COMPARISON: CHARACTERISTICS OF DIFFERENT TYPES OF PROJECTS

Determining whether a project requires IRB review depends on if it constitutes **HUMAN SUBJECT RESEARCH**. Please contact the WMed IRB (irb@med.wmich.edu) with any questions in making a determination.

	HUMAN SUBJECT RESEARCH	QUALITY ASSURANCE/ QUALITY IMPROVEMENT	PROGRAM EVALUATION
PURPOSE	Develop or contribute to generalizable knowledge (e.g. testing hypothesis)	Improve a practice or process within a particular institution or ensure it confirms with expected norms	Improve a specific program, only to provide information for and about the setting in which it is conducted
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
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 program
MANDATE	Activities not mandated by institution or program	Activity mandated by the institution or clinic as part of its operation	Activity mandated by the program, usually its funder, as part of its operations
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
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 of undergoing a particular practice or process expected to be used; exclusion of information from some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly – benefit, if any, to individuals is 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
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 research from other research studies	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/forums; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools, or provide benchmark 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 publically 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