Quality Improvement Activities and the Common Rule

August 3, 2022 – 2 pm EST / 11 am PST

Presented by:
Linda Reuter, MS, CIP
BRANY

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Today's Moderator & CITI Program

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to promoting the public's trust in the research enterprise by providing high quality, peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics pertinent to the interests of member organizations and individual learners.

Webinar Features

Questions and Answers

- You can submit a question during the presentation by selecting “Q&A” icon on the bottom of the screen.
- Questions will be addressed at the end of the presentation.

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About Today's Presenter

Linda Reuter, MS, CIP
IRB Director – BRANY

Ms. Reuter began her career in IRB Administration at Northwell Health, New York's largest healthcare provider, serving New York City, Long Island, and Westchester. She held various positions within the Health System's HRPP over a 20-year period. Linda formed IRB Consulting, LLC, in 2012, providing IRB administrative services, training and education, audit services, and general consulting to numerous IRB programs, including BRANY and HRP Consulting Group, as well as several local institutions.

She currently serves as the Director of the BRANY IRB.

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Conflicts of Interest Disclosure: Linda Reuter

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity.

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Learning Objectives

- Determine if a quality improvement (QI) activity is regulated research per the revised Common Rule.
- Summarize characteristics of QI activities.
- Consider potential overlap of regulated research and QI.
- Review key differences between QI and research.

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Regulatory Background

Defining Research with Human Subjects

Research or Quality Improvement

Application and Case Studies

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Regulatory Background

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History and Purpose of the Human Research Protection Regulations

- Regulatory origins lie in prior research atrocities
- Risk was not proportionate to potential benefit
- Threats to the well-being of individuals
- The Report by the National Commission (1978) made a distinction between research and audit/improvement activities
- Recommendations noted that the practitioners in improvement activities did not have the same conflicts of interest as researchers, and the Commission did not recommend applying the same guidelines as for research to health program improvement activities (National Commission 1978)

Do HHS regulations only apply to federally funded research?

- The HHS regulations do not cover non-federally funded research, but most organizations extend their application of these rules to **all** their human subject research regardless of funding source.

(Federal Register 2017)

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Are QI activities subject to the Common Rule?

- The Common Rule does not specifically regulate QI activities.
- QI activities can be regulated by the Common Rule, if
  - The activity meets the definition of human subjects research; and
  - The institution is engaged in the research

Who determines if the QI activity is subject to the Common Rule?

- Whether a QI activity project requires IRB review depends on:
  - Institutional policy
  - Reviewing IRB requirements
  - Sponsor or funder requirement
- Often researchers cannot self-determine
- IRBs can provide a non-human subjects research determination to provide documentation that the QI project is not subject to the Common Rule

Regulatory Background

Defining Research with Human Subjects

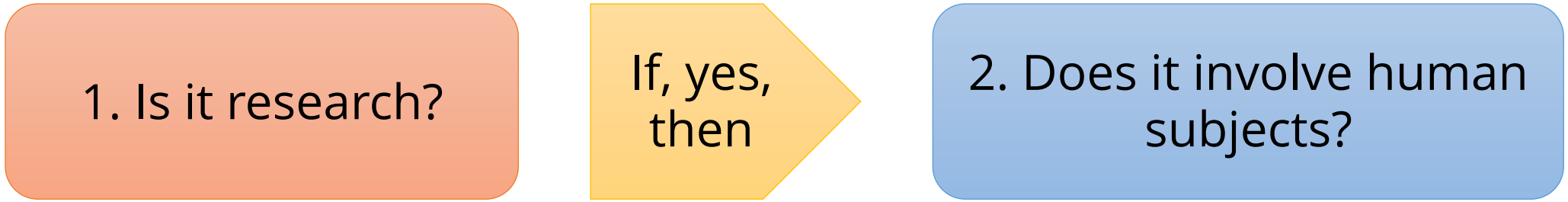
Research or Quality Improvement

Application and Case Studies

How do you determine if the Common Rule applies?

- It can be difficult to determine if a **research** or **evaluation** activity meets the regulatory definition of **research involving human subjects.**

- Ask these questions, in this order:



(45 CFR 46, Subpart A)

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Defining "Research" and "Human Subjects"

Does the activity involve ***research***?

