Charles Darwin University Human Research Ethics Application Form

The University is committed to upholding the highest standards of research conduct and integrity and minimizing harm to participants, researchers, third parties and the University. This ethics application gives you the opportunity to present your finalised research plans precisely, clearly and concisely. The methodology and methods of your research, your oversight of its conduct and the requirements of any third-party involvement needs to be complete and correct to avoid delay. Higher Degree Research applications will be reviewed only after Confirmation of Candidature is granted.

As an accountable and responsible researcher, you are required to meet all obligations under the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) and any other relevant legislation or guidelines. Retrospective ethics approval will not be granted.

First Nations Research

Where the primary focus of the project is within the scope of First Nation research, it is essential that Section 13 of this form is completed. Applicants should also refer to the following policies and guides:

- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)
- A Guide to applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)
- NHMRC Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)

It is requested that First Nations research ethics proposals are accompanied by a completed and signed research agreement (or a reasonable equivalent) with an appropriate organisational head, community group leader, Elder or advisory group. For more information on research agreements, applicants should refer to CDU's Aboriginal and Torres Strait Islander Research Agreement (ATSIRA) template

Exemption

To apply for written confirmation of an exemption (NS 5.1.22) see section 1b.

Prior HREC Review (Reciprocal approval)

To apply for CDU approval for a protocol with prior approval by another NHMRC registered human research ethics committee (HREC), please complete the Charles Darwin University Human Research Reciprocal Application Form.

Protocols requiring ethical approval by the NT Department of Health and Menzies School of Health Research HREC should be first submitted to that ethics committee on their approved form, and then submitted to CDU as a Reciprocal Proposal.

Submission of Application

Read the full text of all questions. Respond concisely to all applicable sections, using clear language suited to be understood by an informed critical layperson. Prepare your Information for Participants and Informed Consent Forms as attachments. Be sure to proofread carefully and complete the checklist before submitting.

All ethics applications require review and authorisation by the appropriate Faculty Dean/Institute Director or deputy. Where the appropriate authorising officer is also a member of the research team this authorisation should be completed by the relevant Pro-Vice-Chancellor or University Secretary.

NB: To be considered at the next available HREC meeting, the complete proposal must be received on or before the submission date, as indicated on the CDU website. Receipt of all proposals will be acknowledged automatically upon submission.

Further Queries

Should you have any queries regarding human research ethics, or difficulties using this form, please contact the CDU-HREC Ethics Team based within the Office of Research and Innovation by phone (08) 8946 6063 or email ethics@cdu.edu.au

- All relevant answers must be completed. Depending on your response to a given answer, additional information may be required. You will be unable to continue until the required answers have been completed.
- Progress on this form can be saved and completed at a later stage.
- When selecting 'save and continue later', a link will be generated which can be emailed to you. This will allow you to return to complete the form. This will also allow you to share the form with others to complete certain parts of the form.
- Please review the checklist at the end of this form carefully, to ensure the application is complete. This will assist with a more timely review.
- Ensure that all supporting documentation is attached to the application. There is an option to attach documents at the end of this form.

Workflows:

Workflows have been enabled with this form to facilitate authorisations and signatures as follows:

1. **Section 16: Authorising Declaration:** Please add the Project Title and email address of the Authorising Officer (College Dean or duly appointed agent). Complete the form and attach documents. Complete the remainder of the form and click 'submit'. This will be sent to the email address provided in Section 16 for the Authorising Officer to complete and sign.
2. Once the Authorising Officer has signed, they must click 'submit'. This will create the next workflow.
3. The final workflow will be sent to the Principal Investigator to complete the application checklist and submit the completed application.

Once the Principal Investigator clicks **submit** after all the above workflows are complete, the application will automatically be sent to ethics@cdu.edu.au in PDF format, along with all relevant attachments.

A copy of the application will also be emailed to the PI listed on the application form,

HUMAN RESEARCH ETHICS APPLICATION

NB: Every item on this application requires completion. If it is not relevant, then note as n/a (not applicable). Incomplete and carelessly presented applications will not be considered.

Project Title *

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Principal Investigator

The Principal Investigator (PI) must be a suitably qualified Charles Darwin University honorary or substantive staff member with sufficient research experience and expertise that is relevant to this project. Correspondence about the application will be sent to the investigators listed in this section who are asked to distribute it to other researchers involved in the project. The PI for student projects is the primary research supervisor.

Title *

Dr.

