****

|  |
| --- |
| Human Research Ethics CommitteeEthics Approval for Research Involving HumansAPPLICATION FORM - EXPEDITED REVIEW |

**ATTENTION MAC USERS: THIS FORM CAN ONLY BE COMPLETED ON A MAC IF IT HAS A VERSION OF MS WORD LESS THAN 3 YEAR OLD, HOWEVER, THIS STILL HAS SOME LIMITATIONS AND THE TICK BOXES WILL NOT WORK. TO OVERCOME THIS PROBLEM PLEASE PUT AN ‘X’ NEXT TO THE CORRECT BOX OR HIGHLIGHT THE CORRECT RESPONSE. IF NOT IT SHOULD BE COMPLETED ON A PC TO ENSURE THAT THE COMPLETE FUNCTIONALITY OF THE FORM IS OPERATIONAL.**

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 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 addressed by the research design
* E3 full HREC review = Potential for significant 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 Committee website](http://www.une.edu.au/research/res-services/rdi/human-research-ethics).

NOTE: Human research is to be informed by and comply with the [*National Statement on Ethical Conduct in Human Research, 2007*](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) *(updated May 2015)*.

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 2007 (updated May 2015).

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. 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/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 are clearly detailed. The researchers should provide a step by step explanation of all requirements. In addition, factors that will impact on participants should be considered.

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 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 placing an ‘x’ in 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 (2007) incorporating all updates as at May 2015 (PDF, 600KB)](https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf)

How to use this application form

Commence at Part A. Answer the questions and follow the instructions to determine the level of review required for your research. If your project qualifies for expedited review (E1 or E2) you will complete all of this form. If your research is E3 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. [To print hidden text select

Tools⏐Options⏐Print⏐Hidden Text.]

**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***

****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Office use:* | **Reference Number** |  | **Date Received** |  |  E1 ❑ E2 ❑ E3 ❑ |

|  |
| --- |
| Human Research Ethics CommitteeEthics Approval for Research Involving HumansAPPLICATION 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)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A1 | Exposure of participants to ionising radiation [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A2 | Accessing personally identifiable information or records without specific consent from the individuals to whom the information or records relate [**NS2.3.6**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A3 | Use of drugs; alternative or complementary therapies or care; or surgical or other therapeutic or diagnostic procedures and devices [**NS3.3**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A4 | An innovation or intervention which is not standard practice in the study population [**NS3.3**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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) [**NS3.4; NS2.3**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A6 | Human genetic studies [**NS3.5**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A7 | Human stem cells [**NS3.6**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A8 | Focusing on women who are pregnant, and/or research involving the human foetus [**NS4.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A9 | People who are highly dependent on medical care and who may be unable to give consent, e.g. unconscious or too ill [**NS4.4**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A10 | Focusing on people with a cognitive impairment, an intellectual disability, or a mental illness [**NS4.5**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A11 | Focusing on illegal activity or the likelihood of discovering an illegal activity [**NS4.6**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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 [**NS4.7**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | Yes |  |  | No | X |

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

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

|  |  |
| --- | --- |
|  |  |
| **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.  | Exploring the key skills, knowledge and attitudes of health literate students. |  |
|  |  |

|  |  |
| --- | --- |
|  |  |
| **Project Summary** Provide a brief plain English snapshot of the project (max. 100 words). **Max 6 lines**.Provide a lay persons snapshot of the project. Include central aims, study population, method and technique (eg surveys, interviews, observations, etc).  | This research aims to generate consensus of key health literacy indicators amongst two panels, composed of teachers, students, academics and members of health organisations. Data generated from this process will be used to construct a survey which will be distributed to teachers and students in order to validate the panel’s indicators.  |  |
|  |  |

#### PART B2 – PRINCIPAL INVESTIGATOR 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.

|  |  |
| --- | --- |
|  |  |
| **Name** *(eg. Dr James Nightly)***(one name only)** | Dr Julie Muller |  |
|  |  |
| **UNE Staff Number** | 235676 |  |
|  |  |  |
| **Qualifications** | BSc (PE), BSc (History) (PSU Orlando), BEd (Hons) (UNE), Ph.D. (UNE). |  |
|  |  |
| **School**  | Education |  |
|  |  |
| **Mailing Address** | Milton Building, University of New England, Armidale, 2351 |  |
|  |  |
| **Phone No.** | 02) 6773 3333 |  |
|  |  |
| **Fax No.** | 02) 6773 5078 |  |
|  |  |
| **Email Address** | jmuller77@une.edu.au |  |
|  |  |

#### PART B3 – CO-INVESTIGATOR/CO-SUPERVISOR other than student researchers

List all co-investigators on the project who are **not** students conducting the research as a component of their studies. This includes Co-Supervisors. **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.

|  |  |
| --- | --- |
|  |  |
| **Name** *(eg. A/Prof Larry Brown)* | Professor Noel Turner |  |
|  |  |
| **UNE Staff/Student Number** | 987123 |  |
|  |  |  |
| **Qualifications** | BSc(Hons) (Belf), MA (Lond), MSc (Leeds), PhD (UNE), PGCE (Leeds) |  |
|  |  |
| **Role** | Co-Supervisor |  |
|  |  |  |
| **School**  | Education |  |
|  |  |
| **Mailing address** | FEHPS Building, University of New England, Armidale, NSW, 2351 |  |
|  |  |
| **Phone No.** | (02) 6773 3333 |  |
|  |  |
| **Fax No.** | (02) 6773 2445 |  |
|  |  |
| **Email**  | nturner96@une.edu.au |  |
|  |  |

|  |  |
| --- | --- |
|  |  |
| **Name** *(eg. Mrs Jane Smith)* | Dr Anna Frank |  |
|  |  |
| **UNE Staff/Student Number** | 1234567 |  |
|  |  |  |
| **Qualifications** | BEd (PE)(Hons)(UNSW), MProfEd&Training (Sydney), DipProfCounselling (AIPC), PhD (UNE) |  |
|  |  |
| **Role** | Co-Supervisor |  |
|  |  |  |
| **School**  | Education |  |
|  |  |
| **Mailing address** | Milton Building, University of New England, Armidale, 2351 |  |
|  |  |
| **Phone No.** | 02) 6773 3333 |  |
|  |  |
| **Fax No.** | 02) 6773 5078 |  |
|  |  |
| **Email**  | afrank3@une.edu.au |  |
|  |  |

|  |  |
| --- | --- |
|  |  |
| **Name** *(eg. Mr Mohammed Ali)* | Ms Leanne McDonald |  |
|  |  |
| **UNE Staff/Student Number** | 00045692 |  |
|  |  |  |
| **Qualifications** | HSC |  |
|  |  |
| **Role** | Research Assistant |  |
|  |  |  |
| **School**  | Education |  |
|  |  |
| **Mailing address** | Milton Building, University of New England, Armidale, 2351 |  |
|  |  |
| **Phone No.** | 02) 6773 3333 |  |
|  |  |
| **Fax No.** | 02) 6773 5078 |  |
|  |  |
| **Email**  | lmcdonal@une.edu.au |  |
|  |  |

