What Questions Should I Ask?

**What is the purpose for the trial?**

What exactly will happen to me in the research? How much time will my participation take? What does it mean if I am randomized?

**Will the research help me personally?**

Is there a chance I might receive a placebo or “sugar pill” instead of the investigational drug?

**How does my care in the trial compare with what I would receive outside the trial?**

What other nonexperimental treatments are available to me if I don’t want to participate in this study? Will being in this study prevent me from participating in other kinds of studies or treatments—now or later?

**Will there be any unpleasant side effects?**

What are the risks to me? What are the benefits?

**What if I change my mind?**

Can I leave the study at any time? If so, what happens to the data already collected?

**Will it cost me anything personally?**

Do I have to pay for clinical care completed as a part of the study? How much does my insurance pay? Do I have to pay the co-pay? Will it impact my insurance lifetime maximum or annual limit?

At Emory, there are many opportunities to participate in research dedicated to finding treatments and improving lives. Someday, you or a family member may want to take part in a research study. If this happens, this information may help you make the decision that is best for you.

If you are interested in learning more about a clinical trial, talk to your doctor or visit clinicaltrials.emory.edu or emoryhealthcare.org/clinicaltrials or call Emory HealthConnectionSM at 404-778-7777

- clinicaltrials.gov
- researchmatch.org

Other important links...

- Medicare: www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/
- Food & Drug Administration (FDA): www.fda.gov
- Office for Human Research Protections (OHRP): hhs.gov/ohrp
- National Institutes of Health (NIH): nih.gov
- National Cancer Institute (NCI): cancer.gov

If you have any questions about your rights as a research volunteer, please contact the Emory University Institutional Review Board (IRB) at (404) 712-0720 or (877) 503-9797 or irb@emory.edu. You may also share your experience as a research participant with the IRB through our Research Participant Survey at surveymonkey.com/s/6ZDMW75.

Before participating in research:

- Know what you’re getting into
- Ask questions
- Learn as much as you can
- Know the pros and cons

It’s YOUR DECISION
Research discoveries can improve people’s health

Why Emory? Why Research?
Emory is one of the nation’s leading research universities. The university’s team works together in a three-fold mission—providing excellent care for patients, conducting cutting-edge research, and educating tomorrow’s health care leaders. Emory’s research teams are internationally recognized for conducting pioneering clinical trials and other research studies across a broad range of diseases, such as cancer, heart disease, and diabetes.

What Is Research?
Doctor-scientists do research, often called clinical trials, because they are looking to find better ways to prevent, treat, and cure diseases. Research is not the same as clinical treatment. A research study may or may not help you personally. However, the results could help others who have a health problem in the future. Taking part in research is voluntary.

Participating in research can range from answering some questions or providing a blood sample to joining a clinical trial that is investigating new drugs and devices.

How Does Clinical Research Make A Difference?
Clinical trials and other research studies are the only way to develop new methods to better understand and treat diseases. Discoveries that have been developed as a result of clinical trials include:

- New drug treatments for cancer, high blood pressure, and diabetes
- Diagnostic tools, such as X-rays and blood tests
- Vaccines to prevent life-threatening diseases
- Methods for managing chronic diseases that currently have no known cure, such as Alzheimer’s
- Improved medical devices, such as lasers used in surgery, pacemakers, and artificial joints

How Do Clinical Trials Work?
Drugs and devices are tested first in a laboratory. After proving safe and effective in the lab, testing begins in people. The doctors, nurses, and other staff on your research team will closely monitor your progress. You may have more tests and doctor visits than you would have if you were not in the trial. You may have responsibilities, such as following the treatment plan, filling out forms about your health, and taking your study drug exactly as prescribed.

What Do I Need To Know About Clinical Trials?
There are four phases or types of clinical trials:

- **Phase I Trials** test a new drug or treatment in people for the first time. Because of this, these studies may be riskier for you as a volunteer.
  - Phase I trials usually enroll a small number of volunteers. These trials are used to test how safe new drugs or treatments are in humans, what dose works best, and what side effects occur.

- **Phase II Trials** build on Phase I trials, further testing the effectiveness and safety of a drug, device, or procedure.
  - These trials usually involve 100 to 300 people.

- **Phase III Trials** test the treatment in several thousand people to prove its effectiveness, safety, and likely side effects, and also to compare the treatment to other available treatments.
  - After a successful Phase III trial, the sponsor may request the U.S. Food and Drug Administration (FDA) to approve the drug or device so doctors can start using it for their patients.

- **Phase IV Trials** are conducted after the treatment has received FDA approval to continue to study the treatment to figure out its best use.

Why Should I Participate In A Clinical Trial?
Volunteering for a clinical trial is a personal decision that should be made with your family and/or doctor. You may decide to volunteer for a number of reasons:

- To understand more about a medical condition, such as high blood pressure or diabetes
- To have access to a medicine or treatment that is not available to the general public
- To help advance science for future generations

What If I Decide To Participate?
One of the most important responsibilities of researchers is to make sure that you are fully informed about the research study before you sign up. The Institutional Review Board makes sure the appropriate steps are taken to minimize your risk and protect your rights and welfare.

You will go through an informed consent process during which you will be told about the possible risks and benefits of the research study, and you will be given a chance to ask questions and have them answered to your satisfaction.

Be sure you understand fully what participation in a trial will mean for you before you consent.