Introduction

• You may have heard references to research studies on TV or the radio and wondered what they are

• Research studies are also called clinical trials, drug trials or drug studies
What Is a Research Study?

- A research study tests the effect of a medication, medical device or treatment in a group of volunteers.
- Studies measure a drug’s ability to treat a medical condition, the drug’s safety and possible side effects.
Why Are Research Studies Needed?

- Medical researchers are constantly looking for new or better ways to treat illness or disease.
- Their discoveries cannot be put into general use until careful testing has been done.
Who Sponsors Research Studies?

- Research studies are sponsored by pharmaceutical companies, research institutes or other health organizations
  - Pharmaceutical companies often provide the funds for conducting the study
  - They often design the protocol (a set of detailed guidelines that clinical investigators follow)
- The same study may be conducted at several different locations
Who Conducts Research Studies?

- Only trained doctors, nurses and researchers actually conduct the study.
- The study coordinator is in charge of the day-to-day running of the study.
- The principal investigator has overall responsibility for carrying out the protocol.
The Food and Drug Administration (FDA)

• The FDA is a government agency that is responsible for many aspects of research studies
  – Regulates the conduct of research studies
  – Enforces laws on the manufacture, testing and use of drugs and medical devices
  – All new drugs and devices must be approved by the FDA before they can be used by the general public
  – The FDA must approve each study before you can participate in it.
Why Should You Participate in a Research Study?

• To help yourself
  – You may have a beneficial effect from the study drug
  – You will receive a great deal of personal medical attention usually at no cost (often free labwork, free ekgs, sometimes free colonoscopies).

• To help others
  – Research study volunteers help make new treatments available to people who need them
What Are the Different Types of Research Studies?

• Phase I studies – Healthy volunteers and sometimes animals
  – Main purpose is safety
  – Small number of subjects (20-100)
Phase II Studies

- The main purpose is safety and effectiveness
  - Several hundred patients, few months to 2 years
  - Randomized controlled - Active drug is compared to placebo (inactive substance or "sugar" pill) or standard treatment
Phase III Studies

• These studies also use patients
  – Once the drug is at Phase III, there is a more thorough understanding of its effectiveness, benefits and side effects.
  – Large numbers of subjects participate in this phase—Several hundred to several thousand for several years
  – 70 to 90% of drugs successfully complete phase III trials
  – After Phase III, the drug is usually approved for sale
Phase IV Studies

- Also called post marketing studies
  - Compare study drug to similar drugs on market
  - Studies are done on the long term effectiveness or effect on quality of life
  - Phase IV studies look at new indications for the drug
Who Is Eligible to Be in a Research Study?

• Almost anyone can be in some type of study
• Each study has certain requirements about health, medications or age depending on what specific questions are being asked
• You must meet the requirements of a particular study to be an eligible volunteer
What Is Involved in Participating in a Research Study?

- Participating in a research study is much like a regular visit to a clinic or doctor’s office, but with even greater personal attention
- What will occur at each visit will depend on each individual study
What Are the Risks of Participating in a Study?

• Risks vary from study to study
• Researchers expect certain results but since the treatment is still being studied it is impossible to say exactly what the risks may be
• If a side effect or adverse event occurs, it is generally temporary and will go away as soon as the treatment is stopped
Informed Consent Form

• Anyone participating in a research study is required to sign an “informed consent” form
• It is also signed by the investigator and/or study coordinator
• It details the nature of the study, the risks involved and what will happen
• It also informs study subjects that they have a right to leave the study at any time and who to call if they have questions
Institutional Review Board (IRB)

- Any physician awarded a research study must get approval from the IRB before beginning the study.
- The IRB is composed of physicians and lay people.
- The board reviews each study to ensure patients’ rights are protected and that there are no unnecessary risks in the study.
If You Are Thinking About Participating in a Research Study

• Think it over carefully
• Weigh possible benefits against risks
• Make sure all your questions are answered by the study personnel