NT Department of Health and Families and
Menzies School of Health Research

Human Research Ethics Committee of the NT Department of Health & Families and the Menzies School of Health Research
(AHEC Code No: EC00153)

Policy and Procedures Manual

Third Edition
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1. Abbreviations

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<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>AESC</td>
<td>Aboriginal Ethics Sub-Committee of the HREC</td>
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<td>AHEC</td>
<td>Australian Health Ethics Committee</td>
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<tr>
<td>Aust. Code</td>
<td>Australian Code for the Responsible Conduct of Research</td>
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<td>CDU</td>
<td>Charles Darwin University</td>
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<td>CT</td>
<td>Clinical Trial</td>
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<td>DHF</td>
<td>Department of Health and Families</td>
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<td>DSMB</td>
<td>Data Safety Monitoring Board</td>
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<td>HoMER</td>
<td>Harmonisation of Multi-centre Ethical Review</td>
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<td>HREC</td>
<td>Human Research Ethics Committee of the Northern Territory Department of Health and Families and the Menzies School of Health Research, unless otherwise specified</td>
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<td>Menzies</td>
<td>Menzies School of Health Research</td>
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<td>NEAF</td>
<td>National Ethics Application Form</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NS</td>
<td>National Statement on Ethical Conduct in Human Research 2007</td>
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<td>NT</td>
<td>Northern Territory</td>
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<tr>
<td>NTDHF</td>
<td>Northern Territory Department of Health and Families</td>
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<tr>
<td>PIS</td>
<td>Participant Information Statement</td>
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<tr>
<td>QAAR</td>
<td>Quality Assurance, Audit Registration</td>
</tr>
<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
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<tr>
<td>SUE</td>
<td>Serious Unexpected Event</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>WWCC</td>
<td>Working With Children Clearance</td>
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2. Introduction

The Human Research Ethics Committee (HREC) of the Northern Territory (NT) Department of Health and Families (DHF) and the Menzies School of Health Research (Menzies) is a joint committee of NT DHF and Menzies. The Australian Health Ethics Committee (AHEC) code number for this HREC is EC00153.

The Committee’s role is to consider the ethical aspects of human research conducted by the NT DHF, Menzies, other organisations from the Northern Territory which do not have their own human research ethics committee, and human research projects being conducted in the Top End by interstate or overseas research organisations.

Under the Harmonisation of Multi-centre Ethical Review (HoMER) scheme, this HREC may also consider applications for the review of human research that will be conducted elsewhere in Australia and not just in the Top End of the Northern Territory.

The only other organisation in the Top End that has a human research ethics committee is the Charles Darwin University (CDU). Human research being conducted in Central Australia is considered by the Central Australian Human Research Ethics Committee of the NT DHF.

The HREC operates under the guidelines established by the AHEC, a sub-committee of the National Health and Medical Research Council (NHMRC).

2.1 National Statement on Ethical Conduct in Human Research

The National Statement on Ethical Conduct in Human Research 2007 (NS) is the authoritative Australian document on ethical principles and standards of practice in health research. It was jointly developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors’ Committee and released by the Australian Government in March 2007.

The Statement also covers the responsibilities of institutions in which health research is conducted, including the requirements that each institution:

- establish and support a HREC to consider the ethical aspects of proposed research
- monitor the conduct of research that has been approved by the HREC
- establish and support a process to receive and consider any complaints about the conduct of research projects.

The NHMRC will not fund research which does not meet these standards, or which is conducted in institutions which do not meet these standards.

This Statement is not ‘legislation’, and so is not directly enforceable through legal processes, but it would be expected that the courts would regard it as an authoritative statement of ‘acceptable practice’ in human research.

All researchers submitting applications to the HREC are required to have read the NS, and other documents such as the Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research and the Australian Code for the Responsible Conduct of Research (Aust. Code) before submitting an application to the HREC. These documents can be obtained from the NHMRC web-site:

http://www.nhmrc.gov.au
3. Terms of Reference

3.1 Auspicing Institutions

The Human Research Ethics Committee of the Northern Territory Department of Health and Families and the Menzies School of Health Research (HREC) is established by the Governing Board of the Menzies School of Health Research (Menzies) and the Chief Executive Officer of Northern Territory Department of Health and Families (NT DHF) to operate as the Human Research Ethics Committee for each institution. The Committee operates in accordance with the National Statement on Ethical Conduct in Human Research 2007 (NS), issued by the National Health and Medical Research Council (NHMRC).

3.2 Scope of HREC

The Committee’s role is to consider the ethical aspects of human research conducted by the NT DHF, Menzies, other organisations from the Northern Territory that do not have their own human research ethics committee, and human research projects being conducted in the Top End by interstate or overseas research organisations.

Under the Harmonisation of Multi-centre Ethical Review (HoMER) scheme, this HREC may consider applications for the review of human research that will be conducted elsewhere in Australia and not just in the Top End of the Northern Territory.

The committee may accept the review and approval granted by another accredited lead HREC for multi-centre research under the HoMER system when the application is lodged on a National Ethics Application Form (NEAF) and includes Part D. Aboriginal & Torres Strait Islander Research of the NT DHF & Menzies HREC application form. Approval is subject to review by the Aboriginal Ethics Sub-Committee of the HREC.

The only other organisation in the Top End that has a human research ethics committee is the Charles Darwin University (CDU). Human research being conducted in Central Australia is considered by the Central Australian Human Research Ethics Committee of the NT DHF.

3.3 Roles and Responsibilities of HREC

The Committee shall perform the following functions:

3.3.1 Consider ethical implications of all proposed human research projects and determine whether or not they are acceptable on ethical grounds.

3.3.2 Monitor human research projects until completion so that the Institutions may be satisfied that they continue to conform with approved ethical standards.

3.3.3 Maintain a record of all human research projects considered by the Committee. The applications for human research projects shall be preserved in the form in which they are approved, including any amendments subsequent to approval.

3.3.4 Maintain communication with the NHMRC’s Australian Health Ethics Committee (AHEC) and provide access, upon request, to information in the HREC’s records.

In carrying out its functions, the HREC:

3.3.5 conforms with the NS and other guidelines on human research in particular fields that may be published from time to time.

3.3.6 takes account of local circumstances and cultural sensitivities.
3.3.7 ensures that procedures relating to participants’ consent to be involved in research projects are observed.

3.3.8 ensures that no member of the HREC adjudicates on proposals in which they may be personally involved (directly or indirectly).

3.3.9 will maintain the confidentiality of all matters relating to proposals under consideration by the HREC.

3.3.10 will not at present be remunerated, as appointment to the HREC is voluntary. This policy is currently under review.

### 3.4 Membership

Members are appointed for a two-year term commencing 1st January in the relevant year or such other time as a vacancy occurs. Members may be re-appointed at the end of each two-year term for a maximum of three terms.

Members of the HREC are appointed by the Chief Executive Officer, NT DHF, in accordance with the criteria specified in the NS Section 5.1.29–5.1.36:

3.4.1 A Chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under the National Statement

3.4.2 A Deputy Chairperson, with experience equivalent to the Chair, who can fulfil the role of Chair on a short term basis if required

3.4.3 At least one lay woman not associated with either NT DHF or Menzies and who does not currently engage in medical, scientific, legal or academic work

3.4.4 At least one lay man not associated with either NT DHF or Menzies and who does not currently engage in medical, scientific, legal or academic work

3.4.5 At least one person who performs a pastoral care role in a community, for example, a Minister of religion or an Aboriginal elder

3.4.6 A lawyer, preferably one who is not engaged to provide an advisory service to the institutions

3.4.7 At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional

3.4.8 At least two people with current research expertise that is relevant to the research proposals under review at a particular meeting. These can be sourced from the list of additional appointments as required (See 3.4.8).

3.4.9 Additional appointments, specific to this HREC include:

- one member with experience of clinical service delivery in a hospital setting
- one member with experience of clinical service delivery in an Aboriginal community setting
- one member with experience in clinical research
- one member with experience in social science research
- one member with experience in epidemiological research
- one member with experience in laboratory research
- the Chair (or nominee) of the Aboriginal Ethics Sub-Committee
3.4.10 One member with clinical experience is nominated as the ‘clinical adviser’, and one
with research experience as the ‘research adviser’, to consider in more detail technical
aspects of complex projects when necessary.

3.4.11 The Ethics Administration Officer is appointed by the Menzies School of Health
Research and is not a member of the Committee.

3.5 HREC Reporting Procedure

3.5.1 The HREC reports annually to the Governing Board of the Menzies School of Health
Research and the Executive Committee of NT Department of Health and Families.

The HREC annual report includes:
- list of members, including category and period of membership and number of
  meetings attended
- number of applications received
- number of applications approved, resubmitted, not approved
- monitoring process
- number of projects notified as completed
- number of projects with approved status at the end of the reporting period
- number of projects which have submitted an annual report form by the due
date
- number of complaints received and outcome.

3.5.2 Minutes of each HREC meeting are submitted to the Board of the Menzies School of
Health Research which includes the Chief Executive of the NT DHF and the Vice
Chancellor of CDU.

3.5.3 The HREC provides regular reports to the AHEC in accordance with NHMRC
requirements.

3.5.4 HREC Terms of Reference, Procedures manual, membership list, meeting dates and
submission deadlines are available on the HREC page of the Menzies website
www.menzies.edu.au
4. Sub-Committees Structure and Function

As well as the main HREC there are two sub-committees of the HREC:
- the Aboriginal Ethics Sub-Committee (AESC)
- the Fast Track Committee.

