INVESTIGATIONAL DRUG SERVICE (IDS)

IDS Fee Schedule

Central IDS Pharmacy
UC Davis Health
Investigational Drug Pharmacy, Rm 1107
2315 Stockton Blvd
Sacramento, CA 95817
hs-ids@ucdavis.edu
Central IDS Phone: 916-703-4093
Central IDS Fax: 916-703-7048

Cancer Center IDS (IDSCC) Pharmacy
UC Davis Comprehensive Cancer Center
Investigational Drug Pharmacy
4501 X Street, Rm 1008A
Sacramento, CA 95817
hs-idsc@ucdavis.edu
IDS Cancer Center Phone: 916-734-7176
IDS Cancer Center Fax: 916-734-2260

NOTE: this information is provided FOR REFERENCE ONLY. This information is NOT to be used by researchers to determine the actual IDS fee charges associated with a specific protocol or proposed study. Actual IDS fees will be outlined in a formal, written IDS Fee Schedule to the research team by the IDS staff. The IDS Fee Schedule is based on specific information provided in the protocol, Investigator’s Brochure, and/or the Pharmacy Manual.

Sponsor: 
IRB#: 
Protocol #: 
Dispensing Location(s): IDS 
Study Title:

Protocol Set-up and First Year Inventory Standard Trials
One-time, non-refundable fee charged upon pharmacy study activation or date of first shipment receipt (whichever comes first). Set-up fees include but are not limited to protocol review, site qualification visits, site initiation visits, development of study specific dispensing procedures, EMR entry and label design (mandatory), randomization scheme (if needed), provision of GCP-compliant storage and inventory system including temperature monitoring, IXRS training/set-up, study drug supply security, creation of pre-printed prescription/order template, first year study drug inventory, in-service training for essential pharmacy personnel, drug destruction, and scheduled monitoring visits (equivalent to 6 hours per year, based on rate of $150 per hour).

<table>
<thead>
<tr>
<th>Fee Description</th>
<th>Fee Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Protocol Set-up</td>
<td>$3400-3900</td>
</tr>
<tr>
<td>24-Hour and/or 7 days per week</td>
<td>$4500*</td>
</tr>
<tr>
<td>Cryogenic Liquid Storage Fee</td>
<td>$250</td>
</tr>
<tr>
<td>Non-standard Pharmacy Personnel Training ($150 per hour)</td>
<td></td>
</tr>
<tr>
<td>TOTAL SET-UP FEE</td>
<td>$</td>
</tr>
</tbody>
</table>
**Protocol Set-up and First Year Inventory Oncology/Cancer Center Trials**

One-time, non-refundable fee charged upon pharmacy study activation or date of first shipment receipt (whichever comes first). Set-up fees include but are not limited to protocol review, site qualification visits, site initiation visits, development of study specific dispensing procedures, EMR entry and label design (mandatory), randomization scheme (if needed), provision of GCP-compliant storage and inventory system including temperature monitoring, IXRS training/set-up, study drug supply security, creation of pre-printed prescription/order template, first year study drug inventory, in-service training for essential pharmacy and nursing personnel, hazardous/cytotoxic drug destruction, and scheduled monitoring visits (equivalent to 6 hours per year, based on rate of $150 per hour).

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<td>$</td>
</tr>
</tbody>
</table>

*One-time fee up to $4500, based on IDS’ feasibility assessment

**Protocol Set-up (UCDH Investigator-Initiated Trials)**

One-time, non-refundable fee charged upon pharmacy study activation or date of first shipment receipt (whichever comes first). The Protocol Set-up fee for UCDH Investigator-Initiated Trials (IIT) applies to UCDH PI initiated studies only. This fee requires approval by an Investigational Drug Service Pharmacy Staff Pharmacist. Set-up fees include but are not limited to the services detailed above in Protocol Set-up fees for Standard and Oncology/Cancer Center Trials.

| TOTAL SET-UP FEE | $1500 |

**Study Modification Fee (Standard and Oncology/Cancer Center Trials)**

Study amendments and/or modifications that include changes such as (but are not limited to): the addition of a new treatment arm, addition of investigational products or study drugs, modified dosing schemes, expansions, and/or modified scope of intent may be subject to a study modification fee. This fee is not inclusive of any costs or fees associated with dispensation of investigational products. Determination of the study modification fee shall be subject to the discretion of the IDS pharmacy staff. This fee will be invoiced to the sponsor at the time of each eligible amendment and/or study modification throughout the duration the study.

| TOTAL STUDY MODIFICATION FEE | $150 per hour (NOT TO EXCEED $2000) |

**Annual Maintenance Fee (Standard and Oncology/Cancer Center Trials)**

The Annual Maintenance Fee will be applied to multi-year studies on the anniversary of the pharmacy study activation date or date of first shipment receipt (whichever comes first). The Annual Maintenance Fee includes but is not limited to a quarterly study drug inventory by IDS, study drug accountability, receipt and disposition, scheduled monitoring visits (equivalent to 6 hours per year, based on rate of $150 per hour), temperature monitoring, and query responses.

| Base Annual Inventory Fee | $2150-2400 |
| Cryogenic Liquid Storage/Monitoring Fee | $250 |
| **TOTAL ANNUAL MAINTENANCE FEE** | $ |
Annual Maintenance Fee (UCDH Investigator-Initiated Trials)
The Annual Maintenance Fee for UCDH Investigator-Initiated Trials will be applied to UCDH PI initiated studies only. This fee will be applied to multi-year studies on the anniversary of the pharmacy study activation date or date of first shipment receipt (whichever comes first). The Annual Maintenance Fee includes but is not limited to services detailed above in Annual Maintenance Fees for Standard and Oncology/Cancer Center Trials.

| TOTAL ANNUAL MAINTENANCE FEE | $500 |

Study Close Out Fee (Standard and Oncology/Cancer Center Trials)
Study closure activities include but are not limited to final drug accountability, return or destruction of remaining study drug inventory, and provision and archiving of study documentation.

| TOTAL STUDY CLOSE OUT FEE | $500 |

Dispensing Fees
Dispensing fees will be charged based upon protocol-specific study drug dispensing requirements. Dispensing fees are charged for each prescription number generated. The dispensing fee(s) will be calculated based upon maximum chargeable cost per patient per pharmacy visit. Amount charged may be lower than estimated cost depending on actual prescription. UCDH Investigator-Initiated Trials will not be charged dispensing fees. Additional charges for shipping will apply beyond the fees listed below.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Type of Dispense</th>
<th>BASE COST per Rx number</th>
<th>Additional Fees</th>
<th>MAX CHARGE per Rx number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RANGE: $50-500</td>
</tr>
</tbody>
</table>

MAXIMUM CHARGE PER PHARMACY VISIT

The above IDS Fee Schedule is based on review of:
Protocol version: __________ (DATE)
Pharmacy Manual version: __________ (DATE)

IDS Fee Schedule subject to change upon further review of study materials if necessary.

Pharmacy activity will not commence until signed agreement and required study documents, including DaFIS/Kuali account information, are received by IDS.

IDS Fee Schedule:
Provided to: Provided by: Date:

Agreement to IDS Fee Schedule
I, (the study PI) ____________, understand the fees as described above and agree to pay the above charges.

DaFIS/Kuali account: ____________
Bills will be emailed quarterly (with a read receipt) for review and approval. If no response is received within 30 days, the account will be automatically charged.

PI Signature: ___________________________________________ Date: ____________________