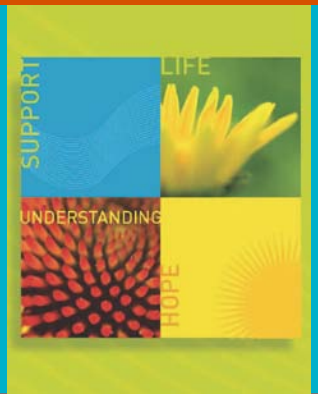
Understanding Clinical Trials



Understanding Clinical Trials

What is a clinical trial?

- A clinical trial is a research study to determine how new or experimental drugs or treatments work

Understanding Clinical Trials

Before any clinical trial begins, the compound/treatment is first studied in labs.

Why Get Involved?

Why would you get involved in a clinical trial?

Clinical trials are well-designed and well-executed. Taking part in a clinical trials you can:

- Play an active role in your own health care.
- Gain access to experimental drugs and new treatments before they are widely available.

Why Get Involved?

Why would you get involved in a clinical trial?

- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

Why Get Involved?

- The treatment being studied may be more helpful than the standard treatment.

Clinical Trial Protocol

A protocol is a study plan that the trial is based on. The plan is carefully designed to:

- reduce risks
- safeguard the health of participants
- answer specific research questions

Clinical Trial Protocol

A protocol describes

- what type of people may participate
- schedule of tests, procedures, medication and dosage
- length of study

Clinical Trial Protocol

The protocol may require more of your time and attention than would a non-protocol treatment, including:

- trips to the study site
- more medical interventions
- hospital stays
- complex dosage requirements

Safeguards in Clinical Trials

Most clinical research is federally regulated with built-in safeguards designed to protect the participants.

Safeguards in Clinical Trials

Your information will remain confidential both during the trial and after.

Internal Review Board

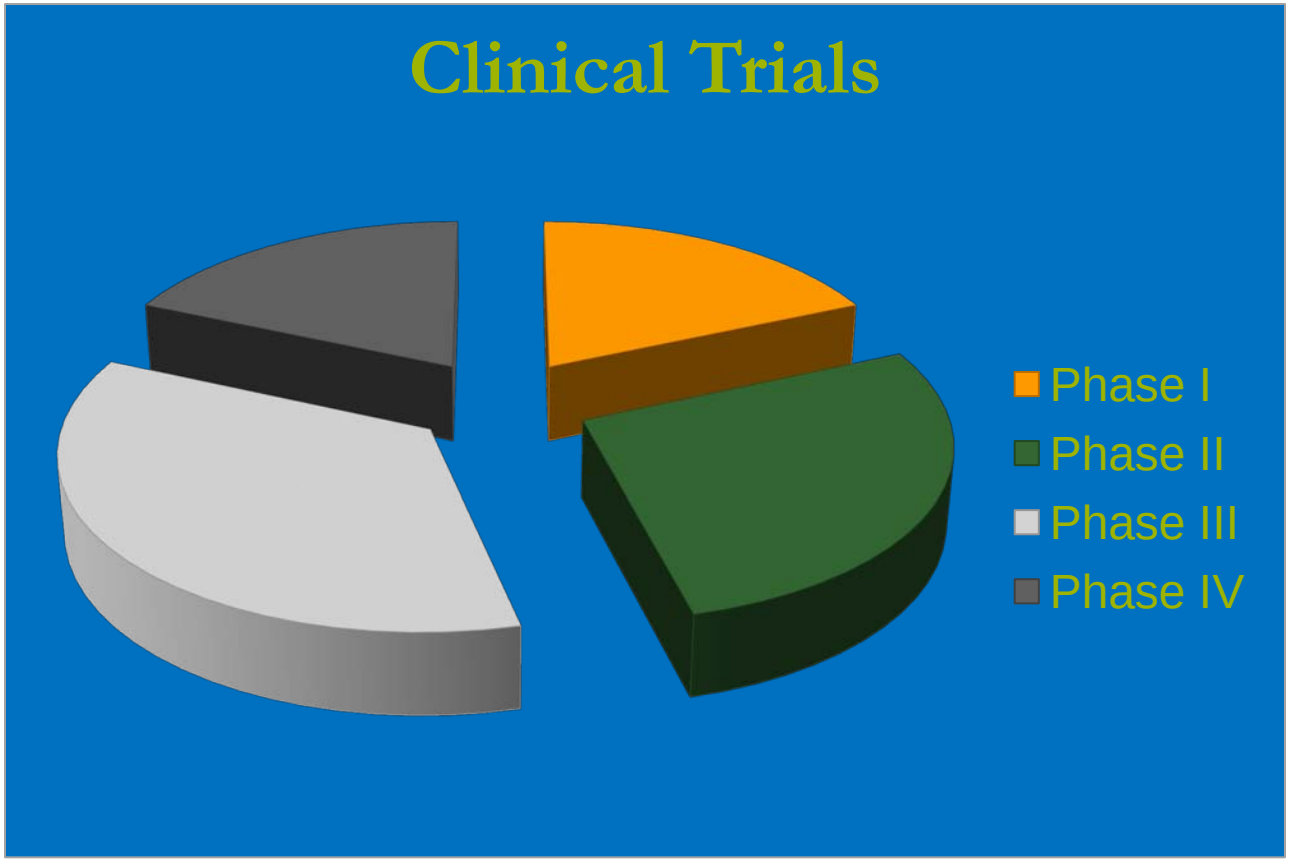
An **IRB** (Internal Review Board) is an independent committee of physicians, statisticians, community advocates, and others. Its function is to ensure that a clinical trial is ethical and the rights of study participants are protected.

