

*How will my rights
and safety be protected?*

Ethical codes and laws protect the safety and rights of people who take part in research. Federal law requires every research study to be approved and monitored by an Institutional Review Board (IRB). IRB oversight ensures that a research study is ethical and that the safety and rights of participants are protected. It also makes sure that the risks are as low as possible and that there are potential benefits, either to the participants or to individuals in the future.

The USF IRB is an independent committee of professional people such as doctors and college teachers, as well as members of the community. All universities, hospitals, and other institutions that conduct or support human subject research must have that research reviewed by an IRB.

*What should I consider before
choosing to take part in a study?*

Find out as much as you can about the research. A member of the research team should answer all of your questions about the study. Some of the answers may be found in the informed consent document. Before you decide, be sure you know the answers to these questions:

- What is the research question (purpose)?
- What should I expect while I'm a participant?
- What tests and treatments are involved?
- How do the known risks, possible side effects, and potential benefits in the study compare with alternatives that are available to me?
- How might this research affect my daily life?
- Will there be any costs to me?
- How long will I be involved in the study?
- Who is going to be in the study?

*Will my information
be kept confidential?*

Researchers must keep information about you confidential (secret). That means they cannot share the information with anyone except those individuals named in the informed consent process. The researchers report the result of the study at scientific meetings, in professional journals, to study sponsors, and to various government agencies. However, the names of the participants are never used in any reports.

*What if I have more questions
about volunteering for research?*

Contact the USF Division of Research Compliance at (813) 974-9343 or at the address below.

*This brochure was made possible in part by a grant
from the National Institutes of Health.*

USF Office of Research

Karen A. Holbrook, Ph.D.

Vice President for Research & Innovation

Abdul S. Rao, M.D., M.A., D.Phil.

Sr. Associate Vice President for Research

Institutional Review Board

Barry B. Bercu, M.D. **Paul Stiles, Ph.D.**
Chairman Chairman
Biomedical IRB Social/Behavioral IRB

**12901 Bruce B. Downs Boulevard, MDC35
Tampa, Florida 33612-4799**

Phone: (813) 974-9343

Fax: (813) 974-5618

Web Site: www.research.usf.edu/cs

Volunteering For Medical Research



It's a Big Decision!

Here are some facts to
help you decide.

USF UNIVERSITY OF
SOUTH FLORIDA

Why is choosing to participate in research an important personal decision?

Without medical research, medicine would not have made the advances that we enjoy today. For you and for future patients, research is essential. Volunteering for medical research provides participants with opportunities to contribute to society, to the community, and to others who have health problems. Those who volunteer in medical research are participating in the development of new medical treatments that may be more effective or that may lead to cures for life-threatening and chronic diseases.

This pamphlet addresses some of the frequently asked questions about medical research studies. In addition to reading this pamphlet, it is often helpful to talk to family members, a physician, counselor, and/or friends as you try to decide whether or not to volunteer for a medical research study.

What is human subject research?

A research study is a set of carefully controlled procedures designed to answer a research question. Any research study that collects information about people or uses existing information or specimens collected from people is considered human subject research.

There are many different types of research studies. Medical research tries to find answers about specific health questions. Some research studies determine whether experimental treatments are better than those currently used. Medical researchers hope that their studies will help to improve health care and people's health.



Who can take part in a research study?

Each research study has requirements about who can participate. Using specific requirements is an important principle of research that helps to produce reliable results. These requirements are called inclusion and exclusion criteria. Inclusion criteria explain exactly what kinds of people may participate, while exclusion criteria explain exactly what kinds of people may not participate.

These criteria are often based on such factors as age, gender, medical history, current health, and past medical treatments. Some research studies seek subjects with specific illnesses or conditions, while others need healthy subjects.

A person must qualify for the study before being asked to join as a human subject. It is important to understand that these criteria are not used to reject people personally. Instead, the criteria identify appropriate participants and help to minimize the risks those participants face. The criteria also help researchers answer the research questions.

What is informed consent?

Informed consent is the process of learning the key facts about a research study before deciding whether to participate. The consent process continues to provide information to you throughout your time in the study.

To help you decide whether or not to participate, the researchers and staff will meet with you to explain the details of the study. You should feel free to ask any questions and to tell them if you don't understand something. If your native language is not English, translation assistance can be provided.

The research team then provides an informed consent document that explains details about the study, such as its purpose, its length, required procedures, and key contacts. Known risks and potential benefits are also explained.

If you decide to participate, you must sign the informed consent document. You will be given a copy of the document to keep. Informed consent is not a contract; by signing it you do not give up any of your rights and you can quit at any time. If you decide to quit, you should tell the research team.

How can I prepare for the first meeting with the researchers?

- Bring a friend or relative along for support and to hear the responses to your questions.
- Bring pen and paper to take notes.
- You can ask questions or stop the discussion if you don't understand what is being said.
- Make a list of questions to ask.