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:

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Fee</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Fee**</td>
<td>$750 Protocol Review</td>
<td>One-time cost incurred regardless of study enrollment</td>
</tr>
<tr>
<td></td>
<td>$750 Study Initiation</td>
<td>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.</td>
</tr>
<tr>
<td>Simple Dispensation</td>
<td>$50/dispensation</td>
<td>Order verification and dispensation that involve minimal manipulation of final dosage form, including oral dosage forms (capsules, tablets) and blinded kits.</td>
</tr>
<tr>
<td>Moderate Dispensation</td>
<td>$80/dispensation</td>
<td>Oral chemotherapy requiring Personal Protective Equipment; IV preparations with minimal effort; Controlled substances; IVRS entry or Randomization of subjects required by pharmacy</td>
</tr>
<tr>
<td>Complex Dispensation</td>
<td>$150/dispensation</td>
<td>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</td>
</tr>
<tr>
<td>Special Compounding</td>
<td>$90/hour</td>
<td></td>
</tr>
<tr>
<td>Storage/ Maintenance Fee***</td>
<td>$750 annually (billed as $62.50 per month) per site</td>
<td>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</td>
</tr>
<tr>
<td>Close-Out Fee</td>
<td>$500 per site</td>
<td>Includes return or destruction of remaining study materials; return of pharmacy records to Study Team as appropriate</td>
</tr>
<tr>
<td>Coordinating Center Services</td>
<td>$100/shipment to external sites***; $50/shipment to MS sites</td>
<td>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!</td>
</tr>
</tbody>
</table>

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Updated Jun 2017