

**Darling Downs West Moreton Health Service District
Human Research Ethics Committee (HREC)
EC00184**

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

Closing Date Applications to be submitted by 12 midday	Human Research Ethics Committee (HREC)
January 23/12	February 07/12
March 19/12	April 03/12
May 14/12	May 29/12
July 09/12	July 24/12
September 03/12	September 18/12
October 29/12	November 13/12

SUBMISSION OF DOCUMENTS	
POSTAL ADDRESS	PERSONAL DELIVERY
Darling Downs West Moreton Health Service District (HREC)	Jacqueline Robinson
The Park - Centre for Mental Health, Locked Bag 500 Sumner Park QLD 4074	Acting-Chair /Ethics Officer /RGO The Park - Centre for Mental Health, Locked Bag 500 Sumner Park QLD 4074
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- 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 West Moreton Health Service District HREC EC00184
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

A) Mandatory components for all submissions to an HREC		YES	No. of copies required
1.	Cover letter, signed by Coordinating Principal Investigator with: <ul style="list-style-type: none"> o Brief description of project, including phase of study if a clinical trial o List of all sites where study is to occur, applicable to this HREC application o List of supporting documents submitted and uploaded onto online forms o HREC reference number (for multi-centre studies only – as allocated by QH Central Coordinating Service) 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 		1
2.	For low and negligible risk (LNR) research studies – Completed LNR application form accessed from: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp and all supporting documentation		1
3.	For all other studies: Completed online NEAF with ‘ <i>Submission Code</i> ’ accessed from online NEAF website: https://ethicsform.org/au/SignIn.aspx		16
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)		16
4.	CV for researchers who have not submitted a CV within last 2 years		1

B) Other items that may be required depending on the particular research project application being submitted		YES	NO	N/A	No. of copies required
5.	Data collection tool(s) e.g CRF				16
6.	Master Participant Information Sheet and Consent Form (PICF)				16
7.	CTN/CTX form(s)				1
8.	Investigator’s Brochure				16
9.	Questionnaires/other instruments				16
10.	For industry sponsored studies: Form of indemnity (Medicines Australia HREC Review Only form) if HREC is not located at a participating site.				1
11.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)				16
12.	Letter of invitation/Letter to GP, etc.				16
13.	Participant diaries				16
14.	Participant wallet card				16
15.	Other correspondence, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.				16
<u>Research using gene technology</u>					
16.	<u>Institutional Biosafety Committee (IBC) approval</u>				16
17.	Licence for dealings with a Genetically Modified Organism (GMO)				16
<u>Research which is using radiological procedures that are performed specifically for research</u>					
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				1