



U.S. Department of Health and Human Services



Agency for Healthcare Research and Quality

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Institutional Review Board (IRB) Challenges in QI & Research

Presented By:

Holly Taylor, PhD, MPH; Mark Schreiner, MD; Alexander Fiks, MD, MSCE

Moderated By:

Rebecca Roper, MS, MPH, Director, Practice-Based Research Network Initiative,
Agency for Healthcare Research and Quality

Sponsored by the AHRQ PBRN Resource Center

May 27, 2015



Agenda

- Welcome and introduction
- Presentations
- Q&A session with all presenters
- Instructions for obtaining your CME Certificate of Participation

Note: After today's webinar, a copy of the slides will be e-mailed to all webinar participants.



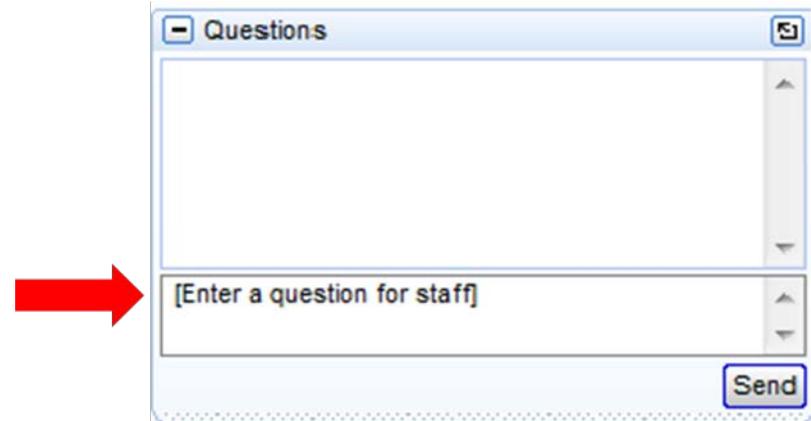
Disclosures

- Today's presenters have no financial relationships to disclose.
- Today's presenters will not discuss off label use and/or investigational use of medications in the presentation.



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Today's Presenters

Simple Interventions to Improve Informed Consent



Holly Taylor, PhD, MPH
Associate Professor

Johns Hopkins Bloomberg School of Public Health
Johns Hopkins Berman Institute of Bioethics



Today's Presenters

Is this quality improvement or human subjects research?
Implications for practice-based research



Mark Schreiner, MD

Executive Vice-Chair, Committees for the
Protection of Human Subjects (IRB),
The Children's Hospital of Philadelphia (CHOP)



Alexander Fiks, MD, MSCE

Associate Medical Director, Pediatric
Research Consortium (PeRC)

Associate Director, Pediatric Research in
Office Settings (PROS)

Simple Interventions to Improve Informed Consent

Holly Taylor, PhD, MPH

Johns Hopkins Bloomberg School of Public Health

Johns Hopkins Berman Institute of Bioethics

Source

Kass N, Taylor HA, Ali J, Hallez K. A Pilot Study of Simple Interventions to Improve Informed Consent in Clinical Research: Feasibility, Approach, and Results *Clinical Trials* 2015; (12)1: 54-66.

Background

- Previous research indicates that study participants have poor understanding.
 - Unaware of enrollment
 - Poor understanding of:
 - benefits
 - potential risks
 - randomization

Source: Kass et al (2015)

Background

- Consent forms are long and complex.
- Previous work to identify methods to improve subject understanding have mixed results, but evidence that subjects benefit from:
 - shorter forms
 - dialogue with study team members

Source: Kass et al (2015)

Background

- Limitation of previous work is that it has been conducted in simulated settings.
- Our goal was to develop and test simple, feasible, inexpensive interventions among ongoing trials.

Source: Kass et al (2015)

Interventions

- Bulleted **“fact sheet”** about the study to be used in addition to the consent form
- **“Structured conversation” - VOICE**
 - Each research participant is asked a short set of questions
 - 6 core, 2 additional questions if clinical trial
 - The research coordinator immediately corrects anything that is stated incorrectly- “corrective feedback”

Fact Sheet

Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Date: October 26, 2009
Principal Investigator: Clifton Bingham, M.D.
Application No.: NA_00001898

Sites of Research:
Johns Hopkins Hospital
Arthritis Center at Johns Hopkins Bayview Medical Center
Good Samaritan Hospital

Patient I.D. Plate

**RESEARCH PARTICIPANT INFORMED
CONSENT AND PRIVACY AUTHORIZATION FORM**

Protocol Title: Comprehensive Oral Health Assessment in Patients with Arthritis and Autoimmune Inflammatory Diseases

Application No. : NA_00001898

Sponsor: National Institutes of Health, National Institute of Arthritis & Musculoskeletal & Skin Diseases

Principal Investigator: Clifton O. Bingham III, M.D.

1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- We may learn things during the study that might make you want to stop being in the study. If this happens, we will tell you about it. You can then decide if you want to stay in the study.

2. Why is this research being done?

This research is being done to look at oral health in patients with rheumatoid arthritis and other autoimmune diseases (diseases where the immune system attacks the body).

Rheumatoid Arthritis (RA) is a chronic inflammatory joint disease. The cause of rheumatoid arthritis and other forms of inflammatory arthritis is unknown. The immune system normally functions to protect the body against infections. In RA the immune system begins to attack your own body with destruction of the joints.

Periodontal disease (disease of the tissue around the tooth) is caused by a bacterial infection in the mouth that causes an immune and inflammatory response that destroys the gums and leads to tooth loss. Some small studies have shown that patients with RA have higher rates of periodontal disease than

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Combined Informed Consent/Authorization October 2005 Version 8

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Principal Investigator: Clifton O. Bingham III, M.D.

We are asking if you want to join a research study. Here are some important things you should know about this study:

- You are being asked to join this research study because you have **rheumatoid arthritis (RA), another autoimmune disease, or periodontal disease. You may also be a healthy volunteer.**
- The purpose of this study is to help us figure out if periodontal disease (swelling of the gums and tissues that support your teeth) is more common or more severe in people with RA or autoimmune disease than in people without RA or autoimmune disease. To find this out, the researchers want to include both people who have RA or autoimmune disease and people who have periodontal disease, but who do not have RA or autoimmune disease. The researchers also want to include people who are healthy.
- You will not get any medical treatment for your RA or any other autoimmune disease in this study.
- You will not get any dental treatment or any treatment for oral health problems in this study. You will get a written report at the end of your oral health evaluation with recommendations for further treatment. We can provide referrals to a dental clinic, but we will not provide dental care.

Page 1 of 13

Combined Informed Consent/Authorization October 2005 Version 8

Structured Conversation

1. If you were going to tell a friend what this study was about, what would you say?
2. What are the main things you will do or will happen to you while you are in this research study?
3. What are the risks, or bad things that might happen to you if or when you join this study?

Structured Conversation

4. What are the benefits, or good things that might happen to you if or when you join this study?
5. What will happen if you decide you don't want to be in the study?
6. What will happen if you decide to be in the study but later change your mind?

Structured Conversation

7. Does everyone in this study get the same thing? That is, does everyone get the same study medicine or treatment?
8. Tell me in your own words how the researchers will decide whether you get the [TBA] or the [usual care/or TBA]?

