

HREC Amendment Checklist

This amendment checklist applies to the Royal Brisbane and Women's Hospital (RBWH) and The Prince Charles Hospital (TPCH) Human Research Ethics Committees (HRECs).

Your submission should include:

- Please upload amendment requests and supporting documentation into Ethics Review Manager (ERM) - <https://au.forms.ethicalreviewmanager.com/>
- In the study's Ethics application on ERM, please select the 'Create Sub-Form' action tile and select 'Amendment'. Complete and submit the sub-form in the same manner as the main Ethics application form.
- Please ensure that all documents have document identifiers in the footers, i.e. version numbers, dates (dd/mm/yyyy) and page numbers.
- Detailed covering letter explaining the rationale for changes to the study and study documents. For commercially sponsored studies, please also submit the Metro North Office of Research Invoicing Details Form.
- If you have not submitted a progress report within the last 12 months, please include with this amendment. Please note that ongoing ethical approval is now contingent upon the submission of an Annual Progress Report, to be received by 30 April each year.
- **RBWH and TPCH:** No hard copies are required

Possible changes to your study	Yes	No	N/A
It is important that all documents be proof-read and checked for typographical, grammatical and cut and paste errors. Has this been done?			
Site amendment:			
Is this amendment to add additional site/s?			
Have you submitted a covering letter with details of the new site/s and investigator/s; together with CVs?			
Protocol amendment:			
Is a Protocol Amendment being submitted?			
Has the Principal Investigator provided a covering letter explaining the changes to the Protocol?			
Has an amended Protocol with tracked changes been provided? OR Does the Protocol Amendment have a separate summary attached, explaining the changes?			

Possible changes to your study	Yes	No	N/A
Has the Metro North Office of Research Invoicing Details Form been provided?			
Does the Protocol Amendment require a revised Participant Information Sheet & Consent Form (PICF)? If so, has this been submitted? Please provide one tracked change & one clean copy with a new sequential version number and amended date in the footer.			
Does the Protocol Amendment require the submission of any extra documents, e.g. Questionnaire, Advertisement, etc?			
If so, do each of these documents have a version number and date in the footer?			
Has an Annual Report been submitted to enable on-going ethical approval? When was the last Annual Report submitted? /...../.....			
Does the Protocol Amendment refer to the expansion of recruitment of patients? If so, how many more participants/patients need to be recruited?			
Amended Information Sheet & Consent Form (PICF):			
Please indicate which PICF has been amended? i.e. Participant PICF; SDM (Substitute Decision Maker) PICF; Genetic PICF			
Has a tracked change version and clean copy of the PICF been attached?			
Has the Coordinating / Principal Investigator provided a covering letter explaining the changes?			
1) Do existing participants need to be re-consented to the new or amended PICF?			
2) Does the amendment in the PICF relate to additional risks to the patient?			
3) Do all Consent Forms have provision for the participant signature and the date?			
Does the amended PICF have a new sequential version number and amended date in the footer?			
Does the PICF have the full title of the study at the top of the Information Sheet and at the top of the Consent Form?			
Updated Study Documents:			
Is an updated Investigator's Brochure being submitted?			
Please provide one tracked change & one clean copy of amended documents with a new sequential version number and amended date in the footer.			
Has the Principal Investigator explained the rationale for the updates in a covering letter?			

For further information, please use the contact details on the final page:

Ethics Committee

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 2 Building 34 Royal Brisbane and Women's Hospital Butterfield Street, Herston, Qld 4029 Email: RBWH-Ethics@health.qld.gov.au Phone: (07) 3647 1007

Research Governance Officers

Metro North Hospital and Health Service
Research Governance Office Block 7 Level 7, Royal Brisbane and Women's Campus Email: MNHHS-RGO@health.qld.gov.au Additional contact details: Rebekah Steele, Research Governance Manager. Ph: 3647 9550 (Mon-Fri) Vanessa Constable, Research Governance Officer. Ph: 3883 7243 (Mon; Wed-Fri) / 3647 8052 (Tues) Therese Starr, Research Governance Officer: Ph: 3646 5033 (Mon-Fri) Lisa Bryant, Research Governance Officer. Ph: 3646 5047 (Mon-Tue) / 3139 4407 (Wed-Fri)

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
05/12/2019	3.0	HREC Coordinators, The Prince Charles Hospital & Royal Brisbane & Women's Hospital
31/03/2022	4.0	HREC Coordinators, The Prince Charles Hospital & Royal Brisbane & Women's Hospital