Internal Review Board

All institutions that conduct or support research involving people must, by federal regulation, have approval from an **IRB.**

Phases of Clinical Trials

There are Four Phases of Clinical Trails



Phases of Clinical Trials

Phases of clinical trial

- Phase I
  - small group of people
  - evaluate safety
  - determine safe dosage
  - identify side effects

Phases of Clinical Trials

Phases of clinical trial

- Phase II
  - larger group of people
  - how well the drug or treatment is working
  - evaluate safety

Phases of Clinical Trials

Phases of clinical trial

- Phase III
  - larger group of people
  - confirm how well the drug or treatment is working
  - monitor side effects
  - compare it to commonly used treatments

Phases of Clinical Trials

Phases of clinical trial

- Phase IV
  - takes place after drug is use by general public
  - determine long-term safety and effectiveness
  - obtain additional information including
    - risks
    - benefits
    - optimal use

Qualifying

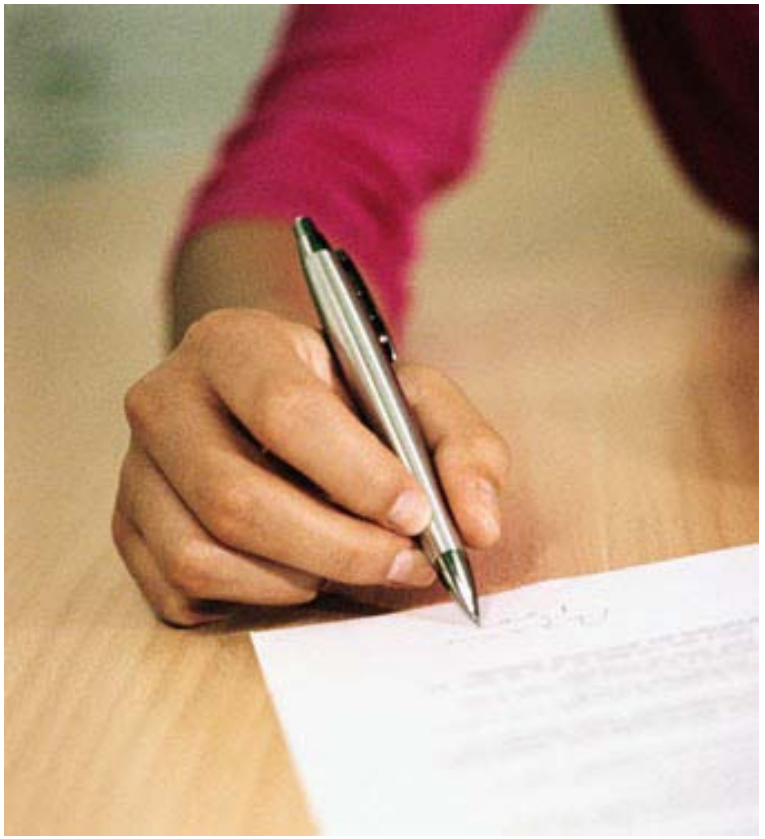
Who qualifies?

