Introduction To Investigational Drugs and the Investigational Drug Service – IDS
OBJECTIVES

- To identify what an investigational drug is and its place in clinical trials
- To learn about the different types of investigational drugs
- To learn about the different types of clinical trials
- To learn how investigational drugs are managed at the University of Kentucky Hospital
- To identify how to access protocol specific information on the use of investigational drugs at the University of Kentucky Hospital
WHAT IS AN INVESTIGATIONAL DRUG?

- An Investigational Drug is one that is under study (as in clinical trials), but does not have the permission from the U.S. Food and Drug Administration (FDA) to be legally marketed and sold in the United States.
WHAT TYPES OF INVESTIGATIONAL DRUGS ARE THERE?

- NEW CHEMICAL OR BIOLOGICAL ENTITIES THAT HAVE NEVER BEEN TESTED ON HUMANS.
  - Phase I Trials (initial pharmacokinetic studies)
  - Phase II Trials (initial small scale trials in patients with disease)
  - Phase III Trials (trials in larger targeted populations with disease)

- CURRENT FDA-APPROVED DRUGS THAT ARE BEING TESTED FOR ADDITIONAL INDICATIONS OF USE.
  - Phase IV Trials (post-marketing trials)
WHO CONDUCTS CLINICAL TRIALS OF INVESTIGATIONAL DRUGS?

- Pharmaceutical and Bio-Tech companies.
- Federal agencies such as the National Institute of Health (NIH) or the National Cancer Institute (NCI).
- Cooperative research groups such as the Southwest Oncology group (SWOG) and the Eastern Cooperative Oncology Group (ECOG).
- Individual Investigators.
WHAT IS MY ROLE IN CLINICAL TRIALS?

- Non-study related nurses may be required to administer and monitor investigational drugs to study patients.

- Familiarize yourself with any specific nursing protocol requirements and adverse effect profile of the drug.

- Document any observed side effects, know anticipated effects.
Is a Copy of the Protocol and Consent Form Available?

- Since the protocol is “proprietary property” of the sponsor and contains confidential information, access must be limited. However, upon request, the study coordinator or Principal Investigator can provide you with a copy of the protocol.

- A copy of the Consent Form can be found in the patient’s chart. The Consent Form contains pertinent information about the protocol.
WHAT IF I HAVE A QUESTION ABOUT A STUDY PROTOCOL OR AN INVESTIGATIONAL DRUG?

- The Investigational Drug Service (IDS) provides a Drug Monograph for all non-FDA approved investigational drugs. The monograph is sent with the first dose and is kept in the patient’s chart. Additional copies can be obtained from the IDS.

- For medical questions, contact the Principal Investigator or Sub-Investigator(s) for the study.

- For protocol-related questions, contact the Study Coordinator or Principal Investigator.

- For study drug-related questions, contact the IDS Research Pharmacist or Central Pharmacy.
HOW ARE INVESTIGATIONAL DRUGS MANAGED AT THE UNIVERSITY OF KENTUCKY HOSPITAL?

- The Investigational Drug Service (IDS) supports all clinical drug-related research conducted by investigators at the University of Kentucky Hospital.
- The IDS is part of the Department of Pharmacy.
- The IDS manages both in-patient and out-patient studies.
  - All inpatient drug studies involve the IDS.
  - Some outpatient studies involve the IDS.
- The Investigational Drug Service can be reached at 323-2894 or 323-6969. The Research Pharmacist is also available on pager #2688.
- You may also contact the Department of Pharmacy Services if unable to reach the investigator or the IDS.
How Can I Get More Information About the Investigational Drug Service?

- Visit the University of Kentucky Hospital Investigational Drug Service (IDS) Web-page at:

  http://www.hosp.uky.edu/pharmacy/ids/default.html