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Frequently Asked Questions Guide for Research Participants About Research Studies

What is a research study?
A research study is a project that aims to gather information and/or answer a question(s) about a certain topic. It is a way for scientists, researchers, and other personnel to find out information about a particular topic to answer a specific question in relation to that topic and provide findings to the research community and society at large.

Who usually sponsors research studies?
Studies may be sponsored or funded by various individuals, foundations, groups and/or Federal Agencies (such as the National Science Foundation (NSF) and the National Institutes of Health (NIH)). And, although research can be sponsored by different agencies, the agencies do not have a role in conducting or carrying out the research, nor do they influence the results of the research.

Who leads research studies?
Each research study is led by a Principal Investigator (PI) or Project Director (PD). This role is generally held by a research scientist with a terminal degree in the area of the research topic. The PI/PD manages the project and is responsible for ensuring compliance and safety of project facilitators and participants. The PI/PD's name, email, and occasionally phone number are listed on the Participant Consent Form that you complete before participating in a study, so that you may contact him/her at any time.

Who else is involved in research studies?
Each study may include a variety of researchers and participants such as the PI, co-PIs, senior personnel, postdoctoral researchers, graduate students, undergraduate students, and research subjects or participants.

Who reviews a study?
At the University of Nebraska, all proposed research studies that involve human subjects that are not exempt must be reviewed by an Institutional Review Board (IRB).

What is an IRB?
The IRB assures the protection of all human subjects in research projects conducted by anyone on the premises of UNO, and provides oversight for all research that is conducted elsewhere by UNO faculty, students, staff, or other representatives. The IRB also protects the investigator and the institution through a comprehensive review process prior to allowing the research to begin. All human subject research must be reviewed and approved by the IRB prior to beginning such research. See more about "who is on the IRB below."

The Office of Research and Creative Activity (ORCA) at UNO manages compliance for human subject research (and other regulated research types) in cooperation with the University of

Nebraska Medical Center (UNMC), where the IRB Office is located. See ORCA's Compliance and Policies page for additional details.

Who is on the IRB?
The Institutional Review Board, or IRB for short, is made up of research professionals and community members (i.e. non-research professionals) and review research study proposals prior to allowing research to begin to assure protection of all human subjects in research projects.

What training must be completed by individuals who work on research projects involving human subjects?
Faculty, employees, students and other institutional representatives who will be working on a research project that involves human subjects are required to complete human subjects' research training via the Collaborative IRB Training Initiative (CITI).

Researchers should also be familiar with UNO's policy on Integrity in Research and Creative activity, and federal requirements for Responsible Conduct of Research (RCR):

- RCR Policy for UNO
- NSF Resources for Responsible Conduct of Research
- NIH Office of Research Training in the Responsible Conduct of Research
- DHHS ORI Introduction to the Responsible Conduct of Research

Why do people volunteer for research studies?
People may volunteer for research studies for a variety of reasons. For one, they may be granted access to a treatment or intervention free of charge. Additionally, some people enjoy helping advance science through their involvement in research studies.

Is there any reason I would have to participate in a research study to receive treatment?
No. Research studies are 100% voluntary with all risk and study information provided prior to making the decision to participate. There is no obligation for people to participate in a research study! And, if you do agree to participate in a study, but change your mind later on and want to withdraw, you may do so without any penalty or negative effect.

What do I need to know before I decide to participate?
It is important to check with the PI/PD who leads the research study to fully understand what the benefits and risks are in relation to participating in the study. Always make an informed decision on if you will participate AFTER you have received answers to all of your questions.

I'm considering participation in a research study. What questions should I ask before agreeing to enroll?

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Questions to ask vary study by study, but it is important to make a sound decision based on the information provided to you in relation to risks involved with participating in the study and potential benefits of participating in the study. Questions might also surround study duration.

What is "informed consent?"
This means that the research team has provided you with complete information regarding the study. Prior to committing to the study, information will be given to you in writing so that you understand what will occur in the study. This is an ongoing process throughout the study to weigh in on benefits and risks associated with the study.

What if I change my mind about participating?
It is your right to step away from the study at any time, should you choose to do so!

Who should I talk to if I have questions and/or concerns while participating in a research study?
The PI/PD of the study is in charge of overseeing all facets of the research study. They are the main point of contact to address in regards to questions about participating in a research study. You will find their contact information on the consent sheet. Research subjects, staff, and investigators may also report problems or complaints to the IRB securely and confidentially via EthicsPoint. Additional details are available here.