



## 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 22, 2014

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### Overview

FDA drug accountability regulations, TJC hospital accreditation standards, and accreditation standards of the AAHRPP human subjects protection program require a uniform and centralized plan for the management of investigational drugs used in human subject 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 or a drug provided free of charge by an external entity in a human subject research protocol. It does not apply to principal investigators who will use devices only.

### 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 any investigational drug (excluding radio-pharmaceuticals) used in an in-patient or out-patient research protocol in which human subjects participate and that requires informed consent when:

1. the drug is not FDA-approved ;
2. the drug is FDA-approved, but is provided free of charge for the clinical investigation;
3. the drug has special storage conditions, inventory, or dispensing requirements; or
4. the research sponsor requires management by the Emory IDS.

#### **7.14-B Procedure for Principal Investigators**

The principal investigator (PI) will apply the **IDS Decision Tree** (see Forms and Attachments section below) 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 dispensation by the Emory IDS or affiliate pharmacy is required and a Prospective Reimbursement Analysis (PRA) is needed, the PI will submit a **Protocol Approval Package** (see Forms and Attachments section below) and Investigator Brochure, if available, to the Office for Clinical Research (OCR). If no PRA is needed, the PI will supply the aforementioned documents 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 PI to set up the drug management and dispensation plan for the research protocol or, if an affiliate pharmacy is used, will set up the audit schedule.
4. If an affiliate pharmacy is used, the PI is responsible for contacting the pharmacist to arrange for drug management and dispensation and ensuring appropriate documentation.

#### **7.14-C Operational Structure for the Emory IDS**

The Emory IDS directly serves principal investigators who conduct human subject research at Emory Locations, including the Emory University Hospital, The Emory Clinic, Wesley Woods, the Hope Clinic, the Woodruff Memorial Building, and the Clinical Research Network sites within the Emory system. The Emory IDS oversees service provided by pharmacy staff in its Emory Midtown Hospital branch to principal investigators who conduct human subject research protocols at Emory Midtown Hospital and the Medical Office Tower. The Emory IDS has memoranda of understanding (MOUs) with the Veterans Administration Medical Center, Grady Health System (Grady Memorial Hospital), and Children's Healthcare of Atlanta for such service provided by affiliate pharmacies. These MOUs require comparable policies and procedures for investigational drug management, establish service expectations, provide for annual audits by the Emory IDS, and establish the affiliate's liability and responsibility for IDS when Emory faculty conduct human subject research protocols in these locations. Affiliate locations will be 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 staff serve the Emory locations listed above by direct pickup or courier, Monday through Friday from 8:00 A.M. to 5:00 P.M. During evenings, weekends, and holidays, Emory IDS staff or Emory Healthcare (EHC) pharmacy 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 dispensation 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 Applications 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 drug management by the IDS or affiliate pharmacy impractical. An exception request should be made only under exceptional circumstances, such as:

1. the study requires that the drug be administered immediately or within a very limited time window (30 minutes or less) according to the protocol, drug labeling, or investigational drug brochure because of drug degradation, instability, etc.;
2. documented sponsor or labeling restrictions that do not allow the drug to be transported; or
3. the impossibility of advanced scheduling of a subject's visit when the protocol requires preparation of the drug dose at the last minute or under emergent circumstances (e.g.,

in the emergency room).

The PI who requests an exception will document the following as part of the request:

1. certification by IDS of proper drug storage, inventory, and preparation conditions
2. agreement 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 and/or withdrawal of the exception may occur. At a minimum, the management of the drug would revert to the Emory IDS.

A request for an exception to allow a PI to manage the investigational drug personally will be considered on a case-by-case basis and will be reviewed by a designated committee, which includes representation from the Emory IDS, and the Office of Research Compliance.

#### **7.14-E Delivery of Investigational Drugs 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 Investigational Drug Service will dispense investigational drugs and deliver them to the principal investigator's site or authorized study personnel who 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 Investigational Drug Service with a notice that contains the following information:

- (a) the phone number for the Investigational Drug Service;
- (b) directions to contact the principal investigator of the study or the Investigational Drug Service with any questions the subject has about the study drug; and
- (c) notice that the Investigational Drug Service 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 or Investigational Drug Service with any questions regarding study medicines.

#### **Definitions**

**Investigational Drug** - any drug used in an in-patient and out-patient human subjects research protocol for which informed consent is required, regardless of whether the drug is FDA approved.

**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.

#### **Related Links**

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

#### **Forms and Attachments**

IDS Decision Tree : [download](#) IDS Exception Request Form : [download](#) Protocol Approval Package : [download](#)

#### **Contact Information**

Subject	Contact	Phone	Email
For clarification of policy:	Kris West	404-727-2398	kwest02@emory.edu
For question about the forms or process:	Emory IDS Pharmacist, Susan Rogers	404-712-7485	susan.rogers@emoryhealthcare.org

### Revision History

- Version Published on: Feb 05, 2008 (*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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