

GUIDE TO SUBMITTING AN AMENDMENT FOR SITE AUTHORISATION

Adventist HealthCare

Please choose the most appropriate option:

1. Where the amendment request is to a research project being conducted at multiple sites and the amendment request has undergone single ethical review by a NHMRC Certified HREC which has granted ethical approval of the amendment for an Adventist HealthCare site and an external entity agreement is in place between the Lead HREC and AHCL, submit the amendment to the Research Office by following ***Procedure 1***.

PROCEDURE 1

Step 1:

Submit the following documents electronically to the Manager, Research Office ResearchGovernanceOffice@sah.org.au for site authorisation.

- Cover letter
- Copy of NHMRC Certified HREC letter approving the amendment
- Copy of full HREC submission
- Site Specific PICF documents based on approved Master and on site letterhead. Submit documents as clean and tracked changes. The version number and date must be updated in the footer.
- Other site specific participant documents based on approved Master and on site letterhead. Submit documents as clean and tracked changes. The version number and date must be updated in the footer.

Please note: The maximum document size is 10MB and the mail box limit is 10MB.

Step 6:

Fees are payable to the Research Office for governance review and site authorisation of an amendment to an authorised research project. A Tax Invoice will be issued upon receipt of the amendment. The fees are outlined in the *Fee Schedule*.

If you wish to discuss submission of the amendment in person the Manager, Research Office may be contacted on (02) 94879604.