Navigating the "IRB" When You're Not Doing Research

How To Describe Your Quality Improvement Project

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Disclaimer

The author of this presentation is not a representative of any federal agency or health-care related institution. This presentation was created with information found in US HHS and HIPAA regulations, the UMSON Doctor of Nursing Practice project review processes, and interpretations from the author's Quality Assurance (QA) and Institutional Review Board (IRB) reviewer perspective.

It is recommended that any project intended to be published and/or implemented within a healthcare related system undergo an authoritative review process to determine whether their project is considered human subjects research or not.

Objectives

01

What is the difference between research and quality improvement (QI)?

02

Understand perspectives around “research” and “non-human subjects research” (research vs QI)

03

Identify common problem themes noted in NHSR applications

Quality Improvement vs. Research *Legal Definitions*

Quality Improvement:

Not legally defined!

However- “performance improvement” ***activities*** are covered by HIPAA regulations

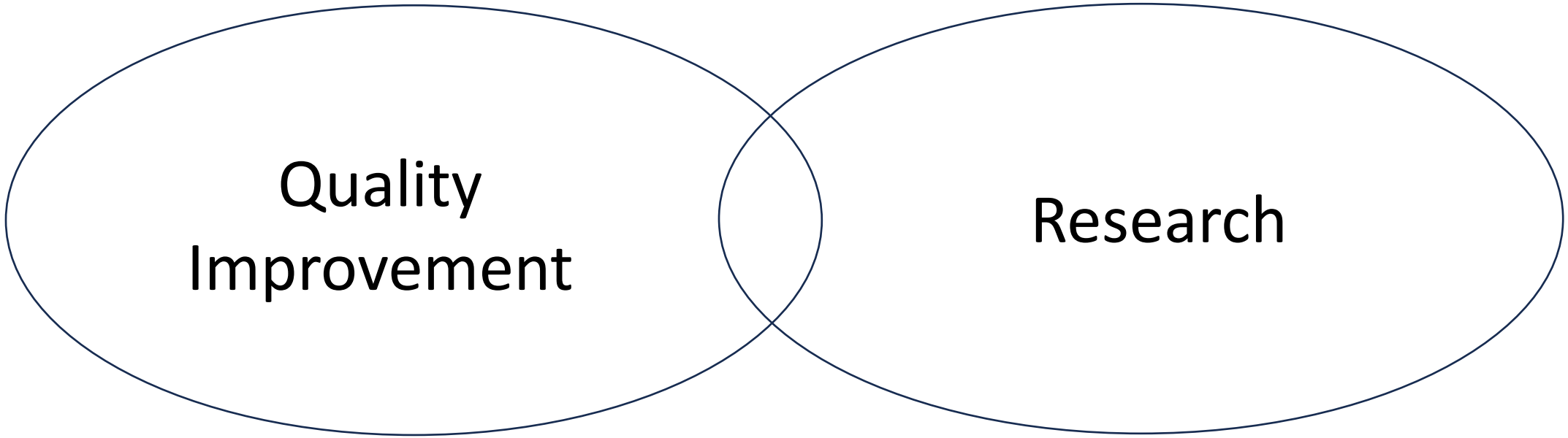
Research:

Legally defined by HHS (45CFR46), HIPAA (45CFR164)

Quality Improvement is NOT Research*

*Exceptions

Per HIPAA, “Research” is defined as: “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 164.501



Quality Improvement Intention:

Improve site performance via documented adherence to a practice change!

What does the data tell us in a performance improvement project?

-whether the change worked in the setting

-whether changes may need to be made to the plan

What about demographics?

What about outcomes data?

Performance improvement data is not meant to:

- challenge literature
- re-evaluate efficacy of the practice
- make generalizable inferences
- evaluate the outcomes themselves

Perspectives

Do these words have the same meaning across all audiences?

Audience	Word Choice						
	Research	Study	Project	Staff	PI	Shareholder	Nurse Champion
Researcher	x	x		x			?
Nurse Leader					x		x
Entry Level RN		x	x		?		
Clinic Site Reviewer		x	x		x		
IRB Member/ HRPO staff	x	x		x	x	?	?

