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Feature Article

Quality Assurance, Research, and Everything In Between

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Educational Objectives:

At the end of this activity, participants should be able to:

- List the conditions under which IRB review is required for research studies.
- Define "human subjects" and "research" as they are stated in the federal regulations.
- List three differences between quality assurance and research.
- Use the information provided to understand how the IRB differentiates between quality assurance projects and human subjects research.

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Introduction

Under the federal regulations, institutions holding a Federalwide Assurance (FWA) must assure to the government that all nonexempt human subjects research conducted by employees or agents of the institution receives IRB review and complies with the regulations under 45 CFR 46. Conversely, projects that are conducted purely for quality assurance purposes and do not meet the definition of human subjects research do not fall under the 45 CFR 46 regulations and do NOT require IRB approval. Unfortunately, because research and quality assurance projects both

utilize similar methodologies (surveys, interviews, analysis of documents and data) and often collect data about humans, it may be difficult to distinguish between quality assurance activities and human subjects research. The purpose of this article is to describe the differences between these two types of activities, and to describe the regulatory and institutional requirements for review of each.

Who are human subjects?

According to 45 CFR 46. 102(f) in the federal regulations, **human subject** means a ***living*** individual ***about whom*** an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, OR
- Identifiable private information.

These regulations go on to state that ***intervention*** includes both physical procedures by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes. The regulations state that ***interaction*** "includes communication or interpersonal contact between investigator and subject" (in person, by mail, telephone, email, etc.). It should be noted that these definitions are purposefully broad enough to include humans involved in social behavioral--as well as biomedical--research.

Based on the definition above, an investigator may assume that he/she has human subjects if he/she collects private, identifiable information *about* people for research even if he/she does not intervene or interact with them.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; and that the information he/she has provided for specific purposes will not be made public (for example, a medical record).

Information is **individually identifiable** if the identity of the subject is or may readily be ascertained by the investigator. Information is also individually identifiable if the individual can be associated with the information (i.e., the information does not contain any direct identifiers, but the person's identity can still be ascertained through deductive disclosure from the data that is collected).

What is Research?

According to 45 CFR 46 102(d), research means a **systematic investigation** (including research development, testing and evaluation)

designed to develop or contribute to generalizable knowledge.

In a recent presentation for PRIMR (Public Responsibility in Medicine and Research) on April 22, 2008, Jeffrey M. Cohen, PhD, CIP (President, HRP Associates, Inc.), defined systematic investigation as "an activity that involves a prospective research plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question".

Investigators may have heard that "designed to contribute to generalizable knowledge" means only that the results will be published or presented at a scientific meeting. While these activities do represent a contribution to generalizable knowledge, they represent only part of the regulatory intent. Cohen offers a broader definition based on regulatory guidance by stating, "Investigations designed to contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy or generalize findings." This does not refer to statistical generalizability but, instead, to the ability to draw conclusions and apply them to populations outside those being studied.

What is Quality Assurance?

Quality assurance (QA) or Quality Improvement (QI) are like human subjects research but do not specifically meet the definition of human subjects research. The federal regulations under 45 CFR 46 do not provide a specific definition for quality assurance (QA). In his presentation, Cohen defined QA as "a systematic collection and analysis of information about the effectiveness of a program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development." It is sometimes called "program evaluation." QA involves gathering information from or about human beings. QA/ QI activities are usually undertaken to assess the effectiveness of a specific program, practice or service. QA/QI projects that do not involve human subjects research do NOT require IRB review. This does not mean that there are not ethical concerns related to QA/QI projects, just that these concerns are addressed by institutions in various ways other than by IRB review. For more information about these issues please see Why We Need Ethical Oversight of Quality Improvement Projects, Editorial, Thomas V. Perneger, International Journal for Quality in Health Care, 2004, Vol. 16: 343-344, Number 5.

Quality assurance, human subjects research or both?

QA projects can sometimes go beyond the scope of quality assurance activities. These projects may not only evaluate existing processes, but also test new procedures or interventions. According to guidance from the Office of Human Research Protections (OHRP), such activities may actually be *both* QA and human subjects research. If this is the case, the overall project must be reviewed as human subjects research, IRB approval is necessary, and the regulations under 45 CFR 46 apply.

The following table may assist investigators in differentiating between QA and human subjects research activities. In the end, however, the IRB has the final responsibility for determining whether projects meet the definition of human subjects research.