*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.

|  |  |
| --- | --- |
|  |  |
| **Name** *(eg. Ms Beth Schmidt)* | Miss Eloise Sutcliff |  |
|  |  |
| **UNE Student Number** | 222220001 |  |
|  |  |  |
| **Qualifications** | B. Ed (PE)(Hons) – University of Bingara Grad. Cert. Outdoor and Environmental Education – University of Bingara |  |
|  |  |
| **School**  | Education |  |
|  |  |
| **Mailing address** | Arts/Education Building, University of New England, Armidale, 2351 |  |
|  |  |
| **Phone No.** | (02) 6773 3449 or 0300 123 456 |  |
|  |  |
| **Fax No.** | N/A |  |
|  |  |
| **Email (**please use UNE email**)** | esutcliff007@myune.edu.au PhD |  |
|  |  |
| **Name of degree program**  |  |  |
|  |  |
|  | Undergraduate |  | Honours |  |  Postgraduate Coursework |  | Postgraduate Research |  |  |
|  |  |
| **University of New England?** |  Yes |  |  | Other *(please specify)*: |  |
|  |  |
| **Principal supervisor** | Dr Julie Muller |  |
|  |  |

*Copy this table and repeat for each additional student.*

#### PART C – IDENTIFYING ETHICAL ISSUES

Your responses to 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)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C1 | Will participants of this research be quoted either directly or using a pseudonym, in the reporting? |  | YesGo to [**D1**](#D1) | X |  | NoGo to [**C2**](#C2) |  |

Will participants be quoted verbatim in reports?

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C2 | Will participants of this research be identifiable in the reporting? |  | YesGo to [**D2**](#D2) |  |  | NoGo to [**C3**](#C3) | X |

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) |  | YesGo to [**D17**](#D17)then [**C8**](#C8) |  |  | NoGo to [**C8**](#C8) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C4 | Will the research involve pain or discomfort for participants? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D8**](#D8) |  |  | NoGo to [**C11**](#C11) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C5 | Is there a risk of physical injury to participants? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D7**](#D7) |  |  | NoGo to [**C10**](#C10) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C6 | Could the research cause participants psychological or emotional stress? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D9**](#D9) |  |  | NoGo to [**C12**](#C12) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C7 | Might the research expose participants to civil, criminal or other proceedings? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D10**](#D10) |  |  | NoGo to [**C13**](#C13) | X |

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?

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C8 | Could the research expose participants to economic loss or damage to their reputation? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D12**](#D12) |  |  | NoGo to [**C15**](#C15) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C9 | Might the research have a negative impact on personal relationships? [**NS2.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D13**](#D13) |  |  | NoGo to [**C16**](#C16) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C10 | 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) |  | YesGo to [**D3**](#D3) |  |  | NoGo to [**C4**](#C4) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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; NS3.3.5**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D17**](#D17) then [**C17**](#C17) |  |  | NoGo to [**C17**](#C17) | X |

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 | Will the research involve deception or limited disclosure to participants? [**NS2.3.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D15**](#D15) |  |  | NoGo to [**C19**](#C19) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C13 | Will the research involve covert observation? [**NS2.3.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D14**](#D14) |  |  | NoGo to [**C18**](#C18) | X |

This is observation of others without their knowledge.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C14 | Will existing databases, databanks or human tissue banks be accessed for this research? [**NS3.2**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D6**](#D6) |  |  | NoGo to [**C7**](#C7) | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C15 | Will the research involve collection, extraction or use of human tissue (including cell lines), blood or other body fluids? [**NS3.4**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D6**](#D6)then[**D17**](#D17) then [**C9**](#C9) |  |  | NoGo to [**C9**](#C9) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C16 | 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) |  | YesGo to [**D4**](#D4) | X |  | NoGo to [**C5**](#C5) |  |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C17 | Are potential participants in a dependent or unequal relationship with the researcher/s? eg lecturer/student, doctor/patient, teacher/pupil, employer/employee [**NS4.**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)**3** |  | YesGo to [**D5**](#D5) |  |  | NoGo to [**C6**](#C6) | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C18 | Is this research being conducted overseas? [**NS4.8**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |  | YesGo to [**D16**](#D16) |  |  | NoGo to **[C20](#C20)** | X |

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| C19 | Will the research involve the collection of sensitive personal information?  |  | YesGo to [**D11**](#D11) |  |  | NoGo to [**C14**](#C14) | X |

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.

|  |  |
| --- | --- |
| **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 E3 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)**.** |

#### 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? |  | YesGo to D1b | X |  | NoGo to [**D19**](#D19) |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | D1b | Will the potential participants be quoted for the purpose of reporting, presenting at conferences & publishing? |  | YesGo to D1c | X |  | NoGo to D1c |  |
|  | D1c | Will specific consent for quoting be obtained? |  | YesGo to D1d | X |  | NoGo to [**D19**](#D19) |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | D1d | Are there strategies in place for participants to confirm their consent to be quoted? |  | Yes Go to [**D17**](#D17)thenGo to [**C2**](#C2) | X |  | NoGo to [**D19**](#D19) |  |

