

University of South Carolina Institutional Review Board

Guidance - Quality Improvement Activities

Quality Improvement (QI) activities are done to improve the quality of programs, services, medical care, etc. QI activities usually are done for internal purposes only. The results of the QI activity are not intended to apply beyond the specific organization, and conclusions are drawn only in relation to that organization. In other words, if the results of the QI activity are shared outside the organization (i.e. published or presented), it would be for the purpose of sharing a “QI case study” (i.e. “This worked for us, it may work for you.”) Other organizations may choose to interpret the results and draw their own conclusions. The key is that the organization conducting the QI activity is not designed or intended to draw broad conclusions, but to inform itself about its performance. To determine whether QI activities involving human participants or individually-identifiable data must be submitted to the IRB, consider the definition of [research](#).

A. Overview of the differences between QI and Research

	Research	QI
Purpose	To test a hypothesis in order to create/expand knowledge Activity is designed to yield generalizable findings.	To assess and improve a process, program, or system. Findings are relevant to a specific organization; however, may be of interest to other similar organizations.
Benefits	Knowledge obtained may or may not benefit current subjects, but is intended to be broadly useful and may benefit future patients, providers and certain communities.	Knowledge obtained is intended to improve the performance of an organization. Improved performance and efficiency yields benefits to all parties.
Methods	Systematic data collection	Systematic data collection
Analysis	Statistically prove or disprove hypothesis	Compare a program/process/system to an established set of standards, or to establish internal benchmarks
Result	Answer a research question and produce generalizable knowledge that may be applied broadly.	Improves or creates a program/process/system that results in greater safety, efficiency or satisfaction within an organization.

B. Issues to Consider

1. What often distinguishes QI activities from research is whether the activities are designed to develop or contribute to generalizable knowledge. For purposes of this policy, "generalizable knowledge" is information (findings) that can be applied to populations or situations beyond those being immediately studied.

2. Publication or presentation of findings is not the criterion for determining whether a QI activity involves research. Findings from a QI activity may be generally interesting, but usually these activities are not designed or intended to yield generalizable information. Sharing such findings through publications or presentations may be helpful, but this does not make an activity research.

3. If QI activities are a systematic investigation AND will develop or contribute to generalizable knowledge, IRB review is required. It is important to note that at the onset, many QI activities have only local (organizational) improvement intentions. If during the process of data collection or analysis, the QI purpose is expanded and revised to yield generalizable findings, IRB review should occur.

C. If an investigator is unsure as to whether or not the activity meets, or does not meet, the definition of human subjects research, please consult with the IRB.