First Name *

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Last Name *

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Staff ID *

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Qualifications *

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Role in project *

Principal Investigator - CDU staff

Email Address *

ethics@cdu.edu.au

Phone (business) *

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Faculty/Institute/Centre *

ORI: Office of Research and Innovation

Is this project part of a CDU Course, including Higher Degree Research? *

(•) Yes ( ) No

If yes, indicate the type of course *

Postgraduate Research - PhD

Student

Please enter details of the student researcher

Title (student) *

Ms.

First Name (student) *

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Last Name (student) *

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Student ID *

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Qualifications (Student) *

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Role in project (Student) *

Student

Email address (Student) *

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Phone (Student) *

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Faculty/Institute/Centre: (Student) *

ORI: Office of Research and Innovation

Proposed commencement date *

16/03/2023

Expected completion date *

16/03/2023

Does this project have specific funding? *

- (●) **Yes**
- ( ) **No**

Please indicate whether the funding is from CDU or external sources, or both. *

- (●) **CDU**
- ( ) **External**
- ( ) **Both**

Is the internal CDU funding through the Rainmaker Grant? *

- (●) **Yes**
- ( ) **No**

Please provide Pure ID number *

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Section 1: Special Approval Notifications

1a (i) Is this project considered to be First Nations research? First Nations research refers to research with First Nations Peoples, their lives, culture, and issues, not necessarily as participants or researchers within the study. If YES, please ensure Section 13 of this form is completed. *

(●) Yes ( ) No

1a (ii). Have you read the NHMRC Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, keeping research on track II and the AIATSIS code and do you agree to abide by the values and principles outlined in these documents during your research? *

(●) Yes ( ) No

Please click on the following links to review Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities, Keeping research on track II and the AIATSIS code of ethics

1a (iii). If this project is First Nations research, has consultation with relevant First Nations Peoples, communities, individuals and/or groups been undertaken? If Yes, please attach the completed research agreement to this application. The Aboriginal and Torres Strait Islander Research Agreement (ATSIRA) should include details of the agreed upon aims, outcomes and community benefits of the research. For further information, see Keeping Research on Track II. *

(●) Yes ( ) No

1b. Is this Exempt Research for which you require a confirming letter from the HREC? *

(●) Yes ( ) No

If you have answered YES, (i) explain how the research only involves the use of existing collections of data or records that contain only non-identifiable information, (ii) explain why the only foreseeable risk is inconvenience for participants and (iii) complete the application by moving forward and filling out the Applicant Declaration (Section 15) and Authorising Officer Declaration (Section 16). *

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1c. Has this proposal previously been reviewed and approved by an Australian Human Research Ethics Committee registered by the NHMRC? *

( ) Yes (●) No

1d. Has the project been approved by peer review, e.g., by assessors for a funding body that has awarded a grant for the project or by the CDU Confirmation of Candidature procedure? *

○ Yes ◉ No

If you have answered NO, provide sufficient information to allow the CDU-HREC to assess the research merit and integrity of the proposal, as outlined in the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), hereafter known as NS, (Chapter 1.1 and 1.3).

Please attach a brief, one-page abstract addressing the following: research question/aim/purpose, methodology, design, sample/population, setting, recruitment/sampling methods, data collection methods and analysis methods.

Alternatively, this information can be provided below.

Research question/aim/purpose:

Your aim(s) should arise from your literature review and state what the study hopes to accomplish

Design and Methodology:

Provide an outline of the research design, methodology selected and study timeline in line with the National Statement 1.1 (b), (d), (e) and (f) t

Sample/Population Size:

Please specify the overall number of participants to be included in this research, the number of participants to be recruited per participant gr

Research Setting:

Recruitment/Sampling Method:

Please outline the methods planned to recruit participants into the study. If sampling is used please provide details of how this will be done.

Data collection methods:

Analysis method/s:

1e. Is this a program of research undertaken for educational purposes within a non-clinical Coursework unit covered under a CDU-HREC Program Approval? *

(●) Yes ( ) No

If yes, once this application is approved you may submit proposals for particular research projects within the program as variation requests. Such requests may seek approval for changes such as additional student researchers, changes to the research location, minor adjustments to recruitment procedures.

Section 2: Research Categories

Check all research categories relevant to this research proposal. At least one category should be marked for each grouping. For "Other" specify in fewer than 6 words.

