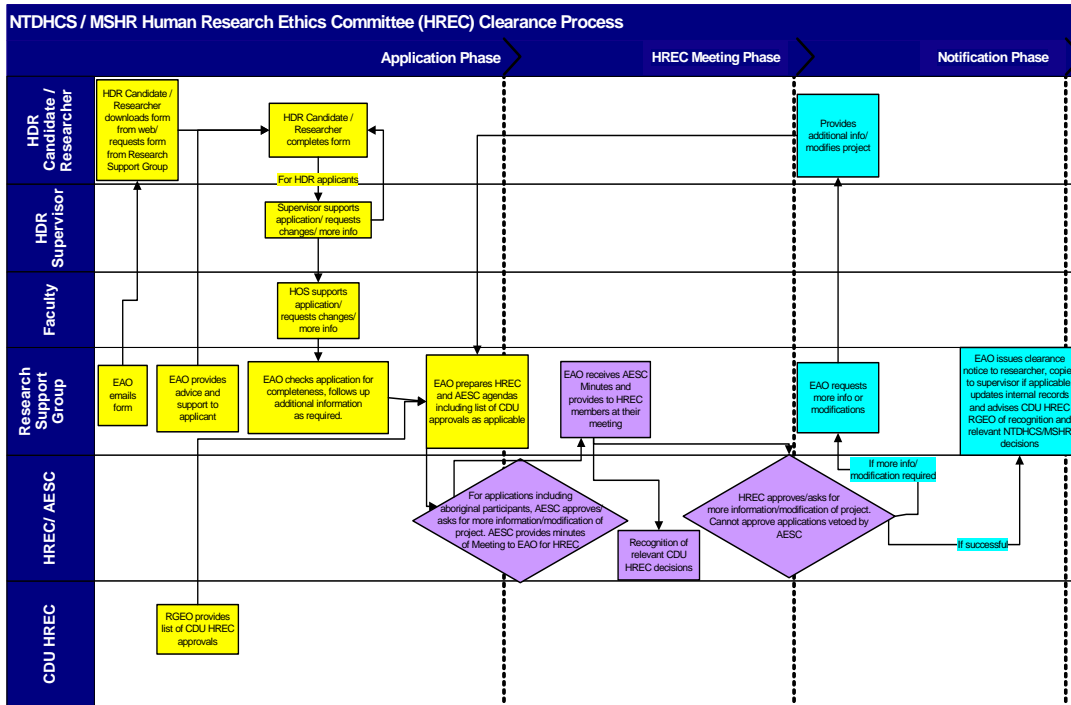
 <b>Charles Darwin</b> UNIVERSITY	<b>NTDHCS &amp; MSHR Human Research Ethics Committee (HREC) Clearance Process</b>	<b>No. 3.2.15 Version 1.</b>
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**Endorsed by Academic Board at Meeting 02/05 on 20th May 2005**

<b>Intent:</b>	<b>Attributes:</b>
<p>The purposes of the NTDHCS &amp; MSHR Human Research Ethics Committee (HREC) clearance process for research projects are to:</p> <ul style="list-style-type: none"> <li>• Ensure research projects conform with national guidelines established and published by the National Health &amp; Medical Research Council (NHMRC), the principal one being the <i>National Statement on Ethical Conduct in Research Involving Humans</i>.</li> <li>• Protect the welfare and rights of participants in research and other activities, and also non-participants who may be affected by the activities. This objective is based on the principle of respect for the inherent dignity and autonomy of individuals.</li> <li>• Assist applicants to structure and refine their ideas and to ensure that their chosen research project is conducted ethically within both the University community and the general community in relation to research and other activities involving humans conducted under the auspices of the NTDHCS &amp; MSHR.</li> </ul>	<p>Essential features of the NTDHCS &amp; MSHR Human Research Ethics Committee (HREC) clearance process are:</p> <ul style="list-style-type: none"> <li>• Completion of the HREC application form</li> <li>• Approval by supervisor and HOS</li> <li>• Review and authorisation/ refusal by NTDHCS &amp; MSHR Human Research Ethics Committee</li> </ul> <p>Where a research project requires HREC clearance, the research cannot commence until NTDHCS &amp; MSHR Human Research Ethics Committee (HREC) clearance has been granted. The NTDHCS &amp; MSHR Human Research Ethics Committee (HREC) recognise approvals from CDU Human Research Ethics Committee.</p>

