UNIVERSITY of MARYLAND
SCHOOL OF NURSING

QI vs. Research

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Disclaimer

The views and opinions expressed in this presentation are my opinion and do not necessarily reflect the opinion of any other organization including the UMB HRPO and UMSON.

Overview

- Definitions
- Similarities and Differences
- Ethical Considerations
- Human Research Protections at UMB
- Key points, pitfalls, and reminders

What is QI?

Quality improvement consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups (HRSA).

Systematic: Having or involving a system, method, or plan

Action: the fact or process of doing something, typically to achieve an aim

Measurable improvement: quantifiable positive change

Health care services: medical care or utility/facility

Health status of targeted patient groups: the state of body and mind for specific groups of people within a specific setting

What is Research?

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102)

Systematic: Having or involving a system, method, or plan
Investigation: Searching inquiry for facts; detailed or careful examination
Develop: to form the basis for a future contribution
Contribute: giving/supplying results
Knowledge: truths, facts, and/or information

Generalizable: *Universally or widely acceptable*
Generalizable Knowledge: *Universally or widely acceptable truths, facts, and/or information*

Summary Comparison

RE: QI, Think: *when you systematically apply what is already known into the local practice, intended to quickly improve patient care/system within a specific setting.*

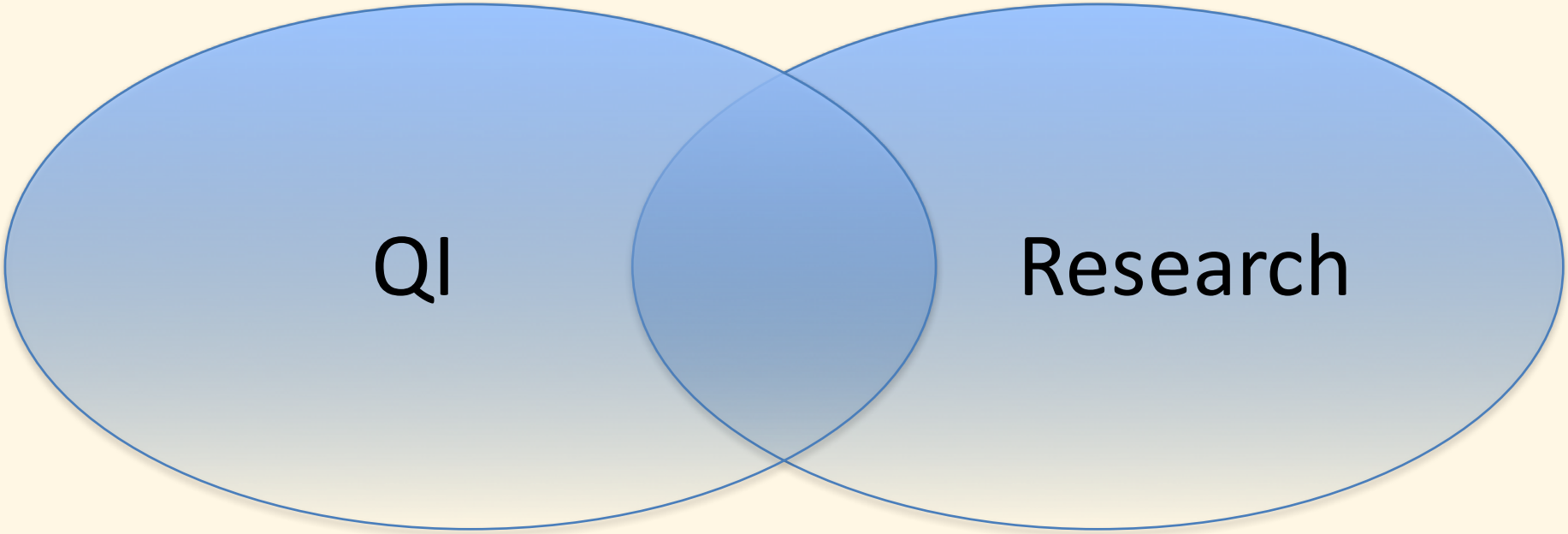
RE: Research, Think: *when you use a systematic approach to discover something that is unknown. Intended for widespread applicability, time consuming, may not directly affect patient care within a specific setting.*

Generalizability

- Is the systematic investigation designed to develop or contribute to generalizable knowledge?
  - If the answer is YES, your study may be research.
  - If the answer is NO, specify why specific to the clinic/setting, AND why NOT specific to OTHER clinics/settings.

