

Are You Thinking About Being in a Research Study?

CONTENT AUTHORS

- Cheryl Savini, CIP
- Judy Matuk, MS
- Diane Paul, MS, RN
- Alavy Sos, MS, CIP

INTRODUCTION

The goal of this module is to: (1) help you understand what research is, (2) provide you with the that may help you decide whether to participate in a research study, or (3) to help you understand research in order for you to help someone else (such as a family member) make a decision about taking part in research.

In the next section, you will find a list of definitions to help you familiarize yourself with some of the words used in research, and links to other websites and organizations that may provide you with more in-depth information.

What is research?

Research is the collection of information (data) to obtain more knowledge or to answer a specific question about a certain topic. For the information to be helpful in better understanding the topic, the gathering of information or the testing of an idea must be done in a very organized manner. A "researcher" or "investigator" is the person who conducts research.

Content

[What are the types of research that include human subjects?](#)

[What are my rights as a human subject?](#)

[What questions should I ask before I decide about being a human subject?](#)

[What is the informed consent process?](#)

[What is expected of you after you have said 'yes' to being a human subject?](#)

[Who protects people who agree to be research subjects](#)

WHAT IS RESEARCH INVOLVING HUMAN SUBJECTS?

When research calls for getting personal information from, or about people, then the researcher is doing research involving human subjects. Research can involve such things as asking simple questions about the foods people like, or it can involve looking at the good and bad effects of one or many drugs for

treating a disease. Studies can also get information about people without directly speaking to them, or asking them to do things. For example, a study may take personal information from medical or school records in order to answer a research question.

[Definitions of Commonly Used Terms](#)

[Links to Additional Information](#)

[Regulations](#)

WHAT ARE MY RIGHTS AS A HUMAN SUBJECT?

As a subject in a research study, protecting your rights is one of the most important jobs a researcher has.

Before you enter a study, **you have the right to be given all the information you need to make an informed decision about being in the study.** We will be discussing the information you should know in this module.

Some examples of what you must be told are:

- Why the study is being done.
- Your option to withdraw from the study at anytime without any penalty and without having to give a reason.
- What is expected of you.
- What will be done to you for research reasons.
- How long you will be in the study.
- The bad things and good things that could happen to you in the study.



You have the right to be given all this information in words that you **understand**.

You also have the right to be **given as much time as you need to make your decision**.

Another right you have is to **ASK QUESTIONS** and have a detailed conversation about the study with the person asking you to volunteer! That is what helps you make informed decisions about whether to be in a study, or continue once you have said yes. You may ask as many questions as you like, as many times as you like, to make sure you understand what is being told to you. The person who is asking you to be in the study may also ask you questions to make sure you understand what they have explained.

WHAT QUESTIONS SHOULD I ASK BEFORE I DECIDE ABOUT BEING A HUMAN SUBJECT?

Here are some of the questions you might want to ask while you are deciding whether or not you want to be a human subject. Remember, of course, that you can ask any question that you want to make sure you understand what is being told to you, and you can ask the same question as many times as you want.

General Questions:

- Why is the study being done?
- What will be done to me if I say yes to be in the study?
- How long will I have to be in the study?
- What can I do instead of being in this study? What other choices do I have?
- Do I get paid to make up for the time and effort I will put in by being in the study? If yes, how much? How often?
- What are the bad effects ("risks") that can happen to me if I'm in this study? How often can the bad things happen (rarely? A lot?)? Do the bad effects go away after I stop being in the study?
- Are there good effects ('benefits') that can happen to me if I'm in this study? What are they?
- Is being in the study going to cost me anything?
- Will my being in a study affect any of my family members?
- What happens to the information I give you or any information you find out about me?
- Will you share my information with anyone who is not part of the study team?
- Who will know that I'm in the study?
- Will I find out my own study results, if tests are done?
- Will I find out the results of the whole study?
- Who do I call if I have questions?
- What if I want to stop taking part in the research study? Will anything bad happen to me?

Additional Questions for Bio-medical Studies:

- Do I have to stay in the hospital? For how long?
- How will being in this study affect my life?
- Will I have to make extra trips to the doctor's office?
- Has this drug/device/treatment been tested before in people?
- Do I have to stop taking any medications I am already taking?
- Should my regular doctor know that I am in the study?
- Should my regular doctor get my test results from this study?
- Will my insurance company have to pay for any costs I have for being in this study?
- If my insurance pays for standard care costs, what will be my out-of-pocket expenses?
- Who will pay if I am injured while on the study?

How do I decide about being a research subject?

After you have asked all your questions and you have been told about the research study, you now have to ask yourself:

- Could this research help me personally?
- Do I still want to be a part of the research study even if the study won't help me personally, but may help others?
- Do I understand what the research is about and what is expected of me?
- Am I comfortable with what's going to happen to me?
- Do I have the time to commit to the research study?

