As a research subject, you have the following rights:

- To be treated in a caring and polite way.
- To be told what the study is trying to find out.
- To be told what will happen to you, and whether any of the procedures, drugs, or devices are different from what would be used in standard practice.
- To be told about possible side effects or discomforts that may happen during the study.
- To be told if you can expect any benefit from being in the study and, if so, what the benefit might be.
- To be told of other choices you have, and how they might be better or worse than being in the study.
- To be told what sort of treatment is available if any medical problems arise.
- To be allowed to ask any questions about the study, both before agreeing to be involved and during the course of the study.
- To be free from pressure when deciding if you want to be in the study.
- To be told about new information learned during the study that might affect your safety or your willingness to continue to take part in the study.
- To refuse to be in the study, or to change your mind about being in the study after it has started. This decision will not affect the care you receive at the hospital.
- To get a copy of your signed consent form.

For more information, or for comments and suggestions, e-mail us at: info@connecttoresearch.org

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Your Guide to Understanding the Clinical Research Process

Should I Be a Research Subject?

Why Volunteer in Clinical Research?

- The development of new medical treatments and cures would be impossible without the active participation of research volunteers.
- By volunteering in a study, you will help others by contributing to medical research.
- You could also help researchers to learn about a disease or condition.
- In some cases, you can try a new treatment before it is available outside of research studies; however, these new drugs, procedures, or devices may or may not be more effective than the ones that are already available.

10 Questions to Ask Before Enrolling in a Study

1. Why is the research being done?
2. What will be done to me as part of the research?
3. How will I benefit from the research?
4. Could the research hurt me?
5. What will the researcher do with my information?
6. Will the research cost me anything?
7. Who pays if I’m unexpectedly injured in the study?
8. How long will the study last?
9. What happens if I decide to leave the study early?
10. Who should I call if I have a question about the research?
The term “clinical research” describes studies to collect new information on human health and disease. Clinical research involves research volunteers to test new drugs, procedures, or devices; to understand different diseases; or to better understand how the human body works.

There are several types of clinical research studies, including the following:

- **Genetic studies** find the role of genes in different diseases.
- **Prevention studies** test ways to prevent specific diseases.
- **Behavioral studies** test how people act in different situations.
- **Physiological studies** increase understanding of how the human body functions.
- **Clinical trials** are studies of a drug, procedure, or medical device used in healthy volunteers or people who have a specific disease.

Clinical trials of new drugs are done in different phases:

- **Phase I studies** test a new drug for the first time in humans to see if it is safe.
- **Phase II studies** are done in more people to see how effective the new drug is.
- **Phase III studies** are done in large groups of people to see if the new drug works well, has side effects and how it compares to other drugs.
- **Phase IV studies** are done after the medication is approved by the U.S. Food and Drug Administration (FDA) to get additional information.

What Are the Risks?

There may be risks for research volunteers. Some tests or procedures can have unpleasant or even serious side effects, including life-threatening ones. The new drugs, procedures, or devices under study can have side effects that are not well known. New treatments are not always better than the standard care to which they are being compared.