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? |  | YesGo to D2b |  |  | NoGo to [**D19**](#D19) | X |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | D2b | Will the potential participants be identifiable for the purpose of reporting, presenting at conferences & publishing? |  | YesGo to D2c |  |  | NoGo to D2c |  |
|  | D2c | Will specific consent for identification be obtained? |  | YesGo to D2d |  |  | NoGo to [**D19**](#D19) |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | D2d | Are there strategies in place for participants to confirm their consent to be identified? |  | Yes Go to [**D17**](#D17)thenGo to [**C3**](#C3) |  |  | NoGo 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? |  | YesGo to [**C4**](#C4) |  |  | NoGo 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? |  | YesGo to D4b |  |  | NoGo to [**D17**](#D17)then D4b | X |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | D4b | Will assent of the children be obtained?  |  | YesGo to D4c |  |  | NoGo to [**D17**](#D17) then D4c | X |

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?  |  | YesGo to D4d |  |  | NoGo to D4d | X |

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? |  | YesGo to [**D17**](#D17)then D4e |  |  | NoGo to [D4e](#C5) | X |
|  | D4e | Is the research contrary to the best interests of the children? |  | YesGo to [**D19**](#D19) |  |  | NoGo to [**C5**](#C5) | X |

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? |  | YesGo to [**D17**](#D17)then D5b |  |  | NoGo 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? |  | YesGo to [**D17**](#D17)then D5c |  |  | NoGo 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? |  | YesGo to [**D19**](#D19) |  |  | NoGo 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? |  | YesGo to D6b |  |  | NoGo to D6e |  |
|  | D6b | Is the tissue retained in an identifiable or potentially re-identifiable form?  |  | YesGo to D6c |  |  | NoGo to [**C7**](#C7) |  |
|  | D6c | Is there existing consent from the individuals involved, which will cover this research?  |  | YesGo to [**C7**](#C7) |  |  | NoGo to D6d |  |
|  | D6d | Will consent be obtained from the individuals involved, which will cover this research?  |  | YesGo to [**C7**](#C7) |  |  | NoGo to [**D19**](#D19) |  |
|  | D6e | Are you using a database or databank? |  | YesGo to D6f |  |  | NoGo 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?  |  | YesGo to D6g |  |  | NoGo to [**C7**](#C7) |  |
|  | D6g | Is there existing consent from the individuals involved, which will cover this research?  |  | YesGo to [**C7**](#C7) |  |  | NoGo 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? |  | YesGo to D7b |  |  | NoGo 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? |  | YesGo to D7c |  |  | NoGo 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)? |  | YesGo to D7d |  |  | NoGo 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? |  | YesGo to [**D17**](#D17) then [**C10**](#C10) |  |  | NoGo to [**D19**](#D19) |  |

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| D8 | D8a | Will prior warning be given to potential participants? |  | YesGo to D8b |  |  | NoGo 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? |  | YesGo to D8c |  |  | NoGo to [**C11**](#C11) |  |
|  | D8c | Will there be an appropriate screening process of the potential participants to identify those at a higher risk? |  | YesGo to D8d |  |  | NoGo 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?  |  | YesGo to [**D19**](#D19) |  |  | NoGo 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? |  | YesGo to D9b |  |  | NoGo 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 |  |  | NoGo to [**C12**](#C12) |  |
|  | D9c | Will there be an appropriate screening process of the potential participants to identify those at a higher risk? |  | YesGo to [**D17**](#D17) then D9d |  |  | NoGo 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?  |  | YesGo to [**D19**](#D19) |  |  | NoGo 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? |  | YesGo to D10b |  |  | NoGo 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? |  | YesGo to [**D17**](#D17) then [**C13**](#C13) |  |  | NoGo 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? |  | YesGo to D11b |  |  | NoGo 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? |  | YesGo to [**D17**](#D17) then [**C14**](#C14) |  |  | NoGo 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? |  | YesGo to [**C15**](#C15) |  |  | NoGo 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? |  | YesGo to [**C16**](#C16) |  |  | NoGo 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? |  | YesGo to D14b |  |  | NoGo 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? |  | YesGo to [**D17**](#D17)then [**C18**](#C18) |  |  | NoGo 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? |  | YesGo to [**D19**](#D19) |  |  | NoGo to D15b |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | D15b | Have any alternatives involving full disclosure been considered? |  | YesGo to D15c |  |  | NoGo 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? |  | YesGo to D15d |  |  | NoGo 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? |  | YesGo to [**C19**](#C19) |  |  | NoGo to [**D19**](#D19) |  |

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

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? |  | YesGo to [**D17**](#D17)then D16b |  |  | NoGo 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? |  | YesGo to D16c |  |  | NoGo 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? |  | YesGo to D16d |  |  | NoGo 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 others factors that may compromise free and informed consent? |  | YesGo to [**D17**](#D17)then D16e |  |  | NoGo 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? |  | YesGo to [**D17**](#D17) then D16f |  |  | NoGo to [**D19**](#D19) |  |
|  | D16f | Will you be applying for or have you applied for a UNE travel grant? |  | YesGo to D16g  |  |  | NoGo to [**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)). |

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? |  | YesContinue |  |  | NoGo 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 [D1d]:** Participants will be advised via the Information Sheet for Participants and Consent Form that they will be quoted anonymously.**Question [D4a]:**Parental/carer consent will not be required as only young people aged16 or 17years will be recruited. These participants will provide young person’s consent.**Question [D4b]:**Young person consent will be obtained. |

|  |  |
| --- | --- |
| **D18** | **If you have completed questions in Part D but were not advised that an E3 application was required then your project appears to qualify for Expedited Review E2. Proceed to** [**Part E**](#PartE)**.** |

|  |  |
| --- | --- |
| **D19** | Your project requires full E3 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**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |

