethics/hrec-forms)) |  |
| * Approval(s) from any other HREC’s |  |
| * Data Management Plan (template found [here](https://une.au.libguides.com/RDM)) |  |
| * Risk Management Plan (template found [here](https://www.une.edu.au/safety/whs-forms/risk-management-forms)) |  |
| * Letters of support where necessary |  |
| * Certified Translations of all relevant documents i.e., ISP, Consent Form, Survey, etc (certification can be done by anyone that can read both the English and translated versions and is willing to sign that they are the same). Please include the following wording on each document***.***   ‘I ………………….. (name of translator) certify that this is a true and accurate ………… (name of translated language, e.g. Arabic, Chinese, etc) translation of this document that will be used for the research entitled ……………………………… (title of the project) conducted by…………………………….. (Names of the researchers). I can be contacted via email ……… (add email address here) and my phone numbers is ………  Translators Signature: |  |

|  |
| --- |
| **Comments**  You are invited to add comments to supplement your application if you think something has not been covered, or to provide feedback on this form. |
|  |

#### APPENDIX – How to submit your application.

***DO NOT submit these instructions with your application***

**Submitting your applications:**

**Before you submit:**

* **Incomplete** applications **will not** be accepted; nor will applications, **submitted on old** **versions of the form**. It is your responsibility to ensure that your application is complete and on the latest version of the application form.
* The application must identify all the researchers involved with the project. They must all sign the Declaration at Part F1. A student is not and **cannot** be the Principal Investigator or Project Supervisor. This responsibility must be undertaken by the student’s supervisor.
* The Head of School Declaration at Part F2 must be completed. **Note:** It is the applicant’s responsibility to ensure the completed declaration is submitted with their application.

**Submit to:**

 [humanethics@une.edu.au](mailto:humanethics@une.edu.au)

**Questions can be directed to:**

Mrs Jo-Ann Sozou

Research Ethics Officer

Research Services

T.C Lamble Building

University of New England

Armidale NSW 2351

MCj04338610000[1] 02 6773 1115

***It is advisable to*** ***keep an electronic copy, complete with signatures, for your personal records.***

**Closing date for applications:**

Applications will be accepted at any time. **E1 &** **E2** applications should be submitted to the Human Research Ethics Officer by **12 noon every** Tuesday to make the meeting held on the Thursday of the following week.

***DO NOT submit these instructions with your application***