



Policy Brief

3/20/2024

7.14 Investigational Drug Management for Clinical Studies

Responsible Department: Office of Research Administration

Scope:

- **Summary**

Food and Drug Administration (FDA) drug accountability regulations, The Joint Commission (TJC) hospital accreditation standards, and accreditation standards of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) require a uniform and centralized plan for the management of investigational drugs used in human subjects research. The purpose of [Policy 7.14](#), in keeping with Emory University's comprehensive approach to research integrity, is to assist principal investigators (PIs) in further protecting human subjects who participate in research protocols at Emory through improved drug security, safety, and accountability.

- **Applicability**

The policy to PIs who will use an investigational drug in a human subjects research protocol when the investigational drug is (a) not FDA-approved; or (b) an FDA-approved drug that is subject to an Investigational New Drug application (IND); or (c) an FDA-approved drug (including an approved drug that is used as a test article but is determined to be IND exempt) that is provided to research subjects free of charge. This policy does not apply to PIs who will use devices, radiopharmaceuticals, cellular pharmaceuticals managed by an Emory Core Facility, or blood and blood components managed by the Blood Bank in human subjects research.

How to Comply with the Policy

- Adhering to the requirement to use the Emory Investigational Drug Service (IDS) or its Affiliate Pharmacy as established by section 7.14-A.
- Following the procedure for IDS submission as established by section 7.14-B.
- The PI using the IDS Decision Tree to determine whether the Emory IDS or its affiliate pharmacy in Emory's affiliated institutions must manage and dispense any drug used in the human subjects research protocol.
- Being aware of the operational structure for the Emory IDS as established by section 7.14-C. Section 7.14-C identifies the PIs the Emory IDS serves and identifies the affiliate pharmacies.
- Understanding how to request an exception to the policy requiring investigational drug management by the Emory IDS as established by section 7.14-D.
- If the PI determines that management and dispensing of an Investigational Drug used in the research protocol by the Emory IDS or its affiliate pharmacy is required but desires to manage the Investigational Drug in the study personally, he or she may submit an IDS Exception Request Form (link also provided in Policy 7.14), along with the protocol, by e-mail to the Emory IDS pharmacist prior to beginning a new research protocol.
- Section 7.14-D provides greater detail regarding the required information that the PI must provide in the IDS Exception Request Form.
- Adhering to requirement regarding the administration of investigational drug to subjects enrolled in clinical trials as established by section 7.14-E.
- Administration of investigational drugs, or teaching research subjects to self-administer investigational drugs (other than oral or topical), should be done by an individual who is:
 - Acting within the laws and regulations defining scope of practice;
 - Acting within the applicable facility's policies and procedures (including privileging/credentialing and/or protocol agreements with supervising or delegating physicians); and



- Has been delegated to perform the activity as documented by the PI on the study Delegation Log.
- Adhering to the requirements surrounding investigational drug counselling for subjects enrolled in clinical trials as established by section 7.14-F.
- Discussions with research subjects which involve the use of clinical judgment, medical decision-making, or consideration of a subject's specific characteristics or clinical situation require an appropriately licensed and trained study team member.
- Section 7.14-F also establishes requirements regarding informed consent, subsequent discussions with subjects regarding study drugs, and teaching self-administration of study drugs.
- Complying with the protocols surrounding the delivery of drugs used in human subjects research protocols to the PI's Site or to study personnel as established in section 7.14-G.

Noncompliance with the Policy

If PIs are noncompliant with any section of [Policy 7.14](#), he or she will be at risk of a research noncompliance investigation, which may lead to recommended disciplinary action.