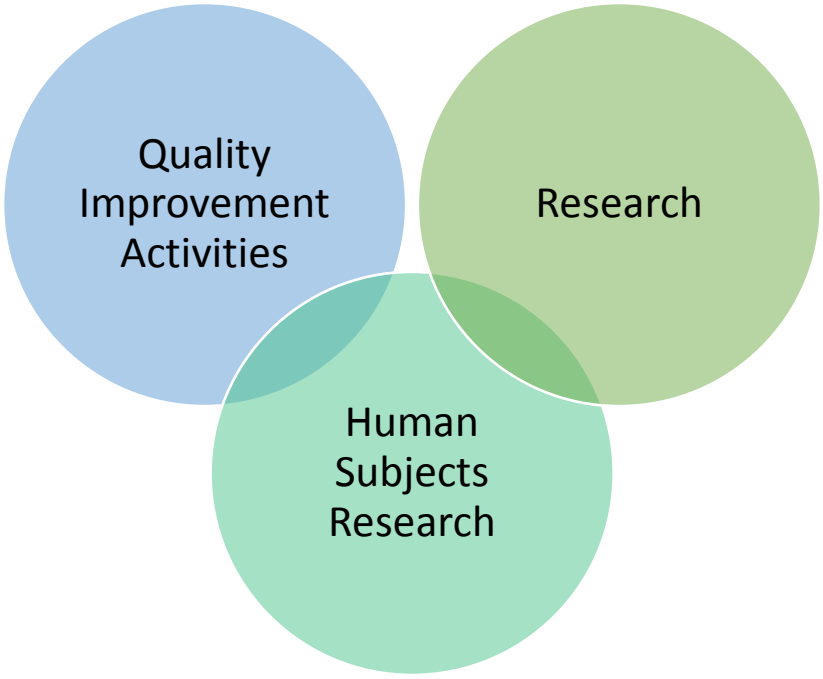
Lifespan
Delivering health with care®

Quality Improvement Activities

Most projects conducted for the purposes of quality assurance or quality improvement (QA/QI) do not require IRB review.

QI/QA projects which meet the definition of "research" and involve "human subjects," as defined in the federal regulations, require IRB review and oversight.



Note that the determination of whether or not a project constitutes research is separate from whether or not the project involves human subjects and only when both definitions are met does the project require IRB review.

Lifespan
Delivering health with care®

Frequently Asked Questions (FAQ)

What is QI?

- QI is a systematic investigation, data-driven activity designed to measure, analyze, improve and control health care.

What is Research?

- Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

What distinguishes QI from research?

- Generalizable knowledge.

When is IRB approval needed (i.e., when is QI human subjects research)?

IRB approval may be required when the activity involves some of the following characteristics:

- seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge;
- when the methodology employs a standard research design, such as randomization;
- when the protocol is fixed with a rigid goal, methodology, population, time period, etc.;
- when the funding for the activity comes from the outside organizations such as the NIH or those with a commercial interest in the results;
- when there will be a delay in the implementation of results;
- when the risks from the intervention to participants are greater than minimal

Can QI studies be published or presented?

- Intent to publish does not meet the definition of research. QI findings may be published but should not be represented as research. If the project is submitted to the IRB prior to the initiation, and not deemed to be research, a determination letter will be published that can be provided.

What ethical oversight is appropriate for QI activities that aren't research?

- The IRB provides ethical oversight for human subjects research. Hospital departments and divisions should review all proposed QI activities to ensure that the risks to participants are not greater than minimal and that there are appropriate protections for individual's privacy and confidentiality of their identifiable data.

Does HIPAA Privacy Rule still apply?

- QI/QA activities fall under the category of 'health care operations' for which no HIPAA Authorization or Waiver of Authorization needs to be sought. However, privacy and confidentiality of data still apply.

Does funding = research?

- No. However, if the project has received funding to be conducted as a research study it cannot proceed as QA/QI.

Lifespan
Delivering health with care®

QI or Research Worksheet

	Quality Improvement	Human Subjects Research
Purpose	Intent of project is to improve a practice or process within a particular institution or ensure it confirms with expected norms.	Intent of project is to develop or contribute to generalizable knowledge
Design	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization to different practices or processes.	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization of individuals to different treatments, regimens, or processes
Population	Responsibility to participate as a component of the program or process. Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information could significantly affect conclusions	Usually a subset of individuals; no obligation to participate. May involved statistical justification of sample size to achieve endpoints.
Benefits	Participants of process/system/program expected to benefit directly from the activities	Participants may or may not benefit directly; often a delayed or incidental benefit to individuals or future knowledge
Risks	Does not place participants at risk with the possible exception of risks to privacy or confidentiality of data	May place subjects at risk
Goal	Findings of the project are expected to directly affect institutional practice and identify corrective action(s) needed.	Findings of the project are not expected to directly affect institutional or programmatic practice
Analysis	Compare program, process or system to established standards (standard of care)	Statistically prove or disprove a hypothesis
Results	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. Intent to publish or present generally presumed at onset of project.	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 projects. Intent to publish or present may or may not be presumed at onset of project.

Lifespan
Delivering health with care®

Dos and Donts

- Terms such as ‘research’ and ‘human subject’ have distinct definitions in the federal regulations, and use of such terms may invoke a set of requirements that perhaps do not apply.
- When referring to QI projects, it is best to avoid use of the terms ‘research’ ‘study’ and even ‘study intervention’. More appropriate terms might include ‘project’ or ‘proposal’.
- Similarly, for research, the people participating are referred to as ‘subjects’ or ‘participants’. For Hospital QI projects, the participants are generally ‘patients’. Likewise, ‘researchers’ generally conduct ‘research’, but ‘clinicians’ undertake QI.