**HUMAN RESEARCH ETHICS COMMITTEE
of NT Health and Menzies School of Health Research (EC 00153)**

**NT HREC APPLICATION FORM**

**Intention to Lodge a Research Ethics Application**

You are required to email the Ethics Administration Office NTHREC@menzies.edu.au your intent to lodge an application for ethics review **two** (2) weeks prior to the submission deadline. Your email notification that includes the title of the study and the name of the principal investigator will ensure that your application is logged as an agenda item.

This Committee does not grant retrospective ethics approval. Please ensure that the commencement dates and timeline are correct prior to submission and include enough time to allow for the approval process. (“*A judgement that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released”, page 7 of the National Statement on Ethical Conduct in Human Research*).

**Plain Language**

*Section 5.2.7 of the National Statement on Ethical Conduct in Human Research*

* This application should be completed in terminology readily understood by an informed layperson as the reviewing committee consists of members from varied backgrounds.
* Please refer to the checklist for a description of supporting documentation.

**Acronyms**

* Acronyms to be used as nicknames for studies should not have the potential for ridicule or misrepresentation.
* The first time an acronym is used in the application the words must be written out in full, with the acronym placed in parentheses immediately after.

**Legislation and Guidelines**

Applicants should have read, and be familiar with, the following documentation and ensure that the application is consistent with:

* *National Statement on Ethical Conduct in Human Research,* 2023
* *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* 2018
* *Australian Code for the Responsible Conduct of Research*, 2018
* Mandatory reporting obligations for all people, under section 26 of theNT *Care and Protection of Children Act 2007*
* Mandatory reporting obligations for all people, under theNT *Domestic and Family Violence Act 2017*
* The Commonwealth *Privacy Act 1988.* NHMRC has issued Guidelines Under Sections 95 and 95A of the *Privacy Act 1988*
* The Northern Territory *Information Act 2017*

**Permits to undertake research and enter remote communities**

* Please ensure that a permit to enter lands for the purpose of research has been sought from the appropriate land council.
* Please note that letters of support from communities and other health service providers may be necessary to support your application.

**Part D Aboriginal and Torres Strait Islander Health Research**

*Section 4.7 of the National Statement on Ethical Conduct in Human Research*

* Please ensure that Part D of the application is completed and each of the six core values are addressed under separate headings, even if your project is not specifically targeting Aboriginal and Torres Strait Islander people.

**Menzies School of Health Research**

* Projects conducted by Menzies staff require review and sign of by the Director, or the Director’s delegate.

**Research within Northern Territory Health (NT Health)**

Site Specific Assessment (SSA) is a component of institutional research governance and separate to the ethical review of research proposals by a recognised Human Research Ethics Committee (HREC). The SSA process involves assessing the suitability of the research proposal for the Health Service site and ensures that adequate resources exist for satisfactory conduct and completion of the project. The NT Research Governance Office(s) assess whether appropriate consultation and approval has been granted by local decision makers to permit the research to be undertaken at the site. For further information please visit - <https://health.nt.gov.au/data-and-research/nt-health-research>

**Researchers are encouraged to discuss their proposal and seek in-principle support/endorsement from the appropriate delegate/s at the Health Service, individual sites and the Research Governance Office before proceeding with developing formal ethics and SSA submissions.**

The [SSA application](https://health.nt.gov.au/data-and-research/nt-health-research/forms-and-process) should be completed and submitted by the Site Principal Investigator concurrently with the completion and submission of the ethics application to ensure it is reviewed in a timely manner.

NT Health sites include all services provided through NT Health and regional health services.

Please note: Endorsement from NT Health Divisional Co-Directors, General Managers and Unit heads is no longer an Ethics requirement but a site Governance requirement, and a letter of support from NT Health RGO is not required to be lodged with this ethics application.

**Data from NT Health**

* Projects intending to access NT Dept of Health data should note that they should contact the NT Dept of Health Data Quality and Governance division by email DataReleaseRequests.DoH@nt.gov.au  to obtain the most recent version of the data release guidelines and application forms. Applications for data release can be submitted in parallel to ethics applications.
* The data owner for CAHS local/client data is the Executive Director Medical Services. The data owner for TEHS local/client data is the Executive Director Clinical Innovation & Research. Researchers requiring access to TEHS local/client data are advised to indicate this when applying for Site Specific Authorisation, so that authorisation for data access can be included in the SSA by the NT RGO.

**Submission**

The following documents must be received by the submission closing date by **COB 4pm** for an application to be considered at the Ethics Committee meetings:

* One electronic single file of the research ethics application including associated documents forwarded to NTHREC@menzies.edu.au Please ensure that the attachments to the research ethics application are emailed as a single document only (preferably one pdf) , and not an email with multiple attachments.

Please note that hand written applications will not be accepted. Please ensure that the Track Changes function is disabled.

If the Principal Investigator will not be contactable on his or her normal phone number (as listed in the application) when the Ethics Committees convene, please supply additional details on how he or she may be contacted during the meeting times as listed above.

Please ensure that all attachments to the application are collated. It is the responsibility of the researcher to ensure that the application is complete, with all relevant documentation attached and this includes obtaining the signatures of the Principal Investigator, co-investigators and the Sponsor/Department Head prior to submission.

