

Northwestern University IRB Guidance on Quality Improvement and Program Evaluation Projects

Determining if an activity is **Research** or **Quality Improvement (QI)/Program Evaluation (PE)** can be challenging. Federal regulations require human subjects research to be reviewed and approved by the IRB, while activities that are solely QI/PE do not require IRB oversight. However, some QI/PE activities may also be research and therefore need IRB approval. This Guidance provides assistance in determining which projects are solely QI/PE, which are human subjects research, and which are both QI/PE and research.

If you are unsure whether your project is human subjects research, you may request a determination by the IRB – you must submit your request using the Human Research Determination Form (HRP-503), which is available on the IRB website. If your project has external funding from a federal agency or other organization that indicates the funder views the project as human subjects research, you must take that into consideration in deciding whether IRB review is needed for your project.

Definitions and Criteria

Quality Improvement (QI):

There is no regulatory definition for QI. 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. (Institute of Medicine). QI is designed for the purpose of improving the quality of a service, a program, a process, etc.

Program Evaluation (PE):

PE is a systematic method for collecting, analyzing, and using information to answer questions about projects, policies and *programs*, particularly about their effectiveness and efficiency. The purpose of PE is to assess that a program is doing what it is intended to do.

Research:

The IRB regulations define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Systematic Investigation:

An activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, many non-research activities also include systematic investigation. Conducting a systematic investigation does not, in and of itself, mean that a project is “research” requiring IRB review.

NOTE: The intent to publish findings is an insufficient criterion for determining whether a QI activity constitutes research. Simply because a project intends to publish its findings does not render that project “research” as defined in the IRB regulations.

The following table summarizes characteristics of QI/PE and research:

Research vs. Quality Improvement Comparison

	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	Usually 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

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

Examples of QI/PE activities that are NOT research include:

Implementing a practice to improve the quality of patient care, and collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes does not satisfy the definition of “research” in the IRB regulations, and the IRB regulations therefore do not apply to such quality improvement activities.

Similarly, measuring and reporting provider performance data for clinical, practical, or administrative uses would not require IRB review. The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

Examples of projects that are QI/PE and NOT human subjects research:

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.
- Assessing whether a campus security training course improves knowledge of faculty, staff, and students.
- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.
- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

Please see [HHS FAQs on Quality Improvement](#) for more information.

Examples of Activities that are likely QI/PE AND Research:

- A project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results.
- Collaborative (multi-site) – All the sites are trying to improve some aspect of clinical care (ex. implementing an application to help improve making clinical decisions). The whole department decides this app will improve care, and implement the app. They collect data as the app is implemented, and in addition, analyze this data for generalizable knowledge.
- A teacher implements a practice to have all students reflect on their learning by keeping a journal, with the intention of improving teaching practice. However, the teacher also wants to prove that this method works, so the teacher analyzes student journals with grades to generalize the success of this method.

Examples of Activities that Begin as QI/PE and Become Research:

If you begin QI/PE activities with the intent to eventually use the activity or data for research, it is best to submit to the IRB prior to beginning the activity. However, if after a QI/PE project is completed, you want to study it further and make it generalizable (research), then IRB submission is required (typically using secondary data).

For example:

- A QI/PE project is implemented, and upon completion, the investigator realizes they want to do research about the project and interview clinicians. The data they will collect from the interviews will be used for research, therefore, they would submit to the IRB before beginning interviews.
- A team uses biologic samples to compare two different types of tests to determine which one is better and therefore which one should be used at NU [intent to improve care at NU]. After they complete the comparison, they realize they want to share the success of these tests because they believe it will help other institutions [intent to contribute to generalizable knowledge]. They then submit to IRB and request to use the data collected for the QI/PE project as secondary data for research.

- A surgeon believes that a certain technique will improve their own practice, so they implement it and record results as part of clinical practice. They then decide that this practice would help others, so they go back to their data to systematically analyze and generalize outcomes and results. They would need to submit to the IRB prior to the review of gathered data.
- A school decides to begin an afterschool program to help with academic success. The school gathered academic data which proved that the program was successful. After a few years of the program being a success, someone decides that they want to share that program with others. They can submit to the IRB to be able to analyze the previously collected data.

Publishing the findings of QI/PE Projects

Even though most QI/PE activities aren't research, there is much to be learned from sharing descriptions of these non-research activities. Guidelines developed by SQUIRE (Standards for Quality Improvement Reporting Excellence) provide a framework for reporting the findings of QI/PE initiatives. (See <http://www.squire-statement.org/>)

When discussing QI/PE projects in publications and presentations, do not refer to QI/PE as research.

If the project was not submitted to the IRB for a determination, the following statement may be included in the manuscript/presentation: "This project was undertaken as a Quality Improvement project and as such does not constitute human subjects research."

If the project was reviewed by the IRB and was determined not to be human subjects research, the following statement can be included in the manuscript/presentation:

"This Quality Improvement project was reviewed by the Northwestern University Institutional Review Board and determined not to meet the criteria for human subjects research."

Quality Improvement/Program Evaluation or Research Checklist*

This checklist will help you determine whether a proposed project is QI/PE or potentially human subjects research. If all of the check marks are inside the shaded gray boxes, then the project is very likely QI/PE and not human subjects research. Projects that are not human subjects research do not need review by the IRB.

Consideration	Question	Yes ✓	No ✓
PURPOSE	Is the primary aim or motive of the project either to: <ul style="list-style-type: none"> • Improve care/processes right now? <li align="center">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: <ul style="list-style-type: none"> • 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? <ul style="list-style-type: none"> • Control group • Randomization • Fixed protocol 		
RISK	Is the risk related to the project minimal and no more than usual care or practices (including the unavoidable minimal risk in implementing any changes made in processes of care)?		
PARTICIPANTS	Will the activity only involve participants (patients, parents, students, 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? <ul style="list-style-type: none"> • 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 QI/PE screening checklist was developed by the Children’s Hospital of Philadelphia IRB – we thank the CHOP IRB for allowing us to include this checklist.