Adventist HealthCare Research

Apply for Ethical Review of a Lower or Higher Risk Study

REQUIRED DOCUMENTS

☐ PROTOCOL

Submit your research outline on the most suitable AHCL Protocol Template. There are two templates available for download on our website, one for SPONSORED CLINICAL TRIALS and one for OBSERVATIONAL or EXPERIMENTAL RESEARCH (not sponsored), which are the only templates the AHCL HREC accepts for review. Any sections that are irrelevant to your project's design may be crossed out. See: www.sah.org.au/research-ethical-review

☐ HUMAN RESEARCH ETHICS APPLICATION

This form can be completed online at https://hrea.gov.au/. Download the ZIP or PDF file once completed and attach it to your submission email.

☐ CURRICULUM VITAES (CV)

All investigators contributing to the project must submit **signed and dated** CVs (dated within 3 years of project submission) for an assessment of adequate clinical and research skills.

☐ GOOD CLINICAL PRACTICE CERTIFICATE (GCP)

A valid GCP certificate (dated within 3 years of project submission) is required for all prospective studies. Retrospective studies do not require GCP.

☐ PARTICIPANT INFORMATION & CONSENT FORM (PICF)

Consent is one of the most important considerations in modern era research, and participation needs to be the result of an informed decision made by participants.

For prospective studies: Submit a PICF either on the AHCL HREC template (for download on the website) or alternatively use one of the NHMRC PICF templates (at the bottom of that webpage).

For retrospective studies: If participants have already consented to their data being used for research, the HREC will need to review the consenting process. Submit any information that showcases the process you have applied, for example a copy of the medical intake form seeking consent for research.

If the HREC regards the consent inadequate, you may need to re-consent participants or apply for a Waiver of Consent[1].

INSTRUCTIONS

Send **one email** to the Research Office containing all documents to start the ethical reviewing process.

An office internal review will be conducted including a risk assessment to determine the most appropriate reviewing pathway for your proposal. We may request additional information if required.

Refer to our website for HREC submission deadlines: www.sah.org.au/ethics-committee

CASE STUDIES and EXEMPTIONS from ethical review don't follow this process. Please refer to the respective GUIDES on our website: www.sah.org.au/research-office

[1] Refer to our Guide: *Apply for a Waiver of Consent for Retrospective Research* for details. Available for download on the Research Office website at: www.sah.org.au/research-ethical-review.