

What is the difference between research and quality improvement? Do I need to submit my project to the IRB?

The purpose of this handout is to clarify the difference between research and quality improvement (QI). Understanding this difference is important because research involving human subjects must be submitted to the KPSC Institutional Review Board (IRB) for ethical review.

If a research study is not submitted to an IRB for ethical review, the study results will not be publishable or presentable at any conferences or meetings. Submission of a research study to the IRB for ethical review must occur before the research study is conducted. The KPSC IRB cannot retroactively approve research that was conducted prior to seeking IRB review and approval.

What is human subjects research?

- A *human subject* is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through an intervention or interaction with the individual, or (2) Through identifiable private information (for example, through medical records).ⁱ
- *Research* is defined in federal regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” A key aspect of this definition is that a researcher has the goal to contribute generalizable knowledge. If the investigator has any intent of sharing the results of the study outside of KP or with the general public, for example, through publications, newsletters, conference posters or presentations, or peer-reviewed articles, the study is considered research.ⁱⁱ
- *Unless it is classified as “Non Human Subjects Research”, all human subjects research must be ethically reviewed by the IRB. This is both a federal regulation and KP institutional policy.*

What is a quality improvement (QI) project?

- QI is designed for the purposes of developing, planning, monitoring, or informing institutional policies and practices.ⁱⁱⁱ In general, QI is a systematic, data-guided project intended to improve the way in which care is provided for members/patients directly affected by the QI project.
- QI results are sometimes published in a journal or presented outside KPSC. However, if the information from a QI project is intended to be placed in the public domain and the project involves human subjects or uses identifiable data



from human subjects (e.g. medical record data), then it may be considered “human subjects research” and require IRB approval. The nature of the analysis and application of the results can make a QI project qualify as “human subjects research.”

- *QI projects are not covered by IRB requirements. KPSC employees are authorized to use protected health information for QI projects without patient authorization.*

What if I am still unclear about whether my project is research or a quality improvement (QI) project?

- Because the distinction between research and quality improvement (QI) projects is often unclear, the KPSC IRB has developed a formal procedure to help investigators determine whether their project is research or QI.
- The investigator should download and complete the short form “*QI/QA Versus Research Determination Form*” from the “Other Forms” section on the bottom of the webpage <http://irb.kp-scalresearch.org/appformrept.html>. Scroll down to the bottom of the page to find this form. This form is also posted on the GME Research Program website on the Institutional Review Board (IRB) page.
- Email the completed form and any surveys or data abstraction forms that will be used in your study to Marcela Sanchez at the IRB (Isabel.M.Sanchez@kp.org). Your documents will be reviewed by an IRB Board Member within approximately 2 business days, and you will receive guidance about how to proceed with your study.

ⁱ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>

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ⁱⁱⁱ <http://answers.hhs.gov/ohrp/categories/1569>