

**Townsville Health Service District  
Human Research Ethics Committee (HREC)  
EC00183**

**HREC application submission dates, HREC meeting dates & HREC site requirements 2012**

Closing Date Applications to be submitted by 12 midday, two weeks prior to meeting	Human Research Ethics Committee (HREC) First Thursday of the month, except January
19 <sup>th</sup> January	2 <sup>nd</sup> February
16 <sup>th</sup> February	1 <sup>st</sup> March
22 <sup>nd</sup> March	5 <sup>th</sup> April
19 <sup>th</sup> April	3 <sup>rd</sup> May
24 <sup>th</sup> May	7 <sup>th</sup> June
21 <sup>st</sup> June	5 <sup>th</sup> July
19 <sup>th</sup> July	2 <sup>nd</sup> August
23 <sup>rd</sup> August	6 <sup>th</sup> September
20 <sup>th</sup> September	4 <sup>th</sup> October
18 <sup>th</sup> October	1 <sup>st</sup> November
22 <sup>nd</sup> November	6 <sup>th</sup> December

<b>SUBMISSION OF DOCUMENTS</b>	
<b>POSTAL ADDRESS</b>	<b>PERSONAL DELIVERY</b>
HREC Coordinator	HREC Coordinator
The Townsville Hospital	Medical Services Support Unit
PO Box 670	Ground Floor, Medilink Building
Townsville QLD 4810	4796 1140

- For all studies other than Low & Negligible Risk Research a completed online NEAF with 'Submission Code' accessed from online NEAF website: <https://ethicsform.org/au/SignIn.aspx> should be submitted
- All supporting documents should be uploaded with the NEAF under the "Documents Tab" on the Online Forms website: <https://ethicsform.org/au/SignIn.aspx>
- All documents should be copied double sided, collated and contain version numbers, version dates and page numbers. Do not bind the documents.
- The closing time for submissions is 12 midday. Please note: There are no exceptions to the closing time without prior agreement by the HREC Administrator
- All multi-centre research studies should be submitted through the QH Central Coordinating Service 07 323 40654. QH HREC should not accept direct submission of a multi-centre research study
- Please note: *Incomplete submissions will not be accepted*

**Townsville Health Service District HREC EC00183**  
**Research Study Checklist for Coordinating Principal Investigators**

A copy of this checklist should be included with every new research project application submitted to the reviewing HREC

<b>A) Mandatory components for all submissions to an HREC</b>		<b>YES</b>	<b>No. of copies required</b>
1.	Cover letter, signed by Coordinating Principal Investigator with: <ul style="list-style-type: none"> <li>o Brief description of project, including phase of study if a clinical trial</li> <li>o List of all sites where study is to occur, applicable to this HREC application</li> <li>o List of supporting documents submitted and uploaded onto online forms</li> <li>o HREC reference number (for multi-centre studies only – as allocated by QH Central Coordinating Service)</li> <li>o For commercially sponsored studies the name and address of the sponsor organisation/CRA for the HREC review invoice (must be Australian address) must be included in the cover letter</li> </ul>		15
2.	For low and negligible risk (LNR) research studies – Completed LNR application form accessed from: <a href="http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp">http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp</a> and all supporting documentation		1
3.	For all other studies: Completed online NEAF with ‘Submission Code’ accessed from online NEAF website: <a href="https://ethicsform.org.au/SignIn.aspx">https://ethicsform.org.au/SignIn.aspx</a>		15
3.	Study protocol ((Although the protocol may have the same information as the NEAF or LNR application form, the protocol is the study working document. It is the formal design or specific plan for the research. When revisions occur during the course of the research you will need to submit a revised protocol as an amendment. The protocol should include a version date/number which is changed as the document is updated)		15
4.	CV for researchers who have not submitted a CV within last 2 years		15

<b>B) Other items that may be required depending on the particular research project application being submitted</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>No. of copies required</b>
5.	Data collection tool(s) e.g CRF				15
6.	Master Participant Information Sheet and Consent Form (PICF)				15
7.	CTN/CTX form(s)				15
8.	Investigator’s Brochure				15
9.	Questionnaires/other instruments				15
10.	For industry sponsored studies: Form of indemnity ( <a href="#">Medicines Australia HREC Review Only form</a> ) if HREC is not located at a participating site.				15
11.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)				15
12.	Letter of invitation/Letter to GP, etc.				15
13.	Participant diaries				15
14.	Participant wallet card				15
15.	Other correspondence, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.				15
<b>Research using gene technology</b>					
16.	<u>Institutional Biosafety Committee (IBC) approval</u>				15
17.	Licence for dealings with a Genetically Modified Organism (GMO)				15
<b>Research which is using radiological procedures that are performed specifically for research</b>					
18.	Independent assessment report or verification by a Medical Physicist (or District Radiation Safety Officer) of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol				15