A QI project may be designed to meet the needs of a specific organization aligned with that organization's specific policies, procedures, and needs and intended solely for improvement of that organization. Because the project is designed as a QI project and within the scope of the institutional needs, procedures and policies it is not intended to be generalizable to other settings.

Similarities and Differences

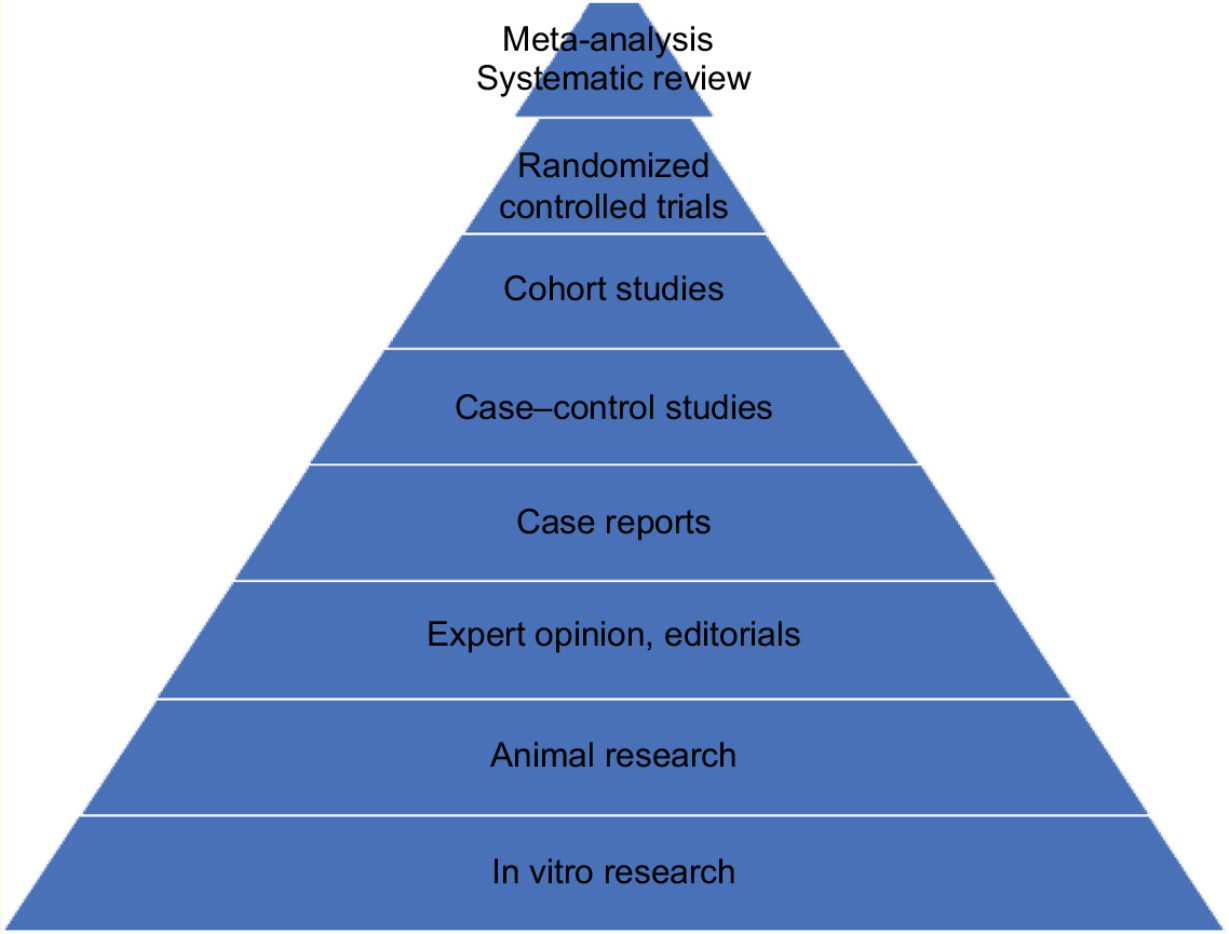


QI Methods

- PDCA cycle (Plan-Do-Check-Act)
- DMAIC (Define, Measure, Analyze, Improve, Control)
- Six Sigma Approach
- Fishbone Diagram

+ many many more!

