

The Right Prescription for Working with Investigational Drug Service at BMC

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IDS Pharmacy Manager

What is Investigational Drug Services?

- IDS is a division of pharmacy, with appointed investigational pharmacists, specializing in the handling, storage, labeling, and distribution of investigational agents in accordance with the most current regulatory requirements maintained by the FDA, Joint Commission, ICH, and GCP Guidelines.

Do ***ALL*** study drugs need to be
stored and dispensed by BMC
Pharmacy?

yes / no

All medications used in Investigational Protocols at
BMC must be stored, labeled, and dispensed by BMC
IDS Pharmacy. (JCAHO Medication Management Standard 7.40)

Policy Exceptions

- In the event that the IDS pharmacy experiences a staff shortage or there is an unexpected delay in the recruitment of staff, the PI may be allowed to store and dispense the study drug. Exceptions will be handled on a **case-by-case** and only if the following conditions are met:
- **Approval** must be granted by both the PI and the **Dir. of Pharmacy**.
- If the IRB has already granted approval for the IDS pharmacy to store and dispense the study drug, the IDS pharmacy must provide the PI with a written authorization allowing this exception of practice. The PI must amend the protocol and obtain **IRB approval** to store and dispense the study drug

What does BMC IDS need from the Research team to get started?

- Protocol activation, GCRC meetings
- Lead time and **materials** in advance of proposed study startup to prepare for study and get procedures written and in place.
- A current copy of the study Protocol, all pharmacy related amendments, Investigator pharmacy brochures, IRB Approval letter, and 1572 (if an IND study)
- IDS Charge Form

IDS PHARMACY CHARGES

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- **DOSE PREPARATION AND DISPENSING FEE:**
- **HIGH-RISK OR COMPLEX PREPARATION FEE**
- **COMPLEX AND DOCUMENTATION FEE**
- **24 HOUR ON-CALL SERVICE FEE** (*WEEKEND STUDY DRUG PREPARATION BY BMC PHARMACY*)
- **WEEKEND STUDY DRUG PREPARATION BY IDS PHARMACISTS**
- **COMPOUNDING SERVICE**

Does a protocol with study drug need to be reviewed by BMC Pharmacy?

Yes. All studies involving drugs to be used as part of a research study must be reviewed for **feasibility** by the BMC IDS Manager or Director of Pharmacy and signed *prior* to IRB review.

-IRB approval alone is not sufficient to activate dispensing of investigational medication from the IDS.

How do I obtain study drugs from BMC IDS Pharmacy?

- For any outpatient study medication, a **Study Drug Request Form** must be faxed to IDS Pharmacy
- A **Study Drug Request Form** must be signed by either a primary investigator or a sub-investigator
- Last page of **informed consent** form if first dispensing
- **Call** BMC IDS Pharmacy if a subject is waiting at clinic
- Written **expiration/retest date** on the study material
 - Written sponsor/manufacture memo on expiration/retest date
 - Certificate of analysis per GMP
 - Regulatory affairs agency (FDA) memo to a sponsor

How are the drugs handled for Inpatient protocols?

- For inpatient study medication, an order must be put in via SCM. Once the order has been verified, study drug will be placed inside the **Pyxis** under “Investigational Study Drug”
- Parenteral study medications are prepared according to the specific protocol. All parenteral study drugs are given a 24 hour expiration unless otherwise designated by the manufacturer.

What if someone enrolled in an outpatient study is admitted to BMC?

- Once admitted, IDS Pharmacy is contacted by research team.
- If PI wants to continue the study drug during hospitalization, an order is placed into SCM and the drug is loaded into the Pyxis machine on that floor.
- PI's consent of continuation must be documented in 'Additional Information' in SCM

Mr. Smith was admitted to BMC E6N. He is taking an experimental study drug from a BMC protocol in a stroke prevention trial.

- What should the covering physician do?
 - ◆ Research team should be contacted by physician to see if it is ok to continue study drug and to ensure safety and rule out any contraindications based on the patient's current condition
 - ◆ *Upon request*, IDS pharmacy will provide information about the study medication as well as contact information of the Principal Investigator and research team.
 - ◆ The physician should see if patient can bring in their own study medication

If research team is on a pager, please respond to your pager. BMC IDS Pharmacy cannot verify the scm order without research team doctor's approval

Who should be contacted if a patient is admitted who is currently enrolled in a non-BMC study?

