menzies school of health research

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Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (EC 00153)

LOW RISK HUMAN RESEARCH – GUIDELINES

SECTION 1: LOW RISK HUMAN RESEARCH – ETHICS APPLICATION PROCESS

1.1 CLASSIFYING RISK and REVIEW

The person applying for human research ethics clearance should familiarise themselves with the National Health and Medical Research Council (NHMRC), *National Statement on Ethical Conduct in Human Research, 2007, Updated 2018* (N.S.). The N.S. classifies research according to the potential degree of risk involved. (N.S. 2.1).

Low Risk Research (N.S. 2.1.6)
Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
Negligible Risk Research (N.S. 2.1.7)
Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than an inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

1.2 REVIEW REQUIREMENTS

Institutions may establish different levels of review for human research investigations that contain different levels of risk (N.S. 5.1). Investigations of any level of risk including negligible risk, being undertaken by staff, students or contractors at Menzies School of Health Research and NT Health should be assessed through the Ethics Administration Office using the processes and forms outlined below. Researchers from other organisations should check their own institution's requirements for low or negligible risk investigations. Researchers from organisations that do not have their own reviewing processes and who wish to undertake human research in the northern part of the NT may also apply through the Menzies Ethics Administration Office.

1.3 CHOOSING THE CORRECT FORM

- LOW RISK ETHICS CLEARANCE FORM
- OTHER LOW RISK HUMAN RESEARCH – RISK ASSESSMENT CHECKLIST
- HREC APPLICATION FORM

1.3.1 LOW RISK ETHICS CLEARANCE FORM

To be used by applicants undertaking any of the following human research:

- negligible/low risk quality assurance activities and audits being undertaken by students from Flinders University, Charles Darwin University, NT Clinical School, and NT Medical Program
- other low risk quality assurance activities whereby de-identified/unidentified data collected during routine clinical care is compared to a set of existing industry approved standards or standard clinical practices

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- retrospective case studies consisting of analysis of de-identified/ unidentified clinical data concerning patient(s) that were treated according to national guidelines and agreements and not subject to experimental or new protocols or primary research.

1.3.2 OTHER LOW RISK HUMAN RESEARCH – RISK ASSESSMENT CHECKLIST

- To be completed by all those who wish to apply for low risk human research ethics clearance who do not conform to the criteria outlined in section 1.3.1 including those completing more complex audits, evaluations, and some stakeholder consultations. The checklist will assist in determining whether or not your project is eligible for expedited review using the low risk research ethics clearance process.

1.3.3 HREC APPLICATION FORM

To be used by applicants undertaking:

- low risk human research that did not qualify to use the LOW RISK ETHICS CLEARANCE FORM including those undertaking more complex audits, evaluations, some stakeholder consultations and prospective case studies;

or

- human research that is greater than low risk.

These forms are available from the Menzies School of Health Research website:
http://www.menzies.edu.au/page/Research/Ethics_approval/Forms/

1.4 DETERMINING LEVEL OF RISK

Please complete the risk assessment checklist in SECTION 2 of this document to determine whether or not your project is eligible to be considered by the Low Risk Assessment Process.

1.5 COMPLETING THE APPLICATION

1.5.1 AUDIT / CASE STUDY

- The LOW RISK ETHICS CLEARANCE FORM may be submitted at any time.
- Site specific requirements apply. Refer to form for details
- Fully endorsed forms should be emailed to ethics@menzies.edu.au
- Your application will be reviewed in an expedited manner by the HREC Chair or the Fast Track Sub-Committee.

1.5.2 OTHER LOW RISK

- Please submit the RISK ASSESSMENT CHECKLIST and the HREC APPLICATION FORM at any time.
- Applications using this process are not restricted to the submission deadlines imposed on full applications for projects with greater than low risk, and may be submitted at any time and may be eligible for expedited review.
- Projects deemed to be of low risk will be assessed by the Fast Track sub-committee of the HREC in an expedited manner. The HREC administration will endeavour to provide the researcher with a decision within three weeks following submission.
- If the project is deemed by the sub-committee to present a greater than low risk, the researcher will be notified within three weeks and the application will be assessed by the full HREC at its next meeting.

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- Completed checklists and application forms should be emailed to ethics@menzies.edu.au and a hard copy delivered to Menzies School of Health Research.

1.5.3 GREATER THAN LOW RISK

- Please submit a completed HREC APPLICATION FORM by the submission deadlines listed on the Menzies School of Health Research website. http://www.menzies.edu.au/page/Research/Ethics_approval
- The application will be reviewed by the full HREC at its next meeting.
- Completed application forms should be emailed as a single pdf file to ethics@menzies.edu.au and a hard copy delivered to Menzies School of Health Research.

Please ensure that:

- the completed risk assessment checklist is attached if low risk
- all required signatures have been obtained*
- copies of Information Sheets, Consent Forms, Research Instruments (survey, interview questions etc) and support or approval letters from participating organisations* as appropriate have been attached
- data collection does not commence until written approval has been received from the Chair of the Human Research Ethics Committee.

