

Important Information for Monitors/Sponsors

MAIN FACILITY

Penn Investigational Drug Service
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Philadelphia, PA 19104
Phone: 215-349-8817 Fax: 215-349-5132
E: PennIDS@mail.med.upenn.edu

NORTH SATELLITE

Penn Investigational Drug Service NORTH
51 N. 39th St - 103 Mutch Bldg.
Philadelphia, PA 19104
Phone: 215-662-9995 Fax: 215-243-4645
E: IDSNorth@mail.med.upenn.edu

Emergency ONLY: (800) 670-3151

STAFF DIRECTORY

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Interns

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Rotation Students – Summer Term

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Associate Director / Finance

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10-156 Smilow Translational Research Center

Scientific Director

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Chair, Systems Pharmacology and Therapeutics
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Independent Quality Control Officer

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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

Facilities

| | IDS Main | IDS North |
|----------------------------|----------|-----------|
| Controlled R/T (20-25c) | X | X |
| Refrigeration (2-8c) | X | X |
| Freezer (-20c) | X | X |
| Freezer (-80c) | X | X |
| Liquid Nitrogen (-180c) | X | |
| Emergency Generators | X | X |
| Quarantine | X | X |
| Sterile glovebox isolators | X | X |

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, Tryptan 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)

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.

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 hand-written 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).