2a. Participants *

- [ ] Healthy members of the community
- [ ] University students
- [ ] Employees or officers of a specific company or organisation
- [ ] Members of a specific community group, club, or association
- [ ] Clients of a service provider
- [ ] Health Service clients (e.g., users or clients of a health service)
- [ ] School children
- [ ] Hospital in-patients
- [ ] Clinical clients (e.g., patients)
- [ ] First Nations people
- [ ] Member of a socially disadvantaged group
- [ ] Person in a dependent or unequal relationship (e.g., student/supervisor or doctor/patient relationships, incarcerated persons)
- [ ] Person with an intellectual or mental impairment
- [ ] Person dependent on medical care
- [ ] Cadavers or cadaveric organs, human tissue, or bodily samples
- [x] Other

Other participants

2b. Participant Age Range *

- [ ] Children (under 14)
- [x] Adults (aged 18 or over)
- [ ] Young People (aged 14 – 17)
- [ ] Post-secondary students (aged below 18)

2c. Research Procedures *

- [ ] Anonymous questionnaires or surveys
- [ ] Coded (potentially identifiable) questionnaires or surveys
- [ ] Identifiable questionnaires or surveys
- [ ] Examination of normal educational practice or education instructional strategies, instructional techniques, curricula, or classroom management methods, journal, existing data, documents etc.
- [ ] Examination of medical, educational, personnel or other confidential records
- [ ] Observation (overt)
- [ ] Observation (covert)

- [x] Interviews (structured or unstructured)
- [ ] Telephone interviews
- [ ] Collection of body tissue or fluid samples
- [ ] Procedures involving physical experiments (e.g., exercise, reaction to computer images)
- [ ] Procedures involving administration of substances (e.g., drugs, alcohol, food)
- [ ] Physical examination of participants (including e.g. blood pressure and heart and temperature monitoring)
- [ ] Surgical procedures
- [ ] Aggregated quantitative analysis
- [ ] Aggregated qualitative analysis
- [ ] Individual/case qualitative analysis
- [ ] Focus groups/yarning circles
- [ ] Other

2d. Research Areas *

- [ ] Social Science research
- [ ] Humanities research
- [ ] Educational research
- [ ] Psychological research
- [ ] Biomedical research
- [ ] Epidemiology
- [ ] Health/Nursing/Midwifery
- [x] Other

Other Research Areas

2e. Ethically Sensitive Designs *

- [ ] Comparison or evaluation of clinical procedures
- [ ] Comparison or evaluation of counselling or training methods
- [ ] Clinical trial
- [ ] Comparison or evaluation of drugs or surgical or other therapeutic devices
- [ ] Investigation of effects of an agent (drug or other substance)
- [ ] Payment of money or offering rewards
- [x] including prizes Other
- [ ] Not applicable

Other Ethically Sensitive Designs

Section 3: Additional Members of the Research Team

Are there additional members of the research team? *

(•) Yes ( ) No

If there are more than four additional members of the research team, please provide details as an attachment to the application.

Title (additional member 1)

First Name (additional member 1)

Last Name (additional member 1)

CDU Staff/Student ID (additional member 1)

Qualifications (additional member 1)

Role in project (additional member 1)

Other (additional member 1)

Email address (additional member 1)

Phone (business) (additional member 1)

Organisation/Faculty (additional member 1)

Other organisation (additional member 1)

Title (additional member 2)

First Name (additional member 2)

Last Name (additional member 2)

CDU Staff/Student ID (additional member 2)

Qualifications (additional member 2)

Role in project (additional member 2)

Other (additional member 2)

Email address (additional member 2)

Phone (business) (additional member 2)

Organisation/Faculty (additional member 2)

Other organisation (additional member 2)

Title (additional member 3)

First Name (additional member 3)

Title (additional member 4)

First Name (additional member 4)

Last Name (additional member 3)

Last Name (additional member 4)

CDU Staff/Student ID (additional member 3)

CDU Staff/Student ID (additional member 4)

Qualifications (additional member 3)

Qualifications (additional member 4)

Role in project (additional member 3)

Role in project (additional member 4)

Other (additional member 3)

Other (additional member 4)

Email address (additional member 3)

Email address (additional member 4)

Phone (business) (additional member 3)

Phone (business) (additional member 4)

Organisation/Faculty (additional member 3)

Organisation/Faculty (additional member 4)

Other organisation (additional member 3)

Other organisation (additional member 4)

Section 4: Description of the Project

Describe the project so that it can be understood by an intelligent, critical lay reader, using clear and concise language. (Approximately 200-250 words - if more space is required please attach a Word document) (NS 5.2.7) *

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Section 5: Aims and significance of the project

List the research aims, objectives and/or research questions. Please state the justification and potential significance of the research. (Approximately 150-200 words - if more space is required please attach a word document) (NS 1.1 (b), 1.1 (d) and 3.1.1)
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Section 6: Research Setting