**HUMAN RESEARCH ETHICS COMMITTEE
of NT Health and Menzies School of Health Research (EC 00153)**

**RESEARCH ETHICS APPLICATION CHECKLIST**

**Please use this list to ensure the completeness of your application.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Mandatory components for all submissions to a Human Research Ethics Committee** | **YES** | **NO** | **N/A** |
| 1. **Cover letter signed by the Principal Investigator**.* A brief description of the project including the Phase of the study if it is a clinical trial.
* A list of all NT sites applicable to the HREC application for the research study.
* An explanation of any NT involvement and local investigators if not explained in a multi-site application and a clear explanation of how the project will be facilitated in the NT.
* A list of supporting documentation submitted including version dates/numbers.
* For commercially sponsored research studies; the name and address of the sponsor organisation/CRO/CRA for the HREC review. (Australian address).
* Principal Investigator should not be a student. If the project is student research, then the student’s main supervisor should be listed as Principal Investigator.
 |  |  |  |
| 2. **HREC Application Form or HREA plus Part D attachment** |  |  |  |
| 3. **Study Protocol / Project Description*** The protocol may contain some of the information in the research ethics application, but the protocol is required because it is the working document for the study; the formal design or specific plan for the research. If revisions occur during the course of the research, a revised protocol must be submitted to the reviewing HREC as an amendment. The protocol must include a version date/number, which is changed as the document is updated.
 |  |  |  |
| 4. **CV for Principal Investigator. Summarised CV with recent relevant experience – maximum 10 pages.** * **CVs are not required for other researchers**
 |  |  |  |
|  |
| **Other components that may be required depending on the research project** | **YES** | **NO** | **N/A** |
| 5. **Letters of Approval from other Human Research Ethics Committees.** |  |  |  |
| 6. **Master Participant Information Sheet (PIS)*** Full letterhead with contact details.
* Mandatory statement underneath research title **“This Is For You To Keep”**.
* If more than one PIS e.g. different target groups of participants, it should be clear which group the PIS is aimed at, e.g. stated in a header or footer with version number.
* Written in plain simple English.
* Local researcher’s name and contact details included. (Site specific).
* Contains relevant information (i.e. description of research, aim of research, what is required of participants, storage of data, risks and benefits, future use of samples and data, withdrawal options).
* A paragraph on assurance of confidentiality.
* A section on concerns and complaints with contact details of this Ethics Committee.(phone: 08 8946 8600, email NTHREC@menzies.edu.au )
 |  |  |  |
| 7. **Master Participant Consent Form (CF)*** Full letterhead with contact details.
* Mandatory statement underneath research title **“This Means You Can Say NO”**.
* If more than one CF e.g. different target groups of participants, it should be clear which group the CF is aimed at, e.g. stated in a header or footer with version number.
* Written in plain simple English.
* Local researcher’s name and contact details included. (Site specific).
* Consent for all procedures e.g. access to medical records, audio/video recording – dot points for non-optional items; Yes/No boxes only for optional items.
* A space for study participant’s printed name and signature, and date and time of consent.
* A space for witness / interpreter’s printed name and signature.
* A space for the researcher’s printed name and signature.
 |  |  |  |
| 8. **CTN Form(s)** – include original CTN forms with details for each site. (Clinical trials only) |  |  |  |
| 9. **CTX Form** (Clinical trials only) |  |  |  |
| 10. **Investigator’s Brochure** |  |  |  |
| 11. **Questionnaires/surveys/interview guides/distress protocol/other instruments** |  |  |  |
| 12. **Data collection tool(s)** e.g. Data Collection Form, Case Report Form. |  |  |  |
| 13. **Certificate of Insurance** (Clinical trials) |  |  |  |
| 14. **Clinical Trial Registration Number and public register details** |  |  |  |
| 15. **Form of Indemnity (Medicines Australia HREC Review Only Form) for each participating site.** |  |  |  |
| 16. **Copy of the Form of Indemnity (Standard Form) for each participating site.** (Clinical trials) |  |  |  |
| 17. **Advertising materials** (including transcript for advertisement, flyers, e-mail, website, letter, telephone calls etc). |  |  |  |
| 18**. Letter of invitation / Letter to GP etc** |  |  |  |
| 19. **Participant diaries** |  |  |  |
| 20. **Participant wallet card** |  |  |  |
| 21. **Other correspondence** e.g. FDA reviews, correspondence with other HRECs, expert independent reviews, peer review etc |  |  |  |
| 22. **Working with Children Clearance** **inc. for anyone working in a remote community regardless of whether or not children are the main participants in the research.** |  |  |  |
| 23. **Aboriginal and Torres Strait Islander Research, Part D of HREC form, also to be included with HREA*** Please note that applications will not be accepted without completion of this section if it is applicable in the research study
 |  |  |  |
| 24. **Community Support*** Attach letters of support from relevant participating communities and organisations
 |  |  |  |
| 25. **Stakeholder support inc. remote health services. Examples:** [**https://www.menzies.edu.au/page/Research/Ethics\_approval/4\_Stakeholder\_site\_support\_and\_permits/**](https://www.menzies.edu.au/page/Research/Ethics_approval/4_Stakeholder_site_support_and_permits/)* Letter of Support
* Funding
* Support staff available
* Agreement of other resources providers involved. (e.g. Pathology Department).
* Letters of support from Community Authorities/relevant organisations
* SA-NT Datalink feasibility
 |  |  |  |
| 26. **NT Health Site Specific Authorisation*** All research studies conducted at NT Health sites includes all services provided through NT Department of Health, Central Australian Health Service (CAHS) and Top End Health Service (TEHS) require Organisational Site-Specific Authorisation (SSA). This is obtained through the NT Health research governance office (nthealth.rgo@nt.gov.au).
* NT Health letter of support is **NOT** required to be attached to the ethics application
 |  |  |  |
| 27. **Signatures*** PI may sign on behalf of other investigators if applicable
* Department head printed name, signature and role in the Organisation/Institution
* Organisational Head or delegate if application is from Menzies School of Health Research researchers
* If it is impossible to ascertain original signatures and only electronic signatures can be provided; please attach a letter or email from the researcher involved as evidence of consent for the use of their electronic signature and acknowledgement of support to the research study
 |  |  |  |
|  |
| **Research using gene technology** | **YES** | **NO** | **N/A** |
| 27. **Ionising Radiation Certificate** |  |  |  |
| 28. **Institutional Biosafety Committee (IBC) approval letter**. |  |  |  |
| 29. **Licence for dealings with Genetically Modified Organism (GMO)** |  |  |  |
| **Research using radiological procedures that are performed for research** | **YES** | **NO** | **N/A** |
| 31. **For each site in the Northern Territory,** **either*** A letter from the Principal Investigator stating that radiation exposure is part of normal clinical management/care.
* If radiation exposure is **additional** to that received as part of normal clinical management/care, an independent assessment report by a Medical Physicist of the total effective dose and relevant organ doses including risk assessment.
 |  |  |  |

Research Ethics Fee Schedule

From 1st October 2023, NT HREC fees apply for the following application types, noting that there is no fee for review of NT Department of Health or Menzies School of Health Researcher-led projects, including projects led by community groups and not for profit groups (this applies to items 5, 6, 9.2 and 10).

