## University of Minnesota Medical Center, Fairview Investigational Drug Service

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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 over 2,400 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 part 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 printed material pertinent to pharmacy dispensing
- Preparing an Investigational Drug Data sheet (1 or 2 pages of primary information about the study) that is then provided to pharmacy staff who need to know about the study.
- Preparing drug randomization schedules (if applicable)
- Preparing capsules and matching placebos (if applicable)
- Setting up the drug study in one or more pharmacies (i.e. Outpatient, Inpatient, Discharge, Riverside Campus and Investigational Drug Pharmacy) to make getting study drug as convenient as possible for the patients and study personnel.
- Preparing the proper paperwork 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.
- Preparation and maintenance of blinding information.
- Preparation and maintenance of drug dispensing information (directions for proper preparation of study drug).
- Assisting with monitoring visits from drug companies and federal agencies.
- Monitored and alarmed storage facilities for all drug requiring refrigeration or freezer storage.
- 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 procedures.
- 24-hour availability for inpatient dispensing and emergencies.
- Offering Pharmaceutical expertise, confidentiality and security for the study.

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, we need the following items:

- A copy of the current protocol with amendments, if any
- A copy of the Investigator Brochure (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 1572 form
- A Fairview Research Institutional Account number

There are fees that are 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 273-6212 for additional information.