Describe the locations where consultations with stakeholders or participants and data will be collected. Explain any legal, regulatory, or ethical issues of relevance such as a requirement for a research visa, the value of a research partner located at an in-country institution. *

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Section 7: Research Methods

7a. Describe planned research methods as follows: i) study design and methodology ii) data collection methods, instruments, and procedures iii) planned analysis methods iv) sequencing of all research activities v) identification of potential limitations of the study. *

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7b. Provide an indicative sample of questions from any questionnaires or interview schedules to be used (or lines of questioning in less structured interviews). These must give a good sense of the most intrusive / sensitive areas of questioning. Alternatively, you may include in your application pack a clearly titled document setting out the questions (e.g., a copy of an online survey). *

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7c. Provide details of the relevant research expertise and experience of the team to conduct the proposed project. (NS 1.1 (e)) *

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7d. Indicate whether any element of the research plan (e.g., recruitment, data collection or analysis) will be conducted by an external service provider such as a market research company. If this is the case, indicate how the research team will ensure that the service provider conducts themselves in accordance with University, human research ethics policies and processes, and in compliance with national ethical standards. *

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Section 8: Participants

8a. Describe the planned participants and population(s) under study, addressing (i) the target group(s) from which they will be drawn, (ii) how many participants will be involved, (iii) their age range and (iv) whether they share any common characteristics (e.g., university students, religious sects). (NS 1.4) *

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8a (i) What are the participant inclusion and exclusion criteria for this study? (NS 1.4 (a), 3.1.14 and 3.1.15) *

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8a. (ii) Identification, first contact and recruitment of the participant pool: How will participants be recruited? Explain (i) how persons will be identified as potential participants, (ii) how they will be approached initially, (iii) how they will be informed about the research project and (iv) how they will be screened for inclusion or exclusion. If some form of advertisement or flyer is to be used, include the text here or include a clearly titled copy in your submission pack. (NS 2.2.6 and 3.1.12-3, 17-21) *

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MINORS

8b. Does the research involve a participant pool that could potentially include minors (persons aged under 18 years)? *

(•) Yes ( ) No

If yes, please indicate (i) the ages and / or age range of participants, (ii) how you intend to seek the informed consent of the parent / guardian of the minors and (iii) how you intend to seek the assent / consent of the minors. (NS 4.2). Please include evidence of a valid Working with Children (OCHRE) certificate or card. *

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COGNITIVE IMPAIRMENT, INTELLECTUAL DISABILITY OR MENTAL ILLNESS

8c. Does the participant pool include persons who have impaired capacity? *

(•) Yes ( ) No

If yes, please indicate (i) the nature of the impairment (e.g., age, brain injury, unconsciousness, mental illness, intellectual disability) and (ii) whether this is likely to be intermittent or enduring, and how recruitment will be conducted. (NS 4.5) *

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LANGUAGE CONSIDERATIONS

8d. Will the research be conducted in a language other than one that is likely to be familiar to the potential participants, and/or is the literacy level of the potential participant pool likely to be an issue? *

(●) Yes ( ) No

If yes, explain how these issues will be addressed? (NS 2.2.1-3 and 5.2.17) *

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DEPENDENT OR UNEQUAL RELATIONSHIPS

8e. Are potential participants in a dependent relationship that is likely to impact upon the nature of their participation and / or raise additional ethical issues? *

(●) Yes ( ) No

If yes, explain how this will be addressed? (NS 4.3) *

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INCENTIVES

8f. Will any reimbursement or inducement be offered to participants? *

(●) Yes ( ) No

If yes, provide details of any reimbursement or inducement that will be offered to participants. Where the inducement comprises an award that is won by one or only a few of the participants, explain how the procedure satisfies the requirement for beneficence. (NS 2.2.10, 2.2.11 and 3.1.10) *

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PEOPLE IN OTHER COUNTRIES

8g. Does the research involve people in other countries? *

(●) Yes ( ) No

If yes, explain how the project recognises the beliefs, customs, and cultural heritage of those peoples insofar as they differ from those of the National Statement (e.g., cultural aversion to signing consent documents). (NS 4.8) *

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Section 9: Benefits and Potential Risks

9a. What are the anticipated benefits of the research? *

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9b. To whom will the benefits flow? *

