



OAKLAND CITY UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Quality Improvement or Research:

Do I Need IRB Approval?

Determining if an activity is Research or focused on Quality Improvement (QI) can be challenging. Federal regulations require human subject research to be reviewed and approved by an Institutional Review Board (IRB), while strictly QI activities do not require IRB oversight. However, some QI activities may also be research and therefore need IRB approval.

	Research	Continuous Quality Improvement
INTENT	Contribute to generalizable knowledge.	Improve a program, practice, process, or service of a specific institution.
DESIGN	Develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatment regimens, programs, or processes.	Not intended to develop or contribute to generalizable knowledge does not involve randomization of individuals (although random sampling could be part of the design), but may involve a comparison of variations in programs.
EFFECT ON PROGRAM OR PRACTICE EVALUATED	It is not the specific intent that findings of the activity will directly affect institutional or programmatic practice; however, they may influence future policies.	The findings of the activity are expected to directly affect institutional practice and may identify corrective action(s) needed.
POPULATION	Usually involves a subset of individuals; generally, the statistical justification for sample size is used to ensure endpoints are met.	Includes all or most receiving a particular treatment, program, or process (although random sampling could be part of the design); exclusion of information from some individuals significantly affects conclusions.
BENEFITS	Participants may or may not benefit directly; benefit, if any, to individuals or practice is incidental or delayed.	Participants or practices are expected to benefit directly from the activities, although

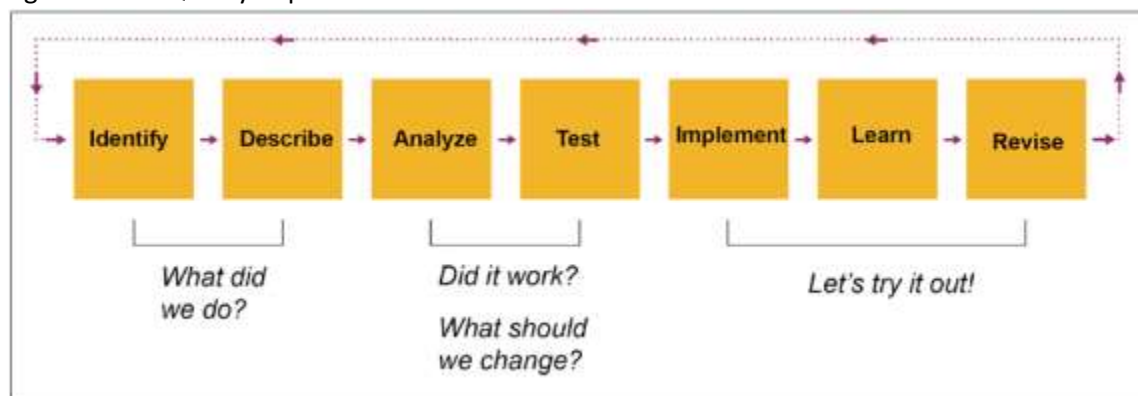
		those benefits may not be immediately realized.
RISKS	May place participants at risk.	It does not place participants at risk with the possible exception to the risks to privacy or confidentiality of data.
DETERMINATION OF RESULTS	The intent to publish or present the findings is generally presumed at the outset; dissemination of information usually occurs in research/scientific publications or other research/scientific forums; results expected to develop or contribute to generalizable knowledge or to advance a scientific body of knowledge.	The intent to publish or present is generally NOT presumed at the outset; dissemination of information may occur in quality improvement publications or presentations; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge.

Adapted in part from Indiana University's Defining Research vs. Quality Improvement/Quality Assurance (<https://research.iu.edu/compliance/human-subjects/guidance/quality.html>) and Virginia Commonwealth University's Quality Improvement vs. Research – Do I Need IRB Approval (https://research.vcu.edu/human_research/research_qi_guidance.pdf).

Continuous Quality Improvement

Continuous Quality Improvement is the systematic process of identifying, describing, and analyzing strengths and problems and then testing, implementing, learning from, and revising solutions. More simply, one can describe QI as an ongoing cycle of collecting data and using it to make decisions to improve program processes gradually.

Figure 1: The Quality Improvement Process



The Oakland City University IRB considers QI to involve:

Data collection and analysis for an institution's own internal operation monitoring and program improvement purposes, that is, only if:

- a) the data collection and analysis is limited to the use of data initially collected for any purpose other than the currently proposed activity, or
- b) is obtained through oral or written communications with individuals.

