

Key Definitions in IRB Review Process

A. "Human Subject " (defined in 45 CFR 46.102f)

Notes: This definition does not include information obtained by observation in public places, from public records, or private information recorded in such a way that the subjects cannot be individually identified. Research in which aggregates (i.e., organizations, industries, communities) are the unit of analysis, or research on persons no longer alive, also do not constitute "human subjects" research.

B. "Research" (defined in 45 CFR 46.102e)

In practice, investigators may find it difficult to distinguish between "research" and "non-research" activities. Specifically, two kinds of investigations are difficult to classify: (1) activities designed to evaluate a school, business, institution, or individual; and (2) activities designed to provide students with an opportunity to discover for themselves already existing and accepted knowledge. The purpose of these guidelines is to help investigators identify clear cases of research that must be reviewed (at some level) by the Human Subjects Institutional Review Board or its designee.

Federal Regulations specify "research" as "a systematic investigation designed to develop or contribute to generalizable knowledge." In order to apply this definition, one must look at both the intention of the investigation and the dissemination of data gathered.

Research: In research studies the purpose of the activity will be to contribute to generalizable knowledge and any data gathered may be shared with a research or practitioner community or the public at large. These activities require the review and approval of the HSIRB (or its designee). This category includes "evaluation research" when the findings are potentially reportable to a wider community.

Evaluation: A member of the College community may agree to evaluate a program, school, institution, or individual. The purpose of the activity will be to develop information about the subject of evaluation. Any data gathered will be shared only with the client (and, if appropriate, the College faculty supervising the evaluation).

Inquiry: Faculty frequently assign inquiry activities that require students to discover for themselves known principles or phenomena. The purpose of these activities will be the education of the individual student through an inquiry approach. Any data gathered will be shared only with the course instructor.

Notes: Those engaged in evaluation or inquiry forfeit their rights to publish data as research data unless the HSIRB reviews the activity.

Research projects within the context of methods courses usually will require some form of IRB review. Because such courses are designed to lead students to conduct "research," it is considered appropriate that the students become familiar with the process of human subject protection.