HREC Submission checklist

This submission checklist is for Coordinating Principal Investigators (CPIs). A copy of this checklist should be included with each new ethics application to the Royal Brisbane and Women's Hospital (RBWH) and The Prince Charles Hospital (TPCH) Human Research Ethics Committee's (HREC).

For the ethical and scientific review of multi-centre clinical research under the National Approach to Single Ethical Review of Multi-Centre Studies, please refer also to that CPI checklist available at: http://www.health.qld.gov.au/ohmr/html/regu/mou_serp.asp

All applications:

- For all research applications, please complete the Human Research Ethics Application (HREA). Submission of requests for exemption for QA/Audit activities, please see the HREC Exemption guidelines. All applications should be submitted via Ethics Review Manager (ERM) - https://au.forms.ethicalreviewmanager.com/
- Upload all supporting documents to the Online HREA form under the "Documents" tab. All documents require a document identifier: version numbers, dates (dd/mm/yyyy) and page numbers, which must be included in the footer.
- Once the Ethics application is finalised on ERM, please sign the application and press 'Submit'.
- **TPCH:**
  - 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 Low-Negligible Risk (LNR) applications.
  - For hard copy submissions, applications should be posted or delivered to the HREC office address (page 4).
  - Once submitted via ERM, please send all documentation to ResearchTPCH@health.qld.gov.au
- **RBWH:**
  - No hard copies required.
  - Once submitted via ERM, please send all documentation to RBWH-Ethics@health.qld.gov.au

The closing time for all applications is 12.00 pm (midday).

Please note there are no exceptions. Incomplete applications will not be accepted.

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No	Description	TPCH HREC # Hard copies	RBWH HREC # Hard copies	Check for Yes
Mandatory components for all HREC submissions				
1.	**Cover Letter** (signed by the Coordinating Principal Investigator) including: • Brief description of the project, including Phase of the study if a clinical trial • List of all sites and Principal Investigators requiring approval • List of supporting documents submitted and confirming they have been uploaded into ERM • Name, address, telephone number and email of the sponsor organisation/CRA for commercially sponsored research • If participants are not being consented for the use of their confidential health information in a research study, please justify a waiver of consent in accordance with the National Statement section 2.3.10	2*	Nil	
2.	**Study Protocol** Must be submitted with all applications irrespective of risk level. The Protocol is a study's working document. It is the formal design or specific plan for the research. It should be robust, providing clear and detailed information on the research study. The Protocol should include a document identifier, version number and date.	2*	Nil	
3.	**CV / Resume** For researchers and Clinical Trial Coordinators who have not submitted a CV within the last 2 years	1	Nil	

***Only 1 copy is required for LNR applications (see the HREC Low Negligible Risk research review process)**

No	Description	TPCH HREC # Hard copies	RBWH HREC # Hard copies	Check for Yes
Other items which may be required, depending on the research application being submitted				
4.	**Data collection tool(s)**	2*	Nil	
5.	**(Master) Participant Information Sheet & Consent Form (PICF)**	2*	Nil	
6.	**CTN / CTX Form(s)** *(copy of eCTN Registration to be submitted with application)*	1	Nil	
7.	**Investigator's Brochure/s**	1	Nil	
8.	**Questionnaires / other instruments**	2*	Nil	
9.	**For industry sponsored research -** Medicines Australia Form of Indemnity for Clinical Trials (Standard form for HREC Review Only) - if HREC is not located at a participating site and for the review of private sites	3*	Nil	
10.	**Advertising materials** (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)	2*	Nil	
11.	**Participant Letter of Invitation** / Letter to General Practitioners etc.	2*	Nil	
12.	**Participant Diaries**	2*	Nil	
13.	**Participant Wallet Card**	2*	Nil	
14.	**Other correspondence**, e.g. Food and Drug Administration reviews, correspondence from other HRECs, expert independent reviews, peer reviews, Victorian Module etc.	2*	Nil	
For research using Gene Technology:				
15.	**Institutional Bio-safety Committee approval**	2	Nil	
16.	**Licence** for dealings with a Genetically Modified Organism	2	Nil	
For research which is using radiological procedures that are performed specifically for research:				
17.	**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	Nil	

***Only 1 copy is required for LNR applications (see the HREC Low Negligible Risk research review process)**

For more information please contact:

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** Executive Suites, Lower Ground Floor Dr James Mayne Building 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 & Royal Brisbane & Women's Hospital
13/09/2017	2.0	HREC Coordinators, The Prince Charles Hospital & Royal Brisbane & Women's Hospital
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