

Quality Improvement vs. Research: Understanding the Distinctions

1. Introduction

The distinction between Quality Improvement (QI) and Research is critical to ensure compliance with regulatory requirements and the ethical conduct of human subjects activities. Correct classification determines whether IRB review is required and what level of oversight applies. This document provides clear guidance to help determine whether a project qualifies as QI or Research, including examples and decision-making criteria.

2. Definitions

Quality Improvement (QI): Activities designed to improve the quality, efficiency, or effectiveness of processes, programs, or outcomes within a specific institution or program. QI typically involves systematic efforts to enhance internal operations or performance.

Research: As defined by 45 CFR 46.102(I), research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research activities often require Institutional Review Board (IRB) oversight before initiation.

3. Key Differences

Category	Quality Improvement (QI)	Research
Purpose	Improve internal processes or outcomes within a specific organization.	Generate generalizable knowledge applicable beyond the organization.
Design	Flexible; adapts to local needs and goals.	Structured, hypothesis-driven, and protocol-based.
Participants	Individuals within the organization or system.	Human subjects representing a broader population.
Risk	Usually minimal; often part of routine care.	May involve greater risk; requires IRB review.
Publication	Findings used internally to improve practice.	Findings intended for external dissemination or publication.

4. Oversight and Review

Projects that qualify as research must undergo IRB review before initiation. QI activities typically do not require IRB review if their intent is solely to improve internal operations. However, QI activities require HRPP acknowledgment to confirm that they do not meet the definition of human research.

5. Examples

****Example 1 - Quality Improvement:****

A hospital implements a new checklist to reduce surgical site infections and tracks infection rates before and after implementation to improve patient safety.
→ QI because it aims to improve internal processes and outcomes.

****Example 2 – Research:****

A team designs a randomized study to compare the effectiveness of two infection control checklists across multiple hospitals to publish findings.
→ Research because it intends to generate generalizable knowledge.

****Example 3 – Borderline Scenario:****

A QI project that later shows promising results and is analyzed for publication may need retrospective IRB review to determine whether it meets the definition of research.

6. Determining If IRB Review Is Needed

To determine if IRB review is required, consider the following questions:

- Is the project designed to contribute to generalizable knowledge?
- Is the project systematic in nature?
- Are human subjects involved?

If the answer to any of the above is 'Yes,' the project is likely qualified as research and must undergo IRB review. If all answers are 'No,' it is likely a Quality Improvement project, though HRPO documentation is still advised.

7. Conclusion

Proper classification of activities as QI or Research ensures appropriate oversight and protection of participants. When in doubt, consult the IRB or HRPO office before initiating a project to ensure compliance with institutional and federal requirements.