



Client Alert

Contact Attorney Regarding
This Matter:

Tracy M. Field
404.873.8648 - direct
404.873.8649 - fax
tracyfield@agg.com

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

Are Quality Improvement Activities Considered Human Subjects Research?

New Guidance From OHRP

Faced with increasing attention on documenting the delivery of quality patient care, providers are establishing more formal means to measure the effectiveness of their services. In establishing such programs, providers may conduct a systematic approach to review patient data, record outcomes and identify other relevant information that could be used to promote quality improvement activities.

In conducting these sorts of reviews, there have been reports that some institutions as well as the Office for Human Research Protections (OHRP) consider this work as human subjects "research" that is subject to review and oversight by an institutional review board (IRB). In some instances, the IRBs have concluded that because quality improvement reviews can result in publications or lead to conclusions that are "generalizable," the activities constitute human subjects research. Providers and IRBs have struggled with how to decide whether their quality improvement activities are subject to these additional regulations. Obviously, projects subject to additional regulatory oversight are more costly, in terms of time and resources than those reviews that are in place to document or enhance patient care.

Fortunately, on December 30, 2008, the Office for Human Research Protections (OHRP) posted ten "Frequently Asked Questions (FAQ)" regarding how it views quality improvement activities within its regulations for human research subject protection. Although these FAQs are not binding regulations, they could help providers and IRBs in addressing the differences between research and quality improvement programs. Indeed, the FAQs state that routine quality initiatives involve "data collection" and "standards adoption" compared to research studies that are used to establish new clinical practices. Notably, OHRP states that plans to publish results of a quality improvement project should not automatically result in categorizing the study as "research."

Although these FAQs are not extensive, they could be useful in attempting to define what constitutes research versus quality improvement initiatives for providers.

To review OHRP's new FAQs, please see <http://www.hhs.gov/ohrp/qualityfaq.html>.

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