Wayne State University
Institutional Review Board (IRB)

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Human Participant Research vs. Quality Improvement

The regulatory definition of Human Participant Research (HPR) under 45 CFR 46.102(d) is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Only HPR requires IRB review and IRB oversight. Quality Improvement projects may not meet the definition of HPR; see chart below.

	Research	Quality Improvement
Purpose	To test a formal hypothesis, answer a research question or advance science or discipline.	Assess an internal process, program, or system.
Starting Point	A prospectively designed, formal, written research hypothesis.	Assess a process or an established set of standards.
Benefits	Knowledge sought may not benefit subjects involved in study.	Knowledge sought directly benefits process, program, or system and may benefit patients.
Risks/Benefits	May put participants at risk	No risk, with exception of possibly privacy and confidentiality concerns.
Data Collection	Systematic data collection	Systematic data collection
Objective	To answer research question	Improve program, process, and/or system
Testing/ Analysis	Involves an in-depth review of relevant literature. Determine validity of hypothesis	Assess impact of a change in a process or compare the program, process, or system to a set of standards
Intended Result	Share findings with individuals associated with investigation and individuals not associated with investigation. **Designed to develop or contribute to generalizable knowledge.**	Share findings with only those individuals associated with the process, program, or system. Publishing results of QI is permissible.
***Generally*, if the conditions stated above fit, then IRB review and approval is:**	**Required**	**Not Required.** Use the HPR Form or contact the IRB Education Coordinator when unsure if IRB review is required for a project.

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