AHCL RESEARCH ETHICS AND GOVERNANCE FEE SCHEDULE

1. PURPOSE (OPTIONAL)

1.1. To provide an overview of the fee structure for ethical and governance reviews on research projects at Adventist HealthCare Limited (ACHL).

2. SCOPE (MANDATORY)

2.1. This document is aimed at research projects requiring ethical review by the AHCL HREC and/or research projects requiring site governance review at an AHCL facility.

3. DEFINITIONS (OPTIONAL)

3.1. **Amendment charges** are applied by receipt of a submission. Researchers are encouraged to submit all documents that require review at the same time, i.e. in one submission, to avoid extra charges.

3.2. **Amendment (standard)** means any alteration to documentation to an existing ethically and/or governance approved project at AHCL unless they fall into the category of a minor or complex amendment.

3.2.1. One charge applies per submission if the update of study documents relates to a Protocol or IB change.

3.2.2. If the amendment does not relate to a Protocol or IB update, one separate charge will be applied and includes the review of up to three (3) documents.

3.2.3. Additional fees will be charged for additional documents to the study that have not been reviewed previously, and one charge will be applied for up to three (3) documents. For example, two additional PICFs = $500.00

3.2.4. Examples of standard amendments are updates to Protocols, IBs, PICFs, Research Agreements/Contracts (or similar), Addendums, Appendices; as well as change of personnel and additions of study sites

3.3. **Amendment (complex)** means a protocol amendment that involves an update to the project aims, objectives or the study design, participant's safety or mental integrity, quality or safety of any therapeutic good used in the study. An amendment is also classified as complex when a review impacts additional hospital resources in addition to those already sourced, necessitating further coordination and review of budget and governance processes.

3.4. **Amendment (minor)** means any of the following updates: to site name or address, progress reporting, safety reporting, final reporting, CTN acknowledgment, insurance certificate; none of these incur a fees.

3.5. **Commercially sponsored research** means:

The research is initiated by a pharmaceutical/device company or a cooperative collaborative group with commercial funding and the IP belongs to the commercial entity.

3.6. **Cooperative/Collaborative group research** means:

3.6.1. The co-operative group must be the primary author and custodian of the research protocol

3.6.2. The sponsor is a research institute, university or collaborative group.

3.6.3. The research addresses clinical questions and not industry or commercial interests

3.6.4. The cooperative group must declare the nature of any sponsorship from a pharmaceutical/medical device entity or other entity that may directly benefit commercially from the research outcomes.

3.6.5. The research project must have a Principal Investigator accredited or employed by AHCL

3.7. **Greater than low risk** means research that falls within the definition of greater than low risk within the National Statement i.e. where the risk to participants is greater than discomfort.

3.8. **Investigator Initiated research** means:

3.8.1. The principal investigator is accredited or employed by Adventist HealthCare Limited (AHCL) or the Sydney Adventist Hospital

3.8.2. The principal investigator is the primary author or custodian of the study protocol

3.8.3. If the principal investigator is only affiliated with the Australian National University or Avondale University, a co-investigator must be accredited or employed by AHCL

3.9. **Negligible risk research** means research that falls within the definition of negligible risk within the National Statement i.e. no foreseeable risk of harm or discomfort and no more than inconvenience to participants

3.10. **Low risk research** means research that falls within the definition of low risk within the National Statement i.e. where the foreseeable risk is one of discomfort

3.11. **Submission** means documentation forwarded to the Research Office for governance review with the intention of commencing research at AHCL and/or with the intention of ethical review by the AHCL Human Research Ethics Committee (HREC). The documentation does not have to be submitted in its entirety to constitute a submission; however, the review of a submission will only commence once all required documents have been received by the Research Office.

3.12. **Withdrawing a submission**. Submissions can be withdrawn by calling or emailing the Research Office before ethical approval or site specific authorisation was granted. After approval or authorisation, a final report will need to be submitted to the Research Office alongside a notification of completions or early discontinuation of the study. Submission charges still apply to submissions that are withdrawn.

