

SCHEDULE OF FEES FOR CLINICAL TRIALS PHARMACY SERVICES

EFFECTIVE DATE: July 2020

REVIEW DATE: May 2021

SERVICE PROVISION

Objectives of the Pharmacy Clinical Trials Service:

- Support and promote medical and pharmacy research as well as the safe and ethical use of investigational products (IP)
- Ensure, the storage and distribution of IP by pharmacy comply with relevant Acts, Standards and Professional Codes of Practice

The Pharmacy Clinical Trials Service provides the following:

- Reviewing protocols
- Pharmacist attendance at investigator and initiation meetings
- Development and allocation of randomisation codes
- Facilitating regular monitoring and routine auditing visits
- Education and training of pharmacists, pharmacy students and other healthcare professionals
- Counselling of participants and monitoring compliance
- Drug storage and environmental monitoring
- Stock management , dispensing, accountability and control of all investigational drugs
- Aseptic and cytotoxic manufacturing
- Therapeutic drug monitoring
- Procedures associated with trial completion
- Destruction of IP if requested as per protocol
- Archiving of records for a minimum of 15 years

References:

1. SHPA Standards of Practice for Pharmacy Investigational Drugs Services. Aust J Hosp Pharm. 2006; 36(1): 46-53
2. National Statement on Ethical Conduct in Human Research involving Humans. Commonwealth of Australia published 2007.
3. Access to Unapproved Therapeutic Goods. Clinical Trials in Australia. October 2004
4. Human Research Ethics Committees and the Therapeutic Goods Legislation, June 2001.
5. SHPA Clinical Trials Starter Kit (members only)

Please note: The following fee schedule outlined is applicable on a per site basis.

1. Establishment (Once off, fee payable from site initiation visit (SIV))

Per site **\$1,600.00**

2. Administrative

- i) Annual fee (Payable from 1st anniversary of SIV for preceding year and pro-rata at close-out) **\$1,200.00**

- ii) Significant amendments or extensions to protocols/IBs/manuals **\$ 350.00**
This fee will be charged if the amendment results in a change to pharmacy process from the time of site initiation and/or if changes are deemed significant enough to require documented pharmacy staff training. Processes may include changes to storage, dispensing, accountability, returns or destruction.

3. Dispensing/Preparation (Includes accountability)

- i) *Pre-packed trial -medicines**
1-3 items per visit/dispensing occasion **\$ 100.00/occasion**
4-6 items per visit/dispensing occasion **\$ 190.00/occasion**
7 or more items per visit/dispensing occasion **\$ 250.00/occasion**

- ii) *Manufacturing of cytotoxic, sterile and non-sterile preparations**
(Includes basic consumables, accountability and dispensing fees)
Simple preparation (1-4 vials per preparation) **\$ 190.00/item**
Complex preparation (5 or more vials per preparation) **\$ 210.00/item**

- iii) Standard of care treatments (as part of treatment or comparator arm not supplied by sponsor)*
Each item **\$ 30.00**

**Additional \$15/item for narcotic drug dispensing*

4. Destruction

- i) Labour (min 30 minutes) **\$ 80.00/hr**

5. Quarterly Storage (up to 30cmx30cmx30cm)

- i) Monitored ambient storage **\$ 150.00**

- ii) Monitored Narcotic **\$ 200.00**

- iii) Monitored and alarmed fridge storage **\$ 200.00**

- iv) Monitored Freezer storage **\$ 200.00**

Please note: Bulky storage (requiring more than 30cmx30cmx30cm) needs to negotiated separately

6. Relabelling (min 30 minutes)	\$ 80.00/person/hr
7. Close out (once off flat fee)	\$ 350.00
8. Call back and Overtime	
i) Call back fee (minimum 3 hours)	\$ 150.00/hr
ii) Over time (min 1 hour)	\$ 150.00/hr

9. Storage of archives

Study pharmacy binders are preferably archived with main study binders; costs for archiving will be invoiced as part of investigator payments.

Pharmacy off-site storage is also available at commercial rates.

10. Drug Transfer

i) Administrative fee (min half hour)	\$ 80.00/hr
ii) Transport costs	Commercial Rates

11. Reimbursement of commercially obtained medications

Includes reimbursement of commercial drugs (if requested and approved by the sponsor) and consumables used in the preparation and administration of trial drugs. Stock will be purchased specifically for the protocol and will be invoiced to the sponsor at the time of purchase.

A handling fee of 10-20% will be charged on top of the cost of the drug/consumables being reimbursed.

12. Miscellaneous

i) Remote Monitoring (min 30 minutes)	\$ 80.00/hr
ii) Training of staff on amendments not included in amendment fee above (eg. online training modules and face to face) (min 30 minutes)	\$ 80.00/person/hr

Pharmacy reviews the fee schedule every year and reserves the right to implement the new schedule if the duration of the study exceeds 2 years. All pharmaceutical company sponsored trials will be subject to these rates. Trials of high complexity may be subject to extra charges.

Pharmacy fees will be billed separately and require payment directly from the company involved. GST increment will be calculated on all items.

EFT payments made to:
Account Name: Eastern Health
BSB Number: 083 153 Account Number: 515 264 726
Bank: National Australia Bank Branch: 902 Whitehorse Road Box Hill 3128
Swift code: NATAAU 3303M

Send remittance details to: Luisa Stanghi (Email: accountsreceivable_fmis@easternhealth.org.au)