***Please note:**

- *All research conducted by Menzies School of Health Research staff and students must be signed off by the Menzies Director.*
- *Some projects may require support from other bodies e.g. data custodians, professional bodies, community health boards*
- *Top End Health Service Sites: All research studies conducted at Top End Health Service Sites (Royal Darwin Hospital, Palmerston Regional Hospital, Katherine Hospital, Gove District Hospital, Top End Mental Health & AOD services, Top End Primary Health Care) require Organisational Site Specific Authorization prior to submission to the TEHREC. The Research Governance Office (RGO) at Top End Health Service will facilitate this process, ensuring that the principles, requirements and standards for organisational governance of research are implemented.*

  Of priority for the RGO is involvement of TEHS staff at the outset of the research process. To this end, endorsement by Unit heads, Divisional Co-Directors/General Managers is an integral component of the governance process.

  Researchers are advised to include evidence of endorsement by the local TEHS Unit head and Co-Director or General Manager prior to submission to the RGO by completing the relevant sections at the end of the low risk application form, or by submitting email endorsement when lodging the form via rgo.tehs@nt.gov.au. Please ensure that email endorsements include the project title.
  The completed form is submitted electronically first to the Top End Health Service (TEHS) Research Governance Office (rgo.tehs@nt.gov.au) for site specific assessment (SSA), then to the TEHREC (ethics@menzies.edu.au).

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LOW RISK HUMAN RESEARCH – GUIDELINES

SECTION 2: RISK ASSESSMENT CHECKLIST

2.1 INVESTIGATOR INFORMATION

Title of project		
Name of Chief Investigator (CI)		
Will the project describe or analyse routine care, or the data obtained from routine care, such as to determine adherence to guidelines or standard clinical practice, or to record the results of routine care? AND Is the risk that individuals may be identified in reports or publications resulting from this investigation considered to be negligible?	Yes ☐	No ☐
Is the investigation a retrospective case study/series consisting of analysis of data concerning patient(s) that were treated under routine care according to national guidelines and agreements and not subject to experimental or new protocols or primary research? AND Is the risk that individuals may be identified in reports or publications resulting from this investigation considered to be negligible?	Yes ☐	No ☐

If **YES** to any question in 2.1, then it is not necessary to complete the remainder of the checklist. Please complete the **AUDIT / CASE STUDY – ETHICS CLEARANCE APPLICATION FORM**. All other researchers applying for low risk ethics clearance including those conducting other audits, evaluations, prospective case studies, and some stakeholder consultations must complete the remainder of the low risk checklist and submit the checklist with a completed HREC Application Form for expedited review.

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2.2 SPECIFIC HUMAN RESEARCH CATEGORIES

Will the following categories of people be specifically targeted or likely to be targeted as direct participants? (*National Statement 5.1.6*)		
Female participants who are pregnant and/or the human foetus (N.S. 4.1)	Yes ☐	No ☐
Participants who are highly dependent on medical care who may not be able to give consent (N.S. 4.4)	Yes ☐	No ☐
Participants with a cognitive impairment, an intellectual disability, or a mental illness (N.S. 4.5)	Yes ☐	No ☐
Participants belonging to the Aboriginal or Torres Strait Islander People (N.S. 4.7)	Yes ☐	No ☐
Participants who may be involved in illegal activities, where the research is intended to study or expose illegal activity (N.S. 4.6)	Yes ☐	No ☐
Will the research involve any of the following? (*National Statement 5.1.6*)		
Interventions and/or therapies, including clinical and non-clinical trials, and innovations (N.S. 3.3)	Yes ☐	No ☐
Human genetics, epigenetics or human stem cells. (N.S. 3.5)	Yes ☐	No ☐

2.3 PARTICIPANT VULNERABILITY – OTHER RISKS

Will the following categories of people be specifically targeted or likely to be targeted as direct participants?		
Participants with an unequal or existing relationship with the researcher e.g. student/teacher, colleague, employer/employee, relative, friend.	Yes ☐	No ☐
Participants aged less than 18 years	Yes ☐	No ☐
Members of any socially identifiable group with special cultural or religious needs or political vulnerabilities	Yes ☐	No ☐
Residents of a custodial institution.	Yes ☐	No ☐
Will the research involve any of the following?		
Risk to participants that is greater than discomfort (discomfort may include minor side effects related to measuring blood pressure and anxiety induced by an interview (N.S. 2.1)	Yes ☐	No ☐
Participants who are identifiable in any final report or presentation when specific consent will not be sought or given.	Yes ☐	No ☐
Participants who are unable to give free and informed consent because of difficulties in understanding information provided (e.g. language difficulties or not of an English speaking background)	Yes ☐	No ☐
Research in a country other than Australia (N.S. 4.8)	Yes ☐	No ☐

