Important questions to ask before deciding to participate in a clinical study or trial.

- What is the purpose of the trial?
- How does it differ from current standard therapy for my condition?
- Has the drug or treatment(s) ever been tested before?
- How much time will I need to commit to this study?
- What are the risks and possible side effects of the treatment(s)?
- Who will pay for the treatment(s)?
- Will I receive travel reimbursement or any type of compensation for my time or expenses?
- How long is the trial expected to last?
- What will happen to my medical care if I opt not to participate?
- Will my insurance cover any part of this study?

Patient Guide to

CLINICAL RESEARCH TRIALS

Carolinas HealthCare System

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Carolinas HealthCare System

OFFICE OF CLINICAL AND TRANSLATIONAL RESEARCH

Research at CHS

Research is one of the three key core missions of Carolinas HealthCare System (CHS), along with patient care and education.

CHS has an array of research programs which include an average of 1,000 active clinical studies at Carolinas Medical Center. In addition, there are more than 350 investigators leading clinical trials with their staff.

At CHS there are many types and levels of development for each study by phase, including:

- Phase I studies test the safety and tolerability of potential new drugs.
- Phase II studies establish optimal doses and effectiveness.
- Phase III studies are designed to lead to FDA approval for new drugs and devices.
- Phase IV studies provide continual monitoring of new drugs or devices after their initial approval.

Clinical studies are the lifeblood of future advances in our ability as an integrated, comprehensive healthcare system to offer the very best options for patient care and treatment.

What is clinical research?

Clinical research is the examination of biomedical or clinical questions where human subjects participate in a study. Clinical research can take many forms.

Not all clinical research studies involve medical treatments or experimental therapies. Some include observational studies in which people are followed over a period of time to determine health outcomes.

Clinical research may also be used to determine the usefulness or safety of a new diagnostic procedure or drug treatment in the form of a clinical trial. Clinical research studies are planned in advance and follow a defined protocol plan.

How to participate?

A person has to give informed consent to participate in a clinical trial after having learned about the study and having had the chance to ask questions. You should be fully aware of the purpose, risks, benefits, alternatives and expectations of the trial before agreeing to participate. When you give informed consent, you sign a document that describes the rights of the participants as well as details of the study. Also included are names of investigators who are conducting the study and contact information for them.

Even if you decide to participate in a study, you may stop your participation at any time.

How are research subjects protected?

Clinical trials are required to maintain strict patient privacy. Your name will not be published with the study data nor will it be included in any publicly available information. In addition, researchers follow human subject protection regulations designed to protect you. Each study is reviewed by the CHS Institutional Review Board (IRB) or designee. The IRB ensures subjects are protected.

If you have questions about your rights as a research participant, contact Carolinas HealthCare System IRB at 704-355-3158.