



Overview of Investigational Drug Service and Practice Update

Northwestern Memorial Hospital Pharmacy

October 2018

IDS Pharmacists

Manager: Kristen March, Pharm D.

Practice Coordinator: Sean DeFrates, Pharm D.

IDS Pharmacists

James (Jay) Hilao, Pharm.D.

Jane Regalado, Pharm.D.

Eunice Lee, Pharm.D.

Yiota Terzis, Pharm.D.

Cindy Zhao, Pharm.D.

Developmental Therapeutics Pharmacists

Marina Grishchenko, Pharm.D.

Tetyana Melnyk, Pharm.D.

Kayte O'Brien, Pharm.D.

Yvonne Tsao, Pharm.D.

Where Are We located?

- Main IDS pharmacies
 - Lower concourse (LC-700) of NMH Feinberg Pavilion
 - 12th floor NMH Feinberg Pavilion (12-738)
 - DT Pharmacy Olson 1st floor 01-034

- Shipping Address
 - Northwestern Memorial Hospital
c/o Investigational Pharmacy
251 E. Huron St.
Feinberg 12-738
Chicago, IL 60611



How to Contact Us?

- Email (preferred)
 - invdrugser@nm.org
- IDS Pharmacy contact
 - 312-926-0747 (phone)
 - 312-921-6557 (pager)
- NMDT Pharmacy contact
 - 312-472-6387 (phone)
 - 312-472-5244 (pager)





Study Initiation Procedures



Submitting a New Trial

- IDS should receive a copy of protocol PRIOR to grant/contract submission to sponsor and prior to IRB submission
 - Assist with budget planning
 - Review feasibility and logistical issues from pharmacy perspective
- Check Pharmacy Box in Study Tracker

Adding Pharmacy to Study Tracker

- Compliance
- Subjects
- Calendar
- Reports
- Settings
- Charts
- Users
- Budget

Study Properties

Recruitment

Affiliations

Support Services

Epic Billing

Activities

Arms/Populations

Study Schedule

Study Documents

Edit Affiliations

Please check the administrative units below with which this study is affiliated. If this study is supported by clinical research staff from the institutes/centers below then check this box. Checking this box might also enable this study's recruitment information, if [recruiting publicly](#), to appear on the website of the corresponding administrative units.

Institutes

- Bluhm Cardiovascular Institute
- NUCATS Institute
- Robert H. Lurie Comprehensive Cancer Center
- Institute for Public Health & Medicine

FSM Departments and Centers

- Medicine-Pulmonary and critical care

Please check the healthcare organizations(s) where this study takes place. Some options have already been checked, and cannot be changed, because Study Tracker pulls the information from eIRB.

Sites

- Northwestern Memorial HealthCare
 - Lake Forest Hospital
 - Northwestern Memorial Hospital
 - Northwestern Memorial Faculty Foundation
 - NMHC Clinical Research Unit
 - NMHC Research Pharmacy
- Northwestern University
 - Rehabilitation Institute of Chicago
 - Ann & Robert H. Lurie Children's Hospital of Chicago

Check this box! NMHC Research Pharmacy



Verifying the credentials with prescriber

Only providers listed on the authorized prescriber list (APL) are authorized to prescribe study medications.

- The study staff must provide a written listing of physicians who are authorized per the study protocol to prescribe study medication.
- APL should be posted and updated in StudyTracker
- In addition, study coordinator should send an updated list when there are any changes.
- For NCI-sponsored studies, study coordinator should provided the staff list with an active registration with the NCI. Pharmacy will verify that the physician has an active registration.

Submitting a New Trial

Study Initiation

- Include IDS when SIV is scheduled
 - Allows us to ask questions pertaining to study while sponsor is here
 - To schedule SIV email IDS pharmacy at invdrugser@nm.org
- Inventory logs
 - Thorough NU accountability logs are used for non-NCI studies

Study Product Accountability Record

251 E Huron LC-700 Chicago, IL 60611

PAGE ____ OF ____

Clinical Research Site Name					Protocol Number				
Drug Name :					Dose Form and Strength:				
Protocol Title:					Dispensing Area				
Investigator: Maria Matsangou, MD					Storage Temp		Manufacturer		

	Date	Pt Initials	Pt ID. Number	Dose	Quantity Dispensed/Received	Balance Forward Balance	Lot Number	Exp Date	RPh Initials Rx Number	Vial numbers
1										
2										
3										
4										
5										

Temperature Monitoring

24/7 monitoring

- All IDS refrigerators and freezers monitored with CimScan[®]
- Continuous monitoring system with audible alerts for out of range temperatures
 - Does not allow for individualized temperature range setting
- IDS team can provide physical printouts for monitoring visits or upon request



Active Study Procedures



Active Study Procedures

When New Patient is starting:

- Notify pharmacy when patient is in screening
 - **If drug-drug interaction is a concern, pharmacy can perform screening procedures.**
- If pharmacy screening is needed, email IDS at invdrugser@nm.org with the list of patient home medications
- Give 24 hours for review

Oral Prescriptions

Active Study

- Rx should be sent to IDS prior to patient arrival

Ideally, the **24 hours** before, but **AT LEAST 2 hours** before when it is due

- Rx may be sent via IDS email invdrugser@nm.org or hand-delivered
- *Prescriber signatures are required on all prescriptions* prior to drug pick up
- Investigational drug order form (IDOF) to be used
- If study kits are assigned by IWRS, IWRS assignment should be sent with the prescription or at least 2 hour prior to drug pick-up

OUTPATIENT INVESTIGATIONAL DRUG ORDER FORM

INSTRUCTIONS:

Completed forms should be emailed to Investigational Pharmacy personnel at invdrugser@nm.org. Any questions or concerns call pharmacy at (312) 926-0747.