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Some form of deception or covert observation.	Yes ☐	No ☐
Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities.	Yes ☐	No ☐
Randomisation or the use of control groups or placebos.	Yes ☐	No ☐
The use without consent of personal information in medical research , and personal health information (N.S. s2.3.9)	Yes ☐	No ☐
Testing of non-standard protocols and equipment.	Yes ☐	No ☐
Sampling of tissue, blood or any bodily fluid or DNA extraction.	Yes ☐	No ☐
Are any of the following topics covered in part or in whole?		
Research about parenting issues	Yes ☐	No ☐
Research investigating sensitive personal or cultural issues	Yes ☐	No ☐
Explorations of grief, death or serious/traumatic loss	Yes ☐	No ☐
Mental disorders e.g. Depression, mood states, anxiety	Yes ☐	No ☐
Gambling	Yes ☐	No ☐
Eating Disorders	Yes ☐	No ☐
Illicit drug use/ Substance abuse (prescription or over the counter)	Yes ☐	No ☐
Self-report of criminal behaviour	Yes ☐	No ☐
Any psychological disorder	Yes ☐	No ☐
Suicide risks/anger management	Yes ☐	No ☐
Gender identity/ Sexuality	Yes ☐	No ☐
Race or ethnic identity	Yes ☐	No ☐
Fertility/ Termination of pregnancy	Yes ☐	No ☐
Establishment of a new Register or Databank.	Yes ☐	No ☐
Establishment of cord blood, DNA, or tissue banks.	Yes ☐	No ☐
Are any of the following procedures to be employed?		
Use of personal data obtained from a Commonwealth or State Government Department/Agency with participant consent	Yes ☐	No ☐
Deception of participants or concealing the purposes of the research	Yes ☐	No ☐
Audio or visual recording without consent	Yes ☐	No ☐
Recruitment of a third party or agency (asking participants to provide information about another person)	Yes ☐	No ☐
Withholding from one group specific treatments or methods of learning from which they may 'benefit' (eg medicine or teaching)	Yes ☐	No ☐
Psychological interventions or treatments	Yes ☐	No ☐

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Experimental manipulation or includes the presentation of any stimulus other than question-asking.	Yes ☐	No ☐
Non-standard application or variation of existing interventions and/or therapies outside currently accepted guidelines	Yes ☐	No ☐
Application of physical stimulus/Invasive physical procedures/Infliction of pain	Yes ☐	No ☐
Administration of drugs/ Administration of other substances or devices	Yes ☐	No ☐
Exposure to ionising radiation	Yes ☐	No ☐
Use of medical records where participants can be identified or linked	Yes ☐	No ☐
Risks to researchers		
Are there risks to the researcher? (eg research conducted in unsafe environments or trouble spots including politically unsafe areas)	Yes ☐	No ☐
Risks to non-participants		
Are there risks to non-participants in the research, such as participant's family members and social community? (eg effects of biography on family and friends or infectious disease risk to the community)	Yes ☐	No ☐

2.4 RISK MITIGATION

Does the research involve only a negligible risk where there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than an inconvenience? (*NHMRC National Statement 5.1.6, 5.1.22, 2.1.7*)	Yes ☐	No ☐
Does the research involve only the use of existing collections of data or records that contain only non-identifiable data about human beings? (*NHMRC National Statement 5.1.6, 5.1.22*)	Yes ☐	No ☐

2.5 CHECKLIST OUTCOME

1. If **NO** has been selected for all questions in Sections 2.2 and 2.3, the project is likely to be eligible for expedited review under the Low Risk Assessment Process. Please complete an HREC Application Form and submit together with the completed checklist and all required attachments as described in Section 1.4 of this document to the Menzies Ethics Administration Office: ethics@menzies.edu.au
   Please find the application form here:
   http://www.menzies.edu.au/page/Research/Ethics_approval/Forms/HREC_Application_Form/

2. If you have selected **YES** to any of the items in Sections 2.2 and 2.3, AND **YES** in section 2.4, the project is also likely to be eligible for expedited review under the Low Risk Assessment Process.

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3. If you answered **YES** to section 2.2 but **NO** in section 2.4 your research is unlikely to be eligible for Low Risk expedited review and an HREC Application Form must be submitted by the next deadline for review by the full HREC.

4. If you answered **YES** to any item in Section 2.2 and 2.3 of the checklist but believe that your proposal may still be considered to be of negligible or low risk due to the nature of the participants or the project, please contact the HREC secretariat ethics@menzies.edu.au to determine whether or not Low Risk Assessment can proceed. Justification may be required to accompany the HREC Application Form.

Please provide justification here:

If after consultation with the HREC secretariat, it is advised that the project is likely to be eligible for expedited review under the Low Risk Assessment Process. Please complete an HREC Application Form and submit together with the completed checklist and all required attachments as described in Section 1.4 of this document to the Menzies Ethics Administration Office: ethics@menzies.edu.au
Please find the application form here:
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