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Demystifying Human Subjects Research Versus Quality Improvement: A Compliance Case Study

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A Tale of Research Compliance







Children's Hospital Colorado



University of Colorado
Anschutz Medical Campus

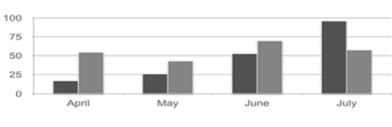


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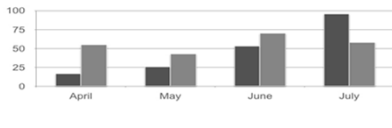
Background

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Results

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Conclusions

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Implications

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References

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Methods

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It's all about intent!

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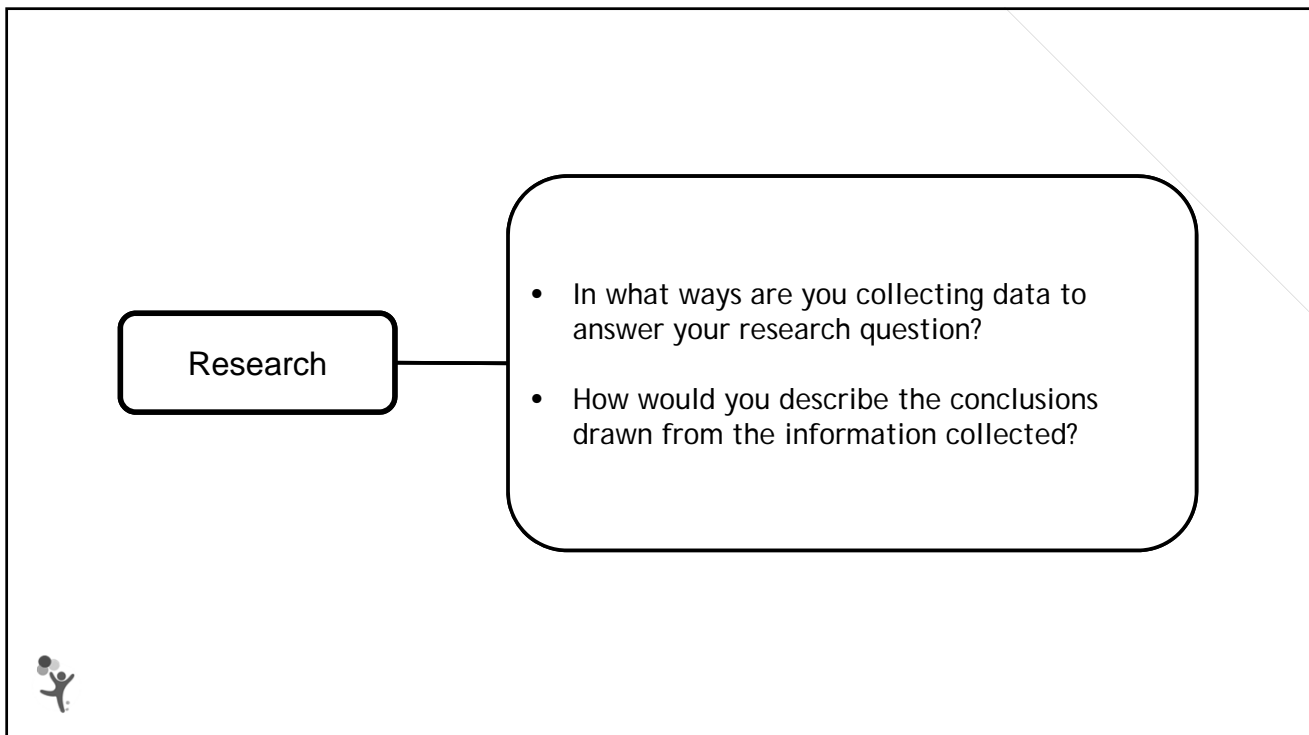
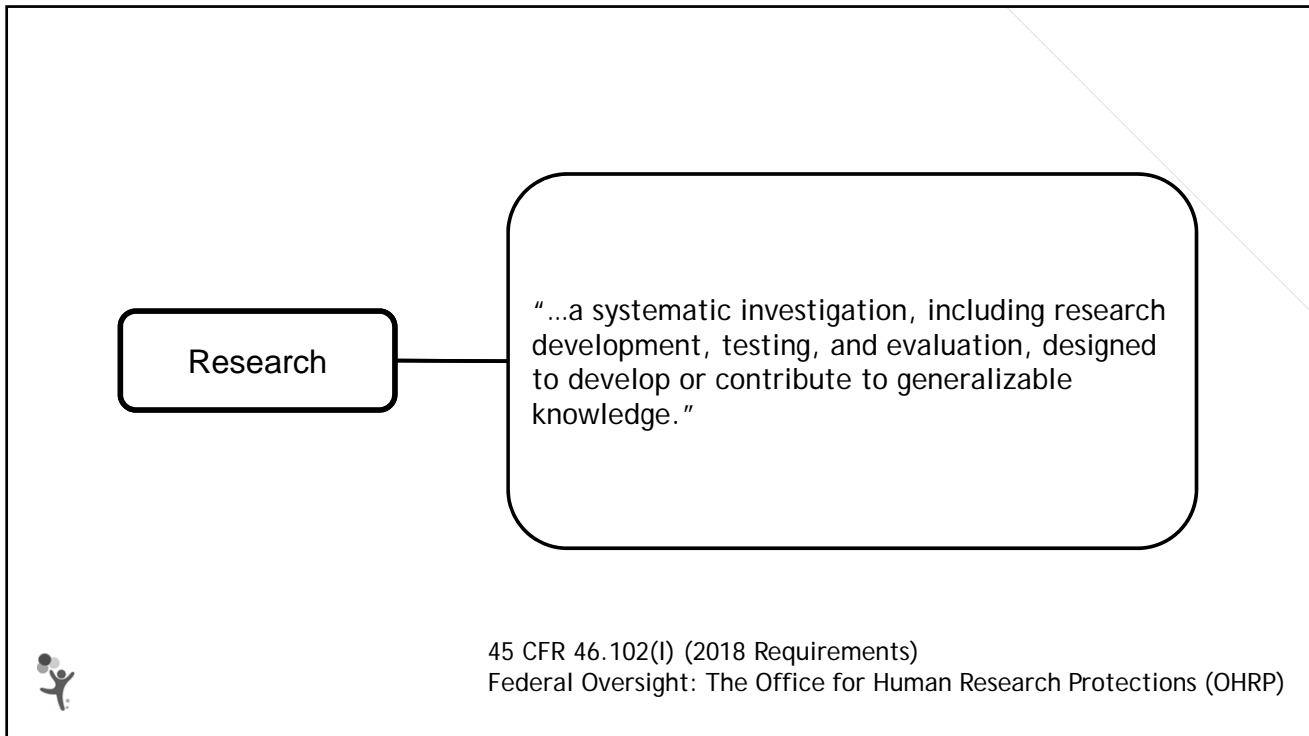