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) | Background:Health literacy is a growing area of interest across many fields and has been defined and used in a range of different ways. The bulk of early research was predominantly based within the healthcare setting (Davis et al., 1991; Parker, Baker, Williams, & Nurss, 1995) and has been criticised for focussing only on ‘functional’ health literacy skills (Pleasant & Kuruvilla, 2008). In more recent times a broader understanding of health literacy has been advocated within the field of health promotion (Kickbusch, 2001; Nutbeam, 2008). In 2012, the Health and Physical Education Shape paper for the Australian curriculum emphasised that the key learning area should develop students’ health literacy (Australian Curriculum and Assessment Reporting Authority, 2012). Despite this obvious growth and interest in health literacy, there remains lack of consensus surrounding its definition and conceptualisation, particularly within the school setting. Aims:This research explores the concept of health literacy within the school setting and aims to reach consensus on the skills, knowledge and attitudes that the BARS panel determine are important for a health literate student. Validity of the BARS process will be ensured through surveys with school-based teachers. The results of this research may provide a foundation upon which future investigation of health literacy assessment and pedagogical practices can be based.Method: Phase 1: Two panels (composed of teachers, students, academics, curriculum writers and members of health organisations) will meet to discuss and reach consensus of the key knowledge, skills and attitudes important for a health literate student. Lists from both panels will be amalgamated and emailed out to all panel members for review and feedback. Phase 2: The data generated from Phase 1 will be used as the basis for a survey that will be administered to a sample of school-based teachers.References:Australian Curriculum and Assessment Reporting Authority. (2012). The Shape of the Australian Curriculum: Health and Physical Education (pp. 1-32). Sydney, NSW: ACARA. Davis, T. C., Crouch, M., Long, S. W., Jackson, R., Bates, P., George, R., & Bairnsfather, L. (1991). Rapid assessment of literacy levels of adult primary care patients. Family Medicine, 23(6), 433-435. Kickbusch, I. (2001). Health literacy: Addressing the health and education divide. Health Pomotion International, 16(3), 289-297. Nutbeam, D. (2008). The evolving concept of health literacy. Soc Sci Med, 67(12), 2072-2078. Parker, R., Baker, D., Williams, M., & Nurss, J. (1995). The Test of Functional Health Literacy in Adults: A new instrument for measuring patients' literacy skills. Journal of General Internal Medicine, 10, 537-541. Pleasant, A., & Kuruvilla, S. (2008). A tale of two health literacies: public health and clinical approaches to health literacy. Health Promot Int, 23(2), 152-159. |

|  |  |
| --- | --- |
| **E2** | **List the experience and skills of each researcher** [**NS1.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |

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) | Dr Julie Muller has supervised seven HDR students to completion across a range of topics using mixed methodology and has led twelve research consultancies and three large-scale research projects. Health and Physical Education has been her pre-service teacher education discipline responsibility for over 20 years at UNE. This tertiary experience builds on 9 years of school-based teaching in Orlando, USA and AustraliaProf Noel Turner has taught Science and Health at the primary and tertiary level. He has been actively engaged in research for more than 20 years and has more than 100 publications, including an edited book on Health Education. He has also supervised a number of HDR students to completion. Dr Anna Frank has twenty years’ experience teaching school-based Health Education including one year as a Regional Drug Education Consultant together with eight years of tertiary teaching related to both community and school-based perspectives on Health. Annette has skills in social research relevant to Eloise’s study e.g. collecting and analysing data pertaining to people’s perceptions; survey method; and ethical reporting of findings.Dr Leanne McDonald is a leading scholar and curriculum developer at the National level. She has extensive teaching experience in Health Education in both the secondary school (14 yrs) and tertiary setting (10 yrs). Dr McDonald is an adjunct appointed specifically to contribute to this research. Dr McDonald is an active and successful supervisor of postgraduate students in the School of Human Movement at the University of Queensland. Miss Eloise Sutcliff is currently undertaking her PhD. She completed Honours at the University of Bingara, looking specifically at the physiological factors that predict running performance. Eloise has worked as a Secondary Health and Physical Education teacher for fourteen years.  |

|  |  |
| --- | --- |
| **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? (*X all that apply)*  |
|  | Children less than 18 years | X |  |
|  | The general public |  |  |
|  | Students or staff of the University of New England |  |  |
|  | Students or staff of other universities or colleges | X |  |
|  | School children, i.e. obtained through schools  | X |  |
|  | Employees of schools |  |  |
|  | Registers or databases |  |  |
|  | Members of community groups or organisations | X |  |
|  | Employees of organisations | X |  |
|  | 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)* |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| **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” |
| Phase 1: Participants will be drawn from the following…...- Health Education/Physical Education and Literacy Academics from Australian Universities - Teachers from Primary schools in the Brisbane area Universities - Teachers from Primary schools in the Brisbane area |
| Phase 2: Teachers will be recruited from Independent and Government schools across Victoria, New South Wales and Queensland. |

|  |  |
| --- | --- |
| **E3.3** | How, and by whom, will potential participants be selected, initially contacted and recruited? [**NS1.4; NS3.1**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)  |
|  | **Details** (Max 300 words) | Phase 1: The student researcher will identify potential participants from the list above (E3.2) and make initial contact via email or phone call. Participants will be provided with information about the workshop and invited to participate as a panel member. Follow-up information and details of the health literacy workshop will be provided for interested participants. The Health Literacy workshop will be scheduled to coincide with the Physical Education National Workshop, which is being held on the 6th-7th January 2016 in Bli Bli, Queensland.Phase 2: School Principals in Victoria, New South Wales and Victoria will be contacted via email, inviting teachers and to complete the survey. Follow-up information and instructions for will be provided for interested schools. |

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.

|  |  |
| --- | --- |
| **E3.4** | How many participants will be recruited and what is the rationale for that number? |
| *Total number of participants to be recruited:* | Phase 1: A total of 20 participants (10 for each panel) will be recruited to participate in the health literacy workshop. Phase 2: The survey will be sent to up to 1000 teachers. As the usual response rate is around 30%, it is expected that around 300 surveys will be completed and returned. |
| *Rationale:*(Max 300 words) | Phase 1: This number is consistent with previous implementations of the Hybrid BARS process (ie. 6-10 members on each panel). Phase 2: Considering the expected response rate of surveys, this number will allow enough data to carry out multivariate analysis.  |

|  |  |
| --- | --- |
| **E3.5** | List the inclusion and exclusion criteria [**NS1.4**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |
|  | **Details**  | Inclusions: Phase 1: Must belong to one of the groups identified in E3.2Phase 2: Must be currently teaching in a full-time, part-time or casual position. The teachers need to have an interest, prior experience or education background in Health Education. Exclusion: Phase 1: Students below 16yearsPhase 2: Teachers who have no interest or background in Health Education forschool-aged children. |

|  |  |
| --- | --- |
| **E3.6** | What will be required of the participants? |
|  | **Details** (Max 300 words) | Phase 1: Participants will be required to participate in a one-day workshop as a member of one of two panels of ‘experts’. The day will be structured to enable participants to brainstorm and discuss the key skills, knowledge and attitudes of a health literate student. By the end of the day, each panel must produce a list of agreed upon health literacy indicators. Following the workshop, the compiled lists of both panels will be emailed to all participants for feedback (including wording and item inclusion and exclusion). The final data from this process will be used to construct a survey. Phase 2: Participants will be required to complete an electronic survey which will be estimated to take 20 minutes to complete. |

