Adventist HealthCare Research

Apply for Ethical Review of Lower Risk or Higher Risk Research

REQUIRED DOCUMENTS

Lower Risk review (AHCL Institutional Low Risk Ethics Committee (ILREC))

☐ PROTOCOL

The AHCL ILREC review projects using the approved template OBSERVATIONAL or EXPERIMENTAL RESEARCH (not sponsored) at the link below (Resources, Forms and templates tab). Any sections that are irrelevant to your project's design may be crossed out. See: www.sah.org.au/research-ethical-review

☐ CURRICULUM VITAES (CV)

All investigators contributing to the project must submit CVs (with research experience within 5 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 researchers (except medical students).

☐ 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. Please note, the below applies to studies being reviewed by the AHCL ILREC.

For prospective studies: Submit a PICF either on the AHCL ILREC template (for download on the website) or alternatively use one of the NHMRC PICF templates or the National PICF.

For retrospective studies: If participants have already consented to their data being used for research, the AHCL ILREC 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 AHCL ILREC regards the consent inadequate, you may need to re-consent participants or apply for a Waiver of Consent[1].

Higher Risk review (external HREC)

Documentation requirements differ between HRECs, please make enquiries with the chosen HREC to ensure the correct documentation is submitted.

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 review pathway for your proposal. We may request additional information if required.

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.