Title: **Investigational Drug Service Functions**	**Policy Number:** **C – PHA - 0021** **Policy Type:** Clinical Operations **Effective Date:** 11/09
Replaces (supersedes): **Title:** N/A	**Policy Chronicle:** Date Original Version of Policy was Effective: 09/06 Reviewer Signature: _____ Helen Gibbons, Medication Safety Systems Manager
Area of Operation(s): Inpatient and Ambulatory Care	
Regulatory Agency / Standards: TJC MM.7.40 FDA 21 CFR 50, 56 and 312 HHS 45 CFR 46 FDA HHS ICH Good Clinical Practice Consolidated Guideline	**This Policy has been Reviewed and Approved Electronically:** Steven Cano, Sr. Director / Chief Pharmacy Officer J. Glover Taylor, Director, Sponsored Research Administration Mark Albanese, M.D., Co-Chair, Institutional Review Board Thomas Smith, R.N., Sr. Vice President of Patient Care Services and Chief Nursing Officer Allison Bayer, Chief Operating Officer Somava Stout, M.D., Chair, Medical Executive Committee
Keywords(s):	Investigational Drugs, Medication, Pharmacy, Protocol, Research, Study

I. Purpose

To provide all Cambridge Health Alliance (CHA) research personnel and investigators with guidance on the proper utilization of the Investigational Drug Service (IDS) in the Department of Pharmacy.

II. Personnel

Medical staff, nursing staff, pharmacy staff, principal investigators (PI), research assistants (RA), research coordinators (RC), contract research organizations (CRO), clinical research administrators (CRA), and other ancillary care providers.

III. Policy

All investigational drugs will be procured, stored, compounded and dispensed in a standardized manner under the control of the CHA Department of Pharmacy.

IV. Definition

Test Articles – also referred to as **Investigational Drugs** or **Study Drugs**. Encompasses those medicinal drugs, biological products, medical devices, and placebos which:

1. have received U.S. Food and Drug Administration (FDA) approval for use in humans (investigational drugs), or
2. have been approved by the FDA but are being used under protocol for human research and may be outside FDA approved labeling (study drugs).

V. Procedures

A. Investigational Drug Service Overview

The central CHA IDS is located in the Department of Pharmacy at The Cambridge Hospital (TCH). The IDS is in a secure, limited access area of the hospital.

The IDS plays an important role in ensuring that clinical trials are conducted in accordance with FDA regulations and International Conference on Harmonisation good clinical practice guidelines. The IDS also ensures compliance with sponsor requirements regarding drug dispensing, monitoring, & accountability.

There are additional regulatory requirements for dispensing investigational or study drugs versus marketed drugs. These include, but are not limited to:

- verification of protocol approval by the CHA Institutional Review Board (IRB)
- presence of an executed patient informed consent
- additional record-keeping
- preparing (compounding) and/or packaging of final product
- labeling of dispensed product
- disposal of unused or partially used medications.

B. Investigational Drug Service Requirements

The IDS is available for inspection by all potential investigators and sponsors by appointment made with the IDS Coordinator. The IDS should be notified as soon as possible of upcoming monitoring visits. Generally, the study monitor will visit the IDS during each monitoring visit.

The IDS staff will be included during the study initiation visit.

The IDS oversees all pharmacy procedures & processes for all drug studies (inpatient and ambulatory) at CHA hospitals and clinical sites, as well as services provided by other pharmacist(s), technician(s), and/or supporting pharmacy personnel on behalf of the IDS.

The IDS staff will be responsible for the maintenance of files on each study that includes accountability records, manifests, and study correspondence.

The IDS is responsible for the education of pharmacists, technicians, nurses, RCs and RAs throughout CHA who will be handling the drugs for each protocol.

The IDS charges for its services; the IDS cost will change from study to study and is based on a formal cost schedule. An IDS budget will be developed for the investigator to adequately plan for all necessary pharmacy costs. The IDS will charge the study budget for its services.

Adverse events possibly involving a test article shall be reported by the PI, RA or RC to the IDS, in addition to the IRB and sponsor (as applicable).

Institutional Review Board approval of a study will be verified before IDS services are provided.

