

**QLD Children's Health Services (RCH) Human Research Ethics Committee (HREC)
EC00175**

Deadlines for submitting applications & Meeting Dates for 2012

CLOSING DATE	Human Research Ethics Committee (HREC)
Monday 16th January	Monday 30th January
Monday 5th March	Monday 19th March
Monday 16th April	Monday 30th April
Monday 4th June	Monday 18th June
Monday 16th July	Monday 30th July
Monday 27th August	Monday 10th September
Monday 8th October	Monday 22nd October
Monday 19th November	Monday 3rd December

Submission of Documents:

POSTAL ADDRESS	PERSONAL DELIVERY
QLD Children's Health Services (RCH) Human Research Ethics Committee (HREC) Royal Children's Hospital Level 3, Foundation Building Herston Road Herston QLD 4029	Royal Children's Hospital Department of Paediatrics and Child Health Level 3, Foundation Building Herston Road Herston QLD 4029

- 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 must be collated and contain version numbers, version dates and page numbers.
- Information on HREC site specific requirements eg; the number of documents required to be submitted can be found on the REGU website: HREC & Research Governance Officer Contacts under 'Site requirements' http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp
- The closing time for submissions is 330pm. 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

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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 		11 collated
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 paper and 1 electronic copy
3.	For all other studies: Completed online NEAF with 'Submission Code' accessed from online NEAF website: https://ethicsform.org/au/SignIn.aspx		11 collated
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)		11 collated
4.	CV for researchers who have not submitted a CV within last 2 years		1

B) Other items that <u>may</u> 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				11
6.	Master Participant Information Sheet and Consent Form (PICF)				11
7.	CTN/CTX form(s)				1
8.	Investigator's Brochure				1
9.	Questionnaires/other instruments				11
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)				11
12.	Letter of invitation/Letter to GP, etc.				11
13.	Participant diaries				11
14.	Participant wallet card				11
15.	Other correspondence, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.				11
<u>Research using gene technology</u>					
16.	<u>Institutional Biosafety Committee (IBC) approval</u>				1
17.	Licence for dealings with a Genetically Modified Organism (GMO)				1
<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