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 2025 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

Some research projects that utilise existing, publicly available non-identifiable data **and** which are of lower risk and do not involve special groups of participants e.g. cognitive impairment, mental illness, First Nations (including possible impact), dependent on medical care, illegal activity, pregnant mother or foetus or dependent/unequal status (often children),may be eligible for exemption as per Chapter 5.1 of the National Statement. A letter of Exemption can also be sought from the CDU-HREC where required.

To apply for written confirmation of an exemption, please review the National Statement 2025 and complete the Application for Exemption form. The decision as to whether to grant an exemption from review for a research projectis the responsibility of the institution — it is not the responsibility of the researcher (NS 2023). If an exepmtion is granted, you will receive formal letter of exemption. If it is determined that the research activity is not exempt from review, then you will be required to complete this Application Form.

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.

Review Pathways

Executive Review:

Projects that pose only a lower risk as described in the updated National Statement 2025 (formerly known as negligible risk), i.e., no more than an inconvenience, and that do not involve any procedures or participants that require full CDU-HREC approval, may be eligible for consideration under the Executive Review Pathway.

Under the Executive Review Pathway, projects are reviewed by the Chair of the CDU-HREC, rather than the full CDU-HREC.

Such proposals can be submitted at any time independent of the advertised submission deadlines, using the same form and process indicated below.

NB: Please be aware, if the project is deemed to be higher risk, you will be notified and your submission will be reviewed at the next available CDU-HREC meeting.

NB: Please be aware that the National Statement on Ethical Conduct in Human Research 2025 contains updates to Chapter 2.1 'Risk and benefit'. Please also the the FAQs relating to these changes, which may affect whether your application will be considered Lower Risk.

Committee review

Projects posing a higher risk OR that involve research categories listed below requiring full HREC review as specified in the National Statement 2025 will be reviewed by the full CDU-HREC.

Research Categories requiring full HREC review:

- Participants with cognitive impairment, mental illness,
- First Nations (including possible impact),
- Participants dependent on medical care,
- Participants involved in illegal activity,
- Pregnant women/foetus, dependent/unequal status,
- Often resaerch being conducted outside of Australia
- Often children

Submission deadlines and meeting dates are listed here. **Late submissions will be forwarded to the next scheduled CDU-HREC review.**

The same ethics proposal form is used for both the Lower Risk and Committee review pathways.

All ethics applications require review and authorisation by the appropriate Faculty Dean/Fauclty Associate Dean of Research (ADR)/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 humanethics@cdu.edu.au

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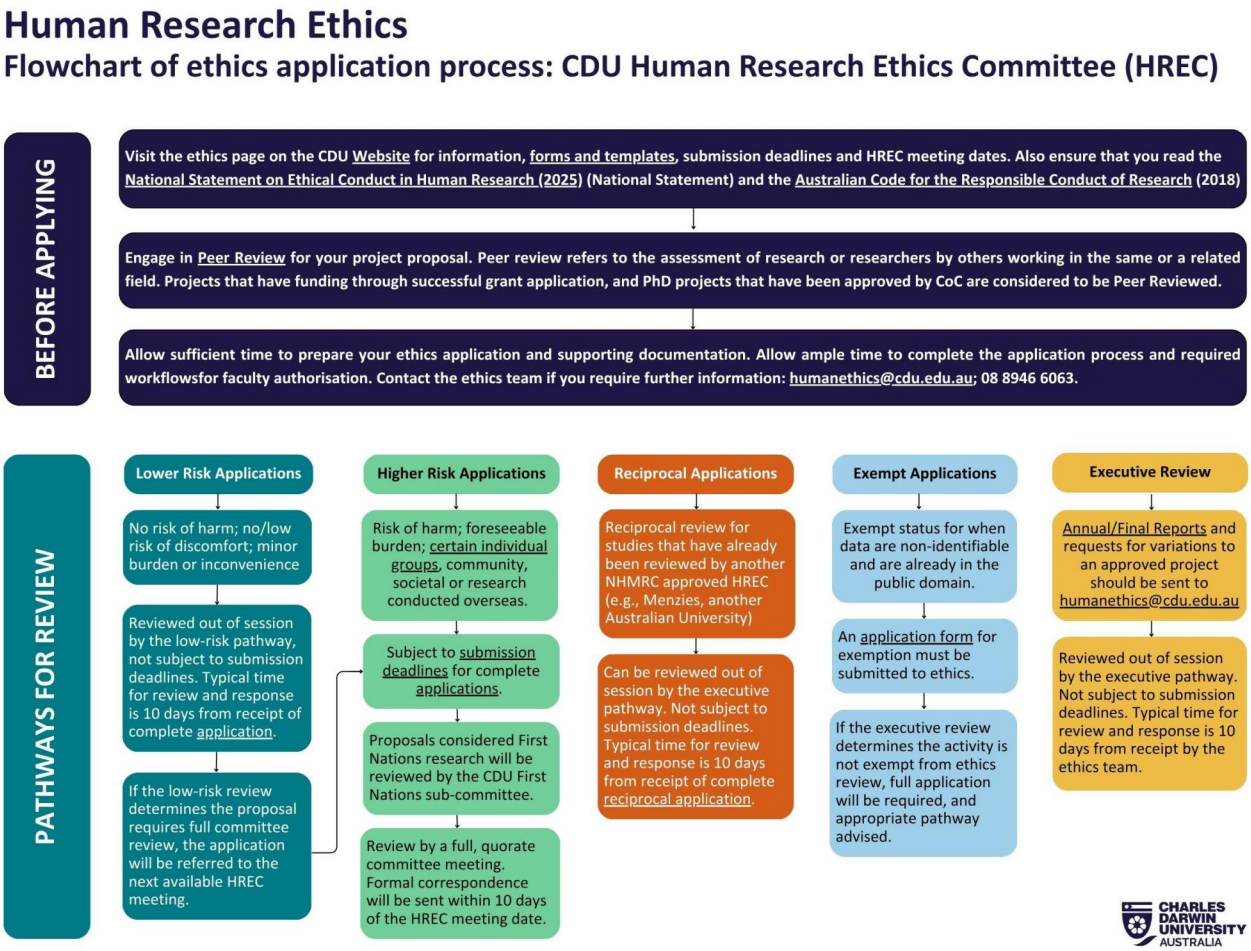

