

Quality Improvement Activities

Introduction:

Any activity conducted that is considered “human subject research” under the Federal Regulations must receive IRB review and approval prior to engagement, per the UHCMC Federal Wide Authorization (FWA) agreement held with OHRP.

Institutions engage in “quality improvement” projects or activities which are designed to evaluate outcomes and determine appropriate institutional practices. In most cases, these activities do not qualify as “human subject research” that would require IRB review and approval under the Federal Regulations. 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. In these situations, prospective IRB approval is needed prior to engagement in the activity. Investigators CANNOT assume that their protocol is “quality improvement” simply because the ultimate goal of their research is to improve the quality of specific aspects of patient care. The IRB welcomes the opportunity to talk with any investigator who is trying to determine if their initiative should be submitted for a determination.

Definitions:

Research: As defined by Department of Health and Human Services (DHHS) Office of Human Research Protection (OHRP) under 45 CFR 46.101 (d) research is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge). As defined by the Food and Drug Administration (FDA) under 21 CFR 56.102 (c), a clinical investigation (research) involves a test article and one or more human subjects.

The term "research" designates an activity designed to test a hypothesis, allow conclusions to be drawn, and thus to develop or contribute to generalizable knowledge.

Quality improvement in healthcare is a process by which individuals work together to improve systems and processes with the intention to improve outcomes. The primary goal is to improve care for the specific population impacted by the intervention.

Anonymized: Information (data) which does not contain or link to any type of individual identifier. Coded information (information that has a code or study number, but no direct identifiers like name or birthdate) is NOT considered anonymized.

De-identified: Information (data) which does not contain any direct individual identifiers, like name, address, birthdate, etc... Information that is coded is considered de-identified.

Policy:

Activities that are strictly “quality improvement” do not require IRB review and approval prior to engagement. Quality improvement activities are generally limited to: (a) implementing an evidence-based 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. Quality improvement activities are intended to apply to those patients who are being treated within the QI initiative, and are not intended to be generalized to those beyond the protocol. Quality improvement activities include protocols which provide the same treatment to all subjects- these may be “bundled” interventions or single interventions, but the key point is that subjects (patients) are not randomized to differing treatment groups. Quality improvement includes those interventions (or “bundles” of interventions) which research has previously demonstrated to be beneficial. Examples of projects that qualify as “quality improvement” are:

- Initiatives in which UH departments or facilities collect and submit identifiable (including coded) clinical data to a database maintained by an outside entity that will aggregate the data with information from other institutions and report benchmarking standards to the participating institutions (e.g., submission of transplant data to the United Network for Organ Sharing).
- Initiatives (whether for benchmarking or other purposes) that use **anonymized** information.
- Initiatives include (a) delivering healthcare and (b) measuring and reporting provider performance locally for clinical, practical or administrative issues.
- Initiatives that involve the submission of identifiable data as required by state or federal law for quality measurement or reporting purposes. For example, if the Centers for Disease Control and Prevention (CDC) mandates that hospitals report to the agency, or to a database maintained by a third party on behalf of the agency, all incidences of meningococemia are treated, that reporting effort does not require UHCMC IRB review if the information will be used by the hospital, the agency, and/or any third party only for quality assurance or improvement purposes.

- Practice changes that are planned as part of ongoing improvement in patient care services, but for which evaluation data is needed to confirm expected effects of the change in practice.

In addition, the outcomes of a quality improvement initiative may be published or generally disseminated without the need for an IRB approval.

If at some point the purpose of a quality improvement initiative changes to include research components, then the initiative/database must be submitted for UHCMC IRB review at that time. An example is when a department determines that an initiative is effective (by comparing historical data to the data collected during the initiative) and determines that a more systematic investigation should occur.

Projects which qualify (in part or as a whole) as “human subject research” require prospective IRB review and approval. Typically those are conducted not only to improve quality of care but also to establish scientific evidence to determine how well the intervention achieves its results. Projects that utilize an “intervention” group and a prospective or historical “control” group typically qualify as research, as the use of a control group is a validated scientific technique to conduct a systematic investigation. Examples of quality improvement projects that qualify as research (and require UHCMC IRB approval) are:

- An initiative in which a UHCMC investigator proposes to collect and/or study a set of identifiable clinical data, analyze the data for general trends, and publish a paper in a scientific or other professional journal based on his or her work.
- An initiative in which UH institutions submit identifiable (including coded) clinical data to a database maintained by an outside entity that will use and/or share the data for research purposes in addition to providing any benchmarking analyses to participating institutions.
- An initiative that is required by law, but in which the hospital, the relevant state or federal agency/government body, and/or a third party will be using or sharing the data for research purposes in addition to quality measurement purposes.

REFERENCES

[45 CFR 46](#)

[21 CFR 50, 56, 312, and 812](#)

[OHRP Assurance Information](#)

[OHRP Quality Improvement Activities Frequently Asked Questions](#)