- Research is defined as a ***systematic investigation***, including research development, testing and evaluation, designed to develop or contribute to ***generalizable knowledge*** (45 CFR 46.102[l]).

Does the **research** involve ***human subjects***?

- Human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research:
  - (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - (2) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens"

(45 CFR 46, Subpart A)

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Understanding Identifiability in Data

- Researchers may use different terms to describe their datasets. There are misconceptions about common terminology that can lead to confusion.
- There are regulatory standards. It is important to know which regulations may apply to the research (for example, FERPA or HIPAA).
- Knowing how identifiable, how sensitive, and how re-identifiable the data are can help the IRB understand which safeguards need to be in place.

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OHRP Decision Charts

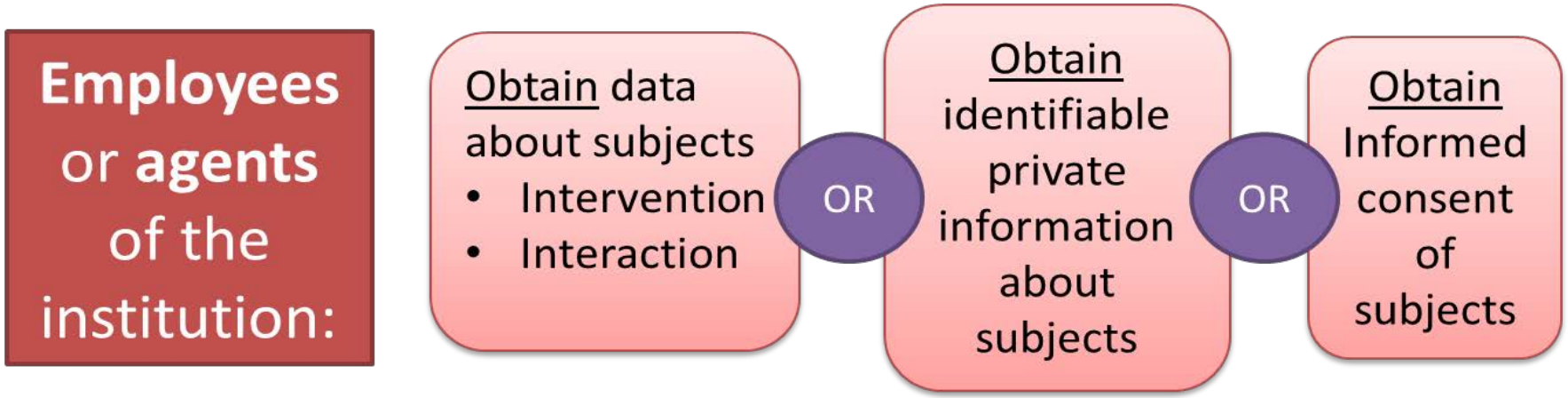
- OHRP provides decision charts to help work through the process of making regulatory determinations.

- For example, Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR Part 46? https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1

Research with Human Subjects – Determining Engagement

Is the institution **engaged** in the research?

- Awardee institutions are always considered to be engaged.
- True even where all activities involving human subjects are carried out by employees or agents of another institution.



(HHS 2008)

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When is an institution **not** engaged?

Institution is not an awardee institution, and its employees or agents do not obtain consent or administer intervention, but they do …

- Perform commercial services for investigator (e.g., clinical lab for routine blood tests)
- Perform routine clinical procedures for routine follow-up (e.g., physical exam)
- Inform prospective subjects about research
- Permit use of facilities for research
- Release identifiable private information or identifiable biological specimens (limited cases)
- Obtain coded private information or biological specimens (only when recipient would never be able to break the code)
- Review identifiable private information for auditing or federal reporting purposes
- Author a paper, journal article, or presentation describing a human subjects research study

(HHS 2008)

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Levels of Review

- For non-exempt regulated research, what are the different levels of IRB review?
  - **Expedited**
    - Not greater than minimal risk
    - Must meet one or more categories on “list” to qualify
  - **Convened IRB**
    - Greater than minimal risk
- The IRB can waive the requirement for obtaining and documenting informed consent for any level of research they review.

