

## SA HEALTH RESEARCH ETHICS AND GOVERNANCE FEES SCHEDULE

This schedule replaces the December 2017 SA Health Research Ethics and Governance Fees Schedule, and is effective as of 15 April 2019.

### 1. Clinical Trials Research Ethics Review Fees

#### a. Clinical Trials with Full Commercial Sponsorship

Item	Cost (GST Exc)	GST	Total
HREC Review Fee (Including CPI site)	\$5000	\$500	\$5500
HREC Review Fee for each additional site, charged on a per site basis	\$500	\$50	\$550
Addition of sub-study	\$1500	\$150	\$1650
Major Amendment	\$1000	\$100	\$1100
Minor Amendment	\$600	\$60	\$660
Other Amendment	\$300	\$30	\$330

#### b. Cooperative Research Group (CRG) Clinical Trials/Non-Commercially Sponsored Clinical Trials

*Note: fees for CRG trials can only be reduced or waived at the discretion of the HREC/Institution upon request.*

Item	Cost (GST Exc)	GST	Total
HREC fee (including CPI site)	\$2000	\$200	\$2200
HREC Review Fee for each additional site, charged on a per site basis	\$200	\$20	\$220
Major Amendment	\$400	\$40	\$440
Minor Amendment	\$200	\$20	\$220
Other Amendment	\$100	\$10	\$110

## 2. Clinical Trials Research Governance Review Fees

### a. Clinical Trials with Full Commercial Sponsorship

Item	Cost (GST Exc)	GST	Total
Initial SSA Review Fee	\$3000	\$300	<b>\$3300</b>
Contract Amendment	\$400	\$40	<b>\$440</b>
Review of monitoring documentation (non SA Health HREC review only)	\$200	\$20	<b>\$220</b>

### b. Cooperative Research Group (CRG) Clinical Trials and other Non-Commercially Sponsored Clinical Trials

Item	Cost	GST	Total
Non - commercially sponsored CTN Clinical Trial SSA review	\$1000	\$100	<b>\$1100</b>
Non-commercially sponsored clinical trial with no CTN submission	\$300	\$30	<b>\$330</b>

*Note: the single fee for CRG and non-commercially sponsored trials covers the life of the study including any amendments received post-approval. Payment of the TGA's CTN submission fee (and any other relevant CTN fee) is the responsibility of the CRG or PI and not the Institution.*

### 3. Contract Review Fee

A Contract Review Fee will apply to the review of 'non-standard' research agreements that require site review by an appropriate officer. This fee may be altered to cost recovery at the discretion of the Institution.

Item	Cost (GST Exc)	GST	Total
Contract Review Fee	\$300	\$30	\$330

### 4. Definitions

#### CPI Site

This refers to the lead site in a clinical trial at which the Coordinating Principal Investigator is based.

#### Major Amendment

A major amendment includes the following:

- All protocol amendments, defined as changes to the protocol which may include:
  - Revision of the study design due to safety issues
  - Revisions in drug dosage, participant groups and numbers of study participants
- Investigator Brochure updates, where there are associated changes required to the PICF.

#### Minor Amendment

A minor amendment includes the following:

- Protocol revisions limited to the correction of language, grammar and numbering in a protocol
- Participant Information Sheet amendments requiring HREC review
- Changes to previously approved recruitment material (e.g. flyers, advertisements or letters of invitation)
- Other documentation requiring HREC review and approval

#### Other Amendment

Any other amendment requiring review by the HREC, including:

- Participant Information Sheet amendments with changes of no ethical significance, e.g. administrative changes.
- Investigator Brochure updates where there is no change required to the PICF.