

(responsibilities continued)

- Arranging your own transportation to and from the study site(s)
- Following the directions of the researchers
- Making sure your contact information is up to date
- To the best of your ability, providing accurate information about your past/present medical history if it is relevant to the study
- Seeking healthcare for any medical conditions unrelated to the study
- Asking the researchers to completely answer any questions you may have at any point
- Informing the research staff of any adverse events you experience while enrolled in the study
- Informing the Institutional Review Board Office if you feel your rights as a subject are being violated. The phone number for the IRB is provided below and also in the informed consent form.

If you have questions regarding your rights as a volunteer in a research study you may call the Institutional Review Board Office at the **University of Connecticut Health Center at 860-679-1019**.



Made available by the:

Human Subjects Protection Office
University of Connecticut Health Center
263 Farmington Avenue
Farmington, CT 06030-2806
860-679-1019
860-679-3054

For more information visit the Health Center's IRB web site at:
<http://resadm.uhc.edu/hspo/index.html>

A Guide to the Rights and Responsibilities of Volunteer Research Participants

An overview of the clinical research process and your rights and responsibilities as a participant.

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WHAT IS CLINICAL RESEARCH AND HOW DOES IT BENEFIT SOCIETY?

Clinical research is designed to evaluate health risks and to test new approaches to the diagnosis, treatment and prevention of specific diseases or disorders. Clinical research may help to improve the quality of healthcare or may involve gathering information about health risks. The knowledge that may be gained from this type of work can be of great value to our society.

To ensure the safety of volunteers who enroll in clinical studies, each project must be approved by an Institutional Review Board (IRB) before it can begin. During the review process, the IRB evaluates the potential risks and benefits associated with the study and decides whether or not to approve it.

WHO PARTICIPATES IN CLINICAL RESEARCH STUDIES?

All types of people are eligible to participate in research studies. Volunteers include adults, children, healthy individuals, and individuals with illness. Each study has a specific set of criteria that determines who is eligible to participate. People who choose to participate in clinical research studies may do so in hopes of improving their own health or advancing scientific knowledge about the cause, treatment and prevention of disease. Some people may benefit directly from participating in a study, for example if a drug being used in the study proves to be effective. Some people may not benefit directly, but their participation may help to advance knowledge that could benefit others in the future.

AM I ELIGIBLE?

Your eligibility may be determined by various factors, depending on the nature of the study. If you meet the screening conditions, you will be given an “Informed Consent Form” containing a detailed written description of the project, any risks involved, and your rights as a participant. If the screening process involves any type of intervention, such as obtaining a blood sample or personal health

information, the consent process will be conducted prior to the screening to ensure that you are informed of what will be required of you and of any potential risks to your well-being. By signing and returning the consent form you agree to participate. If you should have second thoughts about participating, or become uncomfortable during the study, you have the right to withdraw at any time without any penalty whatsoever.

WHO WILL BE CONDUCTING THE STUDY?

Each study has a Principal Investigator (PI) who is in charge of the project. The PI may be a physician, a dentist, a basic research scientist or other faculty member. Colleagues of the PI from either within or outside the institution may also be involved with conducting the study. In addition to the PI and colleagues, a Research Coordinator or a Nurse, who is specially trained in clinical research, could be involved with conducting a study. The Research Coordinator or Nurse usually serves as your main point of contact regarding scheduling issues and any questions or problems you may have relating to the study.

WHAT SHOULD I CONSIDER BEFORE DECIDING WHETHER OR NOT TO PARTICIPATE?

Participating in clinical research may have a significant impact on your life. It is important that you are well informed and feel confident about your decision. You may want to consult with your doctor, family members and the research staff of the project to discuss any concerns you may have. Before finalizing your decision, be sure you know the answers to the following questions:

- What are the major goals of the study?
- What will be required of me?
- What are the risks, how likely are they to occur and what will be done to minimize them?
- What role will I play in the study – healthy volunteer or patient volunteer?

- Is the study likely to benefit me directly?
- What are the potential benefits to others?
- How long is my participation required?
- What discomforts, inconveniences and costs are involved?
- Do I want to participate in this study?

WHAT ARE MY RIGHTS AS A PARTICIPANT?

As a research participant, you are guaranteed certain rights to ensure that you are treated in an ethical and respectful manner. Although these rights are explained in greater detail during the informed consent process, the list below will give you an idea of some of your basic rights.

As a research participant, you have the right to:

- Be treated with respect
- Know the risks involved with the study
- Know what alternatives are available
- Withdraw from the study without penalty
- Make your decision without feeling any pressure from the research staff
- Know the name, credentials and contact information of the Principal Investigator
- Know the purpose of the study
- Know who will have access to your information
- Know what procedures may be performed and what drugs may be used.
- Seek additional help or clarification during the informed consent process, or at any time during the study.

WHAT ARE MY RESPONSIBILITIES?

In addition to complying with the specific requirements of a study in which you may enroll, you will also be expected to adhere to a general set of responsibilities that pertain to all research participants. These responsibilities include:

- Arriving for all scheduled appointments or calling ahead if you are unable to keep an appointment

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