

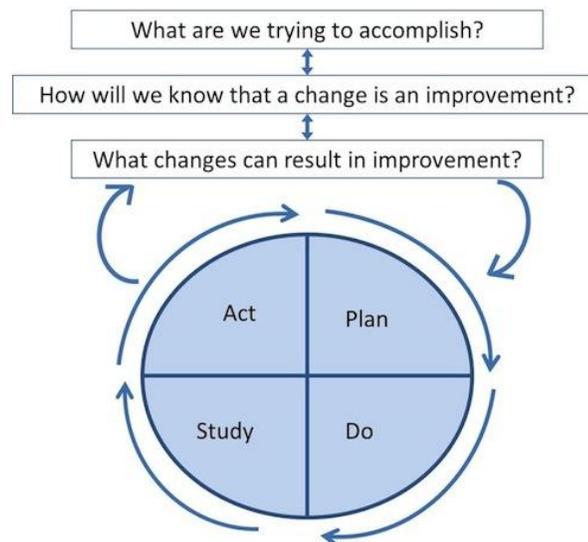
This document will help an investigator determine if his or her study qualifies as research or quality improvement.

	Human Subjects Research	Quality Improvement
Purpose	Designed to develop or contribute to generalizable knowledge	Designed to implement knowledge, assess a process or program as judged by established/acceptable standards
Starting Point	Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	Knowledge-seeking is integral to ongoing management system for delivering health care
Design	Follows a rigid protocol that remains unchanged throughout the research	Adaptive, iterative design
Benefits	Might or might not benefit current subjects; intended to benefit future patients	Directly benefits a process, system or program; might or might not benefit patients
Risks	May put subjects at risk	Does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data
Participant Obligation	No obligation of individuals to participate	Responsibility to participate as component of care
Endpoint	Answer a research question	Improve a program, process, or system
Analysis	Statistically prove or disprove hypothesis	Compare program, process, or system to established standards
Adoption of Results	Little urgency to disseminate results quickly	Results rapidly adopted into local care delivery
Publication/Presentation	Investigator obliged to share results	QI practitioners encouraged to share systematic reporting of insights

When is IRB approval needed for QI activities?

When the activity involves some of the following characteristics:

- seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge;
- when the methodology employs a standard research design, such as randomization;
- when the protocol is fixed with a rigid goal, methodology, population, time period, etc.;
- when the funding for the activity comes from outside organizations such as the NIH or those with a commercial interest in the results;
- when there will be a delay in the implementation of the results;
- when the risks from the intervention to participants are greater than minimal



Definitions

Quality Improvement

Systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings. The QI process involves evaluating and learning from experience.

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
