Policy 7.14

Investigational Drug Management for Clinical Studies

Responsible Official:	VP for Research Administration
Administering Division/Department:	Office of Research Administration
Effective Date:	January 01, 2008
Last Revision Date:	May 22, 2024

Policy Sections:

Overview

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 this policy, 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

This policy applies 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, radio-pharmaceuticals, cellular pharmaceuticals managed by an Emory Core Facility, or blood and blood components managed by the Blood Bank in human subjects research.[1]

Policy Details

7.14-A Requirement to Use the Emory Investigational Drug Service or its Affiliate Pharmacy

The Emory Investigational Drug Service (IDS) or its affiliate pharmacy will manage and dispense all drugs (excluding radio-pharmaceuticals, cellular pharmaceuticals managed by an Emory Core Facility, or blood and blood components managed by the Blood Bank) used in an inpatient or outpatient human subjects research protocol when drugs fall within any of the following categories (all drugs in these categories being collectively referred to in this policy as "Investigational Drugs":

1. The drug is not FDA-approved; or
2. The drug is FDA-approved but is subject to an IND; or
3. The drug is FDA-approved (including any drugs used as test articles that are determined to be IND exempt), but it is provided free of charge to research subjects for purposes of the clinical investigation.

7.14-B Procedure for IDS Submission

The PI will 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.

1. If management and dispensing by the Emory IDS or affiliate pharmacy is required and a Coverage Analysis (CA) is needed, the PI/Clinical Research Coordinator (CRC)/Regulatory Specialist will submit using the eFORM and required study documents to Woodruff Industry Sponsored Clinical Trials (WISC)/Office for Clinical Research (OCR). If externally sponsored, the PI/CRC/Regulatory Specialist submits these documents to the Research Administration Service (RAS), through the Intent to Submit form, where RAS representative then uploads them into Emory Proposal Express (EPEX). If no CA is needed, the PI/CRC/Reg Spec will submit the eFORM, attaching the protocol, Informed Consent Document, and Investigator Brochure. The study team representative is responsible for directly submitting Investigator Brochure and Pharmacy manual(s) to the Emory IDS.
2. The WISC/OCR will work directly with the Emory IDS or its affiliate pharmacy to obtain the necessary information for budget development if the WISC/OCR is developing and negotiating the budget.
3. Upon Notice of Award, the Emory IDS pharmacist will work with the study team to set up the drug management and dispensing plan for the research protocol.
4. If an affiliate pharmacy is used, the PI is responsible for contacting the pharmacist to arrange for Investigational Drug management and dispensing and ensuring appropriate documentation.

7.14-C Operational Structure for the Emory IDS

The Emory IDS serves PIs who conduct human subjects research at Emory locations. Affiliate pharmacies at the Veterans Administration Medical Center, Grady Health System (Grady Memorial

[1] Note that for studies using Schedule I Controlled Substances as the test article, special arrangements must be made with IDS in advance to ensure that IDS is authorized to dispense such substances Practitioner/registrant dispensing may be used if IDS dispensing is not authorized.

Hospital), and Children's Healthcare of Atlanta provide Emory faculty with Investigational Drug management conducted in these locations. Affiliate locations are staffed and operated by those entities.

The Emory IDS has four locations: Emory University Hospital (F506); The Emory Clinic Building A (Suite AT111); Emory University Hospital Midtown (Suite 1600) and the Hope Clinic on Winn Way in Decatur, GA. Additional sites may be added as approved by appropriate state licensing authorities. The Emory IDS serves Emory locations by direct pickup or courier, Monday through Friday. During evenings, weekends, and holidays, Emory IDS staff will respond when paged, as needed.

7.14-D Request for Exception to the Policy Requiring Investigational Drug Management by the Emory IDS

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** (see Forms and Attachments section below), along with the protocol, by e-mail to the Emory IDS pharmacist prior to beginning a new research protocol. The PI will explain the exceptional circumstances that make Investigational Drug management by the IDS or its affiliate pharmacy impractical. An exception request should be made only under exceptional circumstances, such as a study that requires an Investigational Drug used in the research protocol be prepared or administered immediately or within a very limited time window (15 minutes or less) because of emergent circumstances, drug degradation, instability, etc. or labeling restrictions that do not permit the Investigational Drug to be transported.

Requests for an exception will document the following as part of the request:

1. Proper drug storage, inventory, and preparation conditions.
2. An agreement by the PI to undergo an audit by Emory IDS, with any associated costs to be borne by the site. If any serious deficiencies are noted upon audit, implementation of corrective action is required and may include withdrawal of the exception whereupon the management of the drug would revert to the Emory IDS.

A request for an exception to allow a PI to manage Investigational Drugs will be considered on a case-by-case basis and reviewed by the Emory IDS with input as necessary from the Associate Dean of Clinical Research and the Office of Research Integrity and Compliance.