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.

|  |  |
| --- | --- |
| **E3.7** | What, if any, are the benefits of this research for participants, the wider community or both? [**NS1.6**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |
|  | **Details** (Max 300 words) | Participants involved in the health literacy workshop will have the opportunity to make a contribution to the current understanding of health literacy within the school context. Data generated through this research can provide a foundation upon which future investigation of health literacy assessment and pedagogical practices can be based. The educational community will benefit from a research informed basis of health literacy as it moves into the schools with the release of the National Curriculum in HPE in 2014-2015. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **E3.8** | Will participants receive reimbursement, payment or rewards for participating in this research? [**NS2.2.10; NS3.3.5**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) | Yes |  |  | No | X |

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.

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

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

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

|  |  |
| --- | --- |
| **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.  |

|  |  |  |
| --- | --- | --- |
|  | **Details** (Max 300 words) | Phase 1: 4 senior secondary school students aged 16 years or over will participate in the workshop. These students will be accompanied by a teacher from their school. |

|  |  |
| --- | --- |
| **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.

|  |  |
| --- | --- |
| **Details–** Explain how the data will be analysed. (Max 300 words) | Phase 1: Data generated through the health literacy workshop will undergo validation through member checking with the original panel members. Only items that reach a level of agreement of 90% will be retained.Following this analysis, the survey instrument will be formulated.Phase 2: Responses from the survey will be subject to Rasch analysis (Quest), as well as a range of other quantitative statistical measures. |

|  |  |
| --- | --- |
| **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 | X |  |
|  |  Face-to-face interviews (in person or via SKYPE) |  |  |
|  |  [Telephone Interviews](http://www.une.edu.au/research/research-services/research-development-and-integrity/ethics/human-research-ethics/hrec-forms-and-guidelines) (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  | X |  |
|  |  Identifying **paper-based** questionnaires, surveys or diaries  |  |  |
|  |  Record or document analysis |  |  |
|  |  Recording – audio or video | X |  |
|  |  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 | X |  |
|  |  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)* |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| **E5.2** | If any of the procedures or tests you intend to use, are listed on the *HREC Database of Approved Procedures and Tests*, please identify them by the registration number and title and risk level. Otherwise, provide details and ***attach*** a copy of questionnaires, surveys, interview scripts, tests, instruments or procedures that are not on the Register. |
|  | **Details** (Max 300 words) | Phase 1: Hybrid Behaviourally Anchored Rating Scale (BARS) methodology will be used in order to generate consensus of the key skills, knowledge and understanding of health literate students. Further information regarding this process has been attached to the application.Phase 2: Data collected from Phase 1 will be used in the construction of a survey to be distributed to teachers and students. Once constructed, this survey will be forwarded as a variation to this ethics application. |

|  |  |
| --- | --- |
| **E6** | **Informed consent** [**NS2.2**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) |

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.

|  |  |
| --- | --- |
|  Written informed consent | X |
|  Recorded informed consent |  |
|  Parent, Guardian or Carer consent |  |
|  Child’s assent with parent or guardian consent |  |
|  Young persons (16-17 years) consent | X |
|  Implied consent | X |
|  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)Phase 1: Participants aged 18 years or over will provide written informed consent. Student participants in the workshop will be aged 16 years or over and will provide young person’s consent.Phase 2: Implied consent will be assumed if surveys are returned. |

|  |  |
| --- | --- |
| **E7** | **Communication of results or reporting** [**NS1.1; NS1.3; NS1.4; NS2.2.6; NS3.1.4; NS3.1.11**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)  |

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 | X |
|  Published in future journal articles | X |
|  Presented at conferences | X |
|  Other *(please specify below)* | X |
| **Please provide details.** (Max 300 words)Phase 1: All panel members will be provided with the final results of the workshop and feedback process. This will be emailed to all panel members.Phase 2: A brief report of key findings will be emailed to any interested participants, following the completion of the study. Furthermore, it is expected that results will be reported through peer-review publications and conference presentations. |

|  |  |
| --- | --- |
| **E8** | **Duration of data collection for research.** (‘Start date’ must be after meeting date) |

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.

|  |  |  |  |
| --- | --- | --- | --- |
| **Start:** | **01/01/2018** | **End:** | **01/01/2019** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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).* | YesGive details |  |  | NoGo to E10 | X |
| *Name of other HREC* | *Reference No.* |  |
|  |  |
|  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **E10** | **Is the research funded by an internal or external grants body or sponsor?**  | YesGive details |  |  | NoGo to E11 | X |
| *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**](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) | YesGive details |  |  | NoGo 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) |  |

