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Guidance on Quality Improvement Projects vs. Research Studies

What is Research? Research is defined in [45 CFR 46.102\(I\)](#) as follows: "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Research yields valid results through rigid implementation of a fixed protocol. The focus of research is on long-term gains in knowledge. The Office of Human Research Protections (OHRP) offer guidance of how to [determine if a project is research](#) and if it is [human subjects research](#).

What is Quality Improvement (QI)? Quality improvement is not defined by OHRP. The National Institutes of Health (NIH) has offered guidance on the subject. Specifically, "quality improvement, also sometimes referred to as quality assurance, is also systematic, but the goal is to improve care, processes, or outcomes in an organization. A straightforward definition of QI is 'a systematic, data-guided activity designed to bring about immediate improvement in a local setting,'" (Bass III & Maloy, 2020, p. 57). QI projects identify promising improvements, implement small scale changes, monitor results, and decide about additional changes and wider implementation.

How are QI and Research similar?

- Both follow a systematic process of investigation carefully designed to get valid results.
- Both may use human subjects as participants.
- Both involve analysis of data.
- Both may involve the implementation of a new intervention.
- Both may result in presentation or publication.

How is a QI project different from a Research study?

- QI projects intend to improve a program, practice, process, or service of a specific institution or organization.
- QI projects are often flexible and incremental in design, employing strategies such as a plan-do-study-act cycle.
- QI uses data analysis to find out whether the workforce is following best practices and professional guidelines.
- QI implements a new practice or process to improve (for example) workflow, patient safety, staff expertise, cost effectiveness, etc.
- QI interventions often have been proven to be successful elsewhere and are widely accepted in the profession/discipline. QI projects evaluate the best strategies to implement these interventions locally.



- QI projects can help characterize populations to better serve their needs or improve their care.
- QI projects aim to directly benefit existing populations (e.g. students, patients, etc.) by implementing immediate local improvements.
- QI projects do not increase risk to populations beyond the risks that are involved in the services they are already receiving.
- QI tools are applicable primarily to the unique characteristics of a local setting.
- The results of QI projects typically are evaluated by an internal committee or executives who decide whether or not to permanently adopt the new practice.
- QI projects involve all or most of a population receiving a particular treatment, program, or process.
- **The primary difference is a QI project's lack of an intent to contribute to generalizable knowledge.**

Can a project be both QI and Research? Yes, some projects contain elements of both. If the intent of the project is developing new, generalizable knowledge using human subjects data, the project must be reviewed and approved by the UWG IRB before it begins. Additionally, some activities may begin as QI and evolve to have a research purpose. In such cases, an IRB application would be needed at that time. It is important to keep in mind that retroactive IRB approval of research data cannot happen.

Do researchers need to collect informed consent in a QI project? No, informed consent is not required for quality improvement projects since they pose no risk to potential participants.

How do I obtain determination of a QI project rather than a Research study at UWG?

Determinations of QI vs Research are made on a case-by-case basis. Researchers are encouraged to seek formal determination about their project from the IRB to ensure compliance requirements are met. Such determinations can also be helpful when submitting a manuscript for publication. Complete the [Determination of Human Subjects Research](#) form on the UWG IRB's Forms webpage. The results of this form must be sent to irb@westga.edu for review. Determinations are typically made within 3-5 business days of submission.

Can you present the results of a QI Project? Yes, presentation or publication does not change the project from QI to Research. When presenting or publishing results from your project, you must refrain from referring to it as "research." This is because it does not meet the federal definition of research and was not reviewed and approved by the IRB. UWG requires the following statement to be included in any publication or presentation: "This project was undertaken as a quality improvement project and was determined to not need formal review from the University of West Georgia's Institutional Review Board."

For further guidance, please review the [Research/Evaluation/Assessment Table](#) on the UWG IRB website, reach out the IRB at irb@westga.edu, or listen to CITI Program's On Research Podcast with Tiffany Gommel on [Quality Improvement vs. Research](#).



Reference: Bass III, P. F., & Maloy, J. W. (2020). How to determine if a project is human subjects research, a quality improvement project, or both. *The Oschner Journal*, 20(1), 26-61.

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