QUALITY IMPROVEMENT VERSUS RESEARCH

We often get questions whether the assessment projects we conduct in the Division of Student Life are considered research. The majority of the projects we work on in the Division are quality improvement projects. Kelly O'Berry, from the University of Iowa Institutional Review Board, outlines clearly and concisely what a quality improvement project is and whether it is considered research in her article, "Do Quality Assurance/Quality Improvement Projects Need IRB Approval?"

Do Quality Assurance/Quality Improvement Projects Need IRB Approval?

Quality Assurance/Quality Improvement (QA/QI) projects typically do not meet the definition of human subjects research, because they are not intended to "contribute to generalizable knowledge". Generalizable knowledge is knowledge that can be applied to an entire population i.e. all college students.

A Definition of Quality Assurance/Quality Improvement:

QA/QI projects are systematic, data-guided activities that seek to evaluate or identify ways to improve quality, outcomes, system performance or any other kind of improvement to an existing service. In QA/QI projects, providers and/or participants evaluate their daily experiences to identify ways to improve care or services and implement changes. The project may involve collecting data on the effects of those changes and assessing the results.

Differences Between QA/QI and Research Projects:

Points to Consider	Research	QA/QI
Purpose	To test a hypothesis or establish clinical practice standards where none are currently accepted	To assess or promptly improve a process, program or system; OR improve performance as judged by accepted/established standards
Starting Point	To answer a question or test a hypothesis	To improve performance or quality of a service
Benefits	Designed to further scientific knowledge in a particular field of study; subjects may or may not directly benefit	Designed to promptly benefit a process, program or system; may or may not benefit patients or clients
Risks/Burdens	Possible risks (physical, legal, social, psychological, financial must be disclosed to subjects	By design, projects do not increase patient/client risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection through intervention or interaction	Systematic data collection through interaction
End Point	Answer/address a research question	Promptly improve a program or process or system

Testing/Analysis	Statistically prove or disprove a hypothesis	Compare a program or process or system to an established set of standards

Table adapted from QA/QI guidance from the Stanford University Human Research Protection Program

View O'Berry's full article here.

Sharing the Results

It is acceptable to publish or share results for a quality improvement projects at a conference, summit, or other event. Ensure, as you describe the project, that it is clear that the project was intended for quality improvement and was not/is not intended to be research.

Ask if You Need IRB Approval

The University of Iowa IRB has a brief form in the eResearch (HawkIRB) system to ask if IRB approval is needed. The Human Subjects Research Determination (HSRD) form collects the information that an IRB Chair would need to make a determination about whether the project needs IRB approval. The IRB Chair will typically agree with you if you indicate that your project meets the definition of research. Use this form if, (1) You are not sure if your project meets the definition of human subjects research, or (2) You are pretty sure your project does not need IRB approval but you want a determination memo from an IRB Chair. You should receive a response in 2-5 business days; either a determination or a request for clarification.

If you have any questions about whether your project would qualify as quality improvement or research please reach out to the Office of Assessment, Improvement, and Research (teri-schnelle@uiowa.edu).