

## IRB Review of Quality Assurance (QA) / Quality Improvement (QI) Projects

QA/QI projects can overlap with research methodologies and the federal regulations that protect human research participants. QA/QI projects often include activities such as conducting surveys, reviewing identifiable data, drawing conclusions about problems, and suggesting methods for improvement. The key is to determine the intent of the project and whether this type of project meets the federal and local IRB definition of research.

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(1))

A **Systematic Investigation** typically includes the following elements:

1. An attempt is being made to answer a specific question (in some cases, this would involve formulation of a hypothesis);
2. Data or information is collected in an organized and consistent way using a recognized method;
3. Data or information is analyzed in some way, involving recognized quantitative or qualitative data analysis methods; and
4. Conclusions are drawn from the results of the analysis.

**Generalizable Knowledge:** A systematic investigation is typically designed to develop or contribute to generalizable knowledge when the following conditions are satisfied:

1. The information generated increases an established body of knowledge or enhances an established theoretical framework;
2. The results are expected to apply to a larger population beyond the site of data collection or the group studied; and
3. The project is intended to yield the results that can be replicated in other settings using the same research design.

**US Department of Health and Human Services (HHS) Office of Human Research Protection (OHRP) Quality Improvement FAQs:** <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

### **Local Policy:**

Certain kinds of investigative activities are not human subjects research (NHSR) as defined in the federal regulations for the protection of human subjects, while other minimal risk activities qualify for exemption from IRB oversight. OHRP policy guidance recommends that the determination that a study qualifies for exempt status be made by someone other than the investigator. Under UTCOMC IRB Policy the determination must be made by the IRB.

- A. If you wish to conduct a QA/QI project and only present the results within your class/program/clinic/hospital, this does not qualify as human subjects research under the federal regulatory and local IRB definition of “research”. In other words, you are not contributing to generalizable knowledge overall, but only aiming to improve quality of care/services/etc. at one program, hospital (e.g., Methodist University Hospital), or specific hospital system (e.g., Methodist Healthcare).

### **Submission to the UTCOMC IRB:**

1. Start a new application in the UTCOMC IRB electronic system, IRBNet System. [www.irbnet.org](http://www.irbnet.org)

2. Complete IRB Form J (Request for Non Human Subject Research/QI)
3. The checklist of documents required to upload for QI/NHSR submissions is under the Library Tab in IRBNet under READ ME FIRST.
4. If based on the answers to Form J the project qualifies as research an IRB Initial Application Smart Wizard must also be completed for exempt or expedited review request. **IF YOU PLAN TO PUBLISH OR PRESENT YOUR FINDINGS OUTSIDE OF THE INSTITUTION, YOUR PROJECT AUTOMATICALLY QUALIFIES AS RESEARCH BASED ON UT POLICY AND FEDERAL REGULATIONS**

**PRESENTED PROFESSIONALLY** means you wish to present your study in a public format with the research purpose of relating generalizable knowledge. Examples of this would be:

- Conducting a poster presentation about your project at a professional conference
- Presenting an invited lecture at another academic institution regarding your project
- Describing the results of your project at a grand rounds or colloquium in your academic department

Examples of presentations that would NOT be considered for research purposes would be:

- Presenting your project at a hospital in-service as part of a quality improvement project
- Describing the results of your project for a hospital quality assurance committee
- Presenting your project to classmates as part of a course requirement

- B. In general, professional publishing meets the definition of “research” because you are contributing to generalizable knowledge overall. If you think you **may** professionally present or publish the QA/QI project, then you have a research intent in addition to the quality assurance/quality improvement intent for your project. In other words, your project likely meets the federal regulatory and local IRB definition of “research”.

\*If you are unsure whether your project would qualify for NHSR status, Exempt status, or Expedited review, please contact the IRB office at 423-778-3818.