

QI, research, or both?

QI projects may come under the federal definition of research and may require institutional review board (IRB) review and approval if they involve human participants or individually identifiable data. QI programs and QI research should not pose any risk to individuals, infringe on individual privacy, or breach individual confidentiality. Research in this context is defined as follows: 45 CFR 46.102(d) of the federal regulations defines research as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge (Reproduced from the Institutional Review Board Guidebook (1993). http://www.hhs.gov/ohrp/archive/irb/irb_chapter1.htm. Accessed February 8, 2015.)

One characteristic that distinguishes a QI program from QI research is whether the activities are intended or created to develop or contribute to generalizable knowledge. Results or research findings, when they are generalizable knowledge, can be applied to populations or situations beyond those being immediately studied. When quality improvement initiatives are not intended to yield generalizable knowledge, IRB review is not mandatory.

In contrast, QI research that is planned in advance to go beyond the scope of the unit, department, or services would require IRB approval. For example, the QI team may want the results from its analysis and the interpretation of its quality initiative to be disseminated across a larger scope and to a broader community of scholars. In other cases, quality improvement research may be intended for application beyond the current quality control efforts or improvements, as when new procedures or processes are shared with a larger audience (outside of one system).

If at least one of these descriptions of QI research applies to the team's QI plan, the next consideration would be whether the proposed activities and strategies are a systematic investigation. When applying the concept of systematic investigation, the team would determine whether information beyond what is routine for patient care will be collected. For example, adding surveys or more data collection through qualitative means, which is typically not part of routine care delivery, would go beyond a QI program. Another consideration with a systematic investigation would be to determine if the team will be assessing the effectiveness of processes or procedures and comparing two or more treatments, interventions, or processes. When such comparison is contemplated, and manipulation is done to determine if one practice is better, the effort would qualify as QI research. When QI activities entail a systematic investigation that will develop or contribute to generalizable knowledge, per 45 CFR 46.102(d), IRB review is mandatory (HHS, nd.) (Harris, pp. 65-66).

Harris, J. L. (2019). *Project Planning and Management, (3rd Ed)*. Jones & Bartlett Learning,.

VitalBook file.