Investigational Drug Management for Clinical Studies

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Office of Research Integrity and Compliance

Emory Policy 7.14

- Created in 2008
- Establishes requirement for IDS to manage investigational drugs used in human subject research protocols
- Defines exception process
- Includes
  - Administration
  - Counseling

Investigational Drug Management for Clinical Studies

Requirement to use IDS

The Emory Investigational Drug Service (IDS) or its affiliate pharmacy will manage and dispense all drugs used in an inpatient or outpatient human subjects research protocol when drugs fall within any of the following categories:

- The drug is not FDA-approved; or
- The drug is FDA-approved but is subject to an IND; or
- 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

The Policy does not include:

- devices,
- radio-pharmaceuticals,
- cellular pharmaceuticals managed by an Emory Core Facility, or
- blood and blood components managed by the Blood Bank

PI may submit an **IDS Exception Request** if the PI determines that there are exceptional circumstances that make Investigational Drug management impractical**.**

Study Team Members

- **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.

Drug Administration

Administration of investigational drugs require 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

Drug Counseling

An appropriately licensed and trained study team member is required to conduct 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**

Informed Consent Process

As part of the consent process, study subjects receive information about the effects and potential side effects of the study drugs.

- As allowed by SOP and delegated by the PI, a non-licensed 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.
- 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 is also available to provide drug counseling to the subject.

Subsequent Discussions Regarding Study Drugs

- Questions regarding the correct method for taking the investigational drug may be answered by a non-licensed study team member by referring the subject to the drug label instructions, informed consent or study protocol.
- Questions or issues not addressed by the drug label, informed consent or study protocol, should be referred to a pharmacist or licensed study team member.

Consent Template Language

The IRB has added consent template language

How will your study drug be provided ?

- The study drug that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the study drug. The number for the pharmacy is included on your study drug package, if given one.

- Note: The research team for this study includes non-licensed team members who may obtain your consent, or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

Teaching self administration

Teaching subjects 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 is acting within:
  - the laws and regulations defining scope of practice,
  - the applicable facility's policies and procedures (including privileging/credentialing and/or protocol agreements with supervising or delegating physicians), and
- delegated to perform the activity as documented by the PI on the study Delegation Log

Questions

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