4. DETAILS (MANDATORY)

4.1. Those that fall within the scope of this document have an obligation to read and understand the AHCL Ethics and Governance fee structure.

5. REFERENCES (MANDATORY)

5.1. National Health and Medical Research Council, (2007 updated 2018). **National Statement** on Ethical Conduct in Human Research.

5.2. AHCL (1 Nov 2013). Research Ethics and Governance Schedule of Fees Version 1-Nov-3013.

6. ACKNOWLEDGEMENTS

6.1. Northern Sydney Local Health District (n.d.). Fee Policy. Northern Sydney Local Health District. Fees and payments - Research Ethics and Governance - Northern Sydney Local Health District (nsw.gov.au)
6.2. Macquarie University (2022). Research. Macquarie University. Macquarie University - Research - PhD & MRes, Fellowships, Facilities (mq.edu.au)
6.3. Cabrini Health Australia (2022). Research & Education. Cabrini Health Australia. Cabrini Health Australia - Not-for-profit Health Services
6.4. Ramsay Health Care (2022). Research. Ramsay Health Care. Ramsay Health Care - Ramsay Health Care | Australia

7. RELATED POLICY or OTHER DOCUMENT (OPTIONAL)

7.1. AHCL Research Policy
7.2. Operations Manual: Human Research Ethics Committee Executive Officers (OME)
7.3. Operations Manual: Human Research Ethics Committee (OMC)

8. REVIEWED BY (MANDATORY)

8.1. Shari Emerton, Research Officer, Research Ethics and Governance Office
8.2. Daniela von Hieber, Manager, Research Ethics and Governance

AHCL RESEARCH ETHICS AND GOVERNANCE FEE SCHEDULE

AHCL RESEARCH ETHICS AND GOVERNANCE FEE SCHEDULE

Research type	Ethics fees (excl. GST)	Governance fees (excl. GST)	Amendment fees (excl GST)
Investigator initiated [1]	Nil	Nil	Nil
Cooperative/collaborative group [2] without commercial sponsorship	Low/negligible risk[3]: $300.00 Greater than low risk[4]: $500.00	$500.00	Standard: $150.00 Complex: $450.00
Commercially sponsored [5] (includes Pharmaceutical and collaborative/cooperative group)	$3,000.00	$3,600.00	Standard: $500.00 Complex: $1,700.00

AHCL ethics and governance fees are charged per submission of documents to the Research Office for review. For a definition of amendment types, please refer to Section 3 of the AHCL RESEARCH ETHICS AND GOVERNANCE FEES policy.

---

[1] Investigator initiated research has the following characteristics:
- The principal investigator is accredited or employed by Adventist HealthCare Limited (AHCL)
- The principal investigator is the primary author or custodian of the study protocol
- If the principal investigator is affiliated with ANU then there must be a co-investigator on the project accredited or employed by AHCL

[2] Cooperative/Collaborative group without commercial sponsorship has the following characteristics
- The co-operative group must be the primary author and custodian of the research protocol
- The sponsor is a research institute, university or collaborative group.
- The research addresses clinical questions and not industry or commercial interests
- The cooperative group must declare the nature of any sponsorship from a pharmaceutical entity or other entity that may directly benefit commercially from the research outcomes
- The research project must have a PI accredited or employed by AHCL

[3] Low/negligible risk research projects fall within the definition contained within the National Statement:
- Negligible risk projects: no foreseeable risk of harm or discomfort and no more than inconvenience to participants
- Low risk: where the foreseeable risk is one of discomfort

[4] Greater than no risk research projects fall within the definition contained within the National Statement:
- Where the risk even if unlikely is more serious than discomfort, the research is not low risk.

[5] Commercially sponsored research has the following characteristics:
- The research is initiated by a pharmaceutical/device company or a cooperative collaborative group with commercial funding
- The research is conducted to investigator a medication/device for commercial exploitation by its manufacturer/sponsor
- The study protocol has been developed and is the responsibility of a pharmaceutical/device company of other commercial entity