

How do I Volunteer to Participate in a Clinical Research Study?

If you think you might be interested in participating in a research study, tell the researchers associated with the study of your interest in learning more. Someone from the research team will explain the details of the study to you. Information must include the following:

- The purpose or goals of the study
- A description of the study
- Why the study is being done
- Information about the treatment being studied and how the treatment will be administered
- Exactly what your participation involves – the exact tests and procedures you will be required to go through, and the amount of time the study will take
- The known risks and benefits of participation
- Other treatments that are currently available
- Contact information on the investigators
- Contact information for the Institutional Review Board
- A statement that your participation is voluntary and that you may stop or withdraw from the study without penalty

Can I Change My Mind?

YES. If you decide to be in a study now and you change your mind later, that is okay. You just have to tell the study doctor or the study staff as soon as you change your mind. They may ask you to come back for a final visit to check your health.

What Types of Questions Should I ask the Researcher?

Volunteering to be in a clinical research study is an important decision. If you have questions or concerns about the Human Research Protection Program at MUSC, or would like a list of some general questions about taking part in clinical research contact any of the departments listed below. Not all the questions on the list will apply to the clinical study you are thinking about.

[Office of Research and Sponsored Programs](#)

843.792.3838

[Office of Research Integrity](#)

843.792.4148

[University Compliance](#)

843.792.7795

The Medical University of South Carolina (MUSC) is a public institution of higher learning the purpose of which is to preserve and optimize human life in South Carolina and beyond. The university provides an environment for learning and discovery through education of health care professionals and biomedical scientists, research in the health sciences and provision of comprehensive health care.

MUSC's Confidential Hotline: 800.296.0269



HUMAN RESEARCH PARTICIPANT BROCHURE

*Rights, Responsibilities, Benefits, and Risks of
Human Research Study Participation*

What You Need to Know As a Human Research Study Participant



Study participants are an important part of all successful human subjects' research. Whether you are a first time subject or a frequent volunteer, you may have questions, concerns, or comments. We hope this brochure will help guide your decisions. Thank you for your interest in our research.

What is Clinical Research?

Clinical Research – also called “Human Research” or “Clinical Trials” -- test new treatments in people. Progress in medicine simply doesn't happen without clinical trials. Clinical trials are research studies to test new drugs, devices or treatment strategies on humans.

Clinical trials are essential to improving health care for all people. Volunteers are critical to helping researchers learn how safe and effective a new treatment will be. Information on MUSC studies and how to volunteer is available at:

www.muschealth.com/clinicaltrials/muscct.htm

www.musc.edu/catalyst/sub/mrs.htm

www.ClinicalTrials.gov

www.aahrpp.org/www.aspx?PageID=175

Who Volunteers for Research?

People who volunteer for research come from all walks of life. Volunteers may be healthy and participate in clinical research, or they may be patients or other people with health problems.

People with a specific type of medical condition or disease may be asked to volunteer for a research study because doctors want to learn more about their condition, or there may be a promising new treatment being studied.

Because disease and life-threatening conditions affect everyone regardless of race, gender, age, and national origin, volunteers are needed for many types of research studies.

Are there Risks and Benefits of Participating in a Research Study?

The risks and benefits are different with each research study. There may or may not be benefit to you if you volunteer to be in a research study. You might get better or you might get worse. You might get the chance to receive a new treatment that is not yet available to the general public. No one can predict the outcome of the research study or how it will affect you. There could be benefit to others from what is learned from the study in which you volunteer.

There may or may not be risks when you participate in a research study. Medicines and treatments can cause side effects. Sometimes the risks of a new drug or treatment are not known in a study. Also, you may have many more scheduled appointments, lab tests, and procedures than you would under regular, standard care.

The researcher will give you a form that will tell you about the risks of the study. This paper is called the **informed consent form**.



Can Children Participate in Clinical Research?

Yes, children can participate in research studies. A child's parent or guardian must give permission for their child to participate. An adolescent child may be asked to give their approval to take part in a study if they are old enough to understand what the study is about.

How Long Does a Research Study Take?

Each study is different. The amount of time a study takes depends on the research questions the study is designed to answer. A study may take a few hours, a few months, or even years to finish.

What is an Institutional Review Board (IRB)?

The IRB is a group of people (doctors, pharmacists, nurses, and members of the community) who review and approve research at MUSC before it is allowed to begin. They also monitor each study while it is being conducted to be sure study participants are safe. This is the law.

Who Pays for Research?

Depending on the type of services you receive in a study, some or all of those services may be paid for by the organization that sponsors the research. In some cases, you or your insurance may pay for services related to the study. If you have questions regarding who is paying for certain services, please speak with the researcher or the study coordinator before participating as a study volunteer.