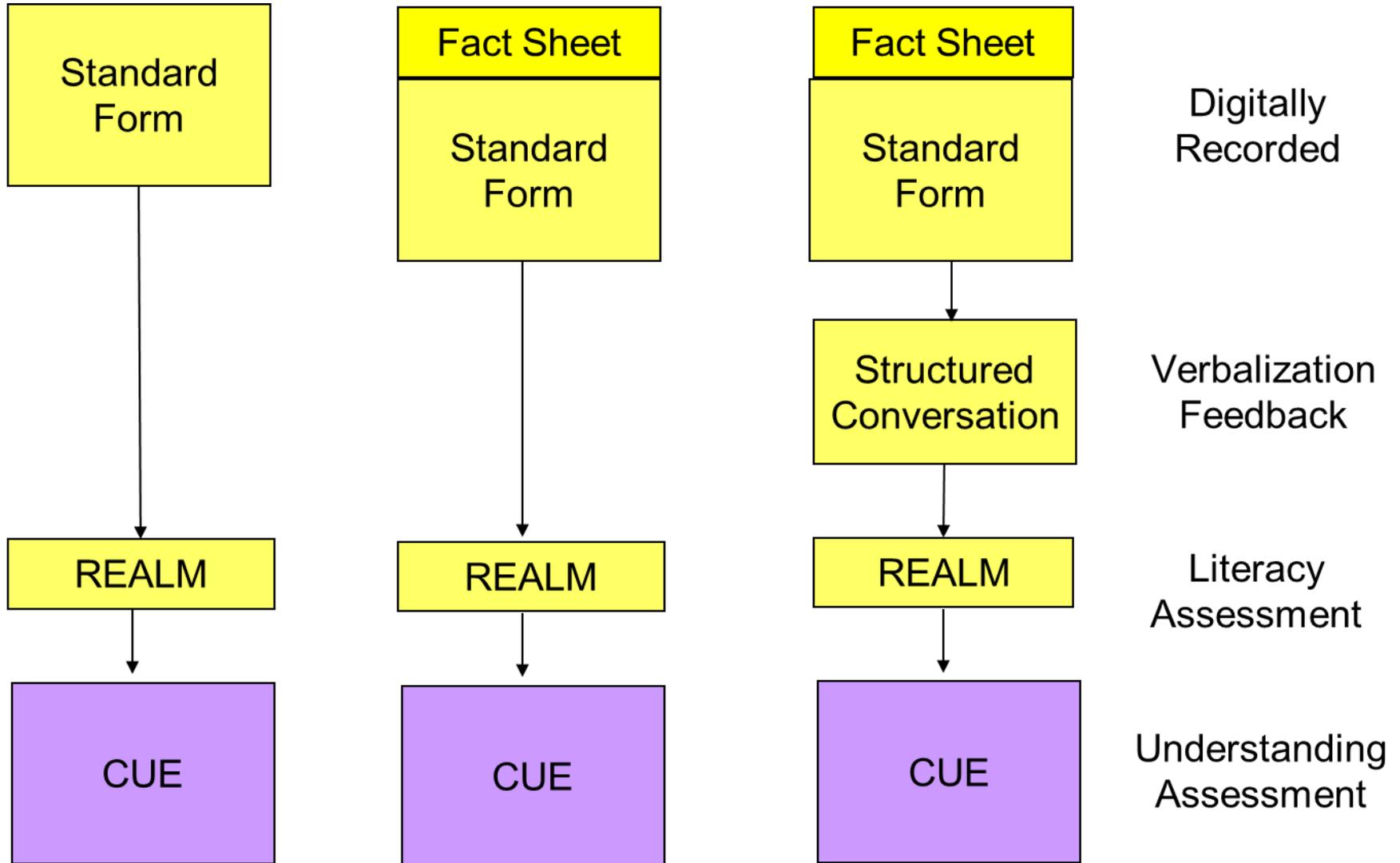
Assessment of Understanding

- Based on similar existing instruments.
- Consists of approximately 50 open and closed-ended questions:
 - items generic to any study
 - Items specific to the study under consideration
 - Assessment of attitudes, opinions about consent process
 - Basic demographics

Health Literacy

- Rapid Estimate of Adult Literacy in Medicine (REALM)
 - standard tool to assess health literacy.

Pilot Study



Findings

- 8 collaborating studies (3 others failed to enroll minimum).

Collaborating Studies

- Emphysema progression and effect of a particular medication in COPD
- Screening study to determine eligibility for other COPD studies.
- Trial comparing oral health status in patients with arthritis or an autoimmune disease to patients who do not have either.

Collaborating Studies

- Randomized weight loss trial comparing meat to mushroom diets.
- Study assessing accuracy of test for detection of glaucoma among patients with and without glaucoma.
- Study creating Genome-wide Association Study (GWAS) registry for Sjogren's Syndrome.

Collaborating Studies

- Phase I industry sponsored trial of a new HIV drug provided in combination with a standard TB drug.
- Randomized Phase II scleroderma related pulmonary arterial hypertension drug trial.

Findings

- 144 subjects (one asked to have data removed)
 - Mean age 51.5 years
 - 67% female
 - 54% White; 42% African-American

Findings

- As measured by responses to open-ended questions, subjects who received fact sheet and structured conversation understand better key elements of consent compared to those who did not.

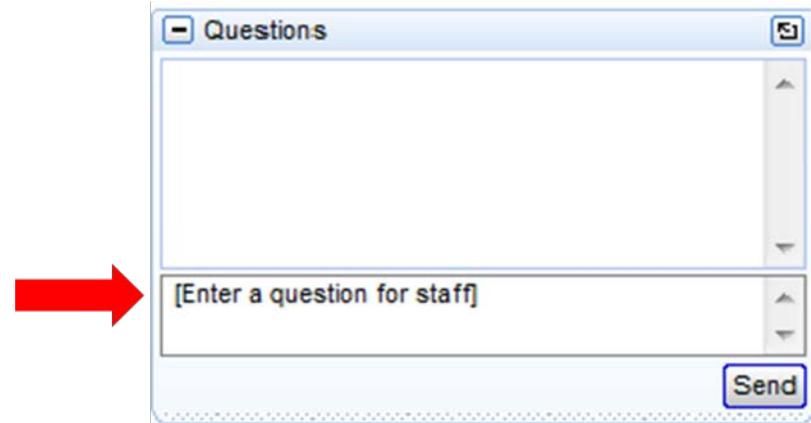
Lessons Learned

- Our original plan to modify entire consent form as component of intervention was neither feasible nor practical.
- A key component of intervention implementation is careful and ongoing training of collaborating study staff.
- Both interventions were highly regarded as useful by study staff.



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Is this quality improvement or human subjects research? Implications for practice-based research

Mark Schreiner, MD
Executive Vice-Chair
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Alexander Fiks, MD, MSCE
Associate Medical Director, PeRC
Associate Director, PROS



Grinding to a Halt: The Effects of the Increasing Regulatory Burden on Research and Quality Improvement Efforts

Infectious Diseases Society of America*

Infectious Diseases Society of America, Arlington, Virginia

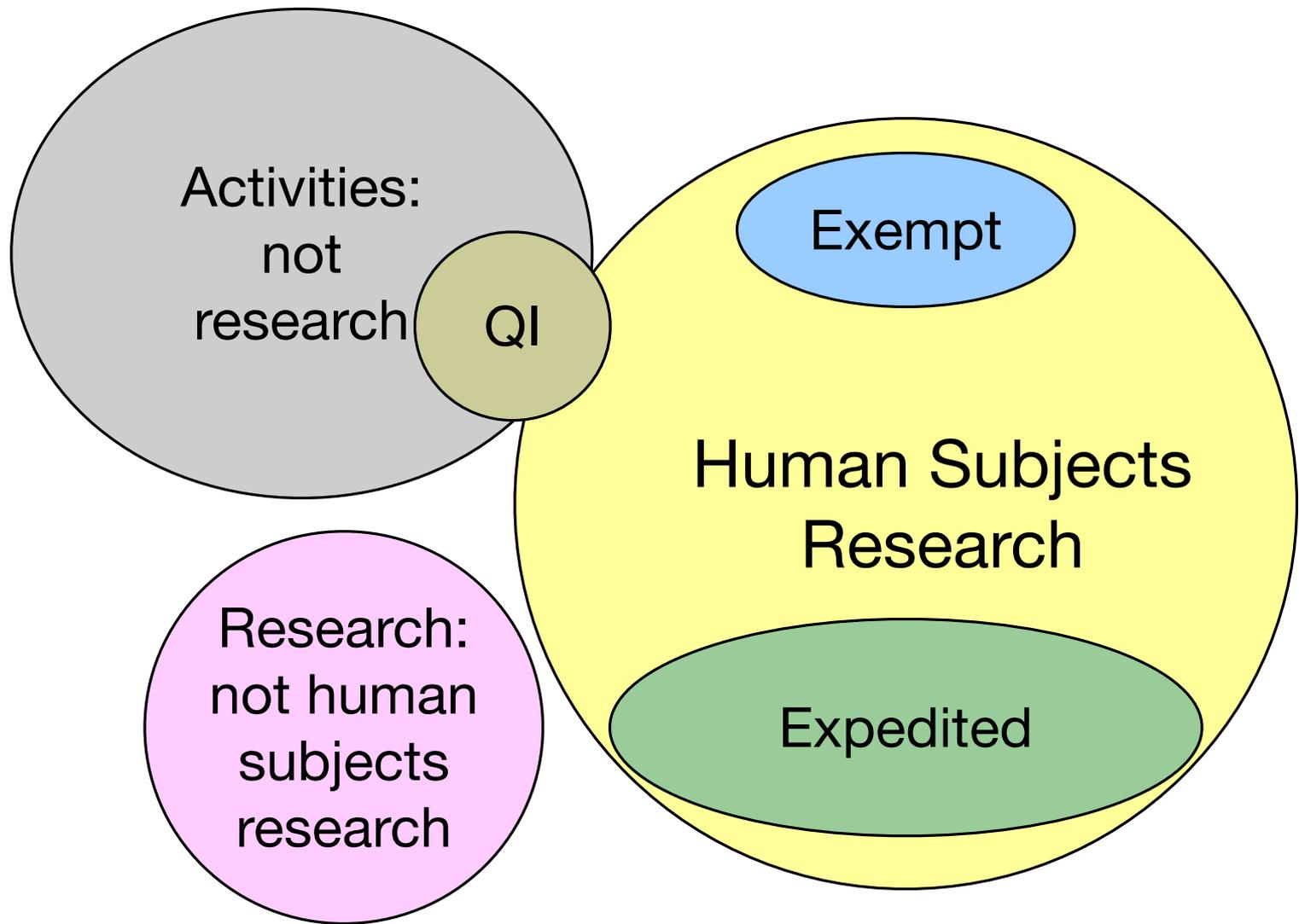
- “Quality improvement efforts are held up by uncertainties about when and how IRB review should be done.”

