

Pharmacy Services

The Investigational Drug Study Service exists as a subdivision of the Pharmacy. Its focus is customized services directed at clinical research trials to satisfy or exceed regulatory and accreditation requirements.

The Pharmacy requires funding for its services. A comprehensive pharmacy protocol plan between the Principal Investigator and the Clinical Research Pharmacist must be completed before services will be provided. Contact the Clinical Research Pharmacist (ext 52014 or 56803) to set up a meeting. It is suggested that this meeting occurs in the early planning phase of the trial.

Services provided by the Pharmacy Department are:

- Assistance with protocol design and development
- Assistance with Investigational New Drug (IND) exemptions in conjunction with the CCI
- Development and/or maintenance of randomization schedules
- Drug procurement, storage, accountability, and, when necessary, disposal
- Preparation, packaging, labeling, blinding, and dispensing
- Assistance with drug sponsor site visits and study initiation meetings
- Monthly reports to the Principal Investigator (if requested)
- Clinical services including patient education, monitoring compliance and inservices for practitioners

The use of drugs in clinical research for human subjects must first be approved by the CCI. Following such approval, the procedures described below apply.

1. All drugs used for investigational purposes must be stored in the Pharmacy Department. This includes drugs used in Phase I, II, III FDA studies as well as drugs with FDA-approved New Drug Applications (NDA) or Abbreviated New Drug Applications (ANDA) that are being used for investigational purposes or in conjunction with a clinical drug study.
2. The Principal Investigator must make arrangements for the Pharmacy's participation prior to receipt of drug or enrollment of patients, and prior to final budget submittal.
3. A fee schedule for the Pharmacy's services has been devised and must be agreed upon prior to the Pharmacy's involvement in the study.
4. A protocol must include authorized prescribers designated by the Principal Investigator.
5. All drugs for clinical study purposes shall be shipped directly to the Pharmacy Department. If a sponsor insists on shipping to the Principal Investigator, it should be shipped in care of the Pharmacy Department to ensure proper handling and storage requirements.
6. Investigational drugs will be stored in the Children's Hospital Central Pharmacy and dispensed only upon the receipt of a signed informed consent and a prescription or medication order from the responsible investigator or his/her designee.

To contact the Pharmacy regarding a protocol, call the Clinical Research Pharmacist, Rocco Anzaldi, RPh (Rocco.Anzaldi@tch.harvard.edu) at 617-355-6803, Monday through Friday, 8:00 am - 4:00 pm

Other Contacts for Planning Clinical Research

When planning clinical research, it is important that all investigators consider the monetary and manpower resources necessary to conduct the research protocol. This planning must take place as the protocol is developed. The following is a list of departments and individuals that should be contacted if the research requires the services of their departments. **It is essential that you contact these individuals for accurate budgeting information when preparing clinical trial budgets.**

Department	Contact	Phone/Beeper
Admitting	Theresa Howe	56647
Biomedical Engineering	Walter Lloyd	56166
Center for Ambulatory Treatment & Clinical Research (CAT/CR)	Pat Pratt	56235
Clinical Labs/Laboratory Medicine	Mary Ellen Cortizas Janet Matsubara	56347 56142
Clinical Trial Agreements	John Counts	58354
GCRC Core Lab	Irena Clark	5309/0212
Nuclear Medicine	Royal Davis	54003
Office of Sponsored Programs (OSP)	Liam O'Connor	57044
Physical Therapy	Claire McCarthy	57212
Radiation Safety Committee (RSC)	William Lorenzen	57516
Radiology	Linda Poznauskis	57236/1572
Research Finance		57054
Respiratory Therapy	John Thompson Peter Betit	56034/1398 56037/1152
Safety	JoAnn Grandchamp	8100/0089