Implementation of accepted practice to improve the delivery or quality of care or services (including but not limited to education, training, procedures related to care or services) provided by a specific institution, that is, only if the purposes are limited to:

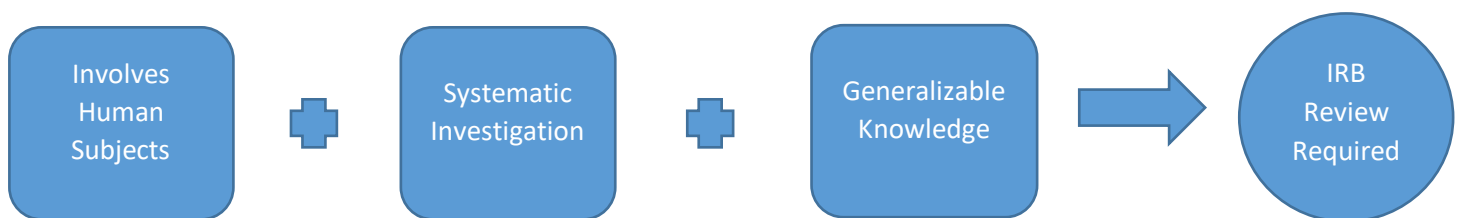
- a) altering the utilization of the accepted practice; and
- b) collecting data to evaluate the effects on the utilization of the practice.

NOTE: QI activities are not designed to contribute to generalizable knowledge.

What is research?

The Common Rule defines research as “a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.” [Source: Code of Federal Regulations 45 CFR 46.102 - <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>]

Please be aware that the intent to publish is an insufficient criterion for determining whether a project 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 nonresearched 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. [Source: OHRP FAQs - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>]



If an activity meets the definition of human subjects research under 45 CFR 46.102(I), then HHS regulations apply, and an IRB review is required.

Research or Continuous Quality Improvement Concerns

The activity is not intended for generalizable knowledge.

Please consider the primary intent and design of the project. Simply publishing or presenting the results of a QI project does not make it research. If the primary intent of the project is not generalizability (e.g., it is program evaluation/practice improvement related to a specific initiative) OR the project is not

designed in a way that the findings would be generalizable (i.e., limitations to project design), then the answer to this question is "True". If the project is standardized using systematic research methodologies with strong external validity in order to obtain reproducible results, then it would be considered research. If the intended outcome is simply to report on what happened at the institution/program, this does not indicate research design or intent as it may or may not be generalizable outside of the institution.

The project is intended to directly affect institutional or programmatic practice.

If the intention upon designing and conducting the project is to improve or evaluate a specific practice/program, then IRB review is not likely required.

The activity is intended to improve a process or delivery of care within a specific health care setting.

If the activity is specific to improvement in a specific health care setting, then it is likely Quality Improvement.

The project has not received funding to be conducted as a human subjects research study.

The purpose of this question is to determine whether the project has received funding to be conducted as a research study and not, for example, quality improvement or program evaluation. If you are unsure, consider contacting your program officer for the funding or funding entity to determine whether the funding source requires a specific level of IRB review and oversight. If the answer to this question is "False," IRB review may be required.

The activity does NOT involve adherence to a process or protocol.

If the activity requires rigid and strict adherence to a process or protocol, it is indicative of a "systematic investigation" which would mean that the activity may be research, and IRB review may be required.

There is sufficient existing evidence to support implementing this practice, or the change is being mandated by institutional policy.

If the practice being implemented is based on some existing evidence or information that indicates the practice should be effective when implemented locally, the activity is likely Quality Improvement. If the activity will try to test or prove something that is untested or unproven in other settings, the answer is "False," it is most likely research, and IRB review is required.

The project is part of Oakland City University's assessment of student learning efforts.

Academic assessment data (e.g., grades, coursework, surveys, interviews, etc.) are only used to provide feedback to students, improve a course or program, or report findings to offices that focus on the assessment of student learning for University-wide educational program improvement including accrediting agency reporting. For such cases, IRB approval is not required. However, the results are to be disseminated outside of the university (e.g., publish, present findings at a conference, report findings to a granting agency), IRB approval is required. [See Oakland City University Policy 2430 in the faculty or staff handbooks]