Should I take part in a research study?

Here are some things you should know.

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

- Your decision will not affect your relationship with the organization conducting the research.
- You need to weigh both the risks of the study and the benefits
- It may be help to talk with family, friends, or other people you trust
- If you decide to take part in a research study, you can change your mind and stop or leave the study at any time without anyone holding it against you

If you have any questions, concerns, or complaints about research, or just want to talk to someone about research in general, please contact:

Saint Francis Health System
Institutional Research Ethics Board
6161 S. Yale
Tulsa, OK 74136
918-494-2495

Should I take part in a research study?

We are committed to responsible research. Research has significantly contributed to improvements for many people from every walk of life.

Many advances in knowledge would not have been possible without individuals willing to take part in research. You may be asked to volunteer for a research study. This booklet will help you understand your rights as a research volunteer and help you to decide if you should take part. It will also help you understand some of the basic requirements for good research. We urge you to review this information and discuss it with other people you trust.

What is a research study?

A research study is an organized activity to learn more about a problem or answer questions. Many different kinds of studies are conducted. For example, a study may test if a product, such as a drug or equipment, is safe and effective. A study may be done to find out what education practices work best. A study may use a survey or an interview to understand needs, problems, or feelings people have about an important topic. A study may be done to determine the best way to treat or prevent an illness.

Why volunteer for a study?

There are many reasons to take part in research. You may want to:

- help scientists find out more about how the human body and mind work
- help other people
- help find a cure for an illness

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. If you choose to do so, you have many important rights.

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. You may get better as a result of your taking part in the study, you may stay the same, or you may even get worse. No one can predict the outcome of a research study or how it might affect you. The study may not help you personally, but your taking part may result in information that helps others in the future.

Are there risks or side effects in a research study?

Sometimes research procedures may cause discomfort and side effects. The questions being asked could make you uncomfortable. The risks and side effects of the research may not be known completely when you start the 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 study for as long as you take part in the 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 about the research study. 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 booklet with you. The following is a list of sample questions. Not every question will apply to every study.

Remember, if you do not understand the answer to one of your questions, ask the question again and ask the person to explain the answer in a way you can understand it. If you forget the answers to the questions during the study, just ask them again.

- Who is doing this study and what question might it answer?
- Will this research help in understanding my condition? If so, how?
- What tests or procedures will be done?
- Will I have to make extra trips?
- What could happen to me, good and bad, if I take part in the study?
- How long will this study last?

- What will happen to any specimens that I give?
- Who has reviewed and approved this study?
- Could I get worse during the study? What will happen if I do?
- What other options or choices do I have if I decide not to take part?
- Will I be charged anything or paid anything to be in this study?
- If I decide to take part in this study, how will it affect my daily life?
- What will happen to me at the end of the study?
- Will I be told the results of the study?
- Who will find out that I am taking part in this study?
- How do I end my taking part in this study if I change my mind?
- Whom do I contact for questions and information about the study?

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. Your agreement to volunteer should be based upon a clear understanding of what will take place in the study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

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

Who will answer my questions about the informed consent document?

You should take your time when you read the consent document. 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. If English isn't your native tongue, ask for an interpreter to be present when you are discussing the study with the research staff. The written and verbal informed consent information will be given to you in a language that you know. You can take the information home with you and discuss it with your family, friends, a health care provider, or others before you decide whether or not to take part in the study.

If you decide to take part in the study, you will be asked to sign the informed consent document. However, the informed consent process is more than just signing a piece of paper. It is a

process that goes on throughout the study. During the course of the study, you may be told of new findings, benefits or risks. At that time, you can decide whether or not to continue your taking part in the study. You may change your mind and leave the study before it starts or leave at any time during the study or the follow-up period.

Who will see my records?

Like your medical record, the information in your research record will be confidential. Information will be given only to the researchers who carry out the study or to those who make sure that the study is safe and carried out the way it was planned. The groups of individuals who might look at your records are the research staff, The Institutional Research Ethics Board (IREB), the company or group funding the 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 study is conducted using acceptable research practices.

What is an IREB?

The Institutional Research Ethics Board (IREB) is a group of people such as scientists, non-scientists, and people from the local community who ensure that human research is ethical.

The IREB serves to protect your rights and your welfare before and during the research study. For example, the IREB makes sure that any risks in the research study are as small as possible. The IREB does not make a decision for you. The IREB decides, when approving research studies, that it is reasonable to ask people whether they want to be involved in it, The IREB also reviews each study while it is going on to make sure volunteers are protected.