

Institutional Review Board for Human Use

TO: Cheryl Perry, Ph.D.
Administrative Director
Pediatric Research Office

FROM: Cari Oliver, CIP 
Office of Institutional Review Board (OIRB)

DATE: September 7, 2016

RE: UAB IRB Guidance – Quality Improvement Clarification

Per Federal regulations, a research project involving human subjects requires IRB review and approval before it may begin. Quality Improvement (QI), however, is not subject to Federal regulation or IRB review. The OHRP defines research as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The OHRP does not define quality improvement. It may be difficult for a project leader to determine whether a project is research or QI.

Most QI projects do not require IRB review, and nothing has to be submitted to the UAB IRB. In some cases, however, QI activities are designed to accomplish a research purpose in addition to the purpose of improving the quality of healthcare provided and will require review by the UAB IRB. It is important to understand that the intent to publish is an insufficient criterion for determining whether a QI activity constitutes research. Sometimes formal IRB determinations that the projects do not require IRB oversight are requested by journals, conferences, funding sources, and others.

Confusion also exists regarding QI when the project is funded or is conducted at multiple sites. Although these types of QI activities are more likely to also have a research component and consultation with the IRB is advisable, being funded or conducted at multiple sites alone is not enough to determine whether or not a project is research vs. QI.

In general, project activities where data are gathered for improvement of operations AND to generalize the results across institutions should be viewed as research. Circumstances differ between projects; even seemingly small differences between projects may have a large impact on the determination. Therefore, the UAB IRB has asked that when any uncertainty exists, you should consult the IRB. Types of projects that are more likely to require IRB guidance include projects that involve multiple sites, randomization, testing a hypothesis, and funding.

The UAB IRB has designated Cari Oliver (croliiver@uab.edu, 975-3931) as a contact for QI questions. Please look for upcoming guidance and tools on our website to help you take the proper steps in regards to quality improvement projects.