

## 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 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:		
<b>Review Fee*</b>	\$750 Protocol Review	One-time cost incurred regardless of study enrollment *\$750 for Review and \$375 for review of protocols involving only routine care treatments For clinical trials involving more than one Mount Sinai site, a <i>single</i> review fee per study is incurred.
<b>Initiation Fee**</b>	\$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
<b>Simple Dispensation</b>	\$50/dispensation	Order verification and dispensation that involve minimal manipulation of final dosage form, including oral dosage forms (capsules, tablets) and blinded kits.
<b>Moderate Dispensation</b>	\$80/dispensation	Oral chemotherapy requiring Personal Protective Equipment; IV preparations with minimal effort; Controlled substances; IVRS entry or Randomization of subjects required by pharmacy
<b>Complex Dispensation</b>	\$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
<b>Special Compounding</b>	\$90/hour	
<b>Storage/Maintenance Fee***</b>	\$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
<b>Close-Out Fee</b>	\$500 per site	Includes return or destruction of remaining study materials; return of pharmacy records to Study Team as appropriate
<b>Coordinating Center Services</b>	\$100/shipment to external sites****; \$50/shipment to MS sites	Includes receiving shipment requests, preparing shipments, and generating packing list/transport records – <i>Excludes</i> the cost of courier service. Study Team must approve, arrange, and provide airbill/courier service for <u>each</u> shipment. ****IND required to ship to external sites outside of NYS. Confirm plan with IDS coordinator!