Research Methods



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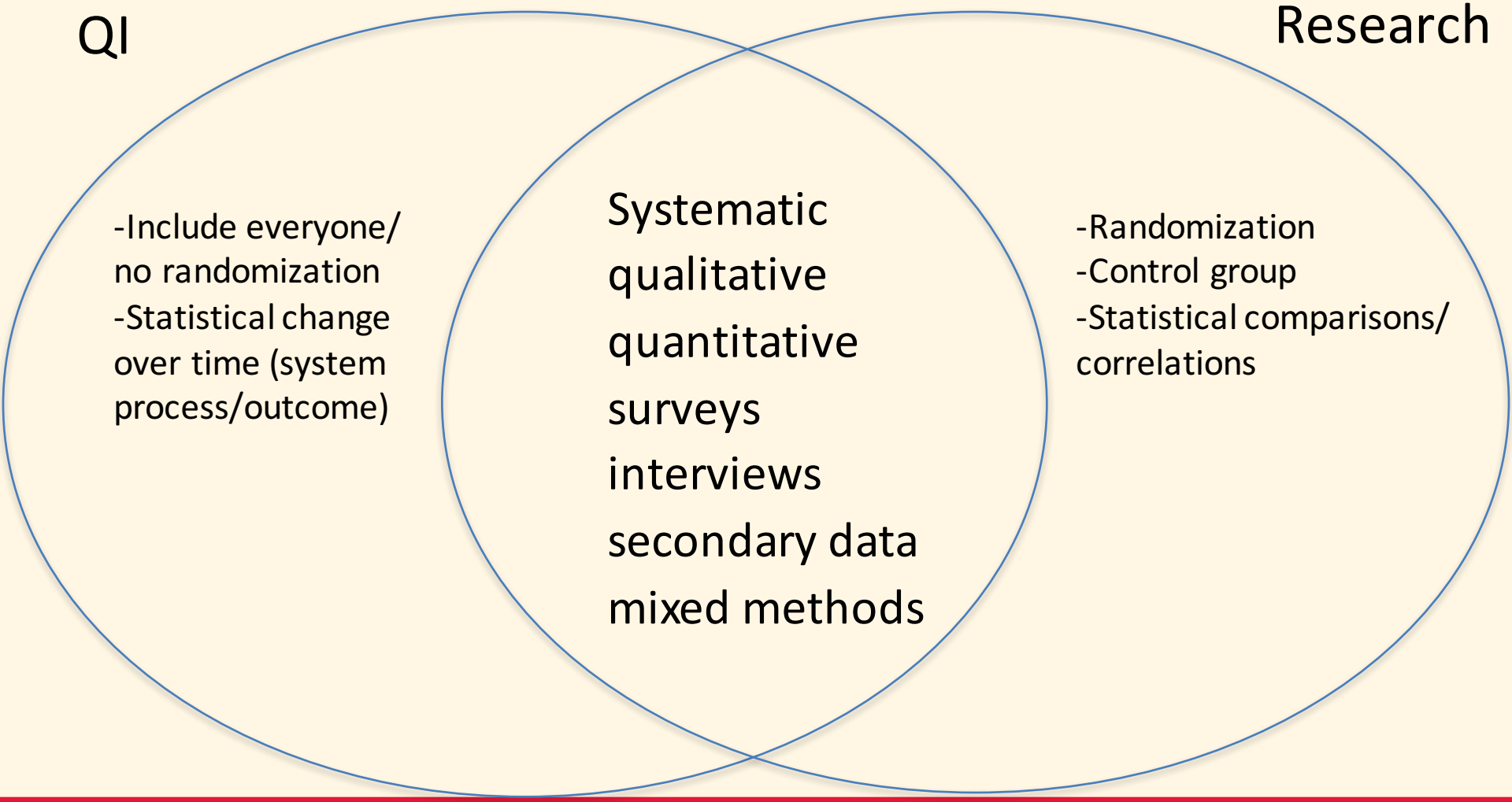
Purpose

