Pharmacy Department
Schedule of Fees for Sponsored Clinical Trials
From September 2024

The Pharmacy Department of Calvary Mater Newcastle remains committed to supporting research activities within this hospital. The fees levied by this department are to ensure that pharmacy resources will not be diverted from primary patient care, while still ensuring a high quality clinical trial service is upheld.

The Fees are the minimum payable, and are dependent upon trial complexity and unexpected events relating to each individual trial. Fees are based on the guidelines from *NSW Association of Directors of Pharmacy of University Teaching Hospital*, "Guiding Principles for Clinical Drug Trial Fees" and are reviewed and updated annually. The Pharmacy should be given the opportunity to amend the CTRA annually in line with fee increases or with each document amendment (whichever is sooner).

1.	**Pharmacy Establishment Fee** (one off payment that does not include 1st year administration fee) Base rate Phase 1 & GMO or Multiple Manipulation Aseptic Manufacturing	 **$2500.00** **$3000.00**
2.	**Pharmacy Annual Administration Fee** (this may be determined from trial start up (SIV) or first shipment arrival - whichever occurs first)	**$2800.00**
3.	**Costs Recovery Items (items not covered in Schedule)** (per hr, min fee 1 hr) (includes but not limited to relabelling, remote/offsite monitor visits, IWRS, shipping returns)	**$ 110.00**
4.	**Pharmacy Close Out /Trial Completion Fee** (payable on correspondence after close out visit)	**$ 600.00**
5.	**Dispensing Fees**	
	Simple Dispensing (per item) **Complex Dispensing/Recordable drug/S8** (per item) **Aseptic Dispensing/Sterile manufacturing** (per item) **Phase 1 & GMO or Multiple Manipulation Aseptic manufacturing** (per item)	**$ 110.00** **$ 220.00** **$ 330.00** **$ 440.00**
6.	**Commercially obtained drug and/or consumables costs and handling fee** (If a trial requires commercially obtained drugs the following will be applicable) **Commercially obtained drug and/or consumables reimbursement** **Commercially obtained drug and/or consumables handling fee** (per invoice)	 **$ Cost** **$ 150.00**
7.	**Emergency Call In** (per event)	**$ 800.00**
8.	**Storage Fees** (charged from arrival of stock, then annually)	
	Refrigerated Storage (per year) **Shelf Storage** (per year) (for bulky trials requiring a large amount of space, this may be negotiated) **Storage of Returned or Expired Stock** (per quarter beyond 3 months) **Freezer Storage** (per year)	**$ 600.00** **$ 400.00** **$ 400.00** **$ 700.00**

	Narcotic Storage S8 – Shelf (per year)	**$ 600.00**
	Narcotic Storage S8 – Fridge (per year)	**$ 800.00**
9.	**Drug Transfer Fee (e.g. site to site transfer)** (per transfer) **+ Transport cost (commercial rates)**	**$ 110.00**

Definitions

1. Pharmacy Establishment Fee

This is a one-off payment that does not include 1st year administration fee. This may be charged if there is RGO approval/site activation to cover work undertaken to set up the trial even if trial is ceased before any patients are recruited. This fee also covers the review and acceptance of our standard operating procedures (SOPs).

2. Pharmacy Annual Administration Fee

This may be determined from trial start up (SIV) or first shipment arrival - whichever occurs first. This fee is payable until trial close out is completed.

3. Cost Recovery Items

This will be calculated and charged on an as needs basis. Additional costs and an amendment may be required for high complexity trials. These items include but are limited to:

- Consumables, equipment
- Complex sourcing and approvals
- Re-labelling
- Remote monitor visits
- IWRS processing (such as returns, destruction etc.) or submitting DCFs on behalf of sponsor
- Shipment box returns (where pharmacy needs to organise courier)
- Organising of dispensed medicines to be delivered to trial participant home
- Site specific issues
- Additional electronic recording and accountability (i.e double handling a task)
- Electronic Data Capture (EDC) form data entry

4. Pharmacy Close Out / Trial Completion Fee

This includes all procedures associated with the finalisation of the study which may include but is not limited to: completion of drug accountability log or IWRS, stock return or destroyed, archiving of records and/or final monitoring meeting.

