Quality Improvement/Quality Assurance (QI/QA) is often described as "systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery"[1], and the combined efforts of everyone to make changes that will potentially lead to better patient outcomes, better system performance, and better professional development.[2] In medical institutions, QI/QA 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 accreditation and hospital standards.

Research is defined in 45 CFR 46.102(d) and 45 CFR 164.501 as "a systematic investigation, 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. 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.

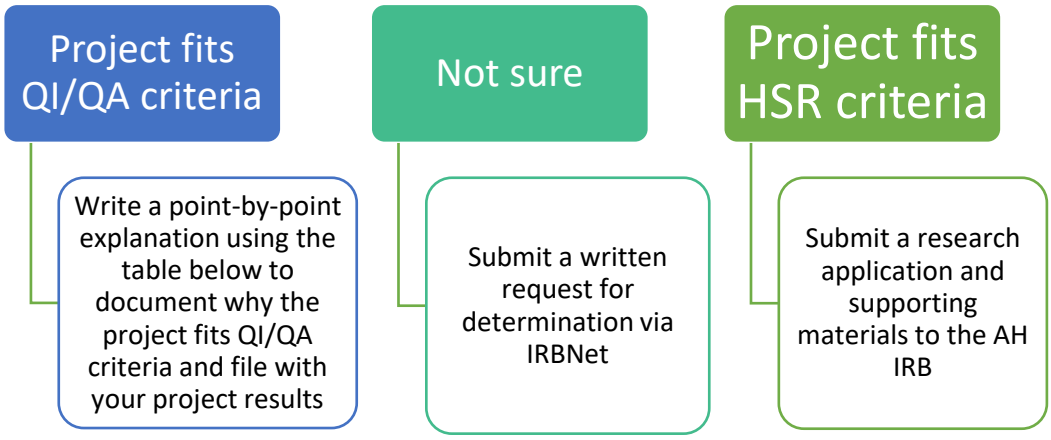
Because QI/QA activities are data-driven and involve human participants, there can be overlap with research methodologies common to human subjects research. Where overlap exists, the federal regulations that protect human research participants may apply.

When an activity involving the inclusion of people is intended to 1) evaluate an existing practice and attempt to promptly improve it and 2) the data from the evaluation is not intended to be applied to populations other than the population under study, then the IRB would likely not classify this activity as research, and the activity would not be subject to the DHHS human research regulations.

When an activity involves the inclusion of people to test a new, modified, or previously untested intervention, service, or program for which there is insufficient evidence to determine whether it is safe and/or effective, this is research involving humans, and it is subject to IRB review and approval. A comparative intervention study examining two evidence-based methods, with people randomized between the two methods to determine which is better, is also regarded as research involving humans.

NOTE: The IRB has no oversight of QI/QA projects and does not grant approval for their conduct. You must follow any departmental requirements and organizational policy regarding the conduct of QI/QA projects once the IRB has provided its determination.

Evaluate your project against the below QI/QA and HSR information and follow the below diagram.



What are some differences between QI/QA and Human Subjects Research (HSR)?

Both research and quality improvement are systematic investigations that may involve human participants, but they differ in important ways.

Points to consider	Research	QI/QA
Purpose	To test a hypothesis or establish clinical practice standards where none are accepted AND develop or contribute to generalizable knowledge	To assess or promptly improve a process, program, or system; or improve performance as judged by accepted/established standards
Starting Point	Independent of routine care	Integral to ongoing management and delivery of healthcare
Design	Follows a rigid protocol that remains unchanged throughout the process	May adapt and change based on the knowledge gained
Benefits	May or may not benefit subjects	Designed to promptly benefit a process, program, or system; may or may not directly benefit patients
Risks/Burdens	May place subjects at risk and stated as such	Does not increase patient risk, with exception of possible privacy/confidentiality concerns
Participant Obligation	Individuals may choose whether or not to participate	Individuals are subject to the activity as a component of care or practice
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.
Publication/Presentation	Obligation to share results with the scientific community	Encouraged to share insights with the institution and externally, when applicable

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What are some examples of QI/QA?

- ensuring new evidence-based interventions are incorporated into practice
- improvement of over-all quality of life
- studying the effect of education on nursing practice
- ensuring that patients receive evidence-based interventions for their particular illness
- improvement in patient and family comprehension

- reduction in in-patient admissions, ER visits, costs of service, length of stay, etc.
- usual care practices, and
- interventions offered to all patients.[4]

QI/QA 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.

Introducing QI/QA 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.[5]

Can a project be both QI/QA and HSR?

Yes. The following characteristics **make it more likely** that a project involves both QI/QA and research and would fall under the jurisdiction of both the hospital and IRB.

- 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.
- 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]

Is it research if I intend to publish?

By itself, intent to publish is not sufficient to require IRB review and approval. When QI/QA 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.[7]

Data presented externally must be formatted in a way that is not in conflict with patient safety work product guidelines. It is recommended that you consult with AdventHealth Risk Management.

What if I need to access PHI?

HIPAA makes an exception for QI/QA 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. These activities are subject to POLICY CW CR 640 and CW CR 605. For questions, contact your AdventHealth Privacy Office.

What if I am sharing results?

If you will be sharing QI/QA findings with external companies or institutions, contact AdventHealth Legal. If you will be sharing data or data sets with anyone outside your department, you must contact your AdventHealth Legal department to determine what agreements will be needed.

Can I conduct QI/QA for education/degree requirements?

Yes. You must have a sponsoring department and AdventHealth must have an agreement with your school or university for you to conduct a QI/QA project to fulfill a course or degree requirement. For more information, students should contact their sponsoring AdventHealth department representative. Advanced Practitioner students must apply with our Graduate Medical Education (GME) department at https://www.adventhealthorlandogme.com/

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

Submit a request in the IRB electronic submission system, utilizing "1B Form: Determination of QIQA vs Research." For help with this process, contact the AdventHealth IRB at 407-200-2677 or orl.irb.general@adventhealth.com. If you do not seek written determination from the IRB based on this guidance, it is important that you maintain documentation of your own determination that the project is solely QI/QA.

Resources and References

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

[2] Lo B, Field MJ, eds. *Conflict of Interest in Medical Research, Education*, and Practice, National Academies Press, 2009., p. 29.

[3] *Distinction: Human Subject Research – vs. – Quality Improvement*, OASD(HA)/TMA, HRPP at Tricare, Human Research Protection Program, Falls Church, VA

[4] Dubler N, *A Process of Quality Improvement: Informed Participation and Institutional Process*, from a lecture given at Yale University 10/23/2008, Montefiore-Einstein Center for Bioethics, The Albert Einstein College of Medicine

[5] 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,

[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: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html