4.1 Aboriginal Ethics Sub-Committee Terms of Reference

The principal role of the AESC is to ensure that Aboriginal people benefit from research being conducted on Aboriginal people, in Aboriginal communities and on Aboriginal health issues.

4.1.1 Scope of the AESC

4.1.1.1 The AESC exists as a separate committee to the HREC because Aboriginal people have greater confidence to discuss research proposals and consider issues important to them in a separate forum, which allows freer discussion of Aboriginal cultural issues without domination by technical advice and expert opinion.

4.1.1.2 In considering health research proposals, members are guided by the NS, the NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, and principles and priorities specific to Aboriginal people in the NT including promoting education of Aboriginal people in the conduct of research, and promoting employment opportunities for Aboriginal people in health research.

4.1.2 Roles and responsibilities of the AESC

4.1.2.1 To protect the interests of Aboriginal people involved in health research, and of the wider Aboriginal community affected by health research.

4.1.2.2 To ensure research is conducted in a culturally appropriate manner.

4.1.2.3 To consider the ethical issues involved in research proposals from the perspective of Aboriginal people, with particular attention to the specific interests of Aboriginal participants in research projects and the interests of Aboriginal communities affected by research projects.

4.1.2.4 To advise the HREC of ethical issues in relation to each research proposal involving Aboriginal people, to advise of recommendations to improve each proposal, and to advise of decisions of the Sub-Committee on whether to approve each proposal.

4.1.2.5 To ensure research projects involving Aboriginal people will benefit Aboriginal people.

4.1.3 AESC Reporting

4.1.3.1 The AESC reports to the HREC through the Sub-Committee Chair (or delegate) as a member of the HREC, and through the minutes of the Sub-Committee.

4.1.3.2 The HREC will not over-rule a decision of the AESC that a research proposal should not be approved (i.e. the Sub-Committee has the right of veto over applications that involve or possibly impact on Aboriginal people).

4.1.3.3 Where the HREC disagrees with such a decision the Chair of the HREC will advise the Principal Investigator of the research proposal of the Sub-Committee’s decision and reasons for it.

4.1.3.4 Where the HREC disagrees with an AESC decision the Chair of the HREC will advise the Sub-Committee in writing of the reasons why the HREC disagrees with
the Sub-Committee decision, and request that the Sub-Committee work towards a consensus with the HREC.

4.1.3.5 A minimum of three members must be present at each Sub-Committee meeting. If less than three members are present and another meeting cannot be scheduled before the next meeting of the HREC, the Sub-Committee meets informally to provide advice to the HREC. This advice is taken by the HREC as final advice on all research proposals considered. An informal Sub-Committee meeting does not have the right of veto described above.

4.1.4 AESC Membership

4.1.4.1 The members of the Sub-Committee are Aboriginal people including at least one member in each of the following categories:

- a person with experience in health service delivery in government run health services
- a person with experience in health service delivery in Aboriginal Medical Services
- a person with experience in health research
- a community member not engaged in health research or service delivery
- a male Aboriginal Elder
- a female Aboriginal Elder.

4.1.4.2 The Sub-Committee also has two non-voting members who may not be Aboriginal people:

- a scientific adviser with expertise and broad experience in health service delivery and health research and
- a secretary.

4.1.4.3 All vacancies on the AESC are advertised throughout Menzies and the NT DHF, Aboriginal organisations and the local press as appropriate, and by seeking interested people through networks in the Aboriginal community.

4.1.4.4 Applications for AESC membership are considered by a selection panel consisting of the Chair of the HREC and two members of the Aboriginal Sub-Committee, at least one having relevant health service delivery/research experience.

4.1.4.5 The selection panel considers applications for membership and may interview potential members if necessary. The selection panel makes a recommendation, via the HREC Chair, to the Chief Executive Officer, NTDHF, on suitable applicants for appointment.

4.1.4.6 Members are appointed for a two-year term commencing 1st January in the relevant year or such other time as a vacancy occurs. Members may be re-appointed at the end of each two-year term, to a maximum of three terms.

4.1.4.7 At the expiry of each member’s term, the Chair will advise the Chief Executive Officer, NTDHF, on whether to re-appoint the retiring member or advertise the vacancy based on the interest of the retiring member in re-nominating for membership; the attendance record of the retiring member at meetings; the performance of the duties of members as specified in the relevant duty statement; the balance of the experience required on the committee.

4.1.4.8 Should the member’s term be renewed, the Chair of the HREC will advise the Director of Menzies of the renewal.
4.2 Fast Track Committee Terms of Reference

4.2.1 The Fast Track Committee is responsible for considering new applications for research projects with relatively minor ethical implications as defined in the NS Chapter 2.1 Risk and Benefit and Chapter 5.1.18–5.1.21 for research involving no more than low risk.

4.2.2 Applications that have been considered by the HREC and require revisions prior to approval may also be delegated to the Fast Track Committee for consideration and final approval.

4.2.3 The Fast Track Committee membership will rotate through the members of the main Human Research Ethics committee and the Aboriginal Sub-Committee. It will consist of:

- one lay person, lawyer or minister of religion
- one member of the Aboriginal Sub-Committee
- one member with research experience
- one member with health service delivery experience.

4.2.4 One of these members will be appointed by the main committee as Chair of the Fast Track Committee for a period of 6 months commencing with the first meeting in each calendar and financial year. Other members will be appointed for the period between each meeting of the HREC.

4.2.5 The Chair of the Fast Track Committee provides a written report to each meeting of the HREC summarising decisions made by the Fast Track Committee since the previous HREC meeting.

4.2.6 The decisions of the Fast Track Committee are ratified at the HREC meeting.

4.2.7 If the Fast Track Committee decides that the level of risk is not minimal, the applications will be referred to the full HREC.

4.2.8 Any research applications approved by the Fast Track Committee will be subject to the same monitoring procedures as those projects approved by the full HREC.
5. Committee Processes

5.1 Appointment of HREC Members

5.1.1 All vacancies are advertised throughout both Menzies and the NTDHF and the local press as appropriate.

5.1.2 Applications for Committee membership are considered by a selection panel consisting of

- the Chair
- one member with experience in health research or service delivery
- one member without research or service delivery experience
- one member of the Aboriginal Sub-Committee.

5.1.3 The selection panel considers written applications for membership, and may interview potential members if necessary. The selection panel makes a recommendation to the Chief Executive Officer, NTDHF, on suitable applicants for appointment.

5.1.4 Letters of appointment, including assurance of indemnity, are signed by the Chief Executive Officer, NTDHF. The Director of Menzies is advised of appointments and prepares a letter of welcome to the HREC.

5.1.5 Upon acceptance of appointment, members are advised of the requirements for confidentiality regarding Committee deliberations and the content of applications before the Committee, and sign a confidentiality agreement to this effect.

5.1.6 On appointment, members are asked to declare any existing conflicts of interest that will affect their ability to participate in the HREC. Members agree to inform the Chair of any conflicts of interest should they arise during the term of their membership. Members accept that they may be excluded from discussions and decision making if a significant conflict of interest occurs.

5.1.7 Members are appointed for a two-year term commencing 1 January in the relevant year or such other time as a vacancy occurs. Members may be re-appointed at the end of each two-year term, to a maximum of three terms. At the expiry of each member’s term, the Chair will advise the Chief Executive Officer, NTDHF, on whether to re-appoint the retiring member or advertise the vacancy based on:

- the interest of the retiring member in re-nominating for membership
- the attendance of the retiring member at meetings
- the performance of the duties of members as specified in the relevant duty statement
- the balance of the experience required on the Committee.

5.1.8 Should the member’s term be renewed, the Chair of the HREC will advise the Director of Menzies of the renewal.

5.1.9 The Ethics Administration Officer must be advised of and record all offers, acceptances, confidentiality agreements, and conflicts of interest. Copies of all correspondence and agreements must be retained on the HREC files with the Ethics Administration Officer.

5.1.10 The Chair is nominated by the HREC and appointed by the Chief Executive Officer, NTDHF

5.1.11 The Deputy Chair is nominated and approved by the HREC to fulfil the role of Chair if required.
5.2 Conflicts of Interest

In accordance with the NS Section 5.4 an ethical review body requires its members and any experts from which it seeks advice to disclose any actual, perceived or potential conflict of interest in research that is to be reviewed.

5.2.1 Existing conflicts of interest will be declared on appointment to the Human Research Ethics Committee of the Northern Territory Department of Health and Families and Menzies School of Health Research.

5.2.2 Any conflicts of interest that arise during the term of appointment to this HREC will be communicated to the Chair of the HREC either in writing before each meeting or verbally at each meeting where it will be recorded in the Minutes.

5.2.3 Where a conflict of interest exists, the significance of conflict will be determined by the remaining members of the HREC. Members or advisors with that conflict may be requested to withdraw from any discussion or decision-making regarding applications with which they have the conflict of interest. The absence of the member concerned will be noted in the Minutes.

5.2.4 A conflict of interest will include any:
- Personal involvement or participation in research under review
- Personal relationship with a researcher or researchers under review
- Financial interests in research under review
- Involvement in competing research.

5.2.5 On occasions when the Chair is absent or excluded because of a conflict of interest, the Deputy Chair will assume the position of Chairperson. If both the Chairperson and the Deputy Chairperson are absent or excluded, the meeting will appoint a chair.