NHSR Determination vs IRB Approval: UMB Operations

UMB HRP Components

- Institutional Official
- Human Research Protections Office
- Institutional Review Board
- Research Subject Advocate
- Office of Research and Development
- HIPAA Privacy Officer
- University Counsel
- Conflict of Interest Officer and Advisory Committee
- Research Integrity Office
- Investigational Drug Service
- Deans/Department Chairs
- Investigators and Research Staff
- Division/Departmental/School Signatories
- Environmental Health and Safety
- Institutional Biosafety Committee
- Radiation Safety Committee
- Baltimore Veterans Affairs Maryland Health Care System: Research and Development Committee

Human Research Protections Office (**HRPO**): **Staff** that either route research applications for IRB review –And/Or- **determine** that the project is **not human subjects research (NHSR)**

Institutional Review Board (***IRB***): ***Volunteers*** who ***review research*** applications ***and approve*** if appropriate

What is the difference between an NHSR determination and an IRB approval?

Question 1:

A clinician wants to submit an application to cover the activities outlined in their QI plan (i.e., implementation and data collection). The results are is not intended to be generalized, but will be used to guide local processes.

Should the clinician seek IRB approval or an NHSR determination?

A) IRB Approval
B) NHSR Determination

Question 2:

A Not Human Subjects Research (NHSR) Determination is provided by _____.

A)The Human Research Protections Office (HRPO)
B)Institutional Review Board (IRB)

QI vs. Research

	Quality Improvement	Research
Intent	Change/improve a site process/practice	Inform/produce generalizable knowledge
Starting Point	A gap in performance of practice, process, or system	A gap in knowledge evidence
Method	Plan-Do-Study-Act (PDSA), Six Sigma, Lean Principles	Scientific process
Outcomes	Expected based on previous research; Produces evidence for application at the local level (unit, department, organization)	Determined by results of research being conducted; Generates new knowledge for broad application
Data Collection	HIPAA	GCP (ALCOA)
Results	Based on adherence to change	Based on statistical significance
Regulation(s)	45CFR164	45CFR46
Generalizable to other settings?	No	Yes

Is this QI or research?
Is this ready for submission?

Question 3

You read a research article which showed a decrease in patient requests for anti-anxiety medication prior to minor, superficial surgeries under local anesthesia when provided with a VR nature experience prior to and during the procedure. The outpatient surgery center you work for has a high number of patients that request anti-anxiety medication. You want to implement this VR experience into practice to reduce patient anxiety and anti-anxiety medication requests. Your boss is supportive, so you conduct a literature review and draft a project plan.

Does this sound like research or QI?
Is this ready for submission?

Question 4

You noticed the timeline to patient discharge was lengthy at your hospital so you contact your library to assist with a literature search to see if there was any research on process improvements in the post-operative setting which shortened time to discharge.

Would a submission of an NHSR application be appropriate here?

Question 5

You heard about a new technology on the market that can interpret other languages in real time. Thinking of the diverse patient population in your area, you want to implement and evaluate this technology to promote equity among patients who do not speak English as a first language.

NHSR Application Summary Writing Tips

- Word choice, writing skill, critical thinking around what information to include and who the audience is
- Non-Generalizability intent; your language reflects your understanding of non-generalizability
- HIPAA minimum data necessary standard adherence
- Appropriate use of privacy and confidentiality terminology

Word choice - Writing skill - Critical thinking

Healthcare QI practitioners need to be able to think like a research reviewer when writing their proposals. A research reviewer does not need to think like a healthcare QI practitioner.

<u>Summary Writing Tips:</u>

- Avoid research “type” words in project summary (i.e., Research, Study, Evaluate, Investigator, Participant/Subject, Eligibility criteria, Protocol, etc.)
- Summary makes very clear that:
  - Project purpose is to improve site performance
  - Data collection purpose is to measure adherence to performance improvement plan
  - Outcomes are expected based on previous research

Focus on NON-Generalizability of Project (rationale for not meeting definition of research)

Summary Writing Tips:

-Evidence of site-specific need for QI supports the non-generalizable intent.

