POLICY: SCHEDULE OF FEES FOR CLINICAL DRUG TRIALS  
NSW Teaching Hospitals Pharmacy Departments  

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, 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:
2. SHPA Clinical Trials Starter Kit (members only) 
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 (1)

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 (1)

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 in both trial logs and narcotic registers
- a trial where the pharmacy department conducts the randomization including either packaging the materials or logging the patient data for randomization eg IVRS, IWRS
- 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
- Trials where the stock management system (dispensing and returns) is managed through the interactive web response system (IWRS).

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.
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 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.

**Establishment Fee ($1500)**

This is independent of participant accrual and includes the administrative procedures with setting up a trial.

- 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).** ($1350/ year)

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
- 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;
- Module training
- Amendment training

**Completion** $ 375 /Trial

This includes all procedures associated with finalization of the study, eg:

- completion of drug accountability registers;
- Stock Return to the Monitor (Additional Fees apply if Pharmacy is required to Destroy Drugs)
- archiving of records;
- Final monitoring meeting.
Additional activities not covered above (based on overtime rates) - includes activities which may take more than 10 minutes to complete, eg. Re-labeling, remote monitor visits, IWRS returns $85.00 per hour per staff member.

Drug Costs only Covered-Handling fee 10-20%
If trials require reimbursement of commercially obtained drugs, a handling fee of 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 clinic trials. Where the standard of care involves PBS sourced items the sponsor will need to make provision to pay the co-payment.

Dispensing Fee

<table>
<thead>
<tr>
<th>Simple Dispensing</th>
<th>Complex Dispensing</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Item</td>
<td>$60.00</td>
</tr>
<tr>
<td>Item 2 + subsequent items</td>
<td>$40.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complex dispensing with Aseptic Manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Item</td>
</tr>
<tr>
<td>Item 2 + subsequent simple dispensing items</td>
</tr>
</tbody>
</table>

| One Item         | $150.00 |
| Complex dispensing with Aseptic Manufacture |
| Item 2 + subsequent items | $75.00 |

Call back or cost of call back $450 (minimum)

Storage

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

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. 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

S8 storage $350 /Trial/Year

Storage of archives (ie $10/Trial/Year) (onsite within pharmacy) Commercial rates

Storage of archives off-site Commercial rates
Drug Transfer Costs
Handling Fee $50.00
Transport costs
rates
Drugs transferred to another institution, or delivered to patients by courier, which would involve:
  o transport costs
  o education/information
  o quality assurance for handling/transport
  o 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.

Miscellaneous 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:

- Consumables, equipment
- Remote Monitoring Trials

This will be calculated and charged on an as needs basis. Hospitals may need to charge additional costs for trials of high complexity. Investigators should factor in increases of approximately 4% per year (based on salary increases).
SUMMARY OF SITE COSTS

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>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Establishment Fee (Does not include 1st years administration fee)</td>
<td>$1500(one off)</td>
</tr>
<tr>
<td>Pharmacy Annual Administration Fee (This may be determined from trial start up (SIV)</td>
<td>$1350(per year)</td>
</tr>
<tr>
<td>Simple Dispensing (1st item on a script)</td>
<td>$60</td>
</tr>
<tr>
<td>Simple Dispensing (2nd, 3rd etc items on a script)</td>
<td>$40</td>
</tr>
<tr>
<td>Complex Dispensing (1st item on a script)</td>
<td>$75</td>
</tr>
<tr>
<td>Complex Dispensing (2nd, 3rd etc items on a script)</td>
<td>$40</td>
</tr>
<tr>
<td>Complex Dispensing with Aseptic Manufacturing</td>
<td>$150</td>
</tr>
<tr>
<td>Complex Dispensing with Aseptic Manufacturing (2nd, 3rd etc items on script)</td>
<td>$75</td>
</tr>
<tr>
<td>Fridge</td>
<td>$500/year</td>
</tr>
<tr>
<td>Shelf Storage</td>
<td>$300/year</td>
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<tr>
<td>Accountable Drug Shelf Storage</td>
<td>$350/year</td>
</tr>
<tr>
<td>Pharmacy Close out fee (Payable after close out visit)</td>
<td>$375 (one off)</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</td>
<td>$450 (minimum)</td>
</tr>
<tr>
<td>Miscellaneous Fee eg. Relabeling, remote monitor visits etc</td>
<td>$85/hour</td>
</tr>
<tr>
<td>Handling fees (drug costs only covered)</td>
<td>10-20% Or as negotiated</td>
</tr>
</tbody>
</table>