C. Protocol Review

All drug research protocols are reviewed by the IDS Coordinator early in the development phase (i.e., ideally before IRB submission), to identify any IDS related issues, including any pharmaceutical and clinical pharmacy requirements. In any case, final study approval will not be granted until the IDS review has been successfully completed.

Investigators must provide a copy of the study protocol, investigator's brochure and any drug-related forms from the sponsor/CRO to the IDS as early as possible. The IDS Coordinator will review this material; meet with sponsor representatives, PI, RA / RC, and other study personnel to assess the potential IDS impact and requirements.

D. Management of Test Articles

1. Procurement

The PI will supply to the IDS all documents necessary for ordering initial and subsequent shipments of test articles from the sponsor were applicable.

The PI will instruct the sponsor to ship all drugs to the IDS in care of the TCH Inpatient Pharmacy. Test articles sent to other areas should be forwarded immediately to the IDS for processing. No test articles should be delivered to an investigator's or researcher's clinic office.

If problems develop in obtaining test articles from either sponsor or supplier, the PI will be notified.

2. Inventory Control

Test articles stored in the pharmacy will be kept in the IDS facility or apart from common drug stock in an area of limited access.

Test articles subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 will be stored in the controlled substance room.

Test articles will be stored under the proper environmental conditions as specified in the study protocol, investigators brochure, and/or drug monograph as provided during study initiation or protocol review.

All test articles, whether study or investigational, will bear the designation: "For Investigational Use Only."

The standard IDS accountability log will be used unless the study sponsor specifically designates other forms.

Test articles may be stored in other areas (satellites) as long as CHA medication management policies and procedures for inventory control and dispensing as well as applicable state and federal law are adhered to.

3. Study Closeout

Final reconciliation of accountability logs will be completed by the IDS Coordinator upon notification of a study closeout by the protocol sponsor or PI. A closeout audit by the protocol study monitor will be arranged as required.

The IDS study binder and all associated paperwork will be maintained in the "Closed Studies" section of the IDS files, until archived. Closed study binders will be archived for 15 years after study closure.

E. Ordering / Preparing / Dispensing of Test Articles

1. Ordering

Only the PI, Co-PI or registered investigator who are members of the CHA professional staff possessing prescribing privileges, may prescribe investigational drugs.

Prescriptions must be written on the IDS fax prescription form, CHA prescription pad with the same information, or on a CHA physician's order form (inpatient units).

Test articles must be prescribed according to protocol requirements. When the research subject is a CHA patient, orders are considered a part of the medical record and must conform to internal policies. When appropriate, pre-printed physician order forms will be used to ensure adherence to protocols.

Prescriptions will be faxed, delivered or scanned to the IDS in a timely manner (coordinated with the IDS) in advance of a subject's visit.

The pharmacist will screen the order to verify that the following information is present: subject identifier including date of birth, protocol name (number if applicable); test article name, dosage form and strength; dosage and route of administration; frequency of administration; dilution (if applicable); and infusion rate (if applicable); name of authorized prescriber and signature of the same.

Action on any faxed or delivered prescription is contingent upon receipt of a copy of the signed Informed Consent Form (signature page).

Incomplete, inaccurate, or questionable orders will be clarified with the prescriber directly or via the RA/coordinator.

Special arrangements must be made for inpatient studies taking place at CHA that are emergent or critical-care in nature.

2. Preparing and Dispensing

During specified operating hours Monday through Friday, the IDS Coordinator will sign out and dispense a patient specific supply of test article upon notification from any Pharmacy Department of receipt of an authorized physician's order.

The label for the dispensed product will contain the following information except when identifying the drug would violate the double-blind nature of a study: patient name or identification number, protocol name (when applicable), name of test article, dosage, route of administration, expiration, and the words: "For Investigational Use Only."

During hours other than those covered by the IDS Coordinator, a designated pharmacist will follow "After-Hours Procedures", and use the study specific "IDS Dispensing Instructions." In cases, where these are either not established and medication is needed on an emergent basis the IDS Coordinator may be paged.

If a multi-center study utilizes the IDS as the central pharmacy, additional arrangements must be made in advance. Facilities to which drug will be transferred must have in place written procedures governing the proper handling of investigational drugs, consistent with the requirements of the protocol and reasonably acceptable to the IDS.