

Guidance: Research Activities vs Quality Assurance or Improvement

Overview

Quality Assurance/Quality Improvement (QA/QI) and research activities both use scientific methodology, so it is difficult to define research activities that require IRB review by the methods they employ. The purpose of this document is to outline differences between research and QA/QI activities and to provide examples of QA/QI activities that are not research, QA/QI that may be both research and QA/QI, and QA/QI activities that become research.

Definitions

There is no regulatory definition, but often QA/QI is described as “systematic, data-guided activities designed to bring about immediate (or nearly immediate)”¹ improvements to educational outcomes, system performance, professional development, health care, or other processes. QA/QI can occur in clinical settings (for example, modifying nursing rotations) or non-clinical settings (for example, improving curriculum or a business practice).

Does my QA/QI project constitute human research and require review?

QA/QI activities designed solely for internal purposes, with no external application or generalization, usually do not constitute human subject research and usually do not require IRB review or exemption. These QA/QI activities do not meet the regulatory definition of research because they are solely designed for QA/QI purposes.

QA/QI activities may also include or introduce a research component and constitute human subject research, and therefore require IRB review or exemption, when they are *also* designed to develop or contribute to generalizable knowledge. These QA/QI activities meet the regulatory definition of research, and therefore are both research and QA/QI.

See [HHS guidelines and FAQs](#) for more info.

What are some differences between Research and QA/QI?

Points to consider	Research	QA/QI only
Purpose	Designed to contribute to generalizable knowledge.	Not intended or designed to contribute to generalizable knowledge; designed to assess or promptly improve a

¹ Lynn J, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med* 2007;146:666-674

		process, program, performance, or system..
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
Population	Usually involves a subset of individuals representative of a broader population; 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	Designed to contribute to generalizable knowledge and participants may or may not benefit directly.	Designed to promptly benefit a process, program, performance, or system.
Analysis	Statistically prove or disprove a hypothesis.	Compare program, process or system to established standards.
Dissemination of Results	Intent to disseminate results presumed at the outset of project; 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; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, etc. rather than to develop or contribute to generalizable knowledge

Examples of QI activities that are likely not considered research

- Creating a new submission form and evaluating how the new form speeds up turnaround times via analysis of turnaround times and interviews with key stakeholders. While other universities might find the results interesting, the form is very specific to Northeastern’s portfolio and, therefore, the results are not generalizable.

- Implementing a practice to conduct depression screening at patient intake. Chart reviews will track the number of referrals and data will be presented to leadership to help them determine if the practice should continue. Since results will only be used for internal use, the activity is not generalizable.
- Conducting a new type of educational outreach in the form of monthly presentations. Attendees will be asked to take a survey of how they felt the presentation helped them and attendance data will be collected to help inform how future presentations should be conducted. While other universities might find the results interesting, data is too specific to Northeastern to be generalizable.

Examples of activities that are likely QI and research

- A research team asks teachers to have all students reflect on their learning by keeping a journal, with the intention of improving teaching practices. This new activity will be conducted in several classrooms in a couple of schools. The research team aims to determine whether journaling will help students retain knowledge when compared with control classrooms. While the activity will help improve teaching at the schools it is occurring in, by conducting it in several classrooms and having intervention and control arms, it is also designed to produce generalizable knowledge about how students learn.
- A researcher wants to pilot an interventional program at Northeastern. The program will monitor student grades, attendance, and dining hall usage to flag students for referrals to counseling. The researcher hopes that this pilot data will demonstrate that the program can be implemented at universities across the country. While this is occurring at Northeastern, it is designed to demonstrate whether the program can be implemented outside the limited setting and, as such, the resulting knowledge is intended to be generalizable.

Activities that begin as QI and become research

Please note: If you begin QI activities with the intent to use the activity or data for research eventually, it is best to submit to the IRB prior to beginning the activity. However, if after a QI project is completed, you want to study it further and make it generalizable, it is then defined as research and an IRB application is necessary.

- A school starts an after-school 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, because of the amount of data, it is clear that the data could demonstrate that the after-school program can be effective outside the district. Data from the QA/QI project will be collected and re-analyzed with an eye towards demonstrating the generalizability of the project.

- A QI project was implemented, and upon being completed, the investigator realizes they want to research the project and interview stakeholders to collect additional data to demonstrate the generalizability of the project. The data they will collect from the interviews will be used for a research project; therefore, they will need to submit to the IRB before beginning these interviews.
- A researcher believes that a certain technique will improve their own practice, so they implement and record results as part of standard 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. The new analysis of the data is intended to yield generalizable results.

References & Resources

- Lynn J, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med* 2007;146:666-674
- Lo B, Field MJ, eds. *Conflict of Interest in Medical Research, Education, and Practice*, National Academies Press, 2009. http://www.nap.edu/catalog.php?record_id=12598, p. 29
- [DHHS: Quality Improvement Activities FAQ](#)
- [University of California at San Francisco](#)
- [Virginia Commonwealth University](#)
- [The Ohio State University](#)