- Shall be handled in accordance with the “Patient’s Own Medication” policy
- Ordering physician must consult with the outside investigator and get their permission to continue therapy while subject is inpatient at BMC
- Order is entered into SCM as a nonformulary medication
 - ◆ Note in the additional instructions field the primary investigator contact and their approval
 - ◆ Ordering physician shall provide documentation on identity of the study medication and appropriateness of use

How does a physician put an order into SCM for an investigational study drug?

- A MD must be trained to enter SCM order entry.
- Select “**Investigational Study Drug**”
- This selection will require the physician to enter the **study drug name, dosage strength, dosage, BMC Protocol #, Protocol Title, name of PI, and note of approval** by PI or sub-investigator

Investigational Drug Storage & Handling

- Acceptable storage conditions, temperature, storage times, reconstitution requirements (if applicable) should be determined by the sponsor for all investigational products (GCP 5.13.2)
- Packaging of study drugs to prevent contamination and deterioration during transport and storage (GCP 5.13.3)
- Address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subject, return of unused drugs (GCP 5.14.3)

Investigational Drug Storage & Handling

- Storage of study drugs under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the study drugs are not affected (FDA 211.142)
- The study drugs should be stored according to regulatory requirements (GCP 4.6.4)
- The study drugs should be used only according to the protocol (GCP 4.6.5)

Drug Accountability

- Records of the study drug's delivery, inventory, use by each subject, and return/disposition of unused drugs must be kept (GCP 4.6.3)
 - ◆ Drug accountability records:
 - ◆ Shipping/Receipt logs
 - ◆ Perpetual inventory and monthly inventory
 - ◆ Lot numbers/Kit numbers/Expiration dates
 - ◆ Patient-specific dispensing/return logs
 - ◆ Record of final drug disposition (e.g. destruction or return to sponsor)

Investigational Drug Disposal

- Before returning medication to IDS Pharmacy, SC shall count and document on the bottle and any other required documents per sponsor.
- Once drugs are returned to the pharmacy by the study coordinator, they are double checked and logged in the accountability record. If there is any discrepancy, SC will be contacted.
- Investigational drugs are then stored under the PI's name until the study monitor visits to return them to the sponsor
- If determined in the protocol that the drug can be disposed of by IDS/BMC policy.
 - Placed in marked biohazard bins to be incinerated
 - All patient information removed on boxes

Returned Drug Process

- At the conclusion of the study, ensure that all documentation regarding receipt, storage, dispensing, return of used containers, and accountability is complete and accurate
- Drug obtained from a Sponsor for the specific purpose of a research study must be returned to/by Sponsor or be discarded on site per BMC policy upon written authorization from the Sponsor to do so.
- Unused study drug must NOT be passed on to other Investigators, used for animal research, or dispensed to non-study subjects
- Drug study records must be kept for a duration of years (per Sponsor requirements)

Site Monitor Visit Notification

Adequate warning must be given when study monitors/auditors/inspectors visit so appointments can be scheduled and appropriate study documents made ready

**** Handling of returned drugs****

Contact Information

- We look forward to assisting your investigations in the future!
- ◆ Investigational Drug Services Dept.
 - ◆ Hyeseon Hong, Pharm.D
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What is an IND and when is it needed?

- The Investigational New Drug application is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans.
 - ◆ IND also referred to as Form 1571
- IND is required when the investigational drug is a completely new chemical or if it is intended to support a:
 - ◆ New indication
 - ◆ Change in the approved route of administration or dosage level
 - ◆ Change in the approved patient population
 - ◆ Significant change in the promotion of an approved drug

The 3 Types of IND Applications

- Investigator IND
 - ◆ Submitted by a physician to propose studying an unapproved drug, or an approved product for a new indication/patient population
- Emergency Use IND
 - ◆ Allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND (in accordance with 21CFR, Sec.312.23 or Sec.312.34). Also used for patients who do not meet criteria of an existing study protocol or if an approved study protocol does not exist.
- Treatment IND
 - ◆ Submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place

What information must the IND contain?

- FDA Form 1571 Section 12
 - ◆ Form FDA 1571
 - ◆ Table of Contents
 - ◆ Introductory Statement
 - ◆ General Investigational plan
 - ◆ Investigator's brochure
 - ◆ Protocol(s)
 - ◆ Chemistry, manufacturing, and control data
 - ◆ Pharmacology and toxicology data
 - ◆ Previous human experience
 - ◆ Any additional information

What is a 1572 form?

- The 1572 is the statement of the investigator that he/she will abide by the federal guidelines set forth in the Code of Federal Regulations for the use of drugs in an investigational setting.
 - ◆ Any study operating under an IND requires a 1572
 - ◆ Post marketing and observational studies do **NOT** require a 1572

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