



The University of Toledo
Human Research Protection Program
Center for Creative Education Building, Suite 2102
3000 Arlington Ave., Toledo, Ohio 43614-2570

Do I Need IRB Approval to Collect Data for Quality Improvement/ Quality Assurance Projects?

Activities conducted for the sole purpose of quality improvement or quality assurance (QI/QA) **usually** do not require IRB approval, because they **usually** do not meet the definition of “research” as defined in [45 CFR 46.102](#): “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Whether or not the findings will be presented or published outside of UToledo is not relevant to the question of if the activities meet the definition of research.

If the QI/QA activities meet the definition of research, then IRB approval would be needed only if the research involves human subjects. As defined in [45 CFR 46.102](#), human subject means “a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

Please review the OHRP [guidance](#) on quality improvement activities to learn more about when QI/QA activities may or may not require IRB approval.

We strongly encourage UToledo faculty and staff who plan to engage in QI/QA activities to submit a “new IRB research” xForm in IRB Manager to receive a “Not Human Subjects Research” determination, if appropriate. This is the only way that HRPP staff can provide a formal determination that your planned activities do not meet the definition of research with human subjects and thus do not require IRB approval. Such determinations cannot be made retroactively, so it is advised that you do not begin collecting data until you have received a formal determination. Please note that many journals and academic and professional organizations may ask for documentation if you wish to disseminate your findings.