5.3 Training of HREC Members

New HREC members attend an induction session with the Ethics administration officer and must complete an online training module (see below). They are paired with a more experienced HREC member in a mentoring role. Further training opportunities are offered to HREC members when they become available.

5.3.1 Induction

New members of the HREC attend an induction session where the ethics administration officer gives an introduction to the ethics approval process, privacy issues and how the committee operates in accordance with the National Statement on Ethical Conduct in Human Research.

The initial induction session includes the following items:
- Power point presentation: Ethics and privacy are not footnotes.
- List of meeting dates for next 12 months.
- HREC Policy & Procedures Manual
- HREC Proposal evaluation check sheet.
- Fast track processing flowchart
- Clarifying Conflicts of Interest discussion paper
- Conflict of Interest Declaration Form
- Confidentiality Agreement
NH&MRC National Statement on Ethical Conduct in Human Research

Aboriginal and Torres Strait Islander resource package:

Keeping research on track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics

Values and ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander Health Research

NH&MRC Australian Code for the Responsible Conduct of Research

NH&MRC Challenging Ethical issues in contemporary research on Human Beings

Useful reading:


Weblinks:


Other required reading not contained in induction pack:

Publications available from Ethics administrator:

Use and disclosure of genetic information to a patient’s genetic relatives under Section 95AA of the Privacy Act 1988 (Cth). Guidelines for health practitioners in the private sector. Issued by NHMRC 2009.


Ethics and the exchange, sale of and profit from products derived from human tissue: An issues paper. NHMRC public consultation draft. 2009.

Publications not available from Ethics administrator:

NH&MRC Monitoring and reporting of safety for clinical trials involving therapeutic products

Human research ethics committees and the therapeutic goods legislation


**Miscellaneous:**
Relevant articles are tabled at HREC meetings to keep the HREC up to date with ethics issues and are available from the HREC administrator.

### 5.3.2 Mentorship

Individual mentorship is available from the administration officer and all new members are teamed with an existing member as a mentor “buddy”.

### 5.3.3 Further Training

Following the induction, all HREC members are encouraged to participate in the following training activities:

- The Office for Human Protections (USA) online training program available at: [http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp](http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp)
- The Monash University Online Training in Ethics for Human Ethics Research Committee members [http://www.cems.monash.org/online-ethics-training-course.html](http://www.cems.monash.org/online-ethics-training-course.html)
- Workshops and seminars relevant to the roles of the HREC that are presented from time to time at Menzies and the DHF
- Regular monitoring of the NHMRC website and Tracker for any updates.
- Training workshops which may be offered at other institutions.

### 5.4 Vacating Membership

#### 5.4.1 Appointment of a member may be terminated by the Chief Executive Officer of NTDHF if a member:

- Resigns by giving written notice to the Chair or the Ethics Administration Officer;
- Dies or due to mental or physical ill-health becomes incapable of performing membership duties;
- Is absent from more than 3 consecutive meetings;
- Is absent from 3 committee meetings in a calendar year without tendering written comments on research proposals and an apology to the Chair, and the Committee has recommended the appointment be terminated

#### 5.4.2 When a vacancy in membership arises, the vacancy will be advertised and a new member will be appointed for a term commencing immediately and continuing until 31 December two years post appointment.

#### 5.4.3 Due to the requirement to maintain minimum numbers and appropriate composition of membership, leave of absence from the Committee or a Sub-Committee for more than three consecutive meetings will not be approved.

#### 5.4.4 The Chair of the HREC will advise the CEO of NTDHF and the Director of Menzies, of terminating appointments.

#### 5.4.5 The Ethics Administration Officer must be advised of and record all cessations of appointment.
5.4.6 Vacating HREC members will be asked to complete a clearance form relating to confidential material when they terminate their position on the committee.

5.4.7 Vacating HREC members will also be invited to complete a voluntary exit questionnaire to provide feedback to the HREC relating to its operating procedures.

5.4.8 Vacating HREC members are presented with a certificate with details of their meeting attendance.

5.5 Administrative Support

5.5.1 Administrative support to the HREC will be provided by staff of the Menzies School of Health Research.

5.5.2 Ethics administration staff members are given the same induction presentation as new HREC members (section 5.3.1).

5.5.3 Detailed administrative processes are contained in the Menzies Research Administration Unit’s document *Standard Operating Procedures: Ethics Officer (Human Ethics)*.

5.5.4 The Ethics admin team participate in on-the-job training, monitor NHMRC updates and current literature, and attend seminars and other training opportunities when accessible.

5.6 Frequency of Meetings

5.6.1 The HREC usually meets six times per year on the 3rd Wednesday of February, April, June, August, October, and 2nd Wednesday in December) The closing date for applications is usually three weeks prior to the meeting date. Please contact the Ethics Administration Officer to confirm meeting and closing dates. (Submission deadlines and meeting dates are also available on the HREC page of Menzies School of Health Research website www.menzies.edu.au.

5.6.2 The Aboriginal Sub-Committee meets one week before the HREC, on the 2nd Wednesday of the same months. The Fast Track Committee meets electronically as required.

5.6.3 HREC Members are informed of meeting dates for each year by the August meeting of the preceding calendar year.

5.6.4 Members are reminded in writing of meeting dates at the start of each calendar year, at the end of each meeting where it is recorded in the agenda and minutes, and 2 weeks before each meeting when relevant papers are distributed.

5.6.5 Meetings of the HREC and AESC are held in the Board Room at the Menzies School of Health Research unless the meetings coincide with a meeting of the Menzies Board, in which case the HREC will meet in other suitable meeting rooms.

5.7 Attendance of HREC members at Meetings

5.7.1 Members are expected to attend each scheduled bi-monthly meeting and a quorum will be 50% + 1 of the registered members.

5.7.2 Prior to attendance at the meeting Members are expected to have read all documents and completed an evaluation sheet for each application to be considered. The Ethics Administration Officer may also assign to each HREC member one or more applications for which a member is required to prepare a brief summary and introduction for the meeting.

5.7.3 In the event that a member is unable to attend a meeting, they should provide advice in writing in advance to the Chair or the Ethics Administration Officer. A member
who is unable to attend the meeting should also provide to the Chair or the Ethics Administration Officer a completed evaluation sheet for each application to be considered prior to the commencement of the meeting. If written evaluations are received for each application under review, this advice will constitute attendance at the meeting.

5.7.4 At the end of each meeting, members are required to provide the Ethics Administration Officer with their completed evaluation sheets and, with the exception of the NTDHF Manager Freedom of Information & Privacy, to return all applications to the Ethics Administration Officer for confidential disposal. The NTDHF Manager Freedom of Information & Privacy retains a full set of meeting papers as the formal records of the HREC for the NTDHF.

5. 8 Attendance of Observers and Advisers at Meetings

In accordance with the NS Chapter 5.2.18 – 5.2.20:

5.8.1 The Chair of the HREC may invite persons who are interested in being appointed as members to an HREC meeting as an observer in order to assist the individual to make an informed decision regarding their potential involvement. In such cases, the observer must be asked to sign a confidentiality agreement with regard to the knowledge obtained during the course of their observations.

5.8.2 The Chair of the HREC may invite the Principal Investigator to attend the HREC meeting where it is felt that further explanation of a research project may assist the Committee members, but this is not a common practice. The visiting researcher will be asked to sign a confidentiality agreement at the start of the meeting.

5.8.3 The HREC may invite the Principal Investigator of a research project with an existing approval to provide a presentation to the HREC on the project’s conduct and progress. The visiting researcher will be asked to sign a confidentiality agreement at the start of the meeting.

5.8.4 The HREC may request the attendance of advisers at HREC meetings. Such advisers are bound by the same confidentiality agreements as HREC members and confidentiality agreements are signed before the expert attends a HREC meeting. Experts invited to elaborate on a specific application being considered by the HREC will attend the HREC meeting for the time that application is being discussed only. Declaration of potential conflict of interest are requested at the meeting and recorded in the meeting minutes. If a conflict of interest is declared by the expert they will be asked not to continue with discussion of the specific application and must leave the meeting until discussion of that application is finished.

5.8.5 Other persons may be invited to observe meetings from time to time. In all cases, their attendance should be approved by the Chair in advance of the meeting and confirmed by the members of the HREC prior to their attendance; their attendance will be recorded in the Minutes of the Meeting; and the observer will be expected to sign a confidentiality agreement with regard to the knowledge obtained during the course of their observations.

5. 9 Expert advisers

5.9.1 Aboriginal and Torres Strait Islander perspectives on appropriate human research are sought from the AESC, the Menzies Indigenous Development Unit and the Menzies Indigenous Reference Group.
5.9.2 The close proximity of this HREC to Royal Darwin Hospital and its affiliation with CDU ensures that advice may be sought from a pool of specialists and consultants as required.

5.9.3 Advisers are required to complete a confidentiality agreement and declare any conflicts of interest.

5.9.4 The attendance of advisers at meetings may be requested and this attendance is subject to sections 5.8.4 and 5.8.5 above.
6. **Who should apply to the HREC?**

The HREC considers the ethical aspects of research projects.

### 6.1 Researchers

6.1.1 All research projects being conducted by staff of the NT DHF or Menzies

6.1.2 External researchers in health services funded by the NT DHF must be approved by the HREC.

6.1.3 Researchers from other institutions who wish to access NT DHF facilities, resources, and data.

6.1.4 Students who are enrolled at Charles Darwin University via Menzies, and are undertaking health research projects, are required to apply to the HREC. For these projects, the Ethics Administration Officer will advise the CDU HREC of the outcome of the application.

