Charles Darwin University Human Research Ethics Proposal Form

The University is committed to minimizing risk to participants, researchers, third parties and the institution itself and you must have ethics approval for research involving human participants. You should apply only when the methodology of your research, your oversight of its conduct and the requirements of any third parties are fully understood.

Your ethics proposal explains how the research can be conducted ethically and with minimal risks to participants. The University's human research ethics approval procedures are designed to ensure that all students and staff, as well as the institution, are meeting all obligations under the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) and any other relevant legislation or guidelines. *Charles Darwin University will not grant retrospective ethics approval.* Higher Degree Research applications will be reviewed after Confirmation of Candidature is granted.

Aboriginal and Torres Strait Islander Research

Where the primary focus of the project is within the scope of Indigenous research, it is essential that section 13 of this form is completed. Applicants should also refer to the AIATSIS guidelines (GERAIS 2012) and the NHMRC Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018).

All Aboriginal and Torres Strait Islander research ethics proposals require a completed and signed research agreement with an appropriate organisational head or community group leader or Elder. The agreement should be included with your submission. For more information on research agreements, applicants should refer to Keeping Research on Track II (2018) and CDU's information sheet and Aboriginal and Torres Strait Islander research agreement template.

Exemption

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

Prior HREC Review

To apply for CDU approval for a protocol with prior approval by another NHMRC registered human research ethics committee (HREC) see section 1c.

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

Proposal Submission

Read the full text of all questions. Respond concisely to all applicable sections, using plain language readily understood by an informed layperson. Prepare your plain language statements and consent forms as attachments.

All ethics proposals require signing off from the appropriate Head of College/Institute Director as the Authorising Officer. Where the appropriate authorising officer is also a member of the research team this authorisation should be completed by the relevant Pro-Vice-Chancellor.

Once completed, the proposal should be saved and submitted with all supporting documentation, by email to ethics@cdu.edu.au with all signees copied [CC] into the email. To be considered at the next HREC meeting the proposal must be received on or before the submission dates, as indicated on the website. Receipt of all proposals will be acknowledged.

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

HUMAN RESEARCH ETHICS PROPOSAL

version 4 March 2019

Project Title

Principal Investigator

The Principal Investigator must be a suitably qualified Charles Darwin University staff member with relevant experience. Correspondence about this application will be sent to the investigators listed in this section who must distribute it to other researchers involved in the project.

Title:	Choose an item.	
Family Name:		
Given Names:		
Staff ID:		
Qualifications:		
Role in project:	Choose an item.	Other:
Email address:		
Phone (business):		
Organisation/ Faculty:	Choose an item.	Other:

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

☐ Yes. Indicate the type of the Course:	Choose an item.	☐ No

Student

Please enter details for the student if this is a higher degree research project.

Title:	Choose an item.	
Family Name:		
Given Names:		
Student ID:		
Qualifications:		
Role in project:	Choose an item.	Other:
Email address:		
Phone (business):		
Organisation/ Faculty:	Choose an item.	Other:

Proposed commencement and completion dates of the project

From (DD MMM YYYY):		To (DD MMM YYYY):	

Does this project have specific funding?

☐ Yes	☐ No
If you have answered YES, indicate whether the funding is from CDU or external sources, or both.	
☐ CDU	☐ External
List all funding sources, including grant titles and codes.	

1 Special Approval Notifications

1a i. Aboriginal and Torres Strait Islander Research	
Will this project involve Aboriginal and Torres Strait Islander research? Aboriginal and Torres Strait Islander research means research with Aboriginal and Torres Strait Islander Peoples, their lives, culture and their issues, not necessarily as participants or researchers within the study. If this is Aboriginal and Torres Strait Islander research, please ensure Section 13 of this form is completed.	☐ YES ☐ NO
ii. Have you read the NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders and Keeping research on track II and do you agree to abide by the values and principles outlined in these document during the course of your research?	☐ YES
ii. If this project is involves Aboriginal and Torres Strait Islander research, has consultation with relevant Aboriginal and Torres Strait Islander Peoples, communities and/or groups been undertaken? *If **Yes**, please attach the Indigenous Research Agreement to this application. The Aboriginal and Torres Strait Islander Research Agreement should include details of the agreed upon aims, outcomes and community benefits of the research. For further information, see Keeping research on track II.* *If **No**, please provide details below of progress towards consultation with appropriate Peoples, communities and/or groups.*	☐ 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 any participants and **(iii)** complete the application by moving forward and filling out the Applicant Declaration (Section 15) and Authorising Officer Declaration (Section 16).*

