

# Glossary

This is a list of useful definitions of terms relevant to Research on Human Subjects.

## Consent Form

A [Consent Form](#) is used by any researcher who intends to work with human subjects in order to seek legally effective "informed consent from each prospective subject or the subject's legally authorized representative." Under federal regulations, this is a mandate, not an optional matter, because informed consent is "one of the primary ethical requirements underpinning research with human subjects," reflecting the principle of respect for persons.

Missing or inadequate Consent Forms are the most common reason for delays in the processing of IRB application.

## Cooperative (multi-site) Research

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. [45 CFR 46.114]

## DHHS

Department of Health & Human Services

## Exculpatory language

When the language used asks to waive (or appear to waive) any legal rights, or asks to release the investigator, any funding organization, Anoka-Ramsey Community College and/or Minneapolis Community & Technical College liability for negligence. When used, the subject is "signing away" rights.

## Formal Application

A Formal Application to the IRB is a federal requirement for faculty, students, and staff who plan to do Research on Human Subjects. It consists of

an [IRB application form](#), a [Consent Form](#), and a list of questions if the subjects will be interviewed.

### **IRB Application Form**

The [IRB application](#) is a form used by the ARCC/MCTC IRB Committee to approve Research on Human Subjects as required by the federal government

### **Legal Adult**

In Minnesota, a legal adult is a person at least 18 years of age.

### **Minimal Risk**

Minimal risk means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [45 CFR 46.102(i)]

Minimal risk means that the subjects' responses, if linked to identifying information, would not reasonably be expected to place the subjects "at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing." [63 FR 60364-60367, November 9, 1998]

### **OHRP**

Office for Human Research Protections

### **Primary Reviewer**

A member of the IRB Committee who is the first one to read the IRB application after submission.

### **Research**

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstrations and service programs may include research activities. [45 CFR 46.102(d)]

Research activities that involve human subjects and are conducted with the intent of presenting findings to external audiences, such as in a journal article or poster presentation at a conference are considered "research" and require IRB approval. Research activities that involve human subjects but are being conducted solely for educational purposes are not considered "research" and do not require IRB approval. Educational research activities that pose more than minimal risk (as defined above) to human subjects should be reviewed and approved by the researcher's supervisor prior to starting any research activities.

### **"Vulnerable Public"**

Children, prisoners, pregnant women, mentally disabled person, or economically or educationally disadvantaged persons.