(45 CFR 46, Subpart A; HHS 1998)

Regulatory Background

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Sorting Activities: Harry Potter Style

Research
…
Needs IRB

QI
…
No IRB

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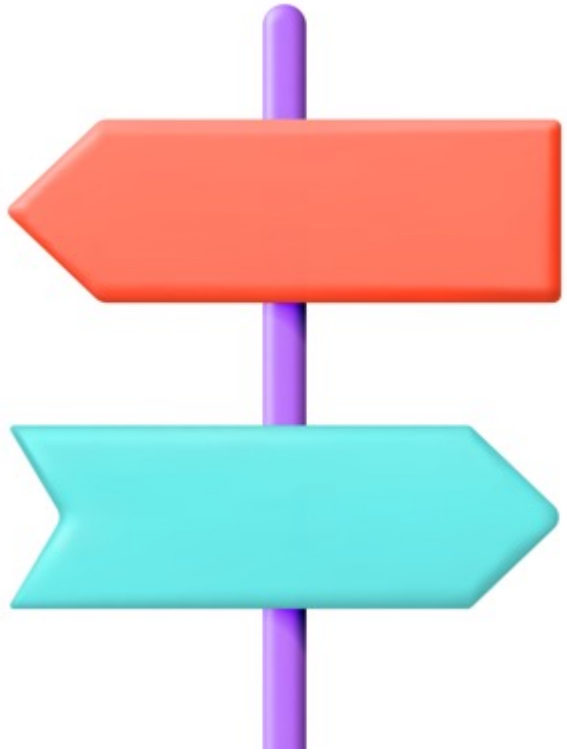
Differentiating Research and Quality Improvement (QI)



"The key difference between these two concepts is that research studies are intended to create new knowledge that can be generalizable to other populations and settings, while QI in health care uses existing knowledge to improve health care outcomes within a local health care institution or setting."

(IOM 2001)

Intent to Publish

"...intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research."

(HHS nd)

Research Characteristics

What are the characteristics of ***research***?

- Develops new knowledge
- Subjects are randomized
- New treatments tested
- Key project roles performed by those whose goal is not immediate improvement to local care
- Results not immediately implemented
- External or separate research funding

(Baily et al. 2006)

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Quality Improvement Characteristics

What are the characteristics of ***quality improvement***?

- Implements knowledge from prior research and practical experience
- Subjects are typically not randomized
- No fixed protocol but fluid in implementation with modifications as experience accumulates
- Known treatments tested with expected improvement
- Results will inform immediate change
- Immediate improvement in care
- Funded by internal clinical budgets

(Baily et al. 2006)

OHRP Examples of QI Activities That Are Not Research

Example 1

- 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.

Example 2

- 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.

(HHS nd)

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OHRP Examples of QI Activities That Are Not Research, Cont.

Example 3

- A clinic increasingly utilized by geriatric patients 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 regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

(HHS nd)

Points to Consider for Determining Research or QI

Purpose

Starting Point

Benefits

(Baily et al. 2006)

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Points to Consider for Determining Research or QI, Cont.

Risks/Burdens

Data Collection

(Baily et al. 2006)

