

What is a research study?

A research study, sometimes also 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 lead 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 of Iowa, all studies that involve human subjects are reviewed by an Institutional Review Board (IRB) before they are allowed to begin.

What is an IRB?

An IRB is a committee of scientists and non-scientists who review projects submitted by researchers at The University of Iowa. Each IRB must also have at least one member who represents the community and is not affiliated with The University of Iowa. At The University of Iowa, there are two IRBs. One IRB reviews studies from researchers in Medicine, Pharmacy, Public Health, and Dentistry. The other IRB



reviews studies from researchers in the Colleges of Liberal Arts, Education, Engineering, Law, Nursing, and Business. Both IRBs consider the risks to the subjects, the anticipated benefits to the subjects and/or others, the importance of the knowledge that may be gained, the recruitment procedures, and the informed consent process that will be used.

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 kind 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, while others last for several years. The research team will describe to you all of the procedures that you will be asked to undergo before you agree to be in the study.

Are there any special rules to help protect certain subjects?

Children, pregnant women, prisoners, and persons with cognitive impairments can all be participants in research studies, but are considered potentially “vulnerable populations.” The US government and The University of Iowa have put in place special rules to protect participants who fall into one of these groups.

Are there risks to being in a research study?

Research studies may involve some degree of risk. A study that asks you to fill out a survey has only minor risks, such as answering questions that make you uneasy. 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 whether or not to be in the study.



Are there benefits to being in a research study?

Not everyone who participates in a research study will benefit personally. Sometimes, your participation in the research study will be of benefit to humanity by helping researchers to learn more about a certain disease or condition. In some studies, however, you may benefit if the experimental drug or procedure makes your disease stop progressing or lessens its effects on you.

Where can I find out more about being in a research study?

The University of Iowa advertises research studies in many ways, such as local newspapers, radio, and postings on bulletin boards. If you are interested in medical research about a specific disease or condition, you can also speak with your doctor or therapist about research studies for which you might qualify.

Finally, the University of Iowa Human Subjects Office has a web site that has information to help the public learn about research studies and being a research subject. The web site address is <http://research.uiowa.edu/hso>.

Where can I find out more about the IRB?

The University of Iowa Human Subjects Office web site is an excellent resource for learning about the functions and responsibilities of the IRB. If you are interested in being a community member on one of the IRBs at The University of Iowa, contact the Human Subjects Office, at 319/335-6564.



Provided by the Human Subjects Office, 300 CMAB, Iowa City, IA 52242-1101, <http://research.uiowa.edu/hso>

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

***Here are a few things
you ought to know . . .***