Investigational Drug Service
University of Pennsylvania, Perelman School of Medicine, Institute for Translational Medicine and Therapeutics
www.itmat.upenn.edu/ids.shtml

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Important Information for Monitors/Sponsors

The IDS is a service center and biomedical core for the School of Medicine, SELF-SUPPORTED through user fees, offering research pharmacy services to the entire University community. In addition, the IDS is the central coordinating pharmacy for several large NIH-sponsored trials and provides limited services to other institutions throughout the region. IDS is working to achieve cGMP for R&D-scale manufacturing and repackaging in 2016.

Scheduling Visits
- **All visits must be scheduled in advance** on our master calendar.
- Audit space with copier, phone, wireless internet and shipping supplies is available for use during your visit. For large groups a conference room may be available with advance notice.

Use our ONLINE SCHEDULING APP:
www.med.upenn.edu/apps/ids/scheduler

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<thead>
<tr>
<th>Facilities</th>
<th>IDS Main</th>
<th>IDS North</th>
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</thead>
<tbody>
<tr>
<td>Controlled R/T (20-25c)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Refrigeration (2-8c)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Freezer (-20c)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Freezer (-80c)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Liquid Nitrogen (-180c)</td>
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<tr>
<td>Emergency Generators</td>
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<td>X</td>
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<tr>
<td>Quarantine</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Sterile glovebox isolators</td>
<td>X</td>
<td>X</td>
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Equipment (IDS Main):
- Lab: water baths, refrigerated centrifuge, vortex, pumps, microscope
- Testing capabilities including:
  - Sterility (Bactec® / Rapid Assay)
  - Endotoxin (USP<85>)
  - Particulates (USP<788>)
  - Gram Staining, Trypsan Blue Staining
  - Bioburden, eColi
- Repackaging:
  - Kirby KL50c high-speed counter
  - Blister Carding – multiple sizes
- Manufacturing:
  - Capsules: 000 through 3, AA, AAel, B
  - Quantos QS30 (capable of API-only fill for capsules down to 0.1mg)

Temperature Records
- Temperature and humidity measured every few minutes, data on secure in-house server
- Alerts to multiple staff
- Temperature charts available at time of visit, monitor can take afterwards.

Inventory Records
- ELECTRONIC inventory, labeling, patient returns tracking, audit trails, 21CFR11.
- Patient records maintained across all trials (IDS monitors co-enrollment in other trials)
- Separate SOP prepared for EVERY trial
- Electronic logs are mandatory and considered source documents. IDS will transcribe activity onto handwritten logs only at sponsor request and this may involve additional cost.

Security
- Electronic locks, multiple security cameras

Record Organization
NOTE that in order to ensure consistency across hundreds of trials, IDS may need to remove some items from sponsor-supplied binders. This is outlined in IDS SOP-301.
- Items not required at the time of dispensing, such as the protocol, IB, correspondence, packing slips and completed prescriptions, are stored in a file cabinet.
- Items that ARE required for dispensing include written procedures, IVRS instructions, dosing worksheets, paper logs if required, etc. All trials will have both a binder and a file in the cabinet.
- At study close, IDS must maintain at least a copy of all of these records. IDS archives its own records through the Penn Records Center (www.archives.upenn.edu/urc).

Tracking Pickups & Deliveries
Pickups & deliveries are logged in an electronic system linked to Penn and UPHS directories to verify identity of staff. Coordinators have the option to receive ‘ready’ email alerts.