

QA/QI vs. Research: Do I Need to Submit for an Exemption or IRB Approval?

There is often confusion in determining whether Quality Assurance (QA) or Quality Improvement (QI) activities fall within the category of research and require submission for an exemption from IRB review or IRB review and approval or do not.

What is QA/QI?

Quality Assurance is defined as a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Quality Improvement is a formal approach to the analysis of performance and systematic efforts to improve it.

Key Concepts

- Quality assurance (QA) and quality improvement (QI) projects may be considered research when there is a hypothesis or question being answered and the information being collected is designed to contribute to generalizable knowledge (i.e. beyond the context of the specific institution(s) conducting project).
- Whether these projects are research is determined by the IRBO on a case by case basis.
- The IRBO makes this determination by evaluating a group of factors including the purpose and intention of the project, level of risk, and methodology.
- Publishing or presenting QA/QI findings does not automatically mean that the project is research.

How the IRBO Makes a Determination

If the IRBO is asked to make a formal determination, we look at a variety of questions:

First, we assess whether the project meets the **definition of research**. Then we determine if the project involves **human subjects**.

When questioning if your QA/QI project needs an exemption or IRB review and approval, the project lead should ask: does the project also meet the **definition of research per the Human Subject Protection Regulations?** That is, is it a systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge? QA/QI activities **are likely not** considered human subject research when:

- The project is undertaken by or for NIH; and
- The goal of the project is immediate improvement in NIH patient safety or care or other internal NIH practices or processes; and
- The project involves an intervention and it has been established in other settings; and
- The project will be adapted over time to accommodate NIH initiatives.

Some questions you can ask to help with these decisions:

- Does the analytical or evaluative component of the activity change the way that clinical care or other activities will be delivered in such a way that introduces or heightens risks to participants (may include randomization)?
- Are participants randomized into different intervention groups in order to enhance confidence in differences that might be obscured by other selection methods?
- Does the project seek to test interventions that are beyond the scope of current science and experience, such as new treatments?
- Does the project involve practices, interventions, or treatments that are not standard (neither consensus-based, nor evidence-based)?

If the answer to ANY of the above is yes, the project is research and should be submitted for an exemption or IRB review and approval.

Publication of findings, methodological design, selection of subjects and hypothesis testing and generating do not necessarily differentiate research from QA/QI activities because these attributes can be shared by both research and non-research activities. Below are elements that are common to QA/QI and research projects. This list is not intended to be comprehensive. Rather, this list of elements can be used to assist staff in determining whether an activity involves research requiring an exemption or IRB review and approval.

Common Elements	QA/QI	Research
Purpose	To assess or improve a process, program, or system in terms of quality, performance, safety, or efficiency within a local setting as judged by established/accepted standards	To test a hypothesis and to contribute to and/or generate new knowledge that can be generalized
Starting Point	To improve performance	To answer a question or test a hypothesis
Benefits	Knowledge sought directly benefits a process/ program/ system, and may or may not directly benefit individuals (e.g. patients, families, or staff)	Knowledge sought may or may not benefit clinicians, the scientific community and current subjects, but may benefit future individuals
Scope of Interest	Specific unit or patient population within an organization	Generalize to populations beyond organization
Risks/Burdens	Does not increase risk to patients or other participants, with exception of possible privacy/ confidentiality concerns	May put subjects at risk
Data Collection	Systematic data collection	Systematic data collection

Common Elements	QA/QI	Research
End Point	Improve a program/ process/system	Answer a research question
Testing/Analysis	Compare a program/process/system to an established set of standards	Statistically prove or disprove hypothesis

Additionally, here are examples of several types of QA/QI projects and whether or not they would also be considered research.

QA/QI Activities that ARE NOT Research:

- A QA/QI initiative (with or without presentation/publication of results) that is conducted within your institution/department only, and that serves to measure or improve your institution/department's ability to meet or exceed an existing national standard of care or benchmark.
- Submission of data to a national or state registry/database that is mandated at the state or federal level with the primary purpose of improving the delivery of clinical care.
- Submission of data to a national or state registry/database that directly impacts reimbursements and funding available from the State, Department of Health, or Federal Centers for Medicare & Medicaid Services (CMS) based on performance and/or clinical or quality outcomes.

QA/QI Activities that ARE Research:

- QA/QI initiatives designed to develop a standard of care or benchmark.
- An activity that proposes comparisons of one or more prospective interventions that are deliberately administered or made available (through a randomization or other process) to some patients or providers or some hospitals (if part of a consortium or organizational effort) and not to others.

What If I Want to Publish the Results of My QA/QI Project?

It is entirely appropriate to disseminate and replicate QA/QI successes, including through channels that are external to an organization such as conferences or publication. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QA/QI project does not obligate submitting for an exemption or IRB review and approval as long as the publication makes it clear the publication is the result of a quality assurance or quality improvement activity as defined above.

If the project is research involving human subjects, submission for an exemption or IRB review and approval is required.

See the *Prospective Data Collection Protocol Template* for projects involving educational research; educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior; or benign behavioral interventions, such as the completion of certain types of tasks or exercises or exposure to certain conditions here: <https://irbo.nih.gov/nih-irb-templates/protocol-templates/>

See the *Retrospective Data or Biospecimen Review Protocol Template* for projects involving retrospective chart reviews or biospecimens and no retention of identifiers here: <https://irbo.nih.gov/nih-irb-templates/protocol-templates/>

See the *IRB Exempt Submissions Guide* here: <https://irbo.nih.gov/irb-review/exempt-research/>

If your project involves other activities that may require IRB review and approval of a research protocol, please see the other protocol templates here: <https://irbo.nih.gov/nih-irb-templates/protocol-templates/>

If the project team wants a formal determination that the project is not research, complete “Not Human Subjects Research Application”. See the “NHSR and Not Research Submissions Guide” here: <https://irbo.nih.gov/irb-review/not-human-subjects-research/>

Informed by:

Washington University in St. Louis HRPO Research Guide (Updated July 24, 2020, v. 23):
<http://online.fliphtml5.com/ikcz/ifub/#p=1>

University of Iowa Hospitals and Clinics, Department of Nursing Services and Patient Care:
<https://www.harrishealth.org/SiteCollectionDocuments/nursing/differentiating-between-ebp-qi-research.pdf>

Oregon State University IRB:
https://research.oregonstate.edu/sites/research.oregonstate.edu/files/irb/comparison_research_v_non_research_v01292018.pdf