



*"Seeking tomorrow's answers to the health questions of today."*



## How do I participate in a clinical research study?

To learn more about participating in a clinical study, simply call us at 352-629-5800 or toll-free at 877-629-5800. One of our study specialists will tell you about our enrolling studies and discuss qualification criteria with you.

Before a pharmaceutical company can bring a new drug to market the investigational drug must be tested in several clinical research studies. A clinical research study is carefully designed to test the safety, effectiveness, and side effects of an investigational medication on a group of volunteers. Clinical research studies are regulated by the Food and Drug Administration (FDA) and monitored by the sponsoring pharmaceutical company. Clinical research studies are an important step in making new medications available for others in the future.



Renstar conducts clinical research studies in the following therapeutic areas:

- Alzheimer's disease
- Dermatologic conditions
- Overactive bladder
- Fibromyalgia
- Psoriasis
- Migraine
- COPD
- Pain
- Diabetes
- Osteoarthritis
- High cholesterol
- Vision problems
- Diabetic peripheral neuropathy
- Healthy patient research studies

For information about currently enrolling research studies, please call our study recruitment specialist at (352) 629-5800



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## Should I Volunteer?

*Your guide to participating in a clinical research study.*







Each year, thousands of people volunteer to participate in clinical research studies. As a volunteer, you may:

- gain access to new investigational drugs or devices that are not otherwise available,
- learn new information about your medical condition,
- receive study-related medicines and study-related medical exams during the study, and
- help others by contributing to medical research.



# Should I Volunteer?

## Who makes sure my rights are protected?

An independent ethics committee, known as an Institutional Review Board (IRB), must review clinical research studies before they begin. The IRB is a group of doctors, nurses, and people from the community. They review all clinical research studies to help protect participants' rights and safety. In addition, the FDA (Food and Drug Administration) sets requirements for drug testing. The FDA reviews the results from certain clinical research studies to decide if an investigational drug can be made available to the general public.

## What is Informed Consent?

Informed consent is the process that takes place before you join a clinical research study. A study doctor, nurse, or study coordinator will go over a consent document that helps explain

why the study is being done and what you can expect. You can ask any questions you have about the study or any part of the consent document you do not understand. If you decide to participate in the research study, you will be asked to sign the consent document.

## Are clinical research studies safe?

The government has put in place strict guidelines and safeguards to help protect those who choose to participate in clinical trials. All research studies are reviewed by the Institutional Review Board who examines the study's protocol to help ensure that the participant's rights are protected, and that the study does not present an undue or unnecessary risk to the participant. In addition, anyone participating in a clinical research study in the United States is required to sign

an informed consent document which details the nature of the study, the risks involved, and what may happen to a participant in the study. The informed consent tells participants that they have a right to leave the study at any time.

## Will participation in a clinical research study cost me anything?

In exchange for the voluntary participation in our research, we provide study-related care, investigational medication, and monitoring for each of our participants at no cost, and there is no need for health insurance.

## Will I be compensated?

Compensation for your time and travel varies from study to study. It is determined by the length of the visits and any requirements placed upon the volunteer subject.

## Who can be in a clinical research study?

Each clinical research study has different requirements for participation. Study criteria are based on factors such as age, gender, or medical condition. Our research team will look at your medical history and study requirements to find out if you are eligible.

## What if I enter a study and change my mind?

You may leave a study at any time. You may choose to take part or not, and you can always change your mind later, even after you enter a trial.

## What can I expect as a study volunteer?

During the study, our research team will review your medical history, give you instructions for participating, and monitor your health. Studies may involve laboratory tests and doctor visits.