|  |  |
| --- | --- |
| **E11** | **Data Storage and Security**  |
|  | Data storage and security of proposed research. |
|  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Does data storage comply with Australian Code for the Responsible Conduct of Research (Research Practice for the Management of Research Data & Primary Records)? [**2.1 & 2.2**](https://www.nhmrc.gov.au/guidelines-publications/r39)
 | Yes | X | No |  |
| If **No**, please provide further details: |
| 1. Will the Principal Researcher be solely responsible for the security of the data during the collection phase of this project?
 | Yes | X | No |  |
| If **No**, please provide further details: |
| 1. What arrangements are in place for data security during fieldwork?
 | Hard copy files will be stored in thePrincipal Researchers UNE office.All electronic data will be stored on Cloud.une.edu.au |
| 1. Who will have access to the raw data?
 | Named researchers only | X | Named researchers plus others (specify below) |  |
| Please give details of others who will have access to the raw data, for what purpose and their connection to the project: |
| 1. Will digital data be kept on cloud.une.edu.au during the active term of the research and until it is disposed of?
 | Yes | X | No |  |
| If **No**, please explain: |
| 1. Will the electronic data be held on a password protected computer?
 | Yes | X | No |  |
| If **No**, please explain why not: |
| 1. Will the data and identifiers be kept in separate, locked filing cabinets?
 |  | X |  |  |
| If **No**, please explain why not: |
| 1. Will hardcopy data be kept in a locked filing cabinet/facilities in the UNE faculty or outside organisation through which the research is being conducted??
 | Yes | X | No |  |
| If **No**, please explain how and where data will be held, including any arrangements for: |
| **i)** | Will data be kept for a minimum of 5 years after successful submission of the thesis or final publication? | Yes | X | No |  | Indefinitely Go to **E11k** |  |
| If **No**, please explain how long the data will be kept:  |
| 1. How will the data be disposed of? Hardcopy data will be shredded and electronic data will be permanently deleted
 |
| 1. Provide the name or role of the person who will dispose of the data? Miss Eloise Sutcliff
 |
| 1. Will some or all of the research data be openly or publicly available at some time in the future? **Note:** It is recommended that unless your data can not be shared for ethical, privacy or confidentiality matters, that you incorporate the future use of data in your research design and include a statement within the Information Sheet for Participants with a statement to this effect.
 | Yes | X | No |  |
| If **Yes**, please explain how data will not be made openly or publicly available in the future.The de-identified data will be published onto figshare (or similar), for other researchers to see. |
| If **No**, please explain why the data will not be openly or publicly available in the future. |

 |

|  |  |
| --- | --- |
| **E12** | **Safety implications** |
|  | Does the proposed research involve work on, use of, or exposure to any of the following? |
|  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Cash reimbursements or payments to research participants | Yes |  |  | No |  |
| Face-to-Face interaction with participants e.g. interviews, procedures | Yes | X |  | No |  |
| Recombinant DNA | Yes |  |  | No |  |
| Genetically modified organisms | Yes |  |  | No |  |
| Biologically hazardous micro-organisms | Yes |  |  | No |  |
| Chemically hazardous materials | Yes |  |  | No |  |
| Human body fluids or tissue | Yes |  |  | No |  |
| Radioisotopes or unsealed sources | Yes |  |  | No |  |
| Ionising radiation | Yes |  |  | No |  |
| Non-ionising radiation | Yes |  |  | No |  |
| Any other potential safety hazard for either participants or researchers? | Yes |  |  | No |  |

If **‘Yes’** explain what safety precautions the researchers will take to keep themselves and their participants safe during this research?Safety Precautions put into place for the researchers include:* Phase 1 testing will be conducted at the University of Queensland and Phase 2 will be conducted in schools.

Safety Precautions put into place for the participants include:* Phase 1 testing will be conducted at the University of Queensland and Phase 2 will be conducted in schools.
 |

#### PART F1 – DECLARATION BY APPLICANTS

All of 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, 2007,* which I have read.
* I undertake to conduct the research in accordance with the approved protocol, the *National Statement*, relevant legislation and the policies and procedures of the University of New England.
* I have read and agree to comply with the University of New England’s Research Data Management Policy and pursuant policies and procedures and have a plan for managing and/or sharing Research Data securely.
* I understand and agree that project files, documents, 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.
* 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.

 **All investigators named at** [**B2**](#B2) **,** [**B3**](#_PART_B3_–) **and** [**B4**](#_PART_B4_–) **are to sign this declaration.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Name* | *Signature* | *Date* |
| Chief investigator or project supervisor | Dr Julie Muller | Julie C Muller | 01.01.2018 |
| Co-Investigator or Student Researcher | Prof Noel Turner | Noel Turner | 01.01.2018 |
| Co-Investigator or Student Researcher | Dr Anna Frank | Anna L Frank | 01.01.2018 |
| Co-Investigator or Student Researcher | Dr Leanne McDonald | L E McDonald | 01.01.2018 |
| Co-Investigator or Student Researcher | Miss Eloise Sutcliff | Eloise Sutcliff | 01.01.2018 |

#### PART F2 – HEAD OF SCHOOL DECLARATION

**Head of School Declaration**

*Where the Head of School 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 the Provost Deputy Vice Chancellor.*

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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title | Prof | First Name | Anne-Marie | Last Name | Morgan |
| Position | Head of School, School of Education |
| Signature | Anne-Marie Morgan | Date | 01/01/2018 |

***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:**

I have **attached** the required documents as follows: *(please X)*

|  |  |
| --- | --- |
| * [***Information Sheets for Participants***](https://www.une.edu.au/research/research-services/rdi/ethics/hre/hrec-forms) ***(ISP)***
 | X |
| * [***Consent Form(s)***](https://www.une.edu.au/research/research-services/rdi/ethics/hre/hrec-forms)
 | X | N/A |  |
| * ***All recruitment material, e.g. emails, advertisements, posters, social media posts***
 |  | N/A |  |
| * ***Surveys and questionnaires (if online exactly as they will appear)***
 |  | N/A |  |
| * ***Focus group and Interview questions***
 | X | N/A |  |
| * ***Telephone script***
 |  | N/A |  |
| * ***Approval(s) from any other HREC’s***
 |  | N/A |  |
| * ***Certified Translations of all relevant documents ie ISP, Consent Form, Survey, etc***
 |  | N/A |  |

|  |
| --- |
| **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. |
| I have only attached the information sheets for participants and consent forms for the first phase of the study. Information sheets, consent forms and a copy of the survey will be forwarded as a variation to this application following collection of data for the first phase of this study.  |

#### 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 of 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.
* Applications should be submitted electronically either as a word document or a colour pdf. Hardcopies will be accepted but must be submitted in colour.

**Submit to:**

![MMj03957370000[1]]() ethics@une.edu.au

**Questions can be directed to:**

 Research Ethics Officer ![MCj04338610000[1]]() 02 6773 3449

 Research Services **OR**

 T.C Lamble Building ![MCj04338610000[1]]() 02 6773 2890

 University of New England

 Armidale NSW 2351

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

**Closing date for applications:**

There is no set closing date for **E1** applications. Applications will be accepted at any time. **E2** applications should be submitted to the Secretary by **12 noon** Friday to make the meeting the following Thursday.

