

Medical College of Georgia Hospital / MCG Health Inc.
Pharmacy Investigational Drug Service (Clinical Research Pharmacy)

The Medical College of Georgia Health Inc. hospital pharmacy has been assigned responsibility for study medication receipt, storage, dispensing, accountability and record-keeping for all human subject research on campus. Establishing one central site for investigational drug management will ensure a consistent process for all MCG research that complies with federal and state mandates and sponsor requirements. The pharmacy will act on behalf of the principal investigator to assure adequate and accurate written records of receipt and disposition of all drug supplies. Additional services (study design assistance, randomization and blinding, patient monitoring etc.) are available by request.

Clinical Research Pharmacy	Phone: 721-0802 (office/voice mail) 721-6411	
	Fax: 721-3827 (Back up Fax # 721-9138)	
	Pager: 721-7243- [Marjorie] 6101 or [Darla] 1499 (Monday-Friday 8:00AM-5:00 PM)	
	Marjorie Shaw Phillips, MS, RPh.	Clinical Research Pharmacist
	Darla Irwin, CPhT	Certified Pharmacy Technician
	Patricia Knowles, R.Ph.	Back-up Pharmacist

Tips for general study management

- For new studies, provide the pharmacy with a copy of the protocol /Investigators Brochure as soon as possible
- Contact Marjorie to obtain information needed on pharmacy costs for the budget
- Coordinate with the Clinical Research Pharmacy staff for initial/pre-initiation site visits by sponsors or CROs: they will need to see the drug storage location and review medication accountability procedures
- Call/ email in advance to schedule appointments for all monitor visits
- Principal Investigator & Study Coordinator should review & “sign off” on proposed pharmacy procedures prior to initiation of each study. **We will work with you to design a process for dispensing to accommodate the needs of the subjects, study staff and individual protocol.**
- Provide a weekly (or monthly) schedule of planned subject visits so the pharmacy will be aware of your needs
- Returned medication / empty containers received from the patient should be dropped off to the pharmacy on the **same day**. (If kept overnight, must ensure they are locked up/limited access and note the date and quantity received from patient so that the accountability records are accurate.)
- Monthly/bimonthly bills will be sent for pharmacy services—please pay these promptly. Notify Darla of any delays (e.g., initial funds from sponsor not yet received)

Information needed for each patient/subject prior to dispensing the first study medication

- copy of the subject’s signed/dated informed consent
- written prescription signed by a physician/investigator with the following additional information listed
subject/patient’s full name and initials, study ID#
home address, date of birth, weight in kg for pediatric patients (or if drug dosed by weight)
allergy status (list any known allergies to medications or “NKDA” for no known drug allergies)
MCG “account number” (the first 7 digits of the CPI number) for that patient (**not dummy study ID**)
short name of study/study drug and protocol number for study

Process for dispensing (when subject/patient’s needs are known in advance)

- provide written prescription at least 24 hours in advance
- the pharmacy staff will have the Rx available for pick up in the Central Pharmacy Clinical Research Pharmacy (2nd floor main hospital, BI-2101) on the day of the visit.

Process for dispensing (when dosing decisions are made after the investigator examines the patient)

- notify the pharmacy in advance of your anticipated needs whenever possible (e.g., if screening for new patients, what hours/days are your clinics--- for returning patients you should provide a list of return appointments)
- provide a prescription from a physician investigator by one of three methods
 1. drop off prescription to Clinical Research Pharmacy staff (BI-2101)
 2. fax copy of prescription to 721-3827 (the pharmacy staff will get the original prescription when the study drug is dropped off/picked up)
 3. have the investigator call in the prescription or dose adjustment to the pharmacist (pager 3-6101; 721-0802)
- filled prescription will be picked up by the study coordinator/investigator or research team member