1c	**Has this proposal previously been reviewed and approved by an Australian Human Research Ethics Committee registered by the NHMRC?**	☐ YES ☐ NO

*If you have answered **YES**, **(i)** enter the name of the approving HREC below, **(ii)** include a full copy of approved application, **(iii)** include a copy of the approval from that HREC and **(iv)** complete the application by moving forward and filling out the Applicant Declaration (Section 15) and Authorising Officer Declaration (Section 16).*

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 **YES**, specify the the nature of the peer review below. If you have answered **NO**, provide an attachment with 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).*

1e	**Is this a program of research undertaken for educational purposes within a non-clinical Coursework unit at Charles Darwin University?**	☐ YES ☐ NO

*If you have answered **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, and so forth.*

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)
- ☐ Aboriginal or Torres Strait Islander 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)
- ☐ 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)
- ☐ 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
- ☐ Other: _____

2d Research Areas

- ☐ Social Science research
- ☐ Humanities research
- ☐ Educational research
- ☐ Psychological research
- ☐ Health research
- ☐ Biomedical research
- ☐ Epidemiology
- ☐ Other: _____

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 including prizes
- ☐ Other: _____
- ☐ Not applicable

3 Additional Members of the Research Team

(Do not include the principal researchers listed above. If additional space is required for more team members, include a supplementary list in the same format as an attachment to your submission pack.)

Title:	Choose an item.	
Family Name:		
Given Names:		
CDU Staff/Student ID		
Qualifications:		
Role in project:	Choose an item.	Other:
Email address:		
Phone (business):		
Organisation/ Faculty:	Choose an item.	Other:

Title:	Choose an item.	
Family Name:		
Given Names:		
CDU Staff/Student ID		
Qualifications:		
Role in project:	Choose an item.	Other:
Email address:		
Phone (business):		
Organisation/ Faculty:	Choose an item.	Other:

Title:	Choose an item.	
Family Name:		
Given Names:		
CDU Staff/Student ID		
Qualifications:		
Role in project:	Choose an item.	Other:
Email address:		
Phone (business):		
Organisation/ Faculty:	Choose an item.	Other:

Title:	Choose an item.	
Family Name:		
Given Names:		
CDU Staff/Student ID		
Qualifications:		
Role in project:	Choose an item.	Other:
Email address:		
Phone (business):		
Organisation/ Faculty:	Choose an item.	Other:

4 Description of the Project

Describe the overall project in terms easily understood by the lay reader, using simple and non-technical language. (Approximately 200-250 words - if more space is required please attach a word document) (NS 5.2.7)

5 Aims and significance of the project

List the specific aims and potential significance of the research questions to be addressed in the research project using simple and non-technical language. (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)

6 Locations at which the project is to be conducted

Describe the locations at which the study involving human participants will be conducted. 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, and so forth.

7 Research Methods

7a	*Describe the research methods, in plain language, including: 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.*
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).*

7c	*Noting the information already provided about the qualifications of individual members of the research team, outline the relevant expertise of the team to conduct the proposed protocol. This response may only require a brief overview of the relevant experience, training or supervision which will enable the research team to conduct the proposed research. (NS 1.1 (e))*
7d	*Indicate whether any element of the protocol (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.*

8 Potential Participants

8a	*Describe the potential participants, 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)*
8a.1	***Rationale for the selection of this participant pool**: Referring to the categories of participants to be involved in this research project identified above, why have participants from this / these group(s) been chosen? (NS 1.4 (a), 3.1.14 and 3.1.15)*
8a.2	***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)** the means by which they will be screened. 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)*