Objectives

- Review related laws and regulations which help define human subjects research.
- Examine real regulatory cases to distinguish quality improvement activities from human subjects research.
- Describe a governance structure that reviews quality improvement activities which aim to evaluate and enhance programs, processes, or systems.

Am I doing research?







Human Subject

"...a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

45 CFR 46.102(e) (2018 Requirements)

Federal Oversight: The Office for Human Research Protections (OHRP)



Human Subject

- What kind of information is obtained?
- How does that information differ from what we obtain as part of routine health care?
- What accounts for accessing and assessing this information? How are those reasons adequate?

Am I improving a health care process, or evaluating a program?




Quality Improvement

"...activities that use data-based methods—some developed in manufacturing industries—to bring about immediate improvements in health care delivery...QI methods enable them (providers) to make change in a systematic way, measuring and assessing the effects of a change, feeding the information back into the clinical setting, and making adjustments until they are satisfied with the results..."




Mary Ann Baily, "Quality Improvement Methods in Health Care," in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, ed. Mary Crowley (Garrison, NY: The Hastings Center, 2008), 147-152.



Quality Improvement

The Department of Health and Human Services (DHHS) defines quality improvement activities as being limited to:

- a) implementing a practice to improve the quality of patient care, and
- b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes.



Quality Improvement

- Does my project evaluate a hospital system or a human subject?
- What program, process or system is being evaluated?
- Are my results meant to impact my institution or are they meant to be generalized?

Research

- Am I testing a hypothesis?
- Do I want to statistically prove or disprove findings and observations to generate knowledge?
- Am I trying to establish new routine care or practice standards where they have not already been accepted?



Quality Improvement

- Do I want to assess, evaluate, or provide feedback to improve a health care program, process, or system?
- Am I trying to find ways to improve performance?
- Do I hope to uncover ways to minimize mistakes?

Example Cases



A clinic implements a widely-accepted assessment as part of routine care to identify patients requiring special services and staff expertise. The clinic audits patient charts to ascertain whether the assessments are performed with the appropriate patients. Afterward, the clinic plans to train staff on using the assessments with patients, if it finds that the assessments are not being administered routinely.



The allergy department wants to compare two different treatment options for therapy. Patients will be randomly assigned to the two different treatment options. The intention is two-fold:

1. To determine best practice; and
2. Publish a paper in a peer reviewed journal.



To understand risks for diseases transmitted from mother to child, independent social workers, not otherwise involved in a mother's care, will conduct maternal interviews. These interviews will take place outside of regular medical visits; compensation of around \$50 will be offered. Written maternal consent will be obtained.