6.1.5 Students enrolled at CDU but who are not affiliated with Menzies should consult the CDU HREC regarding ethics applications. Sections 6.1.3, 6.1.6, and 6.1.7 may apply.

6.1.6 **Research projects with ethics approval granted by another lead HREC must submit Part D, Aboriginal and Torres Strait Islander Research of the NT DHF & Menzies HREC application form to be considered for approval by the AESC before any research is allowed to commence in the NT. Please note that the majority of research conducted in the NT will, deliberately or otherwise, involve or impact upon Aboriginal people.**

6.1.7 It is strongly advised that all projects, including those based in other states, involve a local researcher with research experience in the NT, especially with the community liaison and ethics application phases of the project.

6.1.8 Under the HoMER scheme, this HREC may also consider applications for review of human research projects being undertaken elsewhere in Australia, other than the Northern Territory.

### 6.2 Research

It is impossible to define precisely what constitutes ‘research’.

The NHMRC *NS pp7–9* attempts to provide some guidance on what types of activity should be regarded as research.

6.2.1 Projects which seek funding from research funding agencies such as the NHMRC or Cooperative Research Centre for Aboriginal Health or which may result in publication of results in the form of a thesis, scientific journals or similar, would in most cases be regarded as research and should be considered by the HREC.

6.2.2 The HREC would expect that most projects which involve data collection and analysis would be classified as research projects.

6.2.3 All research projects conducted by students for a tertiary degree (including undergraduate projects that are classified by the teaching institution as a research project) must be considered by the HREC.

6.2.4 The issue of what is research is not so clear for some NTDHF projects. NTDHF is a health service delivery organisation, and most activities of NTDHF are related to organising or delivering health services. As stated in the NTDHF Research Guidelines:

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1 Throughout this document Aboriginal refers to Aboriginal and Torres Strait Islander unless otherwise stated
For the purpose of these guidelines “research” for NTDHF includes applied research and evaluation, but not regular or routine monitoring activities. There is an area of overlap between these activities but in general research involves the generation of new information. Thus, while for example initiation and/or development of new audits or monitoring systems would be included within research and development, regular monitoring of the determinants of health, or states of health and illness are not, and neither are monitoring activities that routinely assess service quality.

6.2.5 Projects undertaken as part of postgraduate training (such as specialist medical training) which are designated as research projects or intended to give trainees research experience require ethics committee approval, even when the project involves minimal or no contact with research participants (such as medical records audits).

6.3 Quality Assurance Audit Registration (QAAR)

If a project fits the NHMRC criteria to be classified as a quality assurance activity or clinical audit, researchers will be required to submit a QAAR application form to the HREC.

Please refer to the NHMRC QAAR checklist document Consideration in determining if an activity such as quality assurance requires ethical review which can be found on the Resources page of the Menzies HREC webpage.

The QAAR application form is available from the Download Forms page of the Menzies HREC web page.

6.4 Other activities

People conducting projects which do not fall into the categories above but which involve:

6.4.1 the use of questionnaires, survey or interviews to obtain any form of personal information;
6.4.2 access to medical or other personal records (other than audits within a department, with departmental approval);
6.4.3 investigations of human behaviour;
6.4.4 routine testing of human subjects;
6.4.5 administration of drugs, ionising radiation, chemical agents or vaccines;
6.4.6 any other experimentation on human beings

should seek the help of the Ethics Administration Officer who can assist with the submissions process.
7. Application Procedures

The HREC application process is documented on the Menzies HREC webpage. The website also contains useful resources that will help you with your application.

7.1 Application timeline

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>-3 weeks</td>
<td>Deadline for receipt of application (dates published on website).</td>
</tr>
<tr>
<td></td>
<td>Notification of receipt of application emailed to researcher.</td>
</tr>
<tr>
<td>-1 week</td>
<td>AESC meeting</td>
</tr>
<tr>
<td>0</td>
<td>HREC meeting (dates published on website)</td>
</tr>
<tr>
<td>+ 2 weeks</td>
<td>Principal investigator notified of outcome</td>
</tr>
<tr>
<td>+ 4 weeks</td>
<td>Deadline for conditional approval issues to be addressed by researchers</td>
</tr>
<tr>
<td>+ 5 weeks</td>
<td>Fast track committee or Chair deals with amendments and notifies Principal investigator</td>
</tr>
</tbody>
</table>

7.1.1 The closing date for applications is three weeks prior to each HREC meeting and these dates are published on the HREC website: http://menzies.edu.au/about-us/menzies-committees/human-research-ethics-committee/.

7.1.2 Researchers must supply the original plus 26 copies of each application (for 14 members of the HREC and 12 members of the Aboriginal Sub-Committee). Only four copies of each application are required for the Fast Track Committee. E-mail applications cannot be accepted. Applications are sent to the Ethics Administration Officer, HREC, at Menzies School of Health Research.

By courier: Menzies School of Health Research
John Mathews Building (58)
Royal Darwin Hospital Campus
Rocklands Drive
TIWI NT 0810

By post: Menzies School of Health Research
PO Box 41096
CASUARINA NT 0811

7.1.3 Alternative arrangements may be considered under exceptional circumstances (such as applications from remote communities with only basic postal services and office equipment). Such arrangements should be approved in advance by the Committee’s Ethics Administration Officer. Late applications will not normally be accepted.

7.1.4 The Ethics Administration Officer peruses each application for errors or deficiencies, and when time allows may bring problems to the attention of the Principal Investigator, but it is the responsibility of the Principal Investigator to ensure that the application form has been completed correctly.

7.1.5 The Ethics Administration Officer compiles the agenda for each meeting and distributes applications, evaluation sheets, and other meeting papers to arrive with committee members at least one week before the meeting date of the AESC, and two weeks before the date of the HREC. The Ethics Administration Officer assigns each application to a member of the HREC to prepare a brief summary and introduce each application at the HREC meeting.
7.1.6 The HREC and/or Chair may request external advice on a complex research project from specialists in the relevant field of research or health practice, either in writing or in person at the HREC meeting.

7.2 Issues which the HREC must consider

In assessing an application the HREC will consider:

7.2.1 the scientific validity of the research protocol.
7.2.2 the availability of adequate resources and skills to successfully complete the project.
7.2.3 the balance between potential benefits and risks of the research.
7.2.4 the maintenance of participants’ privacy.
7.2.5 the method of obtaining consent from the participants.
7.2.6 the degree of support for the project from community representatives.
7.2.7 the degree of support from resource providers.
7.2.9 the safety and welfare of researchers as they carry out their duties specific to the project under review

7.3 Fees for ethical review

A policy to charge fees for ethical review is under consideration by the HREC and is being discussed with other key stakeholders.

7.4 Application forms

There are currently four application forms available for download from the HREC page Menzies website:

7.4.1 The local HREC Application Form may be completed when the research proposal is to be considered by this HREC only.
7.4.2 The National Ethics Application Form (NEAF) should be completed when the research proposal is to be considered by more than one HREC.
7.4.3 Part D: Aboriginal & Torres Strait Islander Research (Attachment for NEAF). This is Part D of the local HREC Application Form. NB: Please note that the majority of research conducted in the Northern Territory will, deliberately or otherwise, involve or impact upon Aboriginal people. All applicants using a NEAF including those with approval from another ethics committee must complete this form.
7.4.4 Application form for Quality Assurance Audit Registration (QAAR).

Please note that the correct name of this Ethics Committee is the Human Research Ethics Committee of the NT Department of Health and Families and Menzies School of Health Research. The AHEC registered HREC code number is EC00153.
7.5 Completing the ethical review application forms

The Application forms must fulfil the following the criteria:

7.5.1 All necessary information must be presented clearly and concisely.
7.5.2 The information must be understandable by the ‘informed layperson’.
7.5.3 The application must succinctly summarise the research project and the ethical issues involved, rather than be a detailed research protocol containing full technical documentation of the project.
7.5.4 Information must be completed within the space provided for each section.
7.5.5 The application must be typed in a font size at least size 10pt and must not be hand written.
7.5.6 The application must have the support of the institution accepting responsibility for the research project and include the signature of the head of the institution.

In order to be considered by the HREC, the application should include:

7.5.7 the qualifications and experience of members of the research team to conduct the described research.
7.5.8 a summary of sources of funding supporting the research.
7.5.9 a brief description of the facilities available for use by the researchers at participating institutions.
7.5.10 contact details for the person to whom any complaints arising from this research should be addressed.
7.5.11 the background to the project – a brief summary of the existing state of knowledge in the area and why this project is being proposed at this particular point in time.
7.5.12 a brief summary of the research protocol ensuring the study’s design is suitable to answer the research questions being asked.
7.5.13 the potential benefits of the research, for participants (if any) and for society more generally
7.5.14 the potential harm to participants, how this is being minimised and monitored, and what measures will be put in place to deal with any harm that occurs
7.5.15 who the research participants will be, and how they will be selected
7.5.16 details of what information or specimens will be collected from research participants
7.5.17 details of how this information or specimens will be stored e.g. Data Safety Management report
7.5.18 details explaining how the research will be monitored e.g. establishment of Data Safety Monitoring Board or equivalent to monitor clinical trials
7.5.19 the method of tracking implantable devices for the life of the device (see section 7.6)
7.5.20 details about what will happen to information or specimens after the project is complete
7.5.21 the information that will be provided to people invited to participate (including a copy of the Participant Information Sheet appropriate for the intended participants)
7.5.22 the procedure to obtain consent from participants (including a copy of the consent form that clearly states what participants are agreeing to, that they can refuse to be
involved with no detriment to their health services, and that they can withdraw at any

7.5.23 details of how participants information will be kept private, and if tissue specimens are to be used, how these will be securely stored, and how and when they will be disposed of.