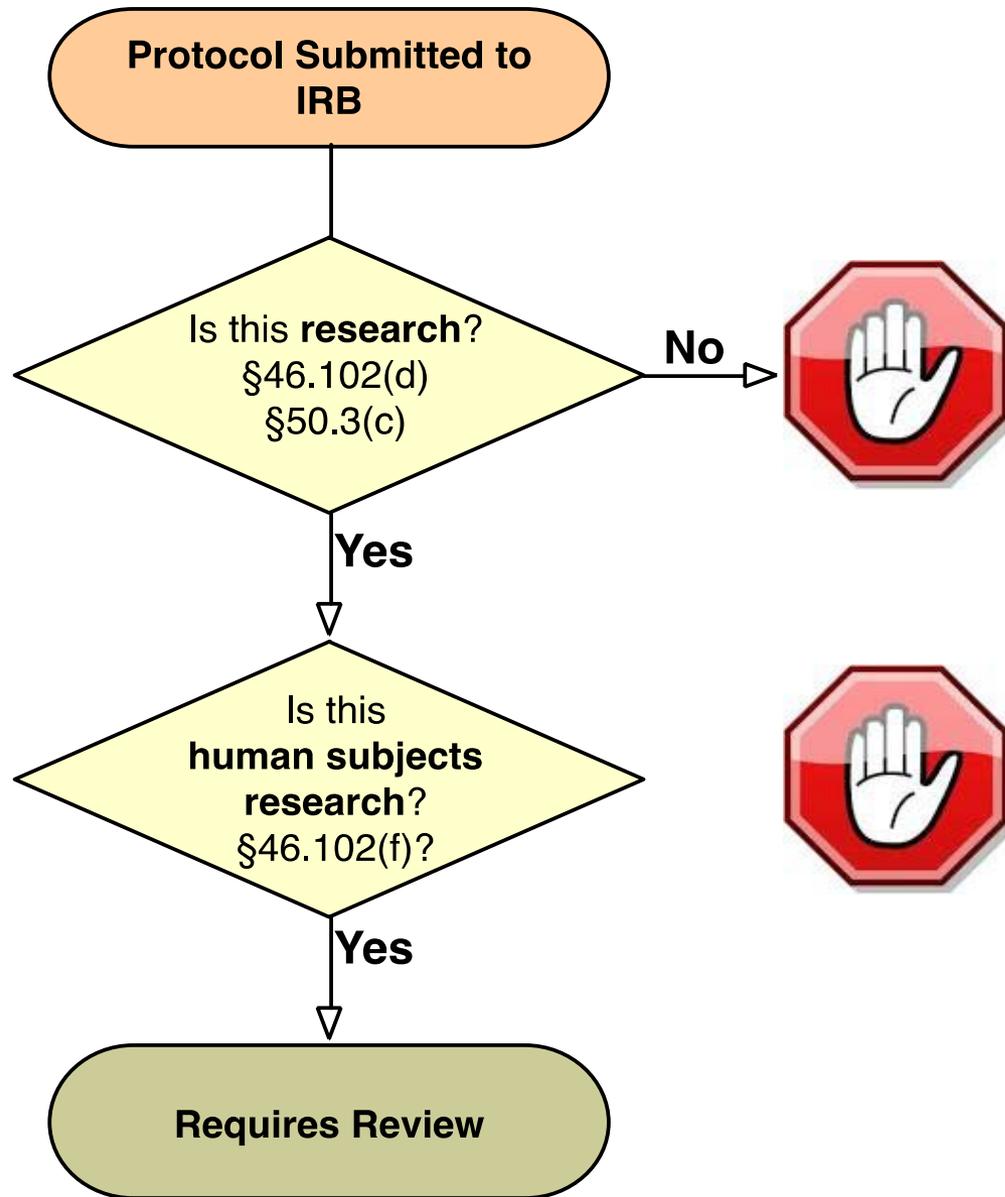
Clinical Infectious Diseases 2009;49:328–35

Quality Improvement and Ethical Oversight

- “QI is an integral part of good clinical practice and is designed to bring about immediate improvements in health care in local settings. In contrast, ...human subjects research is not a necessary, integral element of good clinical practice and that human subjects research aims to generate new, generalizable, and enduring knowledge about human health.”
- Can be overlap between the two

Ann Intern Med. 2007;146:680-681





Research: Regulatory Definition

- ...means a **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**.
 - Research is a set of behaviors or processes not an outcome
 - Many systematic activities are not research (QI)
 - Generalizable knowledge is an outcome that can be related to many non-research activities

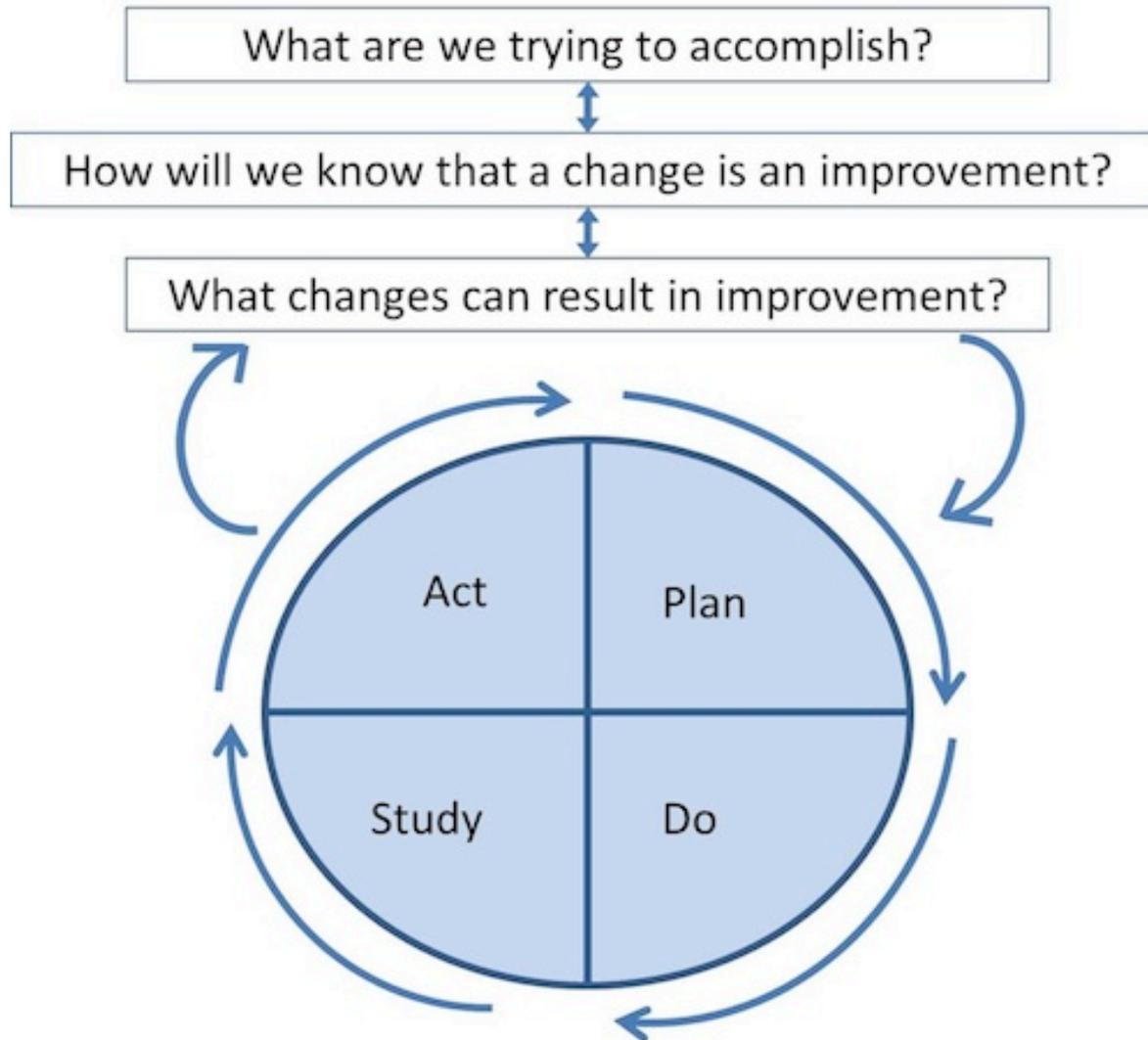
45 CFR 46.102(d)

