

Quality Improvement/Assurance versus Research

The Internal Review Board (IRB) is responsible for reviewing all **Human Subject Research (HSR)**, as defined by federal regulators. The federal definitions for these important terms are provided below:

Human Subject is defined as a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) obtains identifiable private information” (45CFR46.102 (d)).

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(f)).

While this responsibility is broad, it does not include interactions with human beings that are not research. **Quality Improvement/Assurance (QI/A)** activities are often not considered **Human Subject Research**. The definition and decision helps provided below are designed to aid the researcher or clinician in distinguishing between **QI/A** and **HSR**. It should be noted, however, that if any doubt remains after utilizing the provided decision helps, the IRB Chairperson *should be consulted*.

Quality Improvement/Assurance can be defined as any activity designed to improve or assess the effectiveness or efficiency of an institutional process. Such activities are focused on making sure appropriate institutional standards are satisfied or making corrections or improvements to institutional processes. The collection and evaluation of data in the QI/A activity is for internal institutional use.

QI/A projects involving human participants must not:

- Violate participant privacy
- Breach participant confidentiality
- Pose increased risk for participant

Common characteristics of QI/A projects:

- Implementing recognized methodologies to improve performance.
- Collecting data to evaluate implementation effectiveness and/or efficiency.
- Comparing a process to a recognized standard of performance.

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The first decision help is from a research paper from Reinhardt and Ray (2003). They introduce four criteria to distinguish between Quality Improvement / Assurance and Research. If a project qualifies as Research for any of the criteria, it should be considered Research. If Human Subjects are involved, the IRB should be consulted.

Reinhardt & Ray Criteria for Differentiating QI and Research

Criteria	Quality Improvement	Research
Intervention	Accepted practice or treatment intervention not previously implemented	New, untried practice or treatment intervention
Risk	Absence of risk to participants	Presence of risk, however, slight, to the participants
Audience	Primary audience is the organization Information is applicable only to the organization	Primary audience is the scientific community and consumers Information is generalizable
Data Source	Data is from a single organization	Data from multiple organizations

Reinhardt, A.C. & L.N. Ray. 2003. Differentiating Quality Improvement From Research. *Applied Nursing Research*, 16(1): 2-8.

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The second decision help highlights the characteristics of Quality Improvement / Assurance and Research across six traditional categories of consideration. **If *any* of the categories qualify as Research, the project should be considered Research. If Human Subjects are involved, the IRB should be consulted.**

**QI/A or HSR Characteristics
Identify Which is Applicable**

Project Description	Activity
<p><u>Purpose</u> The activity is intended to improve performance on a specific institutional process.</p> <p>The activity is intended to test a hypothesis or research question or establish new standards or procedures where none are already accepted.</p>	<p>QI/A</p> <p>R</p>
<p><u>Methods</u> The activity utilizes established quality improvement methods to introduce or update current procedure.</p> <p>The activity utilizes a traditional research design, with control groups, random selection, statistical analysis, etc., that will result in a statistically valid analysis of hypothesis or research question.</p>	<p>QI/A</p> <p>R</p>
<p><u>Sample</u> The activity includes a sample of the population normally involved in the institutional process being investigated (e.g., clinic patients or program participants).</p> <p>The activity includes a formal sampling plan consistent with a traditional research design (e.g., recruitment).</p>	<p>QI/A</p> <p>R</p>
<p><u>Benefits</u> The activity will likely benefit individuals currently involved in the institutional process (e.g., patients in clinical care or students in an academic program).</p> <p>The benefit of the activity will primarily be the generalizable knowledge obtained and disseminated.</p>	<p>QI/A</p> <p>R</p>
<p><u>Risks</u> The activity will <i>not</i> include any additional risk to the participants above and beyond their involvement in the institutional process (e.g., clinical care or satisfaction measures).</p> <p>The activity will include additional risk to the participants above and beyond normal institutional involvement.</p>	<p>QI/A</p> <p>R</p>
<p><u>Publication Prospects</u> This activity would be completed at the institution if there were no prospects for journal publication.</p>	<p>QI/A</p>

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The activity is primarily focused on producing generalizable knowledge that would likely result in a research journal publication.	R
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References:

1. Code of Federal Regulations. Department of Health and Human Services. Effective July 14, 2009. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
2. Reinhardt, A.C. & L.N. Ray. 2003. Differentiating Quality Improvement From Research. *Applied Nursing Research*, 16(1): 2-8.
3. Wichita Medical Research & Education Foundation. Clinical Quality Improvement Worksheet. <http://www.wichitamedicalresearch.org/wmrefscientificreviewcommittee/procedureguide/>
4. Wichita Medical Research & Education Foundation. Quality Improvement Instructional Information. <http://www.wichitamedicalresearch.org/WMREFScientificReviewCommittee/ProcedureGuide/101947.aspx>
5. Duke University Health System: Human Research Protection Program. 2013. Quality improvement activities in health care versus research. http://irb.duhs.duke.edu/wysiwyg/downloads/QI_policy_and_checklist_4-30-2013jw.pdf
6. OHRP Quality Improvement Activities Frequently Asked Questions. U.S. Department of Health and Human Services. www.hhs.gov

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