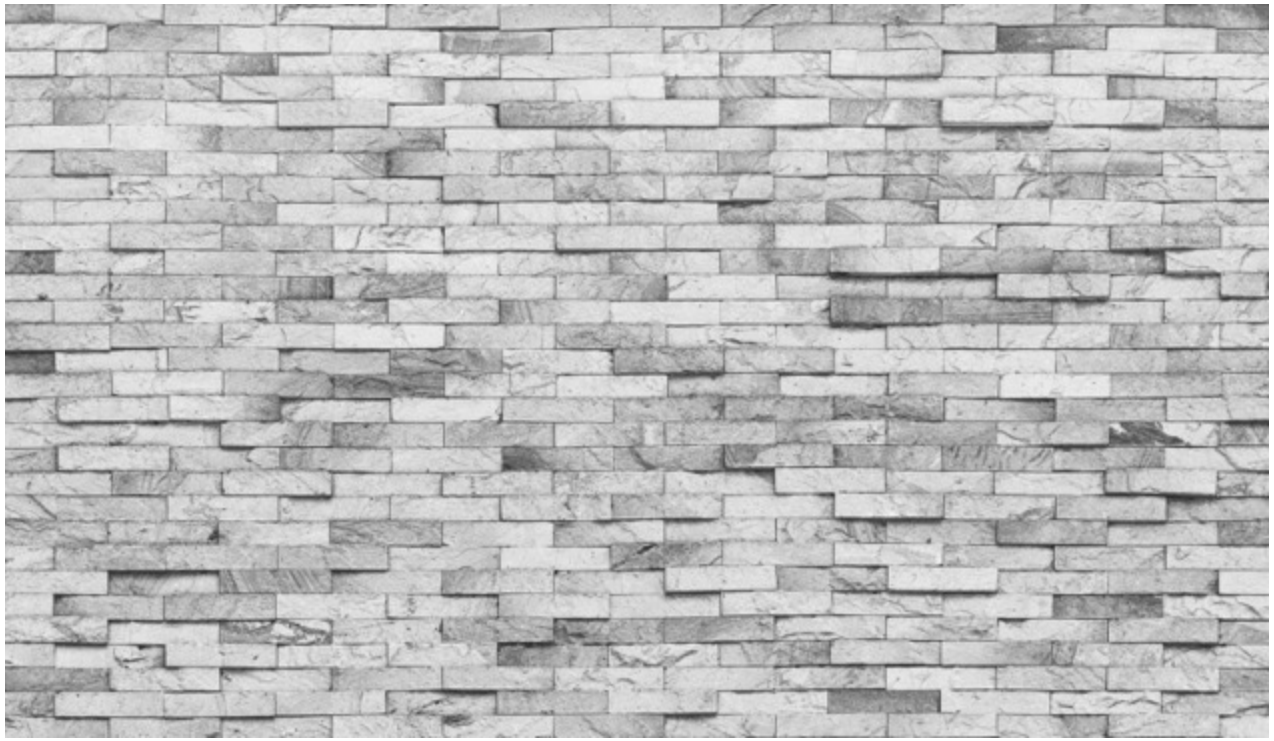
Points to Consider for Determining Research or QI, Cont.

End Point

Testing/Analysis

(Baily et al. 2006)

Grey Area in Determining Research or QI



The Grey Area

- New knowledge generated during the QI activity
- Information may be useful to other institutions
- Additional evidence generated
- Publication of QI activities

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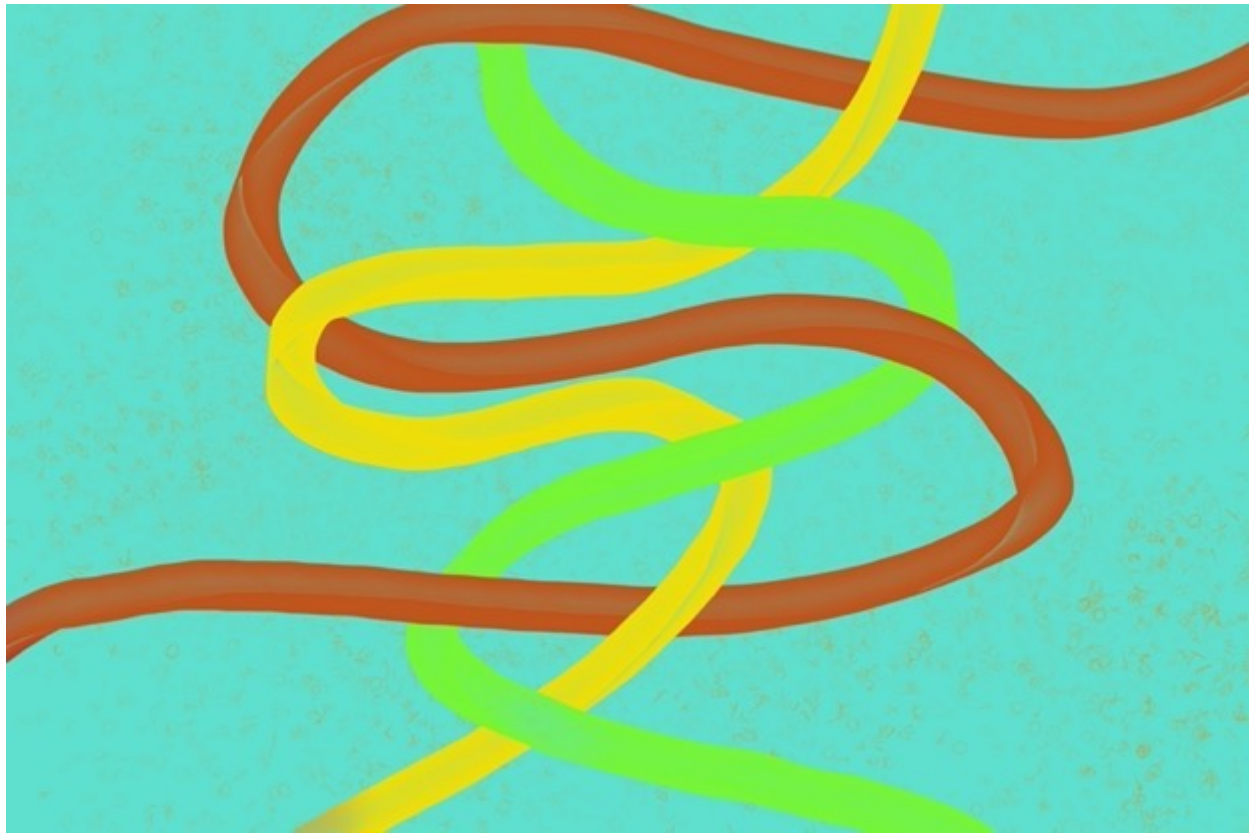
Overlap of Research and QI



