# Investigational Drug Service
## Department of Pharmaceutical Services
## UCSF Health Effective: July 1, 2025

## Investigational Drug Service at
## University of California Medical Centers

This information is provided for reference only.

This schedule describes the fixed fees associated with UCSF Health IDS participation in clinical research studies for fiscal year 2026. **The fees are standardized and non-negotiable**. The fees listed are set based on the costs required to provide the associated services**.** The charges are only incurred when the specified services are required by the study. **The Principal Investigator is responsible to pay for all charges incurred for study activity and management by IDS.**

### 1. Protocol Set-Up

Set-up activities include protocol and budget reviews, site qualification and initiation visits, development of study specific dispensing procedures, medication assessment (special handling, preparation, stability, storage, etc. for non-FDA labeled medications), EMR (electronic medical record) entry and label design, IWRS training/set-up, study drug supply security, creating of prescription/order template, and in-service training for essential pharmacy personnel. This fee is a one-time, non-refundable fee charged by the date of the site initiation visit or first study shipment receipt, whichever occurs first. *The listed set-up fees are starting fees for the type of studies, and additional effort will be billed in one-hour increments at the current hourly rate.*

<table>
<tr><th></th><th>Industry Trials</th><th>Investigator Initiated/ Co-Op/ Government Expanded Access Trials</th></tr>
<tr><td>Standard<br>Beyond 25 hours of service, institutional hourly pharmacist charge ($200/hr) will apply in 1-hour increments</td><td>$4550*<br>$4970**</td><td rowspan="2">$1650</td></tr>
<tr><td>Advanced: Oncology, Immunotherapy, Pediatrics, Vectors, Controlled Substances, Inpatient Beyond 30 hours of service, institutional hourly pharmacist charge ($200/hr) will apply in 1-hour increments</td><td>$5200*<br>$5700**</td></tr>
<tr><td>Off-Hours Dispensing/IDS Support – 24/7 coverage<br>• Covers off-hours pharmacy set-up, logistics planning and training<br>• IP preparation, On-call support<br>• Pharmacy will not be responsible for IWRS responsibilities<br>• 24/7 coverage feasibility review by IDS pharmacist is required to determine the extent of IDS pharmacy participation</td><td colspan="2">$6020***</td></tr>
<tr><td colspan="3">*Protocols that only include drugs or ancillary supplies stored at room temperature<br>**Protocols that include at least one drug or ancillary supply that is stored refrigerated or frozen<br>*** Applies to all studies requiring after hour coverage (both Investigator Initiated and Industry trials)<br>¥For multi-campus studies, only one single set-up fee will be applied (does not apply to regional sites)</td></tr>
</table>

### 2. Annual Maintenance Fee

Annual maintenance and inventory fees will be applied to multi-year studies on the anniversary of the pharmacy set up fee. **If IDS pharmacy anticipates managing any inventory for a study, irrespective of whether IDS pharmacy receives inventory or not, the annual maintenance fee will be applied.** The Annual Maintenance Fee covers, but is not limited to, study drug accountability and storage, receipt and disposition, temperature monitoring. **Please note that studies which require study medication management across multiple UCSF IDS campuses will be charged duplicate maintenance fees PER campus.** Maintenance fees may be omitted for studies that IDS Pharmacy does not manage or anticipated to manage any study drugs for (e.g. study CAR T-cells).

<table>
<tr><th></th><th>Industry Trials</th><th>Investigator Initiated Trials & Expanded Access</th></tr>
<tr><td>Standard</td><td>$2870*<br>$3120**</td><td rowspan="2">$550</td></tr>
<tr><td>Advanced</td><td>$3210*<br>$3450**</td></tr>
<tr><td>24/7 IDS Coverage and Support</td><td colspan="2">$3800***</td></tr>
<tr><td colspan="3">*Protocols that only include drugs or ancillary supplies stored at room temperature<br>**Protocols that include at least one drug or ancillary supply that is stored refrigerated or frozen<br>***Applies to all studies requiring after hour coverage (both Investigator Initiated and Industry trials)<br>¥For multi-campus studies, maintenance fees will apply to each campus that manages study medication.</td></tr>
</table>

