

Glossary

This is a list of useful definitions of terms relevant to research on human subjects.

Consent Form - 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 - 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 - language used asks to waive (or appear to waive) any legal rights, or asks to release the investigator, any funding organization, or Thiel College from liability for negligence. When used, the subject is "signing away" rights.

Formal Application - 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 - form used by the IRB Committee at Thiel to approve research on human subjects as required by the federal government.

Legal Adult - in Pennsylvania, a legal adult is a person at least 18 years of age.

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

Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which 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)]

Thiel College Institutional Review Board

Research Supervisor - member of the faculty whose role is to sign IRB applications in the case where students are the investigators. Please note: this faculty member is not necessarily the student's academic advisor. The supervisor needs to be the individual overseeing the student research project.

Vulnerable Public - children, prisoners, pregnant women, mentally disabled person or economically or educationally disadvantaged persons