What is an Investigational Drug

- new drugs
- old drugs- new indications, new combinations, new components
- investigational use of commercially available drugs

Preclinical Trials

- acquisition of new agent, screening for activity, formulation and production of agent, toxicology
Investigational New Drug Application (IND)

may be filed by:
• innovator/manufacturer
• physician
• academic medical center
• governmental agency -NIH, NCI-

Phase I

small numbers healthy volunteers
toxicity
kinetics, administration route
safe dose range (MTD)

Phase II

treatment or prophylaxis of a specific disease
demonstrate safety and efficacy toxicity-
first controlled trials
Phase III

- expanded clinical trials
- compare to existing standard therapy
- determine optimum dose and schedule
- accumulate information to establish drug effectiveness for specific indications and populations at risk from its use.

• If IND is successful, file New Drug Application (NDA)

Institutional Review Board

University of Washington
Human Subjects Review Board

- appointed by institution-
- Membership: at least 5 members-
- men and women, more than one profession, one non-scientist, one not associated with the institution
- FDA holds this board responsible to protect the welfare and rights of human subjects in research
Institutional Review Board

• Protocols and Informed consents for study subjects are reviewed and approved by the IRB

Informed Consents

Informed Consents should contain information about the treatment or drug and be written in lay language.
Objectives of clinical trial should be explained, including risks and benefits, and any alternative therapies available.
Outlines the responsibility of the investigator to keep the subject informed about additional information that becomes available as the study progresses

Non Research Use of Investigational agents

• Investigational agents may be used emergently or not under the format of a clinical trial.
• Informed consent and IRB approval or notification is required for emergent use.
**Treatment INDs**

- to make certain investigational new drugs available to desperately ill patients before the FDA approves them for marketing.
- These INDs are for pre-approved protocols using the drug in a specific treatment and disease.
  - no comparable drug available
  - immediately life threatening or serious disease
  - drug under active investigation
- drug shows promise of therapeutic benefit

**Compassionate Use**

- allows the use of a drug for patients who are desperately ill, do not qualify for a clinical trial, or when clinical trial is not available.
  - Single Patient Use trials
  - Limited Access Trials

**Pharmacy Based Investigational Drug Service**

FDA vs JCAHO Requirements

ASHP Guidelines on Clinical Drug Research
Pharmacy Based Investigational Drug Service

Basic Activities:
• registration of drug's use in hospital
• procurement
• storage
• preparing
• dispensing
• maintenance of records
• Provision of drug information

Administrative responsibilities
• Reordering Investigational Drugs
• Disposal of Used or Unused drug
• Computerization of drug ordering and control
• Billing for IDS Services

Pharmacy Based Investigational Drug Service

• Pharmaceutical Care
• IRB Membership
• Pharmacotherapeutic monitoring of invest. therapy
• Patient counseling and education
• Data manager
• Adverse Drug Reaction Reporting
• Staff development and inservicing education
Pharmacy Based Investigational Drug Service
Research and Development Activities:
• Protocol development- especially drug delivery and monitoring
• Single and double blind studies
• Randomization
• Pharmaceutical Research-
  – Formulation, Development
• Preparation of dosage forms
• Drug analysis & quality control

Pharmacy Based Investigational Drug Service
Benefits of Pharmacy Based Investigational Drug Service

• to the hospital
• to the nurses
• to the investigators
• to the sponsors
• to the patients