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Process Step



Decision Step




<b>Phase I</b>		
<b>Application Phase</b>		
Process Step	Summary of Process	Responsibility
Applicant obtains forms	The applicant must obtain the HREC application form and guidelines either from the MSHR website <a href="http://www.menzies.edu.au">www.menzies.edu.au</a> or by requesting a copy from the Ethics Administration Officer (EAO) who will email the forms/guidelines to the applicant.	Applicant/EAO
Applicant becomes familiar with relevant literature	Applicant reads and becomes familiar with the relevant guidelines and policies for the conduct of research into human beings (as in Appendix 1)	Applicant
Applicant completes the form	Applicant fully completes the form following the guidelines.  <u>HDR Candidates</u> must submit the form to their supervisor for review.  During drafting of the research proposal, in close consultation with the supervisor, human ethics clearance issues should be identified.  This includes:	Applicant

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	<ul style="list-style-type: none"> <li>• Distributing a questionnaire, interviewing, or speaking formally or informally to people to obtain information you need for your research project;</li> <li>• Obtaining access to information held by indigenous people or communities;</li> <li>• Conducting psychological, medical or any other type of experiments on people;</li> <li>• Obtaining data about individuals from records held by any organisation, even if you are employed by the organisation and access to the records is part of your job.</li> </ul>	
Supervisor supports application/requests changes/more information	Supervisor reviews the HREC application and where necessary requests changes, more information etc. When satisfied with the application the supervisor submits it to the Head of School (HOS) for review.	Supervisor
HOS supports application/requests changes/more information	HOS reviews the HREC application and where necessary requests changes, more information etc. When satisfied with the application the HOS submits it to the EAO for review.	HOS
Application checked for completeness and follow up of any additional information	The EAO checks the application for completeness, correct sign off/approval and at this time may request additional information as required.	EAO

<b>Phase II HREC Meeting Phase</b>		
Process Step	Summary of Process	Responsibility
EAO prepares HREC and AESC agendas	EAO prepares HREC and AESC agendas, including list of CDU approvals as applicable.	EAO
AESC considers applications involving Aboriginal participants and provides minutes of meeting to EAO	For applications including Aboriginal participants, AESC approves/requests more information/modification of project. AESC provides minutes of meeting to EAO prior HREC meeting.	AESC
EAO receives minutes of AESC meeting and provides to HREC members	EAO receives minutes of AESC meeting and provides to HREC members at their meeting	EAO
HREC approves/ requests more information/	The HREC approves/ requests more information/ modification of project.	HREC
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modification of project	<b>HREC cannot approve applications vetoed by AESC</b>	
HREC recognises CDU HREC approvals	HREC recognises and ratifies relevant CDU HREC approvals	HREC

<b>Phase III Notification Phase</b>		
Process Step	Summary of Process	Responsibility
<b>If successful:</b> EAO issues clearance notice to applicant, copies to HDR supervisor, updates internal records and advises CDU HREC RCEO of NTDHCS/MSHR decision	EAO issues HREC clearance notice to applicant, copies to HDR supervisor if applicable, updates internal records and advises CDU HREC RCEO of recognition and relevant NTDHCS/MSHR decision.	EAO
<b>If more information/ modification required:</b> EAO requests more information or modifications	EAO requests more information or modifications.	EAO
Applicant provides additional information/ modification of the project	Applicant provides additional information/ modification of the project for consideration by HREC nominated process (ie. Chair, Fast Track Committee or Full Committee)	Applicant

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## Appendix 1: Essential Reading

Applicants should have read and become familiar with the following documentation.

**NHMRC National Statement on Ethical Conduct in Research Involving Humans, 1999**  
<http://nhmrc.gov.au/publications/synopses/e35syn.htm>

**NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, 2003**  
<http://nhmrc.gov.au/publications/synopses/e52syn.htm>

**The Commonwealth Privacy Act, 1998.** NHMRC has issued Guidelines Under Section 95 and 95A of the Privacy Act 1988

Section 95 <http://nhmrc.gov.au/publications/synopses/e26syn.htm>

Section 95A <http://nhmrc.gov.au/publications/synopses/e43syn.htm>

**The Northern Territory Information Act, 2002**  
[http://notes.nt.gov.au/dcm/legislat/legislat.nsf/0/306b17e5e75d2ff069256e99001ba1fb/\\$FILE/Repi013.pdf](http://notes.nt.gov.au/dcm/legislat/legislat.nsf/0/306b17e5e75d2ff069256e99001ba1fb/$FILE/Repi013.pdf)

**CDU Human Ethics Policy**  
[http://eagle.cdu.edu.au/ntu/apps/ntuinfo.nsf/WWWView/Policy\\_721](http://eagle.cdu.edu.au/ntu/apps/ntuinfo.nsf/WWWView/Policy_721)

**AIATSIS Guidelines for Ethical Research in Indigenous Studies, 2000**  
<http://www.aiatsis.gov.au/corp/docs/EthicsGuideA4.pdf>

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