|  |  |  |
| --- | --- | --- |
| **Item #** | **Type of application**  | **Fee** |
| 1.1 | CTN Scheme Application with a Commercial/Pharmaceutical Sponsor | $4000 |
| 1.2 | HREC Review on behalf of each additional site that is or may be a part of an NMA application with a Commercial/Pharmaceutical Sponsor | $660 |
| 1.3 | HREC Review for the addition of NT as a site as part of an NMA application | $660 |
| 1.4 | HREC Review for Lead HREC for an NMA application  | $6000 |
| 2 | CTX/CTE Scheme Applications | $4000 |
| 3.1 | Pharmaceutical sponsor – sub studies or extensions | $1650 |
| 3.2 | Pharmaceutical sponsor – registry study | $1650 |
| 4 | Clinical Trials supported by, but not instigated by, a Pharmaceutical Company | $1100 |
| 5 | Research Projects funded by Grants | $220 |
| 6 | PhD Projects | $220 |
| 7 | Application for Clinical Trial with sponsorship from collaborative groups | $330 |
| 8 | Single-site, investigator-initiated study where the Principal Investigator is neither a student/employee of the Northern Territory Department of Health or Menzies School of Health Research | $220 |
| 9.1 | Review of an Amendment (including those requesting an extension of Approval)*Amendment for Commercial/Pharmaceutical Sponsored study* | $880 |
| 9.2 | Review of an Amendment (including those requesting an extension of Approval)*Amendment for non-Commercial/Pharmaceutical Sponsored study* | $220 |
| 10 | Applications submitted for review by the Low and Negligible Risk ethics pathway | $220 |

*Listed fees are inclusive of GST*

Invoicing details:
If applicable, please complete and submit this form with your application

|  |  |
| --- | --- |
| Name of person responsible for invoice: |        |
| Email address of person responsible:  |        |
| Name of Principle Investigator:  |        |
| Ethics Reference Number:  |       *(HREC XXXX-XXXX)*  |
| Organisation Name:  |        |
| Organisation Address:  |        |
| Organisation Phone number:  |        |
| Accounts payable email address:  |        |
| ABN:  |        |
| Item # to be invoiced\*: |        |
| Declaration: (     *Name of person responsible)* am authorised to incur the costs associated with this ethics submission: | Signature:      |
| Institutional approval: | Name:     Signature:       |

\*If you are unsure which item applies to your application, please contact ethics@menzies.edu.au

**HUMAN RESEARCH ETHICS COMMITTEE
NT Health and Menzies School of Health Research (EC 00153)**

**NT HREC ETHICS APPLICATION FORM**

|  |
| --- |
| **Principal Investigator’s name (including title):**……………………………………………………………………………………………. |
| **Project Title:**…………………………………………………………………………………………….. |
| **Simplified Project Title** (Optional)**:**……………………………………………………………………………………………... |
| **Organisation accepting responsibility for the project:****[ ]** Menzies School of Health Research **[ ]** Northern Territory Department of Health**[ ]** Charles Darwin University**[ ]** Other (Please Identify)  |

**Enrolment** (Students Only)**:**

**Name of Course:**

**Part A. THE INVESTIGATORS**

Please ensure that the summary of expertise and qualifications are completed.

*Section 1.1(e) of the National Statement on Ethical Conduct in Human Research*

|  |  |
| --- | --- |
| **Principal Investigator’s Name :**(This is the person with overall responsibility for the conduct of the project and reporting against it. If this is a student project, including an advanced clinical trainee’s accreditation project or a higher degree project, then the student’s main supervisor should be listed as Principal Investigator on this ethics application.) |  |
| **Do you identify as an Aboriginal and / or Torres Strait Islander person?** |  |
| **Are there any Nations, Groups, or Communities you identify with or are connected to?** |  |
| **Qualifications :****E.g., Master of Public Health (MPH). Please list in accordance to this format.** |  |
| **Organisational Affiliation :** |  |
| **Position :** |  |
| **Postal Address :** |  |
| **Phone :****Mobile:** |  |
| **Work Email :** |  |
| **Role in the project; describe functions to be undertaken in the project:** |  |
| **Summary of expertise relevant to this research :***(NS Chapter 1.1e, 4.8.7 and 4.8.15)* |  |
| **Please declare any competing interests :** |  |
| **Curriculum vitae (CV) attached to this ethics application\*** | Yes [ ]  No [ ] \* CV only required for Principal Investigator. Summarised maximum 10 pages. |

|  |  |
| --- | --- |
| **2nd Investigator’s Name:** |  |
| **Do you identify as an Aboriginal and / or Torres Strait Islander person?** |  |
| **Are there any Nations, Groups, or Communities you identify with or are connected to?** |  |
| **Qualifications :****E.g., Master of Public Health (MPH). Please list in accordance to this format.** |  |
| **Organisational Affiliation :** |  |
| **Position :** |  |
| **Postal Address :** |  |
| **Phone :****Mobile:** |  |
| **Work Email :** |  |
| **Role in the project; describe functions to be undertaken in the project:** |  |
| **Summary of expertise relevant to this research :***(NS Chapter 1.1e, 4.8.7 and 4.8.15)* |  |
| **Please declare any competing interests :** |  |

|  |  |
| --- | --- |
| **3rd Investigator’s Name:** |  |
| **Do you identify as an Aboriginal and / or Torres Strait Islander person?** |  |
| **Are there any Nations, Groups, or Communities you identify with or are connected to?** |  |
| **Qualifications :****E.g., Master of Public Health (MPH). Please list in accordance to this format.** |  |
| **Organisational Affiliation :** |  |
| **Position :** |  |
| **Postal Address :** |  |
| **Phone :****Mobile:** |  |
| **Work Email :** |  |
| **Role in the project; describe functions to be undertaken in the project:** |  |
| **Summary of expertise relevant to this research :***(NS Chapter 1.1e, 4.8.7 and 4.8.15)* |  |
| **Please declare any competing interests :** |  |

|  |  |
| --- | --- |
| **4th Investigator’s Name:** |  |
| **Do you identify as an Aboriginal and / or Torres Strait Islander person?** |  |
| **Are there any Nations, Groups, or Communities you identify with or are connected to?** |  |
| **Qualifications :****E.g., Master of Public Health (MPH). Please list in accordance to this format.** |  |
| **Organisational Affiliation :** |  |
| **Position :** |  |
| **Postal Address :** |  |
| **Phone :****Mobile:** |  |
| **Work Email :** |  |
| **Role in the project; describe functions to be undertaken in the project:** |  |
| **Summary of expertise relevant to this research :***(NS Chapter 1.1e, 4.8.7 and 4.8.15)* |  |
| **Please declare any competing interests :** |  |

