CAPE FEAR VALLEY HEALTH

IRB Guidance: Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

When determining whether a project requires IRB review depends on whether it constitutes research involving human subjects. The table below is intended to help in determining whether a project requires submission to the IRB as a research project involving humans subjects. If the project involves some characteristics of a research project, submission to the IRB for review is expected. Please contact the IRB Office with any questions for assistance in making a determination.

	RESEARCH	QUALITY IMPROVEMENT	PROGRAM EVALUATION
INTENT	Intent of project is to develop or contribute to generalizable knowledge (e.g., testing hypotheses)	Intent of project is to implement knowledge, improve a practice or process within a particular institution or ensure it confirms with established/accepted standards	Intent of project is to improve a specific program. Project evaluations can be aimed at evaluating a program operations or evaluating its impact
MOTIVATION FOR PROJECT	Project occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure; obtaining grants).	Project occurs regardless of whether individual(s) conducting it may benefits 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.	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.
MANDATE	Activities not mandated by institution or program.	Activities mandated by the institution or clinic as part of its operations.	Activity mandated by the program, usually its funder, as part of its operation.
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of the project are not expected to directly affect institutional or programmatic practice.	Findings of the project are expected to directly affect institutional practice and identify corrective actions(s) needed.	Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements.
POPULATION	Usually involves a subset of individuals – universal participation of an entire clinic, program, or department is not expected; generally, statistical justification for sample sized 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 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.
PARTICIPANT OBLIGATION	No obligation of individuals to participate	Responsibility to participate as part of education or care	Responsibility to participate as part of education or care
RISKS	My place participant at risk	Does not increase risk to participants, with exception of possibly privacy or confidentiality of data	
BENEFITS	Participants may or may not benefit directly – benefit, if any, to individuals 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.
ENDPOINT	Answer a research question	Improve a program, process or system	
ANALYSIS	Test a hypothesis	Compare a program, process or system to established standards or to historical institutional data	
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 or other research/scientific fora; 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 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/for a; 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.
	RESEARCH	**QUALITY IMPROVEMENT**	**PROGRAM EVALUATION**
CLINICAL SETTINGS			
USE OF PLACEBO	Use of placebo may be planned.	Comparison of standard treatments, practices, techniques, processes – placebo would NOT be used.	
DEVIATION FROM STANDARD PRACTICE	May involve significant deviation from standard practice.	Unlikely to involve significant deviation from standard practice.	

Adapted from UW-Madison Health Sciences IRBs, version date 11/2/2008