7.5.24 any conflicts of interest – real or perceived – the applicants may have in carrying out the research (examples include access to participant records during the course of normal professional duties; personal involvement with participants; payments to participants; or other potential conflict or ethical issue). Applications must include details of how these conflicts will be managed by the researcher and the responsible institution. (In accordance with NS 5.2.10 and 5.4.3)

7.5.25 a “Working with children check” for all applicants who will potentially work with children. Under the Care and Protection of Children Act 2007 (NT) from March 1, 2011, individuals are required to apply for a Working With Children Clearance Notice in the Northern Territory. A Clearance Notice is valid for two years, and applies to employers, employees and volunteers in child-related employment settings. Projects being undertaken in states other than the NT will need to comply with that state’s requirements regarding working with children.

7.5.26 a current Police check.

7.5.27 summaries of discussions with communities in which the proposed research will be undertaken, details of type and level of support there is in the communities, and copies of written expressions of support on official letterhead from authorised representatives of those communities.

7.5.28 a letter of support from the Director Remote Health Services of NTDHF if research is to be conducted in a remote facility of the NTDHF or will access any DHF resources. Information is available from:


and the application forms can be downloaded from


7.5.29 a letter of conditional approval from DHF to access data pending ethics approval. Information regarding data access and a data request form is available from the DHF Data Access Protocol and the request form for Remote Health data is available from


7.6 Clinical trial documentation

Researchers involved in clinical trials should be guided by the TGA documents:

Note for guidance on good clinical practice (CPMP/ICH/135/95 - Annotated with TGA comments)

and

Note for guidance on clinical safety data management: definitions and standards for expedited reporting (CPMP/ICH/377/95 - Annotated with TGA comments)

As well as adhering to the application criteria in Section 7.5, applications for approval for clinical trials must include:

7.6.1 Clinical Trial Protocol – 1 original plus 4 copies
7.6.2 Clinical Trial Notification – 1 original plus 4 copies
7.6.3 Certificate of Insurance Liability – 1 original plus 4 copies
7.6.4 Description of the tracking system for any implantable medical devices which may be used in the clinical trial. The tracking system should follow the participant for the life of the device or until such time as the device is removed.

7.7 Participant Information Statement

7.7.1 The Participant Information Statement (PIS) should be presented on letterhead with the name and address of the institute undertaking the research.

7.7.2 The HREC recommends that a PIS should be in the most appropriate medium for the people being consulted as potential participants in each research project. A clear, concise printed information statement that includes all relevant information about the project written in simple English is the best format for most participants. For people who are not competent in reading written English a translation of an English-language statement into their first language would be expected. A recognised translator may need to be used.

7.7.3 Many research projects in the Northern Territory involve Aboriginal people from remote communities, many of whom do not speak English well, if at all, and many of whom are not literate in either English or their Aboriginal language. This is not restricted to older people – many younger adults who have recently completed schooling are not functionally literate either. Written participant information statements are not appropriate for these people. Thorough oral explanation, possibly supplemented by pictorial or audiovisual material, is required in this situation. An oral participant information statement must be based on a written statement that is delivered by a person competent to translate the information into the appropriate Aboriginal language.

7.7.4 In addition, for research projects that are being conducted in particular Aboriginal communities (including Aboriginal communities located in urban areas) a process of community consultation is required. Community consent is required before the project can proceed within each community. Community consultation is also the initial stage of disseminating information to community members who may be approached to be participants in the project.

7.7.5 Initial consultation should be with community leaders and community organisations such as the community association, health service board, women’s group or similar organisation. Staff of the local health service should usually be included in this consultation, but consultation with health professionals alone (including Aboriginal Health Workers) is not regarded to be adequate community consultation. It is advisable for researchers to employ someone with local knowledge during this consultation phase.

7.7.6 All relevant information about the project should be included on the PIS (which is separate from the consent form) and labelled “THIS IS FOR YOU TO KEEP”. The consent form, which would usually be signed by the participant or parent, should be as clear as possible and only include information relevant to documenting participant consent – it should not be used as a substitute for a participant information statement.

7.7.7 The PIS should invite people to participate in a research project; not tell them that they are participating.

7.7.8 The PIS should contain details of the research project including information about how data or specimens will be collected and stored and what will happen to these specimens and data at the end of the research.
7.7.9 The PIS should advise the participant that if they have any concerns or complaints about the research project they may contact the HREC that approved the research and contact details for this HREC should be included.

7.7.10 The PIS should advise the participant that if they require more information about the research then they can contact the principal investigator whose contact details should be included.

7.8 Documentation of consent

The purpose of the consent form is to provide specific information about the conditions of consent and to provide a permanent record that the participant has consented.

Note that the signature of the research participant on the consent form is not the principal act of consent. The participant should express clearly to the researcher that the participant has understood the information provided, is confident to make a decision, and what that decision is. The signature on the consent form is an important confirmation of that consent, but is not consent in itself.

For people who are not literate, a written consent form and signature may not be adequate confirmation of consent, indeed a written consent form may be inappropriate confirmation of consent. A person who is not literate cannot read the information on the form – it must be read to him or her. This person also may not be able to sign their name, other than a cross or similar mark. Such a signature provides minimal if any distinctive confirmation that the person has indeed made that mark. In these circumstances an independent witness (Translator/interpreter) may be required to confirm that the participant information statement has been provided and the consent form read to the participant, and that the participant has consented to be involved in the research project.

While a written participant information statement and signed consent form are required in most situations, they are not always optimal or appropriate. Particularly with Aboriginal participants who are not fluent or literate in English, alternative means of providing participant information and documenting consent may be required. This does not mean that any lesser standard of information is acceptable, nor that any less clearly and freely given consent is acceptable. Most alternative means of providing information and documenting consent will require more imagination and resources rather than less.

The consent form should be a plain English document which is short and concise and must include:

7.8.1 the letterhead with the name and address of the institution undertaking the research
7.8.2 the name and contact telephone numbers of the principal and local investigators
7.8.3 the title of the project
7.8.4 the phrase “THIS MEANS YOU CAN SAY NO”
7.8.5 a statement that the details of the research project have been explained to the participant, and the participant information statement has been read or otherwise viewed and given to the participant
7.8.6 what specific procedures or activities the participant has agreed to
7.8.7 the names of those who provided this information to the participant
7.8.8 a statement that the participant is free to decline to be involved without any effect on their healthcare or other aspects of their lives
7.8.9 a statement that the participant is free to withdraw at any time during the project without any effect on their health care or other aspects of their lives

7.8.10 a statement that the participant does or does not consent to the tracking of any implantable device for the lifetime of the device (if applicable)

7.8.11 a statement that the participant does or does not consent to data or specimens being retained and used for future specified or unspecified research projects. (Refer to section 7.2.8)

7.8.12 the signature of the participant

7.8.13 the signature of the person who witnessed the participant’s consent, which may be the person who provided the participant information.

7.8.14 the signature of an interpreter if present
8. Approvals Procedure

8.1 Summary of approval procedure

8.1.1 The HREC considers the ethical aspects of research proposals as summarised by the Principal Investigator in the HREC Application Form.

8.1.2 Most applications will be considered by both the Aboriginal Sub-Committee and the HREC.

8.1.3 Low risk projects are assessed by the Fast Track sub-committee (Refer to sections 4.2 and 8.8)

8.1.4 Amendments following conditional approval can be assessed by the Chair or the Fast Track Committee. The decisions of the Chair and Fast Track Committee will be considered and ratified at the next HREC meeting.

8.1.5 QAAR applications will be registered by the Ethics Administration officer, approved by the HREC chair and ratified at the next HREC meeting.

8.1.6 Applications approved by another lead HREC will be assessed by the AESC and must include Part D: Aboriginal & Torres Strait Islander Research (Attachment for NEAF).

8.2 Aboriginal Ethics Sub-Committee

8.2.1 The AESC considers all applications considered by the HREC, not only those specifically addressing Aboriginal health issues (with the exception of research to be conducted with Tiwi people or international participants). (Refer to Section 4.1)

8.2.2 The AESC will consider all applications previously approved under the HoMER system received from other institutions.

8.2.3 Approval for a research project requires the approval of both the Aboriginal Sub-Committee and the HREC: if the Aboriginal Sub-Committee does not approve a project, the HREC will not approve the project.

8.3 Tiwi Islands

In deference to the local expertise of the Tiwi Land Council in considering matters to do with the Tiwi people, the AESC does not consider proposals for research with the Tiwi people.

The Tiwi Land Council stipulates that the process for ethical approval of human research projects with the Tiwi people will conform with the agreement between the former Tiwi Health Board and the Menzies School of Health Research (the Tiwi Legal Agreement) as follows:

8.3.1 Researchers present a very brief summary of the research proposal to the Chairman of the Tiwi Land Council.

8.3.2 The Tiwi Land Council considers the brief summary, and provides a written response to the researcher indicating whether or not they would be willing to consider the proposal in greater detail. If the Tiwi Land Council is willing to consider the proposal further, the researcher must obtain HREC approval for the proposal before submitting a detailed proposal to the land council.