The Overlap

- Systematic investigations designed to bring about local improvement AND develop generalizable knowledge at the same time
  - IRB review needed

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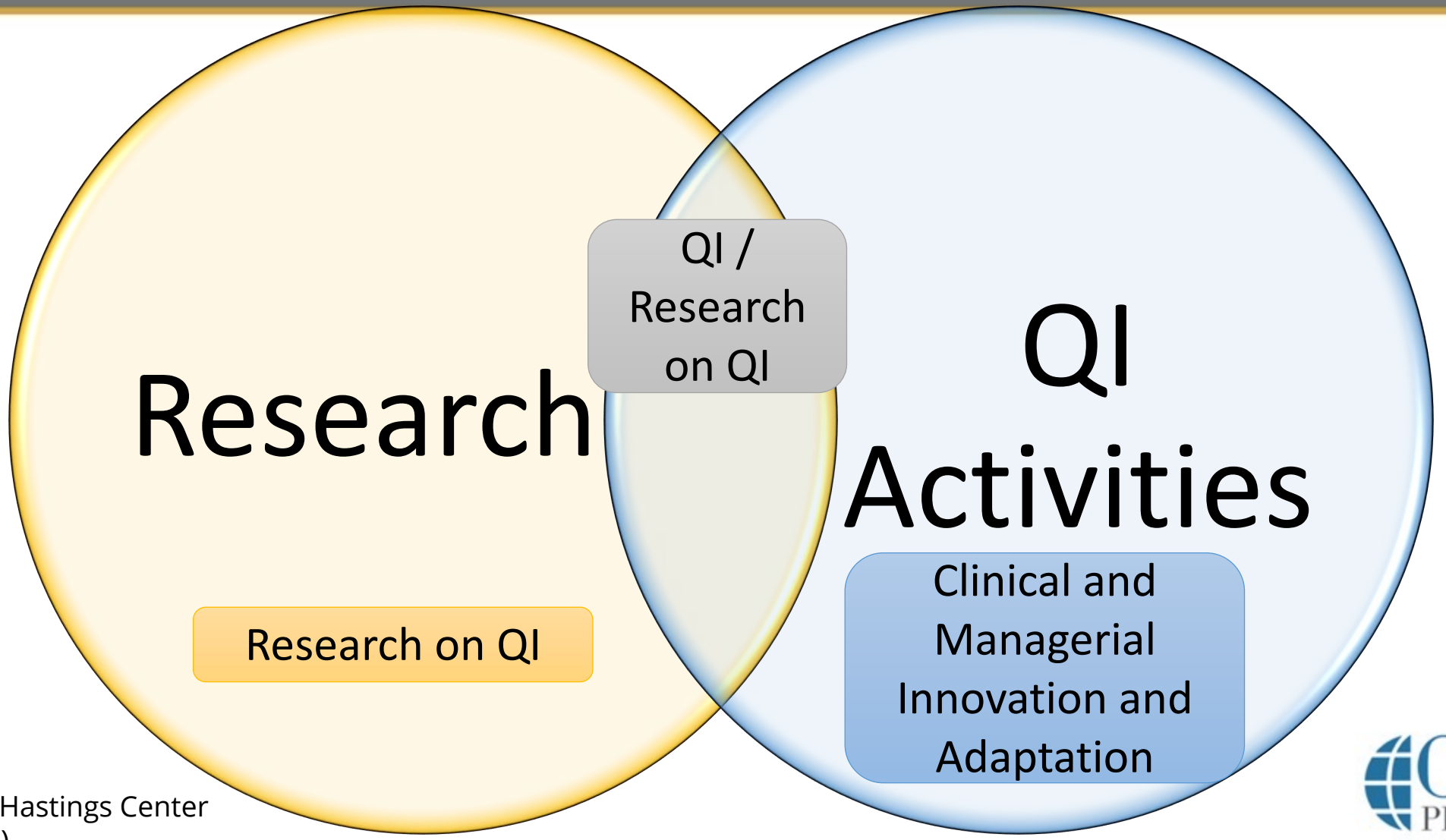
Overlap of Research and QI, Cont.



