Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center

Should I take part in a research study?

Here are some things you should know

What is an IRB?

An 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 make a decision 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 health improvements for many people from every walk of life.

None of the advances in health care would be possible without people willing to volunteer to take part in research study. 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. It will try to 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.

Who will see my records?

Like your medical record, the information in your research study record will be confidential. Information will be given only to the people who need it. This includes researchers and staff who carry out the research study. This includes the 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 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. For example, a research study may test if a treatment is safe and effective. A research study may be done to find out what health care practices work best. A research study may be done to determine the best way to prevent an illness. A research study may use a survey or an interview to understand feelings people have about their health. One type of 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.

Who will answer my questions?

The research team will explain the research study to you. The consent form includes this explanation. You should take your time when you read the consent form. 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. If you decide to take part in the research study, you will be asked to sign the consent form.

The informed consent process is more than just signing a piece of paper. It is a process that goes on 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 to take part in the research study. You may decide not to take part. 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.

Why should I volunteer for a research study?

There are many reasons to participate in research study.
You may want to:

- 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
- Take part in a research study that is trying to 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 or not you will take part. 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.

Your agreement to volunteer should be based upon knowing what will take place in the research 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 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.

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 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 personally. 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 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.

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 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)?
- Will I have to make extra trips?
- What could happen to me, good and 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 it does?
- 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?
- Whom do I contact for questions and information about the research study?

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

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 how we treat you.
- 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. Your decision will not affect how we treat you.

Who will answer my questions?

If you have questions about research at The Lundquist Institute, please contact the individual listed below:

IRB Director
Office of Research Compliance
The Lundquist Institute
MRL Building
1124 West Carson St.
Torrance, CA 90502
Email: irb@lundquist.org
Phone: (310) 222-3624

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