



VOLUNTEERING FOR A CLINICAL TRIAL



CENTER FOR CLINICAL RESEARCH

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ABOUT US

Welcome to the Center for Clinical Research, created to align with Western Michigan University Homer Stryker M.D. School of Medicine's mission to educate and inspire the researchers of tomorrow, as well as to advance knowledge through innovation and discovery. Through collaboration with our community partners, Ascension Borgess Hospital and Bronson Healthcare Group, the Center for Clinical Research brings the latest and most advanced investigational therapies to the region. Our team of physicians, nurses, and healthcare professionals has decades of clinical research experience in numerous therapeutic areas.

For our patients, the Center for Clinical Research provides access to cutting-edge clinical trials in a variety of therapeutic areas. Deciding to participate in a clinical trial can be both intimidating and rewarding. Our experienced staff of health professionals are here to answer questions regarding participation in clinical trials, your rights as a patient, and the benefits and risks of participating in research as well as to guide patients through the process of contributing to the advancement of medicine.

WHAT IS A CLINICAL TRIAL?

Researchers conduct clinical research trials to evaluate the safety and effectiveness of investigational drugs. These investigational drugs are developed by pharmaceutical and biotechnology companies who select qualified physicians, also known as investigators, to conduct clinical trials to determine the risks and benefits of the investigational drug.

Investigational drugs which are found to be safe and effective may then become available for doctors to prescribe, if approved by the FDA. If an investigational drug is determined to be unsafe or ineffective, the study results may still be useful for scientists and for the advancement of medical research.



HOW DOES A CLINICAL TRIAL WORK?

In clinical trials, investigational drugs are often compared with approved drugs or placebo (inactive pill, liquid, or powder) to assess safety and effectiveness. Clinical study participants may be assigned to take:

- Investigational drugs
- Approved drugs
- Placebo
- A combination of these drugs

A placebo is an inactive product used to assess the experimental treatment's effectiveness. The participant, physician, and research staff may not know which volunteer receives a placebo and which receives the investigational treatment. Not knowing which participants are receiving the active treatment allows the physician and research staff to objectively observe the volunteers during the study. Regardless of which treatment volunteers receive, however, the level of medical attention and care that each receives is the same.



CLINICAL TRIAL PHASES

Clinical trials are divided into four phases:

- **Phase I:** Researchers test an investigational drug for the first time in humans by giving it to a small number of healthy people to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The investigational drug is given to a larger number of people who have a particular disease or condition to determine its effectiveness and to further evaluate its safety.
- **Phase III:** Several hundred to several thousand people with the appropriate disease or condition participate in these studies. The investigational drug undergoes additional testing to further determine its safety and effectiveness, monitor side effects, and compare it to commonly used treatments.
- **Phase IV:** After a drug is available by prescription, additional information is gathered to assess the drug's risks, benefits, and use.

After a study phase is complete, the data are collected to determine the drug's effectiveness, its safety, and its side effects. Depending on the results, researchers then determine whether to stop testing or move to the next phase of study. After Phase III of a study is complete, researchers decide if the results are medically important and may submit them to journals for peer-review. Data may also be submitted to the FDA for approval.

If a drug is approved, pharmaceutical companies may continue to conduct studies that compare the new drug—in terms of safety, effectiveness, and cost—to other drugs already on the market or assess the drug's long-term effectiveness and its impact on the quality of a person's life.

PARTICIPATION EXPECTATIONS

There are certain requirements that must be met to be eligible to participate in a clinical study. These requirements are based on such factors as age, gender, the type and stage of a disease, previous and current treatments, and other medical conditions. Medical insurance is not required to participate in clinical studies or to receive study-related medical care and services.

If you are eligible and decide to participate, an informed consent document will be presented to you. This document includes information about the clinical study and what you can expect as a participant, as well as potential benefits and possible risks associated with the research.

You should take your time and read carefully through the informed consent document. When you are satisfied that all of your questions have been answered, you will be asked to sign the document.

As a participant, you may be asked to:

- Take investigational drugs as directed
- Come in for your office visits
- Have laboratory and diagnostic tests

Study participants may also receive, at no cost, study-related medical care, investigational drugs, and laboratory services.

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BENEFITS AND RISKS

What are the potential risks and benefits of joining a trial?

According to the National Institutes of Health (www.clinicaltrials.gov), there are multiple benefits and risks associated with participating in a clinical study.

Benefits

Clinical studies allow eligible participants to:

- Obtain study-related medical care at research facilities during study
- Gain access to research treatments before they are widely available
- Help others by contributing to medical research
- Play an active role in your healthcare

Risks

There are risks to clinical research studies:

- There may be unpleasant, serious, or even life-threatening side effects to the study drug
- The experimental drug may not be effective for the participant
- Study participation may require more time and attention than would a routine treatment, including trips to the study site, more study tests and procedures, hospital stays, or complex dosage requirements