8.3.3 The HREC will only consider applications for research projects with the Tiwi people that include this written initial support from the Tiwi Land Council.

8.3.4 Once approved by the HREC, the detailed proposal, including written HREC approval, is submitted to the Tiwi Land Council.
8.3.5 There is no change to the normal monitoring requirements of the HREC for research projects with the Tiwi people.

8.4 Maningrida

Research with Maningrida requires approval from Malabam Aboriginal Health Corporation, the researchers should make contact with Malabam to ascertain the timing of the next meeting and negotiate the process for tabling a research proposal for community discussion. A letter of community support must be tendered to the HREC before research activity can commence with the Maningrida community.

8.5 NTDHF Remote Services and Data Collections

All proposed research intending to access DHF remote health services data, or resources (staff, vehicles, facilities, medical records) require approval from the Director of Remote Health Services. Researchers are required to submit a copy of the research proposal to the Director for approval. A letter of approval of the proposed research must be obtained from the Director of Remote Health Services. This letter of approval must be tendered to the HREC secretary before research activity commences at the research site. Information sheets and application forms for the DHF approval process can be obtained from the Remote Health ATLAS website.


http://remotehealthatlas.nt.gov.au/research_proposal_form_sections_1&2.doc


8.6 East Arnhemland Community Clinics

All proposed research involving North East Arnhemland communities require approval from the Miwatj Aboriginal Health Corporation. Researchers are requested to contact the Miwatj Service Centre Manager via Ngalkanbuy Health Clinic, Galiwinku for further information regarding the required processes for submitting a research application.

8.7 Communities without a Health Board

On 1 July 2008, the local government super shire system was introduced and local community councils were dissolved. Researchers are now requested to contact the CEO of the relevant shire who will direct the researcher to the relevant shire service manager for further advice and guidance. For further information, researchers are requested to contact the supershire council responsible for the region where the research will be conducted.

8.8 Fast Track approval

The Fast Track Committee (FTC) does not meet face to face. As the Ethics Administration Officer receives proposals, the advice of the HREC Chair is sought as to whether the application is considered suitable for fast tracking.

The Chair may accept applications for consideration by the FTC where the following criteria are satisfied:

29
8.8.1 there is a degree of urgency – there are substantial reasons why the project needs ethics approval before the next HREC meeting, and

8.8.2 the ethical issues involved in the project are relatively minor issues – with low risk which have been frequently discussed and agreed by the HREC as defined in the NS Chapter 2.1 Risk and Benefit and Chapter 5.1.18–5.1.21 for research involving no more than low risk

8.8.3 a modified application that had not been approved by the HREC in its initial submission may be considered by the Fast Track Committee if the researcher has addressed those issues of concern noted by the HREC.

**Fast track procedures:**

8.8.4 If accepted for consideration by the FTC, the Ethics Administration Officer sends a copy of the application, together with the ‘Fast Track Review Form’ to the rostered FTC members for consideration. Applications for consideration by the FTC are sent out to the committee each Friday with a requested return date. Approval from all members of the FTC is required before an application is approved. If any member considers that the application should not be approved by the FTC, the application is referred to the next meetings of the Aboriginal Sub-Committee and HREC.

8.8.5 FTC members are expected to return their recommendation to the Ethics Administration Officer within one week of receiving each application. If after one week not all FTC members have returned their recommendation, the Ethics Administration Officer attempts to contact members who have not responded. If no response is received within a further two working days the recommendations of a minimum of three members are deemed sufficient for a FTC decision.

8.8.6 The Fast Track Committee is authorised to approve a modified application if the Human Research Ethics Committee’s concerns have been adequately addressed. If the Fast Track Committee is not satisfied that the issues have been adequately addressed, a revised application addressing outstanding concerns should be re-submitted to the full HREC.

8.8.7 The Ethics Administration Officer then drafts a response for the Fast Track Chair’s signature. The only possible decisions are ‘approved’ or ‘Forward to Full Committee’ or ‘Delegate to HREC Chair’. If not approved immediately by the Fast Track Process, reasons for the decision are forwarded to the Principal Investigator. The decision of the Fast Track Committee should be forwarded to the Principal Investigator within four weeks of receipt of the application.

**8.9 HREC**

8.9.1 The HREC considers all applications after consideration by the Aboriginal Sub-Committee, including the outcome of the Sub-Committee’s deliberations as summarised in the minutes of the Sub-Committee meeting and by the Chair of the Sub-Committee.

8.9.2 When a member is unable to attend a meeting, the member provides written comments on each application to the Ethics Administration Officer prior to the meeting, to be presented during the Committee’s discussion of each application and accepted as attendance at the meeting. However, while these comments will be presented to the meeting they will not form part of the final decision. Only those members present at the meeting are responsible for the Committee’s decision on each application.
8.9.3 Discussion of each application commences with one member of the Committee briefly summarising each application. The Ethics Administration Officer allocates each application to one Committee member to prepare a brief summary when sending out the papers for each meeting. All Committee members are included in the preparation of summaries.

8.9.4 Decisions on whether to approve a project or not and the type of approval given are determined by a majority vote of the attending committee members.

8.9.5 Where there is inconsistency between the recommendations or comments of the HREC and AESC, the Chairs of each Committee meet as soon as possible after the HREC meeting to resolve the inconsistency. The revised recommendation and comment, and reason for the revision, are reported to the next meeting of each committee.

8.9.6 The HREC Chair and the Ethics Admin officer may hold face-to-face meetings with researchers to resolve issues about a research proposal. Researchers and advisers may be invited to attend HREC meetings to answer queries regarding research proposals. (See section 5.8.2, 5.8.3)

8.10 Management of Conflict of Interest

8.10.1 The HREC will consider any declared conflicts of interest (Section 7.5.24) and assess whether the management of these conflicts by the researchers and the responsible institution complies with NS 5.2.10 & NS 5.4.3.

8.10.2 Conflicts of interest are initially monitored by the HREC by direct communication with the researcher and documentation in HREC meeting Minutes.

8.10.3 The HREC will review any declaration of conflicts of interest it receives from Institutions involved in multi-centre research on a case by case basis and may inform relevant bodies after consideration of the conflict management procedures of the responsible Institution.

8.10.4 The HREC will review any declaration of conflicts of interest it receives from Researchers involved in multi-centre research on a case by case basis and may inform relevant bodies after consideration of the conflict management procedures of the researcher’s responsible Institution.

8.10.5 If the HREC becomes aware of a conflict of interest that is not being managed by a researcher it may ask the researcher for a progress report on the management of this conflict. The HREC Chair may decide to suspend research until such time as the conflict of interest is managed adequately (in accordance with NS 5.4.3).

8.10.6 Where the HREC becomes aware that there may be a conflict of interest involving the institution undertaking the research, the HREC will notify the institution in writing.

8.10.7 If the HREC becomes aware of any conflicts of interest that may have arisen since initial approval by another HREC, it will request from the researcher a report on the management of these changes and require that the researcher informs the original approving HREC of these changes. The HREC may require a resubmission of the application for consideration by the full HREC.

8.11 Projects approved by another Ethics Committee

Some research projects involving local participants and/or researchers are primarily conducted by another institution, such as a multi-centre clinical trial including an NT hospital as one of the trial sites, or a national epidemiological study using data from multiple states.
including the NT. Such projects may have been considered in detail and approved by one or more other Ethics Committees.

8.11.1 Researchers with ethics approval from another institution should discuss their application with the HREC administration officer.

8.11.2 In some cases, the HREC may accept the consideration and approval of another Ethics Committee instead of undertaking detailed consideration of the application itself.

8.11.3 Where there are significant local issues involved which may not have been considered by another Ethics Committee, and/or the researchers propose to access the facilities/resources of the NTDHF, the HREC must consider the project in detail.

8.11.4 Projects approved by other ethics committees need to comply with the specific requirements of this HREC, the NT DHF and individual communities. (See section 6.1.4, 6.1.5 and 8.3 to 8.7)

8.11.5 All projects with approval from another lead ethics committee (under the HoMER system) must submit Part D: Aboriginal & Torres Strait Islander Research (Attachment for NEAF) to this HREC for consideration by the AESC.

8.11.6 If the AESC and HREC have serious concerns with an application that has prior approval from another HREC, this HREC may express their concerns in writing to the original HREC and request a comment.

8.11.7 If the HREC becomes aware of any modifications to a project, including conflicts of interest, which may have arisen since initial approval by another HREC, the Chair will request from the researcher a report on the management of these changes and require that the researcher informs the original approving HREC of these changes. The HREC may require a resubmission of the application for consideration by the full HREC.

8.12 Charles Darwin University

The Menzies School of Health Research became a controlled entity of the CDU in 2004.

Students who are enrolled at CDU via Menzies, and are undertaking health research projects, are required to apply to the HREC of NTDHF/Menzies only. For these projects, the Ethics Administration Officer will advise the CDU HREC of the application for ethics approval and its outcome.

Students enrolled through CDU and not Menzies must apply to the CDU HREC and must also comply with section 8.11.
9. HREC Decisions

9.1 Types of approval

The HREC restricts its decisions to “Full approval”, “Conditional approval” or “Non-approval” of an application. The Committee may:

9.1.1 approve an application, without recommendations.

9.1.2 approve an application, with recommendations. In this case the application is approved unconditionally and the recommendations have the status of informal advice to the researcher, which the researcher is not obliged to take action on.