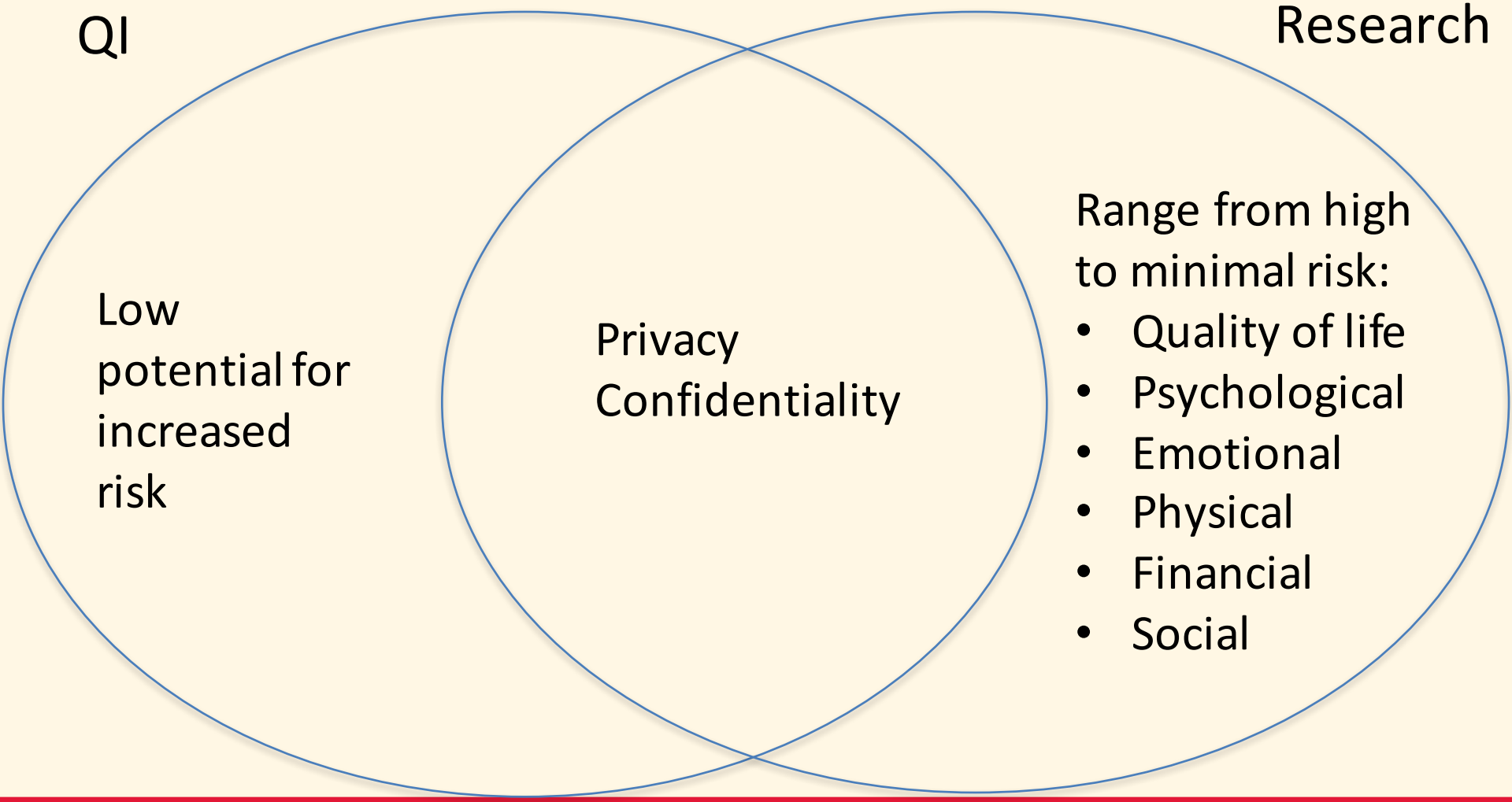
QI Goal: Improving a gap in performance at a specific site. The "performance" is a standard in health care that is not efficiently/appropriately/ consistently being done.

Research Goal: Add new knowledge to what was previously unknown in literature through testing of a hypothesis or a scientific question.