-Methods and results description supports non-generalizability of project.

-Why is the PROJECT so specific to the site (DETAILS!!)

-Why wouldn't the PROJECT work the same at another site (not practice problem, not outcomes)

HIPAA minimum necessary standard

The HIPAA Minimum Necessary standard only permits a covered entity to use the least amount of protected health information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request.

<u>Summary Writing Tips:</u>

-Only use what you need regarding demographics & publication population description requirements

-How will the data inform how you should carry out/amend your project?

-How are you adhering to the minimum data necessary standard?

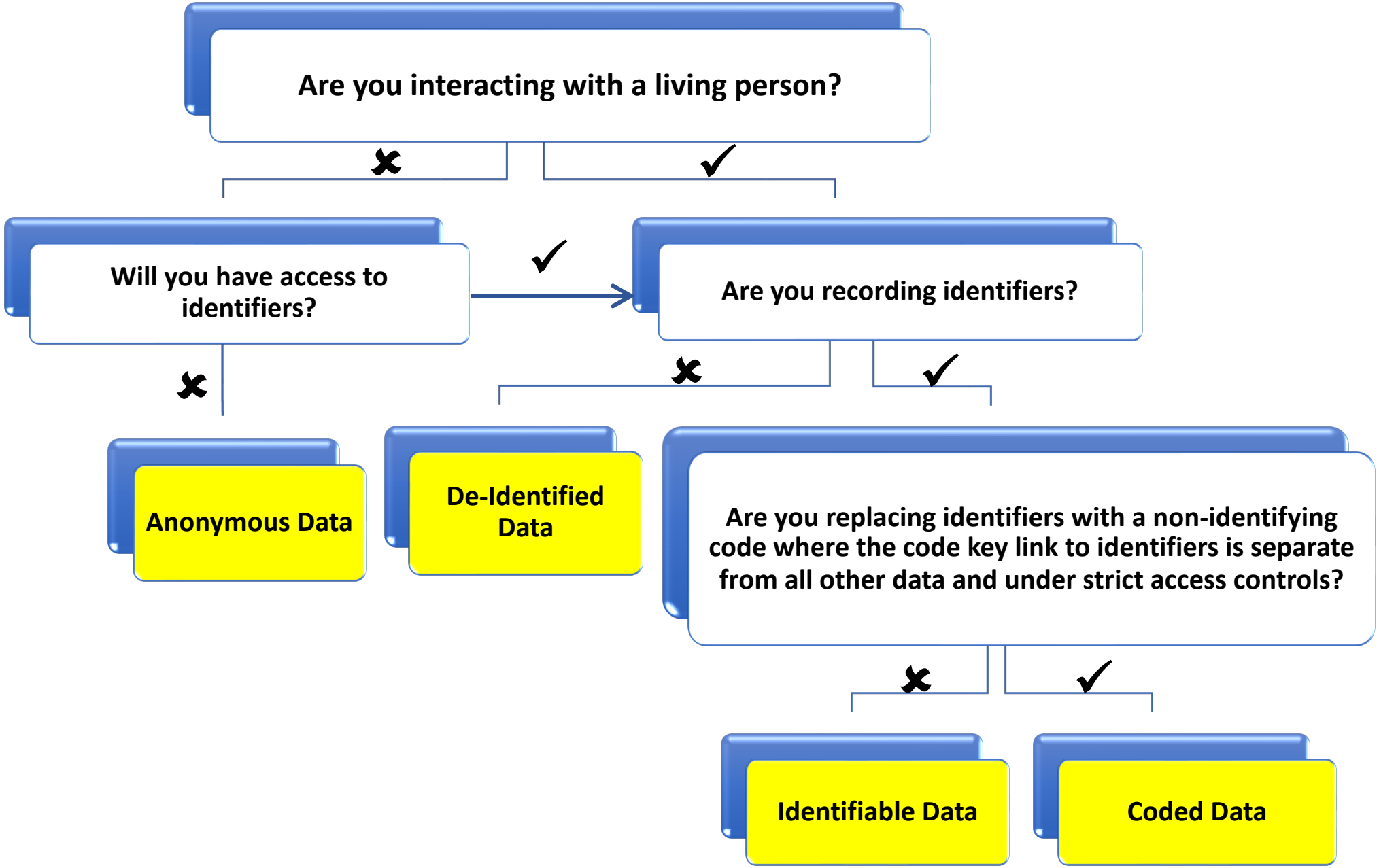
Appropriate use of privacy and confidentiality terminology (assurance of HIPAA compliance)

