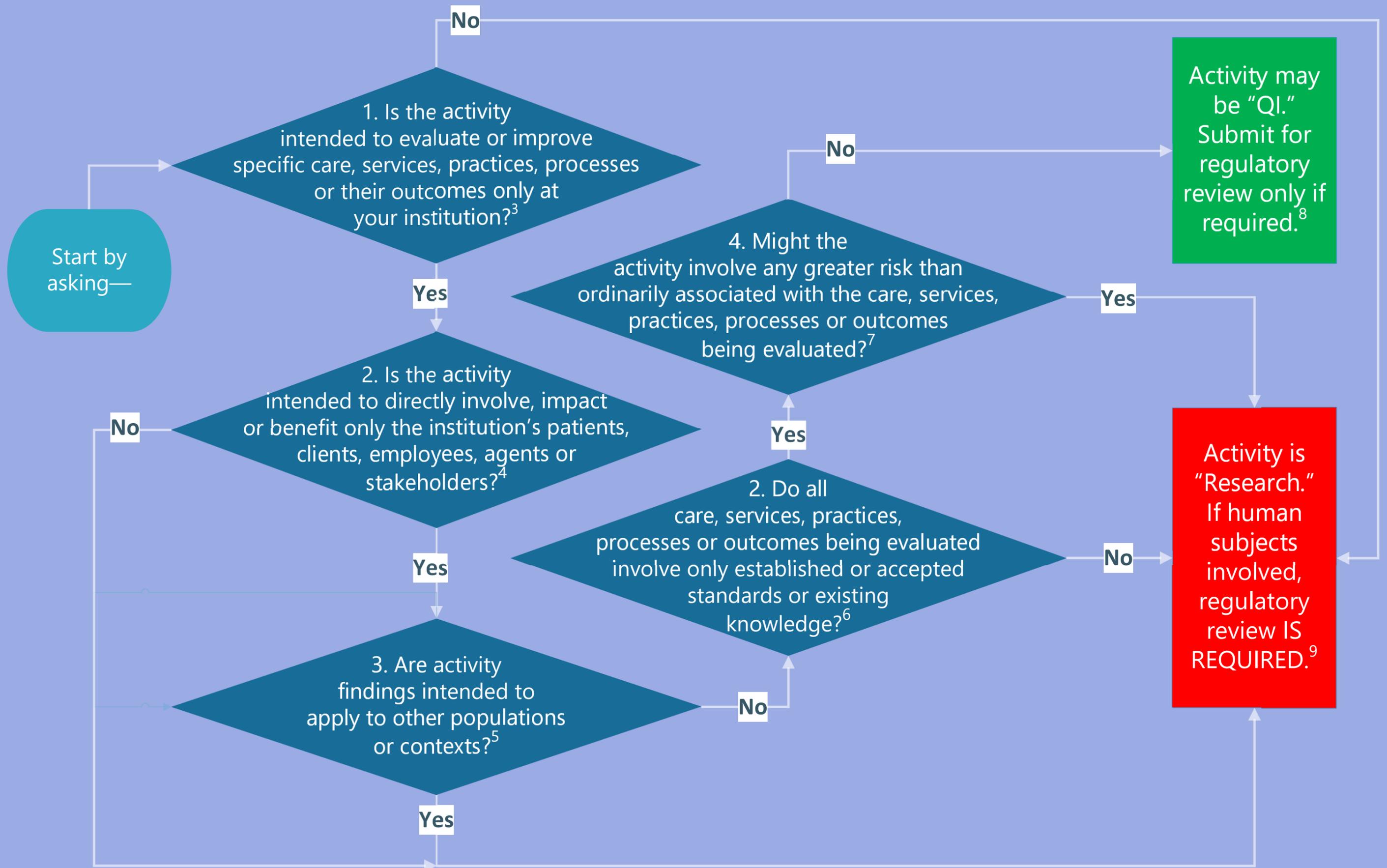


Quality Improvement¹ (QI) or Research²? (OHSP, December 1, 2021)



ENDNOTES:

¹ *Quality improvement* or QI is not defined by applicable federal law. However, authoritative and expert sources identify quality improvement as follows, for example—

“Quality improvement is the framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations. Structure includes things like technology, culture, leadership, and physical capital; process includes knowledge capital (e.g., standard operating procedures) or human capital (e.g., education and training) (U.S. Centers for Medicare & Medicaid Services, 2021).

