Investigational Drug Service at University of California Medical Centers

Description of Investigational Drug Service (IDS) Fees

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. IDS estimates are based on specific information provided in the protocol, investigator brochure and/or the sponsor-provided pharmacy manual.

This schedule describes the fixed fees associated with UCSF Health IDS participation in clinical research studies. The fees are set based on the costs required to provide the associated services and are considered **non-negotiable.** The charges are only incurred when the specified service is required by the study

1. Protocol Set-up

One-time, non-refundable fee charged upon pharmacy study activation. Set-up fees include but are not limited to protocol review, budget review, site qualification visits, site initiation visits, development of study specific dispensing procedures, EMR (electronic medical record) entry and label design (mandatory),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, and drug destruction. Start-up fee includes up to 25 and 30 hours of service for standard and advanced set-up respectively. Beyond 25 or 30 hours depending on initial start-up fee, an hourly pharmacy charge will be implemented based on institution specific rates in 1-hour increments.

	Industry Trials	Investigator Initiated Trials
Standard *Beyond 25 hours, institutional hourly pharmacist charge ($175/hr) will apply in 1-hour increments*	$3930* $4295**	$1500
Advanced: Oncology, Immunotherapy, Pediatrics, Vectors *Beyond 30 hours, institutional hourly pharmacist charge ($175/hr) will apply in 1-hour increments*	$4505* $4925**	$1500
Off-Hours Dispensing – 24/7 coverage • Covers off-hours pharmacy set up and training • IP preparation, On-call support • Pharmacy will not be responsible for IWRS responsibilities • 24/7 coverage feasibility review by IDS pharmacist is required to determine the extent of IDS pharmacy participation	$5200	$3288

*Protocols that only include drugs or ancillary supplies stored at room temperature

**Protocols that include at least one drug or ancillary supply that is stored refrigerated or frozen

2. Annual Maintenance Fee

Annual maintenance and inventory fees will be applied to multi-year studies on the anniversary of the pharmacy study activation date. The Annual Maintenance Fee covers but is not limited to a monthly study drug inventory by IDS, study drug accountability, receipt and disposition, temperature monitoring, and query responses.

	Industry Trials	Investigator Initiated Trials
Standard	$2485* $2695**	$500
Advanced: Oncology, Immunotherapy, Vectors	$2775* $2985**	$500

*Protocols that only include drugs or ancillary supplies stored at room temperature

**Protocols that include at least one drug or ancillary supply that is stored refrigerated or frozen

3. Close Out Fee

Study closure activities include but are not limited to return or destruction of study drug, archiving of study documents, final drug accountability and drug destruction (if needed), provision of outstanding documentation such as temperature monitoring logs, accountability logs, final billing if outstanding balance remains, and storage of protocol specific documents.

	Industry Trials	Investigator Initiated Trials
Close Out	$580	$250

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), or for each dose identified and relabeled by an IDS pharmacist if the investigational drug has been previously dispensed. The estimate fee will be calculated based upon maximum chargeable cost per patient per pharmacy visit. Amount charged may be lower than estimated cost depending on actual prescribed dosage. If any additional pharmacist time is required to handle dispense or return, an additional fee may apply. Additional charges for shipping will apply beyond dispensing fees.

	Fees for Industry & Investigator Initiated Trials
Oral, topical, pre-filled injectable ROUTINE dispense or drug identification and labeling of previously dispensed product.	$58 per each dosage strength
Oral, topical, pre-filled injectable COMPLEX dispense *Requiring elaborate procedures: including, but not limited to non-sterile compounding (hazardous and non-hazardous), medisets or outpatient unit doses, controlled substances schedules III-V, hazardous agents (i.e. oncology medications). Time based & may be amended once product is available on-site.*	$175 *Plus applicable institutional hourly pharmacist charge ($175/hr)*
Injectable ROUTINE dispense *Hazardous or non-hazardous injectable; compounding required. Includes cost of CSTDs and infusion tubing. May be amended for cost of supplies or additional preparation time needed.*	$173
Injectable COMPLEX dispense *Requiring special procedures: vectors, unit dose syringes, large doses, cellular therapy*	$289 *Plus applicable institutional hourly pharmacist charge ($175/hr)*
Controlled Substances *Schedule I and II: dispensing + returns when applicable*	$115 *Plus applicable institutional hourly pharmacist charge ($175/hr)*
Inpatient Unit Dose	$12 *per dose and dosage strength*
Pharmacist required randomization/IWRS Assignment	$46 *per each dispensing*

5. Other Fees

	Industry Trials	Investigator Initiated Trials
Sponsor Visit Fees • *Charged per visit, even in cases of same day cancelations, no shows, or requests for remote monitoring ($150 minimum).* • *Beyond 1 hour, charge $165/hour in 1-hour increments.*	$173 per 1-hour visit	Waived
Protocol Update Fees • *Addition of new IP formulation, protocol arms, re-training or pharmacy manual updates* • *Can be institution specific for complicated protocols/arms* • *Minimum 2 hours per amendment; beyond 2 hours, charge $165/hour in 1-hour increments*	$346	$346

Request for additional IDS pharmacy data AFTER pharmacy close-out visit	Annual maintenance fee + monitoring fees as above
Non-Standard Pharmacy Personnel Training Fees • *Protocol training of inpatient staff, liquid nitrogen training, extensive training or re-training of longer than 1 hour*	*Institutional hourly pharmacist ($175/hr) and technician charge*
Shipping Fees (e.g., FedEx, UPS)	$78/shipment (does not include courier or shipping material fees)
Courier transport fees to Satellite sites (each occurrence)	Institutional hourly pharmacist charge ($175/hr) (does not include courier or shipping material fees)
Drug Delivery Fee	$50 per 15-minute increment
Commercial Drug Access/Procurement Fee (billed at set-up)	$1050/drug x number of drugs listed in the protocol that pharmacy will be required to procure over the course of the study
Hazardous Drug Assessment and Handling Fee (billed at set-up)	$263/drug x the number of IND drugs listed in protocol
Consultation fee • *Consulting on protocol logistics* • *Creation of order sets for radiation oncology protocols or non-IP containing oncology trials*	Institutional hourly pharmacist charge ($175/hr)

6. Additional Notes

a. Investigator Initiated Trials Fees
   - Applies to PI initiated studies and to cooperative trials.
   - This fee requires approval by an IDS Pharmacist.

b. IDS Fee estimates are subject to change upon further review of study materials if necessary.

c. Pharmacy activity will not commence until signed agreement and required study documents are received by IDS from the research team.

d. An annual 5% cost of living and inflation increase will apply to fees in Q1 of each fiscal year.

e. Institution hourly pharmacy charge = pharmacist hourly rate + benefits and will change annually depending on contracts and cost of living increases.