Quality Assurance versus Research		
	QA/QI	**Research**
Purpose	Comprehensive review of key aspects of a process to assure compliance with standards; management tool to improve services, to assure known quality or monitor an existing process (no manipulation)	Test a hypothesis or a new, modified or previously untested intervention, service or program and then generalize findings; systematic comparison of standard and non-standard interventions/procedures
Goal	Measure internal processes for adherence; internal dissemination only	Publish or present to an outside department or institution; generalize the knowledge beyond the group being studied
Who	QA/QI department, managers, and those whose role it is to evaluate quality where QA/QI is mandated	Investigators, researchers and students
Requirements	Institutional protections under HIPAA privacy; no IRB approval needed regulations under 45 CFR 46 do NOT apply	IRB review and approval needed for exempt and nonexempt human subject research; regulations under 45 CFR 46 apply to nonexempt research (i.e., consent, continuing review, reporting unanticipated problems, etc.)

Example of a problem with a study that involved QA and Research

In July of 2007, OHRP sent a determination letter to Johns Hopkins regarding the following study: **Peter Pronovost, et. al. An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU. New England Journal of Medicine 2006; 355: 2725-2732**. This study was not reviewed by the Hopkins IRB under the 45 CFR 46 regulations because they had determined the project to be QA rather than human subjects research. OHRP took the position that this project did meet the definition of human subjects research. A subsequent OHRP letter was sent to Johns Hopkins on November 6, 2007 with a further explanation of how they arrived at the conclusion that this project was human subjects research.

As these letters indicate, the OHRP expects institutions who hold a FWA, to carefully review projects to determine whether or not they meet the definitions of human subjects research and, therefore, are subject to IRB approval and compliance with the regulations under 45 CFR 46.

These OHRP determination letters precipitated a great deal of discussion in the research community. Subsequently, several editorials were written on this topic of QA versus research. These discussions emphasize the fact that distinguishing between quality assurance and human subjects research is sometimes not easy.

"A Lifesaving Checklist", Dr. Atul Gawande, an Op-Ed Contributor to the New York Times; December 30, 2007.

"Pointy-Headed Regulation", New York Times Editorial Staff Response to "A Lifesaving Checklist", Editorials, New York Times; January 27, 2008.

"Quality-Improvement Research and Informed Consent", Franklin G. Miller, Ph.D., and Ezekiel J. Emanuel, M.D., Ph.D. , The New England Journal of Medicine, February 21,2008, (Volume 358:765-767, Number 8).

"Harming through Protection?", Mary Ann Baily, Ph.D., The New England Journal of Medicine, February 21, 2008, (Volume 358:768-768, Number 8).

BUMC institutional policy and procedures

Here at BUMC, any projects that MAY meet the definition of human subjects research must be submitted to the BUMC IRB for an initial review and determination. To obtain this initial IRB review, projects are submitted to the IRB via INSPIR as Exempt applications. For Exempt projects, only a limited number of sections on the INSPIR application

need to be completed. Please click here for instructions for completing the INSPIR application for Exempt review.

A project that is determined to be NOT human subjects research will receive a letter via INSPIR indicating that it is exempt from further BUMC IRB review as long as no changes are made to the project.

A project that is determined to be human subjects research MAY be determined to be Exempt under one of the Federally designated Exempt categories. A letter will then be generated via INSPIR indicating that the project is exempt from further IRB review as long as no changes are made to the protocol.

If a project is determined to be nonexempt human subjects research, then it will need additional IRB review as either an expedited or full board study. The principal investigator will be notified via a letter (modification memo) generated through INSPIR of the IRB's determination. (Note: If the IRB determines that the study is NOT exempt, additional information will need to be added to the protocol prior to Expedited or Full Board review by the IRB. This will be explained in the INSPIR modification memo.)

Summary

All activities that meet the regulatory definition of human subjects research must be reviewed by the IRB. All nonexempt human subjects research must have IRB approval and must comply with the regulations under 45 CFR 46. Most quality assurance activities are NOT human subjects research and, therefore, do not fall under the 45 CFR 46 requirements. However, if any portion of a QA project *might* be human subjects research, then the project must be submitted to the IRB for review and a determination.

Quiz

This Quiz applies to the recertification period from July 1, 2007 to June 30, 2009. CME credits are no longer offered or available as of 9/15/2010.

Click here and close window if you are a BUMC researcher and would like to take the quiz now.

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