Working Document: University of Wisconsin-Madison Health Sciences IRBs, version date 11/2/08

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 human subjects. If the project involves some characteristics of a research project, submission to the IRB for review is expected. Please contact your IRB Office with any questions or 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 improve a practice or process within a particular institution or ensure it confirms with expected norms	Intent of project is to improve a specific program
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 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	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	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
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of the study are not expected to directly 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
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 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
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
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 be 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/fora; 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
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	

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