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9c. Potential risks. Adverse reactions or consequences are possible where research may intrude into personal lives or emotions. Many reactions are to some extent predictable. Some responses are influenced by life experiences. This section asks researchers to consider ALL possible consequences or risks and to explain the risk management processes. Tick the risk categories you have considered in this research and elaborate your responses below. (NS 2.1) *

- [ ] Physical risks
- [ ] Social risks
- [ ] Legal risks
- [ ] Psychological risks
- [ ] Economic risks
- [ ] Devaluation of personal worth
- [ ] Any other risks
- [x] There are no risks

9d. For each of the risks identified in 9c, provide further details of the risk/s. *

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9e. To whom do the risks apply? *

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9f. For each risk identified, what, if any, strategies will be used to (i) negate these risks, (ii) minimize these risks, (iii) manage these risks if an adverse event occurs? (NS 2.1) *

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9g. How do the benefits of the research outweigh the risks? Where the benefits affect people other than the participants, explain why the participants should bear the risk. (NS 1.6, 1.7 and 2.1) *

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Section 10: Informed Consent

10a. Indicate how informed consent or assent will be obtained from participants. *

- (●) Affirm opting in by signed consent
- ( ) Affirm opting in by return of questionnaire
- ( ) Affirm opting in by oral consent
- ( ) Assume opting in, affirm only opting out by writing or oral recording
- ( ) Waiver of consent *

Explain in detail any additional procedures. (NS 2.2).

10b. Will additional consent be obtained from third parties (e.g., parents, partners, data owners, traditional owners, community elders, officials, proprietors)? *

(●) Yes ( ) No

If yes, describe (i) why this is to be done and (ii) outline the process to obtain this consent. (NS 2.2.12 and 2.2.13) *

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10c. Will substituted consent be obtained on behalf of a participant with impaired capacity? *

(●) Yes ( ) No

If yes, note that national guidelines require that consent is obtained from the participant's guardian, attorney (under an enduring power of attorney for personal matters) or statutory health attorney (spouse, carer, relation, or close friend aged over 18 years). Explain any protocol for substituted consent. (NS 2.2.12) *

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10d. Where appropriate, additional strategies should be used to explain what will happen to participants and to help ensure that participants have been accurately and fully informed before consenting. Explain any additional strategies. (NS 2.2) *

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10e. Research sometimes involves deception to achieve its aims. Deception includes withholding information from participants about what will happen to them, or hiding the true purpose of the research, or providing misleading, untrue, or fabricated information. Does your protocol involve deception? *

○ Yes ◉ No

Section 11: Privacy and Confidentiality

11a. Will the research involve access to personal information (i.e., information or an opinion about an identified person) held by an agency/body other than the University and subject to the Commonwealth Privacy Act 1988 or the Northern Territory Information Act 2002? *

- (●) Yes
- ( ) No

If you have answered YES, outline the measures to obtain prior consent from the identified individuals, or the procedures to address the regulatory privacy considerations. If an exemption under the Medical Research Guidelines s95 / s95A of the Privacy Act is to be sought contact the Executive Officer of the HREC for details of the information that must be provided with your application. *

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11b. Indicate in what forms data/information will be collected. *

- [ ] Identifiable information
- [ ] Non-identifiable information
- [ ] Re-identifiable / coded information
- [ ] No personal information will be collected

11c. Indicate in what form data/information will be stored. *

- [ ] Identifiable information
- [ ] Non-identifiable information
- [ ] Re-identifiable / coded information
- [ ] No personal information will be stored

11d. Indicate in what form data/information will be published or reported. *

- [ ] Identifiable information
- [ ] Non-identifiable information
- [ ] Re-identifiable / coded information
- [ ] No personal information will be published

11e. Describe the procedures that will be adopted to ensure confidentiality during the collection of the data, in the storage of the data, and in the publication of results. *

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11f. Does the proposed protocol involve focus groups/yarning circles for participants? *

- (●) Yes
- ( ) No

If yes, outline the procedures for participants to be advised about the impossibility of absolute confidentiality in this setting. Describe how a participant may withdraw from a focus group, and how their contribution will be used if they do withdraw. *

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11g. Will the participants be identifiable, or potentially identifiable in any publication or report? *

- (●) Yes
- ( ) No

If yes, outline the procedures for participants to authorise the release of their responses / information and to confirm the accuracy of attributed comments. (NS 1.11, 2.2.6 (f) and 3.1.42) *

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11h. Will the project involve a recording of participants (audio, video, audio-visual or other)? *

- (●) Yes
- ( ) No

If yes, explain the purposes of this recording. *

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What will happen to the recording? *