Research versus Practice

- “Research designates an activity designed to test any hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.”
- “Research is usually described in a **formal protocol** that sets forth an **objective** and a **set of procedures** designed to reach that objective.”

Belmont Report, 1979

Quality Improvement: PDSC Cycle



	Human Subjects Research	Quality Improvement
Purpose	designed to develop or contribute to generalizable knowledge	designed to implement knowledge, assess a process or program as judged by established/accepted standards
Starting Point	knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	knowledge-seeking is integral to ongoing management system for delivering health care
Design	follows a rigid protocol that remains unchanged throughout the research	adaptive, iterative design
Benefits	might or might not benefit current subjects; intended to benefit future patients	directly benefits a process, system or program; might or might not benefit patients
Risks	may put subjects at risk	does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data
Participant Obligation	no obligation of individuals to participate	responsibility to participate as component of care
Endpoint Analysis	answer a research question statistically prove or disprove hypothesis	improve a program, process or system compare program, process or system to established standards
Adoption of Results	little urgency to disseminate results quickly	results rapidly adopted into local care delivery;
Publication/Presentation	investigator obliged to share results	QI practitioners encouraged to share systematic reporting of insights

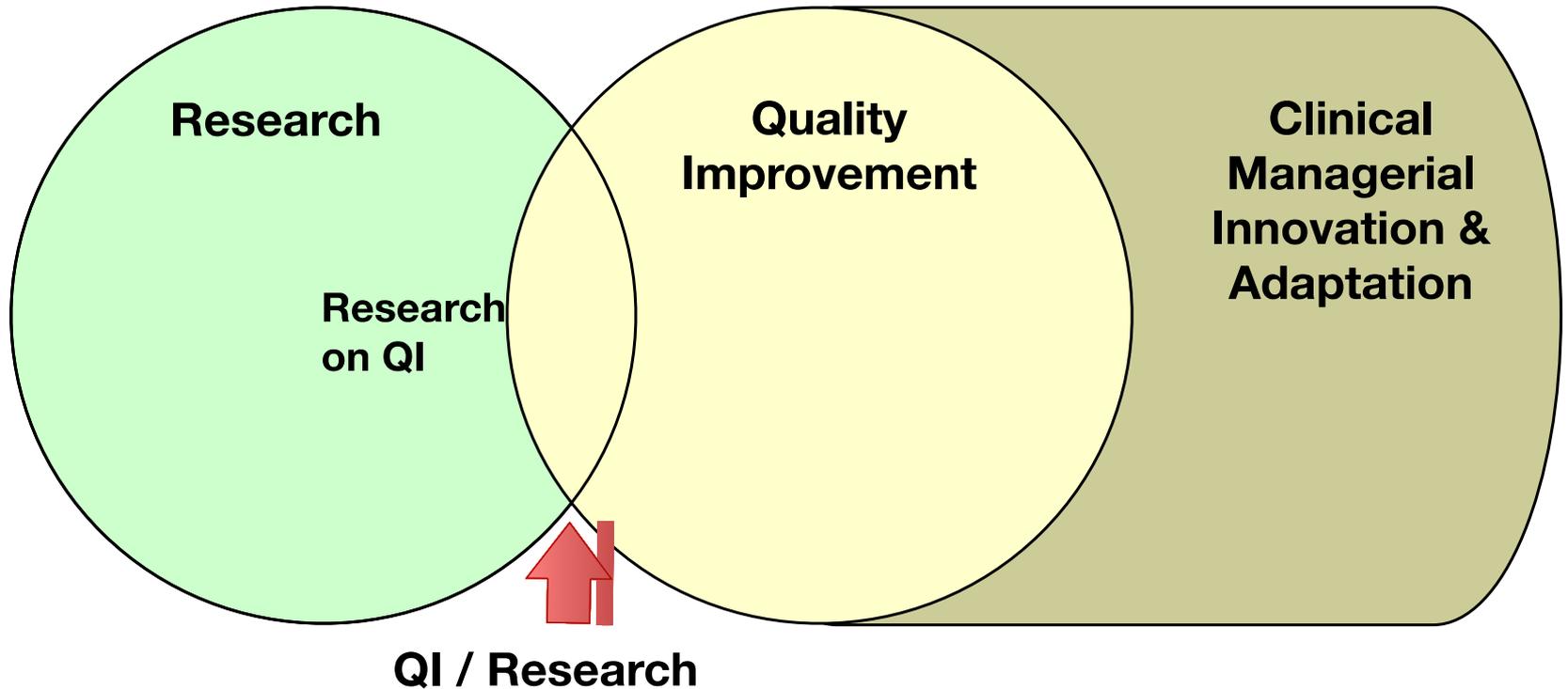
Hastings Center Report July-Aug 2006

Are there types of QI activities that are considered to be research?

- ...if a project involves introducing an **untested clinical intervention** for purposes which include not only improving the quality of care but also collecting information about patient outcomes **for the purpose of establishing scientific evidence** to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.

