Human Research Academy 101
Clinical Research Pharmacy
Investigational Drug Services (IDS)

Marjorie Shaw Phillips, MS, RPh, FASHP
Clinical Research Pharmacist
Pharmacy Manager, Georgia Regents Pharmacy
Learning Objectives

• Define an “investigational drug”
• Describe state/federal regulations, health system standards and local policies that apply to research involving study drugs
• List the services available from Pharmacy
• Explain how (and when) to access Clinical Research Pharmacy services
Investigational Drug Definition

(1) Agent being considered for commercial marketing, not yet approved by FDA

(2) Approved medication being studied for an unlabeled use* or population

*As opposed to unlabeled use in clinical practice

“Drug” is agent used for therapeutic or diagnostic purpose
Regulations & Drug Research

State of Georgia

– Dispensing (any legend drugs, including investigational drugs) is limited to licensed pharmacist, physician or dentist

– Pharmacy Practice Act governs requirements for labeling, documentation of prescription etc.
Georgia Hospital Pharmacy Regulations
– Investigational drugs must be stored in & dispensed from the hospital pharmacy (1990s)
– Matches current standards from The Joint Commission
– Amended in 2002
Georgia Hospital Pharmacy Regulations (2002)

480-13-.09

- Director of Pharmacy responsible for policies and procedures regarding investigational drugs
- Proper labeling
- Committee approval of protocol & investigators
- Informed consent
- Nurses must be educated before administering

290-9-7-.22 addresses drugs brought in by patient
Regulations & Drug Research

Medical Center (Hospital and Clinics)

– Investigational drugs must be stored in & dispensed from the hospital pharmacy including patient’s home meds while hospitalized

– Copy of informed consent filed in medical record accessible in electronic chart using PowerTrials)
If chose not to use the pharmacy for oversight receipt/storage/dispensing/accountability & drug storage temp log, PI must follow all state/federal laws and applicable requirements, get approval from IRB first & have standard operating procedures (SOP)

*Requires approval from site where research being done
Hospitals (Medical Center)

Patient hospitalized with “outpatient” supply of study medication:

– Notify IRB (and pharmacy) of admission
– PI and admitting physician decide on patient needs
– If study drug continued
  • Complete inpatient order (drug, dose, route, frequency) including “may take own investigational”
  • Stored in & dispensed from Pharmacy
  • Fact sheet (IDDS) on inpatient chart
  • Progress note documenting decisions, study
Investigational Drug Storage (FDA requirements)

• Investigator responsibilities 21 CFR 312.61
  Administer drug only to subjects under personal supervision of PI or sub-I & not supply drug to any person not authorized to receive it.

• Secure location (limit access)

• Storage conditions according to instructions on drug label (temperature, humidity, light)
Clinical Research Pharmacy

Clinical Research Pharmacists
Marjorie Phillips, MS, RPh, FASHP
Morgan Kelly, Pharm.D. (focus Oncology)

Clinical Research Pharmacy Technicians
Darla Irwin, CPhT
Crystal Parker, CPhT

Back-up Pharmacist (from main pharmacy)
Regular operations (Campus clinic schedule)
• Monday through Friday, 8:00AM – 4:30 PM

Inpatient studies
• 24 hour service through Inpatient Pharmacy

“On call” & special arrangement (Marjorie)
Clinical Research Pharmacy Services (* = optional)

- Initial protocol review (assess feasibility)*
- Participate in site-selection, pre-study & monitor visits
- Study budgeting for Health Inc. pharmacy services
- Pharmacy procedure & IDDS (fact sheet) development
- Work with study staff on study orders (hospital or clinic)
Clinical Research Pharmacy Services, continued (* = optional)

- Store, dispense & account for study meds from initial sponsor shipment through final drug return
- Quality assurance and compliance monitoring
- Support of investigator-initiated projects (randomization, blinding, study design, accountability form development, preparation of double-blind drug & placebos, patient monitoring) & other contracted services*
Clinical Research Pharmacy Services (Compliance)

- IRB & contract approval before study “opened” for dispensing
- Order form development & approval before inpatient study orders accepted
- Authorized investigator must prescribe study medication (original Rx or call)
- Informed consent documented before study drug is dispensed (copy to pharmacy)
Pharmacy
“DO” List for Coordinators

• Notify about potential/pending studies
• Provide **advance notice** of all monitor visits (including site selection) and subject dispensing visits/needs  { Darla’s calendar}
• Provide protocol for budget evaluation as early as possible
Pharmacy
“DO” List for Coordinators, cont.

• Send protocol/investigators brochure, as well as any amendments or investigator changes, to Pharmacy when submit to IRB (or before); drug accountability logs ASAP

• Bring patient “returns” to pharmacy on same day (or any Rx for a “NO SHOW”). Must not store in clinic or office.

• Alert pharmacy about any patients hospitalized

• Ensure all Rx written completely
Writing a Study Prescription

Includes information not normally found on a commercial Rx (*):

- Study Name (Short Title)*
- Protocol Number*
- Subject Study ID Number*
- Patient full name (and study initials if applicable)
- Medical Record Number (EMRN)
- Allergy status
- Date of birth (highly desirable)
- Drug name, dosage form, route, frequency
- Quantity to dispense
- Refills (if any)

Pharmacy will work with you to develop a template (example) Rx for each study. (Inpatient/clinic orders have different requirements – ASK !)