### 3. Multi-Campus Studies

- For multi-campus **adult** studies **(Parnassus, Mission Bay, and Mt. Zion)**, one single set-up fee and close-out fee will be charged for all campuses. If study set-up (e.g. > 25 hours for standard or > 30 hours for advance) or close out exceeds the allotted time, then an ad-hoc charge of $200/hour billed in 15-minute increments will be charged for any additional time.
- Maintenance fees will be charged for each campus on which study drug is stored and maintained.
- Dispensing fees, monitoring fees, and other fees will be charged at both sites per utilization.
- **The above does not apply to regional sites (Berkeley, San Mateo, etc) and non-campus locations.**
    - **Regional sites and non-campus locations will set-up studies using their own fee schedules independently.**

### 4. Dispensing Fees

Dispensing fees will be charged based upon protocol specific study drug dispensing requirements and drug handling and preparation requirements. Dispensing fees will vary based on the complexity of the preparation (e.g. simple dispense, compounded product, sterile compound, hazardous drug). Dispensing fees are charged for each prescription number generated (i.e., per each dosage strength and each dose dispensed), and for each dose identified and relabeled by an IDS pharmacist if the investigational drug has been previously dispensed. The dispensing fee provided in an IDS budget will be calculated based upon information provided during budget review but may be different at the time of dispense, depending on effort, Sponsor-specific requests and requirements (including IWRS entries and extra documentation) and non-standard materials required. *Additional IDS effort required per dispense will be billed in 15-minute increments at the current hourly rate.*

UCSF Health

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| | Fees for Industry, Investigator Initiated Trials & Expanded Access |
|---|---|
| Non-sterile compounding ROUTINE dispense<br>• Bottles or cartons of oral, topical, pre-filled syringes<br>• Drug identification and labeling of previously dispensed product (includes Patient's Own Medication) | $65 per dosage strength |
| Non-sterile compounding COMPLEX dispense<br>• Requiring elaborate procedures, such as non-sterile compounding or reconstitution, weighing powders/bottles, aliquoting or dilutions, medisets or filling blisterpaks/outpatient unit doses | $200 each<br>Plus applicable non-standard materials costs |
| Sterile compounding ROUTINE dispense<br>• Non-hazardous injectable; compounding required. Includes cost of standard infusion tubing. | $200 each<br>Plus applicable cost for non-standard supplies |
| Sterile compounding COMPLEX dispense<br>• Hazardous injectable; compounding required. Includes cost of CTSDs and standard infusion tubing<br>• Requiring special procedures: vectors, serial dilutions, unit dose syringes, large doses, and cellular therapy | $330<br>Plus applicable non-standard materials cost |
| Controlled Substances<br>Schedule I-V: Will be added on to dispensing fee. | $50<br>Plus applicable reverse distribution charges |
| Inpatient Unit Dose<br>Not applicable if compounding is required or short-stability | $15 per dose and dosage strength |
| Additional time or action required per dispense<br>IDS staff is required to complete extra documentation per dispense by Sponsor/PI, blinding and/or manual randomization, including IWRS entry/confirmation or paperwork, dispensing outside of IDS pharmacy normal operating hours (in addition to dispensing fees), etc | $200/hr<br>billed in 15-min increments |
| Shipping and Courier Transport Fee to patients/other sites/Sponsor<br>• *FedEx/UPS shipments without temperature monitoring: covers printing label/pack lists, packaging up shipment and delivering to loading dock for FedEx/UPS shipments without temperature monitoring*<br>• *Courier +/- temperature monitoring: covers day-of-contact questions and coordination with courier and assistance with packaging up shipment and temperature monitoring device, if applicable, and signing/filing paperwork* | $200/hr<br>billed in 15-min increments<br>Plus applicable courier and shipping material charges |
| Utilization of UCSF Commercially Available Medication Stock<br>• Only applies to studies where NO ACCOUNTABILITY is required for commercially available medications<br>• Applies to studies utilizing UCSF commercial medication stock AND sponsor is reimbursing for them<br>• Does NOT apply to studies where accountability is required for commercially available medications and studies where IDS pharmacy procures medication for study (e.g. medication not available at UCSF) | Passthrough Cost (no IDS dispensing fee and billed through EMR system (e.g. APeX)) |

