

COMPARISON: CHARACTERISTICS OF HUMAN SUBJECT RESEARCH VS. OTHER PROJECT TYPES

Certain activities may have the characteristics of research and involve some level of interaction with people. However, IRB review is only required for projects that meet the federal definition of research involving human subjects. Please use the information below table to determine whether your project meets this federal definition. If the project has one or more of the characteristics in the first column, the project may require IRB review. If the project has none of the characteristics in the first column, please request a determination from the IRB and a formal response will be issued for your records.

	HUMAN SUBJECT RESEARCH	QUALITY IMPROVEMENT OR ASSESSMENT	PROGRAM EVALUATION	STUDENT PROJECT
INTENT	<p>45CFR46.102(d): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.</p> <p>Belmont Report: [T]he term ‘research’ designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.</p> <p>OHRP¹: “The question “what is research” frequently arises in relation to an investigator or institutional activity being planned to gather data to evaluate a specific program, such as a QA/QI activity. Although the determination as to whether the activity will contribute to ‘generalizable knowledge’ is often based on whether the data will be dissemination by means of publication or presentation, this should not be the sole factor used to make the determination. In general, OHRP gives guidance that if the data will be used to draw conclusions related to a larger entity then the activity is considered ‘research’.”</p>	<p>Intent of project is to improve a practice or process within a particular institution or ensure it conforms to expected norms.</p>	<p>Intent of project is to evaluate a specific program, only to provide information for and about that program.</p>	<p>Intent of project is to provide an educational experience about the research process or methods.</p>
MOTIVATION FOR PROJECT	<p>Project occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure; obtaining grants; completing a thesis or dissertation).</p>	<p>Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project.</p>	<p>Project not initiated by the evaluator and occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project.</p>	<p>Project occurs as part of assigned course/class work or a requirement of an educational program in order to learn a new technique or pass a course/fulfill an assignment.</p>
DESIGN	<p>Designed to develop or contribute to the scientific storehouse of knowledge; <u>may</u> involve randomization of individuals to different treatments, regimens, or processes; novel research ideas or experimental activities that are not yet known to be efficacious.</p> <p>May be designed to prove a relationship or correlation.</p>	<p>Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes.</p>	<p>Not designed to develop or contribute to generalizable knowledge; does not involve randomization of individuals, but may involve comparison of variations in programs.</p>	<p>Not designed to develop or contribute to generalizable knowledge; design is often an example or template provided by a professor or course book.</p>
MANDATE	<p>Activities not mandated by institution or program.</p>	<p>Activity mandated by the institution or clinic as part of its operations.</p>	<p>Activity mandated by the program, usually its funder, as part of its operations.</p>	<p>Activity mandated by regularly assigned coursework or educational program.</p>
EFFECT ON PROGRAM OR PRACTICE EVALUATED	<p>Findings of the study are not expected to directly or immediately affect institutional or programmatic practice; although they may also be used for this purpose.</p> <p>Activity will be used to develop a problem statement, research questions, and/or theory-based hypotheses.</p>	<p>Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed.</p>	<p>Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements.</p>	<p>Findings of project are not expected to directly affect the program; the project will mainly generate raw data, not generalizable knowledge.</p>
SUBJECT POPULATION	<p>45CFR46.102(f): Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.</p> <p>May involve a subset of individuals; universal participation of an entire population (e.g., clinic, program, or department) is uncommon; generally, statistical justification for sample size is used to ensure endpoints can be met.</p>	<p>Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals significantly affects conclusions.</p>	<p>Information on participants receiving a particular treatment or undergoing a particular practice or process expected to be used; exclusion of information from some individuals significantly affects conclusions.</p>	<p>Can either include all, most, or a subset of individuals; statistical justification may be used in the context to understand the process of subject selection; however, recruitment often utilizes convenience sampling.</p>
BENEFITS	<p>Participants may or may not benefit directly – benefit, if any, to individuals is likely to be incidental or delayed.</p>	<p>Participants expected to benefit directly from the activities.</p>	<p>No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue.</p>	<p>Participants may or may not benefit directly; benefit is primarily for the investigator conducting project for his/her own knowledge or fulfillment of educational requirements.</p>
DISSEMINATION OF RESULTS	<p>Intent to publish or present generally presumed at the outset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications, grant proposals, or other research/scientific forum; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies.</p> <p>Results of the project will be disseminated outside the institution for the purpose of sharing the <i>outcomes or implications</i> of the project, not just the <i>process</i>.</p>	<p>Intent to publish or present generally not presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge.</p>	<p>Intent to publish or present generally presumed at the outset of the project; dissemination of information to program stakeholders and participants; may be publicly posted (e.g., website) to ensure transparency of results; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge.</p>	<p>Any presentations, posters, or publishing (including online) is simply to document the educational experience or completion of programmatic requirements.</p>

¹ email from the Office of Human Research Protections (OHRP) to Robert W. Flint, Jr., PhD, College of Saint Rose
Sources: Belmont Report; University of Texas at Arlington IRB Office; OHRP; Jeff Cohen of HRP Associates