**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

**STAFF SUPPORT AND EDUCATION**
- Provide education to nursing and pharmacy staff regarding investigational products
- Train pharmacy staff on protocol design, objectives, and procedures
- Create protocol specific case report forms and data collection worksheets
- Prepare placebo formulation
- Compound or manufacture sterile dosage formulations
- Dispose/destroy 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 case report forms and data collection worksheets
- Review protocols prior to PRMC and PPHS submission
- Aid in protocol development and design of investigator initiated trials protocol
- Create randomization schemes
- Meet with study team, sponsors, and auditors to maintain trial integrity
- Comply with sponsor and government requirements

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**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.

<table>
<thead>
<tr>
<th></th>
<th>Federal Sponsors</th>
<th>Non-Federal Sponsors</th>
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<tbody>
<tr>
<td><strong>Initiation Fee</strong></td>
<td>$750 Review +</td>
<td>$750 Review +</td>
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<td>$750 Initiation</td>
<td>$750 Initiation</td>
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<tr>
<td><strong>Dispensing Fees</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Simple</strong></td>
<td>$50/dispensation</td>
<td>$50/dispensation</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>$80/dispensation</td>
<td>$80/dispensation</td>
</tr>
<tr>
<td><strong>Complex</strong></td>
<td>$150/dispensation</td>
<td>$150/dispensation</td>
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<tr>
<td><strong>Special Compounding</strong></td>
<td>$90/hour</td>
<td>$90/hour</td>
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<tr>
<td><strong>Storage/Maintenance Fee</strong></td>
<td>N/A</td>
<td>$750 annually (billed as $62.50/month)</td>
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<tr>
<td><strong>Close-Out Fee</strong></td>
<td>$500/study</td>
<td>$500/ study</td>
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<tr>
<td><strong>Coordinating Center Services</strong></td>
<td>TBD/Contact IDS coordinator</td>
<td>TBD/Contact IDS coordinator</td>
</tr>
</tbody>
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*Initiation Fee: One-time cost incurred regardless 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).

Dispensing Fees:
- **Simple**: Does not require manipulation of dosage form, including oral dosage forms and blinded kits
- **Moderate**: IV preparations with minimal effort; Controlled substances, Oral chemotherapy
- **Complex**: Labor intensive and/or hazardous IV preparations, including chemotherapy, biologics, antibiotics, immunotherapy, virus/bacterial vectors; IVRS required; Advance notice not possible, including STAT preparations and poor stability preparations

Storage/Maintenance Fee:
- 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

Close-Out Fee:
- Includes return or destruction of all remaining study materials; copies of records returned as appropriate

Coordinating Center Services:
- Includes but is not limited to randomization for other sites, managing drug supply for all sites, shipping drug to participating sites, etc.