Approach to Data



Risks


QI
Research
Low potential for increased risk
Privacy
Confidentiality
Range from high to minimal risk:
• Quality of life
• Psychological
• Emotional
• Physical
• Financial
• Social

Benefit/Intention

QI Projects are intended to:

- be implemented and sustained overtime
- directly benefit those involved
- work within clinical care/ doctor-patient relationship

Research Projects are intended to:

- advance/develop knowledge
- not guarantee benefit to participant
- potentially benefit society/science
- work outside of clinical care/ doctor-patient relationship

Results

QI: immediate and ongoing/sustainable, directly impacts those involved

Research: typically time-consuming

Both: may promote further work, may be published

Ethical Considerations

https://thedataist.com/a-proposal-for-data-science-ethics/

Ethics: HIPAA (PHI)

Research: HIPAA Waiver (approved by HRPO/IRB) or HIPAA Authorization Agreement (signed by participant) required

QI: No Waiver or HIPAA Authorization Agreement needed

only view and observe information that is crucial to the outcomes of the project

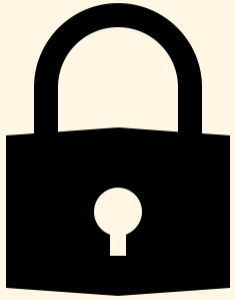
Ethics: Privacy

Research: Participants aware via consent process or consent form; IRB approves HIPAA waiver

QI: Those involved may or may not be aware

Prior to starting a project, thoroughly vet how, specifically, you will protect the privacy of those you plan to collect data from

Ethics: Confidentiality



Prior to starting a project, determine how, specifically, are you securing someone's private or identifying information so that no one else can access it?

Ethics: Oversight

Research: Departmental review, HRPO/IRB

QI: Clinic? Unit? Nurse Champion? No one?

Prior to starting a project, can you describe how you weighed the risk to those involved vs the need to improve quality of care within a setting?

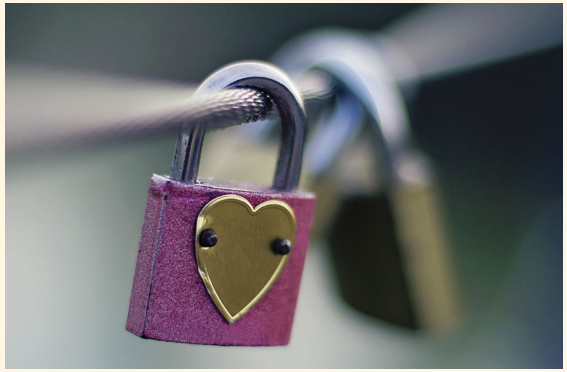
Ethics: Data Best Practices

Research: robust data to support generalizable outcomes

QI: data supports value of local process change

Prior to starting a project, assess the exact data points that are absolutely necessary to achieve your outcome, nothing more. Take only what you need, keep it organized and clean, and protect it.

