

COMPARISON: CHARACTERISTICS OF HUMAN SUBJECT RESEARCH VS. QUALITY IMPROVEMENT, PROGRAM EVALUATION OR CLASS/STUDY PROJECTS

Determining whether a project requires IRB review depends on whether it constitutes research involving human subjects (first column). Please contact the TLI Compliance/IRB Office (310-222-3624) with any questions or for assistance in making a determination.

	HUMAN SUBJECT RESEARCH	QUALITY IMPROVEMENT	PROGRAM EVALUATION	CLASS/STUDENT PROJECT
INTENT	Project is to develop or contribute to generalizable knowledge (e.g., testing a hypothesis).	Intent of project is to improve a practice or process within a particular institution or ensure it conforms with expected norms.	Intent of project is to improve a specific program , only to provide information for and about the setting in which it is conducted.	Intent of project is to provide an educational experience about the research process or methods.
MOTIVATION FOR PROJECT	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).	Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project.	Project not initiated by the evaluator and occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project.	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.
DESIGN	Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; novel research ideas supported by literature search.	Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes	Not designed to develop or contribute to generalizable knowledge; does not involve randomization of individuals, but may involve comparison of variations in programs.	Not designed to develop or contribute to generalizable knowledge; design is often an example or template provided by a professor or course book.
MANDATE	Activities not mandated by institution or program.	Activity mandated by the institution or clinic as part of its operations	Activity mandated by the program, usually its funder, as part of its operations.	Activity mandated by regularly assigned coursework or educational program.
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of the study are not expected to directly or immediately affect institutional or programmatic practice.	Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed.	Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements.	Findings of project are not expected to directly affect the program; the project will mainly generate raw data, not generalizable knowledge.
SUBJECT POPULATION	Usually involves a subset of individuals; universal participation of an entire clinic, program or department is not expected; generally, statistical justification for sample size is used to ensure endpoints can be met.	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.	Information on all or most participants within or affected by receiving a particular treatment or undergoing a particular practice or process expected to be used; exclusion of information from some individuals significantly affects conclusions.	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 sample.
BENEFITS	Participants may or may not benefit directly. If there is a benefit to participants, it is often incidental or delayed.	Participants expected to benefit directly from the activities.	No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue.	Participants may or may not benefit directly; benefit is primarily for the investigator conducting project for his/her own knowledge or fulfillment of educational requirement.
DISSEMINATION OF RESULTS	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.	Intent to publish or present generally <u>not</u> 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.	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.	No intent to present or publish results beyond the classroom, campus, or educational program; any presentations or posters is simply to document completed work/raw data for educational or programmatic requirements and/or to obtain experience.