**Copy and Paste tables to include more Investigators as necessary.**

**Additional contact person**

|  |
| --- |
| **Additional contact other than Principal Investigator for email correspondence, if applicable**  |
| **Name:** |  |
| **Do you identify as an Aboriginal and / or Torres Strait Islander person?** |  |
| **Are there any Nations, Groups, or Communities you identify with or are connected to?** |  |
| **Organisational Affiliation:** |  |
| **Position :** |  |
| **Role in the project; describe functions to be undertaken in the project:** |  |
| **Work Email :** |  |

**Student Investigators**

|  |  |
| --- | --- |
| **1st Student’s Name :** |  |
| **Do you identify as an Aboriginal and / or Torres Strait Islander person?** |  |
| **Are there any Nations, Groups, or Communities you identify with or are connected to?** |  |
| **Qualifications :****E.g., Master of Public Health (MPH). Please list in accordance to this format.** |  |
| **Degree Being Undertaken :** |  |
| **Enrolling University :** |  |
| **Primary Supervisor :** |  |
| **Student’s Postal Address :** |  |
| **Phone :****Mobile:** |  | **Fax:** |  |
| **Work Email :** |  |
| **Role in the project; describe functions to be undertaken in the project:** |  |
| **Summary of expertise relevant to this research** *(NS Chapter 1.1e, 4.8.7 and 4.8.15)* |  |
| **Please declare any competing interests** |  |

**Copy and Paste tables to include more Students as necessary.**

**Describe what training students and co-researchers will receive N/A [ ]**

 **Go to Part B**

|  |
| --- |
|  |

**Part B. THE PROJECT**

**1. Type of research:**

 **Formatting Tip:** Tick all relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’.

**[ ]  Funded research (complete Q34)** **[ ]  Un-funded research**

**[ ]  Staff research [ ]  Student research**

**[ ]  Commercially Sponsored**  **[ ]  Principal Investigator Driven**

 **Clinical Trial**  **Clinical Trial**

**[ ]  Clinical Trial Notification Scheme [ ]  Clinical Trial Exemption Scheme**

(Attach a copy of protocol and (Attach a copy of protocol and

evidence of insurance, and trialevidence of insurance, and trial

registration number to this application) registration number to this application).

**[ ]  Qualitative Research** **[ ]**  **Evaluation**

**[ ]  Audit** **[ ]**  **Other: ………..**

**2. Is this project a continuation of a current or previous project with ethics approval? [ ]  Yes** **[ ]  No**

 **If YES, please provide HREC file reference number: …………………………….**

**3. Has this project been submitted to any other ethics committees?**

 **[ ]  Yes [ ]  No**

 ****

**If YES, please provide the following details :**

|  |  |  |  |
| --- | --- | --- | --- |
| **Ethics Committee**(incl. Human, Animal and Biosafety Committees) | **Status** (To be Submitted, Submitted, Approved,Not Approved) | **Date** | **Copy of Ethics Approval Attached?** |
|  |  |  |  |
|  |  |  |  |

**\*Please note that ethics approval cannot be granted retrospectively.**

**4. Proposed commencement date of project: …………………………………………..**

 **[ ]**  As soon as full ethics approval has been granted

**5. Proposed completion date of project: …………………………………………………**

**6. Summary of the project:**

* In the box below, describe the project in 100 words or less.
* **Formatting Tips:** To tab within a box, hold down the ‘Ctrl’ key when you press the ‘Tab’ key.
* All boxes automatically expand in length.

|  |
| --- |
|  |

**7. Background to the project:**

* Briefly describe the history of the topic you intend to address.
* A formal and comprehensive literature review should have been conducted and be evident in your application.
* Please describe stakeholder involvement in development of the research, if applicable

*Section 1.1(a)(c) of the National Statement on Ethical Conduct in Human Research*

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**8. Aims of the project:**

* Briefly describe your primary research question and what outcomes you hope this project will achieve in 100 words or less.

 *Section 1.1(b) and 1.1(d) of the National Statement on Ethical Conduct in Human Research*

|  |
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**9. Justification:**

* Outline the justification of the proposal.
* What constitutes potential benefit and whether it justifies research may sometimes require consultation with relevant communities and stakeholder groups.

 *Section 1.1(a), 1.6–1.9 of the National Statement on Ethical Conduct in Human Research*

|  |
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**10. Participants:**

* Please read the relevant sections of the *National Statement, Commonwealth Privacy Acts* and *Northern Territory Information Act* to assist you in completing this question.
* Unless participants are being screened for inclusion or exclusion, the following participant groups will likely fall under probable/incidental recruitment
* **Formatting tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specific Participant Groups** | **Targeted** | **Probable** **Incidental** | **Excluded** | **Relevant Section of National Statement/ Privacy Act** |
| Participation of, or impact upon, women who are pregnant and the human foetus | **[ ]**  | **[ ]**  | **[ ]**  | 4.1 (NS) |
| Participation of, or impact upon, children and young people (see ***Working With Children Clearance section below***) | **[ ]**  | **[ ]**  | **[ ]**  | 4.2 (NS)NT Care & Protection of Children Act  |
| Participation of, or impact upon, people in dependent or unequal relationships (*i.e.* patients and health care professionals; students and teachers; employees and supervisors/employers; prisoners and prison wardens; government authorities and refugees; service providers and recipients of those services). | **[ ]**  | **[ ]**  | **[ ]**  | 4.3 (NS) |
| Participation of, or impact upon, persons highly dependent on medical care who may be unable to give consent | **[ ]**  | **[ ]**  | **[ ]**  | 4.4 (NS) |
| Participation of, or impact upon, people with a cognitive impairment, an intellectual disability, or a mental illness | **[ ]**  | **[ ]**  | **[ ]**  | 4.5 (NS) |
| Participation of, or impact upon, people who may be involved in illegal activities | **[ ]**  | **[ ]**  | **[ ]**  | 4.6 (NS) |
| Participation of, or impact upon, Aboriginal and Torres Strait Islander Peoples | **[ ]**  | **[ ]**  | **[ ]**  | 4.7 (NS) |
| Participation of, or impact upon, people in other countries | **[ ]**  | **[ ]**  | **[ ]**  | 4.8 (NS) |

**Will researchers potentially have contact with children even if children are not the targeted participants? [ ]  Yes [ ]  No**

* If yes, please provide details below for all researchers involved.
* Please attach photocopies of Ochre Cards and Clearance Notices to this Application.