- (●) It will be retained and used beyond the initial transcript/analysis
- ( ) It will be erased following transcription

If it is to be retained, how will confidentiality be ensured? How will specific consent for any subsequent use be obtained? *

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11i. Will the research involve the collection of information about the conduct of an undisclosed crime, or an imminent crime, or information that may expose others to criminal, civil or other proceedings, or information that the researcher(s) may be required to disclosure to third parties? *

(●) Yes ( ) No

If yes, how will this situation be handled and what information about these possibilities (and cautions) will be provided to potential participants in the consent form? (NS 4.6) *

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Section 12: Data Storage

12a. Will the data be stored in accordance with CDU Research Data Management Guidelines? *

○ Yes ◉ No

If you have answered NO, describe the proposed data storage protocol, and explain the proposed departure from University policy. *

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12b. Will data be stored in an identified or re-identifiable (coded) form? *

◉ Yes ○ No

If yes, provide the details of its secure storage (include information about location, whether any code key will be stored separately from the data, security, and access control). *

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12c. If the data will initially be collected in an identified or re-identifiable (coded) form, but will be published in a non-identifiable form, provide details of the point at which the data will become non-identifiable and how the data will be rendered non- identifiable. *

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Section 13: First Nation Research

First Nations research means research with First Nations Peoples, their lives, culture, and their issues, not necessarily as participants or researchers within the study.

Does you research involve First Nations research? *

- [x] Yes
- [ ] No

13a. If you have answered YES above, please ensure YES was selected at Section 1a, and include the Agreement with your application.

Please complete the remainder of this section, which is based on the NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (hereafter known as Guidelines). See also the AIATSIS Code for Ethical Research in Australian Indigenous Studies.

Please outline the following:

(i) **How have you consulted with relevant First Nations people and /or communities?** *

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(ii) **How will the results of the research be made available to those persons / communities?** *

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(iii) **How is the research beneficial to those persons / communities?** *

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13b. Spirit and Integrity – explain how the research considers the central core value of spirit and integrity, including researchers' (i) demonstrated respect for cultural inheritance and links that bind generations together, and (ii) credibility of intent through demonstrating adherence to guidelines, behaviour, and perceived integrity. (Guidelines, page 4) *

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13c. Cultural continuity – explain how the research considers issues of cultural continuity, including (i) perceptions and possible community and individual experiences of research as an exploitative exercise, (ii) the critical function of personal and collective bonds, and (iii) recognising and respecting the right to cultural distinctiveness,

values, identity, and self-determination. (Guidelines, page 4) *

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13d. Equity – explain how the research demonstrates equity through (i) recognising and valuing collective and shared knowledge, wisdom, and resources, (ii) equitable relationships between researchers, partners, participants, and communities, and (iii) addressing the importance of fairness and justice in the distribution of research benefits. (Guidelines, page 6) *

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13e. Reciprocity – explain how the research demonstrates reciprocity through (i) inclusion and engagement as the basis for reciprocal arrangements, agreements, and mutual benefit, and (ii) ensuring individuals and communities determine the establishment or enhancement of capabilities, opportunities, or outcomes according to their own values and priorities. (Guidelines, page 7) *

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13f. Respect – explain how the research demonstrates respect through (i) acknowledging and supporting individual and collective contributions, (ii) self-awareness of one's own beliefs and attitudes and affirming the right of others to hold different values, norms, and aspirations, (iii) consideration of all consequences of research, and (iv) fostering trust, openness and engagement with individuals and communities. (Guidelines, page 9) *

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13g. Responsibility – explain how the research demonstrates responsibility through (i) risk assessment, (ii) ensuring that no harm is done to individuals, communities and what is valued by them, and (iii) accountability of the researchers to the individuals, families, and communities. (Guidelines, page 11) *

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Section 14: Other Ethical Issues

14a. Debriefing: Will participants be debriefed at the completion of the research? *

- [x] Yes
- [ ] No

If debriefing will occur, outline the content, i.e., explain what the researchers will do if a participant becomes distressed by the research procedures; if participant distress is foreseen, include the list of other support agencies to whom participants may be referred. If you have answered NO, explain why debriefing is not appropriate. *

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14b. Feedback: In what form will feedback / summary of results be made available to participants? How will the participants be contacted? *

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14c. Control group: Will a control or comparison group be used? *

- [x] Yes
- [ ] No

If you have answered YES, justify the use of a control group, and explain how that group will be assisted if the treatment or intervention proves to be beneficial. *

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Will any treatment or intervention known or shown to be beneficial be withheld from one group of participants? *

- [x] Yes
- [ ] No

If you have answered YES, justify the withholding of the treatment. *

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14d. Other approval: Will the research require the approval or support of another agency (e.g., the approval of an organisation or government department)? *

- [x] Yes
- [ ] No

If you have answered YES, indicate the status of this consultation process to date and / or provide an assurance and account of how approval will be obtained.