“A QI program involves systematic activities that are organized and implemented by an organization to monitor, assess, and improve **its** quality of health care (HRSA, 2011).

A “Data-driven systematic approach by which individuals work together to improve specific **internal** systems, processes, costs, productivity, and quality outcomes **within an organization**” (Shirey et al., J. Cont. Educ. Nursing, 2011).

“A comprehensive system for developing **institution-wide** participation in planning and implementing change (Peterson et al., Quality in Higher Educ., 1997).

² *Research* is defined by applicable federal law as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (<https://www.ecfr.gov/on/2021-07-17/title-45/subtitle-A/subchapter-A/part-46#46.102>). Dissemination or publication of findings is not per se developing or contributing to generalizable knowledge, when dissemination or publication is neither assumed or expected from the outset of an activity, or not intended to be extrapolated to settings or contexts in which an activity does not take place.

³ *Institution* refers to the organization or entity with which the individuals conducting the activity are affiliated as employees or agents (e.g., contractors). An institution may include one or more facilities, units or locations of an organization with a single governance or structure (e.g., colleges and schools of FSU; ambulatory centers or outpatient clinics of TMH or CRMC; schools of the Leon County School District; locations of the Leon County Public Library; offices or divisions of the Florida Department of Children and Families; courts within a state or federal judicial district or circuit; or local offices within a Social Security region). Cooperative activities that involve two or more institutions and which activities are conducted by employees or agents from each of the involved institutions may also be considered an “institution” for the purpose of this algorithm. Otherwise, conducting activities at institutions in addition to or other than one’s own is presumptively research as that term is defined.

⁴ Consider whether activities are limited to only the population or a sample of the population that ordinarily and actually provides or receives care or services or is otherwise directly involved in practices or processes related to care or services that take place at the institution. If activities are planned to involve, impact or benefit others outside the institution, then the presumption is that the activity is research as that term is defined.

⁵ When findings, outcomes and conclusions are intended to apply to (a) populations that are not ordinarily or actually providing or receiving care or services or populations that are not otherwise directly involved in the practices or processes related to care or services that take place at the institution at which the activity is conducted or (b) other institutions or contexts not involved in the activity, then the presumption is that the activity is research as that term is defined.

⁶ Consider whether activities will involve use of only an established body or set of standards or knowledge against which care, services, practices, processes or outcomes at the institution will be evaluated, compared or measured. If not, or if the activity involves conjecture, unproven theories or hypotheses, then the presumption is that the activity is research as that term is defined.

⁷ If the probability and magnitude of any harm or discomfort anticipated in the activity is greater than those that may ordinarily be associated with the care, services, practices, processes or outcomes undergoing evaluation, then the activity may require IRB review.

⁸ Generally, QI activities (except as noted above) do not require IRB review. **IMPORTANT NOTE:** Publication/Graduate school/sponsor policy may require an official regulatory determination about whether IRB review is required and if so whether IRB approval or exemption was granted. If so, BEFORE undertaking any QI or research activity submit in RAMP IRB* an HRP-503d (Template Determination Form) and related materials for review. By law retroactive regulatory determinations are not permitted so plan accordingly. HRP-503d is not a complete IRB application but does ask for information about your activity that may be sufficient to deem your activity as QI. *RAMP IRB: <https://myramp.research.fsu.edu/>

⁹ If research may involve “human subjects” (see algorithm at <https://www.research.fsu.edu/media/7360/engagementdecisionchart20211201.pdf>), regulatory review is required. Submit in RAMP IRB* an HRP-503 or HRP-503a (Template protocols for biomedical research or social, behavioral or education research) for review. If no human subjects are involved, IRB review is not required, but see important note above about applicable publication, graduate school or sponsor requirements. *RAMP IRB: <https://myramp.research.fsu.edu/>