OHRP - Quality Improvement Activities FAQs

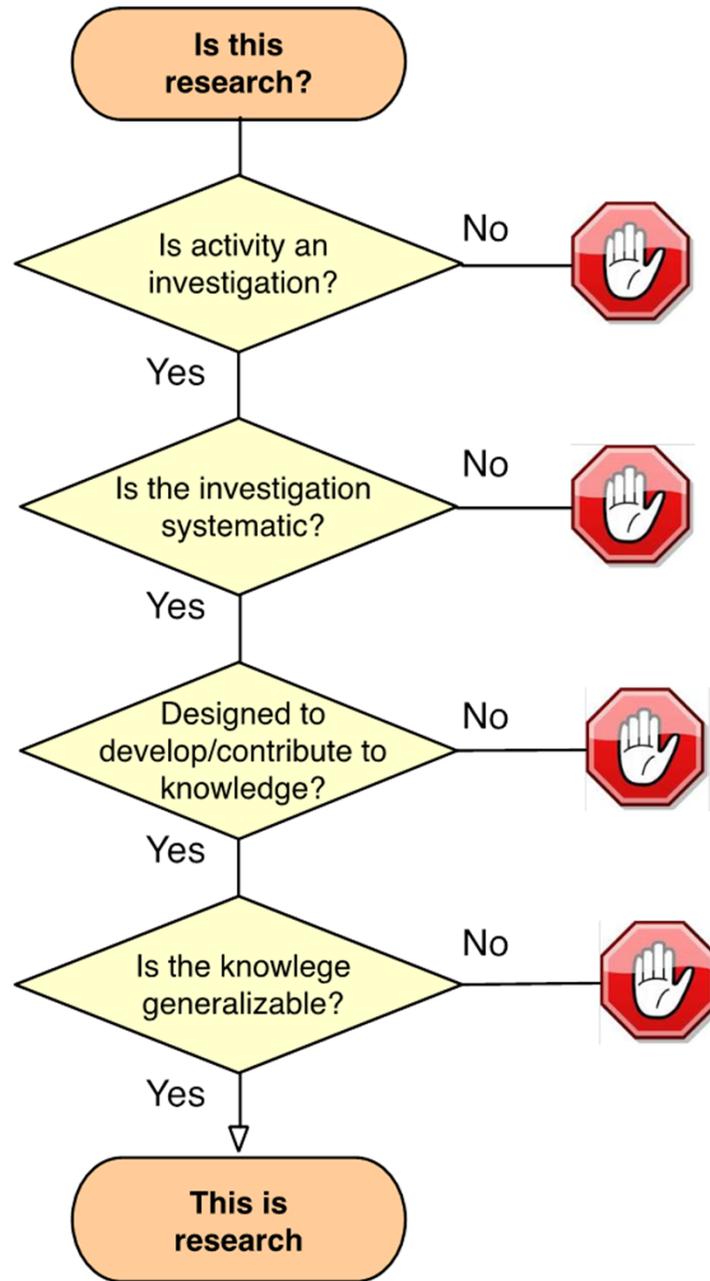
Intersection of QI and Research



Adapted from: Hastings Center Report, July - Aug 2006

When might QI activities be research?: Warning Flags

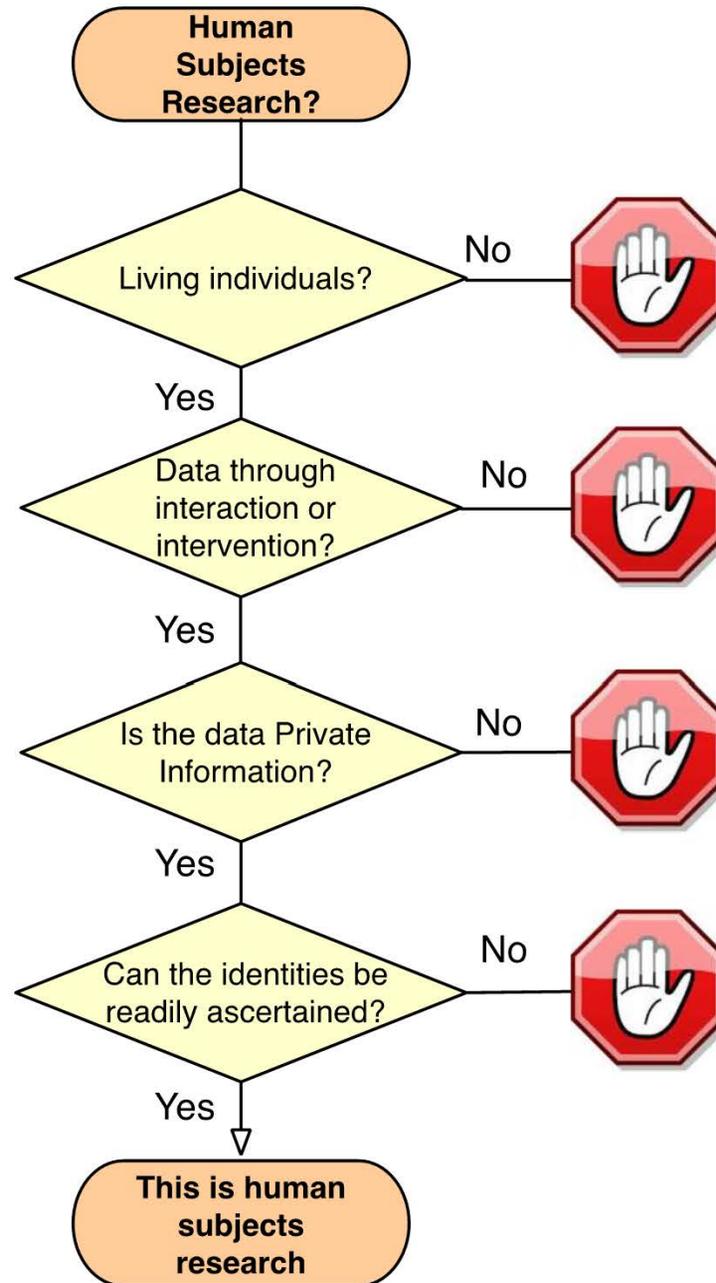
- Intent is to develop new knowledge or validate new treatments/interventions
 - (not to implement existing knowledge)
- Follows a research methodology/design
- Fixed protocol with a rigid goal, methodology, population, time period, etc.;
- Risks from the intervention to participants are greater than minimal
- Funding source requirement (e.g. NIH)



Is it human subjects research?

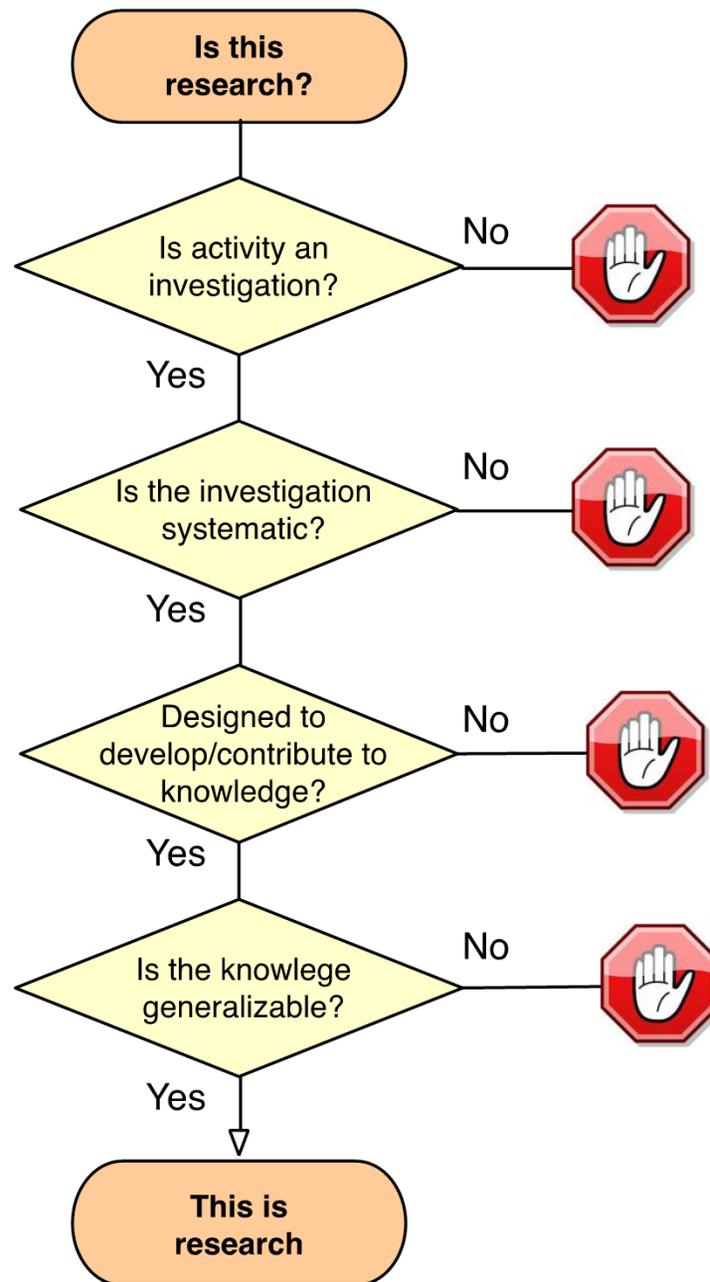
- Human subject: means a *living individual* about whom an *investigator* conducting research obtains:
 1. data through *intervention*; or
 2. *interaction* with the *individual*; or
 3. *identifiable private information**

