THE UNIVERSITY OF TENNESSEE CHATTANOOGA

Institutional Review Board
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Quality Improvement vs. Research

Determining if an activity is Research or Quality Improvement (QI) can be challenging. Federal regulations require human subject research to be approved by the IRB, while strictly QI activities do not require IRB oversight. However, some QI activities may also include research and therefore require IRB approval. Both research and quality improvement are systematic investigations that may involve human participants, but they differ in important ways.

Definitions

Research is defined in 45 CFR 46.102(d) and 45 CFR 164.501 as: "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Quality improvement (QI) in health care, unlike research, focuses on translating existing knowledge from research into clinical practice to improve the quality of health care for individuals and populations. There is no regulatory definition for QI, however it is often described as ""A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product" Source: The Institute of Medicine.

The key difference between these two concepts is that research studies are intended to create new knowledge that can be generalizable to other populations and settings, while QI in health care uses existing knowledge to improve health care outcomes within a local health care institution or setting.

When an activity involving the inclusion of people is intended to evaluate an existing practice and attempt to improve it based upon existing knowledge, and if the data from the evaluation is not intended to be applied to populations other than the population under study, then the IRB would not classify this activity as research, and the activity would not be subject to the DHHS human research regulations.

Examples of QI activities that are likely NOT research include:

- Implementing a practice to improve the quality of patient care
- Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes
- Measuring and reporting provider performance data for clinical, practical, or administrative uses
- A group of affiliated hospitals implements an application to reduce prescription amount errors, and collects patient prescription information from medical charts to assess whether the application helped reduce error rates as expected.

Intent to Publish

The intent to publish is an insufficient criterion for determining whether a QI activity involves research. Even planning to

publish an account of a QI project does not necessarily mean that the project fits the definition of research. People seek to publish descriptions of non-research activities for a variety of reasons, including, for example, if they believe others may be interested in what worked at another institution. Dissemination of QI efforts will require timely publication and sharing of information to create awareness of lessons learned, as well as what QI projects work well within each other's institutions.

When is IRB approval needed for QI activities?

A QI activity may also constitute human subject research if it meets the definition of research.

IRB approval may be required when the activity involves some of the following characteristics:

- seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge;
- when the methodology employs a standard research design, such as randomization;
- when the protocol is fixed with a rigid goal, methodology, population, time period, etc.;
- when the funding for the activity comes from the outside organizations such as the NIH or those with a commercial interest in the results;
- when there will be a delay in the implementation of results;
- when the risks from the intervention to participants are greater than minimal

How Does QI differ from Research?

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	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 action(s) needed
POPULATION	Unusually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	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

Quality Improvement or Research Checklist

The following questions may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects research. If all of the questions below can be answered as a Yes, IRB review is not required. If the answer to any of these questions is no, please consult with the IRB for assistance since IRB review may be required.

PROJECT DESCRIPTION	YES	NO
Purpose Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?		
Scope Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?		
Evidence Is there sufficient existing evidence to support implementing this activity to create practice change?		
Clinicians/Staff Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?		
Methods Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?		
Sample/Population Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?		

Consent Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?		
Benefits Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?		
Risk Is the risk to patients/participants no greater than what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?		

Sources

Code of Federal Regulations. Department of Health and Human Services. Effective 14 July 2009, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

OHRP Quality Improvement Activities Frequently Asked Questions. U.S. Department of Health and Human Services, http://www.hhs.gov.

"Quality Improvement Activities in Health Care Versus Research." Duke University Health System Human Research Protection Program, 3 March 2016, https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/QI_policy_and_checklist_4-30-2013jw.pdf.

"Quality Improvement vs Research." Children's Hospital of Philadelphia Research Institute, https://irb.research.chop.edu/quality-improvement-vs-research.

"Quality Improvement vs. Research – Do I Need IRB Approval?" Virginia Commonwealth University Office of Research and Innovation, https://research.vcu.edu/human_research/research_qi_guidance.pdf.