

RSRB News

Activities that routinely do not require review by the RSRB

Case Report:

A summary of clinical data, including medical history and other relevant information, that was collected initially for the purposes of analyzing and diagnosing the individual's condition and/or for instructional purposes, is considered by the RSRB to be a 'case report' or 'case study'. Because this information was not collected with any intent to test hypotheses or otherwise produce 'generalizable' knowledge, the activity does not meet the criteria for 'research' (45 CFR 46.102 (d)), and ordinarily does not require RSRB oversight.

Program Evaluation:

Program Evaluation involves the systematic collection and analysis of information about the effectiveness of the program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. The intent of these projects is to inform particular programs about that program's effectiveness and needs rather than to contribute to generalizable knowledge, they are not considered research.

Quality Assurance and Quality Improvement (QA/QI) Projects:

QA/QI projects do not require RSRB review and approval except when they involve a "research" component as defined by the federal regulations. Precise definitions to permit the distinction between research studies and QA/QI projects have not been established but, in general, the intent of a QA/QI project is focused primarily on improving patient care within a given patient care environment (e.g., hospital or health care organization) and, as such, the results may not contribute to generalizable knowledge because the outcome may not be generalizable to other patient care environments. Publication of a QA/QI project does not, per se, render that project "research" because the intent was not for generalizable knowledge; however, if the QA/QI project is published, the terms "research" and "investigation" should not be used in the publication.

Research Methods Classes:

Universities and colleges offer courses that require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these courses is to train students and provide them with a closer view of social, educational, or psychological processes, and an opportunity to practice various research methods. Provided the data obtained will not contribute to generalizable knowledge or be published outside of the classroom they are not considered human subject research that require RSRB oversight.

Research On or Involving Deceased Individuals:

Research performed on individuals who have been declared legally dead and/or research involving the collection of tissues from deceased individuals is not subject to prior review and approval by the University of Rochester RSRB. (Note that the federal regulations governing human research subject protections defines a "Human Subject" as "a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the