QUALITY IMPROVEMENT AND RESEARCH

A Peaceful Co-existence

Speaker:
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RESEARCH: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
DEFINITIONS

QUALITY IMPROVEMENT: There is no regulatory definition but often QA/QI is described as “systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery”

DIFFERENCES BETWEEN RESEARCH AND QI

**RESEARCH:**
PI will have a specific hypothesis or research question.

**QI:**
PI will identify a clinical program or protocol that s/he wants to improve.
DIFFERENCES BETWEEN RESEARCH AND QI

RESEARCH:
• PI will conduct an organized review of relevant literature.

QI:
• PI may review other clinical programs or protocols at other institutions, but does not plan a full literature review.
DIFFERENCES BETWEEN RESEARCH AND QI

RESEARCH:
• PI will develop a research design that will lead to scientifically valid findings. Elements of a research design include: Control groups; random selection of subjects, statistical tests, sample design, etc.

QI:
• PI will design a project using QI methods (such as Plan-Do-Check-Act or PDCA cycle) aimed at producing change within our organization. Design does not include sufficient research design elements to support a scientifically valid finding.
DIFFERENCES BETWEEN RESEARCH AND QI

**RESEARCH:**

- Goal is to advance general knowledge in the academic/scientific community or in the PI’s profession.

**QI:**

- Designed to implement knowledge, assess a process or program as judged by established/accepted standards
Most QI projects do not require IRB review, but some do
Does Publishing Mean It’s Research?

- Publication, *by itself*, is not sufficient to require IRB review and approval.
- Even though most QI activities aren't research, there is much to be learned from sharing descriptions of these non-research activities. Lessons learned from a QI activity should be shared with others.
- Publication cannot use the term “research”
If It’s a Multi-Site QI Project, Is It Automatically Research?

• No, but you have to be careful

• Read the whole protocol – what does the lead agency intend to do with the data? Examine all aims.

• Call the IRB as often, these are QI with a research component.
Provonost Letter (OHRP, July 30, 2008)

• Johns Hopkins University participated in a multi-site implementation of a program to reduce catheter-related bloodstream infections that was implemented in Michigan hospitals and described in the New England Journal of Medicine (NEJM) article of 12/28/06.

• JH also planned to carry out a study to improve the understanding of how hospitals implement this program and what factors influence effectiveness.
Pronovost Letter (OHRP, July 30, 2008)

- OHRP found that the actual program implementation was QI but that the evaluation of the data and certain surveys conducted were activities that would involve submission to the IRB.
• OHRP said the critical question was: “Is the program implemented for a research purpose or altered or controlled in some way to answer a research question?”

• This introduces the idea that QI activities can be separable from the research
SO WHEN IS IT RESEARCH?

• Are you seeking to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge?

• Do you have a research question in addition to the goal of improving healthcare?

• Are you employing a standard research design, such as randomization?
SO WHEN IS IT RESEARCH?

• Is the protocol fixed with a rigid goal, methodology, population, time period, etc.?

• Will there be a delay in the implementation of results?

• Are the risks from the intervention to participants greater than minimal?
IRB PLANS

- Comprehensive guidance by end of year
- QI checklists
- IRB QI Liaison – Cari Oliver (975-3931)