Quality Improvement vs. Human Subjects Research: Quick Guidance

A Tallahassee Memorial HealthCare IRB Guidance Document

Purpose

This document provides guidance on when quality improvement/assurance activities may fall under the purview of the TMH IRB. Contact the TMH IRB Office at 850-431-2522 or IRBOffice@tmh.org if you have additional questions or need assistance regarding Quality Improvement projects.

Quick Points

- *Research* is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".
- *Quality review study* is defined as an "assessment, conducted by or for a Quality Improvement Organization, of patient care problems for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up".
- The HIPAA regulations define *health care operations* to include "conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs,…".

Discussion

"Generalizable" Debate: The Federal Regulations governing the protection of human subjects (45 CFR 46) define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". The section of this definition that causes researchers and IRBs the most confusion is the "designed to develop or contribute to generalizable knowledge". **Research activities tend to focus on creating new knowledge for the scientific community to benefit future patients, and focus less on the immediate care of the individual patient.[1] Quality improvement activities tend to focus on improving systems and organization performance based on findings from internal quality assurance activities (internal audits/gap analysis) with the intention to improve outcomes to benefit current patients.** A helpful and accurate way to determine if study activities are human subjects research, and therefore subject to human subject regulations, is to consider why the project is being done, and what it is designed to achieve. Clinical trials are designed to generate knowledge regardless of specific settings with the intent to disseminate research findings. Alternatively, quality improvement projects continuously evaluate the current state of patient care, identify problem areas, propose solutions, and re-evaluate if these solutions have produced improved quality of care.

The intent to publish and share the data from an internal quality improvement project does not automatically make the activity human subject research. Other hospitals may benefit from learning how our local hospital addressed a specific problem. Thus, quality improvement activities may be published and presented to other external parties without the requirement of initial IRB approval and oversight. However, quality improvement activities are still strongly encouraged to receive a Non-Human Subject Research Determination from the IRB.

The below table and checklist will assist you in determining if your project is Human Subjects Research or Quality Improvement.

[1] Newhouse RP, Pettit JC, Poe S, Rocco L. The Slippery Slope: Differentiating Between Quality Improvement and Research. JONA 2006:36(4):211-219

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HUMAN SUBJECTS RESEARCH VS. QUALITY IMPROVEMENT AT A GLANCE:

	RESEARCH	QUALITY IMPROVEMENT
INTENT & DESIGN	Intent of project is to contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; funding may be from outside organizations with interest in use of results.	Intent of project is to improve, based on existing evidence, a practice or process within a particular institution or ensure if confirms with expected norms; not designed to develop or contribute to generalizable knowledge; generally does not involve randomization/prospective assignment to different practices or processes.
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of the study are not expected to directly affect institutional or programmatic practices.	Findings are expected to directly affect institutional practice and bring about immediate change.
BENEFITS	Participants may or may not benefit directly – benefit, if any, to individuals incidental or delayed.	Local participants expected to benefit directly from the results of the activities.
RISKS	May put subjects at risk.	Does not increase risk to patients, with exception of possible patients' privacy or confidentiality.
ANALYSIS	Hold analysis until data collection complete to avoid biasing interpretation of results.	Analysis continuous – positive findings immediately implemented. Analysis of data enabled by legitimate access through institutional role.
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 forums; 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; provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge; title should include reference to the quality improvement project.
DEVIATION FROM STANDARD PRACTICE	May involve significant deviation from standard practice.	Unlikely to involve significant deviation from standard practice.

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HUMAN SUBJECS RESEARCH VS. QUALITY IMPROVEMENT CHECKLIST:

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, • 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 made in processes of care)?		
Participants	Will the activity only involve participants (patients, parents, or TMH 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 internal research accounts		
If all the check marks are inside the shaded gray boxes, then the project is very likely QI and not Human Subjects Research. **If the project is very likely QI utilize the Determination Form to submit to the TMH IRB to receive an official determination.** **For questions regarding a QI or Human Subject Research please contact the TMH IRB at IRBOffice@tmh.org.**			

Conclusions

- Focus on the intent, design, and the methods of the quality improvement activity when questioning if your project is QI.
- Inform the IRB if any changes occur to your quality improvement activity that may alter the initial determination.
- Contact the IRB if you have questions about your quality improvement activities.