

QUALITY IMPROVEMENT AND RESEARCH

A Peaceful Co-existence

Speaker:

Cari Oliver, CIP
Assistant Director,
Office of the IRB

DEFINITIONS

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”

Lynn J, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med* 2007;146:666-674

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.

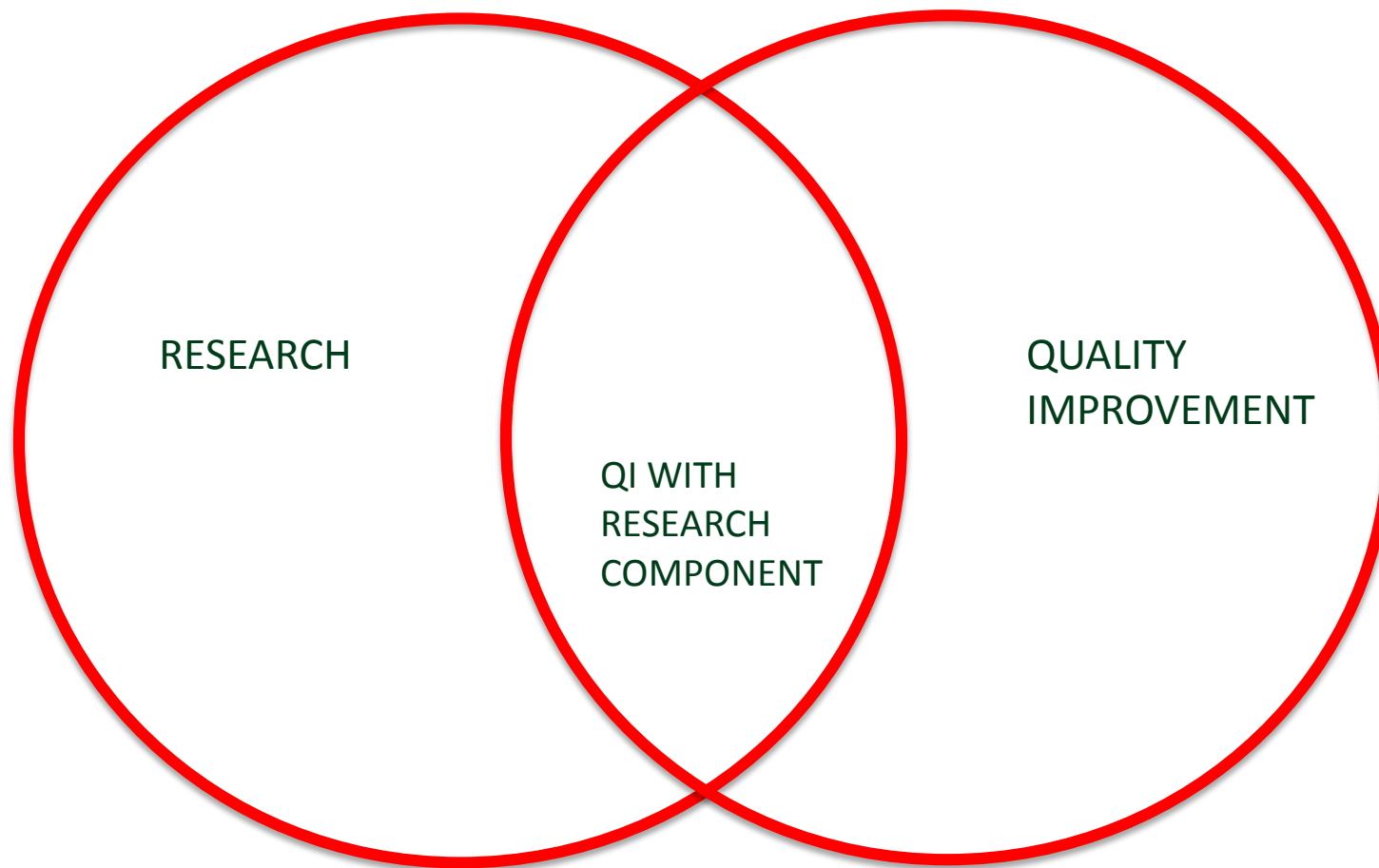
DIFFERENCES BETWEEN RESEARCH AND QI

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 will be a delay in the implementation of results?
- Are the risks from the intervention to participants are greater than minimal?

IRB PLANS

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