Amendment checklist

Your submission should include:

- A detailed covering letter explaining the rationale for changes to the study and study documents (including the name, address and telephone number of the sponsor organization / CRA for commercially sponsored research - must be an Australian address)
- Electronic submission via ERM (https://au.forms.ethicalreviewmanager.com/).

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?			
Has an amended Protocol with tracked changes been provided?			
Has the **Invoicing and Fee Form** (to be completed for all commercially sponsored research) been submitted?			
Does the Protocol Amendment require a revised Participant Information Sheet & Consent Form (PICF)? If so, has this been submitted? Please provide a tracked change & 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 refer to the expansion of recruitment of patients?			

If so, how many more participants/patients need to be recruited?			
Amended Participant Information Sheet & Consent Form (PICF):			
Please indicate which PICF has been amended? i.e. Main PICF; Substitute Decision Maker (SDM) 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 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 contact:

RBWH HREC
Email: RBWH-Ethics@health.qld.gov.au
Phone: (07) 3647 1007

MNHHS Research Governance Office
Email: MNHHS-RGO@health.qld.gov.au
Phone: (07) 3647 9550