(Graphic adapted from Hastings Center Report, Baily et al. 2006)

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Research on QI

- Can be independent of the QI activity or combined into one activity
- May be submitted later to the IRB

Regulatory Background

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QI Activities

Activities whose **primary purposes** are **limited** to:

- **Implementing a practice** to improve the quality of care, **AND**
- Collecting (patient or provider) **data about the implementation**
  - Purpose of data collection:
    - Clinical
    - Practical
    - Administrative

Not a novel practice

Not generalizable

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QI Research Activities

Activities in which the investigator is:

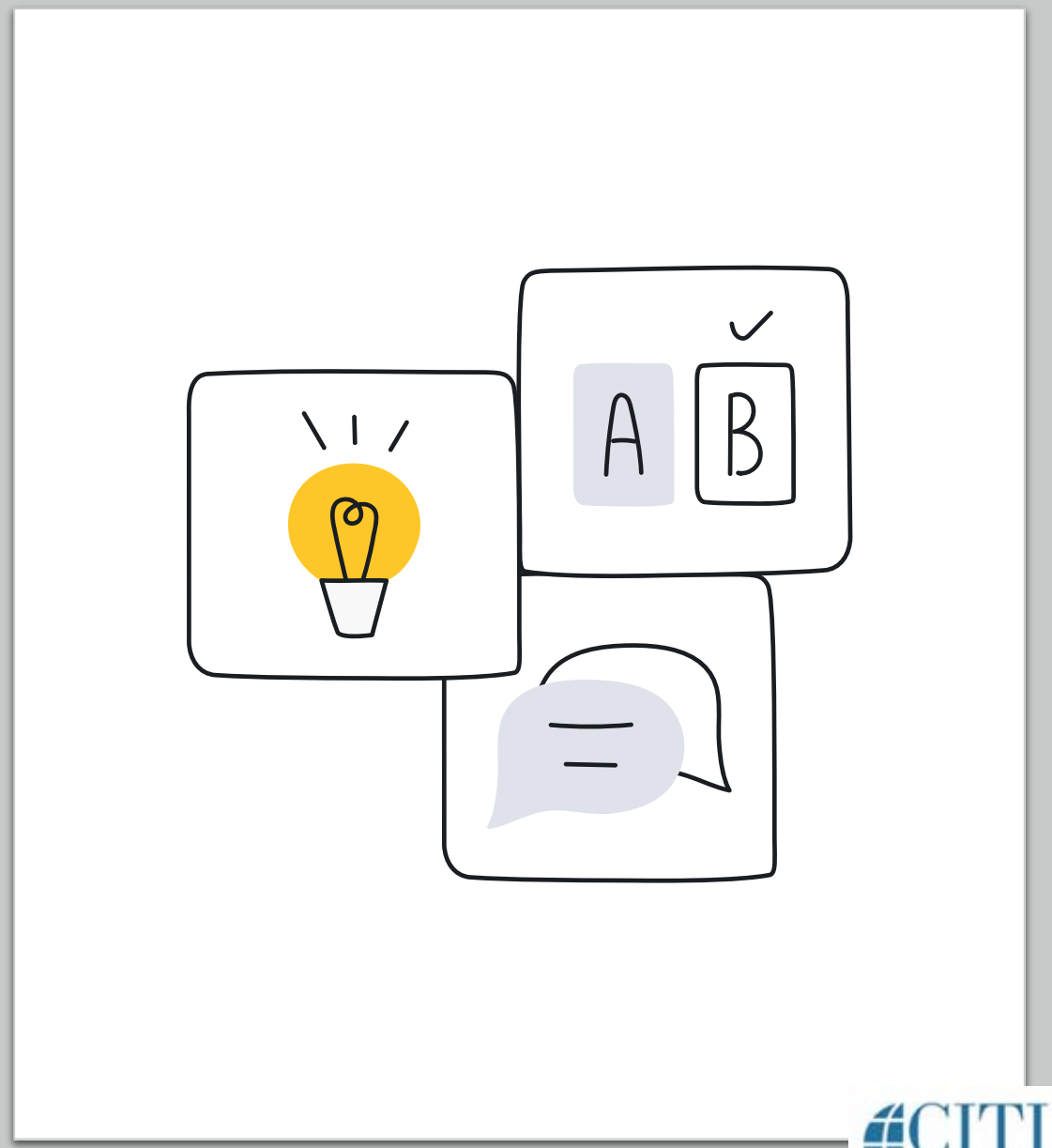
- Introducing an **untested clinical intervention** to improve the quality of care, **and**
- Collecting **data about patient outcomes**
  - Purpose of data collection:
    - Establishing scientific evidence to determine **how well the intervention achieves its intended results**

