Research vs Quality Assurance/Quality Improvement

Human Research Protections Office

Carilion Clinic

Learning Objectives

At the end we will be able to

- Define Research
- Define QA/QI
- Identify the differences between research and QA/QI
- Explain why QA/QIis important
- Identify types of Non-Human Subjects Research (NHSR)
- Understand the considerations for publication of QA/QI findings

Defining Human Subjects Research

https://tinyurl.com/4vuzx2u2

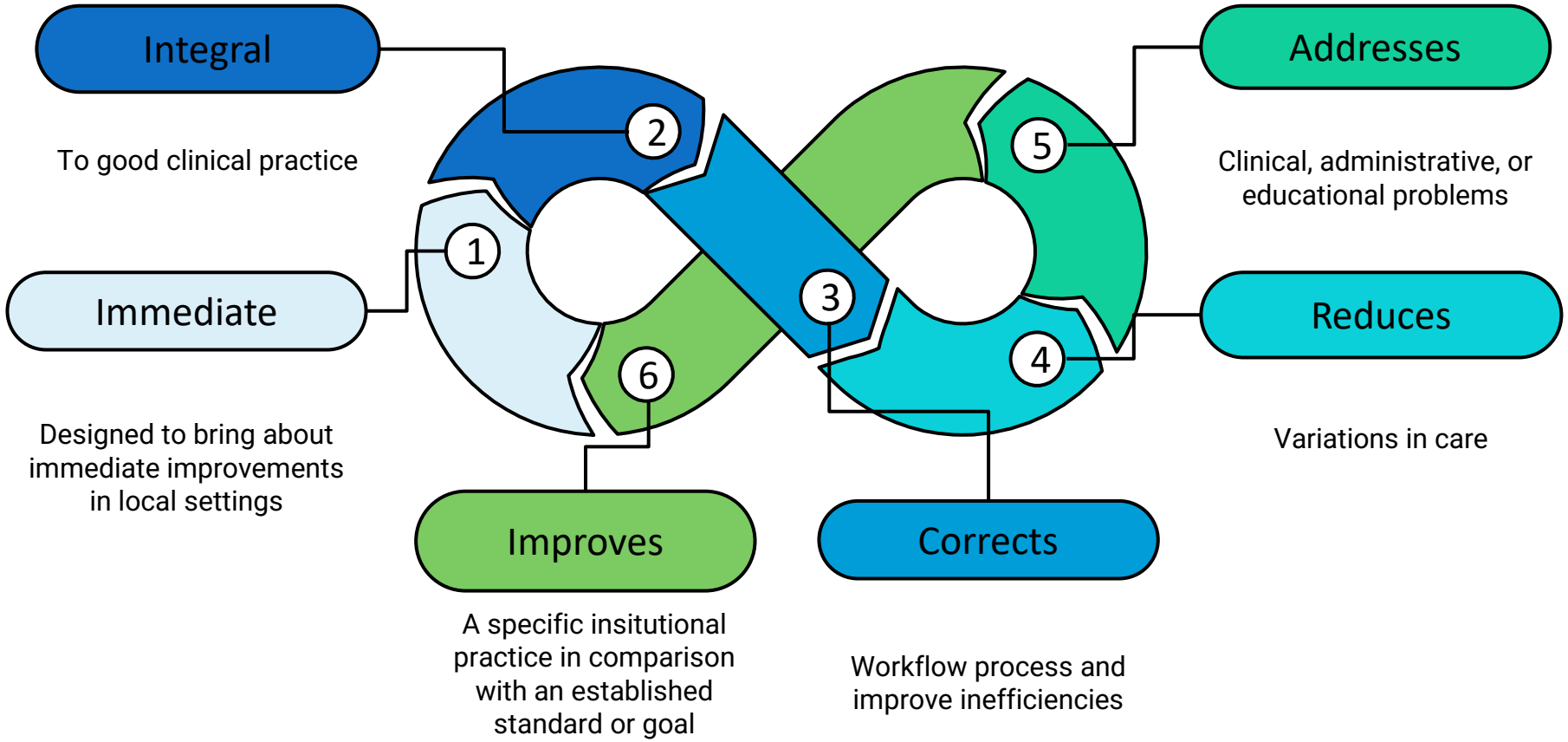
1. Which of the following defines research?
(10 Points)

- An investigation designed to generate new, generalizable, and enduring knowledge about human health
- An investigation that is integral to good clinical practice and designed to generate immediate improvements in patient care inside an organization, facility, or department

