University Hospitals
Clinical Research Center

IRB ADMINISTRATION OFFICE
11100 Euclid Avenue, Lakeside 1400
Cleveland, Ohio 44106
Phone: (216) 844-1529

Quality Improvement FAQs for Clinical Researchers

1) I am confident my protocol is quality improvement. Why do I need IRB review?

   All Quality Improvement protocols should be submitted to the IRB with a request for a determination of "Non-Human Subjects Research." This is institutional policy. The researcher should not make this determination even when he/she is confident the work is QI, because when information is gathered about human subjects the Code of Federal Regulations regarding Protection of Human Subjects is relevant (45 CFR 46) and compliance with the regulations is a federal mandate.

2) I don't want to publish my Quality Improvement project. Do I still need to submit it to IRB?

   Yes. Intent to publish does not distinguish Quality Improvement from research, or determine if the protocol is Exempt or not (i.e. Non-Human Subjects Research determination).

3) So what is the difference between Research and Quality Improvement, anyway?

   Research is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" (45 CFR 46.102(d)); **quality improvement** is an activity conducted by one or more institutions "…whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes".[2]

   In other words…

   A protocol that has comparative intervention arms (of any type, including behavioral, medical, device related or surgical) is **research**, and any protocol that tests a *new* procedure or intervention is likely to be considered **research**. On the other hand, protocols that apply an already evidence-based intervention or intervention bundle (i.e. one that has been documented as effective in published research trials) to all patients with a specific condition, are likely to be considered **quality improvement**. In general **quality improvement** is intended to impact only those individuals who are being treated, whereas **research** is intended to be generalizable.

4) When is my Quality Improvement project also considered research?

   Fortunately the OHRP website has a great Q and A for this, which follows here:

   "*Q: Are there types of quality improvement efforts that are considered to be research that are subject to HHS human subjects regulations?*

   A: Yes, in certain cases, a quality improvement project may constitute non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA. For example, if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations."

   Text copied from: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html

5) If my Quality Improvement project is NOT determined to be Non-Human Subjects Research, and parts of it are considered research, does this mean I have to obtain informed consent from all subjects (patients and/or providers)?

The short answer is "no". But again, the OHRP website has the response to this important question, and it just boils down to the HHS requirements for waiving informed consent:

> *"… the HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research when*
>
> a. *the risk to the subjects is minimal,*
> b. *subjects' rights and welfare will not be adversely affected by the waiver,*
> c. *conducting the research without the waiver is not practicable, and*
> d. *if appropriate, subjects are provided with additional pertinent information after their participation (45 CFR 46.116(d)).*
>
> *Other applicable regulations or laws may require the informed consent of individuals in such projects independent of the HHS regulations for the protection of human subjects in research."*

Text copied from: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html

6) We are doing a project in which there is an educational offering for residents about errors in medicine, with a pretest and a posttest. Surely this is Quality Improvement!

Not necessarily. Things to consider include: Is the educational offering mandatory or voluntary? Are the pre and posttests being used to evaluate the residents? Recall that trainees and employees are a vulnerable population, so additional protections may be needed.

A protocol which includes educational research may be appropriate for a determination of Exempt status category 1 ("Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(i) research on regular and special education instructional strategies, or;
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)"

7) What if I have more questions?

Talk with your Departmental Review Chairperson, or call the IRB at 216-844-1529. We want to talk to you and help you avoid frustrations!

Source documents:

1- Investigator Manual for IRB Submissions – Quality Improvement Activities: https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials/core-offices/institutional-review-board/irb-policies

2-US Department of Health and Human Services Office of Human Research Protection Quality Improvement FAQ from the https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html

3-Squire guidelines (Standards for Quality Improvement Reporting Excellence http://www.squire-statement.org/guidelines

Developed by Lydia Furman MD