

## *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 well-being 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 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.

Researchers must keep information about you confidential, unless they are required by law to release information for a specific reason. The researchers report the results of the study at scientific meetings, in professional journals, to study sponsors, and to various government agencies. The names of participants are not used in any of these reports.

## *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) in the study?
- What should I expect while I'm a participant?
- What kind of 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?

## *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.

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Biomedical IRB              Social/Behavioral IRB

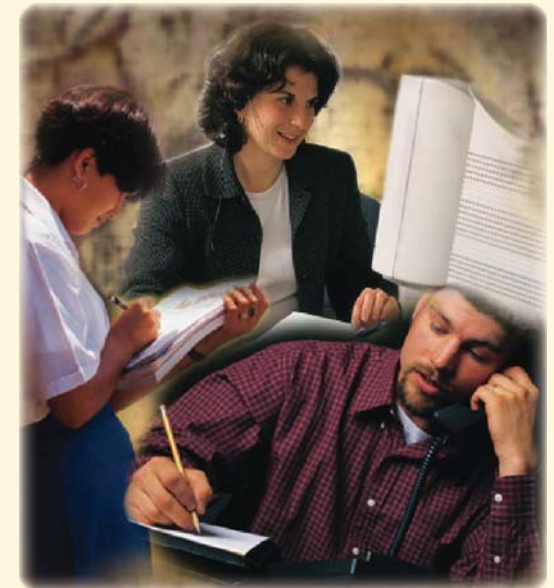
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# **Volunteering For Social & Behavioral Research**



## **It's a Big Decision!**

**Here are some facts to  
help you decide.**

## *Choosing to participate in research is an important personal decision.*

Without social and behavioral research, society would not have attained the level of advances that we enjoy today. Social and behavioral research provides data important to many fields of study, including the social sciences, public health, education, business, and transportation.

Research studies provide participants with opportunities to contribute to society and to their community. Volunteers in research are participating in the development of new information about people, communities, and services that will improve our lives.

This pamphlet addresses some of the frequently asked questions about social and behavioral research. 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 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 types of social and behavioral research studies. Some answer specific questions about behavior or address problems in society. Some determine whether new programs or services are better than those currently used. Others evaluate programs currently offered or the need for additional community services.



## *Who can take part in a research study?*

Each study identifies specific requirements about who can participate. These requirements are called inclusion and exclusion criteria. Inclusion criteria define specific conditions or characteristics that make it appropriate to enroll a person into a study. Exclusion criteria define conditions or characteristics that would make it inappropriate for a person to be enrolled.

These criteria are often based on such factors as age, gender, medical history, life experiences, and current needs. Some research studies seek subjects with specific needs or interests, while others seek a broad range of individuals (often referred to as normal volunteers).

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 the form 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.