Novel practice

Generalizable beyond local institution

Key Differences: QI vs. Research

- Purpose
- Starting Point
- Benefits
- Risks/Burdens
- Data Collection
- End Point
- Testing/Analysis



Publication of QI Projects

If I intend to publish my QI project, does the act of publication make it research that needs IRB review?

- Consider publication relative to **generalizability** and **original intent**

- Conclusions are drawn from particular instances, and
- Information is to be disseminated.
- Generalizable means information that is universally applicable to outside institutions

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QI Projects that Most Likely **Are Not** Research

General Attributes:

- Designed to:
  - Help the institution comply with or meet a recognized, **evidence-based standard of care**
  - **Assess the performance** of the institution and compare to national standards
  - Solve a local problem, and the results of the project are expected to produce knowledge that is locally important, but is **not generalizable** (that is, universally applicable to institutions outside the institution)
- Uses an iterative design which changes quickly as results come in
- Typically, would **still** be performed even if the project team knew that no professional recognition would result

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QI Projects that Most Likely **Are** Research

General Attributes:

- Majority of patients involved **not expected to benefit directly** from the knowledge gained
- Designed to randomize patients to a clinical intervention to **assess its safety or efficacy**
- Multi-center projects collecting data from other national/international sites to create treatment guidelines or other types of **generalizable** (universally applicable) knowledge
- Designed to **advance the scientific literature**
- Designed to **advance** the clinical **care of patients at all US hospitals** (not just local institution)
- Designed to **develop new national practice benchmarks**.
- Typically, would **NOT** be performed if the project team knew that no professional recognition would result

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Case 1

A faculty member from the English department wants to collect and analyze student demographics, student grades, existing drafts of student writing assignments, instructor demographics, and instructor feedback on writing assignments for the past five years in composition courses taught by first year graduate student instructors.

- **Does she need review? Is it research?**

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Case 1: Purpose

Additional Information:

The faculty member will analyze the data to compare the materials from courses taught both before and after the implementation of a new first year instructor training program. The information gathered will be used to internally evaluate and improve the training program.

The data will not be used for any other purposes.

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Case 1: Is it research?