9.1.3 approve conditionally upon recommendations and minor changes to be made and submitted to the Chair for approval. Issues of concern based on the NS are to be addressed within two weeks or the conditional approval will lapse.

9.1.4 not approve an application, with advice to the researcher of issues based on the NS which need to be addressed in a modified application, and authorise the Chair to approve the modified application if the Committee’s concerns have been adequately addressed. If the Chair is not satisfied that the issues have been adequately addressed, a revised application needs to be re-submitted to the HREC, the AESC, or the Fast Track Committee as advised by the Chair.

9.1.5 not approve an application, with advice to the researcher of issues which need to be addressed based on the NS in a modified application, and authorise the Fast Track Committee to approve the modified application if the Committee’s concerns have been adequately addressed. If the Fast Track Committee is not satisfied that the issues have been adequately addressed, a revised application addressing outstanding concerns should be re-submitted to the HREC.

9.1.6 not approve an application, with advice to the researcher of issues based on the NS that need to be addressed in a revised application to be re-submitted to the next HREC meeting.

9.1.7 not approve an application, with advice to the researcher of the reasons based on the NS why the application was not approved.

9.2 Notification of decision

9.2.1 The principal researcher will usually be notified of the HREC decision within 10 working days from the HREC meeting date. Researchers will then have two weeks in which to respond to any concerns that the HREC may have and to submit amendments. A final decision will be made within one week of receipt of the amended application and the researcher notified.

9.2.2 The Ethics Administration Officer will advise the CDU HREC of the outcomes of application for ethics approval that have been submitted by CDU students.

9.2.3 Letters of approval to researchers will state the terms under which approval has been given including the reporting requirements.

9.2.4 In cases where the application has not been approved, the reasons for non-approval are linked to the National Statement on Ethical Conduct in Human Research 2007 and quoted in the written notification.

9.2.5 HREC approval is for a period of 12 months from the date of the HREC meeting, or until the end of the research project if less than 12 months duration.

9.2.6 Approval for subsequent periods of 12 months will be granted on acceptance by the HREC of an adequate annual progress report from the principal researchers, and any other reports as requested in the approval letter.

9.2.7 A copy of the application as finally approved by the HREC is kept on file by the Ethics Administration Officer.
10. Appeals Process

Where a Principal Investigator of a research proposal disagrees with a decision of the HREC, the Principal Investigator may request in writing to the Chair of the HREC that the decision be reconsidered, giving reasons why the researcher feels that the HREC decision is incorrect. The reasons why the decision is incorrect must be based on the NS.

The HREC must reconsider the application, including further information supplied by the Principal Investigator, at the next available meeting (subject to the normal closing dates for applications).

If after a reconsideration of a research proposal the Principal Investigator remains dissatisfied with the decision, or reasons for a decision of the HREC, the Principal Investigator may request in writing to the Director, Menzies, or the Chief Executive Officer, NTDHF, that an independent review of the HREC decision be undertaken. This review will be conducted by a review committee consisting of people who have previous or current experience as members of a research ethics committee, but are not current members of the HREC or Aboriginal Subcommittee, and with minimum membership as defined in the NS. This review should be completed within three months of the receipt of the request for review.

The review committee shall make an independent decision on the research proposal and, where requested by the Principal Investigator or the relevant institutional head, shall consider whether the reasons for the original HREC were reasonable and whether there were any errors in the process undertaken by the HREC, and make recommendations in regard to these considerations.
11. Monitoring Process

Reporting requirements for research projects are stated in the letter of approval sent to the Principal Investigator, and are in accordance with NS 5.5 and should comply with the NHMRC document Monitoring and reporting of safety for clinical trials involving therapeutic products.

11.1 Annual Progress Reports

The HREC will assess the level of risk to participants when determining the reporting requirements of specific projects. A condition of ethical approval is that Principal Investigators must submit an annual progress report on the status of their project. The annual/final report form can be downloaded from the HREC page of the Menzies website (www.menzies.edu.au).

11.1.1 The Ethics Administration Officer maintains a database of all applications considered by the HREC, including the expected duration of each project, the date on which approval expires, and the date on which the next progress report is due (which would normally be the approval expiry date). Six weeks prior to the date each progress report is due, the Ethics Administration Officer sends a notice (by e-mail only) to the Principal Investigator reminding them of the approval expiry date and the requirement for the attached progress report form to be returned (the annual/final report form is also available in electronic format on the Menzies website).

11.1.2 One member of the HREC reviews Progress Reports for all projects due for review at each meeting. Further information is requested from the Principal Investigator if required.

11.1.3 Any progress report considered unsatisfactory will be reviewed by the Chairs of the HREC and Aboriginal Sub-Committee, together with the Ethics Administration Officer and Committee member who initially considered the progress report. This group may request further information from the Principal Investigator, or discuss their concerns with the Principal Investigator and/or other investigators, before making a recommendation to the next meeting of the HREC.

11.1.4 A summary, including recommendation, of all progress reports reviewed, is presented to the HREC meeting for endorsement by the Committee.

11.1.5 Recommendations may be:

- to extend approval for a further period of 12 months
- to extend approval for a period of less than 12 months
- to not accept the progress report at this time, temporarily extend approval for the project while seeking further information from the Principal Investigator or other party
- to not accept the progress report and not extend approval

11.1.6 The Principal Investigator of each project which has had approval extended is advised in writing by the Ethics Administration Officer after each meeting, including the date when the next progress report is due.

11.1.7 The outcome of the review of other projects, and the reason for approval not being extended, and any action required of the investigators, is advised in writing by the Chair within one week of each meeting.

11.1.8 Where a progress report is considered unsatisfactory and approval is not extended, the Chair advises the Principal Investigator and the Head of the Institution in which the research is being conducted in writing that the progress report has not been accepted and approval not extended, and includes the reasons based on the NS for this decision.

11.1.9 A final progress report is due at the completion of the project.
11.2 Reporting variations from original approved application

Researchers must report to the HREC as soon as possible:

11.2.1 any proposed variation to the protocol of the original approved project,
11.2.2 any information, either published or unpublished sources, that the researcher becomes aware of since the original application was approved that may affect continued ethical approval,
11.2.3 if the project is discontinued prior to its original completion date,
11.2.4 any serious adverse events (refer to 11.4),
11.2.5 any conflicts of interest which may arise during the course of the research,
11.2.6 any other unforeseen events that may affect the continued ethical approval of a project.

11.3 Clinical Trial Reporting

11.3.1 Clinical trial reporting should comply with the NHMRC document Monitoring and reporting of safety for clinical trials involving therapeutic products.
11.3.2 Reports from researchers conducting clinical trials will be subject to the same reporting procedures mentioned in section 11.1 AND may have special reporting requirements imposed upon them by the HREC e.g. more frequent reporting.
11.3.3 The HREC will assess the level of risk to participants when determining the reporting requirements of specific projects.
11.3.4 The HREC may require researchers to establish an independent data safety monitoring board (DSMB) with the frequency of monitoring determined by the HREC.
11.3.5 The HREC requires researchers using implantable devices to establish a tracking system for these devices for the lifetime of the device. This requires the consent of the participants. The tracking system report should be included with any progress report.
11.3.6 Any serious adverse events or device incidents must be reported immediately to the HREC and the Therapeutic Goods Administration (TGA).

11.4 Reporting of Serious Adverse and/or Unexpected Events (SAE/SUE)

Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes.

11.4.1 Researchers should take prompt steps to deal with any unexpected risks.
11.4.2 Researchers should report any serious adverse event, serious adverse drug reaction, serious unexpected suspected adverse reactions, or serious adverse device event as soon as possible to:

➢ the institution responsible for the research being conducted
➢ the organisation sponsoring the research (within 24hrs)
➢ the relevant HREC/s
➢ the TGA where applicable (Users Medical Device Incident Report http://www.tga.gov.au/DOCS/pdf/forms/iris_udir03c.pdf)

11.4.3 The Principal Investigator should provide a written report to the HREC Chair as soon as possible after any serious adverse event; serious adverse drug reaction; serious unexpected suspected adverse reactions; serious adverse device event; or any other unexpected event that increases the risk to participants that may affect the continued ethical approval of the project.
11.4.4 The report to HREC should include details of:

➢ The project number, project title and name of Principal Investigator
The date of the report
The date of the event
The event/s that took place (incident/s, location, timing, outcome/s)
The name and age of the participant affected
The likelihood that the event was related to the study
The opinion of the DSMB (or equivalent) as to the likelihood that the event was related to the study, the likelihood of further incidences and an opinion with regard to any increased risks associated with continuation of the research
Any proposed amendments to the research protocol and/or conduct to reduce the likelihood of reoccurrence.

11.5 Response to report of SAE notification

11.5.1 The Principal Investigator will be notified of the receipt by the HREC of the notice of an adverse event and that a decision is pending.

11.5.2 In considering the report, the HREC Chair must consider all the facts provided and may seek additional information as necessary, from the DSMB, the research team and/or the research site in order to make a decision as to whether the trial should:
- be discontinued.
- be suspended, pending amendments to protocol.
- continue with amendments to protocol including the PIS.
- continue under the current protocol.

11.5.3 The HREC Chair will respond to the Principal Investigator in writing, within two weeks of receiving the written report. Reasons for the HREC’s decision must be incorporated in the response. The Principal Investigator has the right to appeal the Chair’s decision under “Appeals Process”.

11.5.4 If the Chair decides that the project should be discontinued, or suspended pending amendments to protocol, the decision will be communicated to both the Principal Investigator and the Head of the Responsible Institution.

