

pharmaceutical and governmental agencies based on their qualifications to conduct clinical trials.

The investigators at NSU are practicing physicians and faculty members at the College of Osteopathic Medicine. They are experts in the area being researched.

Research medication is also known as investigational medication. The clinical testing of an investigational drug is a well-documented process to ensure your medical condition is closely monitored.

All pharmaceutical clinical trials conducted at NSU are reviewed by the U.S. Food and Drug Administration and the Nova Southeastern University Institutional Review Board.

### What Is the NSU Institutional Review Board?

The Nova Southeastern University Institutional Review Board protects the rights of all human research volunteers and assures that you—the volunteer—is not subjected to any unnecessary risks.

The Nova Southeastern University Institutional Review Board approves and monitors clinical trials and requires that volunteers are provided a consent form for review and signature before agreeing to participate in any study.



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To obtain additional information about clinical research trials being conducted at Nova Southeastern University College of Osteopathic Medicine, please contact

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Nova Southeastern University  
College of Osteopathic Medicine

# What Is a Clinical Trial?





## What Is a Clinical Trial?

A clinical trial is a well-planned scientific study of how a medication, device, or treatment affects people. New medications and delivery systems (patches, inhalers, etc.) are being developed and tested on a continuum for treatment of illnesses and impact on quality of life.

As new treatments are being developed, additional volunteers are needed for research. Recruitment programs have opened to the general public, and more people want to know what is available, what is currently being tested, and how they can participate in a trial.

## Volunteering - Why Should I Join?

The reasons people volunteer to participate in a clinical trial are numerous. Some may be suffering from a disease that currently offers no existing treatment. Perhaps the existing therapies have failed to help or are not adequate—a situation that may convince some individuals to supplement the treatments they are currently receiving.

Some people volunteer for clinical trials to obtain study-related medical care. Others get involved to help in the advancement of science and health care treatments. A clinical trial is

research and not the same as treatment.

When considering volunteering for a clinical trial, it is important to ask your NSU study physician and the NSU research staff any questions and address any concerns you may have. The risks and benefits associated with participating in the trial will be explained so that you—the volunteer—can make an informed choice.

## How Safe Is it?

The risks, benefits, and alternative treatments are explained and outlined in your consent form. Clinical trials go through several phases before they are conducted at NSU.

The trial's purpose is to determine how effective the new medications are and to examine any side effects or benefits they may present in the patients. It is important for you to understand the trial may or may not benefit you personally.

Your health and safety are of paramount importance in a clinical trial. The NSU study physician and research team will observe you very closely. You will have scheduled periodic visits to monitor your progress while in the clinical trial.

You will be asked questions as to how you are feeling and will be prompted to alert your NSU medical professional concerning any physical or emotional fluctuations you

may undergo while participating in the trial. It is important that you inform the physician and/or research staff of any symptoms you experience while in the clinical trial.

## What Can I Expect?

Once you have agreed to volunteer for a trial, a member of the NSU research staff will review your medical history. You also may be required to participate in a physical examination, as well as various laboratory tests and other diagnostic procedures.

A detailed description of the study and what is expected of you is outlined in your consent form. The consent form will list all procedures and visits conducted as part of the trial. A copy of the consent form will be given to you.

It is important that you take your medication as prescribed and that you keep all scheduled visits. It is recommended that you do not begin or discontinue any medications without notifying the study physician or research staff.

Your participation is voluntary, and you have the right to leave the trial at any time without penalty.

## Understanding Clinical Trials

A clinical trial is a planned scientific investigation conducted under the supervision of distinguished physicians. These physicians are selected by