**Human Research Ethics Committee of**

**Northern Territory Department of Health**

**and Menzies School of Health Research (EC 00153)**

***Instruction Sheet***

**Intention to Lodge a Research Ethics Application**

You are required to email the Ethics Administration Office ethics@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,* 2007.(Updated 2018)
* *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 is 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 Department of Health, Central Australian Health Service (CAHS) and Top End Health Service (TEHS).

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 ethics@menzies.edu.au (Please ensure that the attachments to the research ethics application are emailed as a single document only, and not an email with multiple attachments.)
* Please contact the ethics administrators to confirm whether or not a hard copy is also required. Please ensure that the file that you email is identical to the hardcopy file.

Delivery address:

Ethics Administrator Officer,
Menzies School of Health Research,
PO Box 41096,
Casuarina NT 0811.

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 the Northern Territory Department of Health and Menzies School of Health Research**

**RESEARCH ETHICS APPLICATION CHECKLIST**

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

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| --- | --- | --- | --- |
| **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.
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| 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.
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| 4. **CV for Principal Investigator. Summarised CV with recent relevant experience – maximum 10 pages.** * **CVs are not required for other researchers**
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| **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 ethics@menzies.edu.au)
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| 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.
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| 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/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.
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| 24. **Community Support*** Attach letters of support from relevant participating communities and organisations.
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| 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
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| 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
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| 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.
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| **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)** |  |  |  |
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| **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.
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