Please see the below the risk table, updated in the National Statement 2025. We recommend reviewing the changes to Chapter 2.1 when indicating the pathway for review.

Figure 1: Risk profiles of research

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

GUIDE TO COMPLETING APPLICATION FORM

- 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 *

Prof

First Name *

Sample

Last Name *

Sample

Staff ID *

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Qualifications *

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Role in project *

Principal Investigator - CDU staff

Email Address *

hayley.germaine@cdu.edu.au

Phone (business) *

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Faculty/Institute/Centre *

FAS: Faculty of Arts and Society

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) *

other/none

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) *

FAS: Faculty of Arts and Society

Proposed commencement and completion dates of the project

Proposed commencement date *

25/08/2026

Expected completion date *

26/08/2026

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 any research that relates to, or may have the potential to impact, the collective rights and interests of First Nations Peoples' lands, waters, cultures and histories. 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 the course of 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

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 2025, hereafter known as NS, (Chapter 1.1 and 1.3).

Please attach a project protocol to this application. A protocol template can be found on our website.

NB: If a project protocol is not attached, the application will be considered incomplete, which may result in a delay of review.

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

(●) 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 *

- [x] 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
- [ ] Other

2b. Participant Age Range *

- [ ] Children (under 14)
- [x] Adults (aged 18 or over)
- [ ] Young People (aged 14 – 17)
- [ ] Not Applicable (no participants will be involved - existing data only)

2c. Research Procedures *

- [x] 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)
- [ ] 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 *

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

2e. Ethically Sensitive Designs *

- [x] 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 including prizes
- [ ] Other
- [ ] Not applicable

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)

Title (additional member 2)

First Name (additional member 1)

First Name (additional member 2)

Last Name (additional member 1)

Last Name (additional member 2)

CDU Staff/Student ID (additional member 1)

CDU Staff/Student ID (additional member 2)

Qualifications (additional member 1)

Qualifications (additional member 2)

Role in project (additional member 1)

Role in project (additional member 2)

Other (additional member 1)

Other (additional member 2)

Email address (additional member 1)

Email address (additional member 2)

Phone (business) (additional member 1)

Phone (business) (additional member 2)

Organisation/Faculty (additional member 1)

Organisation/Faculty (additional member 2)

Other organisation (additional member 1)

Other organisation (additional member 2)

Title (additional member 3)

Title (additional member 4)

First Name (additional member 3)

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) *

- [x] Physical risks
- [ ] Social risks
- [ ] Legal risks
- [ ] Psychological risks
- [ ] Economic risks
- [ ] Devaluation of personal worth
- [ ] Any other risks
- [ ] 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.

