

Before you decide to take part in a research study, you should discuss the study with the study doctor. The information on this webpage may help you before you make a decision.

What is a research study?

A research study is designed to answer a question about a medical condition or illness. Scientists and doctors do research to better understand how and why things happen. Research is not the same as treatment.

A research study may also be designed to test a new exercise program or other non-medical intervention in the routine daily life of a research volunteer or participant. Research may include surveys, interviews or focus groups.

Do I have to take part in a research study?

Taking part in research is always your choice. If you choose to be in a study and change your mind, you can drop out of the study at any time. However, if you decide to stop taking part in the research study, you should tell the study staff so you can be safely removed from the study. If you decide to stop taking part in the study, you will still be able to receive non-research care.

What are some questions I should ask before I decide to participate in a research study?

What is the purpose of the research study?

What will happen to me in the research study?

How long will the study last? How much of my time will the study take?

Are there any side effects involved in the study?

What other options do I have?

Can I leave the study at any time?

Will it cost me to take part in the study?

Are there risks in a research study?

Sometimes there are risks involved in a research study. The risks can be physical or they can affect your privacy. Sometimes the risks are not known until you are involved in a study. There is no guarantee that the treatment in the research study will work. In some studies, you may receive a placebo, which contains no actual medication. Members of the research team will discuss the Informed Consent Form with you. It will list the known risks in the research study. Ask the study doctor about the risks and side effects. Do not agree to take part in the study until **all** your questions are answered.

Will I benefit if I take part in a research study?

There is no guarantee that you will benefit by taking part in the study. You might get better. You might get worse. No one can tell exactly how the study will affect you. There could be a benefit to others from what is learned from your taking part in the study.

Can I take part in a research study if I am a student in the GME or GDE program or a civilian employee or Soldier?

Yes. However, you cannot be forced to take part in the study. Information about you and the research study will not be a part of your academic or personnel record.

What protections are in place for research subjects?

Each research study involving human subjects must be reviewed for scientific guidelines and safety and ethical conduct of the study. An Institutional Review Board (IRB), a group not associated with the research study, reviews it to determine if it is safe and appropriate for the study doctor to conduct the research study. You will also be given an Informed Consent Form or Children's Assent Form (for children 7-17 years old), which will fully explain the study.

What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is a group of people responsible for reviewing research studies involving human beings. The IRB reviews research studies to make sure the safety, rights, and welfare of human subjects are protected.

What is informed consent?

Informed consent is the process of being provided information and answers about the research study. Informed consent begins when the study doctor or study staff member tells you about a research study. Then, you will be given an Informed Consent Form or Children's Assent Form. You should read it carefully. The study doctor or study staff member will discuss the Form with you. You should ask questions about anything you do not understand. If you still do not understand, ask again. All of your questions should be answered before you decide to take part in a research study. You should be able to take the Informed Consent Form home and talk about the research study with you family, friends, or primary care doctor before you decide to take part in the study.

You should never feel pressured to sign the Form or take part in a research study. It is always your decision to be in a study. If you decide to be in a study today and change your mind later, you can drop out. Just let your doctor know so that you can be safely removed from the study. Talk to the study doctor and study staff and ask questions

throughout your time in the study. The study doctor and study staff will keep you informed about any new results which may affect your decision to remain in the study.

What happens to my records from the research study? Who can see them?

The information about you in the research study records is private. The groups that may look at your records are:

- The study sponsor
- The study doctor and study staff
- The IRB
- The United States Food and Drug Administration (FDA)
- The United States Office of Human Research Protection (OHRP)
- The Army Human Research Protection Office (AHRPO)
- The Army Clinical Investigation Research Office (CIRO)

These groups need access to your study records to make certain that the study is conducted legally and safely.

What if I want to stop taking part in the research study?

You can stop taking part in a research study at any time. You should tell the study doctor and study staff so you can be safely removed from the study.

What if I have a complaint or question about my rights as a research subject?

If you have a complaint or question about your rights as a research subject you should contact the Department of Clinical Investigation (DCI) at the number and address listed on the Home tab on this website.

What are my rights as a research subject?

- Be informed of the nature and purpose of the research study
- Receive an explanation of the procedures to be followed in the research study
- Receive a description of any known discomforts or risks involved in the research study
- Receive an explanation of the expected benefits involved in the research study
- Receive an explanation of the other options you have instead of taking part in the research study
- Be provided an opportunity to ask questions about the research study at all times
- Receive the opportunity to drop out of the study at any time
- Receive a copy of the Informed Consent Form or Children's Assent Form
- Be free of force, fraud, deceit, duress, coercion or undue influence throughout the study

What are my responsibilities as a research subject?

- Read all study materials including the Informed Consent Form and take the time to discuss it with family, friends, and/or your primary care doctor before deciding to participate
- Keep all scheduled study visits.
- Ask questions to ensure understanding at any point during the study
- Truthfully answer all questions regarding your health and your taking part in the study
- Take your study medication as directed, if applicable
- Notify the study staff regarding any side effects or hospitalizations that may have occurred between the study visits
- Promptly notify the study staff of any problems or concerns
- Promptly notify the study doctor or study staff you decide to drop out of the study
- Contact the DCI about any questions or complaints regarding your rights as a research subject.