VCU Office of the Vice President for Research and Innovation

Quality Improvement vs. Research – Do I Need IRB Approval?

Determining if an activity is **Research** or **Quality Improvement** can be challenging. Federal regulations require human subject research to re reviewed and approved by the IRB, while strictly QI activities do not require IRB oversight. However, some QI activities may also be research and therefore need IRB approval. Please review the following guidance and use the following REDCap decision tool to determine if your activity likely needs IRB approval PRIOR to beginning the activity.

QI Decision REDCap Survey - Please see page 4 of this guidance document for explanations about each question.

What is QI & how does QI differ from research?

Research vs. Quality Improvement Comparison

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
MANDATE	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system; may or may not benefit participants
RISKS	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
ANALYSIS	Statistically prove or disprove hypothesis	Compare program, process or system to established standards
DISSEMINATION OF RESULTS	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge

Adapted in part from University of Wisconsin-Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

Quality Improvement

There is no regulatory definition for QI, however it is often described as "A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product" Source: The Institute of Medicine.

QI involves implementing previously proven/tested, planned and systematic activities done to improve or satisfy quality requirements.

Examples of QI activities that are likely NOT research include:

- Implementing a practice to improve the quality of patient care
- Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes
- Measuring and reporting provider performance data for clinical, practical, or administrative uses
- A group of affiliated hospitals implements an application to reduce prescription amount errors, and collects patient prescription information from medical charts to assess whether the application helped reduce error rates as expected.

Please see HHS guidelines and FAQs for more information.

Note: A quality improvement activity may also constitute non-exempt human subject research if it meets the definition of research.

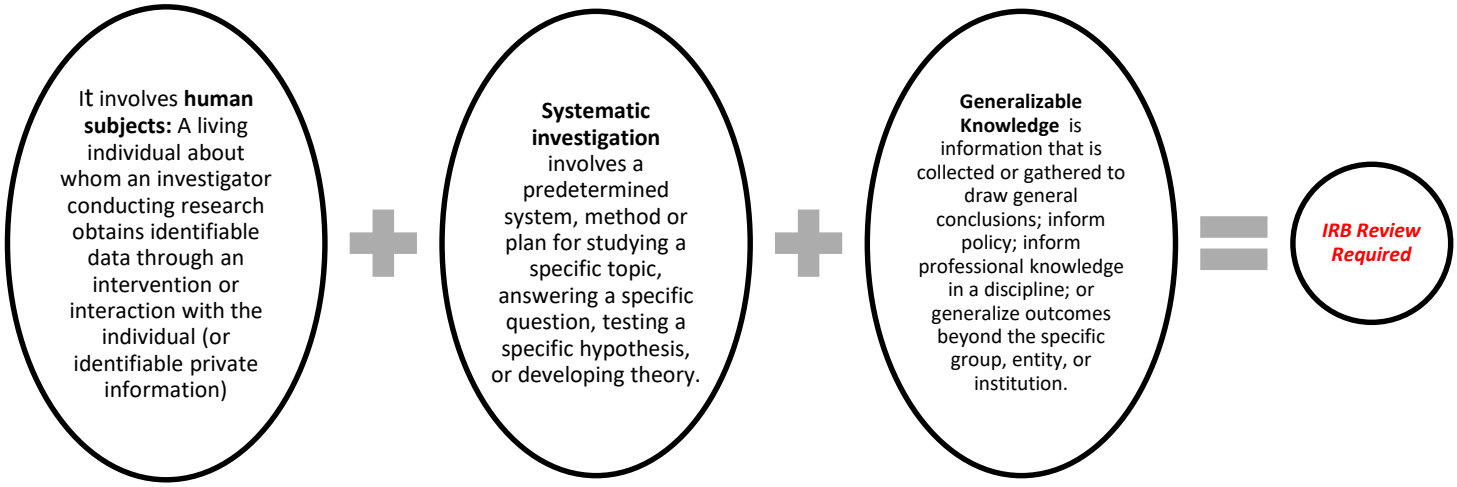
Examples of Activities that are likely QI and Research

- 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.
- Collaborative (multi-site) – All the sites are trying to improve some aspect of clinical care (ex. implementing an application to help improve making clinical decisions). The whole department decides this app will improve care, and implement the app. They collect data as the app is implemented, and in addition, analyze this data for generalizable knowledge.
- A teacher implements a practice to have all students reflect on their learning by keeping a journal, with the intention of improving teaching practice. However, the teacher also wants to prove that this method works, so they analyze student journals with grades to generalize the success of this method.

If an activity DOES NOT meet the definition of research under 45 CFR 46.102(d), then HHS regulations DO NOT apply, and IRB review is NOT required.

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration).



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

Examples of Activities that Begin as QI and Become Research

Please note that if you begin QI activities with the intent to eventually use the activity or data for research, it is best to submit to the IRB prior to beginning the activity. However, if after a QI project is completed, and you want to study it further and make it generalizable (research), then IRB submission is required (typically using secondary data).

For example:

- A QI project is implemented, and upon completion, the investigator realizes they want to do research about the project, and interview clinicians. The data they will collect from the interviews will be used for research, therefore, they would submit to the IRB before beginning interviews.
- A team uses biologic samples to compare two different types of tests to determine which one is better and therefore which one should be used at VCU [intent to improve care at VCU]. After they complete the comparison, they realize they want to share the success of these tests because they believe it will help other institutions [intent to contribute to generalizable knowledge]. They then submit to IRB and request to use the data collected for the QI project as secondary data for research.
- A surgeon believes that a certain technique will improve their own practice, so they implement it and record results as part of clinical practice. They then decide that this practice would help others, so they go back to their data to systematically analyze and generalize outcomes and results. They would need to submit to the IRB prior to the review of gathered data.
- A school decides to begin an afterschool program to help with academic success. The school gathered academic data which proved that the program was successful. After a few years of the program being a success, someone decides that they want to share that program with others. They can submit to the IRB to be able to analyze the previously collected data.

It is important to note that *the intent to publish is an insufficient criterion for determining whether a QI activity constitutes research.*

REDCap Form Question Explanations

Q1. *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.

Q2 *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.

Q3. *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.

Q4 *The project does not involve testing an experimental drug, device (including medical software or assays), or biologic.*

The RedCap QI Decision Form is based on the definition of research pursuant to the Common Rule (45 CFR 46.102(d)). The purpose of this question is to determine whether federal regulations beyond the Common Rule, such as FDA regulations, need to be applied to a project. If the project ***does*** involve testing an experimental drug, device, or biologic, then answer to this question is "False," and IRB review is likely required.

Q5 *The project has not received funding (e.g., federal, industry) 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.

Q6 *Activity does NOT involve randomization.*

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.

Q7 *This is not a multi-site project where all sites implement the same procedures (i.e., a rigid protocol).*

This question is intended to determine whether the project is being implemented at multiple sites where procedures are standardized across sites. Multiple sites may be involved (i.e., a collaborative), but not necessarily carrying out activities according to rigid procedures that are the same at all sites. This scenario may be indicative of a quality improvement initiative. Conversely, If multiple sites are involved and all are implementing standardized procedures, it is an indication that the results may be generalizable (the outcomes are likely not being used for quality improvement or program evaluation at the local institution). If the answer to this question is "False," IRB review may be required, but please contact the ORSP if you are unsure.

Q8. *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 unproved in other settings, the answer is "False," it is most likely research, and IRB review is required.

Q9 *This activity could be considered part of usual care. Consent beyond what is already obtained in clinical practice is not necessary.*

Sources: Stanford, Bon Secour, HHS, Cambridge Health, University of Wisconsin-Madison