

**Gold Coast Health Service District
Human Research Ethics Committee (HREC)
EC00160**

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

Closing Date Applications to be submitted by 12 midday 2nd Wednesday of the month	Human Research Ethics Committee (HREC) 4th Wednesday of the month except April and December
11 January	25 January
8 February	22 February
14 March	28 March
11 April	2 May
9 May	23 May
13 June	27 June
11 July	25 July
8 August	22 August
12 September	26 September
10 October	24 October
14 November	28 November

SUBMISSION OF DOCUMENTS	
POSTAL ADDRESS	PERSONAL DELIVERY
8 Little High Street	8 Little High Street
SOUTHPORT QLD 4215	SOUTHPORT

- 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*

GOLD COAST HEALTH SERVICE DISTRICT HREC EC00160
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 original and 13 copies
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 hard copy 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				1 original and 13 copies
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)				1 original and 13 copies
4.	CV for researchers who have not submitted a CV within last 2 years				1 original and 13 copies
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				1 original and 13 copies
6.	Master Participant Information Sheet and Consent Form (PICF)				1 original and 13 copies
7.	CTN/CTX form(s)				1 original
8.	Investigator’s Brochure				1 original and 13 copies
9.	Questionnaires/other instruments				1 original and 13 copies
10.	For industry sponsored studies: Form of indemnity (Medicines Australia HREC Review Only form) if HREC is not located at a participating site.				1 original
11.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)				1 original and 13 copies
12.	Letter of invitation/Letter to GP, etc.				1 original and 13 copies
13.	Participant diaries				1 original and 13 copies
14.	Participant wallet card				1 original and 13 copies
15.	Other correspondence, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.				1 original and 13 copies
Research using gene technology					
16.	<u>Institutional Biosafety Committee (IBC) approval</u>				1 original and 13 copies
17.	Licence for dealings with a Genetically Modified Organism (GMO)				1 original and 13 copies
Research which is using radiological procedures that are performed specifically for research					
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 original and 13 copies