MINORS
8b *If the participant pool will include minors (persons aged under 18) 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)*
COGNITIVE IMPAIRMENT, INTELLECTUAL DISABILITY OR MENTAL ILLNESS
8c *If the participant pool includes persons who have impaired capacity 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)*
LANGUAGE CONSIDERATIONS
8d *If the research will 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 explain, how will these issues be addressed? (NS 2.2.1-3 and 5.2.17)*

	DEPENDENT OR UNEQUAL RELATIONSHIPS
8e	*If the potential participants are in a dependent relationship that is likely to impact upon the nature of their participation and / or raise additional ethical issues, explain how this will be addressed? (NS 4.3)*
	INCENTIVES
8f	*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)*
	EXISTING RELATIONSHIPS
8g	*Provide details of any existing relationship that the researcher(s) have with the potential participants. (NS 4.3)*
	PEOPLE IN OTHER COUNTRIES
8h	*If people in other countries are among the participants, 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)*

9 Benefits and Potential Risks

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

9b *To whom will the benefits flow?*

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 potential consequences or risks and to explain the risk management processes that will be implemented.* **Tick the appropriate risk categories and elaborate your responses below.** *(NS 2.1)*

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

9d ***For each of the risk categories****, either explain why you believe that there is no risk, or explain the risks associated with the research.*

9e *To whom do the risks apply?*

9f	*What, if any, strategies will be used to **(i)** negate these risks, **(ii)** minimize these risks, **(iii)** and to manage these risks if an adverse event occurs? (NS 2.1)*
9g	*How do the benefits of the research outweigh the risks? Where the benefits accrue to people other than the participants, explain why the participants should bear the risk. (NS 1.6, 1.7 and 2.1)*

10 Informed Consent

10a **Indicate how informed consent or assent will be obtained from participants. Explain in detail any additional procedures.** *(NS 2.2)*

- ☐ 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

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

10c *Will substituted consent be obtained on behalf of a participant with impaired capacity? If so, 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)*

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)*
10e *Research sometimes involves deception in order 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. Deception is basically unethical. 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)*

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.*

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

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

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

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

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

☐ Identifiable information	☐ Re-identifiable / coded information
☐ Non-identifiable 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.*

11f	*If there are participants in a focus group 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.*
11g	*If participants are to be identifiable, or potentially identifiable in any publication or report, 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)*
11h	*If a recording (whether audio, video, audio-visual or other) of participants will be made, explain the purposes of this recording.*
11i	*If a recording is to be made, will this be retained and used beyond the initial transcription / analysis or will it 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?*
11j	*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? If so, 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)*

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.*		
12b	*If the data will be stored in an identified or re-identifiable (coded) form, 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).*	
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.*	

13 Aboriginal and Torres Strait Islander Research

13a	*If you have answered YES to Section 1a, indicate **(i)** Please include the Agreement with your application, and indicate here how you have consulted with relevant Indigenous persons and /or communities, **(ii)** how the results of the research will be made available to those persons / communities and **(iii)** how the research is beneficial to those persons / communities (or at least not contrary to the interests of the persons / communities). Then 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 Guidelines for Ethical Research in Australian Indigenous Studies**.*
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)*

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 the HREC?**	☐ YES ☐ NO

Provide the detail of the additional ethical issues, including matters relating to the ethical principles of respect for persons, beneficence, justice, research merit, and research safety.

15 Applicant Declarations *(This page may be copied and provided separately in the submission pack)*

Project Title _____

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 Aboriginal and Torres Strait Islander research? ☐ YES ☐ NO

Is the Aboriginal and Torres Strait Islander research agreement 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 (DD MMM YYYY) _____

Signed (Student / Co-Investigator) _____ Date (DD MMM YYYY) _____

16 Authorising Officer Declaration *(This page may be copied and provided separately in the submission pack)*

This authorisation is to be completed by the College 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.

