



# Investigational Drug Service



## PRODUCT PROCUREMENT

- Facilitate procurement of investigational products
- Receive investigational products directly from sponsors
- Provide secure storage location
- Provide temperature-monitored drug storage
- Maintain accountability for inventory

## 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 submission
- 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 PREPARATION

- Compound or manufacture sterile dosage formulations
- Prepare placebo formulation
- Prepare blinded preparations
- Label and dispense investigational products in accordance with sponsor and government requirements
- Dispose/destroy investigational products according to regulations

## COORDINATING CENTER ROLE

- Maintain investigational products for multicenter trials
- Package and ship products to participating sites
- Create protocol specific case report forms and data collection worksheets

## STAFF SUPPORT AND EDUCATION

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

## CONTACT US

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## IDS USAGE FEES

The following fees should be used in industry budget negotiations and when preparing federally sponsored grant budgets.

	Federal Sponsors	Non-Federal Sponsors
<b>Initiation Fee*</b>	\$750 Review + \$750 Initiation	\$750 Review + \$750 Initiation
<b>Dispensing Fees</b>		
<i>Simple</i>	\$50/dispensation	\$50/dispensation
<i>Moderate</i>	\$80/dispensation	\$80/dispensation
<i>Complex</i>	\$150/dispensation	\$150/dispensation
<b>Special Compounding</b>	\$90/hour	\$90/hour
<b>Storage/Maintenance Fee</b>	N/A	\$750 annually (billed as \$62.50 /month)
<b>Close-Out Fee</b>	\$500/study	\$500/ study
<b>Coordinating Center Services</b>	TBD/Contact IDS coordinator	TBD/Contact IDS coordinator

<b>*Initiation Fee</b>	One-time cost incurred <b>regardless</b> of study enrollment broken out into \$750 for protocol review and \$750 for the remaining set-up (preparing procedures, initiation meetings, staff in-services, and set-up of computer order entry screens)
<b>Dispensing Fees</b>	
<i>Simple</i>	Does not require manipulation of dosage form, including oral dosage forms and blinded kits
<i>Moderate</i>	IV preparations with minimal effort; Controlled substances, Oral chemotherapy
<i>Complex</i>	Labor intensive and/or hazardous IV preparations, including chemotherapy, biologics, antibodies, immunotherapy, virus/bacterial vectors; IVRS required; Advance notice not possible, including STAT preparations and poor stability preparations
<b>Storage/Maintenance Fee</b>	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
<b>Close-Out Fee</b>	Includes return or destruction of all remaining study materials; copies of records returned as appropriate
<b>Coordinating Center Services</b>	Includes but is not limited to randomization for other sites, managing drug supply for all sites, shipping drug to participating sites, etc.