

**Darling Downs Health Service District  
Human Research Ethics Committee (HREC)  
EC00182**

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

Closing Date Applications to be submitted by 12 midday 2 weeks prior to meeting date	Scientific Review Sub- Committee (SRSC) Usually 2 <sup>nd</sup> Tuesday of the month	Human Research Ethics Committee (HREC) 2 <sup>nd</sup> Thursday of the month except January
27 <sup>th</sup> January	7 <sup>th</sup> February	9 <sup>th</sup> February
23 <sup>rd</sup> February	6 <sup>th</sup> March	8 <sup>th</sup> March
29 <sup>th</sup> March	10 <sup>th</sup> April	12 <sup>th</sup> April
26 <sup>th</sup> April	8 <sup>th</sup> May	10 <sup>th</sup> May
31 <sup>st</sup> May	12 <sup>th</sup> June	14 <sup>th</sup> June
28 <sup>th</sup> June	10 <sup>th</sup> July	12 <sup>th</sup> July
26 <sup>th</sup> July	7 <sup>th</sup> August	9 <sup>th</sup> August
30 <sup>th</sup> August	11 <sup>th</sup> September	13 <sup>th</sup> September
27 <sup>th</sup> September	9 <sup>th</sup> October	11 <sup>th</sup> October
25 <sup>th</sup> October	6 <sup>th</sup> November	8 <sup>th</sup> November
29 <sup>th</sup> November	11 <sup>th</sup> December	13 <sup>th</sup> December

<b>SUBMISSION OF DOCUMENTS</b>	
<b>POSTAL ADDRESS</b>	<b>PERSONAL DELIVERY</b>
HREC Coordinator	HREC Coordinator
The Undercroft	The Undercroft
Mount Lofty Heights Nursing Home	Mount Lofty Heights Nursing Home
MOUNT LOFTY QLD 4350	MOUNT LOFTY QLD 4350
	Phone: 07 4616 4924

- 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*

**Darling Downs Health Service District HREC  
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>	<input type="checkbox"/>	1
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	<input type="checkbox"/>	3
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>	<input type="checkbox"/>	18
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)	<input type="checkbox"/>	18
4.	CV for researchers who have not submitted a CV within last 2 years	<input type="checkbox"/>	1

<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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
6.	Master Participant Information Sheet and Consent Form (PICF)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
7.	CTN/CTX form(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1
8.	Investigator’s Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
9.	Questionnaires/other instruments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1
11.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
12.	Letter of invitation/Letter to GP, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
13.	Participant diaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
14.	Participant wallet card	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
15.	Other correspondence, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18
<b>Research using gene technology</b>					
16.	<u>Institutional Biosafety Committee (IBC) approval</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1
17.	Licence for dealings with a Genetically Modified Organism (GMO)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1
<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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1