* Must be individually identifiable
Different standard than HIPAA



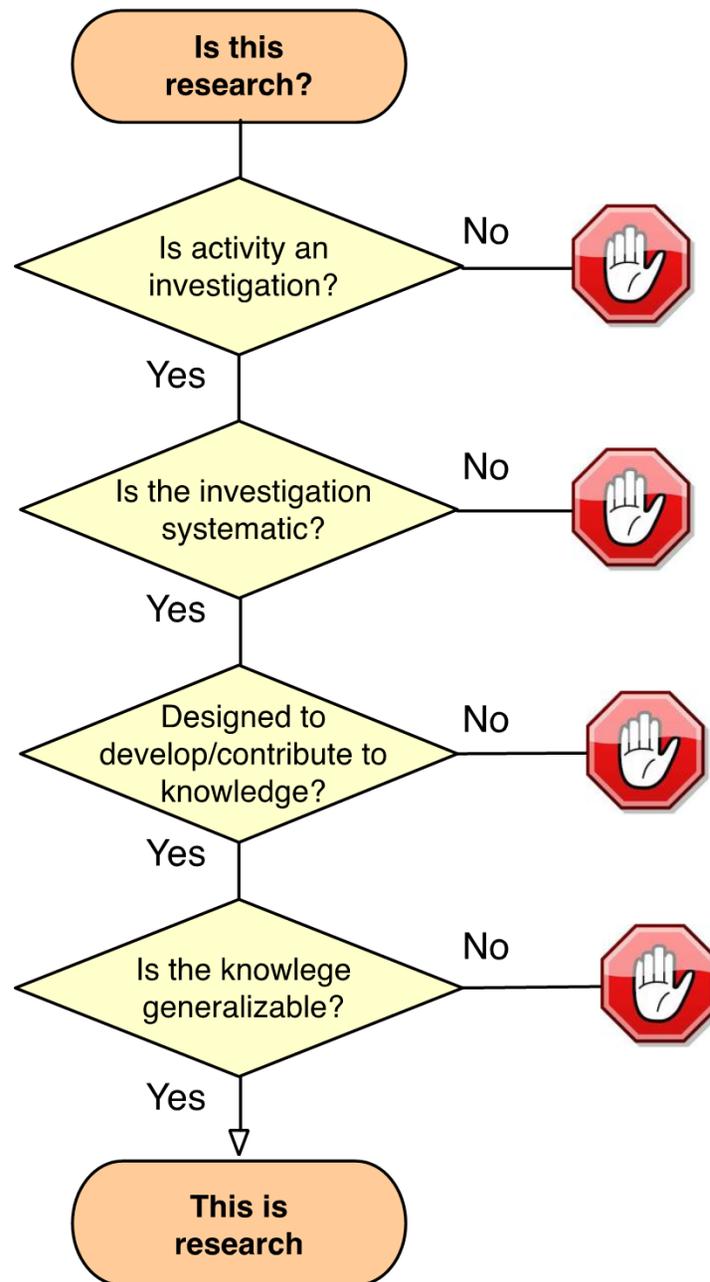
Case Study 1: Parent Satisfaction Survey with Fast Track Clinic

- The purpose of the survey is to determine the parent's satisfaction with the staff, healthcare provider, and care
- Providers will note the child's diagnosis, time spent for the visit, and comment on whether or not the child met the "Fast Track Clinic" criteria
- The intent is to improve triage of patients and to improve parent satisfaction with care



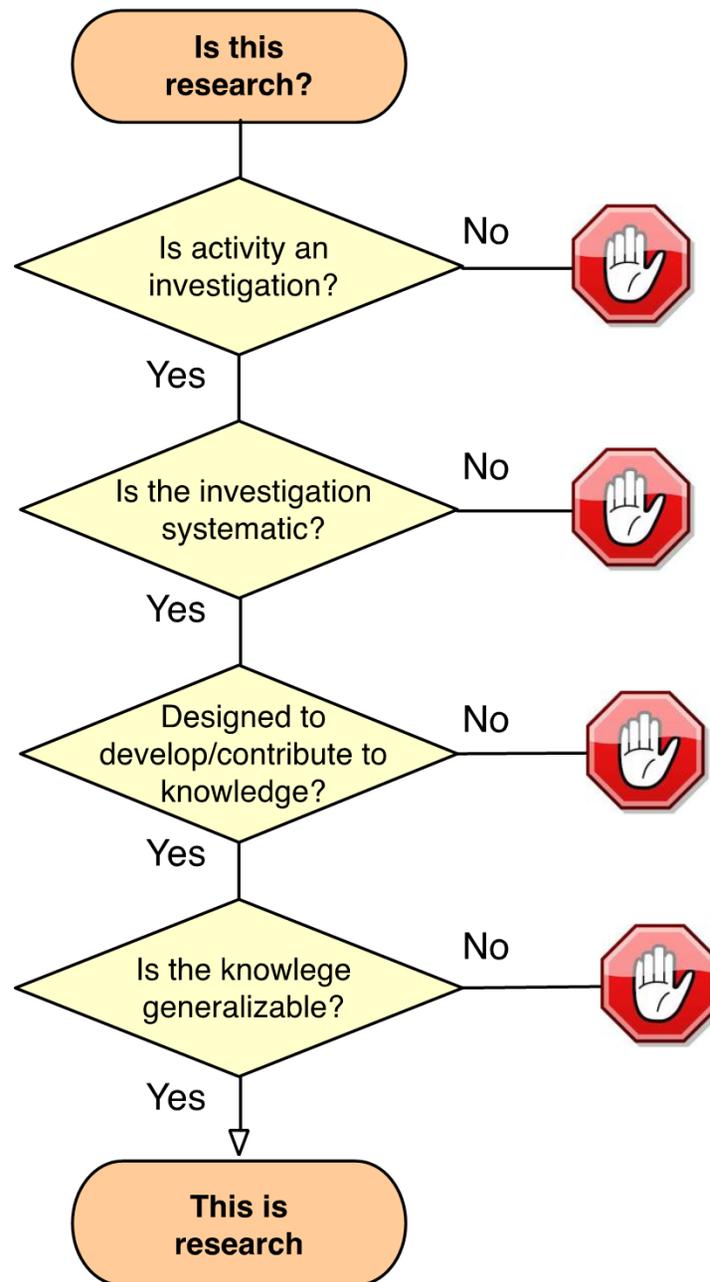
Case Study 2: Impact of Streamlined Documentation Tools

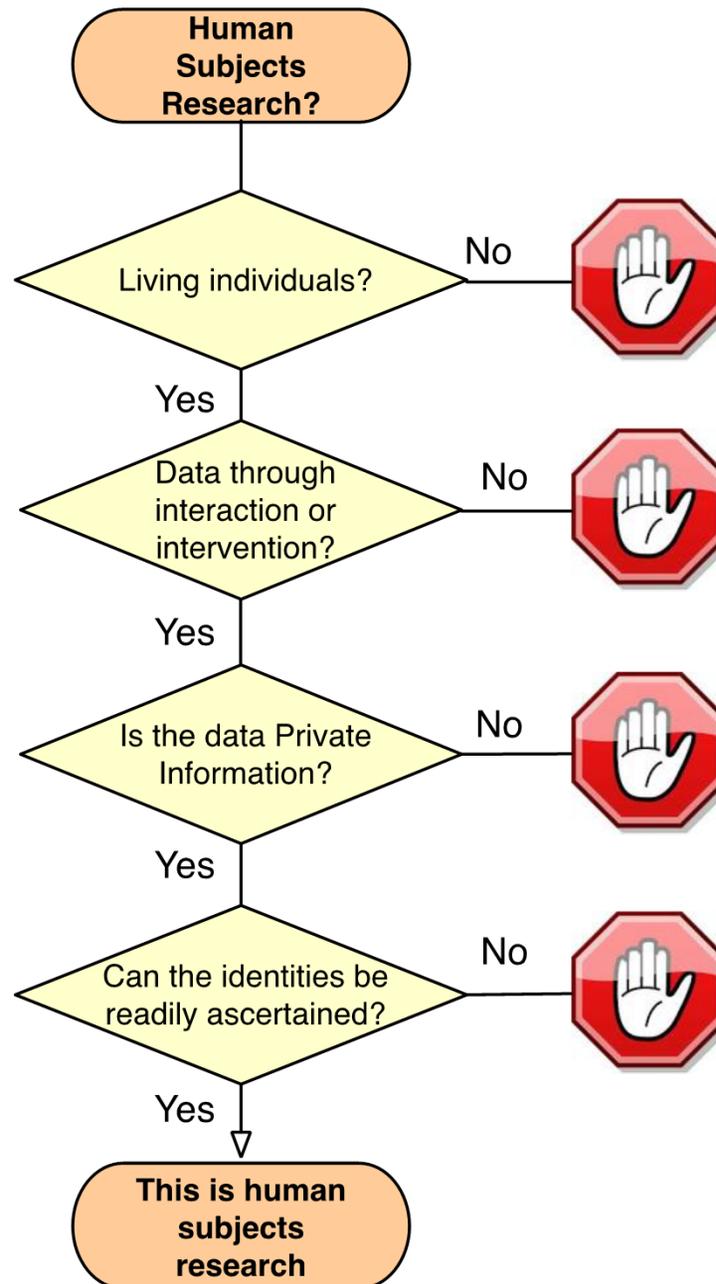
- Conduct focus groups with clinicians working in outpatient settings to optimize the electronic health record (EHR)
- Plan to develop and implement problem lists and other tools to improve experience of working with EHR
- Conduct second round of focus groups to determine the impact of tools on satisfaction with EHR