Ethics: Human Protections

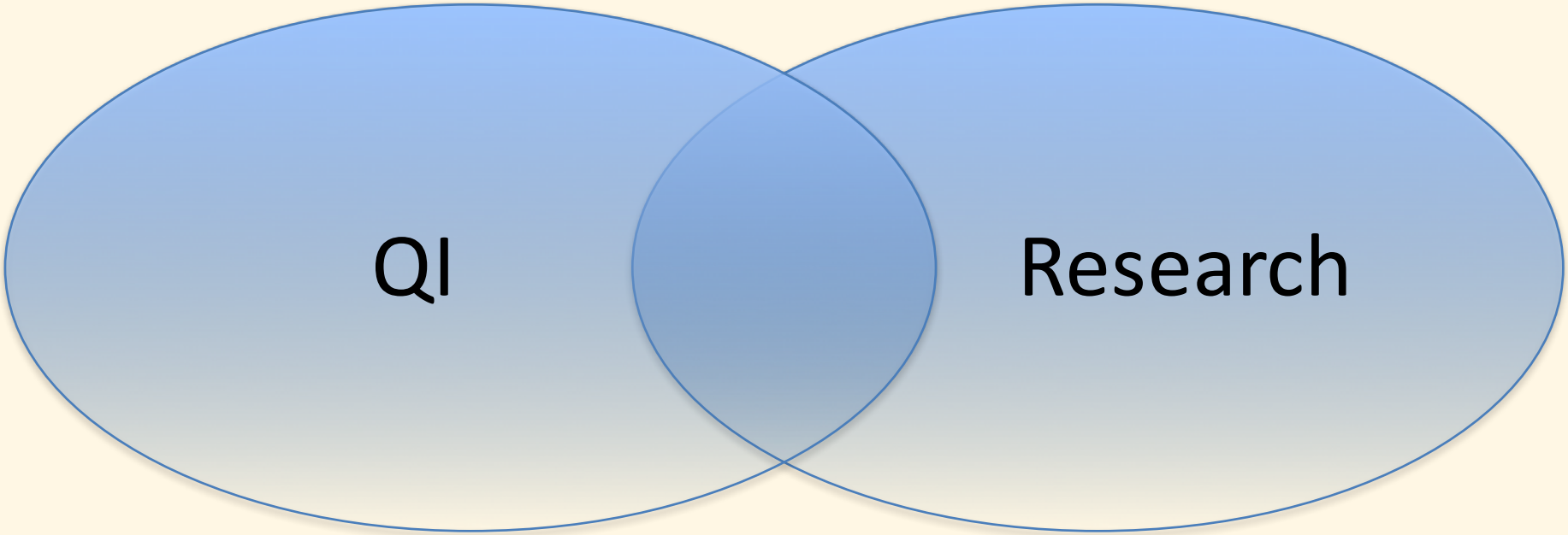


Research: Risks weighed by an HRPO/IRB, and via participants through consent process or consent form. Vulnerable populations considered, requires efforts to protect

QI: Not held to common rule regulations (consent, vulnerable populations, etc.)

Prior to starting a project, determine and be able to explain the precautions you are taking to ensure professional responsibility and low potential for harm.

Summary Example Comparison



QI Summary Example

A records review conducted at the University of Maryland Medical Center (UMMC) Pediatric Emergency Department (PED) discovered that up to 10% of physical injuries sustained by children presenting to the PED are caused by abuse.

The purpose of this Quality Improvement (QI) project is to implement a Child Abuse Screening Program (CASP) over a 15-week period in the Fall of 2018 to improve the detection of child abuse at the UMMC PED. Data recorded for the project will include all pediatric patients age 8 or younger who present to the PED with an injury-related chief complaint.

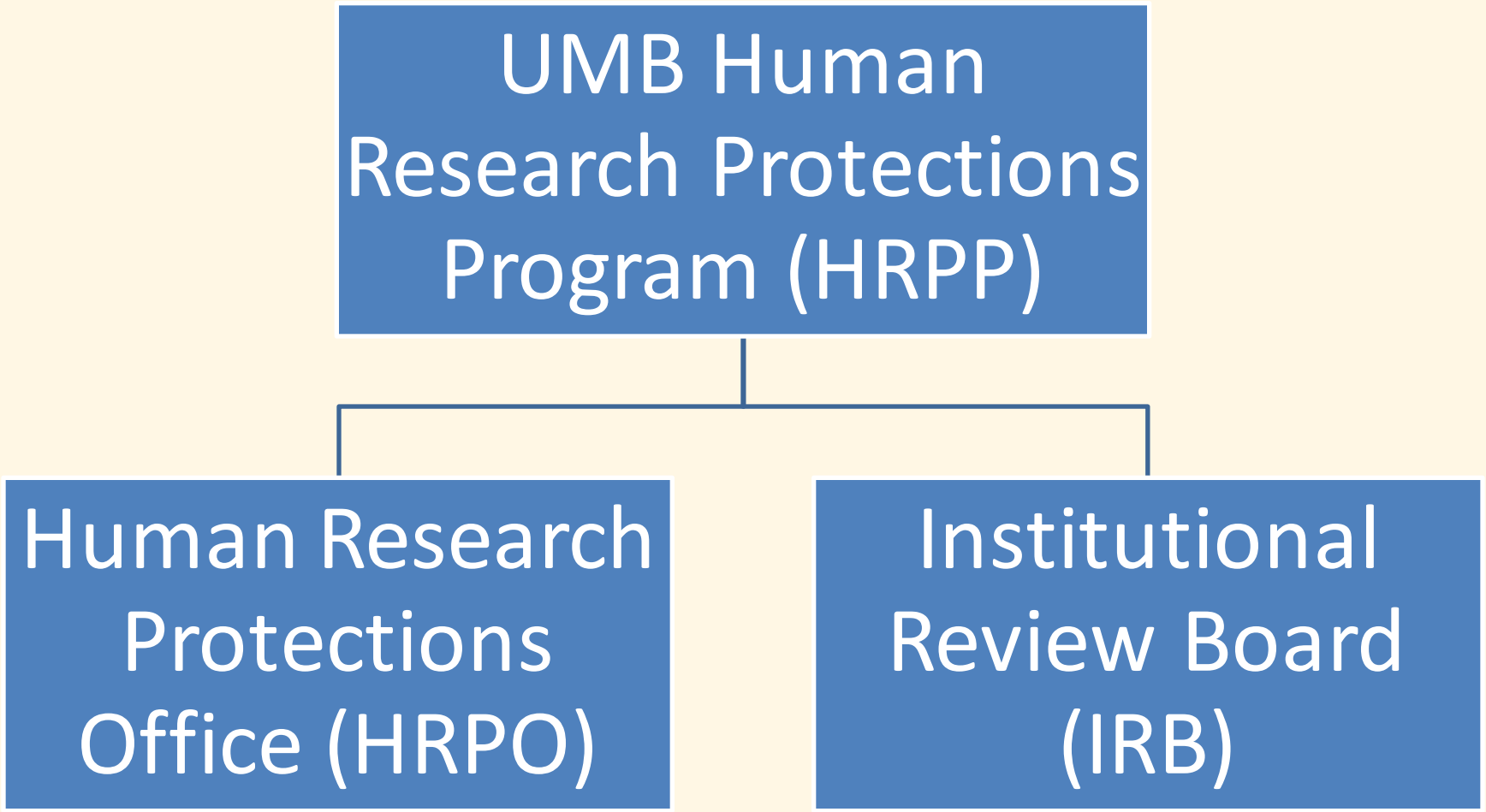
PED physicians, nurses and social workers will be trained on the CASP. Pre/post training data on the provider's understanding of the screening program will be collected anonymously via self-administered, pencil/paper survey.

