



## SA HEALTH RESEARCH ETHICS AND GOVERNANCE FEES SCHEDULE

This schedule is effective from 1 July 2024 and replaces all previous schedules.

### Key information

SA Health Human Research Ethics Committees that review a clinical trial charge the fees set out in *Table 1 Clinical trial research ethics review fees*.

SA Health clinical trial sites charge the fees set out in *Table 2 Clinical trial research governance review fees*.

All prices are GST exclusive.

**Table 1. Clinical trial research ethics review fees**

| Item  | Clinical trial - Cooperative Research Group (CRG)*/Non-commercial sponsorship | Clinical trial - full commercial sponsorship |
|---|---|--|
| HREC review fee Phase 1   | n/a   | \$8250                                       |
| HREC review fee All other phases (Including CPI site)                 | \$1100  | \$6600                                       |
| HREC review fee for each additional site, charged on a per site basis | \$220   | \$550  |
| Addition of sub- study  | n/a   | \$1650                                       |
| Major amendment   | \$440   | \$1100                                       |
| Minor amendment   | \$220   | \$660  |
| Other amendment   | \$110   | \$330  |

*\*Note: Fees for CRG trials can only be reduced or waived at the discretion of the HREC/institution upon request to the applicable Research Office. Research Office contact details can be found [here](#).*

**Table 2. Clinical trial research governance review fees**

| Item  | Non-commercial sponsored CTN clinical trial | Non-commercial sponsored clinical trial with no CTN submission | Clinical trial - full commercial sponsorship |
|---|---|--|--|
| Initial SSA review fee                                | \$1100                                      | \$330  | \$4400                                       |
| Contract amendment                                    |   |  | \$440  |
| Review of amendments (non SA Health HREC review only) |   |  | \$330  |

*Note: The single fee for CRG and non-commercial 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.*

### 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  |
|---------------------|-------|
| Contract review fee | \$550 |

### Definitions

**CPI site:** the lead site in a clinical trial at which the Coordinating Principal Investigator is based.

**Major amendment:** amendments which include:

- Revision of the study design
- 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:** amendments which include:

- 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.