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Research vs. Quality Improvement

Since there is no regulatory definition for Quality Improvement (QI), determining whether an activity qualifies as research or QI can be difficult. Sometimes projects involve both QI and research. It is important to note that an intent to publish or present findings is not a sufficient criterion in determining whether a QI activity constitutes research as defined in the federal regulations (see §46.102 (l)). The table below summarizes the attributes of research and quality improvement.

	Research	Quality Improvement
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.	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
Design	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization.	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
Mandate	Activities not mandated by institution or program	Activity mandated by institution or clinic 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
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
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.
Risks	May place participants at risk	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
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.

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

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The following checklist may be useful in determining whether a proposed activity is QI or human subjects research.

Consideration	Question	Yes	No
PURPOSE	Is the primary aim or motive of the project either to: • Improve care right now for the next patient seen? OR • Improve operations 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 IRB.

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