Policy Brief

Last Revised: 3/20/2024

7.14 Investigational Drug Management for Clinical Studies

Administering Department: Office of Research Compliance & Regulatory Affairs

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

- Use the Emory Investigational Drug Service (IDS) or its Affiliate Pharmacy or request an IDS Exception if there are exceptional circumstances.
- Follow the proper procedure for IDS submission as established by section 7.14-B.
- Use 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.
- Adhere to the 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.
- Comply 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 or study team members are noncompliant with any section of Policy 7.14, they will be at risk of a research noncompliance investigation, which may lead to recommended disciplinary action.