

HAC Policies and Procedures

Investigational Drugs

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Does MCG Or MCGHI Have Any Specific Regulations Regarding Investigational Drugs?

All medications (drugs or biologics) including placebo(s) used in clinical research studies must be labeled, stored, and dispensed according to federal, state, and institutional policies and regulations. All must be shipped to and dispensed by the Medical College of Georgia Health System, Department of Pharmacy, Investigational Drug Service/Clinical Research Pharmacy.

What Is The Investigational Drug Service/Clinical Research Pharmacy?

The Medical College of Georgia Health System, Department of Pharmacy, Investigational Drug Service/Clinical Research Pharmacy is responsible for the receipt, dispensing, accountability and record keeping for all investigational drugs used in research studies involving humans on the MCG campus including Georgia War Veterans Nursing Home (GWVNH) and MCGHI.

Does The MCGHI Clinical Research Pharmacy Charge For Their Services?

Please note that the MCGHI Clinical Research Pharmacy *does* charge for their services. For more information, call (706) 721-0802.

Is It A Conflict Of Interest For The Clinical Research Pharmacist To Serve On The HAC?

The Committee does not feel that it is a conflict of interest.

The Sponsor Shipped The Drug Directly To The Investigator, and Not to the Clinical Research Pharmacy. What Should I Do?

Notify the Clinical Research Pharmacy at (706) 721-0802 and the Office of Human Research Protection (OHRP) at (706) 721-1478 immediately.

What Should We Do If A Research Subject Misses A Scheduled Appointment And We Have Picked Up The Investigational Medicine From The Clinical Research Pharmacy?

If a research subject misses an appointment and the investigational medication was dispensed to the research team member, the medication must be returned to the Clinical Research Pharmacy immediately.

What Do We Do When A Research Subjects Returns Investigational Medication To Us?

If a research subject returns investigational medication (packets, bottles, tablets, capsules, etc.), to the MCGHI Clinical Research Pharmacy upon receipt from the research subject.

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What are the Requirements for Studies that Require an IND or Are Exempt?

1) For studies in which the sponsor is the IND, the investigator is required to:

- a) Provide a copy of the IND filing from the sponsor
- b) Provide documentation from the sponsor or FDA that the IND is valid
- c) Provide documentation from the FDA that the IND is exempt

Note that this documentation should be included in the initial submission for the study. HAC approval will not be granted without this required documentation.

2) For studies in which the investigator is the IND holder and assumes sponsor responsibilities, the following procedure should be followed:

- a) The PI will include in the protocol submission the following parts written to the specifications identified Title 21—Food and Drugs, Chapter 1—Food and Drugs Administration, DHHS, Subchapter D—Drugs for Human Use, Part 312 – Investigational New Drug Application Subpart D, responsibility of the investigator
- b) The PI must send a copy of all correspondence to and from the FDA in the initial submission, including investigator reports. A letter from the FDA regarding the IND status (including exemption) is also required for HAC approval.
- c) The HAC will ensure that at initial and continuing review, these elements are in compliance with:

- § 312.50 - General responsibilities of sponsors.
- § 312.52 - Transfer of obligations to a contract research organization.
- § 312.53 - Selecting investigators and monitors.
- § 312.54 - Emergency research under 50.24 of this chapter.
- § 312.55 - Informing investigators.
- § 312.56 - Review of ongoing investigations.
- § 312.57 - Recordkeeping and record retention.
- § 312.58 - Inspection of sponsor's records and reports.
- § 312.59 - Disposition of unused supply of investigational drug.
- § 312.60 - General responsibilities of investigators.
- § 312.61 - Control of the investigational drug.
- § 312.62 - Investigator recordkeeping and record retention.
- § 312.64 - Investigator reports.
- § 312.66 - Assurance of IRB review.
- § 312.68 - Inspection of investigator's records and reports.
- § 312.69 - Handling of controlled substances.

§ 312.70 - Disqualification of a clinical investigator

d) Investigators must contact the Office of Human Research Protection to schedule a meeting to confirm that the PI is knowledgeable on the requirements associated with 21 CFR §312. Investigational New Drug Application

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e) Investigators assuming sponsor responsibilities are also responsible for registering the study in the Clinical Trials Registry (see HAC Policies and Procedures, Section 2 for more information).

Are There Additional Resources Available to Assist Me With Questions That I May Have Later?

For additional guidance please visit: www.mcg.edu/research/OHRP/scgclinresphar.htm