


THE BENEFIT TO HUMANITY

The University at Buffalo community has defined its goal: to be recognized throughout the nation and world as one of the premier public research universities of the twenty-first century. This goal derives from our understanding that excellence in research can improve the quality of life for individuals all over the world.

If you decide to become a research subject, your participation in a study may lead to discoveries that are the basis for new medications, biomedical devices, or diagnostic tests that serve to enhance the quality of our lives. Participation in social and behavioral research may similarly lead specifically to new behavioral therapies and more generally to a greater understanding of the psychological and social forces that shape our lives.

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So, you're thinking
about being in a
research study?

Here are a few things
you ought to know.

WHAT IS A RESEARCH STUDY?

A research study, sometimes called a clinical trial or research experiment, is a way for scientists and other researchers to find out information about a particular topic or to answer a specific question.

WHO LEADS RESEARCH STUDIES?

All research studies are led by a Principal Investigator (PI). The PI is responsible for the overall management of the research study. If the research study involves human subjects, then the PI is also responsible for assuring the safety of the subjects. PIs are often faculty, physicians, or graduate students.

WHO ELSE IS INVOLVED IN RESEARCH STUDIES?

Principal Investigators often rely on a research team to assist them in the day-to-day operation of their studies. The research team can be made up of research assistants, research nurses, data coordinators, statisticians, and other people with specialized skills needed for the study.

WHO REVIEWS A STUDY?

At the University at Buffalo, an Institutional Review Board (IRB) reviews all studies that involve human subjects before they are allowed to begin.

WHAT IS AN IRB?

An IRB is a committee of scientists and nonscientists who review projects submitted by researchers affiliated with the University at Buffalo (UB). Each IRB has at least one member who represents the community and is not affiliated with UB. There are three UB IRBs: the Children and Youth IRB reviews biomedical research involving minors; the Health Sciences IRB reviews biomedical research on adults; the Social and Behavioral Sciences IRB reviews all nonbiomedical research. These IRBs review research to be carried out by UB researchers on campus, as well as at affiliated local hospitals and other off-campus sites.

WHAT DO IRBs CONSIDER IN THEIR REVIEWS?

All UB IRBs strive to ensure that your dignity as a person is fully respected. Informed consent is the process of information exchange between you and the investigator. IRBs work with the investigator to see that you are fully informed about all aspects of the study in language as clear and comprehensive as possible. IRBs review a proposed study to make sure that your participation will be completely voluntary and without any form of coercion. IRBs also work to protect your well-being by minimizing the risks associated with participation in a study to the extent possible. Justice and fairness are other important considerations. IRBs make sure that certain classes of individuals are not unnecessarily excluded from potentially beneficial research, or that, conversely, certain groups are not asked to bear a disproportionate share of any study risks.

WHO CAN BE A SUBJECT IN A RESEARCH STUDY?

Most research studies have certain criteria that you must meet in order to participate. These criteria are designed to ensure the safety of the subjects, as well as to ensure the usefulness of the research. Some studies have very broad criteria; for example, you must be over 18. Other studies have much more strict criteria for participating; for example, you must have a certain disease.

WHAT KINDS OF PROCEDURES ARE INVOLVED IN RESEARCH STUDIES?

Research studies can involve a wide variety of procedures, ranging from filling out surveys and questionnaires to taking experimental medicines or using experimental devices. Some research studies last only a few minutes; others last for several years. The research team will describe to you all the procedures that you will be asked to undergo before you agree to be in the study.

ARE THERE ANY SPECIAL PROTECTIONS FOR CERTAIN TYPES OF RESEARCH SUBJECTS?

Yes. Additional protections that are specified in federal regulations must be in place before children, pregnant women, prisoners, and persons with cognitive impairments may participate in research studies. These groups are considered “vulnerable populations.”

ARE THERE RISKS TO BEING IN A RESEARCH STUDY?

The risks associated with participating in research studies vary widely. In a study where you are asked to fill out a survey, the risk is virtually nonexistent, unless the survey involves sensitive personal information. For other studies, such as studies that ask you to take an experimental drug, the risks can be much greater; for example, having a bad reaction to the drug. The research team is required to explain to you the foreseeable risks of being in the study before you decide to be in the study.

ARE THERE BENEFITS TO BEING IN A RESEARCH STUDY?

In some research studies, you may benefit directly if an experimental drug or procedure helps treat a medical condition. Or you may learn more about yourself by answering questions and providing your opinion about a range of psychological and social questions. Sometimes, your participation in a study will not afford you any direct benefit, but will contribute to new scientific knowledge that may be a long-term benefit to society.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

You have the right to ask any questions you may have about a study and are encouraged to do so. You have the right to freely decide whether to participate in a study. Once you have decided to participate, and sign an informed consent form, you are still free to withdraw from the study at any time.

WHERE CAN I FIND OUT MORE ABOUT THE PROTECTION OF RESEARCH SUBJECTS?

The UB Human Research Protection Program, part of the Office of the Vice President for Research, provides access to additional information on the protection of research subjects, including resources for research volunteers, on its Web site at www.research.buffalo.edu/rsp/research_volunteers.cfm