Following training, the CASP will be implemented using an anonymized, validated and standard Escape Instrument (a 6-item, yes/no response, pencil/paper screening tool). Completed Escape Instruments will be deposited by the physician/nurse into a locked box in the PED. At the completion of the project, aggregate analytics regarding the project outcomes will be reported to site stakeholders and disseminated through poster presentations and peer reviewed publications. Should the outcomes be favorable, the intention is to sustain the QI initiative on the unit.

To protect patients and practitioners, anonymized training data is collected from providers, and the anonymous Escape Instruments will be destroyed at the end of the project. Data will be stored on an internal password-protected computer.

This project is intended for internal QI purposes at the UMMC PED only. It is not intended to infer correlation and/or causality. The interventions are specifically designed to address a practice gap and meet the workflow at UMMC PED only and are not generalizable to similar healthcare settings or populations.

Human Research Protections at UMB



Levels of HRPO/IRB Review

- Not Human Subjects Research (NHSR) Determination: HRPO Review
- Exempt: HRPO Review
- Expedited: IRB expedited (chair + 1 board member) review
- Full: IRB full board review

Who Decides?

UMB HRPO, not the researcher or practitioner, who makes the final decision as to whether the project meets the definition of research or not.

Key Points, Pitfalls, Reminders

- QI is very important! Improves cost of care, patient experience, healthcare outcomes, and the provider experience at the local level.
- You **CANNOT** go backwards. HRPO cannot provide retrospective approval.
- Changes to previously approved plans are to be communicated to the HRPO/IRB. (HS Research=Mod, QI=new NHSR)
- Site approval/buy-in prior to starting project
- Know and use terms appropriately (privacy/confidentiality, anonymous/de-identified, deidentified/coded, etc.)
- Data collection tools should reflect your outcome
- In describing QI project, avoid research buzz words (study, research, human subject, etc.)
- A project done at multiple sites is likely generalizable.
- If you're switching sites or adding sites, your project is likely generalizable.
- A project can be both QI and Research!

Thanks!

- Emily Werthman, RN
- Renee Franquiz, DNP, RN, CNE
- Debra Bingham, DrPH, RN, FAAN
- Jenni Day, PhD, RN

Resources

- Cambridge Health Alliance QI vs Research
- UMB HRPO
- ICH GCP
- First Clinical Research On- Line Journal
- http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
- https://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf
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