11.5.5 All such reports and decisions regarding the continuation of the research must be lodged with, and recorded by, the Ethics Administration Officer.

11.5.6 The HREC should include details regarding the number and outcomes of such reports in its annual report to the AHEC and the establishing Institutions.

11.6 Failure to Submit Progress Reports

11.6.1 If a progress report has not been received within one month of its due date, the Ethics Administration Officer will email all named investigators advising that the progress report is overdue and requesting that it be submitted within a fortnight of the email.

11.6.2 Should the progress report not be received within a fortnight of sending this advice, all named Investigators and the Head of the relevant institution will be advised in writing that approval for the project has expired and the reasons for the decision.

11.6.3 Should an investigator named on a new application be an investigator on a project which has failed to provide an annual progress report, the new application will not receive notification of HREC approval until such time as the progress report for the existing project is received and has been approved.
11.7 Auditing Approved Projects

11.7.1 The HREC may decide to undertake an audit on any of the projects being conducted with its approval to ensure that approved protocols are being adhered to.

11.7.2 Should the HREC choose to undertake an audit, the Principal Investigator/s of the project/s to be audited will be notified at least 3 working days in advance of the proposed audit.

11.7.3 Procedures for undertaking such audits may include:

- site visits,
- inspection of documentation and/or data storage, and
- interviews with research staff, participants and/or resource providers

11.7.4 Should the HREC choose to undertake an audit, this will be done at the HREC’s expense unless otherwise agreed between the Principal Investigator and the HREC in advance (e.g. costs of accompanying researchers on a field trip).

11.7.5 The audit committee will include as a minimum:

- One member of the HREC who has research experience;
- One member of the HREC who is not an institutional member (i.e. Lay person, legal advisor, or religious/spiritual advisor);
- One member of the AESC;
- An invited non-HREC person with relevant expertise in the type of research being audited.

11.7.6 The nominated members of the audit committee must have no involvement in, or conflict of interest with regard to, the research project to be audited.

11.7.7 The findings of the audit committee will be reported in writing to the Principal Investigator and the HREC.

11.7.8 In the event of a finding that may require suspension of the research, the Responsible Institution will also be notified of the requirement, the reasons, and any steps required in order to re-commence the research project.

11.7.9 The HREC should include details regarding the number and outcomes of such reports in its annual report to the AHEC and the establishing institutions.

11.8 Withdrawal or suspension of HREC approval

11.8.1 If the HREC finds reason to believe that the continuation of a research project might compromise the welfare of its participants, it will immediately seek to establish whether ethical approval should continue or be withdrawn.

11.8.2 If the HREC has reason to withdraw or suspend ethical approval at any time during the course of a research project, the Principal Investigator and the head of the responsible institution will be informed in writing as soon as possible of the withdrawal.

11.8.3 If ethical approval is withdrawn or suspended during the course of a research project, the researcher must immediately cease all research and make arrangements to meet the needs of the participants.

11.8.4 Research may not be resumed until the concerns of the HREC have been addressed and the researcher establishes that participants’ welfare is not compromised.

11.8.5 Modified research protocols must be reviewed and approved by the HREC before research can recommence.

11.9 HREC Record keeping

11.9.1 The HREC keeps a record of all research proposals received and reviewed.
11.9.2 Information about a research proposal applying to NS 5.2.24 is kept on an electronic database.

11.9.3 The electronic database also includes the status of a proposal, relevant legislation, the category of research, and the name of any other review body that may be involved with a particular proposal.

11.9.4 All hard copies of the initial application form and any attachments including PIS, consent form, and community support letters are kept at Menzies in the short term and at a secure off site storage facility in the long term.

11.9.5 Electronic copies are kept of the initial application and all documentation attached to the initial application including PIS, consent form, and community support letters.

11.9.6 Electronic copies are kept of all correspondence between the HREC and researchers including approval letters, progress reports and notifications of SAEs.

11.9.7 Electronic copies of Minutes of each HREC and AESC meeting are kept on the Menzies server and backup files are sent to secure off site storage every week.

11.9.8 Records of multi-centre research are recorded in an electronic database including details of other review bodies involved, the decision/s of each other review body; and details of any amendments required. A copy of the full application and supporting documents is also maintained in hard files and electronically where available.

11.9.9 HREC secretariat staff has access to records and HREC members can access records on request.

11.9.10 All files are retained for at least five years after completion. Files pertaining to clinical trials are held for 25 years. Files relating to projects involving children are kept for 15 years or until the child reaches the age of 25 years, whichever is greater.

11.9.11 Further information relating to HREC document recordkeeping are contained in the Standard Operating Procedures: Ethics Officer.
12. Complaints about Research Projects

People involved in research projects, or others concerned about the conduct of a research project, may raise their concerns in a variety of ways. The most appropriate way in the first instance would be with one of the senior researchers involved in the project. If this is not appropriate, or does not satisfactorily resolve the issue, a person may express their concerns with the head of the institution that is conducting the research project, with the management of the health service organisation in which the research is being conducted, with the NT Health and Community Services Complaints Commission, or with the HREC.

The HREC requires that all researchers inform research participants that they may raise concerns about a research project with the HREC, and all participants must be given contact details of the HREC Ethics Administration Officer. This information should be included on the PIS.

For relatively minor issues, the HREC Chair or delegated committee member discusses the issue with the complainant and the Principal Investigator and attempts to resolve the issue if possible by correcting a misunderstanding, providing additional information, or similar simple remedy.

The HREC Chair may temporarily suspend ethics approval until a complaint has been resolved.

The HREC does not have the resources to investigate and resolve complaints about more serious issues. These are the responsibility of the head of the institution in which the research project is being conducted, or external agencies in exceptional circumstances. The HREC Chair will contact the complainant to clarify the issues involved and to advise the complainant of options available, before referring the complaint to the Head of the institution which is conducting the research project. The HREC Chair will provide written advice to the complainant of this referral, and to the Director, Menzies, and the Chief Executive Officer, NTDHF.

Investigation and resolution of the complaint are the responsibility of the institution in which the research is being conducted. For serious issues a member of the HREC and AESC should be involved in the complaints handling process. A report to the HREC on the outcome of the complaint is required from the institution as soon as possible after the resolution of the issue, or progress reports every three months if resolution takes longer than three months.
Appendix One: Forms and Instructions

**HREC Forms**
All application forms and instructions are available from the HREC page of the Menzies Website:
www.menzies.edu.au

- HREC application form
- NEAF application form
- Part D: Aboriginal & Torres Strait Islander Research (Attachment for NEAF).
- Quality Assurance Audit Registration Form
- HREC Annual / Final report form

**DHF approval application**
The Research Proposal form is available on the Department of Health and Families Remote Health Atlas site

http://remotehealthatlas.nt.gov.au/research_proposal_form_sections_1&2.doc

**DHF data access application**

**TGA forms**
Notification of clinical trial.

Users medical device Incident Report

**NT Govt forms**
Working with Children Clearance (Ochre Card)
Appendix Two: Key Reference documents

The following documents were used in the preparation of the HREC policy and procedures manual.

**NHMRC Documents**

- National Statement on Ethical Conduct in Human Research 2007

- Australian Code for the Responsible Conduct of Research

- Monitoring and reporting of safety for clinical trials involving therapeutic products

- Keeping research on track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics

- Values and ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander Health Research

**TGA Documents**

- Human research ethics committees and the therapeutic goods legislation

- Note for guidance on good clinical practice (CPMP/ICH/135/95 - Annotated with TGA comments)

- Note for guidance on clinical safety data management: definitions and standards for expedited reporting (CPMP/ICH/377/95 - Annotated with TGA comments)

**Other reading**

Appendix Three : HREC Member Selection Criteria

General Criteria
1. experience of a broad range of community activities
2. able to understand/learn and apply research ethics principles
3. interest in health and health research issues
4. able to read and understand HREC application documents
5. able to appreciate the interests of potential research participants and the potential risks and benefits of research proposals, and to assess the balance between the two
6. able to actively participate in and contribute to Committee discussions on research proposals and other research ethics issues
7. availability to attend meetings and to participate in out-of-session activities as required, including participating in the Fast Track Committee which considers and responds to applications eligible for fast-tracking within short timeframes

Lay member
1. interest in and awareness of health consumer issues
2. not involved in health research or health services delivery
3. not directly associated with NT Department of Health and Families or the Menzies School of Health Research
4. not a lawyer or minister of religion (or equivalent)
5. where possible, at least one of the three lay members should be an Aboriginal person

Member with legal experience
1. legal qualifications and experience in the practice of law
2. interest in and knowledge of legal issues relevant to health services or health research is desirable

Member with religious/spiritual experience
1. experience as a minister of religion, spiritual leader or Aboriginal elder
2. interest in and knowledge of religious or spiritual issues relevant to health services or health research is desirable

Members with health services delivery experience
1. experience in the delivery of health or family services
2. experience in service delivery to Aboriginal people in the NT
3. particular experience of service delivery in a hospital setting or in an Aboriginal community setting, depending on the vacancy being filled

Members with health research experience
1. experience in the conduct of health research
2. experience in research with Aboriginal people in the NT
3. experience in clinical, social science, epidemiological or laboratory research, depending on the vacancy being filled

Member with qualitative research experience
1. experience in the conduct of research into health or social issues
2. experience in the conduct of qualitative research
3. experience in research with Aboriginal people in the NT