



Nephrology, Inc. Research



Caring support in uncertain times.

Research

Clinical trials (also called research studies) are conducted to test safety and effectiveness of new medications and new uses for existing medications. The physicians of Nephrology, Inc. value the importance of clinical research and the discovery of new medications to advance the knowledge of medical science. In 2006, in a continuing effort to offer our patients superior care, Nephrology, Inc. established a research program. Participating in research makes it possible for us to offer our patients medical care that may not be available to the general public, and it ensures that we remain on the cutting edge of medical treatment and technology.

What is a clinical trial?

A clinical trial is a research study with human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and improve their health. The physicians and staff at Nephrology, Inc. run these trials according to strict rules set by the Food and Drug Administration (FDA) to ensure that the people who agree to be in the studies are treated as safely as possible.

What happens during a clinical trial?

The clinical trial process depends on the kind of trial being conducted. All Nephrology, Inc. physicians have been trained and have agreed to participate in all clinical research studies being offered at Nephrology, Inc. Therefore, our research participants will remain under the care of their physician during the course of the study. The research team will check the health of the participant at the beginning of the trial, give special instructions for participating in the trial, monitor the participant carefully

during the trial and arrange follow up with the participant at the end of the trial.

Are clinical trials safe?

The government, pharmaceutical and biotechnology industries have standard guidelines that all clinical research sites must follow in order to conduct clinical trials. Audits are performed on a regular basis to make sure the guidelines are being followed. In addition to these safeguards, every clinical trial in the U.S. must be approved and monitored by the Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee that ensures a clinical trial is ethical and the rights of the study participants are protected.

What are the benefits of participating in a clinical trial?

- Gaining access to new research treatments before they are widely available.
- Helping others by contributing to medical research.
- Playing an active role in one's own health care.
- Treating a condition for which there may currently be no effective treatment.
- Participating in the development of medical advances.

What are the risks of participating in a clinical trial?

- The treatment may not be effective for the participant.
- The clinical trial may require more of the participant's time and attention than a traditional treatment would.
- There may be unpleasant, serious or even life-threatening side effects to the treatment.

What questions should patients ask before participating in a clinical trial?

When considering participation in a clinical trial you should know as much as possible about the trial and feel comfortable asking the members of the health care/research team questions about it. The following questions might be helpful for the participant. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
- Why do researchers believe the new treatment being tested may be effective?
- Has it been tested before?
- How often will I need to go to my doctor's office?
- What kind of tests and treatments are involved?
- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- Is there an alternative treatment for my condition?
- What are my responsibilities during the trial?
- How long will I be in the study?
- Will there be any cost to me?

Who can participate in a clinical trial?

All clinical trials have guidelines about who can participate. These guidelines (also called inclusion/exclusion criteria) are based on multiple characteristics such as type and stage of disease, current medical condition, medical history and age.

These guidelines are used to identify appropriate participants and keep them safe. It also ensures that the researchers will be able to answer the questions they plan to study.

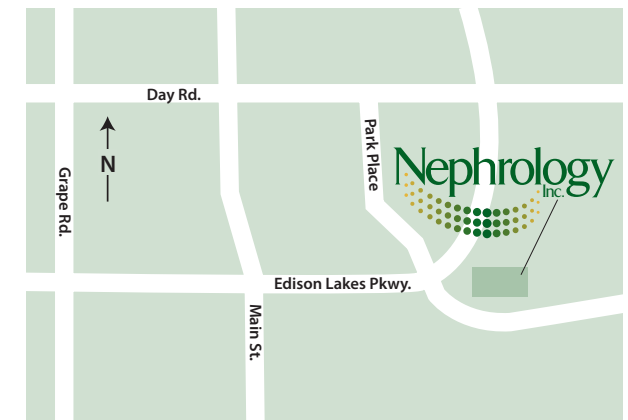
What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. Your doctor or the research nurse will explain the details of the trial to you. A member of the research team will then provide an informed consent document that includes specific details about the trial. Before you can be in the study, you must sign the informed consent form showing that you have been given the study information and understand it. Informed consent is not a contract and the participant may withdraw from the trial at any time.



Nephrology, Inc.

The mission of our practice is to deliver the highest level of professional care in a safe, comfortable and compassionate environment.



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