

## Quick Reference Guide: Quality Improvement or Research?

*In the era of quality improvement, questions about the line between QI and research come up frequently. This guide is a supplement to **HRP-421 WORKSHEET – Human Research**.*

### Definition of Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. ([45 CFR 46.102\(d\)](#))

### General Characteristics of Quality Improvement vs. Research

#### Quality Improvement

- Implement change according to mandates of hospital's Clinical QI program
- Improve process or delivery of care with established/accepted methods
- Implement systematic monitoring to ensure existing quality standards are met
- All participants receive standard of care
- Improve performance in a specific program

#### Research

- May be funded by an external research agency
- Answer a research question/tests a hypothesis
- Uses research design: Group comparisons, randomization, control groups, prospective comparison, cross-sectional, case-control, etc.
- Develops new paradigms or untested methods, establishes a new clinical practice standard
- Follows a protocol that overrides clinical decision-making
- Develop or contribute to generalizable knowledge

### Examples

#### Quality Improvement

Developing an outreach process to facilitate scheduling follow-up appointments for patients with blood pressure readings above goal, and measuring the percentage of follow-up visits scheduled before and after the intervention.

#### Research

Randomizing patients who have blood pressure readings above goal at a primary care visit to receive either an email reminder or a phone call reminder in order to determine which method results in a higher percentage of patients scheduling a follow-up appointment.

#### Quality Improvement

Hospital implements a procedure known to reduce pharmacy prescription error rates and collects prescription information from medical records to assess adherence to the procedure and determine if error rates have decreased as expected.

#### Research

Investigators conduct focus groups and individual interviews with pharmacists at various hospitals in order to analyze likely causes of prescription errors in different types of hospital settings.

## FAQs about Quality Improvement Projects

### *If we want to publish our QI project, is that research?*

Sometimes.

Usually, when you systematically collect information with intent to generalize the results to those outside your local environment, the project is research. The intent to publish can be an indicator that you intend to develop or contribute to generalizable knowledge. However, it is possible to conduct a QI project that is specific to a local or very limited context and publish the results as an example for others to learn from without the project meeting the definition of research. It is also possible that a project is research even if there is no intent to publish.

### *What if I started a QI project, then the results were really interesting, and now I think the knowledge we are gaining might be generalizable, so I want to publish? I didn't have IRB approval when I started. What should I do?*

Stop working on the project and evaluate whether your goal has changed from a local improvement project to a generalizable systematic evaluation (in other words – it's now research). If so, you need IRB approval before continuing with the project and need to submit a New Study to the IRB.

If you are unsure of whether you need IRB approval, submit a Request for Determination. The IRB will determine whether your project qualifies as human subjects research, and if so what level of review/oversight is required. Once this is completed, you can proceed with the project.

**See Also:** FAQs about Quality Improvement Activities from the Office for Human Research Protections (OHRP): <http://answers.hhs.gov/ohrp/categories/1569>.