- [x] 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 consent procedures. (NS 2.2).

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* **Waiver of consent**: If you are seeking a Waiver of Consent, you must refer to the National Statement 2.3.9. Before deciding to waive the requirement for consent, an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk to participants

b) the benefits from the research justify any risks of harm associated with not seeking consent

c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

e) there is sufficient protection of their privacy

f) there is an adequate plan to protect the confidentiality of data

g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled i) the waiver is not prohibited by State, federal, or international law.

*** Please detail your reason for requesting a waiver of consent and address each of the criteria listed above from The National Statement section 2.3.9** *

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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

If your protocol involves deception, fully explain why it is necessary and there is no alternative. How will you subsequently advise the participants that they have been deceived and offer them the opportunity to withdraw? (NS 2.3.1-4) *

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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. *

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

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

- [x] Identifiable information
- [x] 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
- [x] 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

When deciding on storage and access systems, it's crucial to consider how sensitive the data is. Unauthorised disclosure of sensitive information can cause serious damage to individuals and organisations, so mitigating that risk is critical to the data management planning process and to the ethical conduct of research.

Please see the data classification guide

For further assistance or information regarding a DMP, please see here or contact the library at: askthelibrary@cdu.edu.au

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

(●) Yes ( ) No

Please complete a Data Management Plan (DMP) here and attach with this application form. You can login using your CDU credentials to create a DMP.

When deciding on storage and access systems, it's crucial to consider how sensitive the data is. Unauthorised disclosure of sensitive information can cause serious damage to individuals and organisations, so mitigating that risk is critical to the data management planning process and to the ethical conduct of research.

Please see the data classification guide

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 your research involve First Nations research? *

(●) 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? *

.

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

.

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

.

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) *

.

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) *

.

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) *

.

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) *

.

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) *

.

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) *

.

Section 14: Other Ethical Issues

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

(●) 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. *

.

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

.

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

(●) 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. *

.

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

(●) Yes ( ) No

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

.

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

- (●) 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.

.

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. *

.

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). *

.

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: Research involving artificial intelligence, machine learning, large language model technology (“AI”)

Researchers are expected to disclose any planned use of artificial intelligence (AI) within their research project to enable appropriate ethical review. This includes identifying and addressing potential ethical considerations associated with AI use, such as impacts on privacy, confidentiality, consent, fairness, transparency, data quality, and research integrity.

When preparing an ethics application, researchers should carefully consider how AI will be used, assess any associated risks, and describe the measures that will be implemented to mitigate those risks. Providing this information assists the HREC in determining whether additional ethical considerations arise from the proposed use of AI and whether appropriate safeguards are in place.

Researchers should also be mindful of the broader societal implications of AI technologies. The use of AI in research carries responsibilities to ensure that its application is ethical, transparent, accountable, and consistent with relevant legislation, institutional policies, professional standards, and best-practice guidance. Researchers remain responsible for all research outputs generated with the assistance of AI and for maintaining the integrity and quality of their research.

The NHMRC has developed a dedicated Guide for assessing research involving AI to assist Human Research Ethics Committees (HRECs) in reviewing proposals. It addresses key challenges like informed consent, privacy, bias, and algorithmic transparency. Routine AI use in standard software (e.g., word processors) is generally treated as an integrity issue, while novel AI implementations require formal ethical scrutiny.

Please also refer to CDU's Generative Artificial Intellegence Policy

In providing your responses, please consider:

- each stage of the research in which you intend to use AI andeach tool that you intend to use.
- where applicable, include references to the relevant project document/s (with page numbers) thatinclude more complete information that is relevant to your response to the question.

15a. Is AI used for non-routine purposes in the research project? *

(●) Yes ( ) No

The NHMRC Guide for assessing research involving AI outlines non-routine uses of AI as follows:

"The spectrum of non-routine AI use ranges from automation [to generation] to intervention.

Examples of **automation** in research include but are not limited to selection and randomisation ofparticipants; participant reminders; creation of and/or conduct of online surveys; data cleaning, screening and extraction; limited data analysis; data visualization; and research task repetition. It islikely that much of what is currently considered to be non-routine use of automation in research willrapidly be re-categorised as routine use over time.

Examples of **generation** include but are not limited to using AI to draft text (e.g. for developmentof participant information sheets, interview questions, policy briefs, or academic publications); for reviewing literature; for hypothesis generation; or for data analysis.

