Investigational Drug Services

The Investigational Drug Service (IDS) at Mount Sinai supports all Mount Sinai Health System investigators in the conduct of human clinical trials utilizing medications. These clinical trials may be industry or federally sponsored, investigator initiated trials (IIT), and compassionate use/expanded access drugs. IDS ensures efficient management of investigational products (IP), adherence to protocol, institutional, local, and federal guidelines, and support to the clinical research teams for optimal patient care and safety.

DEDICATED RESEARCH SUPPORT

- Aid in protocol development and the design of IIT clinical trials
- Create randomization schemes and randomize subjects for IIT clinical trials
- Member of the Program for the Protection of Human Subjects (PPHS) and Protocol Review and Monitoring Committee (PRMC) to review protocols for operational feasibility and scientific rationale
- Meet with study team, sponsors, and auditors to maintain trial integrity
- Facilitate the creation and review of research specific medication orders/order sets/treatment plans

IP PROCUREMENT AND MAINTENANCE

- Facilitate procurement of IP
- Receive IP directly from sponsors
- Provide secure and temperature monitored IP storage
- Maintain accurate, audit-ready inventory accountability and protocol paperwork
- Provide destruction of IP according to local and federal regulations

IP VERIFICATION AND PREPARATION

- Verify IP is ordered, dispensed, and administered in accordance with sponsor, local, and federal requirements
- Compound or manufacture non-sterile IP in accordance with USP795 regulations
- Compound sterile IP in accordance with USP797 regulations
- Handle all hazardous and anti-neoplastic IP in accordance with USP800 regulations
- Prepare placebo and/or blinded IP formulations
- Label and dispense IP in accordance with sponsor, local, and federal requirements

COORDINATING CENTER ROLE

- Maintain IP for multi-center trials
- Package and ship IP to participating sites in appropriate temperature conditions
- Create protocol specific IP request forms and shipment records

STAFF SUPPORT AND EDUCATION

- Train pharmacy staff on protocol design, treatment plan, and pharmacy procedures
- Provide clinical trial support to providers, nursing, and pharmacy staff as needed

IDS BILLABLE SERVICES	
Review	IDS review of clinical trial protocol for institutional feasibility and scientific rationale. One-time cost incurred regardless of study initiation or enrollment.
Initiation	IDS start-up fee to initiate clinical trial: create pharmacy study procedures, attend site-initiation meetings, in-service pharmacy staff, and set-up of electronic order entry records. One-time cost incurred regardless of study enrollment.
Epic Electronic Medical Record (EMR)	Creation of study specific medication records for sponsor supplied investigational products to be used in the electronic medical record (EMR) system. Creation of study specific therapy and/or treatment plans, if needed, to be used within the EMR system. One time fee includes: creation, review, and subsequent modifications.
New Amendment and/or Pharmacy Manual Reviews	Minimal review: document training/review; no pharmacy relevant changes and/or updates Moderate review: document training/review; pharmacy relevant updates required, including changes to existing IP and/or treatment arms Significant review: document training/review; pharmacy relevant updates required, including addition of new IP and/or treatment arms
Dispensation - *Simple*	Order verification and dispensation of IP that involves zero to minimal manipulation of final dosage form, including oral dosage forms (capsules, tablets) and blinded kits for outpatients.
Dispensation – *Moderate, Nonsterile*	Order verification and dispensation of oral IP requiring Personal Protective Equipment, including oral anti-neoplastic agents, oral IP for inpatients, non-sterile compounds, and controlled substances. Interactive Response Technology (IRT) entry or randomization of subjects required by pharmacy.
Dispensation – *Moderate, Sterile*	Order verification and dispensation of sterile compounds that require minimal to moderate manipulations, STAT preparations, and IP with poor stability.
Dispensation – *Complex*	Order verification and dispensation of complex sterile compounds including sterile anti-neoplastic agents, biologics, viral/bacterial vectors, multiple dilutions/complex manipulations, or other agents that require special handling.
Special Compounding	Requires discussion with IDS Clinical Pharmacy Manager.
Maintenance	Includes storage and maintenance of IP to ensure appropriate temperature controls and monitoring, accurate inventory accountability, quality assurance review for monitoring visits and audits, compliance with MSHS, Joint Commission, state and federal standards.
Close-Out	Includes final review of IDS files and return and/or destruction of remaining IP. ***Pharmacy files must be retrieved by study team ASAP upon close out.***
Coordinating Center Services	Includes all shipment request communication, preparing shipments, and generating packing list/transport records. NOTE: IND required to ship to external sites outside of NYS. Confirm plan with IDS Clinical Pharmacy Manager.

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All fees will be increased by 5% annually in January for all industry-sponsored trials

IDS SERVICE FEES		
	Industry	**MSHS Investigator Initiated**
Review [a, b]	$866 once	$433 once
Initiation	Tiered based on complexity per site *Outpatient (non-oncology):* $875 once for primary site $437.50 once for each MSHS satellite site *Inpatient and/or Oncology:* $1000 once for primary site $500 once for each MSHS satellite site	Tiered based on complexity by site *Outpatient (non-oncology):* $437.50 once for primary site $219 once for each MSHS satellite site *Inpatient and/or Oncology:* $500 once for primary site $250 once for each MSHS satellite site
	Note: Satellite site charge will be generated in conjunction with the arrival of inventory.	
Epic EMR	General (non-oncology) study: $495/study Oncology study: $825/study	General (non-oncology) study: $247.50/study Oncology study: $412.50/study
New Amendment and/or Pharmacy Manual Reviews	Minimal: $50 per amendment / manual Moderate: $150 per amendment / manual Significant: $250 per amendment / manual	Minimal: $25 per amendment / manual Moderate: $75 per amendment / manual Significant: $125 per amendment / manual
	Note: Concurrent protocol amendment and pharmacy manual updates will be charged once.	
Dispensation – *Simple*	$58/dispensation	$58/dispensation
Dispensation – *Moderate, Nonsterile*	$95/dispensation	$95/dispensation
Dispensation – *Moderate, Sterile*	$173/dispensation	$173/dispensation
Dispensation – *Complex*	$210/dispensation	$210/dispensation
Special Compounding	$110/hour	$110/hour
Maintenance [c]	Tiered based on # of IP agents 1 agent: $100/month per site 2 agents: $150/month per site 3+ agents: $250/month per site	Waived
Close-Out	$578/site	$578/site
Coordinating Center Services [d]	$116/shipment	$58/shipment

All IDS fees waived for unfunded Compassionate Use protocols.

[a] $433 for review of protocols involving only standard of care treatments

[b] For MSHS multi-site studies, incurred by primary site only, secondary site(s) waived

[c] **Charged until IDS records returned to study team and study closed with IDS**

[d] Excludes the cost of courier service. Study Team must approve, arrange, and provide airbill/courier service for each shipment.