7.14 -E Administration of Investigational Drug to Subjects enrolled in Clinical Trials

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:

1. Acting within the laws and regulations defining scope of practice,
2. Acting within the applicable facility's policies and procedures (including privileging/credentialing and/or protocol agreements with supervising or delegating physicians), and
3. Has been delegated to perform the activity as documented by the PI on the study Delegation Log

7.14 -F Investigational Drug Counseling for Subjects enrolled in Clinical Trials

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.

Informed Consent: Any subject (or Legally-Authorized Representative of a subject) enrolled in a clinical trial must sign the informed consent, and there must also be an informed consent process approved by the IRB (including advertisements and recruitment, the consent discussion, and follow-up discussions and reconsent as needed). As part of this process, the subject receives information about the effects and potential side effects of the drugs used in the study. As allowed by Standard Operating Procedures and delegated by the PI, a non-licensed research study team member may review the consent document and the study protocol with a subject and answer questions that can be answered by referring to the research protocol or consent form (if permitted by department). Subject questions requiring clinical judgment or based on individualized clinical history (e.g., questions regarding risk of participating based on clinical history) should be referred to the PI, co-investigator, and/or the subject's treating physician. An IDS pharmacist can provide drug counseling to the subject.

Subsequent Discussions with Subjects Regarding Study Drugs: Non-licensed study team members may receive training as to when to alert a licensed study team member to issues reported by subjects either during investigational drug delivery or subsequently. A non-licensed study team member may refer the subject to the drug label, instructions, informed consent or study protocol regarding the correct method for taking the investigational drug as part of the study. Issues or questions not addressed by such documents should be referred to a licensed study team member.

Teaching Self-Administration of Study Drugs: Teaching a subject how to self-administer investigational drugs other than oral or topical drugs should be done by an individual, for whom medication administration or injection is within their scope of practice and who meets the requirements in Section 7.14-E.

7.14-G Delivery of Drugs Used in Human Subjects Research Protocols to PI's Site or to Study Personnel

All Investigational Drugs will be appropriately labeled in accordance with the study protocol and applicable laws. The IDS will dispense Investigational Drugs and deliver them to the PI's site or authorized study personnel will come to an IDS location to retrieve them for transport to the PI's site. Investigational drug for subjects who are inpatients will be delivered to a treating licensed provider. Non-licensed study team members may transport or receive the investigational drug from the courier or IDS, and deliver the investigational drug to the subject. Non-licensed study team members can answer a subject's questions on how to take the drug by reviewing and referring to the instructions laid out in the drug label, informed consent or study protocol. If a question arises that is not addressed by such documents, that question should be referred to a pharmacist or licensed study team member. When dispensing take-home research medications, IDS places an auxiliary label on the outer bag. The label informs the subject to contact the study physician, research nurse, or call the IDS if they have any questions about the study medication. The IDS pager number for 24/7 coverage is included on the label. The subject is encouraged to call for any drug-related concerns.

Definitions

Investigational Drug – A drug used in a human subjects research protocol that is (a) not FDA-approved; or (b) the drug is FDA-approved, but is subject to an IND; or (c) the drug is FDA-approved (including any drugs used as test articles that are determined to be IND exempt) but is provided free of charge to research subjects for purposes of the clinical investigation.

Affiliate Pharmacy - the pharmacy located at an Emory affiliate, including the Veterans Administration Medical Center, Grady Health Systems (Grady Memorial Hospital), and Children's Healthcare of Atlanta at Egleston or Scottish Rite Hospitals.

Emory Locations - Emory University Hospital, Emory University Hospital Midtown and Medical Office Tower, The Emory Clinic, Emory Saint Joseph's Hospital, Emory Johns Creek Hospital, Wesley

Woods, the Hope Clinic, Executive Park, Emory Genetics Clinic, the Woodruff Memorial Building, and the Clinical Research Network sites within the Emory system, as well as any other sites at which Emory investigators conduct clinical investigation to which the IDS, from time to time, elects to provide service.

Radiopharmaceutical -A drug that contains a radioactive substance and is used to diagnose or treat disease, including cancer; also called a radioactive drug.

Controlled Substance – All drugs, substances or immediate chemical precursors listed in Schedules I to V of OCGA Sections 16-13-25 to 16-13-29; and Schedules I to V of Title 21 of the Code of Federal Regulations (CFR) Section 1308. Schedule I *Controlled Substances* are not considered to have any medicinal use, and therefore, regulations for these substances are more restrictive than for substances falling under other Schedules.

Cellular Pharmaceutical: Cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoetic stem cells and adult and embryonic stem cells.

Licensed study team member– Physician, Nurse Practitioner, Registered Nurse, Pharmacist, Respiratory Therapist, Registered Dietician or Physician's Assistant who is licensed in the state of Georgia. Research activities may be limited by Institutional Policy.

Non-licensed study team member – Research team member who does not have a Georgia license to practice as a physician, nurse, nurse practitioner, pharmacist, or physician's assistant.

Related Links

Forms and Attachments

- IDS Exception Request Form: download

Contact Information

Subject	Contact	Phone	Email
For question about the forms or process:	Emory IDS Director, SyTran, Pharm. D, MPH	404-219-6934	sy.quoc.tran@emory.edu ids@emory.edu

Revision History

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