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14e. Conflict of interest: Does the researcher(s) have a relationship or arrangement that could be perceived by the participant(s) as a possible or actual conflict of interest (e.g., is there a financial interest such as a grant or emolument, is there is a likely gain if certain results are found, is there an advisory role)? *

(●) Yes ( ) No

If you have answered YES, indicate how this conflict of interest or perceived conflict of interest will be disclosed to potential participants. *

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14f. Collectivities: Does the research involve the intentional recruitment of members of a social group or issues of significance to a social group? *

(●) Yes ( ) No

If you have answered YES, indicate (i) how you have appropriately consulted with the relevant collectivity, (ii) how the results of the research will be made available to that collectivity and (iii) how the research is beneficial to that collectivity (or at least not contrary to the interests of the collectivity). *

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14g. Other ethical matters: Are there any other ethical issues associated with the research that you wish to bring to the attention of CDU HREC? Ethical issues include matters relating to the ethical principles of respect for persons, beneficence, justice, research merit, and research safety. *

(●) Yes ( ) No

Provide details of the additional ethical issues. *

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Section 15: Applicant Declarations

Project Title (declaration) *

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15a. Is the ethical risk NEGLIGIBLE? The ethical risk is negligible if the proposed research protocol has been designed to entail no more than inconvenience to participants and does not entail foreseeable discomfort or harm. Is the ethical risk of the project negligible? (NS Chapter 2.1) *

(●) Yes ( ) No

15b. Ethical considerations relative to specific categories of participants. In responding to the following questions, note that "involvement" does not occur solely because a person in the designated category might be recruited as a participant. The research should relate to persons or issues in the designated category.

Is this First Nations research? *

(●) Yes ( ) No

Is the Aboriginal and Torres Strait Islander Research Agreement (ATSIRA) attached? *

(●) Yes ( ) No

Does the research involve clinical trials, interventions or therapies, or clinical innovations? *

(●) Yes ( ) No

Does the research involve human tissue samples, human genetics (including population genetics) or human stem cells? *

( ) Yes (●) No

Does the research involve women who are pregnant and / or the human foetus or human foetal tissue? *

( ) Yes (●) No

Does the research involve people who are highly dependent on medical care who may be unable to give consent? *

( ) Yes (●) No

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

( ) Yes (●) No

Does the research involve or investigate illegal activity? *

( ) Yes (●) No

We, the undersigned, confirm that all members of the research team have **read this application** and the current NHMRC National Statement on Ethical Conduct in Human Research. We accept responsibility for the ethical and appropriate conduct of the protocol detailed in this application, confirm that we will conduct this project in accordance with the principles contained in the National Statement, and confirm that the research team will comply with any other conditions laid down by Charles Darwin University.

Signed (Principal Investigator - Staff / Supervisor) *

Date Signed *

14/02/2023

Print Name (PI): *

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Signed (Student / Co-Investigator)

Date Signed (student)

Please Note: This form must be signed and submitted by the Principal Investigator (PI). If someone other than the PI is completing this form, in order to obtain the PI signature, click "save and complete later". This will generate a link to the form, which can be sent to the PI to access and sign.

Section 16: Authorising Officer Declaration

This authorisation is to be completed by the Faculty Dean, or a duly appointed agent, where the research is to be based. Where the appropriate authorising officer is also a member of the research team this authorisation should be completed by the relevant Pro- Vice-Chancellor or University Secretary.

Please provide the email address of the Authorising Officer. A workflow link will be sent directly to the recipient to complete this section when you hit 'submit'.

(**NB**: Please note, that you must ' **submi**t' the form, for it to be sent to Authorising Officer. The form will not be submitted to CDU ethics at this stage).

Project Title (authorising officer) *

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Authorising Officer Email *

ethics@cdu.edu.au

NB: The below is locked for editing by the person completing the application form, as this must be completed by the Authorising Officer.

****Please note, that you must attach all relevant supporting documents below and then 'submit' the form.**

This will not submit the application to ethics at this stage. This will trigger a workflow and will send the application to email address of the Authorising Officer provided above to review and sign.

Once the Authorising Officer has signed and completed the below section, they must then click 'submit'.