Case Study 3: Transition of Medical Care to Adult Provider: Gap Analysis

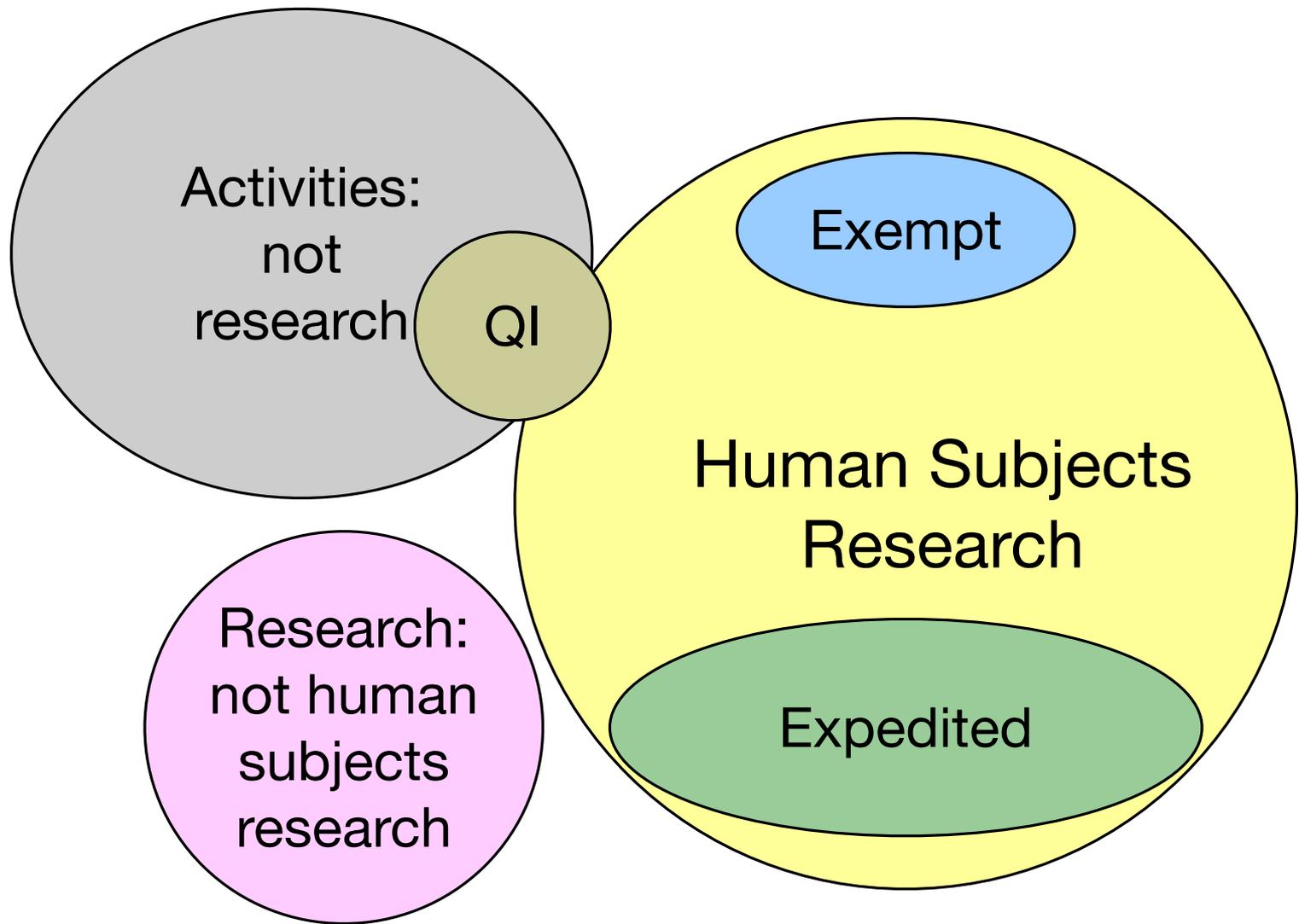
- Objective is to identify best practices, constraints and gaps in service related to the transition of children to adult primary care
- Procedures involve surveys of providers
- Understanding current gaps in care and also best practices will be used to design future initiatives to improve transition from pediatric to adult care





Case Study 4: Improving the Process of Tacrolimus Drug Monitoring

- Objectives are to decrease the rate of clotted or insufficient samples for outpatient blood tests. The intent is to improve family satisfaction by decreasing the need to repeat lab tests
- Plan to look at existing and prospective records to examine the timing of procedures and method of blood draw (i.e., finger stick or needle stick)