Patient Name..... **Sex:** M / F **DOB**.....

Address..... **Zip Code**.....

MRN or SSN: _____ Allergies: _____

Weight _____ Height _____ BSA (M²) _____

Principal Investigator _____ Pt's consent is on file? Yes; No

Diagnosis _____

Study Protocol Name/Number _____ **Cycle Number** _____

Sequence or Registration Number _____

Date drug needed _____ **Time Drug needed** _____

Drug _____ Strength _____ Quantity _____

Dose _____ Maximum or standard dose per protocol _____

Directions _____

Days Supply _____ Next Visit _____

In case of problems with this order, please contact:

Coordinator _____ Phone/pager _____

Patient Sticker or Stamp Above Room # _____

Inpatient Investigational Study Drug Order Form

***This form is for non-chemotherapy investigational drug orders that do not have a pre-printed order set.**

***For study drug from other institution, fill out "Use of an Investigational Drug From Another Institution"**

*** For chemotherapy, fill out "Miscellaneous Investigational Study Template" located under NMInteractive: IP Chemotherapy Templates**

Date:	Patient's study ID:
Principal Investigator's (PI) Name:	Study Coordinator's Name: Pager : _____ phone: _____
Study Protocol:	NMH Study Number: STU _____
<p>Study Drug Name and Sig:</p> <p>Drug Name: _____ Strength: _____ dosage form: _____</p> <p>Direction (should match outpatient label if apply):</p> <p>_____</p> <p>_____</p> <p>First inpatient dose due at : _____ AM/PM on _____ (date)</p>	
<p>Check one box only:</p> <p><input type="checkbox"/> New investigational order PI's signature: _____ pager: _____</p> <p><input type="checkbox"/> Continuation of an NMH outpatient investigational drug</p> <p>I certify that I am the PI, or I had discussed with Dr. _____ (an authorized prescriber for the study). Above investigational therapy has been reviewed and shall start at this time.</p> <p>Signature: _____ pager: _____</p> <p>Pt's written consent is on file with PI _____ Yes; _____ No</p>	

Drug Pick-up and Delivery

Active Study

- All oral medications must be picked up by the study team from IDS.

Please sign PICK-UP log

- Include date/time, person who picked up/delivered

Patient Medication Returns

Active Study

- Study coordinator or research nurse should collect remaining investigational drug, including empty bottles/blister packs, from patient at clinic visit

Returned date should be documented on bottle or bag

- All study products and containers should be returned to IDS pharmacy within **24 hours of receipt**
- IDS staff will document in DARF and destroy per NMH Hazardous Waste Management Program policy which is consistent with federal/state regulations
- Maximum time that IDS will store any returned investigational drug for any reason is 30 days or next monitoring visit, whichever is first

Monitoring Visits

Active Study

- All visits must be scheduled in advance with IDS staff via email
 - **Prefer 1 week notice in advance**
- Monitoring visits **only done in person** (not via phone call or email)
- IDS staff is not responsible for collecting/scanning/emailing documents for purpose of visit
- Requests to visit satellite pharmacy or for pharmacist presence should be noted in original request
- Standard visit will be blocked for 1 hour, if addition time allowed it should be noted in the request
- Request visits through IDS email (invdrugser@nm.org)



Supplemental supplies:



Other pharmacy supplies needed in study:

- Standard of Care drug supplies or commercially available drug supplies:
 - Paid for by the study or supplied by the study
 - IDS will keep track of its use, and data collection if requested
 - Not paid for by the study
 - IDS will have no involvement and shall be paid by patient or patient's insurance
- Other supplies needed for the study:
- any supply not carried by NMH (tubings, bags, needles, blinding packages or labels) must be paid for or provided by sponsor
- - supplies that are sourced from general hospital supply, will not carry a separate charge



Study Closure



Study Closure

- Contact IDS via email to schedule close-out visit (COV)
- IDS staff to ensure all documents available at time of visit
- No remote close-out



Pharmacy-Related RNI



Process for Investigational Pharmacy-Related RNIs

- Email pharmacy with all RNI submission what include “Pharmacy-Related RNI”
- Involve pharmacy when generating CAPA
- *What is considered pharmacy related RNI?*

Pharmacy-related RNI are any deviations where IDS pharmacy was involved.

Process for Investigational Pharmacy-related RNIs

Examples of Pharmacy-related errors:

- Pharmacy preparation / dispensing/handling:
- Labeling,
- Dosing,
- Wrong drug/ wrong patient,
- Wrong dose form,
- Wrong strength,
- Wrong quantity dispensed (different from quantity ordered),
- Improper storage
- Expired drug

Examples of non-pharmacy-related errors:

- Drug order form error (wrong patient, drug, dose, quantity)
- Administration error
- Wrong time given
- Missed dose
- Drug not returned by the patient
- Nursing or study coordinator error



Additional Services



Clinical Services

- Patient education/counseling, upon request
- Home medication review
 - Drug-drug interactions
 - Protocol compliance
- Drug information resource



Questions?

Thank You