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

**School Of Education**

**University of New England**

Armidale NSW 2351

Australia

**Phone: (02) 6773 3333**

**Email:** **esutcliff007@myune.edu.au**

**www.une.edu.au/education**

INFORMATION SHEET

for

PARTICIPANTS

I wish to invite you to participate in my research project, described below.

My name is Eloise Sutcliff and I am conducting this research as part of my PhD in the School of Education at the University of New England. My supervisors are Dr Julie Muller, Professor Noel Turner, Dr Anna Frank and Dr Leanne McDonald.

|  |  |
| --- | --- |
| **Research Project** | **Exploring the key skills, knowledge and attitudes of health literate students.** |
| **Aim of the Research** | The research aims to explore health literacy applicable to the school setting and aims to reach consensus on the key indicators of health literacy for students.  |
| **Health Literacy Workshop** | You are invited to participate in a workshop as part of a panel to identify key indicators of a health literate student. The workshop will involve two identically operated panels, consisting of 6-10 members (including teachers, secondary school students, academics, curriculum writers and members of community health organisations). The day will be structured to enable you to contribute to group discussions and reach consensus on key skills, knowledge and attitudes of a health literate student. At the conclusion of the workshop, results from both panels will be collated and emailed to you for review and comment. The final data from this process will be used to construct a survey that will be distributed to teachers for validation and further feedback. |
| **Confidentiality** | Any personal details gathered in the course of the study will remain confidential. No individual will be identified by name in any publication of the results. All names will be replaced by pseudonyms; this will ensure your anonymity. If you agree I would like to quote some of your responses. This will also be done in a way to ensure that you are not identifiable. |
| **Participation is Voluntary** | Please understand that your involvement in this study is voluntary and I respect your right to withdraw from the study at any time. You may discontinue the workshop at any time without consequence and you do not need to provide any explanation if you decide not to participate or withdraw at any time. |
| **Questions** | The interview questions will not be of a sensitive nature: rather they are general, and will enable me to enhance my knowledge of health literacy in the school setting. |
| **Use of Information** | I will use information from the interview as part of my doctoral thesis, which I expect to complete at the beginning of 2019. Information from the workshop may also be used in journal articles and conference presentations before and after this date. At all times, I will safeguard your identity by presenting the information in a way that will not allow you to be identified. |
| **Upsetting Issues** | It is unlikely that this research will raise any personal or upsetting issues but if it does you may wish to contact your local Community Health Centre 07 3334 2221or Lifeline on 13 11 14. |
| **Storage of Information** | I will keep all hardcopy notes in a locked cabinet in my office at the University of New England’s School of Education. Any electronic data will be kept on cloud.une.edu.au, UNE’s centrally managed cloud server managed by the research team. It will also be kept on a password protected computer in the same location. Only the research team will have access to the data. |
| **Disposal of Information** | All the data collected in this research will be kept for a minimum of five years after successful submission of my thesis, after which it will be disposed of by deleting relevant computer files, and destroying or shredding hardcopy materials. |
| **Approval** | This project has been approved by the Human Research Ethics Committee of the University of New England (Approval No………., Valid to ../../….). |
| **Researchers****Contact Details** | Feel free to contact me with any questions about this research by email at esutcliff007@myune.edu.au or by phone on 0300 123 456You may also contact my Principal supervisor, Dr Julie Muller, at jmuller77@une.edu.au or 02 6773 3333. |
| **Complaints** | Should you have any complaints concerning the manner in which this research is conducted, please contact:Mrs Jo-Ann SozouResearch Ethics Officer Research ServicesUniversity of New England Armidale, NSW 2351Tel: (02) 6773 3449 Email: ethics@une.edu.au |
|  | Thank you for considering this request and I look forward to further contact with you.regards,Eloise Sutcliff |

**School Of Education**

**University of New England**

Armidale NSW 2351

Australia

**Phone: (02) 6773 3333**

**Email:** **esutcliff007@myune.edu.au**

**www.une.edu.au/education**

CONSENT FORM

for

PARTICIPANTS

**Research Project:** Exploring the key skills, knowledge and attitudes of health literate students.

|  |  |
| --- | --- |
| I, ……………………………………………………………………….., have read the information contained in the Information Sheet for Participants and any questions I have asked have been answered to my satisfaction.  | Yes/No |
| I agree to participate in this workshop, realising that I may withdraw at any time. | Yes/No |
| I agree to the workshop being audio recorded. | Yes/No |
| I am over 18 years of age. | Yes/No |

 …………………………….. ………………………….

 Participant Date

 …………………………….. ………………………….

 Researcher Date

**School Of Education**

**University of New England**

Armidale NSW 2351

Australia

**Phone: (02) 6773 3333**

**Email:** **esutcliff007@myune.edu.au**

**www.une.edu.au/education**

CONSENT FORM

for

YOUNG PEOPLE

**Research Project:** Exploring the key skills, knowledge and attitudes of health literate students.

|  |  |
| --- | --- |
| I, ……………………………………………………………………….., have read the information contained in the Information Sheet for Participants and any questions I have asked have been answered to my satisfaction.  | Yes/No |
| I agree to participate in this workshop, realising that I may withdraw at any time. | Yes/No |
| I agree to the workshop being audio recorded. | Yes/No |
| I am 16 years of age or older. | Yes/No |

 …………………………….. ………………………….

 Participant Date

 …………………………….. ………………………….

Researcher Date

**Hybrid Behaviourally Anchored Rating Scales**

Originally developed by Smith and Kendall (1963), Behaviourally Anchored Rating Scales (BARS) attempt to define job performance criteria in “multi-dimensional, behaviour specific terms” (Anshel, Housner, & Cyrs, 1987, p. 81). This process is essentially based upon consensus between members of two or more independent panels, who have familiarity with or expertise in the role under investigation. BARS was first used in order to develop criteria to evaluate the performance of nurses (Smith & Kendall, 1963) but has since been applied to a range of occupations; including store managers (Campbell, Dunnette, Arvey, & Hellervik, 1973) fire fighters (Dickinson & Tice, 1977), and police officers (Cascio & Valenzi, 1977; Landy, Farr, Saal, & Freytag, 1976).

