OFFICE *of* RESEARCH & GRADUATE STUDIES

IRB Guidance for Quality Improvement/Quality Assurance Projects

Quality Improvement (QI) Definition

Quality Improvement (QI) is defined as systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings. QI is an essential part of normal health care operations.

Human Subjects Research (HSR) Definition

Research is defined by the DHHS as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research requires the oversight and approval of an Institutional Review Board when it involves human subjects. Human Subjects are defined as living individuals about whom a research investigator (either professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.

Distinctions between QI and Research

Most (but not all) QI activities do not meet the federal definition of human subjects research requiring the review and oversight of an Institutional Review Board. However, since patient populations are frequently the target of QI activities, the distinction between QI and research is not always clear. To further the confusion, attributes such as systematic data collection and publication/presentation of findings can be features of both research and non-research activities alike. Additionally, activities that start out as QI may lead to regulated human subjects research when a decision is made to use previously collected QI data for a research purpose. The chart below outlines some of the major distinctions between QI and research.

Distinctions between QI and Research *Table 3*

	Research	QI
Terminology	Referred to as a "study"	Referred to as a "project"
Purpose	To establish new knowledge that is generalizable or to reinforce existing knowledge for which inconclusive evidence exists	To assess or improve a process, program, or system or to improve performance as judged by established/accepted standards of care
Control Groups	Participants may be divided into control groups to test a hypothesis or intervention	May or may not involve group assignment but rigor of randomization does not exist
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 beyond the risk of normal process of care, with the exception of possible privacy/confidentiality concerns

Informed Consent	Usually required	Not required, as it is part of the normal process of care
Methods	Rigorous systematic data collection	Systematic data collection, but not necessarily controlled or rigorous
Analysis	Statistically proves or disproves hypothesis; Data typically analyzed after a set end point	Compare a program/process/system to an established set of standards, or to establish internal benchmarks; Data may be continually monitored over time, and adjustments to the project may be made in response to the data
Results	Answers a research question	Improves or creates a program/process/system that results in greater safety, efficiency, or satisfaction
Dissemination	Scholarly, peer-reviewed publications and presentations	Publications and presentations to describe lessons learned; may be published in peer-reviewed journals that accept QI/QA projects

Quality Improvement IRB Checklist

This checklist is intended to provide a tool to help determine which QI projects meet the federal definition of human subjects research thus requiring IRB review and approval. Please answer both sets of questions below.

Quality Improvement IRB Checklist *Table 4*

Part 1: Is this QI? If you answer **NO** to any of the questions in Part 1, then IRB approval is required. If you are uncertain, please consult with your School's IRB Representative, the IRB Chair, or the Office of Research and Sponsored Projects Operations for further guidance.	**Yes**	**No**
Will the project benefit patients and/or improve a process/program/system?	☐	☐
Will all groups in the project receive, at minimum, the usual care at the institution/organization?	☐	☐
Is the purpose to measure the performance of or to determine the effect of a process change intended to improve health care delivery?	☐	☐
Will the results be used to inform and implement improvements in patient care at the institution/organization?	☐	☐
Part 2: Is this regulated human subjects research? If you answer **YES** to any question in Part 2, then IRB approval is required. If you are uncertain, please consult with your School's IRB Representative, the IRB Chair, or the Office of Research and Sponsored Projects Operations for further guidance.	**Yes**	**No**
Is the intent of the project either to establish new knowledge that is generalizable OR to reinforce existing knowledge for which inconclusive evidence exists?	☐	☐
Will patients or personnel be exposed to additional risks beyond those of usual care at the institution OR beyond what is ordinarily expected when practice changes are implemented within a health care environment?	☐	☐
Does the project involve withholding any aspect of usual care?	☐	☐

Does the project involve a drug or device used outside of usual medical practice, including non-FDA-approved agents, or off-label uses of FDA-approved drugs or devices?	☐	☐
Will the safety and/or effectiveness of a drug or regulated device be evaluated or compared to that of another?	☐	☐
Will the project be described as research in publications or presentations? (Note: QI findings may be published, but should not be described as research. The following statement may be used "*This project was conducted as a Quality Improvement initiative, and as such was not formally supervised by an Institutional Review Board";* a formal determination letter from the IRB may also be provided upon request.)	☐	☐

Ethical Conduct of QI Activities

Regardless of whether a project is defined as QI or research requiring IRB review and approval, all UIW students, faculty, and staff are expected to follow adequate, discipline-appropriate guidelines to assure that projects are being conducted in a responsible, professional, and ethical manner. In addition, there may be other federal, state, local, or institutional laws and policies (e.g., HIPAA) that may need to be considered even if federal regulations for human research protections do not apply. If a project is not human subjects research, and the investigator intends to utilize a consent form or to publish/present the results, no references to IRB oversight should be included. When publishers require documentation that the activity is not human subjects research, the investigator should submit a request for a formal determination letter through the Human Subjects Research Determination Questionnaire. If at any point, the purpose and design of the project changes such that it could meet the federal definition of human subjects research, another request must be submitted to determine if the project will require IRB review and approval BEFORE the changes are implemented.

The ethical practice of QI activities in particular should be incorporated into the professional supervision of clinical practice. For further guidance on this matter please see the Hastings Center report "The ethics of using quality improvement methods in health care" available online at http://www.thehastingscenter.org/publications-resources/special-reports-2/the-ethics-of-using-qi-methods-to-improve-health-care-quality-safety/