

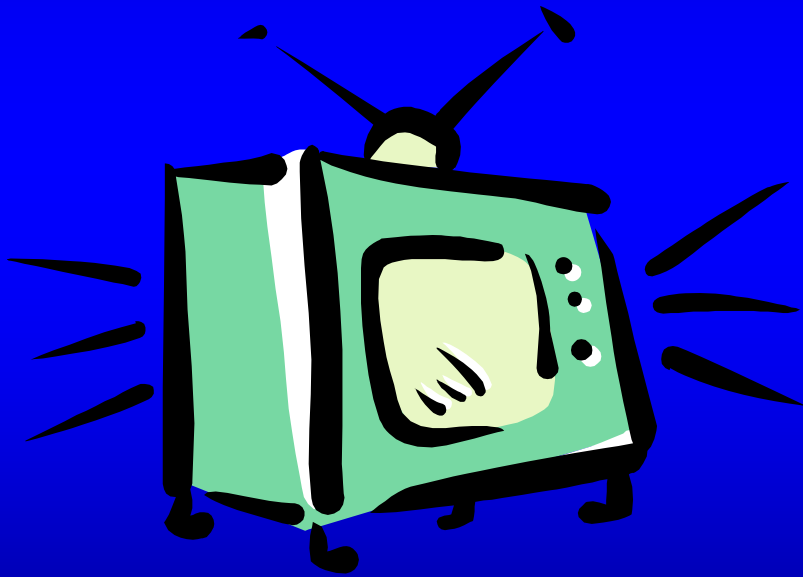
UNDERSTANDING RESEARCH STUDIES

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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)

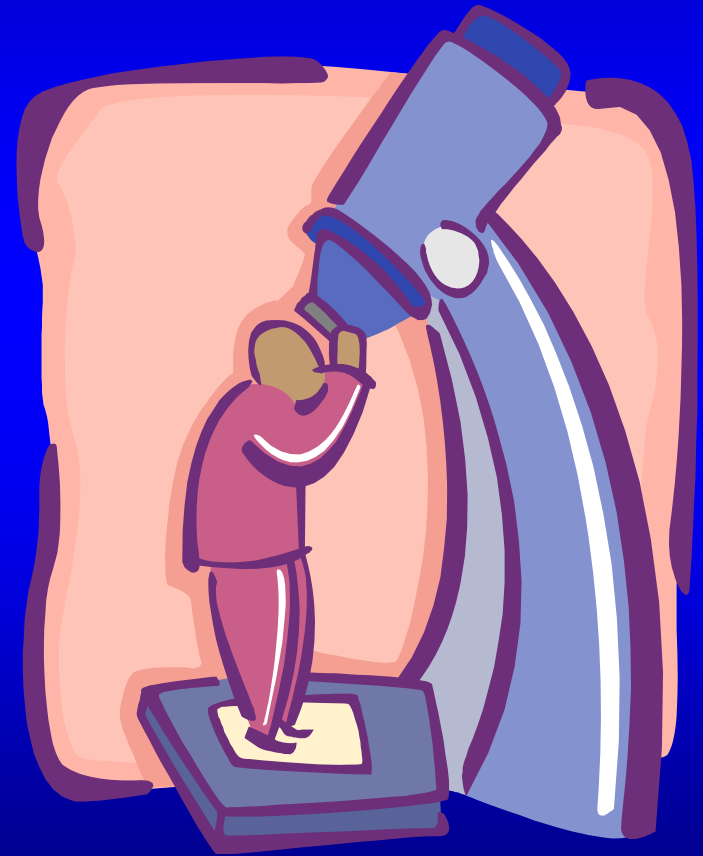
- The FDA is a government agency that is responsible for many aspects of research studies
 - **Regulates the conduct of research studies**
 - **Enforces laws on the manufacture, testing and use of drugs and medical devices**
 - **All new drugs and devices must be approved by the FDA before they can be 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