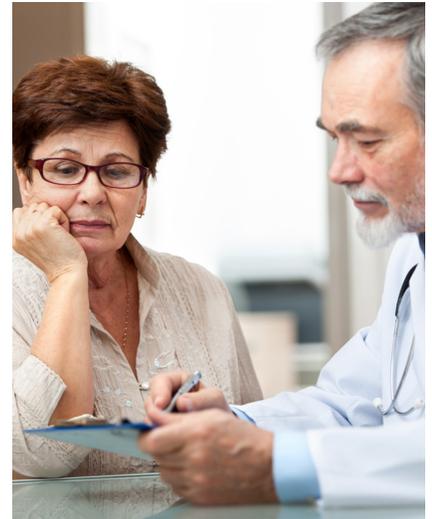


FAQ's for patient/ community



Q What is a clinical research study?

A Researchers evaluate the effectiveness of new medications, treatments and devices through clinical research studies. Investigational drug studies may involve comparing the study drug effectiveness and safety with other marketed medications or placebo (inactive drug), evaluating a drug for a new use, or evaluating different dosages or combinations of medications.

Advances in medicine and science are the result of new ideas and approaches developed through research. New treatments must prove to be safe and effective in scientific studies with a certain number of patients before they can be made widely available.

Through clinical trials, researchers learn which approaches are more effective than others. This method is the most thorough way to test a new treatment. The majority of the present standard treatments were first shown to be effective in clinical trials. These previous trials, even today, help us find new and better treatments.

Q What Kinds of Clinical Trials Are There?

A There are many kinds of clinical trials. Most clinical trials deal with new treatments ranging from studies of ways to prevent, detect and diagnose, control and treat various illnesses. Some studies look at the psychological impact of a disease and ways to improve the patient's comfort and quality of life, including pain control.

Q What is a placebo?

A A placebo is an inactive pill, liquid, or powder that has no treatment value, sometimes called a sugar pill. In clinical trials, experimental treatments are often compared with placebo to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment.

Q What is a control or control-group?

A A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the other group is given either a standard treatment for the illness or a placebo.

Q Does a participant continue to work with a primary health care provider while in a trial?

A Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or complete primary health care. By having the health care provider work with the research team, the participants can ensure that other medications or treatments will not conflict with the study.

Q What are the “rights” of a research participant?

A If you decide to be in a research study, you should carefully read and discuss the Informed Consent Form with the study staff and Principal Investigator before having any procedures done. Any questions you have should be answered. The decision of whether to take part in the study is completely voluntary. A participant should make the decision after much thought, and even take a family member or friend if possible. As a research participant, you have a right to information about the study procedures, study drug, risks and benefits of the study, alternative treatment, confidentiality and if compensation is provided for taking part. If you do not understand why something is being done during the study...ask. If you decide to take part in a study, you also have a right to withdraw from the study at any time.

Q What is an Informed Consent?

A Informed consent must be obtained before any research procedures are done. It is a process and is designed to give information needed to decide about participating in a research study. It allows the volunteer to ask questions and exchange information freely with the investigator.

Q How is a drug approved for testing?

A The Food and Drug Administration (FDA) must authorize a drug company’s proposal to do research studies. Once the studies have been completed, the FDA must review the information for safety and efficacy to determine if the drug works. This process may take many years.

Q Who can participate in a research study?

A Research studies have very strict requirements on the inclusion and exclusion criteria for participation. This means that a patient has to meet the inclusion criteria before being entered into the trial. There are also risks in participating in studies with new drugs. The Principal Investigator should review these risks with the participant to make sure he/she is comfortable with the study. Participants can learn more about the clinical trial process by visiting the FDA’s website.

Q What is a “Phase”?

A According to the National Institute of Health (NIH) clinical trials are conducted in “phases.” The trials at each phase have a different purpose and help researchers answer different questions.

Phase I trials - Researchers test an experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects.

Phase II trials - The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.

Phase III trials - The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments, and collect information that will allow the experimental drug or treatment to be used safely.