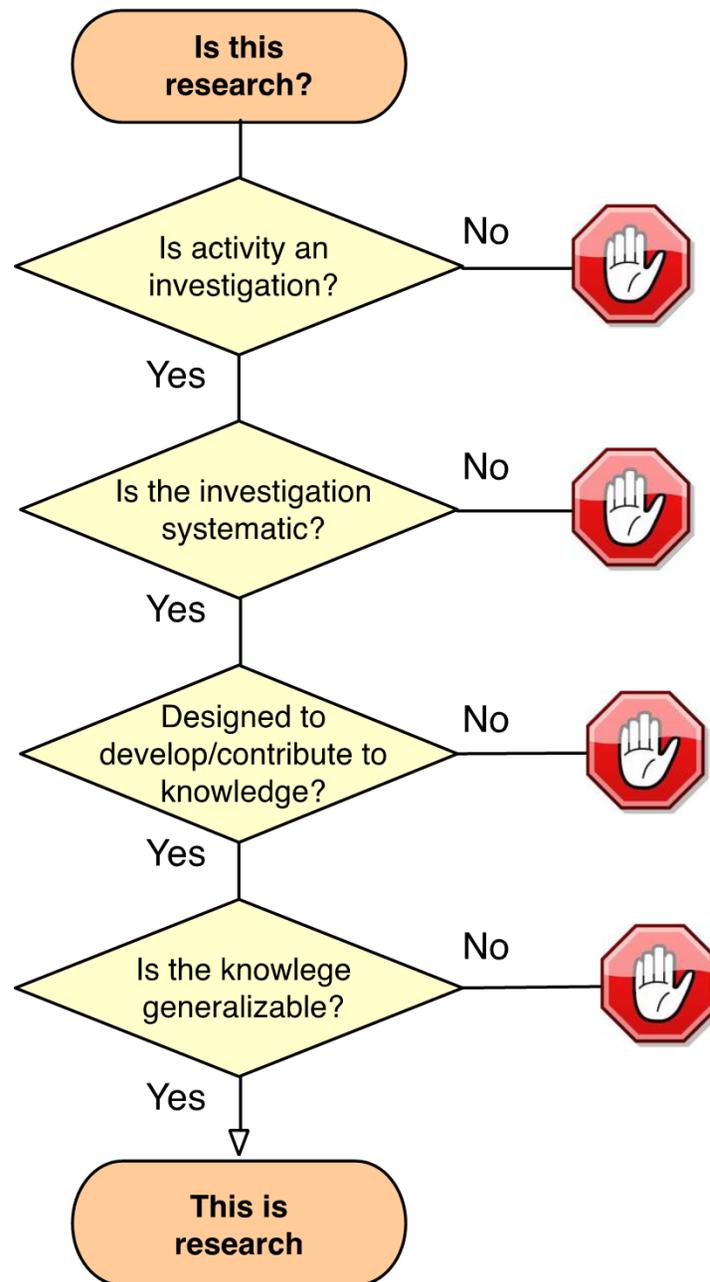


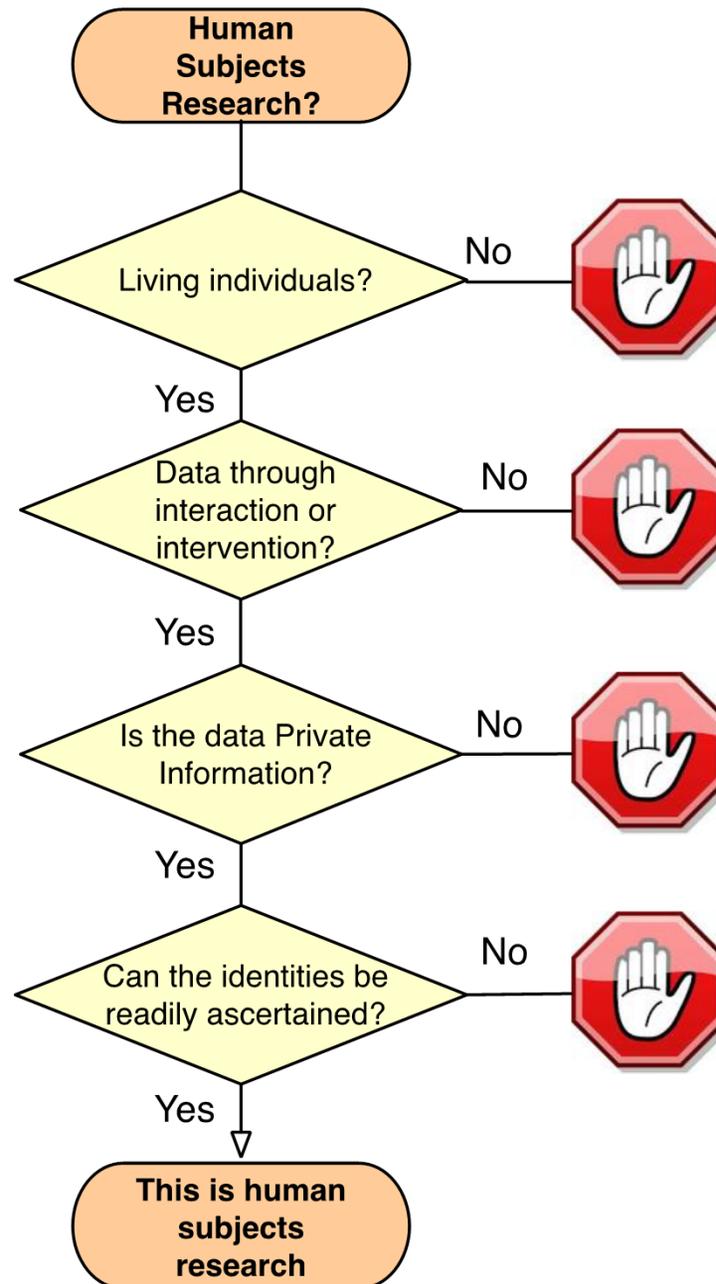
Case Study 5: Participation in Registry

- Patient data from multiple sites sent to a DCC and used to produce both site and patient specific QI reports
- De-identified or limited data sets can be requested from the DCC for research purposes
- The DCC acknowledges that the data might be used for research in the future

Case Study 6: Trial to Improve Outpatient Asthma Care

- Practices will be cluster randomized to a multipart intervention including education, EHR decision support, and receipt of spirometers
- The objectives are to determine if the intervention improves patients' asthma outcomes
- Data from all physicians' patients with asthma meeting age criteria will be included





Case Study 7: Part IV Maintenance of Certification Program to Improve Vaccination Rates

- An iterative process will be implemented with an objective of preventing missed opportunities for vaccination (training, feedback)
- Plan is to implement the intervention and measure change with each PDSA cycle
- Conduct surveys to learn providers impressions of the program
- Plan to publish to help inform other MOC projects

The Ethics of Using Quality Improvement Methods in Health Care

Joanne Lynn, MD; Mary Ann Baily, PhD; Melissa Bottrell, PhD, MPH; Bruce Jennings, MA; Robert J. Levine, MD; Frank Davidoff, MD; David Casarett, MD; Janet Corrigan, PhD, MBA; Ellen Fox, MD; Matthew K. Wynia, MD, MPH; George J. Agich, PhD; Margaret O'Kane, MHA; Theodore Speroff, PhD; Paul Schyve, MD; Paul Batalden, MD; Sean Tunis, MD; Nancy Berlinger, PhD, MDiv; Linda Cronenwett, PhD, RN; J. Michael Fitzmaurice, PhD; Nancy Neveloff Dubler, LLB; and Brent James, MD, MStat

Quality improvement (QI) activities can improve health care but must be conducted ethically. The Hastings Center convened leaders and scholars to address ethical requirements for QI and their relationship to regulations protecting human subjects of research. The group defined QI as systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings and concluded that QI is an intrinsic part of normal health care operations. Both clinicians and patients have an ethical responsibility to participate in QI, provided that it complies with specified ethical requirements. Most QI activities are not human subjects research and should not undergo review by an insti-

tutional review board; rather, appropriately calibrated supervision of QI activities should be part of professional supervision of clinical practice. The group formulated a framework that would use key characteristics of a project and its context to categorize it as QI, human subjects research, or both, with the potential of a customized institutional review board process for the overlap category. The group recommended a period of innovation and evaluation to refine the framework for ethical conduct of QI and to integrate that framework into clinical practice.

[Ann Intern Med. 2007;146:666-673.](#)

For author affiliations, see end of text.

www.annals.org

Ann Intern Med. 2007, 146:666-73

Acknowledgements

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- Additional support is from the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number UA6MC15585 and title “National Research Network to Improve Child Health Care”. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

OHRP: Quality Improvement Activities FAQs

- Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes

<http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/improve-quality-of-patient-care.html>

OHRP: Example 1

Quality Improvement Activities FAQs

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.

OHRP: Example 2

Quality Improvement Activities FAQs

- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.

OHRP: Example 3

Quality Improvement Activities FAQs

- A clinic ... implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff ... if it finds that the assessments are not being administered routinely.

Publication Guidelines for Improvement Studies in Health Care: Evolution of the SQUIRE Project

Frank Davidoff, MD; Paul Batalden, MD; David Stevens, MD; Greg Ogrinc, MD, MS; and Susan Mooney, MD, MS, for the SQUIRE Development Group*

In 2005, draft guidelines were published for reporting studies of quality improvement as the initial step in a consensus process for development of a more definitive version. The current article contains the revised version, which we refer to as Standards for Quality Improvement Reporting Excellence (SQUIRE). This narrative progress report summarizes the special features of improvement that are reflected in SQUIRE and describes major differences between SQUIRE and the initial draft guidelines. It also explains the development process, which included formulation of responses to informal feedback, written commentaries, and input from publication guideline developers; ongoing review of the literature on the epistemology of improvement and methods for evaluating complex

social programs; and a meeting of stakeholders for critical review of the guidelines' content and wording, followed by commentary on sequential versions from an expert consultant group. Finally, the report discusses limitations of and unresolved questions about SQUIRE; ancillary supporting documents and alternative versions under development; and plans for dissemination, testing, and further development of SQUIRE.

Ann Intern Med. 2008;149:670-676.

www.annals.org

For author affiliations, see end of text.

*Members of the SQUIRE Development Group who provided input during the development process and endorsed the SQUIRE guidelines are listed in the **Appendix** (available at www.annals.org).

Ann Intern Med. 2008; 149-670-6

Standards for Reporting (SQUIRE)

Why did you start?

4. **Local Problem:** describes the nature and severity of the specific local problem or system dysfunction
5. **Intended Improvement:** (a) Describes the specific aim (changes/improvements in care processes and patient outcomes) of the proposed intervention
(b) Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing)
6. **Study Question:** primary improvement-related question the study is designed to answer



How to Submit a Question

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The screenshot shows a window titled "Questions" with a text input area and a "Send" button. The input area contains the placeholder text "[Enter a question for staff]".



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- 2.) E-mail PBRN@abtassoc.com to request a copy of your CME Certificate of Participation.



Additional IRB Resources

- AHRQ PBRN Resource Center Webinar: *Strategies to Support Cooperation of Multiple Organizations' Institutional Review Boards (IRBs)*:
 - ▶ Defines collaborative and community-based research
 - ▶ Outlines strategies for collaborating across multiple IRBs for multi-site practice-based research
 - ▶ Discusses IRB ceding processes used by select universities and PBRNs
- View the recording and additional reference materials here:
<http://pbrn.ahrq.gov/events/strategies-support-cooperation-multiple-organizations%E2%80%99-institutional-review-boards-irbs>



Upcoming Events

Upcoming AHRQ PBRN Resource Center Webinars:

- **July TBD, 2015:** *Dissemination and Implementation Research in Health: Translating Science to Practice*
- **August TBD, 2015:** Adaptive Trial Design and Learning Evaluation
- **September 9, 1:30 – 3:00pm ET:** *Using Rapid-Cycle Research to Reach Goals: Awareness, Assessment, Adaptation, Acceleration-A Guidance Document*

Visit <http://pbrn.ahrq.gov/events> for webinar registration information and details on other upcoming PBRN-relevant events

If you have a suggestion for a webinar topic or would like to be a webinar presenter, send your feedback to: PBRN@abtassoc.com



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Thank you for attending today’s PBRN webinar!