Should I take part in a research study?

Here are some things you should know.

What is a research study?

A research study is an organized activity to learn more about a problem or answer questions. Scientists conduct many different kinds of studies.

Social and behavioral research studies investigate how people behave and why. Researchers may use surveys or interviews to identify how people feel or what they know about a particular topic. They may observe people while they perform a certain activity to identify ways to solve social problems and improve health.

Medical research studies may test if a treatment is safe and effective, find out what health care practices work best, or determine the best way to prevent an illness. Like in social and behavioral research, researchers may use a survey or an interview to understand how people feel about their health.

Another type of medical research study is a clinical trial. A clinical trial is a research study that will try to decide whether 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. However, it typically has no value to treat or prevent an illness.

What is an IRB?

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

The IRB serves to protect your rights and your welfare before and during the research study. For example, the IRB makes sure that any risks are as small as possible. The IRB does not decide for you. The IRB decides whether it is right to ask people whether they want to take part in a research study. The IRB also reviews each research study while it is going on to make sure volunteers are protected.

Should I take part in a research study?

Thousands of research studies are being conducted each year. These research studies have contributed to improve the lives of many people from every walk of life.

Medical and societal advances would not be possible without people willing to volunteer to participate in research studies. You may be asked to volunteer for a

research study approved by this IRB. This pamphlet aims to help you understand your rights as a research study volunteer. It will help you to decide if you should take part in a research study. We urge you to review this information and discuss it with other people you trust.

Why should I volunteer for a research study?

There are many reasons to participate in research study.

You may want to:

- Help scientists find out more about how the human body and mind work
- Help find a cure or a better treatment for an illness or a condition that you or someone you know has
- Help other people who are sick
- Help find ways to provide better care
- Help provide better education and improve our communities

If you decide to take part in a research study, you do so as a VOLUNTEER. That means YOU decide whether or not you will take part. Specific information about the study should be provided to you before you can decide to volunteer. If you choose to do so, you have many important rights.

What is informed consent?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. It is more than just signing a piece of paper. It is a process that goes on throughout the research study. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you.

The research staff will assist you with the "informed consent form" that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result, and your rights as a research volunteer. You should take your time when you read the consent form.

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 to take part in the research study. You may change your mind and leave the research study before it starts. You may also leave at any time during the research study or the follow-up period

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, a condition you have may get better as a result of your participation in

the research study. It may stay the same. It may get worse. No one can predict what will happen with a research study or how it might affect you. The research study may not help you directly but it 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 and bad side effects. The questions being asked could make you uncomfortable. The risks and side effects of the research study may not be known completely when you start the research study. The research staff will discuss with you known possible risks so you can decide if you want to volunteer. If you do volunteer, the research staff will tell you about any new risks that they learn about during the research study for as long as you take part in the research study. The researchers and the Institutional Review Board (IRB) will ensure that risks are minimized.

Who will see my records?

Like your medical or educational records, the information in your research study record will be confidential. Researchers will explain to you how they will keep your information safe. Information about you will be given only to the people who need it. This includes researchers and staff who carry out the research study. It may also include the IRB, the company or group funding the research study, and various government agencies overseeing human research. It is important for these groups to be able to look at study records, so they can ensure that the research study is conducted using acceptable research practices.

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 about the research study. The “informed consent form” should answer most of your questions.

If there are any issues that concern you, be sure to ask questions. You might want to write your questions down in advance or take this pamphlet with you. The following is a list of sample questions that should be addressed before you make your decision to participate in a research study. Not every question will apply to every research study.

- Who is doing this research study and what question might 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)?
- What could happen to me, good and bad, if I take part in the research study?

- What will happen to any specimens that I give?
- Could my condition get worse during the research study?
- What will happen if it does?
- What other options or choices do I have if I decide not to take part in this research study?
- How long will this research study last?
- Will I have to make extra trips?
- 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?
- Whom do I contact for questions and information about the research study?
- Who has reviewed and approved this research study?

Who will answer my questions?

The research team will explain the research study to you. The consent form includes details about the study and how it may affect you.

If you have any questions, ask the research staff. If you don't understand something, ask them to explain it to you so you do understand. The information will be given to you in a language that you know. If English isn't your native tongue, ask for an interpreter to be present when you are discussing the research study with the research staff.

You can take the information home. You can discuss it with your family, friends, a health care provider, or others before you decide whether or not to take part in the research study.

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:

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

Who can I contact if I have additional questions, concerns or complaints?

If you have questions, concern or comments about research at Texas A&M University, please contact the office below:

Human Research Protection Program (HRPP)
Texas A&M University
(979)-458-4067
1-855-795-8636
HRPP email: irb@tamu.edu