POLICY: GUIDING PRINCIPLES FOR CLINICAL DRUG TRIAL FEES
NSW Teaching Hospitals Pharmacy Departments
2018-2019

POLICY STATEMENT:
The primary aim of a Pharmacy Investigational Drugs Service is to optimise patient outcomes by working to achieve the best possible quality use of investigational medicines.
The specific objectives are to:
- support and promote the safe and ethical use of investigational drugs;
- apply the principles of pharmaceutical care to the evaluation of new drugs;
- ensure pharmacy aspects of investigational drug use comply with relevant Acts, Standards and Professional Codes of Practice;
- consider the welfare of study participants and protection of their rights and confidentiality;
- Support and promote clinical and pharmacy research.
These fees are a guideline.

SERVICE PROVISION
Pharmacy Investigational Drugs Service generally provides the following:
- stock management, dispensing and control of all investigational drugs;
- drug storage and environmental monitoring
- destruction of drugs if permitted by the protocol
- emergency 24 hour access to the service;
- assistance with adherence to study protocol;
- counselling of participants and monitoring compliance;
- provision of information to participants and their carers, medical and nursing staff
- review of protocols;
- organization of review of study protocol for Drug Committee or scientific subcommittee, where appropriate;
- provision of advice on study design and/or protocol development;
- development/allocation of randomisation codes (eg for blinded studies);
- preparation of placebos and special dosage forms;
- aseptic reconstitution when required;
- adverse drug reaction reporting;
- literature searches;
- collection and analysis of data;
- education of pharmacists, pharmacy students and other healthcare professionals;
- procedures associated with trial completion;
- archiving of records for a minimum of 15 years; For paediatric patients it is for 15 years or the youngest patient has turned 25 whichever is the longer
- ensures adherence to the following standards and guidelines:

References:


To ensure that there are adequate resources for the efficient provision of the Pharmacy Investigational Drug Service, it is necessary to raise the following charges. It should be noted that the charges raised are not for revenue raising purposes but to meet some of the costs incurred in the provision of the service. These fees are based on the average time required by a Grade 3 pharmacist to complete the tasks. This document is reviewed annually.

All drug company sponsored trials will be subject to the attached rates. Rates will be negotiated for investigator initiated or NHMRC trials at a site level depending on the work component required.

Definitions (for this document)

Clinical trial: a planned study in humans designed to report on the effectiveness and or safety of a diagnostic, therapeutic or prophylactic drug

Investigational Drug: Any drug, or placebo that is being tested or used as a reference in a clinical trial, including a registered drug used in a different formulation or used for a TGA unapproved indication or used in doses outside the approved range or a drug available under the Special Access Scheme

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 counseling of the patient so as to achieve the optimum health outcomes.

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

Complex Dispensing: A dispensing episode which requires additional time when compared to a simple dispensing. This may include
- 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 randomization of packaging the materials, logging the patient data for randomization, kit verification or other steps during or after the dispensing process
- Phase 1 trials
- Trials where there are Multiple packs (ie more than 3) of the same item to be labeled or multiple entries into dispensing logs
- Site specific requirements eg paediatric double handling/signing of all logs and prescriptions

Dispensing Items: these are determined by the number of different labels to be generated.
- ie two strengths of the same drug= 2 items
- Two different drugs =2 items

Complex Dispensing with Aseptic Preparation (or controlled environment): Any trial requiring aseptic preparation in a clean room or isolator or hazard cabinet. Fees will be levied for time and clean room consumables

If a commercial supplier be contracted to perform the preparation these costs need to be covered. If specific personal protective equipment is required in order to prepare the substance the sponsor will be billed.
RATES

Charges will be raised on finalization of the set-up procedure or arrival of stock ie once work related to the trial has commenced. (This may include training and set-up meetings, arrival of stock, ethics endorsement) and then at a suitable interval (e.g. quarterly, annually) for all other charges incurred.

Please note if the Pharmacy Manual is not available or if there is a substantial additional complexity that was unknown at the time costs were estimated a recalculation of the fees will occur.

Cost Recovery for Items not covered in the attached schedule
Costed at $90 per hour
This will be calculated and charged on an as needs basis. Hospitals may need to charge additional costs for trials of high complexity.

- Consumables, equipment
- Complex sourcing and approvals
- Re-labeling,
- Remote monitor visits
- IWRs returns
- Shipment box returns (where pharmacy needs to organize courier)
- Site specific issues
- Training of Protocol Amendment, Investigator Brochure or Pharmacy Manual post establishment which require significant changes to processes
- Electronic recording and accountability
- Set up of building and loading care plans (e.g. chemotherapy) into electronic prescribing systems
- Additional temperature monitoring and maintenance requirements

Investigators should factor in increases of approximately 4% per year (based on salary increases)

Establishment Fee $ 1800
This is independent of participant accrual and includes the administrative procedures with setting up a trial. These charges include but are not limited to:

- Review of protocol
- Study design/protocol development/randomisation codes;
- Literature searches;
- Providing advice on approval procedures via Drug and Institutional Ethics Committees (IEC) or Scientific Research Committee.
- Liaison
- Signing off that pharmacy is able to support the research (governance)
- establishing Pharmacy dispensing procedures and producing trial specific protocols;
- education of pharmacists;
- Completion of training for internet data entry when required and GCP training
- Meetings such as pre-site visits or start up meetings
- Budget negotiation.