Project Title _____

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 or peer 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

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

Signed _____ Date (DD MMM YYYY) _____

Print Name _____

17 Supplementary Information

17a Plain Language Information Sheet (Include a draft as an attachment in your submission pack)

The following advice and schematic for a Plain Language Information Sheet is based on the resources available at the web site of the Australian Institute for Aboriginal and Torres Strait Islander Studies (AIATSIS):

A Plain English Information Sheet is a clear and concise explanation of your research project. The Plain English Information Sheet must be distributed to all research participants. It is important that the Statement is recorded in some way as part of your project documentation, and has been acknowledged by the participants on the informed consent form where this form exists. The information includes items that may be obvious to you but are less obvious to the research participants. It can be easy for researchers to underestimate the gap between the language used in universities and in the general community. Complex written English may be even more difficult to understand than complex spoken English. If your audience does have a higher level of English proficiency than that used in the general community, you should use more complex English to avoid giving the wrong impression.

Sometimes you will need to translate the information sheet to a different language. The CDU Human Research Ethics Committee will rely on you to ensure that the translation accurately captures the meaning of the English draft.

Who is involved in the Project?	•The research will be conducted by... •who work for... •The research is supported by... •These key organisations will be helping us... •We have grant funding from... •This research has approval from...
What will the researcher(s) do, and when?	•We are trying to find out... •We are interested in hearing/talking about other related issues or topics... •We will be using these research methods.... •The research will happen during...
What will the researchers do with the information they collect?	•The information will be used to create a report / book / film... •We will discuss with you how your information will be recorded and if it will be kept... •We will negotiate Intellectual Property with research participants
What will happen to the results of the research?	•We will store your information with the research results... •You may access this information... •We aim to find a solution to... but we may not be successfull...

17b Informed Consent Form (Include a draft as an attachment in your submission pack)

The following advice and outline of an Informed Consent Form is based on the resources available at the web site of the Australian Institute for Aboriginal and Torres Strait Islander Studies (AIATSIS):

The Informed Consent Form is an agreement between the researcher and the participant on the conditions, rights and obligations of both parties. The outline aims to help you to create and use an informed consent form. Most importantly the Informed Consent Form ensures that you have evidence of the consent of participants to conduct the research according to your project plan.

Evidence of informed consent can take several forms. It may be given explicitly by signing a consent form or by an audio recording of affirmation. If so, you should collect and retain the evidence of informed consent. Informed consent may also be given implicitly, for example by pressing the "submit" button at the end of an on-line survey. You are encouraged to avoid collecting identifying information (such as a signature on a consent form) in cases where the participants are anonymous.

OUTLINE FOR AN INFORMED CONSENT FORM

[NAME OF RESEARCH PROJECT]

[Name of researcher(s)]

- I have read {or had read to me} the Plain English Information Sheet which explains what this research project is about and I understand it.
- I have had a chance to ask questions about the project, and I am comfortable with the answers that I have been given. I know that I can ask more questions whenever I like.
- I have volunteered to participate in the research. I know that I do not have to participate in it if I don't want to. I agree to *[summarize the mode of participation – "talk to the researcher", "join a focus group", and so forth]*. I know this it will take *[enter the duration].*
- *[any condition relating to choices to not answer particular questions, or to stop recording/filming]*
- I know that I am free to withdraw at any time. If I do withdraw there will be no bad consequences for me.
- If I withdraw none of the information I have given can be used in the research *[qualify this in a focus group or if the data are to be pooled for analysis].*
- I know that the researchers will keep my information confidential *[or other commitment]* so far as the law allows.
- I have been told that we won't talk about *[a particular kind of topic].* I won't pass on any *[particular kind of]* information. If I accidentally tell the researcher these kinds of things, they will try to stop me and will try not to record them.
- I know that I won't get paid for participating in the research project *[or I will be paid XXX to participate].* Even though I am paid I don't have to answer all of the questions.

I have read this Informed Consent Form and I agree with it {OR appropriate format for oral consent}.

Signed by the research participant_____

Name of the research participant_____

Date_____

I agree to having an audio tape made of the interview.

Signed {or orally confirmed} by the research participant_____

I agree to having a video (or photographs) made [include explicit details about everything that the participant agrees to or does not agree to – use in public display, acknowledgement etc].

Signed {or orally confirmed} by the research participant_____