Icahn School of Medicine at Mount Sinai | Mount Sinai Hospital | Mount Sinai Beth Israel

Investigational Drug Service

Mount Sinai West | Mount Sinai St. Luke's | New York Eye and Ear Infirmary of Mount Sinai

DEDICATED RESEARCH SUPPORT

- Aid in protocol development and the design of investigator initiated trials protocol
- Create randomization schemes
- Review protocols prior to PRMC and PPHS approval
- Voting member of PPHS and PRMC committees
- Meet with study team, sponsors, and auditors to maintain trial integrity
- Comply with sponsor and government requirements

PRODUCT PROCUREMENT AND MAINTENANCE

- Facilitate procurement of investigational products
- Receive investigational products directly from sponsors
- Provide secure storage location
- Provide temperature-monitored drug storage
- Maintain inventory accountability
- Dispose/destroy investigational products according to regulations

VERIFICATION AND PREPARATION

- Verify investigational product is ordered according to protocol
- Compound or manufacture sterile dosage formulations
- Prepare placebo formulations
- Prepare blinded preparations
- Label and dispense investigational products in accordance with sponsor and government requirements

COORDINATING CENTER ROLE

- Maintain investigational products for multicenter trials
- Package and ship products to participating sites
- Create protocol-specific investigational product request forms and shipment record

STAFF SUPPORT AND EDUCATION

- Train pharmacy staff on protocol design, objectives, and procedures
- Provide education to nursing and pharmacy staff regarding investigational products

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IDS Fees:		
Review Fee*	$750 Protocol Review	One-time cost incurred regardless of study enrollment *$375 for review of protocols involving only routine care treatments For clinical trials involving more than one Mount Sinai site, a *single* review fee per study is incurred.
Initiation Fee**	$750 Study Initiation	One-time cost incurred regardless of study enrollment; May include preparation of pharmacy study procedure, attending initiation meetings, providing in-services to staff, and set-up of electronic order entry records. **for primary site only; secondary sites waived
***Simple* Dispensation**	$50/dispensation	Order verification and dispensation that involve minimal manipulation of final dosage form, including oral dosage forms (capsules, tablets) and blinded kits.
***Moderate* Dispensation**	$80/dispensation	Oral chemotherapy requiring Personal Protective Equipment; IV preparations with minimal effort; Controlled substances; IVRS entry or Randomization of subjects required by pharmacy
***Complex* Dispensation**	$150/dispensation	Labor intensive and/or hazardous preparations, including IV/SubQ chemotherapy, biologics, antibodies, immunotherapy, virus/bacterial vectors; Advance notice not possible, including STAT preparations and poor stability preparations
Special Compounding	$90/hour	
Storage/ Maintenance Fee***	$750 annually (billed as $62.50 per month) per site	Includes storage of study materials (e.g., inventory, recordkeeping, refrigerator, room temperature, freezer, temperature monitoring software); Quality assurance; Compliance with Hospital, Joint Commission, state and federal standards; Site visits; Audits; Drug destruction; and Overall maintenance ***waived for federally funded studies
Close-Out Fee	$500 per site	Includes return or destruction of remaining study materials; return of pharmacy records to Study Team as appropriate
Coordinating Center Services	$100/shipment to external sites****; $50/shipment to MS sites	Includes receiving shipment requests, preparing shipments, and generating packing list/transport records – *Excludes* the cost of courier service. Study Team must approve, arrange, and provide airbill/courier service for each shipment. ****IND required to ship to external sites outside of NYS. Confirm plan with IDS coordinator!