

Quality Assurance and Quality Improvement (QA/QI) FAQs

What is QA/QI?

Quality Assurance (QA) and Quality Improvement (QI) are complementary endeavors for attaining continual improvement in health care quality. QA/QI generally refers to a range of activities conducted to assess, analyze, critique, and improve current processes of health care delivery in the local institutional setting. QA/QI activities are typically observational and unobtrusive and can involve the collection and analysis of data to which investigators have legitimate access through their institutional roles. These activities do not prevent or hinder the delivery of clinically indicated care to patients, nor do they impose more than minimal additional risks or burdens on patients.¹

QA can be defined as an effort to find and overcome problems with quality, directing the performance and behaviors of practitioners and institutions toward more appropriate and acceptable health outcomes, expenditures, or both. The central QA question is reactive, “Are we doing a task/procedure the way it is supposed to be done?” QI activities are intended improve services or clinical care based on a known issue through a “plan, do, check, act” cycle. With this cycle, processes can be continuously revised and improved on the basis of the data derived from them. The central QI question is proactive, “How can we improve the way we do things?”.

In medical institutions, QA/QI is a necessary, integral part of hospital operations and is not subject to review as research, as defined under federal regulation. Rather, it is governed by Joint Commission and hospital standards. Human Subject Research (HSR) is governed by federal regulation, under IRB oversight.²

What are some differences between QA/QI and Research?³

Points to consider	Research	QA/QI
Purpose	To test a hypothesis OR establish clinical practice standards where none are accepted	To continuously assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards
Starting Point	To answer a new question or test a hypothesis	To improve performance or patient care
Benefits	Designed to contribute to generalizable knowledge and may or may not benefit subjects	Designed to promptly benefit a process, program, or system and may or may not benefit patients
Risks/Burdens	May place subjects at risk and stated as such	By design, does not increase patient’s risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer a research question	Promptly improve a program/process/system
Testing/Analysis	Statistically prove or disprove a hypothesis	Compare a program/process/system to an established set of standards.
Participant Obligation	No obligation of individuals to participate	Responsibility to participate as component of care
Effect on program or practice	Findings are generally not expected to immediately affect or change practice	Findings are expected to directly and immediately affect institutional practice

What are some examples of outcomes, goals and examples of QA/QI projects?

- ensuring new evidence-based interventions are incorporated into practice
- improvement of over-all quality of life
- reduction of morbidity and mortality
- ensuring that patients receive evidence-based interventions for their particular illness
- improvement in patient and family comprehension
- reduction in in-patient admissions and length of stay
- reduction of ER visits
- reduction in costs of service
- comparing usual care practices

QA and QI consist of systematic, data-guided activities to bring about prompt positive changes in the delivery of health care and involve deliberate actions to improve care, typically at the ***institutional level***. Introducing QA/QI methods often means encouraging people in the clinical care setting to use their daily experience to identify ways to improve care, implement changes on a small scale, collect data on the effects of those changes, and assess the results.⁴

A few examples of QA/QI projects include:

- Implementing a new process or checklist in order to reduce pharmacy prescription error rates
- Implementing evidence-based interventions and collecting data on them
- Improvement in patient and family comprehension of medication dosing through use of teach-back method
- Reduction of in-patient admissions and length of stay through use of a new discharge checklist
- Reduction of time in the ER through use of a new triaging method
- Reduction in costs of prescriptions by converting to generic medications

Activities conducted by ***one or more institutions*** are considered to be QI rather than research when the ***primary purposes*** are limited to:

- (a) implementing a practice to improve the quality of patient care, and
- (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes

What is a Learning Health Care System?

Traditional definitions are becoming more and more blurred as a new model of health care is emerging in which practice and learning are integrated, and where a central goal of the health care system is to collect, aggregate, analyze and learn from patient-level data (learning health care systems).⁵ This paradigm suggests that a learning health care system is a natural outgrowth and product of health care delivery that does not need to be subject to oversight by the IRB in many instances.

In contrast, what is Human Subjects Research (HSR)?

The Office of Human Research Protections (OHRP) defines ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(i)). For example, if a project is designed to test a novel hypothesis, replicate another researcher's original study, or withhold any aspect of conventional care shown to be beneficial in prior studies, OHRP's definition of human subject research would apply.

The FDA does not use the term research, but considers it to be synonymous with **clinical investigations**, meaning any experiment that involves a test article and one or more persons and that either must meet the requirements for prior submission to the FDA, or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. (21 CFR 56.102(23)(c)). For example, if you are comparing or assessing the safety and/or effectiveness of a drug, comparing a regulated device to another or assessing effectiveness of a device, you are engaged in a clinical investigation and must follow FDA regulations.