In more recent times a variant of BARS, known as Hybrid BARS, has been applied to both sporting (Anshel, 1995; Dickson, 2000) and educational contexts (Parkes, Reading, & Stein, 2010). Hybrid BARS differs from the original form in that it is only concerned with identifying effective components of performance and does not rate behaviours on a continuum. In addition, the Hybrid variation is able to capture more than simply behavioural aspects of performance, including knowledge, abilities and attitudes.

The Hybrid BARS process consists of five sequential steps, designed to ensure rigorous identification of performance dimensions and competencies.

1. ***Selection and formation of panels.***

Central to the BARS process is the convening of two panels of “experts” (Anshel et al., 1987, p. 82). The members of these panels are selected in order to reflect a cross-section of participants in the field under investigation and are identical in composition. For example, if teachers are selected for participation in the process, then two teachers should be recruited (one for each panel). This process is repeated for the cross-section of participants. A leader from each panel is selected in order to ensure that the group remains on task and achieves the objectives of the meeting. In addition, a process observer leads the BARS process and ensures consistency across both panels. This might be the researcher or another person with BARS experience.

1. ***Meeting to generate performance dimensions and competencies.***

The two panels meet independently and follow a number of clearly defined tasks in order to generate performance dimensions and competencies. These include:

1. Identification of descriptive phrases and words for the role under investigation
2. Classification of descriptive words and phrases into performance dimensions
3. Development of specific competencies within each performance dimension

By the end of the meeting, each panel must produce a list of agreed upon performance dimensions and competencies.

1. ***Amalgamation of lists.***

The list of performance dimensions and competencies from each panel is combined into a single document by the researcher and panel leaders. During this step any duplicated items are combined and ambiguous phrases are reworded. The purpose of these modifications is to provide a consistent language and format and it is therefore important that any changes do not alter the original intent of items.

1. ***Verification of combined list.***

The amalgamated list is emailed to all panel members who have the opportunity to accept, reject or modify each of the performance dimensions and competencies under review. A consensus of 90% is required for items to be retained.

1. ***External validation of performance dimensions and competencies.***

The final list of performance dimensions and competencies generated through the Hybrid BARS process forms the basis of a survey.

References:

Anshel, M. (1995). Development of a rating scale for determining competence in basketball referees: Implications for Sport Psychology. *The Sport Psychologist, 9*(1), 4-28.

Anshel, M., Housner, L., & Cyrs, T. (1987). Defining competence for effective coaching of high school football. *Journal of Applied Research in Coaching and Athletics, 2*(2), 79-95.

Campbell, J., Dunnette, M., Arvey, R., & Hellervik, L. (1973). The development and evaluation of behaviorally based rating scales. *Journal of Applied Psychology, 57*(1), 15-22.

Cascio, W., & Valenzi, E. (1977). Behaviourally anchored rating scales: Effects of education and job experience of raters and ratees. *Journal of Applied Psychology, 62*(3), 278-282.

Dickinson, T., & Tice, T. (1977). The discriminant validity of scale developed by retranslation. *Personnel Psychology, 30*, 217-228.

Dickson, S. (2000). *A multi-faceted analysis of performance criteria: implications for the education and assessment of elite soccer officials in Australia.* Unpublished PhD Thesis, University of New England.

Landy, F., Farr, J., Saal, F., & Freytag, W. (1976). Behaviorally anchored scales for rating the performance of police officers. *Journal of Applied Psychology, 61*(6), 750-758.

Parkes, M., Reading, C., & Stein, S. (2010). *E-learning: Just how difficult can it be.* Paper presented at the ACEC: Digital diversity conference, Melbourne, Australia.

Smith, P., & Kendall, L. (1963). Retranslation of expectations: An approach to the construction of unambiguous anchors for rating scales. *Journal of Applied Psychology, 47*(2), 149-155.

|  |  |  |
| --- | --- | --- |
|  | Dr J Muller, Prof N Turner, Dr A Frank, Dr L McDonald & Miss E Sutcliff | Exploring the key skills, knowledge and attitudes of health literate students. |
| The Committee agreed that an approval number could be issued for this research proposal subject to the researchers satisfactorily addressing the following conditions:1. **The researchers are required to provide the Research Ethics Officer with a letter of support from the QLD Department of Education(for Government schools) or the Principal (for Independent schools) stating that they give permission for the researchers to conduct research using students from their school as participants in this research.**

The researchers have modified the methodology from the initial application to include first year university students, instead of secondary school students. This change has been made as the researchers believe that first year university students have an increased capacity to be reflective and will therefore be able to provide a better snapshot of health literacy skills, knowledge and attitudes. Consequently, other sections of the application have been modified in order to reflect this change in participants:C15: Changed from ‘yes’ to ‘no’D3 and D16: No longer necessaryE1: Plain language changed to include university students in place of secondary studentsE3.1 and E3.2: Altered to reflect change in participantsE3.10: No longer necessaryE6: Consent description changed from secondary students to university students.1. **The Committee recommends that the researchers amend the answer to question E7 to include that the result will be published in the student’s thesis.**

E7 has been amended to include this information.1. **The student researcher is required to return all the data collected during her research, to the Principal researchers once she has successfully completed her thesis. This relates to question E11k on the application.**

E11k has been amended so that all data will be returned to the Principal Supervisor, Dr Julie Muller, after successful completion of the student’s thesis.1. **The researchers are required to provide more details of the safety precautions that will be taken in the ‘Details’ section of question E12 on the application. This should include how student researcher will keep herself safe during the fieldwork i.e. let someone know where she is going and when she will be back, will not be alone with a participant in a closed room etc.**

E12 has been amended in order to include more specific detail about safety precautions that will be taken during the fieldwork.1. **The Information Sheets of Participants must contain the contact details for all researchers involved in this project.**

The participant information sheet has been amended to include the contact details of all researchers.1. **The Information Sheet for Participants must contain a statement informing participants that they will be audio recorded as stated in the answer to question E5.1 on the application and on the Consent Form.**

The participant information sheet has been amended to include a statement that informs participants that the workshop will be audio recorded.1. **The Committee would like the researches to explain how the researchers will obtain lists of potential student participants for this research.**

As outlined in dot point 1, university students will be recruited in place of secondary school students. These university students will be purposively sampled from the University of New England and the University of Queensland, across a range of courses, including Primary Generalist and Human Movement.  |