This administration fee is fixed irrespective whether any patients are recruited. If the trial does not receive ethics approval a reduced fee of $350 will be charged.
Annual Fee Charged from Trial Commencement. This may be determined from trial start-up (SIV) or stock arrival whichever occurs first.

$1800/Year/Trial

This includes all procedures associated with the ongoing administration of the trial, eg:
- Initial stock management and handling & subsequent receiving/recording stock and expiry date management
- Management of Shipments
- managing ongoing standard documentation
- organizing & making available materials for monitors visits
- handling of returned stock;
- procedures associated with submission and review of serious adverse events; procedures associated with submission and review of amendments including updating trial document;
- Module training Amendment training (for minor changes only)
- Monitoring visits preparation and actions
- Email correspondence

Completion $ 450 /Trial

This includes all procedures associated with finalization of the study, eg:
- completion of drug accountability log;
- Stock Return to the Monitor (Additional Fees apply if Pharmacy is required to Destroy Drugs)
- archiving of records;
- Final monitoring meeting.

Drug Costs only Covered- Handling fee 10-20% if trials require reimbursement of commercially obtained drugs a handling fee of 10-20% will be charged.

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.

Dispensing Fee

Simple Dispensing $60.00 per item
Complex Dispensing $80.00 per item
Complex with Aseptic Dispensing $220.00 per item *
* or at Dispensing fee plus cost where expensive consumables or excessive staff time is required.

Call back or cost of call back (does not include dispensing fee) $525 (minimum)

Storage
There are a number of Storage fees that may apply.

Shelf storage of ongoing trials $300/Trial/Year

For bulky trials taking up a large amount of space, this may need to be negotiated at commercial rates. Note. Current commercial rates are $150 per month per cubic meter space. Retrieval fees may also be required.
### Storage of Returned Stock

$300 per trial per year

A charge may be required for bulky trials where patient returns are kept for periods beyond 3 months awaiting a monitor’s visit or for a shorter period where the trial packaging takes up a large amount of space and the returns process requires pharmacy involvement. This may be at commercial rates.

### Refrigerated storage (monitored) Minimum fee

$500/Trial/Year

Additional refrigeration facilities may need to be provided for bulky products. This includes a fee for temperature monitoring and logs.

<table>
<thead>
<tr>
<th>Storage Type</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>S8 storage (shelf)</td>
<td>$350/Trial/Year</td>
</tr>
<tr>
<td>S8 storage (fridge)</td>
<td>$600/Trial/Year</td>
</tr>
</tbody>
</table>

### Storage of archives

(ie $10/Trial/Year) (onsite within pharmacy)

<table>
<thead>
<tr>
<th>Storage Type</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial rates</td>
<td></td>
</tr>
</tbody>
</table>

### Drug Transfer Costs

Handling Fee

$75.00

Transport costs

Commercial rates

Drugs transferred to another institution, or delivered to patients by courier, which would involve:

- transport costs
- education/information
- quality assurance for handling/transport
- administration/paperwork

### Drug Destruction Charges

The costs for destruction vary according to hospital policy, safe operating practices and the requirements of the trial. These charges are negotiated at each site. Examples of drug destruction charges include:

- Commercial rates
- Per 19 Litre Bin + labour cost
- Per kg + labour cost
- Per occasion of service eg $100 per occasion.
## SUMMARY OF SITE COSTS

**PHARMACY**

Pharmacy Fees should be paid separately from the Investigator payments within 30 days of receipt of a tax invoice. The following costs are EXCLUSIVE of GST.

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Establishment Fee (Does not include 1st years administration fee) **</td>
<td>$1800</td>
</tr>
<tr>
<td>Pharmacy Annual Administration Fee (This may be determined from start up)</td>
<td>$1800</td>
</tr>
<tr>
<td>Cost recovery Items (items not covered in Schedule)</td>
<td>$90</td>
</tr>
<tr>
<td>Simple Dispensing</td>
<td>$60</td>
</tr>
<tr>
<td>Complex Dispensing</td>
<td>$80</td>
</tr>
<tr>
<td>Complex Dispensing with Aseptic Manufacturing</td>
<td>$220</td>
</tr>
<tr>
<td>Complex Dispensing with Aseptic Manufacturing Consumables cost</td>
<td>At cost</td>
</tr>
<tr>
<td>Fridge</td>
<td>$500</td>
</tr>
<tr>
<td>Shelf Storage</td>
<td>$300</td>
</tr>
<tr>
<td>Storage of Returned Stock</td>
<td>$300</td>
</tr>
<tr>
<td>Accountable Drug Shelf Storage</td>
<td>$350</td>
</tr>
<tr>
<td>Accountable Drug Fridge Storage</td>
<td>$600</td>
</tr>
<tr>
<td>Pharmacy Close out fee (Payable after close out visit)</td>
<td>$450</td>
</tr>
<tr>
<td>Archiving of Pharmacy Files (onsite/offsite)</td>
<td>Commercial Rates</td>
</tr>
<tr>
<td>After hours call out fee for dispensing (does not include dispensing fee)</td>
<td>$525</td>
</tr>
<tr>
<td>Handling fees (drug costs only covered) (Drugs purchased for sponsors)</td>
<td>10-20% Or as negotiated</td>
</tr>
</tbody>
</table>