Is it *research* according to regulations?

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Questions to ask:

- Is it systematic?
- Is it designed to develop or contribute to generalizable knowledge?
- What is the purpose of the project? How will the data be used?

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Case 1: Determination

Not Research

This project is **not** research (and therefore no need to consider whether human subjects are involved), since the purpose is internal, programmatic development.

The project is **not** intended to create, develop, or contribute to generalizable knowledge.

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Case 1: Further Considerations

But what if…

- The faculty member also knew that, in addition to using the data for internal purposes, she wanted to design the project and data collection in such a way as to allow her to make claims and draw conclusions applicable beyond her program?
  - **Now this meets the regulatory definition of research.**
- Remember, when there is research intent (that is, a project is designed to develop or contribute to generalizable knowledge), review is still required even if the project is also intended for non-research purposes (such as quality improvement).

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Case 2

A hospital system will test a new Emergency Department care management model, expanding implementation of a current successful pilot in six hospitals. The model utilizes a multi-disciplinary team that will comprehensively assess patients who present in the emergency department for an ambulatory-care sensitive condition (ACSC), create a care plan that would avoid an unnecessary hospitalization, and provide ongoing support after discharge, including medication management, education, and linkages with primary care providers.

- **Does this need IRB review? Is it research?**

Case 2: Main Questions

Definitions	Yes	No
Is the project ***research*** according to the regulations?	continue	stop
Does the project involve ***human subjects*** according to regulations?	continue	stop
Is the project eligible for ***exemption***?	continue	stop
Is the institution ***engaged***?	continue	stop

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Case 2: Purpose

The hospital system will analyze the data to compare patient outcomes and ED utilization both before and after implementation of the program. The information gathered will be used to internally evaluate and improve the program.

The data will not be used for any other purposes.

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Case 2: Is it research?

Is it *research* according to regulations?

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Questions to ask:

- Is it systematic?
- Is it designed to develop or contribute to generalizable knowledge?
- What is the purpose of the project? How will the data be used?

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Case 2: Determination

Not Research

This project is not research (and therefore no need to consider whether human subjects are involved), since the purpose is limited to local program implementation and evaluation.

The project is **not** intended to create, develop, or contribute to generalizable knowledge.

Case 2: Further Considerations

But what if…

- The care model was novel, and the hospital system sought to evaluate its effectiveness?
  - **Now this meets the regulatory definition of research.**
- This revised version of the project is designed to develop or contribute to generalizable knowledge (generate new knowledge rather describe implementation of existing knowledge).
- Note: IRB review would still be required even if the project is also intended for non-research purposes (such as quality improvement).

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What if I still don’t know if my activity needs IRB review?

Contact your IRB!

Summary

- Use the regulatory definitions to differentiate between research and QI activities.
- Regulated research requires different levels of IRB review.
- QI activities differentiate from research in key areas such as purpose, benefits, and the way results are used.
- Changes to QI activities can easily trigger regulatory definitions and require IRB review.
- There are many tools (such as OHRP decision charts) to help determine if an activity is regulated research and if so, what level of review may be required. Consult your institution or IRB if in doubt!

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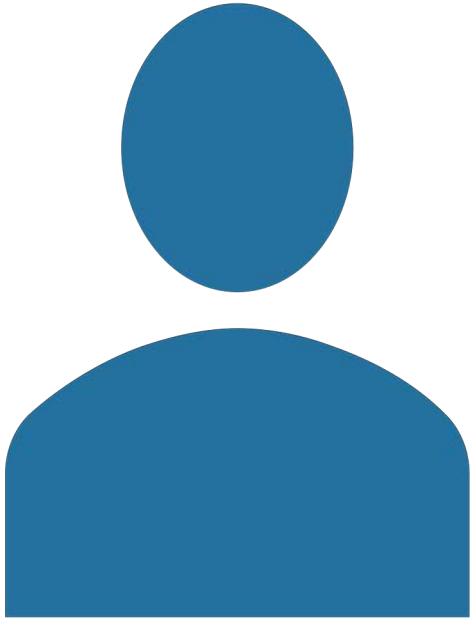
Contact



Linda Reuter – IRB Director, BRANY
LReuter@brany.com

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