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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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- What is Research?
- What is Quality Assurance?
- Quality assurance, human subjects research or both?
- Example of a problem with a study that involved QA and 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.

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**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).

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**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.

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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.


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.

Close Window