

Frequently Asked Questions About Clinical Quality Improvement (QI) Projects and Institutional Review Board (IRB) Review

Overview

This document provides guidance for determining when Quality Improvement (QI) projects involving patients, staff, providers, etc. are subject to IRB review. The bulk of text is derived directly from a similar document from Yale University University's IRB.

Do QI Projects Require IRB Review?

The majority of quality improvement projects do not require review by the IRB. There are, however, cases where the project would fall under the purview of the IRB. Projects which qualify as “research” and which involve “human subjects,” as defined in the federal regulations and further explained below, would require IRB review under Fairfield University policy. The most common reason for QI projects to require IRB review is that they are projects involving systematic investigations intended to develop generalizable knowledge.

It is important to note that language matters. Terms such as ‘research’ and ‘human subject’ have distinct definitions in the federal regulations, and use of such terms may invoke a set of requirements that perhaps do not apply. When referring to QI projects, it is best to avoid use of the terms ‘research’ ‘study’ and even ‘study intervention’. More appropriate terms might include ‘project’ or ‘proposal’. Similarly, for research, the people participating are referred to as ‘subjects’ or ‘participants’. Likewise, ‘researchers’ generally conduct ‘research’, but ‘clinicians’ undertake QI.

What Constitutes “Quality Improvement”?

Quality Improvement (QI) involves systematic, data-guided initiatives or processes designed to enhance health care delivery in a particular setting. QI is intended to use experience to identify effective methods, implement the methods broadly, and evaluate the impact or effect of the implemented changes. As such, QI is an intrinsic part of good clinical practice where lessons learned are used to enhance future healthcare delivery for patients at the institution in which the QI activity is implemented. A QI project may involve implementing a practice to improve the quality of patient care, and collecting data regarding the degree to which implementation of the practice was successful for clinical, practical, or administrative purposes. Process-based QI activities strive to overcome barriers to dissemination and implementation of best practices. Note that these “best practices” represent accepted, evidence-based approaches to caring for patients (such as hand-washing, ordering mammograms for eligible women, or improving glucose control in diabetic patients), rather than experimental/unproven interventions (see “Research” below). Results of a QI project could and should be shared with others, either via presentation or publication. QI activities would not be considered human subjects research.

What Constitutes “Research”?

Federal regulations define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(d)). Under this definition, the project must intend at the outset to generate conclusions which can be applied in or be predictive of similar circumstances. Thus a case study of a single individual would not be considered research.

What Constitutes a “Human Subject”?

A human subject is defined in the Federal regulations as a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) obtains identifiable private information” (45CFR46.102(f)). Key to this definition is that the information collected is about an identified person and is intended for research. A QI project certainly may involve ‘human patients’, but may not involve ‘human subjects’ as described above. Another consideration is that there may be different populations that are the subjects being evaluated. For example, a project might involve both patients and staff in a new activity. Analysis of both groups should determine whether one or both are considered ‘human subjects’.

When Are QI Projects Considered to be Human Subjects Research Requiring IRB Review?

If the proposed project will involve collecting identifiable information about a living individual AND will be used to inform broad policy or generalize findings, then the project must be submitted to the IRB for review.

Note that the determination of whether or not a project constitutes research is separate from whether or not the project involves human subjects and only when both definitions are met does the project require IRB review.

For example, the following may be indicators that IRB review is required:

- The study is funded by an agency or sponsor which seeks to support projects designed to create generalizable knowledge such as U.S. Department of Health and Human Services, National Institutes of Health, National Science Foundation, Agency for Healthcare Research and Quality (AHRQ), pharmaceutical sponsor, etc.
- The study involves multiple individuals’ perspectives on the issue of interest **and** these perspectives are analyzed to reach generalized conclusions.

The following examples are projects which would not require IRB review:

- The goal of the project is to document a specific issue or event, or the experience of individuals, e.g., conducting a root-cause analysis of a medical error.
- The project compares and contrasts policies, procedures or events to identify general commonalities or inform policy decisions without the collection of information about identified individuals.

What if I intend to publish the results of the project?

The intent to publish is an insufficient criterion for determining whether or not a quality improvement activity involves research. Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.

What about informed consent? Is it required?

QI is an integral part of the normal operations of the organization. Someone seeking care from a health care organization cannot insist on the freedom to opt out completely from efforts to improve the quality of care in that organization, as that is contrary to the mission of the organization and moreover might jeopardize the quality of care delivered to him or herself. Conversely, informed consent is required for research, unless stringent requirements are met for allowing waiver of consent.

What is OHRP's view of this issue?

Protecting human subjects during research activities is critical and has been at the forefront of HHS activities for decades. In addition, HHS is committed to taking every appropriate opportunity to measure and improve the quality of care for patients. These two important goals typically do not intersect, since most quality improvement efforts are not research that is subject to the HHS regulations regarding protection of human research participants. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR part 46) may apply. To determine whether these regulations apply to a particular quality improvement activity, the following questions should be addressed in order: (1) does the activity involve research (45 CFR 46.102(d)); (2) does the research activity involve humans (45 CFR 46.102(f)); (3) does the human research fail to qualify for an exemption (45 CFR 46.101(b)); and (4) is the non-exempt human research conducted or supported by HHS or otherwise covered by an applicable assurance approved by OHRP? If the answer to all four questions is, "Yes", then the project falls under OHRP purview and must be reviewed by the IRB.

What are the questions I should consider in sorting through whether or not my project requires IRB review?

Evaluation of a given project may be complex. First, it needs to be established whether or not the proposed activity is considered a QI project or research. Please refer to the checklist in Part 1 of the Fairfield University Application for Quality Improvement Project for a list of questions that will help with that determination. If the answers to all the questions are "yes", then the activity is considered QI and does not require formal IRB review. If the answer to any question is "no", consultation with a member of the Fairfield University IRB is advised.

Second, if the proposed activity is considered research, it needs to be established whether or not the research involves human subjects. If so, then IRB review is required. Does the research involve interaction with a living individual? Does the research involve collection of identifiable private information about a living individual? If the answer to either question is YES, the research involves human subjects and requires IRB review.

What if it is unclear if the project falls within the scope of the IRB?

The IRB can provide assistance in determining if a given project must be reviewed under Fairfield University policy. This is most commonly done through a phone call or email to the IRB chair or a relevant member of the IRB providing a description of the nature of the project. Contact information can be found at fairfield.edu/irb/contact.html.

What must be submitted for IRB review?

Detailed information is available on the Fairfield University IRB website, which can be accessed at fairfield.edu/irb.