 *Section 187 of the Care and Protection of Children Act.*

|  |  |  |
| --- | --- | --- |
| **Researcher Name** | **NT Ochre Card Number** | **Clearance Expiry Date** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**11. Research methodology:**

* Please read the relevant sections of the *National Statement* to assist you in completing this question.
* **Formatting Tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’.

|  |  |  |
| --- | --- | --- |
|  | **Research Methods** | *NS Reference* |
| **[ ]**  | Research involving pre-existing data sets and/or data linkage | 3.1 |
| **[ ]**  | Qualitative research – disciplined inquiry that examines people’s lives, experiences and behaviours and the stories and meanings ascribed to them – through interviews, focus groups, observation, archival, on-line, and/or action research | 3.1 |
| **[ ]**  | Epidemiological research | 3.1 |
| **[ ]**  | Conducting non-invasive physical experiments or examinations | 3.1 |
| **[ ]**  | Conducting trials – trialling new interventions and therapies, including clinical and non-clinical trials, and innovations | 3.1 |
| **[ ]**  | Research involving human tissue, human biological samples inc. cell lines | 3.2  |
| **[ ]**  | Research involving human genomics – studying the structure, location, function, expression, interaction, abnormalities and effects of the genes | 3.3  |
| **[ ]**  | Research involving animal to human xenotransplantation | 3.4 |
| **[ ]**  | Research involving exposure to ionising radiation (\*Attach certificate from ionising radiation expert) |  |
|  | **Other Considerations** |  |
| **[ ]**  | Use of material or procedures of potential danger to the environment |  |
| **[ ]**  | Collecting archaeological data including or impacting upon human remains |  |

**12. Site selection, recruitment, selection criteria, and participant involvement:**

 *Section 1.4, 3.1.12–3.1.22 of the National Statement on Ethical Conduct in Human Research*

* Please list the study sites.

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* Please list the inclusion criteria and the exclusion criteria.

Briefly describe on what basis participants will be included in, or excluded from, the project.

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* Please describe the recruitment process that will be used.

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* Please describe participants’ level of involvement in the study, e.g. time or financial commitment.

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**13. Design & methodology:**

* Briefly outline the methods you propose using to achieve the aims of the project including data sources and data analysis methodology. Please outline in plain English.
* **Please attach a copy of the protocol**
* **Please attach copies of questionnaires or other instruments to be used**.
* **All Clinical Trials must be registered with a publically available register**
* **(**[www.clinicaltrials.gov](http://www.clinicaltrials.gov) **or** [www.ANZCTR.org.au](http://www.ANZCTR.org.au/)**) Please provide registration number.**
* ***Please refer to Chapter 5.2.6 of the National Statement on Ethical Conduct in Human Research, 2007.***

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**14. Sample size:**

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| **TOTAL SAMPLE SIZE** |  |
| **NUMBER OF PARTICIPANTS** |  |
| **NUMBER OF RECORDS** |  |

* Briefly outline and justify the sample size to be used in this research e.g. provide calculations and/or advice from a statistician.

 *Section 1.4, 3.1.2, of the National Statement on Ethical Conduct in Human Research*

* Qualitative researchers should describe their sampling processes and expected individuals/ groups to be included.

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**15. Collection & use of data:**

* Please read the relevant sections of the *National Statement Chapter 3.1 Element 4, Commonwealth Privacy Act* and *Northern Territory Information Act* to assist you in completing this question.
* “The National Statement does not use the terms ‘identifiable’, ‘potentially identifiable’, ‘reidentifiable’, ‘non-identifiable’ or ‘de-identified’ as descriptive categories for data or information due to ambiguities in their meanings. Re-identification and de-identification are best understood as processes that change the character of information and are only used with this meaning.” NS 3.1
* **Formatting tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’.

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|  | **Collection and Use of Data** |  |
| **[ ]**  | Collection and/or use of *non-identifiable data* – where individual identifiers have never existed or have been permanently removed e.g. anonymous survey |  |
| **[ ]**  | Collection and use of *individual data* with the individual’s consent – where the identifiers will be removed, and it will not be possible to re-identify the individual. i.e. it will become non-identifiable. |  |
| **[ ]**  | Collection and use of *individual data* **without** the individual’s consent – where the identifiers will be removed, and it will not be possible to re-identify the individual. i.e. it will become non-identifiable. |  |
| **[ ]**  | Collection and use of *re-identifiable data* with the individual’s consent – where the identifiers will be removed and replaced with a code, but it remains possible to re-identify a specific individual (*e.*g. through linkage of data sets) |  |
| **[ ]**  | Collection and use of *re-identifiable data* **without** the individual’s consent – where the identifiers will be removed and replaced with a code, but it remains possible to re-identify a specific individual (*e.*g. through linkage of data sets) |  |
| **[ ]**  | Collection and use of *individually identifiable data* with the individual’s consent – where individual participants may be identified throughout the study and in final results and publications |  |
| **[ ]**  | Collection and use of *identifiable data* with a community’s consent – where communities may be identified throughout the study and in final results and publications |  |
| **[ ]**  | Collection of *identifiable data* from records held by a Commonwealth government agency without consent of individualsPlease complete s95 Privacy Guideline Supplementary Documenthttps://www.menzies.edu.au/page/Research/Ethics\_approval/Forms/s95\_Privacy\_Guideline\_Supplementary\_Document/ | S95: NPPs (PA) |
| **[ ]**  | Collection of *identifiable data* from records held by a State or local government agency without consent of individuals | NT Info Act |
| **[ ]**  | Collection of *identifiable data* from records held by a private sector agency without consent of individualsPlease complete s95a Privacy Guidelines Supplementary Formhttps://www.menzies.edu.au/page/Research/Ethics\_approval/Forms/s95a\_Privacy\_Guidelines\_Supplementary\_Form/ | S95A: IPPs (PA) |
| **[ ]**  | Use of data previously gathered for another research project – where consent was provided for future use | 2.2.14 (NS) |
| **[ ]**  | Use of data previously gathered for another research project – where consent was *not* provided for future use | 2.2.18 (NS) |
| **[ ]**  | None of the above |  |

**16. How will the identity and privacy of participants be protected?**

* If identifying information is to be made public, justify the public identification of individual participants or communities.