5. **Monitoring Visits and Close Out Fee**

Sponsor review of IDS records should occur during scheduled monitoring visits. This fee will be charged when temporary Vestigo Verify access is made available to one monitor per scheduled visit, which will provide access to drug accountability records, temperature logs and calibration records, and shipment information.

The close out visit should be scheduled when IDS involvement and maintenance is no longer needed for a study (i.e. enrollment is complete, and all active patients completed study treatment). Study closure activities include return or destruction of study drug, final drug accountability, archiving of study documents, and storage of protocol specific documents. Maintenance fees will continue to be billed annually until an IDS close out visit is completed.

| | Industry Trials | Investigator Initiated Trials & Expanded Access |
|---|---|---|
| Sponsor Visit Fees<br>• Charged per visit/Vestigo access set-up, even in cases of last minute cancelations, or requests for remote monitoring<br>• Beyond 1 hour, charge additional $200/hour in 15-min increments | $200 per visit | $200 per visit |
| Close Out to complete IDS pharmacy involvement. | $670 | $275 |
| Request for IDS records AFTER close out visit to complete IDS pharmacy involvement. | CURRENT annual maintenance fee + monitoring visit fee | |

6. **Other IDS Support Fees**

| | Fees for Industry & Investigator Initiated Trials & Expanded Access |
|---|---|
| Consultation/Clinical Oversight fee<br>• Consulting on protocol logistics or drug preparation/handling<br>• Creation of order template for non-IP containing trial or study arm<br>• IDS patient management of study patients receiving standard of care treatments or<br>• CMRs during screening patient counseling/support | $200/hr billed in one-hour increments |
| Protocol Update Fees<br>• Addition of new IP formulation, protocol arms, re-training, updated study orders, or study- related updates | |
| Non-Standard Pharmacy Personnel Training Fees<br>• Examples include protocol training of inpatient staff, liquid nitrogen training, etc | |

## Additional Notes

1. Investigator Initiated Trials Fees: Applies to PI initiated studies and cooperative/NIH trials.
2. Compassionate Use and Single Patient Expanded Access will be charged as IIT fees. Notes as "expanded access" throughout the fee schedule. If there is not funding available, the lead pharmacist must include IDS leadership for review.
3. IDS Fee estimates are subject to change upon further review of study materials and release of updated study information.
4. For studies which need to utilize UCSF Specialty Pharmacy to dispense commercially available medications for outpatient use, refer to job aide. Dispensing fees and costs will be determined by UCSF Specialty Pharmacy.
5. Commercially available medications for on-site use only may be procured by IDS for a study. The amount billed for IP will be equal to the cost of purchased drug and overhead: orders greater than or equal to $1000 will charged $100 per order and orders less than $1000 will be charged $50 per order. These costs are billed at the time of drug purchase and not upon use. All purchases made for a study are final and no refunds/credits are given for unused inventory.
    - Commercial drug cost estimates provided are accurate at the time of budgeting. Because drug pricing fluctuates based on the market value and availability, it must be understood that the price of the medication may change at the time of procurement, and the sponsor will be charged accordingly.
    - The ability for IDS to procure commercially available drugs is not guaranteed and subject to drug shortages outside of IDS' control.
6. An annual 5% cost of living and inflation increase will apply to all fees in Q1 (defined as July 1) of each fiscal year **OR** studies will be updated to the current fee schedule upon budget review for any significant protocol updates (e.g. updated workflow changes or new study drug/formulation, and/or treatment arm)