

SA Health Research Ethics and Governance Fees Schedule

Please note: this document replaces the *SA Health Fees Policy for the Review of Research Ethics and Research Governance Applications*.

This schedule is effective 01/09/14 and will be subject to review in the future.

1. Clinical Trials Research Ethics Fees

a. Clinical Trials with Full Commercial Sponsorship

Item	Total (exc. GST)
HREC Review Fee (Including CPI site)	\$5000 + \$500 per site
Addition of sub-study	\$1500
Major Amendment ¹	\$1000
Minor Amendment ²	\$600
Other Amendment ³	\$300

b. Cooperative Research Group (CRG) Clinical Trials

Note: the fees for CRG trials may be reduced or waived at the discretion of the HREC.

Item	Total (exc. GST)
HREC fee	\$2500 + \$250 per site
Major Amendments	\$500

¹ Major Amendments include:

- 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

² Minor Amendments include:

- Protocol revisions limited to the correction of language, grammar and numbering in a protocol
- Investigator Brochure updates
- Participant Information Sheet amendments (e.g. changes to content requiring HREC review)
- New Recruitment Material (e.g. Flyers, Advertisements, Invitation Letters, Newsletters)
- Other letters (where content needs HREC review and approval)

³ Other Amendments include:

- Minor Participant Information Sheet amendments (e.g. minor wording changes with no ethical significance)
- Review of Patient Cards
- Updates to existing recruitment material (e.g. Flyers, Advertisements, Invitation Letters, Newsletters)
- Retention items (e.g. tote bags, magnets, pens)

2. Research Governance Fees

Note: the SSA Review Fee covers all research governance costs incurred by the site for the life of the study, including the initial SSA review, consideration of SSA amendments, and project monitoring undertaken by the Research Governance Officer. The fees for CRG trials may be reduced or waived at the discretion of the RGO.

a. Clinical Trials with Full Commercial Sponsorship

Item	Total (exc. GST)
SSA Review Fee	\$3000
Contract Review Fee ⁵	\$300

⁵This fee applies to the review of 'non-standard' CTRAs (not the Medicines Australia templates or agreements that have undergone SEBS review), and other trial related agreements and documents that require site review by an appropriate officer.

b. Cooperative Research Group (CRG) Clinical Trials

Item	Total (exc. GST)
SSA Review Fee	\$1500