

Amendment checklist

Your submission should include:

- Detailed covering letter explaining the rationale for changes to the study and study documents (including the name, address and telephone number of the sponsor organisation/CRA for commercially sponsored research - must be an Australian address)
- If you have not submitted a progress report within the last 12 months please include with this amendment
- One electronic and one hard copy of each amended document (please submit double-sided, stapled separate documents)

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? Does the Protocol Amendment have a separate summary attached, explaining the changes? or Has an amended Protocol with tracked changes been provided?			
Have invoicing details (together with Purchase Order / Reference Number, if required) been provided for the sponsor organisation/CRA?			
Does the Protocol Amendment require a revised 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?			
Does the Protocol Amendment involve an extension of the time to conduct the study? If so, what is the extended length of time being sought?			
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. SDM PICF (Substitute Decision Maker); 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 Investigator's Brochure (IB):			
Is an updated Investigator's Brochure being submitted?			
Has the Principal Investigator explained the rationale for the update in a covering letter?			

For further information, please use the contact details below:

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 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

Research Governance Officers

The Prince Charles Hospital	Royal Brisbane and Women's Hospital
Research Ethics and Governance Unit Ascar Yu Email: RGOTPCH@health.qld.gov.au Phone: (07) 3139 4407	Research Governance Office Jacqueline Robinson Email: RBWH-RGO@health.qld.gov.au Phone: (07) 3646 8579

Redcliffe, Caboolture & Kilcoy Hospital, Community, Indigenous Subacute Services
Research Governance Office Vanessa Constable Email: RCRGO@health.qld.gov.au Phone: (07) 3883 7243

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