Investigational Drug Services

**DEDICATED RESEARCH SUPPORT**
- Aid in protocol development and the design of investigator initiated trial protocols
- 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 (IP)
- Receive IP directly from sponsors
- Provide secure storage location
- Provide temperature monitored drug storage
- Maintain inventory accountability
- Dispose/destroy IP according to local and federal regulations

**VERIFICATION AND PREPARATION**
- Verify IP is ordered according to protocol
- Compound or manufacture sterile dosage formulations
- Prepare placebo formulations
- Prepare blinded IP
- Label and dispense IP in accordance with sponsor, local, and federal requirements

**COORDINATING CENTER ROLE**
- Maintain IP for multicenter trials
- Package and ship IP to participating sites
- Create protocol specific IP request forms and shipment records

**STAFF SUPPORT AND EDUCATION**
- Train pharmacy staff on protocol design, objectives, and procedures
- Provide education to nursing and pharmacy staff regarding IP

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### INVESTIGATIONAL DRUG SERVICE FEES

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review*</td>
<td>$750 once</td>
<td>One-time cost incurred regardless of study enrollment; For clinical trials involving more than one Mount Sinai site, a single review fee per study incurred ($375 for review of protocols involving only standard of care treatments)</td>
</tr>
<tr>
<td>Initiation**</td>
<td>$750 once</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 MSHS multi-site studies, incurred for primary site only, secondary site(s) waived</td>
</tr>
<tr>
<td>Dispensation - Simple</td>
<td>$50/dispenation</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>Dispensation – Moderate</td>
<td>$80/dispenation</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>Dispensation - Complex</td>
<td>$150/dispenation</td>
<td>Labor intensive sterile compounds and/or hazardous preparations including parenteral chemotherapy, biologics, antibodies, immunotherapy, virus/bacterial vectors; Advance notice not possible, including STAT preparations and IP with poor stability</td>
</tr>
<tr>
<td>Special Compounding</td>
<td>$90/hour</td>
<td>Needs and requirements discussed with IDS clinical pharmacy manager</td>
</tr>
<tr>
<td>Storage/ Maintenance ***</td>
<td>$62.50/month per site with drug storage</td>
<td>Includes: storage of study materials (e.g., inventory, recordkeeping, refrigerator, room temperature, freezer, temperature monitoring software); Quality assurance; Compliance with MSHS, Joint Commission, state and federal standards; Site visits; Audits; Drug destruction; and Overall maintenance ***waived for federally funded studies Charged until pharmacy records returned to study team.</td>
</tr>
<tr>
<td>Close-Out</td>
<td>$500/site</td>
<td>Includes: final review of pharmacy files; return or destruction of remaining study materials Pharmacy files must be retrieved by study team ASAP upon close out</td>
</tr>
<tr>
<td>Coordinating Center Services</td>
<td>$100/shipment to external sites****; $50/shipment to MS sites</td>
<td>Includes all shipment request communication, 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 clinical pharmacy manager</td>
</tr>
</tbody>
</table>
# Investigational Drug Service Contacts by Site

## MOUNT SINAI HOSPITAL:

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https://icahn.mssm.edu/research/portal/resources/investigational-drug-service

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