- Some do not qualify because
  - other health problems
  - age
  - gender
  - type and stage of a disease
  - previous treatment history

Informed Consent

A document that describes the rights of the person in the study, and includes:

- details about the study, such as
  - purpose
  - duration
  - required procedures
  - key contacts
- risks and potential benefits are explained



Preparation before trial

- Write down questions you have.
- Take someone with you.
- Bring a tape recorder to record discussion to replay later.
- Ask questions about the things you do not understand.

Questions to think about & ask

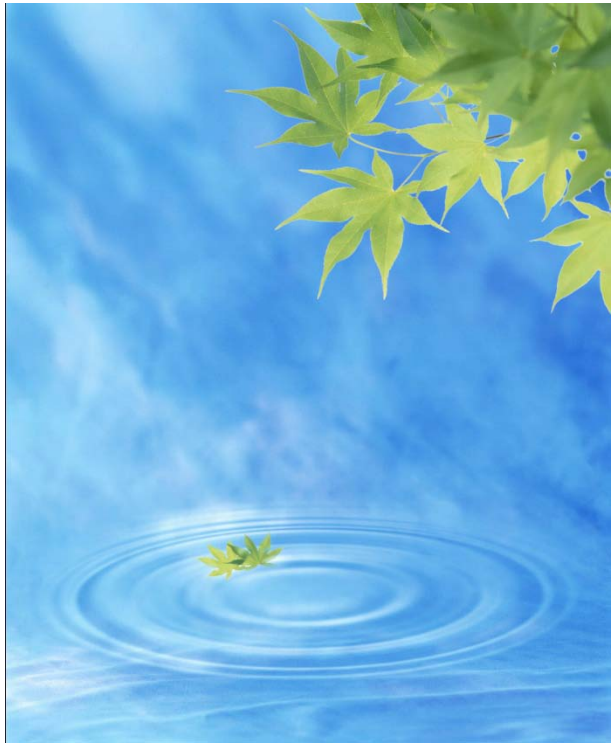
- What is the purpose of the study?
- Who is doing do the study?
- What do researchers expect to learn from the trial?
- Has it been tested before on people?
- What kinds of tests and other medical treatments are involved?

Questions to think about & ask

- What are the benefits to me now and in the future?
- How are the possible risks, side effects managed during the trial?
- How might this trial affect my daily life?
- How long will the trial last?
- Where is the study taking place?

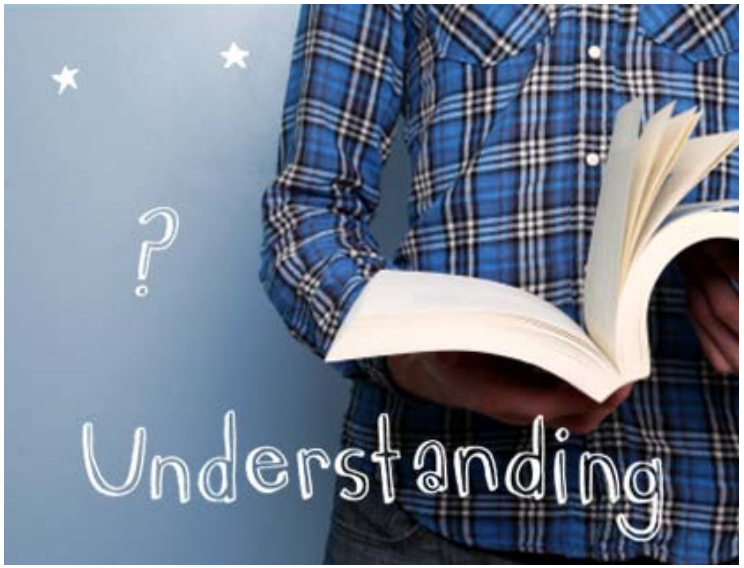
Questions to think about & ask

- Can I talk to others who have been in the trial?
- Who is sponsoring the study?
- Will any part of the study be painful?
- What happens if I experience a lot of pain?
- What type of follow-up care and treatment will be provided?



