MUSC
Medical University of South Carolina

I. POLICY

A. Introduction

Quality Improvement (QI) activities are done to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc. QI projects are usually done for internal purposes only. However, some QI projects may fall under the federal definition of human subject's research, and therefore may require IRB review.

B. Requirements

To determine whether QI activities involving human participants or individually-identifiable data must be submitted to the IRB, consider the definition of research. This policy defines when a QI project involves research and is subject to IRB review.

II. DEFINITIONS

Definitions for the following terms may be found in the HRPP Program Guide Section 1.3 – Definitions of terms:

A. Research – DHHS and FDA Definitions
B. Human Subject – DHHS and FDA Definitions

III. PROCEDURES

A. Overview of the differences between QI and Research

	Research	QI
Purpose	To test a hypothesis OR to establish clinical practice standards where none are already accepted	To assess or improve a process, program, or system OR to improve performance as judged by established/accepted standards
Benefits	Knowledge sought may or may not benefit current subjects, but may benefit future patients	Knowledge sought directly benefits a process/ program/ system, and may or may not directly benefit patients
Risks/Burdens	May put subjects at risk	Does not increase risk to patients, with exception of possible privacy/confidentiality concerns
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	Improves or creates a program/ process/system that results in greater safety, efficiency or satisfaction

B. Issues to Consider

1. What often distinguishes QI activities from research is whether the activities are intended or 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. If there are no intentions to develop or contribute to generalizable knowledge, IRB review is not required.

3. If project 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 projects have only local (organizational) improvement intentions, but during the process of data collection or analysis, it becomes clear that findings could be generalizable or benefit others. IRB review should occur when there is an intention to make findings generalizable.

4. When an IRB Chair, designee or IRB staff member cannot in all fairness decide or agree on whether a submission is research or QI, that application may be referred to the full board for discussion and vote.

C. The QI project must be submitted to the IRB if any of the following are true:

1. the project involves testing an experimental drug, device (including medical software or assays), or biologic

2. the project has received funding (e.g. federal, industry) to be conducted as a human subjects research study

3. this is a multi-site project (e.g. there is a coordinating or lead center, more thanone site participating, and/or a study-wide protocol
4. the primary intent to is to conduct a systematic investigation designed to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs control; comparative effectiveness research; or comparable criteria in alternative research paradigms),

5. results will be used to apply knowledge to other programs outside the institution,

D. If an investigator is unsure as to whether or not the project meets, or does not meet, the definitions above, please consult with the IRB.