

HARRIS HEALTH SYSTEM
INVESTIGATIONAL DRUG SERVICES (IDS)

The following schedule outlines the services available to implement and support a study through the IDS. The services available and charges for those services will apply to research protocols conducted within Harris Health System. Certain research protocols may require services not listed or be of such complex nature that the schedule below may not sufficiently address the costs. In those instances, the IDS will develop an individual budget based on the specific requirements of the study.

IDS Pharmacy Fee Schedule for Research Protocols	
Services	Cost
Study Set-up Fee*: (Inpatient and Outpatient Studies)	
<ul style="list-style-type: none"> • Sponsor Initiated • Collaborative Groups • Physician Initiated 	\$1750
Additional Harris Health sites	\$250/each secondary site
Maintenance Fee ⁺	\$200/annually
Special Storage Requirements	\$15/month for refrigerated and frozen conditions
Special Storage Fee Requirements: Hazardous USP <800>	\$20/month for refrigerated and frozen conditions
Medication Dispensing and Handling Fees:	
<ul style="list-style-type: none"> • Non-Compounded Dose • Non-Sterile Compounding⁺ • Sterile Compounding: (Hazardous/High Risk) • Complex Compounding: (i.e. isotopes) 	\$25/dose or prescription \$30/dose or prescription \$50/dose or prescription \$75/hour
Drug and Supply Cost	Cost + 15%

*Study set-up fee does not include the individual patient pharmacy fees (i.e. preparation of product, dispensing and recording)

⁺Studies active for 6 months or more will be assessed a maintenance fee

*All fees are subject to change

Study Set-up Fee

- Review of study protocol
- Assessment of required IDS services
- Coordination of and participation in initiation visit
- Establishment of Drug Accountability records and binder with required and appropriate documents
- Requisition, receipt and storage of study drug/supplies
- Development and distribution of dispensing guidelines
- Creation of physician order form
- Creation of EPIC and/or BEACON computerized physician order entry template
- Ongoing communication between coordinator, sponsor and investigator
- In-service staff, nursing and providers as needed

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Maintenance

- Requisition, receipt and storage of study drug/supplies
- Maintenance of drug accountability record forms and temperature logs
- Monitoring inventory for appropriate stock of drugs, expiration date, expiration date extension and re-labeling as indicated by the sponsor
- Communication with research team regarding study-related needs
- Continuous review of ongoing protocol updates
- File regulatory documents required by TSBP, FDA, DEA and Sponsor
- Revise order form based on protocol updates
- Investigation and documentation of protocol violations
- Quarantine of IP not approved for destruction by monitor, PI, or sponsor
- Photocopying and distribution of documentation as required by monitor and regulatory representatives
- Monthly invoicing of IDS services
- Participation in study close-out visits and completion of reconciliation documents
- Archive study records for 2 years on-site
- Return of drug/supplies after study closure
- Shipment of study documents to Iron Mountain after 2 years of study closure
- Studies active for 6 months or more will be assessed a maintenance fee

Special Service Fees

- Destruction of IP on-site: \$100/annually
- Special ordering and handling of controlled substances (DEA Form 222): \$25/form
- Request for Harris Health IDS to store and order for other study sites: \$100 (annually)
- Study Monitor Visits >1hour : \$25/visit
- After hours/Weekends randomization and dispensing: \$100/hour
- Relabeling and repacking drug for extended test date: \$25/dose (exception: re-test labels provided by sponsor)
- IP training requiring more than 2hrs./staff member : \$25 for multiple training sessions
- Retrieval of protocol binder(s) from Iron Mountain: \$50 (15-30 day notice required)
- Additional storage for multiple IP stock : \$50 (one-time fee)
- Materials and medication not provided by investigator or sponsor may be obtained by special order for an additional cost.

For information regarding the IDS Pharmacy Fees for (In-House Medical Staff or Collaborative) sponsored studies, please contact the Investigational Drug Service department directly.

Non-formulary (NF) medications will be reviewed independently and must meet Harris Health System Drug Formulary Policy 500; unless supplied free of charge to patient by principal investigator, sponsor, commercial insurance or Patient Medication Assistance Program (PMAP).

If feasible, negotiable set-up fees may be requested for unfunded or minimally funded studies. For questions concerning the pharmacy fee schedule, please contact Celia Fenceroy, Pharm.D., Investigational Drug Service Manager at 713-873-4457 or Celia.Fenceroy@harrishealth.org.