

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

MAIN FACILITY

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

NORTH SATELLITE

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

STAFF DIRECTORY

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Neha Mohan, Nicholas Miller, Kenda Istanbouli,
Timothy Little

General (Group) Emails

Main: PennIDS@mail.med.upenn.edu
North: IDSNorth@mail.med.upenn.edu
Emergency after hours: 800-670-3151

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	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
 - 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, 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.