This will not submit to ethics at this stage either.

When the Authorising Officer "submits" the application, it will trigger the final workflow to the Principal Investigator listed on the project to review, edit (if necessary) and submit to CDU ethics.

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 are appropriate to the study to be undertaken, and the necessary resources are available to enable this research to be conducted.

Scientific Merit

STEP ONE

The research / scientific merit of this project has been considered (tick one statement): *

- By a supervisory panel for PhD projects, internal peer review for academics or external review

for research grants

- ○ By the authorising officer
- ○ Is yet to be considered

STEP TWO

Is there a need for additional review of the scientific merit of the research? (tick if required)

- ☐ I believe that this project requires further review of its research merit

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Research Safety

STEP ONE

The research safety of this project (tick one statement): *

- ○ Does not require special consideration
- ○ Has been considered by a University workplace health and
- ◉ safety process Has been considered by the authorising officer
- ○ Is yet to be considered

STEP TWO

Is there a need for additional review of the research safety of the research? (tick if required)

- ☐ I believe that this project requires further review of research safety

Comments (if required)

Signed (authorising officer) *

Date Signed (authorising officer) *

14/02/2023

Print Name *

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Designation *

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NB: Once signed and completed, please click **' submit'.** This will not submit the form to ethics at this stage. This will trigger the final workflow to the Principal Investigator listed on the project to review and submit to CDU ethics.

Application Checklist

(Please complete checklist prior to submission)

I have reviewed the comments made by the Authorising Officer *

(●) Yes ( ) No ( ) N/A (no comments to address)

Please explain how the Authorising Officer comments were implemented: *

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1. Information Sheet for Participants (ISP) and Consent Form

Is an Information Sheet required for this proposal? *

(●) Yes ( ) No

- [x] Current CDU letterhead with full contact details *
- [x] Full official title of the project included on both the ISP and Consent Form *
- [x] Includes the statement "This Is yours to keep", or equivalent *
- [x] Includes contact details of main researchers *
- [x] Identification of all possible risks for participants *
- [x] Written in clear, succinct, plain English and directed towards the participants *
- [x] Includes statement to direct concerns and complaints to CDU-HREC with correct contact details *
- [x] Includes "This Means You Can Say NO" statement / Consent for ALL procedures *
- [x] Ability for participant to consent to ALL data collection procedures individually (e.g. audio recording videotaping, interviews) *

(refer to Guide to Information Sheet and Informed Consent form)

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2. Application Form

- [x] All relevant answers have been completed *

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4. Research Team

☑ Contact details and qualifications are complete including staff and student numbers. *

Section 15 - Applicant Declaration

☑ Project title included in all applicable areas *

☑ Risk level checked *

☑ Signed and dated by PI (and student, if applicable) *

Section 16 - Authorising Officer Declaration

☑ Project Title included on the declaration *

☑ All relevant boxes have been checked *

☑ Application has been reviewed, authorised, signed and dated by the Faculty Dean, or duly appointed agent (Assistant Dean for Research, PVC or University Secretary) *

NB: Please click 'submit' in order to submit the completed application to ethics@cdu.edu.au

Receipt of submission will be acknowledged when you select 'submit', after all workflows are complete. The application form and any attachments will be sent automatically to ethics@cdu.edu.au.

A copy of the complete application will also be sent to the email address provided for the Principal Investigator.

NB: Please ensure to check spam folders.

If you have selected 'negligible risk', your application will be reviewed though Executive Review and you should normally expect a response within 10 working days of the review date. If the review process assesses the application as higher than negligible risk, you will receive notification from the ethics teams and the proposal will be referred to the next available CDU-HREC meeting date.

Only complete applications received on or before the submission deadline will be reviewed at the next CDU-HREC meeting. Any incomplete submissions will receive correspondence from the ethics team, requesting any missing information.

Further Queries

Should you have any queries regarding human research ethics please contact the CDU-HREC Ethics Team based within the Office of Research and Innovation by phone (08) 8946 6063 or email ethics@cdu.edu.au

ATTACHMENTS: Supporting Documents

Please provide all additional attachments, if applicable, including:

- **Information Sheet for Participants**
- **Informed Consent Form**
- **Questionnaires**
- **Interview Questions**
- **ATSIRA for First Nation research applications Support letters**
- **Research protocol Permits**
- **Ochre card (if the proposal involves participants under 18 years old)**
  Advertising materials (ie. flyers etc)

All relevant files have been attached (below) *

○ **Yes** ◉ **No** ○ **N/A**

Attachments

Brows