

Schedule of Fees for Sponsored Clinical Trials

Updated March 2018*

Establishment Fee: \$1500-\$2300 per Trial (Generally \$1500 for oral therapy and \$1800-\$2300 for IV therapy, depending on trial complexity).

- Review of protocol and protocol familiarisation.
- Attendance at site initiation and selection meetings.
- Sponsor provided training (on-line modules to complete, IWRS training etc).
- Liaising with investigators, trial coordinators and monitors.
- Quality assurance to ensure pharmacy services comply with ethics and governance.
- Establishing pharmacy dispensing procedures and drug accountability forms.
- Education of pharmacy staff**.
- Clinically check CHARM pathway.
- Build and check BATCH sheet (for products compounded in Sterile Production Centre).

Annual Fee Charged from Trial Commencement. \$1300/ year*

- Receiving and maintaining inventory of stock.
- IWRS functions (online stock receipt, subject randomizations, inventory verification, kit allocation).
- Monitoring and audit visits by sponsor.
- Maintenance of drug accountability forms.
- Handling, recording and destruction of returned stock. Drug destruction/returns will occur as per SOP. Requirements outside SOP will incur additional charges. Refer to Drug destruction SOP.
- Expiry date checking.
- Ongoing liaison with investigators, study coordinators and monitors

*Rates may vary depending on trial complexity

Completion \$400 /Trial

This includes all procedures associated with finalization of the study including:

- Completion of drug accountability registers.
- Stock Return or destruction.
- Archiving of records.
- Final monitoring meeting.
- Storage of archives.

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Re-labelling Fee \$120 per hour

- Relabelling of expired stock to extend the shelf life.
- Charged at a minimum of 1 hour per episode.

Supply of commercial stock – cost plus 20%

- Trials requiring the site use commercial stock will incur a 20% charge over the cost of procurement and handling.

*This is capped at \$100 per item for high cost items.

Dispensing Fee – Variable

- Dispensing fees are variable and negotiated on an individual basis based on the complexity of the procedures required for preparation and dispensing.
- As a guide - Oral Dispensing – **\$80 per item**. This is a ONCE off charge for multiple doses of the same item.
- Complex dispensing requiring Aseptic manufacture (please refer to SPC SOP for aseptic manufacturing requirements and procedures). Unless prior approval given, trial products will be manufactured according to this SOP. It is the sponsor's responsibility to raise any issues prior to trial initiation
 - Per item **\$150-200** (this may be higher if preparation is very time consuming).

****Note: commercially available drugs will be ordered from a TGA Licensed external compounder according to current local policy. Refer to SPC Standard Procedures for Preparation of Clinical Trial Products****

Clinical Review Fee - \$40 per visit.

- For every patient visit requiring IMP – an experienced Pharmacist clinical check of the order is necessary.

Room Temperature Storage - \$400/year***

- 24 hour continuous ambient temperature monitoring via building and maintenance service with on-call pharmacist to attend excursions within 30 minutes.
- Weekday recording of maximum/minimum ambient temperatures in a central log
- Annual calibration of ambient temperature monitoring device

Refrigerated or Frozen Storage - \$500/year***

- 24 hour continuous ambient temperature monitoring via building and maintenance service with on-call pharmacist to attend excursions within 30 minutes.
- Weekday recording of maximum/minimum ambient temperatures in a central log
- Annual calibration of temperature monitoring device

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Miscellaneous/Additional Charges

From time to time additional costs may be incurred by Pharmacy in the conduct of clinical trials.

These charges include but are not limited to:

- **Call back/Cost of call back (during weekends/after hours) - \$600 per episode (for after hours/Saturday fees, Sunday fees have an additional cost).**

Note: this is subject to approval from the Director of Pharmacy.

- **Remote Monitoring (if applicable) - \$120 per episode**
- **Supportive Medicines (ie pegfilgrastim, rasburicase etc) will be invoiced as clinically indicated to sponsor.**
- **Consumables and Equipment – Negotiable.**

It is preferable if specific consumable and equipment be supplied by the Sponsor.

**These prices listed are guidelines only, and may vary according to trial complexity. Prices are subject to change at any time at the discretion of the pharmacy department. Pharmacy Quotes will need to be reviewed if Trial Protocol Amendments are made after approval of Pharmacy Quote has been granted. Pharmacy quotes are subject for yearly review.*

***Trial specific delegations and training logs will be signed by trials pharmacists. Rotational pharmacists will undergo training as per local SOP. Refer to Rotational Pharmacist Clinical Trials Training SOP. Note: requirements outside of SOP will incur additional charge.*

****Requirements outside of standard operating procedures may incur additional charges to Fridge/Freezer/Ambient Storage. Refer to SOP. In addition, the storage fees may incur an additional charge if the Trial stock is considered quite “bulky” and requires more than expected storage space.*