

Office of Clinical Research

Effective: June 1, 2009	Revised: November 12, 2020	Revision: 4
Responsibility: OCR		
Policy 1.1.2		

Policy: STORAGE AND CONTROL OF INVESTIGATIONAL DRUGS AND DEVICES FOR CLINICAL RESEARCH

1. BACKGROUND:

Research accreditation standards of the Association for Accreditation for Human Research Protection Programs require the Health Science Center to ensure proper storage, inventory control, dispensing and tracking of investigational drugs and devices.

2. PURPOSE:

To establish policies and procedures to ensure that the handling and storage of investigational products under an IRB approved research protocol meet the Health Science Center standards relating to inventory control, dispensing, and required documentation.

3. DEFINITIONS:

- a. **Investigational drug** includes any drug (approved or unapproved by the FDA) being used in research, other than the use of a marketed drug in the course of medical practice.
- b. **Investigational device** includes any device (approved or unapproved by the FDA) being used in research designed to evaluate safety and effectiveness of that device.
- c. **Investigational product** includes any investigational drug or investigational device or a combination of the two ("combination product") being used in a research designed to evaluate the safety or effectiveness of the drug, device, or combination.

4. REFERENCES:

- a. Applicable Federal Regulations include: 21 CFR §312.61, 21 CFR §312.62, 21 CFR §312.69, 21 CFR §812.100, 21 CFR §812.110, 21 CFR §812.140(a)
- b. Attachments provide sample standard operating procedures outlining responsibilities, required procedures and associated forms and logs.

5. RESPONSIBILITY:

- a. Investigators: All Investigators receiving and storing investigational drugs, investigational devices, or investigational products in their clinic or office areas outside of a hospital pharmacy, hospital designated service for devices, or the Investigational Drug Section of the Cancer Therapy and Research Center must:
 - (1) Maintain proper environmental storage conditions with appropriate security of the items at all times.
 - (2) Ensure and maintain inventory control and investigational product accountability including ordering, receipt, inventory, disposal/removal, and/or following procedures for transfer between institutions.
 - (3) Maintain drug or device accountability documentation and reports.
 - (4) Establish standard operating procedures (see attached example policy and logs for handling of investigational products) and provide for review to the Office of

Clinical Research (OCR) Director or his/her designee for OCR approval. OCR must approve any revisions or modifications to OCR approved policies.

- (5) For Department common storage locations, provide the following:
 - (a) Identify the building, room location for the storage and management of test articles
 - (b) Identify the responsible person, position title, contact number for oversight of the test articles and their contact information

b. Office of Clinical Research (OCR):

- (1) Reviews and approves new/revised Standard Operating Procedures (SOPs) and related documents submitted from Investigators or HSC divisions, departments, and services.
- (2) Inspects the HSC facilities where SOPs are to be implemented for the non-pharmacy storage of investigational products prior to SOP approval,
- (3) Documents the site inspection using the Drug/Device Storage Site Review checklist. This checklist also includes the option to waive physical inspection under special circumstances.
- (4) Documents study specific authorization under a departmental SOP using the Protocol Specific Authorization form.
- (5) OCR may request a site inspection prior to institutional activation of a new protocol for any existing approved SOPs.

c. University Health

- (1) For investigational products stored on University Health premises, OCR will provide the University Health Research Office with an approved signed copy of the SOP, inspection checklist and any protocol specific authorization forms at the time OCR returns to them to the PI and/or study team.
- (2) Prior to SOP approval, OCR will inspect the University Health facilities where SOPs are to be implemented for the non-pharmacy storage of investigational products. OCR will coordinate the inspection with the University Health Research Office. In some instances, site inspection may not be required. Details for not requiring inspection will be documented on the Drug/Device Storage Site Review form.

d. Monitoring of SOP adherence will be conducted by the Office of Research and Compliance (see VPR Policy on Study Reviews for Human Research).

After a study begins, investigators may choose to no longer hold and manage study drugs at their clinics but instead use an institutional pharmacy (e.g., University Health, STVHCS, Mays Cancer Center Investigational Drug Section) where appropriate. This office rather than the investigator (division, department, or service director), will then be responsible for investigational product accountability and procedures.