Institutional Review Board Policies and Procedures Manual

SECTION 7: GUIDANCE ON QUALITY IMPROVEMENT/QUALITY ASSURANCE PROJECTS AND IRB REVIEW

7.1 QUALITY IMPROVEMENT/QUALITY ASSURANCE PROJECTS

A. Overview of the differences between QI/QA and Research

The line between quality improvement (QI) / quality assurance (QA) initiatives and research is often blurred and these can often overlap with research projects. The purpose of this policy is to assist investigators and the IRB in defining when a QI project involves research and is therefore subject to IRB review.

Regulatory Definitions

45 CFR 46.102(d): *Research* is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

42 CFR 480.101(b): *Quality review study* is defined as an "assessment, conducted by or for a Quality Improvement Organization, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up."

45 CFR 164.501(2): HIPAA regulations define *health care operations* to include "conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs…"

45 CFR 46.102(F)(1),(2): *Human subject* is defined as "a living individual" about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. *Identifiable information* is information that contains one or more data elements that can be combined with other reasonably available information to identify an individual.

Research versus QI/QA

In order to determine whether QI/QA activities involving human participants or individually identifiable data must be submitted to the IRB, the investigator and IRB must consider the definition of research as put forth by the federal regulations. As above, research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop and contribute to generalizable knowledge." Research activities tend to focus on creating new knowledge for the scientific community to benefit future patients. A randomized clinical trial with a control arm is clearly designed to develop or contribute to generalizable knowledge because the results will be applicable, regardless of setting.

In general, QI/QA activities are not designed to create new knowledge, but instead use existing knowledge to focus on improving systems and organizational performance with the intention to improve outcomes to benefit current patients. For example, a QI/QA activity designed to improve patient care on a specific unit, program or service area with a set population using established guidelines. In addition, if the QI/QA activity includes measuring these types of outcomes and is shared, either within the Institution or with outside organizations, the activity would not be considered research. This activity is not intended, or designed to, contribute to generalizable knowledge, but is conducted to help to improve the quality of patient care at the local setting using existing knowledge.

A group of leaders convened by the Hastings Center to address ethical requirements for QI/QA defined *quality improvement* as a systematic, data-guided activity, designed to bring about immediate improvements in health care delivery in particular settings. QI/QA is an intrinsic part of normal health care operations and informed consent is not generally required since patients expect their health care provider to continually improve the quality of care provided.

The intent or possibility of publishing results of a QI/QA project does not change the determination of the project to research. If there is the intent or possibility of publishing results of a QI/QA initiative, the methods section should clearly state that the project was undertaken as a QI/QA initiative and that such activity was not formally approved or supervised by the IRB.

Purpose of Activity

What often distinguishes QI/QA 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 immediately studied. Considering why the project is being done (intent), may be a more accurate way of determining if it would be considered research, and is intended to develop or contribute to generalizable knowledge and subject to IRB review. If the project involves a procedure, drug, device or other item that is considered experimental or of questionable value (questionable effectiveness or safety), it would be considered research, and require IRB review.

Alternatively, QI/QA activities are designed to improve the quality of the healthcare patients receive based on existing knowledge. Of note: any research questions that unexpectedly arise as the result of a QI/QA project would need to be submitted to the IRB as a separate project for review/approval.

	Research	**QI/QA**
Purpose	To test a hypothesis *or* to evaluate an innovation, study something new, or study a process that has not yet been subjected to rigorous scientific analysis (not proven effective); includes substantial deviations from established/proven clinical practice	To assess or improve a process, program, or system in a specific unit/area/program *or* to improve performance/delivery of usual care as judged by established/accepted standards; increase patient satisfaction; increase staff efficiency; reduce medical errors; reduce work-related injuries; decrease morbidity and mortality, etc.
Benefits	Knowledge sought may or may not benefit current subjects, but may benefit future patients	Knowledge sought directly benefits a process/ program/ system, and directly benefits patients affected by the problem
Risks/Burdens	Participants incur additional risks and/or burdens in order to produce measurable results necessary for the project	Does not increase risk to patients, with exception of possible privacy/confidentiality concerns

Methods	Systematic data collection above and beyond normal health care practice for the purposes of analysis; use of non-therapeutic/control arms/groups, randomization and/or blinding of treatments; use of a protocol to ensure high degree of standardization	Systematic data collection by staff caring for patients to assess and improve the service area/unit/program and the health patients being cared for; use of QI/QA methods/models such as benchmarking/surveillance activities; all participants receive standard care; does not include any experimental activities; implementation of care practices and interventions that are consensus-based or evidence-based
Analysis	Statistically prove or disprove hypothesis or determine statistically significant differences in comparison groups; controlling for extraneous variables that may affect the outcome; focuses on how the intervention affects the individual subject versus the overall delivery system/process	Compare a program/process/system to an established set of standards, or to establish internal benchmarks; not designed to answer a research question; not intended to contribute to generalizable knowledge (information (findings) that can be applied to populations or situations beyond those immediately studied).
Result	Answer a research question; generalizable knowledge	Improves or creates a program/ process/system that results in greater safety, efficiency or satisfaction

B. When should a QI/QA project be submitted to the IRB for Review?

There are situations when QI/QA activities may meet the definition of human subject research and require IRB review. *There is no simple algorithm to distinguish QI/QA from research.* To assist with determining if a proposed project should be submitted to the IRB for review, the following questions should be asked:

<table>
<tr><td colspan="2">1. Is the project research?</td></tr>
<tr><td><u>Yes</u>
The purpose of this project is to test a hypothesis or something that has not yet previously been proven effective; involves substantial deviations from established practice; may add additional risks or burdens or add control of some extraneous variables</td><td><u>No</u>
The purpose of this project is to observe or evaluate an existing process or system; involves proven clinical practices; and participants are not subjected to additional risks or burdens in order to collect data.
<u>STOP: Does not need to be submitted to the IRB</u></td></tr>
<tr><td colspan="2">2. Will data contribute to generalizable knowledge (see above for definition)?</td></tr>
<tr><td><u>Yes</u>
Data will be shared and applied beyond the study population (i.e. to benefit future patients), contribute to generalizable knowledge (designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program) regarding the effectiveness or safety of the procedure, drug, or device, and/or data will be subject to peer review</td><td><u>No</u>
Data will not be shared or applied beyond the study population and will be used to improve the quality of health care based on existing knowledge
<u>STOP: Does not need to be submitted to the IRB</u></td></tr>
<tr><td colspan="2">3. Does it involve human subjects or their identifiable information?</td></tr>
<tr><td><u>Yes</u>
Data will be collected through intervention or interaction with living individuals or their identifiable information (includes information that will become de-identified)
<u>Submit to the IRB</u></td><td><u>No</u>
All patient-level data or specimens cannot be linked to specific individuals either directly or indirectly through coding systems and were <u>not</u> collected specifically for the currently proposed research project through an interaction or intervention with living individuals and the identity cannot be readily ascertained.
<u>STOP: Does not need to be submitted to the IRB</u></td></tr>
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If the answers to the three questions above are yes, the project requires submission to the IRB for review/approval. When it is not clear if an activity is QI/QA or research, submit to the IRB for determination, review, and approval.