

QA/QI versus Research at Aurora Health Care

The purpose of this document is to provide guidance on Aurora Health Care's (AHC) organizational policy on what does or does not constitute a research activity. Based on the National Bioethics Advisory Committee (NBAC) December 19, 2000 draft document, the following are definitions used to consider what projects constitute quality assurance/quality improvement activities within Aurora Health Care. For a formal determination, please complete the form entitled [Request for Determination of Human Subject Research](#) found on the Aurora IRB web site at www.aurora.org/irb or call the RSPP office at 414.219.7744.

WORKING DEFINITIONS:

Research means a *Systematic Investigation*, including research development, testing and evaluation, designed to develop or contribute to *Generalizable Knowledge*. [45CFR46.102(d)]

Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous for purposes of this part. [21CFR56.102(c)].

Generalizable Knowledge: Knowledge that could be applied to populations outside of the population served by Aurora. This definition can vary. Examples of activities that typically are *not* generalizable include:

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Services, or concepts where it is not the intention to share the results beyond Aurora or any agency supporting the research
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the primary intention to share the results beyond the Aurora community

Human Subject means a living individual about whom an investigator conducting research obtains

1. data through intervention or interaction with the individual, or
2. identifiable private information. [45CFR46.102(f)]

Human subject for FDA-regulated products means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. [21CFR56.102(e)]

Quality Improvement – Projects aimed at improving local systems of care. The intent is to promote “betterment” of a process of care, clinical outcome within the institution.

Quality Assessment – Activities that are designed to determine whether aspects of medical practice are being performed in line with established standards within the institution.

Quality Assurance – Process of reviewing, analyzing or evaluating patient or provider specific data that may indicate (the need for) changes in systems or procedures that improve quality of care. The knowledge generated is typically for local, immediate application within the institution.

Systematic Investigation: The implementation of rule-based methods, specified in the investigation plan, that are repeated with multiple subjects (or their data) in a consistent manner across the subjects. Alternatively, the method may be implemented according to specified rules with a single subject for certain types of investigations. To be considered research, the explicit purpose of the systemic investigation must be to contribute to Generalizable Knowledge.

Internal AHC activities (which may include some data collection and analysis) are not considered research when:

- The purpose of the activity is to assess/evaluate the success of an established internal process/procedure/program in meeting objectives and goals.
- The intended results are to improve the practice/process/program within AHC.
- The evaluation is used as a management tool for monitoring and improving practice/process/program at AHC.

If a project is originally initiated as a local QI project, but the findings are of interest and the project investigator chooses to expand the findings into a research study, IRB review is required at that time. The submission should clearly indicate that the data were originally collected as part of a QI project.

The following questions will guide the IRB's determination and your evaluation of your project:

Does the activity access/use individually identifiable health information for any purpose other than to provide feedback for a practice/process/program within AHC?

Yes – Research. You must submit your project to the Aurora RSPP for further evaluation.

No – Continue to question 2

Does the evaluation or analysis of the practice/process/program change the way the practice/process/program will be implemented in a way that risks may be higher for health care providers or patients who participate (e.g. randomization to different interventions to permit statistical comparison of outcomes; involves an element that may be considered less than standard of care)?

Yes – Research. You must submit your project to the Aurora RSPP for further evaluation.

No – Continue to question 3

Is there outside funding utilizing a "research model" to carry out the evaluation of the program?

Yes – Research. You must submit your project to the Aurora RSPP for further evaluation. Submission application tools are available on the Aurora RSPP web site at www.aurora.org/irb.

No – Not research. You do not need to submit your project to the Aurora RSPP.

If you require written documentation of this determination, please complete the form entitled [Request for Determination of Human Subject Research](#) located on the Aurora RSPP web site at www.aurora.org/irb.