- How does my family feel about my being in a research study?
- Can I agree to take the chance that the bad things ("risks") they have told me might happen to me?
- Do I feel confident that the people who are conducting the study respect me, treat me kindly, and will do everything possible to keep me safe during the study?
- If I am treated on the study, will my health insurance cover medical expenses that are not covered by the study itself?

Finally, depending on the type of study, and the amount of time that will be needed, you may want to speak with your family about helping you make the decision about being in the study.

What about people who are not able to decide for themselves about being a human subject?

You can see that it's a very important decision you have to make when thinking of becoming a human subject. There are research studies that need to answer questions involving:

- children, who are not able to make decisions to be in research because they are too young, OR
- adults who are not able to make decisions because they may be too sick, either mentally or physically to do so.

Children are protected when it comes to being in research studies because there are special rules in place that make sure, with very few exceptions, that:

- Parents give their permission,
- The child agrees, and
- A special committee, called an Institutional Review Board (IRB), makes sure the study is ok for children to be in.

Adults who are too sick to decide to be in research studies are protected under specific research rules too. Only someone who is allowed by law to make decisions for another person can give the researcher permission to include the person in the study. Who is or is not allowed by law to make decisions on behalf of another person depends on state or local laws. If you are asked to give permission on behalf of someone who cannot consent for him or herself, you have to make sure to learn and understand as much as possible about the research so that you can make the best decision. Always ask the question: "Would the person want to be a human subject in this study?"

WHAT IS THE INFORMED CONSENT PROCESS?

The process that involves being given important details, and asking and answering questions about the study, is called the informed consent process. You may also be asked to sign a form that has all the information you've discussed with the researcher. That form is called the Informed Consent Form, and you have the right to be given a copy of it after you've signed it. This is a good thing, since it will also contain names and phone numbers you can call if you have questions later. ([Click here for more information about the informed consent form.](#))

Being a volunteer in a research study is a choice. This means you never have to be in, or continue to be in, a research study. You have the right to say "No, I don't want to be in this study", or "I said yes to being in this study but now I've changed my mind" without having to give a reason, and without any penalties. If you don't want to start, or finish, something you have been asked to do, that's ok. If, for example, you are uncomfortable about answering a certain question, or doing a certain task, simply tell

the researcher as soon as you can. Even though you can leave a study if you want to, sometimes the researcher needs to take certain steps so that you can be removed from the study safely. This really matters in studies where it may be dangerous for you to simply stop a study procedure (For example, if you are going to stop taking a study drug). You may need to slowly withdraw from the study, or come back for a safety visit to make sure you're ok now that you're out of the study.

While you are in a study, **you have the right to be given any new information that the researcher finds out that might make you change your mind about being in the study.** For example, during the study, it may be found that there are bad side effects happening in other subjects that were not known at the time you went in the study. Or, the researcher may decide that she/he wants to do an extra test, or have you come in for an extra visit.

WHAT IS EXPECTED OF YOU AFTER YOU HAVE SAID 'YES' TO BEING A HUMAN SUBJECT?

After saying yes to being in the study, you have to follow the directions given to you as best you can. For example, if you have agreed to come in for a study visit at a certain time, you need to show up on the day and time you were asked to come.

If you have been asked to give information about yourself, you need to be sure that you are telling the truth. If you don't, you may not only hurt the study (that may need certain kinds of people with certain kinds of qualities in order to answer the research question) but you may also put yourself at risk. One of the goals of any study is to keep safe those who are subjects in it. That is why the types of people who can and cannot be in a study are very carefully looked at and approved before a study starts. ([Click here for more information about the recruitment and screening of potential research subjects](#))

During the study, the researcher needs you to tell them if anything begins to bother you, or if you do not feel well during your time in the study. Say, for example, you are answering questions that are very personal and you start to become upset. You should let the person asking the questions know that you are becoming upset. That person will stop asking the questions, and will try to help you feel better. **Or**, if you are taking a **drug** and you start to feel funny or become sick, it is important that you let the researcher know **as soon as you can**. It is more important, however, that at any time you feel the need, you should go to the nearest emergency room, just as you would if you were not in a study.

WHO PROTECTS PEOPLE WHO AGREE TO BE RESEARCH SUBJECTS?

Many groups work together to make sure research subjects are protected when they are in research studies. The main groups are:

The **Researchers**, who make sure your rights are protected and also make sure you are kept as safe as possible the whole time you are in the study. Your safety and rights are more important to the researcher than finding out the answer to the research question.

Researchers are required to be knowledgeable about how to conduct a research study and how to protect those who have volunteered to participate.

The **Institutional Review Board (IRB)**, which is a group of people that are not a part of the research study team, who are specially trained to review, approve, and watch over studies that involve human subjects. This group can be called different names in different places, but they all have to follow the same laws to make sure that the amount of protection they give research subjects is the same.

The State and Federal Government that makes the laws and rules that researchers must follow if they want to *do* research involving human subjects, and IRBs must follow if they want to be able to *approve* research involving human subjects. ([Click here for more information about the rules and regulations for conducting human subject's research](#))