Questions to think about & ask

- How much time will each visit take?
- Will I be reimbursed for my time off work during the trial?
- Will I have to stay in a hospital?
- If this is an outpatient study, do they cover transportation cost?



Questions to think about & ask

- Who will be in charge of my care during the trial?
- What type of long-term follow up care is provided?
- What type of support is available for me and my family during the trial?

Questions to think about & ask

- What information do I need to keep track of at home?
- How will I know that the experimental drug or treatment is working?
- Will results of the trials be provided to me?

What are Placebos

What is a placebo and why do they use them?

- a placebo looks much like the drug being studies but it does not have the study drug.
- some placebos contain sugar
- helps research compare how the two groups respond

Study Groups

There are usually two groups in a trial

- Investigational group that receive the therapy being studied.
- Control group that receive the standard treatment or a placebo.

Adverse Effects

Sometimes there are **adverse effects**. Adverse effects may include:

- headache
- nausea
- hair loss
- skin irritation
- other physical problems

Side Effects

Side-effects are any effect that is not the intended or studied effect. Side effects can be either desired or undesired.

Drugs or treatments used in clinical trials must be evaluated for both immediate and long-term side effects.

At the beginning

The research team will check the health of the person at the very beginning.

At the beginning

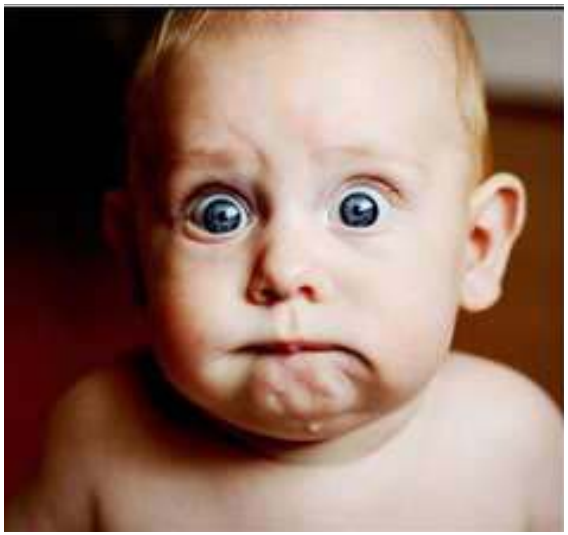
Having a primary health care provider work with the research team the participant can ensure that other medications or treatment will not be a problem during the study.

Risks of Clinical Trials

There are risks to clinical trials.

There may be unpleasant, serious or even life-threatening side effects.

The experimental drug or treatment may not be effective for the participant.



Responsibilities

There are also responsibilities for the person in a clinical trial.

The value of the information collected during the trails will depend upon how carefully the person follows the instructions in the protocol.

Responsibilities

- Make sure that you fully understand the information in the informed consent and are aware of what is being requested of you.
- Give full and accurate information about your health history and medication that you are taking or have taken.

Responsibilities

- Do not miss scheduled visits. The assessments in the study are carefully timed and a missed visit may reduce the value of the information collected.
- Report any adverse event quickly to the investigator or study coordinator at the research site.

Responsibilities

- Report any new illness or new medication or treatment you start while you are in the study.
- Do not stop or alter the dose of medication without speaking with the staff at the research site unless specifically told to do so.

Understanding Clinical Trials

If you are interested in learning more or taking part in a clinical trial, you can:

- visit the FDA website **www.clincaltrails.gov**
- ask your health care provider about trials that might be of interest to you

Resources

- http://www.clinicaltrials.gov
- http://www.nlm.nih.gov/medlineplus/tutorials/clinicaltrials/htm/_yes_50_no_0.htm
- http://www.cancer.gov/clinicaltrials/education/main/Page1
- http://www.nlm.nih.gov/medlineplus/clinicaltrials.html