ARE CLINICAL TRIALS SAFE?

Risks and side effects exist with almost any treatment whether it is standard care or a clinical trial. However, safeguards are in place to make clinical trials as safe as possible and protect patient rights. Before a treatment is tried with patients, it is studied in the laboratory. Laboratory research determines how best to use the new methods with people safely and effectively.

YOUR DOCTOR AND THE CLINICAL TRIAL

Many people ask: *is a referral from my physician required for participation in a clinical trial?* No, you do not need a referral. It is up to you to decide if you wish to participate or not.

However, patients are usually encouraged to discuss participation in the study with their own physician and their family. In order to participate in a clinical trial, you will be evaluated by the medical staff conducting the study to determine if you meet all the medical criteria. If you are eligible, the details of the trial will be explained to you.

CAN CLINICAL TRIAL PARTICIPANTS STILL SEE THEIR REGULAR DOCTOR?

Yes, you can continue to see your regular physician. Clinical trials do not replace normal health care. In fact, trial coordinators at your request, provide regular updates about the study to your regular physician.

We welcome volunteers to participate in our clinical trials, furthering the treatment of diseases.

Without volunteers, new therapies would not be available.

We strive to provide the best possible care and safety of our study volunteer's.

We believe this is a chance to make a difference in the **hope** for tomorrow's cures.

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NewHope Clinical Research

Clinical Research

Hope for the future of medicine!

WHAT IS A CLINICAL TRIAL?

At ***New Hope Clinical Research*** we conduct research studies that evaluate investigational treatment options. Such research relies on people who volunteer to try the new or changed treatment. Clinical trials are conducted in a health care setting, thus the name—clinical trial. Sometimes they are called clinical studies, research protocols, or medical research.

The purpose of a clinical trial is to determine whether a new treatment option is safe, effective, and better than current standard care.

Clinical trials test the safety and effectiveness of investigational treatment options. Standard care is a treatment option that has been proven effective and is currently being used. Likely, the standard care was proven effective based on past clinical trials.

We have one of the most respected groups of experienced clinical physicians, called investigators in these trials. Currently we have a network of experienced investigators of all clinical backgrounds, from Gynecology to Oncology.

Clinical trials are important for advances in medicine and science, improving new ideas developed through research. Today's clinical trials lead to tomorrow's standard care. Clinical trials help scientists develop improved treatments and sometimes lead to cures.

A SAMPLE OF OUR EXPERIENCE IN RESEARCH STUDIES:

- **Bipolar Disorder**
- **Osteoporosis**
- **Anxiety**
- **Alzheimer's Disease**
- **Depression**
- **Urinary Incontinence**
- **Schizophrenia**
- **Osteoarthritis**
- **Cholesterol**
- **Gastroenterology**
- **Migraine Headaches**

WHO CAN BE IN A CLINICAL TRIAL?

People with the condition being studied as well as healthy people can volunteer to participate in a study. Each study has specific requirements for participants. The physician conducting the study will review each volunteer's medical history and the study requirements to determine who can participate. Known risks and discomforts will be explained by the study personnel prior to participating in the study.

HOW ARE EXPERIMENTAL DRUGS TESTED?

The clinical trials are typically divided into different phases. Each phase is designed to gather specific information about the study drug or treatment.

Phase I: The first human tests of these drugs or therapies occur in this phase. Designed to determine the best dose of the study drug and to check for any potential side effects. These trials usually involve small numbers of volunteers.

Phase II: Once a drug has initially been evaluated for safety and tolerability, it must be tested to see how well the study treatment works, usually in a larger group of people.

Phase III: If the treatment is effective in Phase II, it may move on to Phase III. This phase tests how well the drug works in hundreds or even many thousands of people. Often comparing the study drug to an existing standard treatment.

Phase IV: These trials are conducted after a drug has been approved by the FDA and after the drug is on the market. These typically involve a large number of participants.