Human Research Ethics Committee site requirements

Research application checklist for Coordinating Principal Investigators (CPIs)

A copy of this checklist should be included with each new ethics application to the Human Research Ethics Committee (HREC) at The Prince Charles Hospital or Royal Brisbane and Women's Hospital.

For the ethical and scientific review of multi-centre clinical research under the National Mutual Acceptance Scheme refer also to that CPI checklist available at:
http://www.health.qld.gov.au/ohmr/html/regu/mou_serp.asp

All ethics applications for multi-centre research can be booked in through the Central Coordinating Service:
http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp

All applications:

- For all applications please complete either the Human Research Ethics Application (HREA) or the Low or Negligible Risk (LNR) Queensland form accessed via the Online Forms website: https://ethicsform.org/au/
- Upload all supporting documents to the Online HREA or Online LNR form under the "Documents" tab. All documents require a document identifier: version numbers, dates (dd/mm/yyyy) and page numbers must be included in the footer.
- Once the ethics application is finalised create a submission code using the "Submission" tab.
- Hard copies of all documents should be double-sided and stapled as single, separate documents. Please use staples or fold-back clips only; collate one of each separate document into the number of bundles indicated below. Only 1 separate bundle is required for LNR applications.
- An electronic copy of all documents is required on a CD or USB.
- Applications should be posted or delivered to the HREC office address (page 4).
- The closing time for applications is 12 pm (midday). Please note there are no exceptions. Incomplete applications will not be accepted.

No.	Description	TPCH HREC No. of hard copies	RBWH HREC No. of hard copies	Check (☑) for Yes
Mandatory components for all HREC submissions				
1.	Cover Letter (signed by the Coordinating Principal Investigator) including: • Brief description of project, including phase of study if a clinical trial • List all sites to be approved • List of supporting documents submitted and confirmation that they have been uploaded to the documents tab in Online Forms • HREC reference number if allocated by the Central Coordinating Service • Name, address and telephone number of the sponsor organisation or Contract Research Organisation for commercially sponsored research (must be an Australian address) together with Purchase Order Number (if required)	2*	6*	
2.	Ethics application form with a submission code – either a **HREA** or **LNR** form accessed at: https://ethicsform.org/au/SignIn.aspx All supporting documents should be uploaded against the application form using the "Documents" tab.	2*	6*	
3.	Study Protocol (must be submitted with all applications irrespective of risk level)	2*	6*	
4.	Signed and dated CVs for researchers and clinical trial coordinators who have not submitted a CV within the last 2 years (this should be a brief bio-sketch – 2 pages)	1	1	
5.	Electronic copy of all checklist documents on a CD or USB	1	1	

***Only 1 copy is required for LNR applications.**

No.	Description	TPCH HREC No. of hard copies	RBWH HREC No. of hard copies	Check (☑) for Yes or NA for Not applicable
Mandatory if applicable (depending on the research application being submitted)				
6.	Data collection tool(s) that require HREC approval	2*	6*	
7.	Master Participant Information Sheet & Consent Form (PICF)	2*	6*	
8.	CTN / CTX Form(s) *(copy of 'Draft' eCTN Form to be submitted with application)*	1	1	
9.	Investigator's Brochure/s	1	1	
10.	Questionnaires / other instruments	2*	6*	
11.	For industry sponsored research: Medicines Australia Form of Indemnity For Clinical Trials (Standard form or HREC Review Only form if HREC is not located at a participating site)	3	3	
12.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)	2*	6*	
13.	Letter of invitation, letter to General Practitioners etc.	2*	6*	
14.	Participant Diaries	2*	6*	
15.	Participant Wallet Card	2*	6*	
16.	Other correspondence, e.g. Food and Drug Administration reviews, correspondence from other HRECs, expert independent reviews, peer reviews, Victorian Module etc.	2*	6*	
For research using Gene Technology:				
17.	Institutional Bio-safety Committee approval	2	6	
18.	Licence for dealings with a Genetically Modified Organism	2	6	
For research which is using radiological procedures that are performed specifically for research:				
19.	Independent Assessment Report or verification by a Medical Physicist (or Radiation Safety Officer) of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol	2	6	

***Only 1 copy is required for LNR applications.**

For applications or further information, please use the contact details below:

The Prince Charles Hospital	Royal Brisbane and Women's Hospital
Research, Ethics and Governance Unit Building 14 The Prince Charles Hospital Rode Road, Chermside, Qld 4032 Email: ResearchTPCH@health.qld.gov.au Phone: (07) 3139 4500	Human Research Ethics Office Level 7, Block 7 Royal Brisbane and Women's Hospital Butterfield Street, Herston, Qld 4029 Email: RBWH-Ethics@health.qld.gov.au Phone: (07) 3646 5490

Date	Version	Custodian
11/2015	1.0	HREC Coordinators, The Prince Charles Hospital and Royal Brisbane and Women's Hospital
13/09/2017	2.0	HREC Coordinators, The Prince Charles Hospital and Royal Brisbane and Women's Hospital