 *Section 1.11, 2.2.6(f), 2.3.6(e), 2.3.7(b), 3.1.40–3.1.62, 3.3, and 5.4.6 of the National Statement on Ethical Conduct in Human Research*

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**17. Outline procedures to be followed in the event of a participant withdrawing consent or dying:**

* *Please refer to Chapter 2.2.19 and 2.2.20 of the National Statement on Ethical Conduct in Human Research, 2007.*

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**18. Will payments or reimbursements be made to participants? [ ]  Yes**  **[ ]  No**

 ** Go to Q19**

**If YES**, please:

* Provide Information regarding the nature of, and reasons for, these payments i.e. reimbursement of costs, provision of gift vouchers, incentives to participate, etc.
* Explain why it will not form an inducement to participate.
* *Please refer to Chapter 2.2.10 and 2.2.11 of the National Statement on Ethical Conduct in Human Research, 2007.*

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**19. English as a second language:**

* Briefly describe how you will ensure that participants whose first language is not English understand the project’s aims and what they may be agreeing to.
* If applicable, please identify these interpreting and translating services and provide letters of support.

*Section 2.2.3, 2.2.8, 5.2.16 of the National Statement on Ethical Conduct in Human Research*

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**20. How will your proposed methodology ensure respect for the cultural, social and religious beliefs and customs, or cultural heritage of participants?**

* Exclusion: **For research involving Indigenous Australians**, please complete Section D of the application form and enter “*Indigenous Australians – See Section D*” in this box.

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**21. If research is being conducted in countries other than Australia, detail how you will ensure you comply with both Australian requirements and the laws and guidelines of those countries:**

 *Section 4.8 of the National Statement on Ethical Conduct in Human Research*

 **N/A [ ]**

 ⏵Go to Q22

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**22. Consent Procedures:**

* Please read the relevant sections of the *National Statement 2.2, 2.3, 3.1 Element 3, 3.3, Commonwealth Privacy Acts* and *Northern Territory Information Act* to assist you in completing this question.
* **Formatting Tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’.

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|  | **Consent Procedures** | **Any Relevant Documents Attached** | *National Statement reference* |
| **[ ]**  | Informed consent – documented consent of individual | **[ ]**  | 2.2, 3.1.23–3.1.39, 3.3.10–3.3.17  |
| **[ ]**  | Informed consent – documented consent of guardian | **[ ]**  | 2.2.12, 3.1.23–3.1.39, 3.3.10, 4.4–3.3.17, 4.2  |
| **[ ]**  | Informed consent – documented assent of child | **[ ]**  | 2.2.12, 3.1.23–3.1.39, 3.3.10–3.3.17, 4.2  |
| **[ ]**  | Informed consent – documented support of community, institutions or other properly interested parties representing collective interests. | **[ ]**  | 2.2.13, 3.1.23–3.1.39 & 4.7.2  |
| **[ ]**  | Limited disclosure – not involving active concealment or planned deception. | **[ ]**  | 2.3.1–2.3.4 |
| **[ ]**  | Limited disclosure – involving active concealment or explicit deception | **[ ]**  | 2.3.2–2.3.4 |
| **[ ]**  | Opt out approach | **[ ]**  | 2.3.5–2.3.8, 3.3.15  |
| **[ ]**  | Waiver of consent – for research using personal information | **[ ]**  | 2.3.9–2.3.12  |
| **[ ]**  | Waiver of consent – for research using pre-existing data that will be de-identified | **[ ]**  | 2.3.9–2.3.12 |
| **[ ]**  | Other Explanation: | **[ ]**  |  |

**23. Will written informed consent be sought?**

 **[ ]  Yes [ ]  No**

* **If YES**, please attach copies of the proposed Participant Consent Form and Participant Information Sheet with this application.

**The Participant Consent Form** should allow the participant to consent to or give permission to ***each*** proposed intervention, the proposed storage or destruction of any biological samples, being videoed or audiotaped, the proposed level of confidentiality and any dissemination of results.

It is important that the participant consent form states in **bold** ‘**This Means You Can Say NO’** underneath the research title at the top of the page, has a full letterhead with contact details, researchers names and contact details and a space for witness and interpreter signature, name and date in addition to a space for participant signature, name and date.

**The Participant Information Sheet** should be given to the participant to keep, and should contain contact details for the researcher/s in case of an emergency. It should clearly state in **bold**: ‘**This Is For You To Keep’** underneath the research title at the top of the page, a full letterhead with contact details, researchers names and contact details in case of an emergency, written in plain English, a paragraph of assurance of confidentiality and a paragraph on concerns and complaints with the contact details and email address of the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research.

**Both** should clearly identify the organisation responsible for conducting the research and provide information allowing the participant to withdraw from the project at any time without giving a reason or not participate at all.

Please attach these forms with this application.

* **If NO**, will other methods of obtaining consent be sought e.g. oral consent, or acceptance of online survey? **[ ]  Yes.** Please describe. **[ ]  No Go to Q24**

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**24. Will you be accessing personal information *without* consent?**

 **[ ]  Yes [ ]  No**

 ** Go to Q25**

 **(a) If YES, from which organisation/s do you intend to collect information?**

* Please note that receipt of HREC approval does not place any obligation on the proposed organisation(s) to provide the requested information.
* **Evidence of support from the information provider should be attached to this application.**

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| **Organisation** | **Contact Person** | **Phone No.** |
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**(b) Provide details about the information you intend to collect:**

* Detail what sort of information you intend to gather from the listed Organisation(s). ***You must state*** whether the Information will be gained in an **Individually** **Identifiable, Re-Identifiable, or Non-Identifiable** format.

 *Section 3.1 of the National Statement on Ethical Conduct in Human Research*

* **If the information is Individually Identifiable or Re-Identifiable, justify the need for the identifying information – remember that public interest must outweigh an individual’s right to privacy**.

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**(c) Why will individual consent not be sought?**

* If you are gathering Individually Identifiable or Re-Identifiable information, justify your reasons for not seeking individual consent.

 *Section 2.2.18, 2.3.9 – 2.3.12 and 3.1.45 of the National Statement on Ethical Conduct in Human Research*

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**25. Security Plan:**

* Please describe the Security Plan for the protection of the information provided, or the information to be received from persons contacted. The Security Plan should specify the measures that will be taken to protect the information from misuse, loss or unauthorised access during the research project.