2. Which of the following is likely not part of human subjects research?
(10 Points)

- The act of collecting private and identifiable data through interaction or intervention with an investigator
- Actual identifiable private information
- Actual identifiable biospecimens
- Program data collected from the ED to improve wait times between midnight and 5 am

Defining Quality Assurance/Quality Improvement



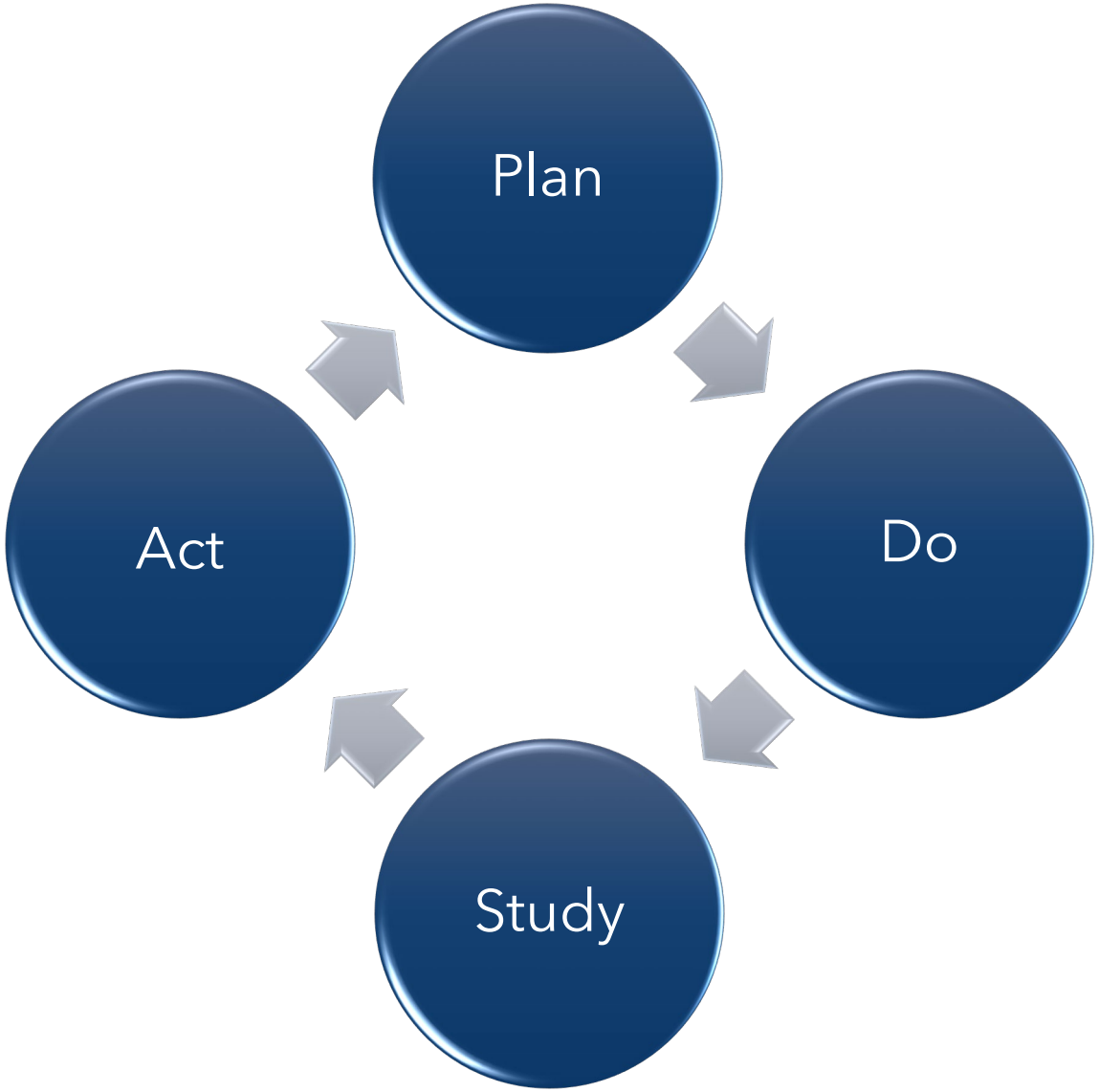
Is there a difference between QA & QI?

- Quality assurance measures compliance against certain necessary standards or guidelines. QA tends to focus on correcting problems in patient care quality, especially the problems of individual practitioners.
- Quality improvement includes a focus on finding opportunities to improve quality by changing systems as well as individual practitioner behavior. Implements the use of statistical profiles of outcomes, structures, and processes as a baseline against which improvement can be measured.

