

**Royal Brisbane & Women's Hospital Human Research Ethics Committee (HREC) EC00172
Metro North Health Service District**

HREC application closing dates, SSC & HREC meeting dates 2012

Closing Date last Tuesday of the month Applications to be submitted by 12 pm	Scientific Sub-Committee (SSC) 2nd Monday of the month	Human Research Ethics Committee 3rd Monday of the month
31 st January	13 th February	20 th February
28 th February	12 th March	19 th March
27 th March	Easter Electronic reviews only	16 th April
*30 th April (Monday)	14 th May	21 st May
29 th May	Queen's Birthday Electronic reviews only	18 th June
26 th June	9 th July	16 th July
31 st July	13 th August	20 th August
28 th August	10 th September	17 th September
25 th September	8 th October	15 th October
30 th October	12 th November	19 th November
27 th November	10 th December	17 th December

POSTAL or COURIER ADDRESS	PERSONAL DELIVERY
HREC Office Royal Brisbane & Women's Hospital Level 7 Block 7 Butterfield Street Herston 4029	HREC Office Royal Brisbane & Women's Hospital Level 7 Block 7 (corner Herston Rd & Bowen Bridge Road) Telephone: 07 3646 6132 Email: RBWH-Ethics@health.qld.gov.au

- For all applications other than low & negligible risk research, please complete the QH online NEAF including "[Submission Code](https://ethicsform.org/au/SignIn.aspx)" accessed at: <https://ethicsform.org/au/SignIn.aspx>
- Please upload all supporting documents to the online NEAF under the "[Documents Tab](#)"
- All documents require document identifier, version numbers, dates and page numbers in the footer. Please copy all documents as single documents and double sided. Please use fold back clips or staples only. Please do not use paper clips. After stapling documents separately please collate one of each into 8 separate bundles.
- **The closing time for applications is 12 midday.** Please note there are no exceptions.
- All multi-centre research studies should be booked in at the QH Central Coordinating Service 1300 753 227 or 07 3234 0654.
- Please note: *[Incomplete applications will not be accepted](#)*

RBWH HREC Site Requirements

Research Application Checklist for Coordinating Principal Investigators

A copy of this checklist should be included with each new research application

A) Mandatory components for all submissions to an HREC		YES	No. of copies required
1.	Cover letter, <u>signed by the Coordinating Principal Investigator</u> including: <ul style="list-style-type: none"> Brief description of project, including phase of study if a clinical trial; List all sites to be approved; List of supporting documents submitted and confirm they have been uploaded to the NEAF HREC reference number if allocated by QH Central Coordinating Service Name, address and telephone number of the sponsor organisation/CRA for commercially sponsored research (<i>must be an Australian address</i>) 	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
2.	For low and negligible risk (LNR) applications – please complete LNR application form accessed at: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
3.	For greater than low risk or special populations please complete the QH online NEAF including 'Submission Code' at: https://ethicsform.org/au/SignIn.aspx	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
3.	Study protocol must be submitted with all applications irrespective of risk level. <i>The protocol is the study working document. It is the formal design or specific plan for the research. It generally goes into greater detail for the conduct of the research. If the study is amended after approval, you may submit a revised tracked protocol with a covering letter explaining the changes. The protocol should include document identifier, version number and date.</i>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
4.	CV for researchers & clinical trial coordinators who have not submitted a CV within last 2 years (brief bio-sketch – 2 pages)	<input type="checkbox"/>	1 + CD/ USB electronic copy of all documents

B) Other items that may be required depending on the research application being submitted		YES	N O	N/A	No. of copies required
5.	Data collection tool(s) that require HREC approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
6.	Master Participant Information Sheet & Consent Form (PICF)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
7.	CTN/CTX form(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1 hard copy for each site
8.	Investigator's Brochure/s	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1 + CD/ USB electronic copy of all documents
9.	Questionnaires/other instruments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
10.	For industry sponsored research: Form of indemnity (Medicines Australia HREC Review Only form) if HREC is not located at a participating site.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3 hard copies to RGO
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"/>	8 + CD/ USB electronic copy of all documents

B) Other items that may be required depending on the research application being submitted		YES	NO	N/A	No. of copies required
12.	Letter of invitation/Letter to GP, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
13.	Participant diaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
14.	Participant wallet card	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
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"/>	8 + CD/ USB electronic copy of all documents
<u>Research using gene technology</u>					
16.	<u>Institutional Biosafety Committee</u> (IBC) approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
17.	Licence for dealings with a Genetically Modified Organism (GMO)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents
<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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 + CD/ USB electronic copy of all documents

ROYAL BRISBANE & WOMEN'S HOSPITAL RESEARCH GOVERNANCE OFFICE

DOCUMENTATION REQUIRED FOR SUBMISSION OF NEW SITE-SPECIFIC ASSESSMENT APPLICATIONS (SSA)

**Research Governance Office, Level 4, UQCCR, RBWH
Phone: 07 3646 8579**

Nº:	Description	Nº: of Copies	Yes, N/A or pending
1.	Copy of covering letter sent to HREC, signed by Principal Investigator containing a brief description of the proposed study	1	
2.	Site-Specific Assessment Form	1	
3.	NEAF	1	
4.	Research related documentation (PICF, questionnaires, advertisements, diaries)	1	
5.	Protocol	1	
6.	Clinical Trial Agreement	3	
7.	Indemnity Form	3	
8.	Insurance Certificate	1	
9.	CaSS approval	1	
10.	Pathology Queensland quote	1	
11.	Pharmacy quote	1	
12.	Radiology quote	1	
13.	QCAT approval	1	
14.	PHA approval	1	
15.	CTN (after HREC approval)	1	

Research Governance Office contacts:

Research Support Officer: Jenny Lonton, phone 07 3646 8579
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Administration Officer: Anitha Vummidi, phone 07 3646 2377
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Director of Research: Professor Lawrie Powell AC, phone 07 3646 2352
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Remember to obtain all signatures prior to submission