In addition, after a treatment has been approved and is being marketed, the drug’s maker may study it further in a phase IV trial. The purpose of phase IV trials is to evaluate the side effects, risks, and benefits of a drug over a longer period of time and in a larger number of people than in phase III clinical trials. Thousands of people are involved in phase IV trials.

Q What are the benefits and risks of participation?

A Known benefits and risks of a study are discussed with participants during the informed consent process and throughout the course of the research study as they are identified. Because new risks may be identified during the study, a participant must consider if continuing in a study is the right thing for them. Discussion with the Principal Investigator will help answer questions about changes to the risks or benefits during the study.

Some benefits in a research study include, having health care provided by physicians with access to latest in treatment options, access to new drugs and interventions that are only available through research, close monitoring of your health care and any side effects, and an opportunity to make a valuable contribution to new treatments for your condition. If the treatment being studied is found to be helpful, the participant may be among the first to benefit.

Certainly there are risks that come with new drugs and procedures and there may be side effects or risks unknown to the physicians. The drugs and procedures used in the study may be proven to be ineffective or less effective than what is currently available. While a study may show that there was some benefit, it may not work for the participant. It is important to remember that the participant has the right to decide to participate or not when the risks and benefits are given to them. The participant has the right to change his or her mind if they feel the risks are outweighing the benefits.

Q How are research participants protected?

A In the United States, the U.S. Food and Drug Administration (FDA) must authorize a drug company's research proposal before a drug study begins. Years of laboratory research are required before an investigational drug is approved for research in people.

An Institutional Review Board (IRB) must also review and approve the study before it begins. These review boards are comprised of health care professionals and non-health care members including representatives from the community, whose mission is to protect the safety and rights of study participants.

Participants in research studies are followed closely by the study team during studies through lab and other diagnostic testing, physical examinations, and evaluation of symptoms and general health.

Study drug safety information is regularly sent out to study teams to keep them up-to-date on current findings. Any significant information is communicated to participants during the study period by the Principal Investigator.

Q What are my responsibilities as a research participant?

A It is vital each participant provides accurate health and medical information to the research team. Participants should be proactive about informing their health care providers about participating in a clinical research trial. During the study, it is important to be an active participant, asking questions and sharing health information as needed with the research team, as well as following study guidelines.

Q Who sponsors clinical trials?

A Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies, in addition to federal agencies such as the National Cancer Institute (NCI), National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Veterans Affairs (VA). Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

Q What happens during a clinical trial?

A The clinical trial process depends on the kind of trial being conducted (see What Kinds of Clinical Trials Are There?). The clinical trial team includes doctors and nurses as well as research coordinators and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed.

Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. Clinical trial participation is most successful when the protocol is carefully followed and there is frequent contact with the research staff.

What kind of preparation should a potential participant make for the meeting with the research coordinator or doctor? In most cases, a participant will be provided the Informed Consent document to take home and read. Plan ahead and write down possible questions to ask. Also, ask a friend or relative to come along for support and help with the information and additional questions.

Q What should people consider before participating in a trial?

A People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it, the care expected while in a trial, and the cost of the trial. The following questions might be helpful for the participant to discuss with the health care team. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
 - Who is going to be in the study?
 - Why do researchers believe the new treatment being tested may be effective? Has it been tested before?
 - What kinds of tests and treatments are involved?
 - How do the possible risks, side effects, and benefits in the study compare with my current treatment?
 - How might this trial affect my daily life?
 - How long will the trial last?
 - Will hospitalization be required?
 - Who will pay for the treatment?
 - Will I be reimbursed for other expenses?
 - What type of long-term follow up care is part of this study?
 - How will I know that the treatment is working? Will results of the trials be provided to me?
 - Who will be in charge of my care?
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Q Where Can I Find Out More About Being in a Research Study?

A If you are interested in medical research about a specific disease or condition, you should speak with your doctor or therapist about research studies for which you might qualify. Email research@rcrh.org or call (605) 716-3982.