

## **University of Minnesota Medical Center, Fairview**

### **Investigational Drug Service**

**Pharmacist-In-Charge: Darlette G. Luke, R.Ph.**

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The Investigational Drug Pharmacy provides many useful services that aid investigators with setting up, organizing, and running their studies. We feel that communication is the key to a well run and properly handled investigational study. We have been coordinating Investigational Drug studies through this office since 1976 and have handled almost 5500 to date. The Investigational Drug Pharmacist will review the protocol, and discuss with the Principal Investigator (or designee) ways to assure that all aspects of the pharmacy portion of the study run smoothly. The Investigational Drug Service provides patients, staff, investigators, and sponsors with a well organized and properly run study that will meet all state and federal rules and regulations.

Services that we provide for investigators include:

- Reviewing the protocol and all materials provided that are pertinent to pharmacy dispensing of the study medication
- Preparing an Investigational Drug Data sheet, containing primary information about the study, that is then used to assist in the training of all pharmacy staff.
- Preparing drug randomization schedules (if applicable)
- Preparing capsules and matching placebos (if applicable)
- Setting up the drug study in one or more Fairview pharmacies to make study drug dispensing as convenient as possible for the patients and study personnel.
- Preparing the proper documentation and records as required by the pharmacy sections of the protocol.
- Proper handling (receiving, storing, preparing and dispensing) of all study drug materials.
- Storage of all pharmacy related study records, during and after the study as defined by federal rules and regulation.
- Preparation and maintenance of blinding information.
- Preparation and maintenance of drug dispensing information including directions for proper preparation of study drug.
- Assisting with monitoring visits from study sponsor and federal agencies.
- Secure access storage facilities for all study related medications.
- Monitoring of alarms and generator power back-up for refrigerators and freezers.
- Billing for all pharmacy related charges for the investigational study.
- Proper handling of study drug when the study has finished: either returned to the study sponsor or destroyed on site following company policy and proper destruction

September 2019

procedures.

- 24-hour availability for inpatient dispensing and emergencies.
- Providing pharmaceutical expertise, confidentiality and security for the study and study subjects.

All investigational drugs are securely stored in one or more of the pharmacies, accessible only to authorized personnel.

In order to provide Investigational Drug Services, provide the following items to IDS:

- **A copy of the current protocol with amendments, if any**
- **A copy of the current Investigator Brochure (if there is one)**
- **A copy of the current pharmacy manual (if there is one)**
- **A copy of the IRB approval letter for the study**
- **A copy of IRB approved consent forms**
- **A copy of the signed FDA1572 and a copy of the signed Delegation of Authority**

There are fees associated with using the Investigational Drug Service. These fees cover the administrative start up costs as well as drug dispensing.

Please call the IDS Pharmacy at 612-273-6212 for additional information.