



## **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:** July 17, 2018

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#### **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 in further protecting human subjects who participate in research protocols at Emory through improved drug security, safety, and accountability.

#### **Applicability**

This policy applies to principal investigators who will use an investigational drug in a human subject 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 principal investigators who will use devices or radio-pharmaceuticals in human subjects research.

## 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) used in an in-patient or out-patient 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 is provided free of charge to research subjects for purposes of the clinical investigation.

### 7.14-B Procedure for IDS Submission

The principal investigator (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 Prospective Reimbursement Analysis (PRA) is needed, the PI/Clinical Research Coordinator (CRC) or Research Administrative Service (RAS) will submit [Office for Clinical Research \(OCR\) Submission Form](#) and required study documents to the OCR. If no PRA is needed, the PI/CRC will submit the OCR submission form, protocol, Informed Consent Form and Investigator Brochure directly to the Emory IDS.
2. The OCR will work directly with the Emory IDS or affiliate pharmacy to obtain the necessary information for budget development if the 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 principal investigators who conduct human subject research at Emory locations. Affiliate pharmacies at the Veterans Administration Medical Center, Grady Health System (Grady Memorial 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 three locations: one in Emory University Hospital (F506); one in The Emory Clinic Building A (Suite 1200); and one at the Hope Clinic on Winn Way in Decatur, GA. Additional sites may be added in the discretion of the IDS, and 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 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 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 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 Drug will be considered on a case-by-case basis and will be reviewed by the Emory IDS with input as necessary from Associate Dean of Clinical Research and the Office of Compliance.

#### **7.14-E Delivery of Drugs Used in Human Subjects Research Protocols to Principal Investigator'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 principal investigator's site or authorized study personnel will come to an IDS location to retrieve them for transport to the principal investigator's site. Licensed healthcare providers that provide Investigational Drugs to study participants shall counsel the study participants on directions for the use of the investigational drugs. Only licensed healthcare providers are authorized to administer Investigational Drugs. Non-licensed healthcare providers may not answer study subjects' questions about Investigational Drugs and may only carry to study subjects' Investigational Drugs that have been dispensed and pre-packaged by the IDS with a notice that contains the following information:

- (a) the phone number for the IDS;
- (b) directions to contact the principal investigator of the study, study nurse or the IDS with any questions the subject has about the study drug; and
- (c) a notice that the IDS has a pharmacist available to answer questions via the provided telephone number on a 24 hour basis.

Appropriate language will be included in study consent forms advising subjects to contact the principal investigator, study nurse or IDS with any questions regarding study medicines.

#### **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 at Emory affiliates 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, The Emory Clinic, Wesley Woods, the Hope Clinic, the Woodruff Memorial Building, and the General Clinical Research Center, 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.

## Related Links

- Current Version of This Policy: <http://policies.emory.edu/7.14>

## Forms and Attachments

IDS Exception Request Form : [download](#)

## Contact Information

Subject	Contact	Phone	Email
For question about the forms or process:	Emory IDS Director, Susan Rogers, RPh	404-712-7485	srogers2@emoryhealthcare.org

## Revision History

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- Version Published on: Aug 30, 2017
- Version Published on: Aug 09, 2017
- Version Published on: Jul 17, 2017
- Version Published on: Jun 27, 2017
- Version Published on: Jul 22, 2014 (*Clarify dispensing of research drugs*)
- Version Published on: Feb 05, 2008
- Version Published on: Feb 05, 2008
- Version Published on: Jan 31, 2008 (*Original Publication*)

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