

<p><b><u>Information Sheet</u></b></p> <p><b>Guidelines for Quality Assurance, Quality Improvement and Research Issues</b></p>	<p><b>Advocate Health Care Institutional Review Board</b></p> <p>205 W. Touhy, Suite 203, Park Ridge, IL 60068-4202  Voice: 847-384-3534; Fax: 847-384-3537  E-Mail: IRBMail@AdvocateHealth.com</p>
Version: 1.1; Date: October 2006	

The terms Quality Assurance (QA) and Quality Improvement (QI) generally refer to **non-research** activities. However, the line between research and QA/QI is not clear in federal standards and making the determination is among an IRB's most difficult tasks. The most important element in determining whether a project is human subject research or QA/QI activity is the research intent of the investigator and a plan to publish and/or present the information outside the institution. However, although the intent to publish is a good measure, it shouldn't be the sole criterion.

Federal law defines human subject research as follows:

**Human subject** means 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) identifiable private information.

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 46.102 (d)]. Research can include a variety of activities, such as experiments, observation, surveys, tests and recordings. Generally research does not include projects for quality assurance (QA), certain aspects of public health practice such as disease monitoring, program evaluation or audits.

This guidance, prepared by the Washington University Medical Center (WUMC) Human Studies Committee (HSC), has been adapted *in part* and modified by the AHC IRB.

**Quality Assurance (QA)**

**Quality assurance** = "Activities that are designed to determine if aspects of medical practice are being performed in line with established standards." The purpose of QA projects is to assure known quality. QA projects are usually performed for internal performance monitoring and auditing purposes only.

**Does a QA project require the IRB review and approval?**

If the answer is "yes" to all of the following questions, the IRB review **is not required**.

1. Will the investigator monitor an existing process without any manipulation of the process?
2. Will physicians and caregivers be permitted to provide clinical standard of care (without intervention) regardless of the conduct of the project?
3. Does the project involve collection of data to which the investigator routinely has access as part of his/her responsibilities within the institution associated with: 1) treatment; 2) billing; 3) performance monitoring; or 4) compliance?

QA projects must not: 1) involve any risk to the subjects; 2) violate patient's privacy; 3) breach a patient's confidentiality; or 4) pose any risk to patients, physicians, staff, or associates.

The IRB review **is required** where:

1. The investigator anticipates in advance of conducting the project that will be analyzed, interpreted, and the findings will be disseminated beyond the scope of investigator's department or division, or
2. The knowledge the investigator will gain from his/her project will be applied beyond quality assurance, service, or training to lead to a new procedure or process.

## **Quality Improvement (QI)**

**Quality improvement** = “An activity specifically initiated with a goal of improving the performance of medical practice in relation to an established standard.” QI projects are more likely candidates for IRB review and often fall in the gray area. They may involve a systematic investigation, testing and evaluation, but with a different purpose in mind than research projects. The purpose of QI studies is to determine quality, improve (change) patient services, or improve (change) the provision of medical care.

### **Does a QI project require the IRB review and approval?**

If the answer is “yes” to any of the following questions, the IRB review is **required**.

1. Does the project explore a previously unknown phenomenon even if a marketed or FDA approved product?
2. Does the project gather information beyond what is routine for patient care, e.g., extra medical tests, surveys, or data collection?
3. Does the project compare two or more treatments, interventions, or processes?
4. Does the project manipulate a current process to determine which is best?

The above guidelines can be applied along with the criterion of intent to publish and/or present the data. If after the QA/QI project is completed, it is discovered that certain information and data might be publishable, which is understood as "contributing to generalizable knowledge," and therefore considered "research," a research plan should be developed for a larger study, which need to be reviewed and approved by the IRB.

### **NOTE**

Not all QA/QI projects, which might be considered research, fall into the category of **human subject** research. It is recommended, that when it is difficult to determine the primary intent of the project and/or whether it involves human subjects, to submit it for the IRB review and approval. Having IRB approval gives investigators more flexibility for subsequent publication and/or presentation of the results.

## **HIPAA Requirement**

If the QA/QI project requires IRB review and approval, then it is research and thus, does not fall under the institution’s Treatment/Payment/Operations (TPO) activities. If the project requires IRB review, the HIPAA requirements are the same as for all other research studies.

### **References**

- ▶ Washington University Medical Center (WUMC), St. Louis, MO; Human Studies Committee (HSC): Quality Assurance and Quality Improvement Research Guidelines.
- ▶ “Identifying Research Intent,” Robert J. Amdur and Marjorie A. Speers, in *Institutional Review Board: Management and Function*, eds. Robert J. Amdur and Elizabeth Bankert (Jones and Bartlett, 2002), pages: 118-124.
- ▶ “Determining When Quality Improvement Initiatives Should Be Considered Research” D. Casarett, J. Karlawish, J. Sugarman. *JAMA*, May 3, 2000, vol. 283, No. 17, pages: 2275-2280.