Important Information for Monitors/Sponsors

The IDS is a service center and core facility for the School of Medicine, supported through user fees, providing research pharmacy services to the entire Penn

**MA IN F A C I L I T Y**

Penn Investigational Drug Service
3600 Spruce St - Ground Maloney Bldg.
Philadelphia, PA 19104
215-349-8817 Fax: 215-349-5132

**N ORTH S A T E L L I T E**

Penn Investigational Drug Service North
51 N. 39th St – 103 Mutch Bldg.
Philadelphia, PA 19104
215-662-9995 Fax: 215-243-4645

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

**S TA F F D I R E C T O R Y**

**Director:**
Kenneth Rockwell Jr, PharmD, MS RockwelK@upenn.edu

**Research Pharmacists:**
Jason DeWitts, PharmD DeWittJ@uphs.upenn.edu
Melanie Furjanic, PharmD starts 6/12/17
Karen Grinnen, PharmD, MS GrissenK@uphs.upenn.edu
Arleen Kessler, PharmD, MBA starts 5/15/17
Benjamin Duy Tran, PharmD** TranB@uphs.upenn.edu
Michele Wisniewski, PharmD* WisnieW@uphs.upenn.edu
Annie Varughese, PharmD VarughA@uphs.upenn.edu

* IDS North lead ** Per-Diem

**Research Technicians:**
Ryan Bowe, BS Ryan.Bowe@uphs.upenn.edu
Susan Carney CarneyS@uphs.upenn.edu starts 5/22/17
Ellen Kim, BS
Mansi Patel, BS PateMan@uphs.upenn.edu
Erin Patton, BS PattonE@uphs.upenn.edu
Shasnettay Warner, MS WarnerS@uphs.upenn.edu

**Office Assistant:**
Letha Gibson GibsonLe@uphs.upenn.edu

**Quality Assurance Officer**
Mary Jane Daub, PhD mdaub@upenn.edu

**Laboratory Manager**
Claudia Mendez-Garcia, PhD cmende@upenn.edu

**Associate Director - Finance**
Jason Molli Molli@upenn.edu
10-156 Smilow Translational Research Center

**Scientific Director**
Garret FitzGerald, MD, FCS
Chair, Systems Pharmacology and Therapeutics
10th Floor, Smilow Translational Research Center

**Interns and Students**
Neha Mohan, Nicholas Miller, Kenda Istanbouli, Timothy Little

---

**Scheduling Visits**
- **All visits must be scheduled in advance** on master calendar.
- Audit space with copier, phone, wireless internet is available for use during your visit.
- IDS requires 2 weeks’ notice of a protocol opening prior to first enrollment.

**Facilities**

<table>
<thead>
<tr>
<th></th>
<th>IDS Main</th>
<th>IDS North</th>
</tr>
</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>
</tr>
<tr>
<td>Freezer (-20c)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Freezer (-80c)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Liquid Nitrogen (-180c)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Emergency Generators</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Quarantine</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sterile glovebox isolators</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**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, Trypan Blue Staining
  - Bioburden, eColi
  - Assays (HPLC/UPLC) coming soon
- 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 to 0.1mg)

**Temperature Records**
- Temperature and humidity measured every few minutes, data on secure in-house server, alerts to multiple staff.
- Multiple backup min/max devices
- 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 for EVERY trial
- Electronic logs are mandatory and considered source documents. IDS will transcribe activity onto handwritten logs only at sponsor request and will involve additional costs.

**Security**
- Electronic locks, multiple security cameras in both IDS facilities

**Record Organization**
NOTE: 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 (protocol, IB, packing slips, correspondence, filled prescriptions) are stored in a file cabinet.
- Items required for dispensing include written procedures, JVRs 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 a 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.