



## CLINICAL RESEARCH

### TGH Office of Clinical Research

409 Bayshore Blvd., 5th Floor  
Tampa, FL 33606  
(813) 844-CORE (2673)  
[research@tgh.org](mailto:research@tgh.org)

Please call or email if you have questions, concerns or complaints, or want to talk to someone about research at this organization.

*Primary teaching hospital for the USF Health Morsani College of Medicine*

# FAQS: PARTICIPATING IN A RESEARCH STUDY



## CLINICAL RESEARCH



### What is a research study?

A research study is an organized activity to learn more about health problems to improve health care. For example, a research study may test if a treatment is safe and effective to find out what health care practices work best. A research study also may be done to determine the best way to prevent illnesses. It may use a survey or an interview to understand feelings people have about their health. One specific type of research study is a clinical trial.

A clinical trial is a research study used to determine if new treatments are safe and effective. In clinical trials, treatments are often compared with placebos to check the effectiveness of that treatment. A placebo is an inactive substance which may resemble an active substance but typically has no value to treat or prevent an illness.

### Why should I volunteer for a research study?

Here are some reasons to participate in a research study:

- Help find a cure for an illness
- Help other people who are sick
- Help find ways to provide better care
- Help scientists find out more about how the human body and mind work
- Find a better treatment for a condition that you have

If you decide to take part in a research study, you do so as a VOLUNTEER. That means YOU decide whether you will take part. If you choose to do so, you have many important rights.

### Should I take part in a research study?

Thousands of research studies are conducted every year. These research studies have contributed to health

improvements for many people from every walk of life. None of the advances in health care would be possible without people who are willing to volunteer to take part in a research study. You may be asked to volunteer for a research study approved by this IRB. This pamphlet will help you understand your rights as a research study volunteer. It will also help you understand some of what is needed for a good research study. We urge you to review this information and discuss it with other people you trust.

### What is informed consent?

Informed consent is the process of learning the key facts about a research study before you decide to volunteer. Before you agree to volunteer, you need to know what takes place in the research study and how it may affect you. Informed consent begins when the research staff explains details about the research study and they will assist you with the informed consent form.

Important details about the research study include tests or procedures you may receive, the benefits and risks that could result, and your rights as a research volunteer.



### Are there benefits to being in a research study?

There may or may not be a direct benefit to you if you take part in a research study. For example, your health or a health condition you have may get better, worse or stay the same as a result of your participation in the research study. No one can predict what will happen with a research study or how it might affect you. However, the research study may result in information that will help others in the future.

### Are there risks or side effects in a research study?

Sometimes research procedures and treatments may cause discomfort or negative side effects. The questions being asked could make you uncomfortable. The risks and side effects of the research study may not be known at the beginning of the research study. The research staff will discuss known risks so you are well informed. If you do volunteer, the research staff will tell you about any risks that they discover during the research study for as long as you take part in the research study.

### What questions should I ask before I agree to take part in a research study?

Before you decide to volunteer to take part in a research study, you need to know as much as possible. If there are any issues that concern you, be sure to ask questions. It might help to write your questions down in advance or take this booklet with you. Not every question will apply to every research study. The following is a list of sample questions:



- Who is doing this research study and what question will it answer?
- Will this research study help in understanding my condition? If so, how?
- What tests or procedures will be done?
- Is it possible that I will receive a placebo (inactive substance)?
- Will I have to make extra trips?
- What could happen to me, good or bad, if I take part in the research study?
- How long will this research study last?
- What will happen to any specimens that I give?
- Who has reviewed and approved this research study?
- Could my condition get worse during the research study?
- What will happen if my condition does get worse?
- What other options or choices do I have if I decide not to take part in this research study?
- Who will be in charge of my care? Will I be able to continue to see my own doctor?
- Will I be charged anything or paid anything to be in this research study?
- If I decide to participate in this research study, how will it affect my daily life?
- What will happen to me at the end of the research study?
- Will I be told the results of the research study?
- Who will find out that I am taking part in this research study?
- How do I end my participation in this research study if I change my mind?
- Who do I contact for questions and information about the research study?

Remember to follow up if you do not understand the answer to any of your questions.

### What is an IRB?

The Institutional Review Board (IRB) is a team of people who review and approve human research. The IRB includes medical professionals, scientists and people from the local community who review human research to make sure it is well planned and ethical.

The IRB serves to protect your rights and welfare before and during the research study. It is in place to ensure no major risks are taken. The IRB does not make any decisions for you but carefully reviews each research study to ensure all volunteers are protected.

### Who will answer my questions?

Our research team will answer any additional questions you have that are not covered in this brochure. We can also provide an interpreter to be present when you are discussing the research study if English is not your native language.

Take time during the decision-making process to review the information with your family, friends, health care provider or



others before you decide to take part in the research study. If you decide to take part in the research study, you will be asked to sign the consent form.

The informed consent process continues throughout the research study. During the research study, you may be told of new findings, benefits or risks. At that time, you can decide whether or not to continue taking part in the research study. You have the right to leave at any time before or during the research study, or during the follow-up period.

### Who will see my records?

Like your medical record, the information in your research study record is confidential. Information will be given only to researchers and staff who carry out the research study. This includes the Institutional Review Board (IRB), the company or group funding the research study, and various government oversight agencies. It is important for these groups to be able to look at your records so they can ensure that the research study is conducted using acceptable research practices.

### What if I do not want to take part in a research study?

If anyone asks you to take part in a research study, you have the right to say no.

### Remember:

- You need to weigh both the risks and benefits of the research study.
- It may be helpful to talk to your family members, friends and health care providers.
- If you decide to volunteer for a research study, you can change your mind and leave the research study at any time. Your decision will not affect how we treat you.