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

Determining if an activity is **Research** or **Quality Improvement (QI)** can be challenging. Federal regulations require human subject research to re reviewed and approved by the IRB, while strictly QI activities do notrequire IRB oversight. However, some QI activities may also be research and therefore need IRB approval. Please review the following guidance and use the Research or Quality Improvement Survey atthe bottom of this document decision tool to determine if your activity likely needs IRB approval prior to beginning the activity.

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
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

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.

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.

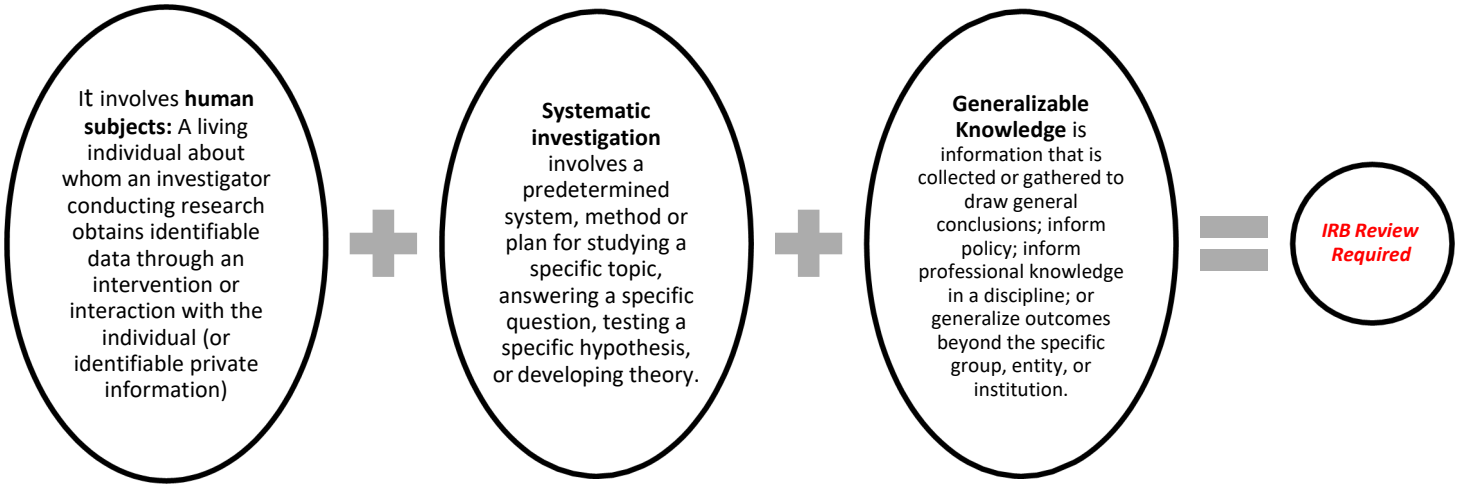
Note: A quality improvement activity may also constitute non-exempt human subject research if it meets the definition of research.

Examples of Activities that are likely QI and Research that require IRB review.

- 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.

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 UNM [intent to improve care at UNM]. 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.

Date:
Department:
Project Title:
Project Leader Name:

Instructions: Answer **YES** or **NO** to each of the following statements:

The purpose of the project is to (**mark which is true)**:	**YES**	**NO**
Improve the process or delivery of care with established /accepted quality standards	○	◉
Implement change according to mandates of HSL's quality improvement programs	○	◉
Improve performance on a specific service or program	○	◉

The project is **NOT** designed to:

Develop or contribute to generalizable knowledge	○	◉
Test the effectiveness of a new intervention on clinical quality	○	◉

The project does NOT follow a research design (such as testing a hypothesis, randomization of patients, or group comparison).	○	◉
The project is flexible to make on-going changes as needed to improve the process or delivery of care, activity or program, and is guided by data, actual experiences or clinical results.	○	◉
The project does NOT follow a protocol that over-rides individualized clinical decision-making.	○	◉
There is NO intention of using the data for research purposes.	○	◉
The project is conducted by clinicians and staff who provide care or are responsible for performance quality at HSL.	○	◉
The project involves as 'participants' the clinicians or staff at HSL, patients who are seen at HSL, or residents who live in HSL facilities.	○	◉
The project has NO funding from research-focused government agencies, sponsors or organizations, and is not receiving funding for the implementation research.	○	◉
The project has NOT been approved by another institution's or agency's IRB as a research study and is not otherwise being conducted under IRB oversight.	○	◉
The clinical practice unit agrees that this is a QI project that will be implemented to improve the process or delivery of care, activity or program. Department Head signature is required on this form.	○	◉

ANSWER KEY

• If the answer to ALL of the questions is YES, the activity is likely a Quality Improvement/Measurement activity that does not meet the definition of research, and therefore may not require IRB review.

• If the answer to ANY of the questions is NO, the project likely does meet the definition of research and will likely require IRB review.