

Determination of Quality Improvement versus Research

Questions frequently arise about whether or not certain projects qualify as human subjects research or if they are considered quality improvement.

Quality Improvement (QI) has been defined as systematic, data-guided activities, designed to bring about immediate improvements in health care delivery in particular settings. Initiators of QI projects identify promising improvements, implement small scale changes, monitor results, and decide about additional changes and wider implementation. Quality improvement is a core function of good clinical care.

Research is defined by the federal government as 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.

Note there are many **similarities** between research and QI:

- Both involve a systematic investigation that is carefully designed to achieve reliable and valid results.
- Both involve analysis of data.
- Both may involve the implementation of a new intervention.
- Both may result in a presentation or publication.

However, there are key **differences** between quality improvement and research projects.

- 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 or not 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 us characterize our population in order to better serve their needs or improve their care.
- QI projects aim to directly benefit existing patients by implementing immediate local improvements.
- QI projects do not increase risk to patients beyond the risks that are involved in care they are already receiving.
- QI tools are applicable primarily to the unique characteristics of our 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.

Informed consent

Informed consent is not required for quality improvement projects since they pose only minimal risk. Because quality improvement is an integral aspect of normal health care operations, consent to be included in QI projects is part of the patient's consent to receive treatment.

Presentations and Publications

The federal agency overseeing research has stated that the act of presenting or publishing a quality improvement project does not change its classification to be research.

Projects that are both Quality Improvement and Research

Some projects contain elements of QI but their focus is developing new, generalizable knowledge. Additionally, activities that start as a QI initiative may evolve to have a research purpose. Examples of projects that could be **both** QI and research are:

- Implementation of a new intervention to improve patient care and analysis of data to establish scientific evidence of the intervention's effectiveness
- Implementation of a novel approach that has not been extensively studied
- Development of new quality assessment or measurement tools
- Use of patient data in order to develop new clinical treatment guidelines

Projects that are both QI and research must be approved by the KUMC IRB before they are initiated.

Obtaining a Determination

Determinations about QI versus research are made on a case-by-case basis. Faculty members and other researchers are encouraged to seek a formal determination about their project to ensure that compliance requirements are met. A formal determination also may be helpful when submitting the manuscript. Please complete the [QI Determination Request Form](#). Determinations are typically made within 2-3 business days.

Additional Resources:

Lynn J, Baily MA, Bottrell M, Jennings B, Levine RJ, Davidoff F, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med.* 2007;146(9):666-673

The federal Office for Human Research Protections provides [Frequently Asked Questions](#) about Quality Improvement Activities.