

Quality Improvement vs Research

	Human Subjects Research	Quality Improvement
Purpose	designed to develop or contribute to generalizable knowledge	designed to implement knowledge, assess a process or program as judged by established/accepted standards
Starting Point	knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	knowledge-seeking is integral to ongoing management system for delivering health care
Design	follows a rigid protocol that remains unchanged throughout the research	adaptive, iterative design
Benefits	might or might not benefit current subjects; intended to benefit future patients	directly benefits a process, system or program; might or might not benefit patients
Risks	may put subjects at risk	does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data
Participant Obligation	no obligation of individuals to participate	responsibility to participate as component of care
Endpoint	answer a research question	improve a program, process or system
Analysis	statistically prove or disprove hypothesis	compare program, process or system to established standards
Adoption of Results	little urgency to disseminate results quickly	results rapidly adopted into local care delivery
Publication/Presentation	investigator obliged to share results	QI practitioners encouraged to share systematic reporting of insights

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.
- Training activities, unless the training activity is conducted for research purposes

Examples of Activities that are likely QI 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 they analyze student journals with grades to generalize the success of this method.

Examples of Activities that Begin as QI and Become Research

Please note that if you begin QI 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 project is completed, and you want to study it further and make it generalizable (research), then IRB submission is required (typically using secondary data).

A QI 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 VCU [intent to improve care at VCU]. 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 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 QI findings

QI projects are generally in-house activities that aim to determine if a particular treatment or procedure at an institution is meeting expected standards. If deficiencies are detected changes might be made to clinical practice, local guidelines updated or staff training provided. QI findings are typically specific to the institution in which the activity was conducted and so the results are usually only disseminated within that institution or health service. Data from a QI project may be published. When QA/QI is published or presented, the intent is usually to discuss potentially effective models, strategies, assessment tools or to provide benchmarks, rather than to develop or contribute to 'generalizable' knowledge. The intent to publish is an 'insufficient criterion' for determining whether a quality improvement activity involves research, according to OHRP. At PHS all Student/ Resident are responsible for submitting a Student / Resident Application in order for a IRB reviewer to determine if their project constitutes as QI or human subject researcher.

What is Generalizable knowledge?

"Generalizable knowledge" means that the intent of the research is to add information to your field of study; the results can be applied beyond the subject population to other settings. It doesn't matter if the results will be published or not, if your research activity is designed with the aim of discovering information that can be applied in other settings, it can be considered research.