

CP-7 – Investigational Drugs¹

Key Points

- An informed consent form is signed prior to use of investigational drugs and a copy of the informed consent form will be included in the patient's medical record.

Policy & Procedure

1. The investigator must submit his/her protocol to the IRB after receiving written approval from his/her clinical departmental review committee; or, in lieu of such a committee, from the department director.
2. Pharmacy Services is represented on each component of the IRB.
3. The investigator ensures that all investigational drugs are stored in and dispensed from Pharmacy Services unless an Investigational Drug Services Exception Request has been approved. Additionally, the investigator must provide Pharmacy Services with the following information:
 - 3.1. A copy of the current protocol as approved by the IRB.
 - 3.2. In a blinded study, Pharmacy Services has a means of identifying each dose in an emergency.
 - 3.3. Additional information about the drug and study regarding storage conditions, preparation, administration, pharmacology, adverse reactions, toxicities and side effects.
4. Pharmacy Services dispenses investigational drugs only in accordance with the current protocol approved by the IRB. Investigational drugs are not administered unless the drugs are dispensed through Pharmacy Services unless an Investigational Drug Services Exception Request has been reviewed and approved by the IRB and Investigational Pharmacy. The conditions outlined in the request (documentation, storage requirements, temperature control) must be monitored periodically by Investigational Pharmacy.
5. An informed consent form is signed prior to use of investigational drugs and a copy of the informed consent form will be included in the patient's medical record.
6. The investigational drug is given by a nurse or physician only on written order by the investigator or his/her designated physician, unless the patient or his family member is administering the medication him/herself, as in an outpatient prescription.
7. Pharmacy Services provides information and assistance to nurses, research staff and physicians regarding investigational drugs and their use.

8. Pharmacy Services dispenses the doses, maintains a record of drug utilization, and provides copies of these records to the investigators as required for reporting drug use. Pharmacy Services is also available to investigators during study monitoring visits.
9. Upon conclusion or termination of a clinical investigation or by request of a sponsor, the drug's disposition is handled per IRB policy, Investigational Drugs or Biologics Used in Research.
<http://www.uhhospitals.org/Research/InstitutionalReviewBoard/PoliciesProcedures/tabid/1296/Default.aspx>

Attachments

A, Investigational Drug Services Exception Request Form

- ¹ Any Food and Drug Administration (FDA)-approved or non-approved medication being used in a human investigation to examine new indications, new routes of administration, and/or new dosage regimens or comparisons to other drug therapies when an Institutional Review Board (IRB) protocol is required.

APPROVALS	
 _____ CHIEF EXECUTIVE OFFICER	<u>3/31/09</u> Date
 _____ SENIOR VICE PRESIDENT	<u>3/31/09</u> Date

Attachment A

Investigational Drug Services Exception Request Form

UHCMC INVESTIGATIONAL DRUG SERVICES: EXCEPTION REQUEST FORM

University Hospitals Case Medical Center (UHCMC) recommends the use of Investigational Drug Services to provide drug management services for trials conducted by a UHCMC investigator. Under certain circumstances, it may be necessary for the preparation, dispensing and/or management of the investigational drug/biologic to be performed outside of Investigational Drug Services. In those circumstances, the principal investigator for the study should complete an exception form and forward it to Investigational Drug Services care of: Michael Banchy, R.Ph at Michael.Banchy@UHHospitals.org or Kathryn Westlake R.Ph.at Kathryn.Westlake@UHHospitals.org.

1. Investigator Name:
2. Investigator Contact Information (e-mail/phone):
3. Division/Department:
4. Study Title:
5. Drug(s) to be used in the study:
6. Reason for the request (please provide a complete explanation of circumstances, timing, location and drug criteria that support the request):
7. Please provide the following information*:

Who will be responsible for the shipping/receiving of the study drug?

Where and how will the study drug be stored?

Who will have access to the study drug?

Who will be responsible for the dispensation and tracking of the study drug? *(Must be IRB- approved Physician Investigator)*

Who will be responsible for providing the study drug to the participant? (i.e. handing the study drug to the participant)

Principal Investigator/Physician are ultimately responsible for care and disposition of study articles.

Please provide a copy of the study protocol and all investigator brochures for each study drug with the signed request form.

Signed: _____
Principal Investigator

**Study drug must be stored in a secured and locked location, accessible to authorized personnel only. These areas must have sufficient security systems in place, such as locks, alarms, window bars, and or security personnel, to prevent unauthorized entry and access to study products.*

IDS INTERNAL USE ONLY	
Request decision (date): Signed: _____ Pharmacist	<input type="checkbox"/> accepted <input type="checkbox"/> not accepted (note reason why):