Can a project be both QA/QI and Human Subject Research?

Yes. Under certain conditions, a QI project may also constitute human subjects research (HSR) under HHS regulations. Such may be the case if the project involves introducing an untested clinical intervention for purposes to improve the quality of care but also collect information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results. The following characteristics **make it more likely** that a project involves both QA/QI and research and would fall under the jurisdiction of both the Hospital and IRB. Consult with the IRB if you are uncertain.

- Randomization of patients into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection (but not to achieve equitable allocation of a scarce resource).
- Testing issues that are beyond current science and experience, such as new treatments.
- The involvement in key project roles of researchers who have no ongoing commitment to improvement of the local care situation.
- Delayed or ineffective feedback of data, especially if feedback is delayed or altered in order to avoid biasing the interpretation of results.
- Funding from an outside research organization with an interest in the use of the results.⁶

If a study includes randomization, is it always considered HSR?

No, not always. Some QA/QI projects may involve randomization although this type of study design is seen more commonly in human subject research. When the intent is to develop generalizable knowledge or test a hypothesis, the project is likely to be considered HSR. As QA/QI projects involving randomization may fall in a gray area, consulting with the IRB for a determination of HSR is strongly recommended.

Is it research if I intend to publish?

No, the intent to publish is an insufficient criterion for determining whether a QA/QI activity involves research, according to OHRP. When QA/QI is published or presented, the intent is usually to discuss potentially effective models, strategies, and assessment tools, or to provide benchmarks, rather than to develop or contribute to generalizable knowledge.⁷

What is generalizable knowledge?

"Generalizable knowledge" is information where the intended use of the results can be applied to populations or situations beyond that studied. A QA/QI study where the **intent** is to assess, improve, or develop programs or services for an organization would NOT be considered generalizable.⁸ Outcomes will remain specific to the organization, programs or services, although other organizations may use the results for their own programs. If the findings are unique to your organization, it is not generalizable.⁹

What if I am getting funding for my project?

Outside external funding may make a difference in distinguishing between QA/QI and research. An NIH research grant to support a project would often be considered research. Internal funding to improve a program may not.

What if I need to access PHI?

HIPAA makes an exception for QA/QI activities, including outcomes evaluation and development of clinical guidelines or protocols. These activities fall under the category of 'health care operations' for which no HIPAA Authorization or Waiver of Authorization needs to be sought. The hospital's Privacy Office can authorize the use of PHI for QA/QI projects. **However, the health care operations exception does not apply to research activities.**

What if I still don't know if I need IRB review?

[Submit an application](#) for Determination of Human Subjects Research through the UNC Office of Human Research Ethics (UNC IRB) and/or contact irb_questions@unc.edu or 919-966-3113 if you are still uncertain how to proceed. A **Not Human Subjects Research (NHSR)** application is typically used for QA/QI activities when seeking a determination from the IRB.

UNC Resources

- UNC OHRE [Standard Operating Procedures](#) (SOPs)
- [UNC Institute for Healthcare Quality Improvement](#) Resources website
- UNC IRBIS (online submission system) - <https://irbis.research.unc.edu/irb/>

References

- 1 Carillion Clinic Institutional Review Board, *Application to Determine if Project is Quality Assurance/Quality Improvement*, August 2012, Roanoke VA.
- 2 Stanford University HRPP, Quality Assessment and Quality Improvement (QA/QI) FAQs; <https://stanfordmedicine.box.com/shared/static/nvuzhf3pjqrzx4890jax7uwbglbxcp4.pdf>
- 3 *Distinction: Human Subject Research – vs. – Quality Improvement*, OASD(HA)/TMA, HRPP at Tricare, Human Research Protection Program, Falls Church, VA.
- 4 [Baily, MA, *The Ethics of Using QI Methods to Improve Health Care Quality and Safety*, A Hastings Center Special Report, July-August 2006, p. S5.](#)
- 5 [Kass N, Faden R, et al. "The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight," *Ethical Oversight of Learning Health Care Systems, Hastings Center Report Special Report 43*, no 1 \(2013\): S4-S15. DOI: 10.1002/hast.133.](#)
- 6 [Doezema D, Hauswald M, " , *Distinction without a Difference? Quality Improvement vs. Research*," from a lecture given January 2010, American Health Lawyers Association, Legal Issues Involving Academic Medical Centers and Other Teaching Institutions,](#)
- 7 [Quality Improvement FAQs from OHRP Guidance](#)
- 8 [Defining Research](#), The University of Iowa; <https://hso.research.uiowa.edu/defining-research#1>.
- 9 [How do the federal regulations define research](#), Harvard University; <https://cuhs.harvard.edu/definition-research>.