A radiologist wishes to create a database to evaluate and forecast radiation dosimetry. This radiologist wants to know if this database can help demonstrate over-exposure incidents in patients having multiple procedures. The database will record patient data collected from medical records. The radiologist will later analyze the data, focusing on over-exposures.

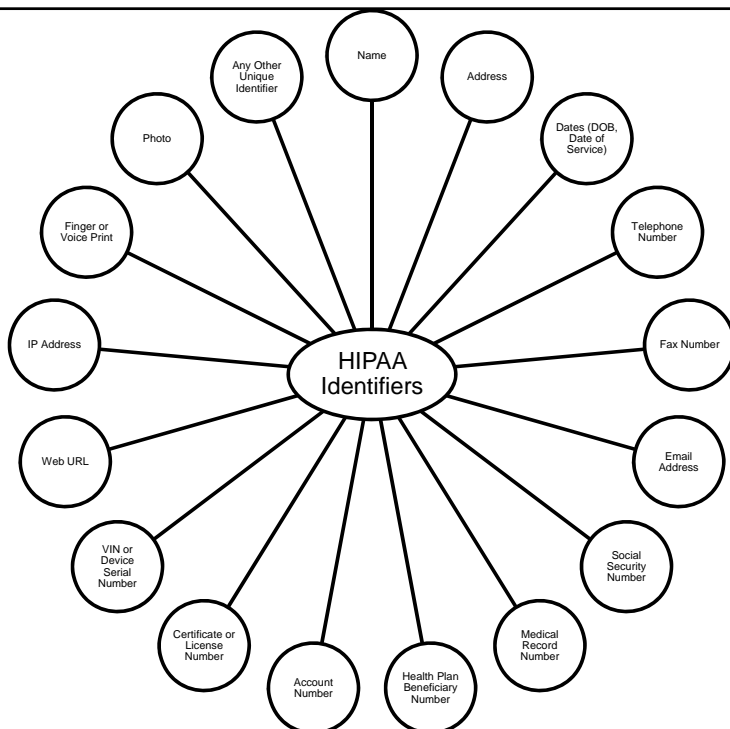


The cardiology department participates in a multi-institutional collaborative seeking to improve cardiac care. The cardiology team enters clinical outcomes data into a database for the consortium. Private health information is entered into a primary database during data collection. All identifying information is removed before sending data outside of the institution. The consortium disseminates de-identified information allowing comparison of practices and outcomes among centers.



HIPAA and Data Sharing

- 45 CFR 46 102(e)(5) defines “identifiable information” as “private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.”
- Do you plan to share de-identified information or a limited data set?
- Is the data being obtained and shared for treatment, payment, or operational purposes?



Organizational Research Risk and Quality Improvement Review Panel (ORRQIRP)

Reviews QI projects to relieve local IRB of administrative burden of reviewing non-human subjects research.

Convenes to review projects that intend to assess or improve a health care delivery process, program, or system at Children's Colorado.

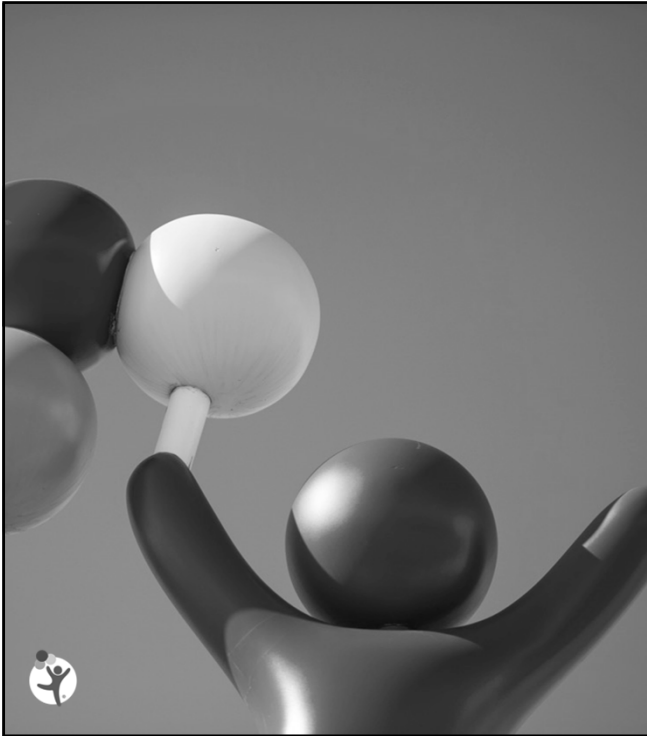
Reviews certain research topics to determine feasibility and acceptable levels of organizational risk with the goal of enhancing research. For these reviews, panel members ensure that deliberations and resulting decisions align with Children's Colorado's, mission, values, and ethical and legal obligations.



Remember:

It's all about intent!





Discussion