Examples of **intervention** include but are not limited to the development of AI tools to improve educational or social outcomes; or to prevent, diagnose or manage disease."

15b. Identify AI use stage (check all that apply) *

- [x] Discovery (concept generation and design)
- [ ] Literature review
- [ ] Planning and development
- [ ] Ethics and/or scientific review
- [ ] Recruitment
- [ ] Intervention (if relevant)
- [ ] Data collection
- [ ] Data management
- [ ] Data analysis
- [ ] Publication

15c. How will the AI tool be used at each relevant stage of the research project? *

.

15d. Will participant data be entered into any AI system operated by a third party? *

- (●) Yes
- ( ) No

Note that submission to and retention of human data to a third party (e.g. OpenAI via ChatGPT, Microsoft via Copilot, Google via Gemini, etc.) where data are very unlikely to remain in Australia may constitute a cross-border disclosure under the Privacy Act 1988. If this is the case, researchers would incur a burden under the Act to ensure sufficient information is given to people from whom data have been collected and that consent exists for such use and disclosure. Use of local AI running on researchers' hardware or mechanisms such as Google NotebookLM may mitigate these concerns.

If yes describe: a) if the data will be retained by the AI system. b) if there are any restrictions, licensing conditions, or ethical considerations in the tool's creation that may affect participants' rights or data privacy. c) whether the data will be used to further train the same model or other models. d) how you will ensure that the data will not be disclosed, exchanged or sold by the third party without participant consent. *

.

15e. Do the data sets that are used to train the AI algorithms adequately represent the population/s impacted by or relevant to the research? *

- ( ) Yes
- (●) No

If not, justify why it is appropriate for this tool to be used on your research cohort. *

.

15f. What are the characteristics of the AI tool that you intend to use?

a. Has the AI system been validated for its intended use/s? If so, how? If not, why not?

b. Is the AI tool non-adaptive or adaptive (involving continuous learning algorithms while theresearcher is using the tool)?

c. If the AI tool is adaptive, what are the limits to permitted adaptations, if any?

d. Is reproducibility and/or replicability important for your AI tool? If so, explain why and howthis has been adequately addressed.

e. Will the AI interact with research participants and/or research staff? If so, how?

Please detail *

.

15g. Describe your plan for oversight of the AI and the outputs of the tools or systems used.

a. What safeguards are in place to include human oversight, especially when critical decisions are necessary or unexpected developments arise?

b. How will you know if the tool has produced biased or unfair outputs? What steps will you take to detect and address the risk of this occurring?

c. Who on the research team has the skills to critically assess the outputs of the AI tools/systems and how will these team members review these outputs before they can have an impact on participants or others?

d. Does your plan include the capacity to monitor and assess the performance of the AI overtime? Explain how this will be done.

e. If relevant, will training be offered to members of the research team or organisational staff who interact with the AI during the research?

Please detail *

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15h. Describe the risks associated with your use of the AI tool in your research and your plan formitigation and management of those risks.

a. What are the potential harms that could result from the use of the AI tool and to whom?

b. How likely are these harms?

c. How will these risks be mitigated and managed, and their successful mitigation andmanagement be evaluated?

d. Will risk assessment be conducted on an ongoing basis during (and potentially after) theproject? If so, will it be conducted in accordance with a defined schedule? If so, what is theproposed schedule?

Please detail *

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15i. What information about the use of AI in the research and the projected impact of any AI-assisted or AI-generated outputs of the research will be made available to participants, and the public (if relevant) and how will it be communicated? *

.

Section 16: Applicant Declarations

Project Title (declaration) *

Sample

16a. Is the ethical risk Lower Risk? The ethical risk is lower risk 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 lower risk? (NS Chapter 2.1) *

- (●) Yes
- ( ) No

NB: Please be aware that The National Statement on Ethical Conduct in Human Research 2025 incorporates a revised Chapter 2.1.

16b. 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

Were any AI tools or AI-generated content used in the preparation, drafting, or completion of this application? *

○ 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 2025. 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.

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

Browse

Signed (Principal Investigator - Staff / Supervisor) *

Date Signed *

25/08/2026

Print Name (PI): *

Signed (Student / Co-Investigator)

Date Signed (student)

25/08/2026

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 17: 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).

Please see below the applicable Authorising Officer contacts per faculty and include the appropriate email address below to trigger the workflow.

