SOUTHERN ILLINOIS UNIVERSITY
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Research vs. Quality Improvement and Program Evaluation

Quality Improvement and Program Evaluation activities are not explicitly defined in our federal regulations. Both activity types do share a commonality though. Generally, these types of activities do not meet the definition of human subject research, but there are gray areas which can complicate that determination. Researchers must ask themselves the following questions in this order:

1. Is the activity **research** as defined under §45 CFR 46.102 (l)? It is important to note that an intent to publish or present findings is not a sufficient criterion in determining whether a QI or PE activity constitutes research as defined in the federal regulations.

   If yes, then...

2. Does the research involve **human subjects** as defined under §45 CFR 46.102 (e).

If the answer to both questions is No, then the project likely qualifies as a QI/PE activity or may fall within one of the exceptions to research. **The investigator must submit a protocol to the SIUE IRB through Kuali Research and request a Not Human Subject Research Determination before beginning the activity.** The SIUE IRB will make the final determination of whether a project qualifies as Not Human Subjects Research.

To help investigators with this type of protocol submission, the table below summarizes the attributes of research, quality improvement, and program evaluation.

	Research	Quality Improvement	Program Evaluation
Intent	Develop or contribute to generalizable knowledge (e.g., testing hypothesis). Typically, research seeks to create new knowledge that can be generalizable to other populations and settings.	Intent to improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge.	Intent of project is to improve a specific program
Design	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization.	Not designed to develop or contribute to generalizable knowledge; adaptive, iterative design; may or may not be systematic; generally, does not involve randomization to different practices or processes	Not designed to develop or contribute to generalizable knowledge; does not involve randomization, but may involve comparison of variations in programs
Mandate	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations	Activity mandated by the program, program stakeholders, as part of its operations

Effect on Program or Practice Evaluated	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective actions if 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; no obligation to participate	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions	Information on all or most participant 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; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system: may or may not benefit participants.	No benefit to participants is expected. The evaluation concentrates on how to improve the program.
Risks	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
Analysis	Statistically prove or disprove hypothesis	Compare program, process, or system to established standards	Asks how well the program works and identifies improvements. The results should directly affect program practice or conduct.
Dissemination of Results	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; 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 disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge.	Intent to publish/present presumed from beginning. Present to program stakeholders. May present/publish widely to report potential effective models, strategies, tools, or provide benchmarks.

Adapted in part from the University of Wisconsin-Madison Health Sciences Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

The following QI/PE Checklist may also be useful in determining whether a proposed activity is QI/PE or human subjects research.

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QI/PE Checklist

Consideration	Question	Yes	No
PURPOSE	Is the primary aim or motive of the project either to: • Improve care/processes right now? OR • Improve operations, processes or efficiency?		
RATIONALE	Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change based on: • Literature, • Consensus statements, or • Consensus among clinician team?		
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback, and incremental changes?		
METHODS 2	Do the methods include any of the following: • Control group • Randomization • Fixed protocol		
RISK	Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes in processes of care)?		
PARTICIPANTS	Will the activity only involve participants (patients, parents, or staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place?		
FUNDING	Is the project funded by any of the following: • An outside organization with an interest in the results • A manufacturer with an interest in the outcome of the project relevant to its products • A non-profit foundation that typically funds research or by internal research accounts		

This screening checklist was developed by the Children's Hospital of Philadelphia

If all of the check marks are inside the shaded gray boxes, then the project is likely QI/PE and not human subjects research. However, even if you believe the project to be QI/PE, **you must still submit a protocol to the IRB for an official determination before conducting the activity.**