Privacy: access to one's self (Pre/existing data collection/security)

Confidentiality: protection of data (During and post-data collection security)

- **Coded:** Identifiers are viewed and recorded but kept separate from all other data (on a code key). Identifiers are replaced with a non-identifying code on data documents.
- **De-identified:** Identifiers were initially viewed and accessed, but the data was recorded without identifiers.
- **Anonymous:** Never at any point were identifiers viewed, accessed, or recorded

Data Confidentiality Method Decision Tree



Examples of NHSR Application Language for QI Projects

Title: Prevention of Spinal Induced Hypotension Through Fluid Co-loading

How can it be improved?

Title: Assessing implementation adherence of research-backed fluid-co-loading practice in a site Labor and Delivery unit to reduce Spinal Induced Hypotension in elective cesarean patients

Examples of NHSR Application Language for QI Projects

The purpose of this IRB submission is to obtain an authoritative determination from the IRB that this performance improvement project does not meet the definition of human subjects research.

How can it be improved?

The purpose of this submission is to obtain an authoritative determination from the UMB HRPO that this performance improvement project does not meet the definition of human subjects research.

Examples of NHSR Application Language for QI Projects

80% of patients undergoing elective cesarean section with spinal anesthesia at the Labor and Delivery Unit of ABC Hospital in San Francisco, California experience spinal induced hypotension (SIH). General practice in elective cesarean sections is to begin fluid administration in the pre-operative period. Current practice does not allow for rapid fluid administration during vasodilation.

How can it be improved?

80% of patients undergoing elective cesarean section with spinal anesthesia at the Labor and Delivery Unit of ABC Hospital in San Francisco, California experience spinal induced hypotension (SIH). A root cause analysis at the site revealed that all elective cesarean procedures began fluid administration in the pre-operative period. Published research demonstrates that a fluid co-load is more preventative of SIH than a pre-operative fluid load in this surgical population and recommends the practice of fluid co-loading at the time of spinal anesthetic administration.

Examples of NHSR Application Language for QI Projects

This project is intended to decrease rates of SIH in the target population at ABC Hospital. Data from this project are unique to the site due to an analysis of root causes, site workflow, resources unique to this site, and the characteristics of the patients (i.e. high rates of comorbidities, low socioeconomic status, lack of prenatal care). Thus, findings from this project are not to be generalized to any setting or population beyond this facility.

How can it be improved?

This performance improvement project aims to measure adherence to a local practice change whereby fluid co-loading in patients undergoing elective cesarean section with spinal anesthesia is implemented to reduce the incidence of SIH as expected by previous published research. The project is not generalizable to other settings because the workflow created to incorporate the practice change is unique to the site-specific root cause of clinical problem, site specific resources and staffing structure. Other units would require a workflow specific to their needs, thus, the project would not be generalizable outside of the Labor and Delivery Unit of ABC Hospital in San Francisco, California.

Thank you!

Questions?

Feedback?

Resources

Duke University Health System Policy:

https://irb.duhs.duke.edu/sites/default/files/2022-04/qi_policy_and_checklist_4-14-2021.pdf

HIPAA Minimum Necessary Rule:

https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/minimumnecessary.pdf

HIPAA Definitions 45 CFR 164.501:

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.501

SQUIRE: http://www.squire-statement.org/