*Please note: The Australian Code for the Responsible Conduct of Research* provides guidance on Management of Research Data and Primary Materials (Section 2), including retention, storage, ownership, security and confidentiality. *National Statement* 3.1 Element 4

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**26. Data Retention and Disposal Plan:**

* Please describe the proposal for the retention and disposal of the information provided, or the information to be received from persons contacted. The Information Retention and Security Plan should specify the period of retention of data after the completion of the project and the measures to be taken to secure the information during that period. It should also specify the date by which the information will be returned or destroyed.
* Provide details as to:
* A) **how and where** the data will be **stored** and **who will have access** to it ***during*** the project;
* B) **how long** the data will be **stored**, and **how it will be disposed** of ***after*** the project; and
* C) detail any agreements with **third parties** to be given access to the data.

Please provide details with reference to password protection, secure servers, and security of data.
 *3.1.44 of the National Statement on Ethical Conduct in Human Research*

*Please note: The Australian Code for the Responsible Conduct of Research* provides guidance on Management of Research Data and Primary Materials (Section 2), including retention, storage, ownership, security and confidentiality. *National Statement* 3.1 Element 4

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**27. Participant feedback, dissemination of results, and publication:**

* Briefly explain how you intend to inform the wider public (including any publications from the research) as well as provide feedback to participants and communities of the project’s outcomes, and their own results if applicable. If you ***do not*** intend to provide participants with feedback, state why this is considered unnecessary.

*Section 1.3(d), 1.4(d), 2.2.6(k), 3.1.63–3.1.72, 3.3 of the National Statement on Ethical Conduct in Human Research*

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**28. Anticipated outcomes:**

* Detail the anticipated outcomes from the project and how they will contribute new knowledge to the field as well as any potential applications of the findings.
* Justify the risks in terms of the likely benefit to be gained.

 *Section 1.5, 2.1, 4.7.7-4.7.9 of the National Statement on Ethical Conduct in Human Research*

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**29. Intellectual property:**

* If there is a possibility of commercial exploitation of the results, has agreement been reached with participants in relation to ownership of intellectual property?
* Describe any potential abuses or misapplications of the results of your project.
* *NS Section 3.1.31, 3.1.44, 3.1 Element 7. 4.7.9, 4.7.11; Aboriginal Guidelines pp17–19*

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**30. Timeline:**

* Please provide a proposed timeline for the project from commencement to completion.
* Note: The term “Completion” includes outputs such as feedback of findings, publication of the research, etc.
* Please note that ethics approval **cannot be granted retrospectively.**

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**31. Risk management strategy:**

* Describe the potential risks involved with the project and how you plan to manage these. Consider whether a distress protocol is required.
* How will you deal with any contingencies and ensure the safety of:
* Researchers (inc personal safety and mandatory reporting obligations under NT law)
* Study participants.
* Organisations involved.
* Data.
* Facilities.
* Equipment.
* Procedures proposed.
* Other relevant risks.

 *Section 2.1, 3.1, 4.6.2, 4.1, 4.4, 4.7.4, 4.8.18, 5.1.2, 5.5.2, 5.5.3 of the National Statement*

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**32. Possible Investigator Conflicts of Interest:**

**(a) Do any potential ‘dependent or unequal relationship’ issues arise between any of the named investigators and the conduct of this research?** (e.g. relationships between researchers and participants that may compromise the voluntary nature of participants’ decisions).

*Section 5.4 of the National Statement on Ethical Conduct in Human Research*

 **Yes [ ]  No [ ]**

 ** Go to (b)**

(**If YES**, please provide details of the conflict of interest and mechanisms in place to address these issues)

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**(b) Do any of the named investigators have access to personal or other sensitive information required for the conduct of this research as a condition of employment, rather than as a researcher?**

 **Yes [ ]  No [ ]**

 ** Go to(c)**

 (**If YES**, please provide details)

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 **(c) Do any of the named investigators have any current or previous affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research?**

 **Yes [ ]  No [ ]**

 ** Go to (d)**

 (**If YES**, please provide details regarding the nature of the affiliation(s) and matters that may need consideration)

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**(d) Do any of the named investigators have any other potential conflict of interest issues not covered above?**

 **[ ]  Yes [ ]  No**

 ** Go to Q33**

(**If YES**, please provide details regarding the nature of the conflict(s) and matters that may need consideration)

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**33. Summary of ethical issues:**

* Briefly summarise all the ethical issues related to this project.
* These should include at a minimum Benefit/Risk, Indigenous Involvement and Capacity Building, and Generalisability.
* What is the overall risk level the research to be undertaken? *2.1.1 – 2.15 of the National Statement on Ethical Conduct in Human Research*

**It is important to familiarise yourself with the National Statement on Ethical Conduct in Human Research (NHMRC) before attempting this summary.**

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| *Risk profiles per the National Statement* |
| **Lower risk** | **Higher risk** |
| **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) |

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**Part C. THE RESOURCES**

**34. Funding:**

* Name all sources of funding, sponsorship and interested parties)
* Please refer to Section 5.3.7 of the National Statement on Ethical Conduct in Human Research, 2007.

**Has this project been submitted for funding? [ ]  Yes [ ]  No Go to Q35**

 **If YES,**

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| **Name of Funding Body :** |  |
| **Title of Application :** |  |
| **Investigators Named on Application :** |  |
| **Duration of Support :** |  |
| **Status** (*i.*e. Submitted, Funded) **:** |  |

**Basis of funding agreement:**

* Provide details about any agreements regarding payment to researchers for enrolment of participants, power of veto over publication, etc.

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**35. Access to resources:**

* Detail what resource support is required for the project to succeed e.g. obtaining data sets, accessing files, use of pathology services, health or community services staff resources and/or facilities etc, and whether you have already obtained the support of the necessary persons to access these resources.
* **If applicable, please attach any letters of support from resource provider(s). These letters should clearly state that the resource providers have considered the resource requirements from their institution and that they are prepared to meet them**.
* Please note that receipt of ethics approval does not place any obligation on the proposed organisation to provide the requested information.

 *Section 1.1(f) of the National Statement on Ethical Conduct in Human Research*

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**Part D. ABORIGINAL & TORRES STRAIT ISLANDER RESEARCH**

Most human research conducted in the NT, including its outcomes and consequences, will have a significant impact on Aboriginal people regardless of whether they are targeted directly or not. This applies to both direct participant involvement and analysis of pre-existing data. In Part D of our application form we use the term “or impact upon” and ask people to consider all ramifications of their research in relation to Aboriginal and Torres Strait Islander People. Researchers should be familiar with relevant guidelines before completing this section.

