Quality Improvement (QI) vs. Human Subjects Research

QI and Human Subjects Research are both rigorous processes and at times involve similar methods, however, the two types of studies have distinctly different overall aims. QI projects use data-driven methods to improve delivery and quality. Such projects examine changes in human behavior and are largely experiential learning processes. Research is a systematic investigation designed to develop or contribute to generalizable knowledge.

In most instances, the goals of human subjects research and QI projects do not intersect, and QI projects are generally not subject to Federal regulatory protections. However, some projects are both QI and human subjects research, and sometimes, a QI project develops into a human subjects research project. Investigators must be aware of the criteria defining human subjects research to ensure that Federal regulations for the protection of human subjects are applied when necessary.

This table is to assist in determining if your project is QI or Human Subjects Research. You may contact the IRB for further assistance with determining the review type for your project.

	Human Subjects Research	Quality Improvement
Purpose	Designed to develop or contribute to generalizable knowledge[1] Reanalyze data from a previous research or QI activity	Identified problem designed to implement knowledge, assess a process, improve a program or delivery of program with consideration of established/accepted standards
Starting Point	Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	Knowledge-seeking is integral to ongoing management of a program or system
Design	Follows a specific protocol designed to answer discrete research questions May be single or multicenter Funding may be external or internal Intends to develop and evaluate/validate a concept or process which can then be generalized to other settings Studies which develop or evaluate a device	Adaptive, iterative Generally single center only Generally not externally funded

[1] Generalizable knowledge is new or confirmed information that has relevance, applicability, or significance beyond the specific context or population from which it was collective. Intended to be disseminated in a public or academic forum, or to inform policy or theory. Based on the ethical principles of the Belmont Report for human subjects research.

	(predictive model, algorithm, toolkit, etc.)[2] Research on educational instructional strategies or curriculum evaluation	
Benefits	Might or might not benefit current participant intended to benefit future individuals	Has the potential to directly benefit a process, system or program; might or might not benefit individuals
Endpoint	Answer a research question	Improve an existing program, process or system
Analysis	Statistically prove or disprove hypothesis	Compare program, process or system to established standards/best practices
Adoption of Results	Intent to contribute to generalizable knowledge Avenues for dissemination could include scientific presentation/publication	Intent to utilize results locally (e.g. for system enhancement) Evidence-based practices, institution-specific processes, measurements to determine if improvement occurs and testing new ideas to change the current process(es) may be shared (e.g. in a QI journal)
Publication/Presentation	Investigator obliged to share results	QI investigators encouraged to share systematic reporting of insights

The following questions can also help an investigator determine if a particular activity is human subjects research and therefore subject to human subjects protection regulations:

1. Does the activity involve research according to definitions outlined in the Code of Federal Regulations at 45 CFR §46.102(d)?
2. Are human subjects involved as defined in 45 CFR §46.102(f)?
3. Does the research qualify for an exemption under 45 CFR §46.101(b)?
4. Is the project nonexempt human subjects research supported by the US Department of Health and Human Services (HHS) or otherwise covered by an institution's Federalwide Assurance (the required federal documentation of an institution's commitment to comply with federal regulations and maintain policies and procedures for the protection of human participants)?

If you can clearly answer yes to the preceding questions, the project is most likely subject to the human subjects research regulations of HHS.

[2] Projects designed to develop and test a device (algorithm, predictive model, etc.) often are by their nature designed to build and contribute a solution that could be generalizable. The development of these tools may also be FDA regulated requiring IRB oversight. Investigators conducting this work should submit to the IRB as research or seek consult prior to initiating their work if they believe the project may qualify as QI.