If you require additional information, please contact humanethics@cdu.edu.au

Faculty of Arts and Society (FAS): adelle.sefton-rowston@cdu.edu.au michael.erdiaw-kwasie@cdu.edu.au felicity.mclure@cdu.edu.au	**Faculty of Science and Technology (FST):** vinuthaa.murthy@cdu.edu.au
Faculty of Health (FoH): kim.caudwell@cdu.edu.au FOH_ResearchHDRAdmin@cdu.edu.au	**Menzies School of Health Research** heidi.smith-vaughan@menzies.edu.au

Project Title (authorising officer) *

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Authorising Officer Email *

humanethics@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)

- [x] 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

If applicable, please contact the PI to make the necessary changes to the application. Please indicate below that you do not authorise this project to proceed as there a need for additional review of the research safety.

Comments (if required)

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I authorise this application to be submitted for ethical review: *

- ○ Without any additional changes to the application
- ◉ If the above comments are addressed prior to submission
- ○ I do not authorise this project to proceed as there a need for additional review of the research safety or research merit (as indicated above)

Signed (authorising officer) *

Date Signed (authorising officer) *

25/08/2026

Print Name *

.

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

☑ 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] If HDR project, the research supervisor is introduced as the PI and is accountable for all details of the study, and the student is introduced as the student (NOT the PI) *
- [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 *
- [x] Research protocol/plan attached, if not previously peer reviewed (e.g. CoC) *

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3. HDR candidates

- [x] Primary research supervisor is the Principal Investigator (PI), HDR candidate is listed as student *
- [x] Confirmation of Candidature (CoC) approval and date included. *

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4. Research Team

- [x] Contact details and qualifications are complete including staff and student numbers. *
- [x] The PI is appropriately qualified and experienced, and is a CDU staff member or has an honorary appointment *

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5. First Nations Research

- [x] Section 13 of the application form has been completed *

Signed ATSIRA attached *

(•) Yes ( ) No

Has a reference group been established that includes First Nations people? *

(•) Yes ( ) No

Section 16 - Applicant Declaration

- [x] Project title included in all applicable areas *
- [x] Risk level checked *
- [x] Signed and dated by PI (and student, if applicable) *

Section 17 - Authorising Officer Declaration

- [x] Project Title included on the declaration *
- [x] All relevant boxes have been checked *
- [x] 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

HREC review outcome *

Please select the CDU-HREC action requested *

- ( ) Response Required (with changes to the application form)
- ( ) Resubmission

HREC Reference Number *

(e.g. H25xxx)

Application Form - Version 2

Have you addressed all of the queries raised by the HREC *

( ) Yes ( ) No

Please briefly explain how the queries have been addressed and list the relevant sections that have been edited (e.g., 7c, 9a etc.) *

As part of your response, please attach the following:

1. Written response to the HREC letter received. Please ensure you include the project title and the assigned HREC referencenumber.
2. Please rewrite each request and then list your response underneath, or detail how this was addressed in the application form.
3. Please to submit amended supporting documents (if applicable), such as an amended Information Sheet for Participants and Consent Form. Please provide both a tracked and clean version of any updated support documents.

Please upload updated/additional supporting documentation. *

Browse

If this is a resubmission, all supporting documentation will be required

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Outcome of Response to Queries / Resubmission *

Please select the CDU-HREC action requested *

- ○ Further Response Required (with changed to application form)
- ○ Second request for resubmission

HREC Reference Number *

(e.g. H25xxx)

Application Form - Version 3

Please be aware that if a third resubmission is required, researchers must wait three (3) months before resubmitting and review. In the rare instance a third resubmission is requested, the HREC Chair and ethics team will be available to discuss the issues with researchers and may offer advice on how to resubmit for future review.

Have you addressed all of the queries raised by the HREC *

○ Yes ○ No

Please briefly explain how the queries have been addressed and list the relevant sections that have been edited (e.g., 7c, 9a etc.)

As part of your response, please attach the following:

1. Written response to the HREC letter received. Please ensure you include the project title and the assigned HREC referencenumber.
2. Please rewrite each request and then list your response underneath, or detail how this was addressed in the application form.
3. Please to submit amended supporting documents (if applicable), such as an amended Information Sheet for Participants and Consent Form. Please provide both a tracked and clean version of any updated support documents.

Please upload additional/updated supporting documentation *

Browse

If this is a resubmission, all supporting documentation will be required

Outcome of Response to Further Queries/Resubmission *