5. Dispensing

The application by a pharmacist of contemporary knowledge, skill, judgment and care in interpreting and assessing the prescriber's instructions against the patient's medication history and personal characteristics, and may also involve the supply of medication as well as the counselling of the patient so as to achieve the optimum health outcomes.

i. Simple Dispensing

A straightforward investigational dispensing episode including verification the trial has ethics approval; the prescriber is authorised to prescribe the drug in the context of this clinical trial, concordance of dosage and instructions with the protocol, labelling and completion of required trial documentation

ii. Complex Dispensing/Recordable drug/S8

A dispensing episode which requires additional time when compared to a simple dispensing. This may include but is not limited to:

- Additional tasks are required such as recording of a trial with narcotics or cannabis in both trial logs and narcotic registers
- A trial where the pharmacy department conducts IWRS transactions such as the randomisation of packaging the materials, logging the patient data for randomisation, kit verification or other steps during or after the dispensing process

- Trials where pharmacy is the unblinded staff member and is required to do additional unblinded tasks
- Phase 1 trials
- Trials where there are Multiple packs (ie. 4 or more) of the same item to be labelled, time consuming labelling of packs (multiple inner and outer labeling) or multiple entries into dispensing logs
- Trials that involve dispensing to inpatients and liaising with ward staff
- Site specific requirements eg. double handling/signing of all logs and prescriptions

iii. **Aseptic Dispensing/Sterile manufacturing**
Any trial requiring aseptic preparation in a clean room or isolator or biosafety cabinet. Fees will be levied for time and clean room consumables.

iv. **Phase 1 & GMO or Multiple Manipulation Aseptic manufacturing**
Any trial requiring aseptic preparation in a clean room or isolator or biosafety cabinet where multiple manipulations are required to prepare the product or additional product handling/clean room cleaning requirements. This also includes any manufacturing where excessive staff time is required.

6. Commercially obtained drug and/or consumables costs and handling fee

If a trial requires commercially obtained drugs or consumables, a handling fee of $150 per invoice will be charged along with the reimbursement cost of the drug or consumable.

Where a trial involves using drugs reimbursed under S100, the sponsor will be required to pay the co-payment unless there is a mechanism such as the NSW Co-payment waiver scheme in place. Patients should not be out of pocket for their participation in clinical trials. Where the standard of care involves PBS sourced items the sponsor will need to make provision to pay the co-payment.

7. Emergency Call In

This covers all call in that is classed as an emergency which includes but is not limited to: after hours, weekends or public holidays. This does not cover dispensing fees.

8. Storage Fees

This includes temperature monitoring, calibration, service and equipment costs. For bulky trials taking up a large amount of space, this may need to be negotiated at commercial rates.

i. Refrigerated Storage (2-8°C and monitored)
ii. Shelf Storage (ambient)
iii. Storage of Returned or Expired Stock

A charge will be required for trials where patient returns or expired stock are kept for periods beyond 3 months awaiting a monitor's visit. For trial returns requiring a large amount of space commercial rates will apply as negotiated.

9. Drug Transfer Fee

This includes drugs to be transferred to another institution. This does not include courier related costs.

Terms

Charges will be raised on establishment of the Trial, and then at three month intervals thereafter.

Pharmacy Fees should be paid separately from Investigator payments and within 30 days of receipt of a tax invoice.

Fees are EXCLUSIVE of GST, which will be charged as applicable.

Unmonitored trials will be charged per item 10 (see above).

The CMN Pharmacy facility is temperature monitored by an annually calibrated min/max NATA certified system; this includes ambient and refrigerated storage and production. All drug refrigerators are also annually NATA calibrated and certified.

Fees for Collaborative, Cooperative and Investigator Led Clinical Trials will be negotiated on an individual basis.

Version Control

Version	Date	Comments
1.0	31st January 2023	Update of 2022-23 Fees and document format as per recommendations from NSW Clinical Trials Pharmacist Group
2.0	8th March 2024	Update of version 1.0 to include meeting recommendations from NSW Clinical Trials Pharmacist Group – changes include update of cost
3.0	20th August 2024	Update of version 2.0 to include meeting recommendations from NSW Clinical Trials Pharmacist Group – changes include update of cost