**Suggested guidelines:**

* *NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018.*
* *NHMRC Keeping Research on Track II. 2018*

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|  | **YES or NO** |
| Is the experience of Aboriginal and Torres Strait Islander people an explicit focus of all or part of the research;  |  |
| Is data collection explicitly directed at Aboriginal and Torres Strait Islander people? |  |
| Are Aboriginal and Torres Strait Islander people, as a group, to be examined in the results? |  |
| Will a significant number of the participant population be likely to be of Aboriginal and Torres Strait Islander origin? |  |
| Will the research output information have a specific impact on one or more Aboriginal and Torres Strait Islander communities? |  |
| Are Aboriginal and Torres Strait Islander health funds a source of funding? |  |

**36. Does this research require the participation of, or impact upon, Aboriginal & Torres Strait Islander people and/or communities**? (Please note that the majority of research conducted in the Northern Territory or involving NT data will, deliberately or otherwise, involve or have an impact upon Aboriginal people.)

 **[ ]  Yes [ ]  No [ ]  Not Applicable (Overseas based Research)**

 **Go to (a) Go to (b) ⏵Go to Part E**

 **a) If YES:**

Please respond to **EACH** of the 6 core values listed below in comprehensive detail with reference to how this project will be of benefit to or have an impact on Aboriginal and Torres Strait Islander Peoples and their communities.

(Please note that these core values were updated in 2018. Equality has been replaced by Equity; Survival & Protection has been replaced by Cultural Continuity; and Spirit & Integrity has been revised. Please consult the suggested guidelines.)

Reciprocity Mutual obligation;

 Benefit through the establishment or enhancement of capacities, opportunities or outcomes.

Respect Acknowledgement of individual and collective contribution, interests and aspirations;

 Acknowledgement and affirmation of the rights to have different values, norms and aspirations.

Equity Acknowledgement that all partners are equal, regardless that they may be different;

 The distribution of benefit;

 The value of collective memory and shared experience as a resource and inheritance.

Responsibility To do no harm to individuals or communities, or to those things that they value;

 Establishment of processes to ensure researcher accountability to individuals and communities, particularly with respect to cultural and social dimensions of community life.

Cultural Continuity Protection against assimilation, integration and/or subjugation of values;

 Respect for social cohesion;

 Involvement that does not diminish the right to assertion or enjoyment of cultural distinctiveness.

Spirit & Integrity Demonstration of other five values and credibility in intent and process;

 An approach that does not impede upon the richness and integrity of cultural inheritance.

Maximum 2 pages.

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**(b) If NO: Please advise *why* you believe this research does not involve, or impact upon, Aboriginal & Torres Strait Islander people. Applicants should acknowledge that, unless being specifically excluded, some participants could be Aboriginal or Torres Strait Islander people, even if they are not being targeted or identified as such.**

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**37. Community support:**

* If you intend undertaking research in a community setting, or intend to identify the community, please outline whether discussions have been held with appropriate community representatives or community organisations and detail any processes and agreements in place for the conduct of the research project.
* **Please attach letters of support from the relevant community authorities. These letters should clearly state that community authorities are aware of the aims and methods of the proposed research**.

*NS Section 2.2.13, 4.7.2, 4.7.10, 4.7.11, 4.7.12; Guidelines pp15-19; KRT pp14-16*

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**38. Ownership of traditional knowledge:**

* Who are the owners of any traditional knowledge?
* If relevant to your research, the consent form should include the clause, “*I understand that the ownership of Aboriginal knowledge and cultural heritage is retained by the informant and this will be acknowledged in research findings and in the dissemination of the research*”.

*NS 4.7; Guidelines pp16–18; KRT pp17–16*

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**Part E. SIGNATURES AND DECLARATIONS**

***RESEARCHERS’ DECLARATION***

* I certify that the information given is correct to the best of my knowledge.
* I acknowledge that I must notify the Committee in advance of any ethically-relevant variation to the project.
* I have read and agree to abide by the relevant parts of the NHMRC’s ***National Statement on Ethical Conduct in Human Research, 2007.***

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| **Principal Investigator:** |
|   |   |   |
| Name | Signature | Date |
| Does this Principal Investigator have authorisation to sign the application on behalf of the other investigators? **[ ]  YES [ ]  NO** |

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| **2nd Investigator:** |
|   |   |   |
| Name | Signature | Date |

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| **3rd Investigator:** |
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| Name | Signature | Date |

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| **4th Investigator:** |
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| Name | Signature | Date |

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| **1st Student Investigator:** |
|   |   |   |
| Name | Signature | Date |
| **2nd Student Investigator:** |  |  |
|   |   |   |
| Name | Signature | Date |

If necessary, please copy and paste to include all researcher signatures.

***INSTITUTIONAL RESPONSIBILITY****:*

1. **Department Head/ Principal Investigator’s Supervisor:**

* I certify that the information given is correct to the best of my knowledge.
* I certify that I am aware of this project and its ethical issues.
* I confirm that the Organisation/Faculty will accept responsibility for the ethical conduct of the research study as outlined above.

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Title First Name Surname

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Position Title Institution

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Date Signature

**2. Menzies School of Health Research Director or Delegate authorisation for research by Menzies School of Health Research:**

I certify that:

* I am aware of this project and its ethical issues and endorse its undertaking.
* The Institution accepts responsibility for the ethical conduct*.* of the research study as outlined above and as set out in the ***Australian Code for the Responsible Conduct of Research*** and ***National Statement on Ethical Conduct in Human Research.***
* I am aware of the resource requirements of this project and have determined they are available.
* The researchers have the expertise and skills to undertake the research competently or will undergo the training outlined in this application to attain them.

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Title First Name Surname

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Position Title

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Date Signature

**3. Applicants for research within Northern Territory Health (NT Health) should also follow the directions for Site Specific Assessment described on page 1 of this from.**

**Submission**

**When you are satisfied that your application is complete and you have referred to the checklist for all inclusions and supporting documents, please submit ALL of the below:**

* One signed electronic copy of the research ethics application plus associated documents merged into one pdf forwarded to **NTHREC@menzies.edu.au**
* Please ensure that the attachments to the research ethics application are merged and scanned with the application and emailed through as one document only, and not an email with multiple attachments.