The Institute of Medicine's 6 Aims of Quality Health Care

- **Safe:** Avoiding injuries to patients from the care that is intended to help them.
- **Effective:** providing services, based on scientific knowledge, to all who could benefit and refraining from providing services to those not likely to benefit (avoiding overuse and underuse).
- **Patient-centered:** providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- **Timely:** reducing wait times and sometimes harmful delays for both those who receive and those who give care.
- **Equitable:** providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.
- **Efficient:** avoiding waste, including wase of equipment, supplies, ideas, and energy.

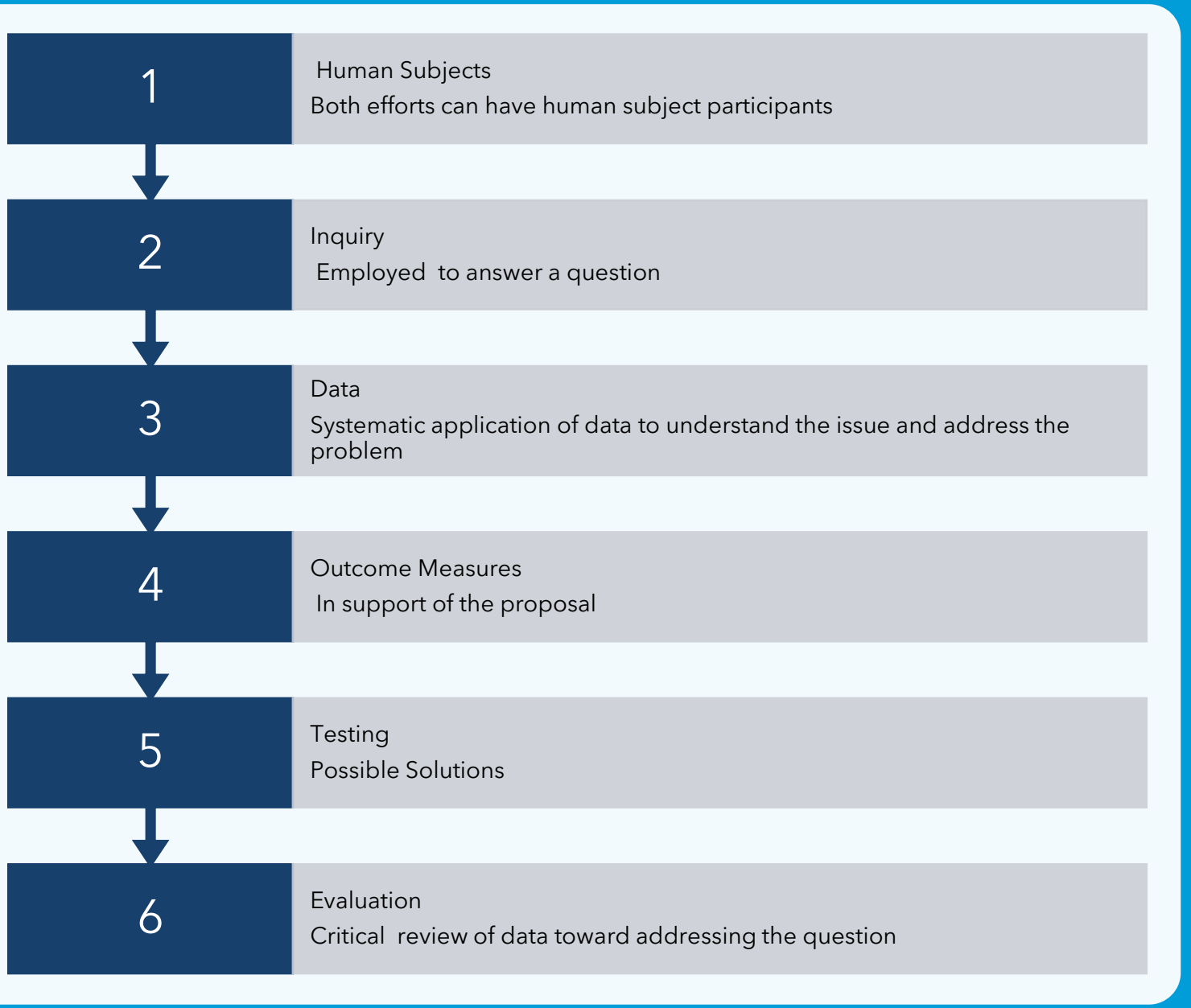
Life cycle of QA/QI



Health and Human Services definition of human subject

- Human subjects are living individuals about whom an investigator (professional or student) is conducting research.
  - Researchers obtain information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or.
  - Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.
  - From 45 Code of Federal Regulations (CFR) 46.102.

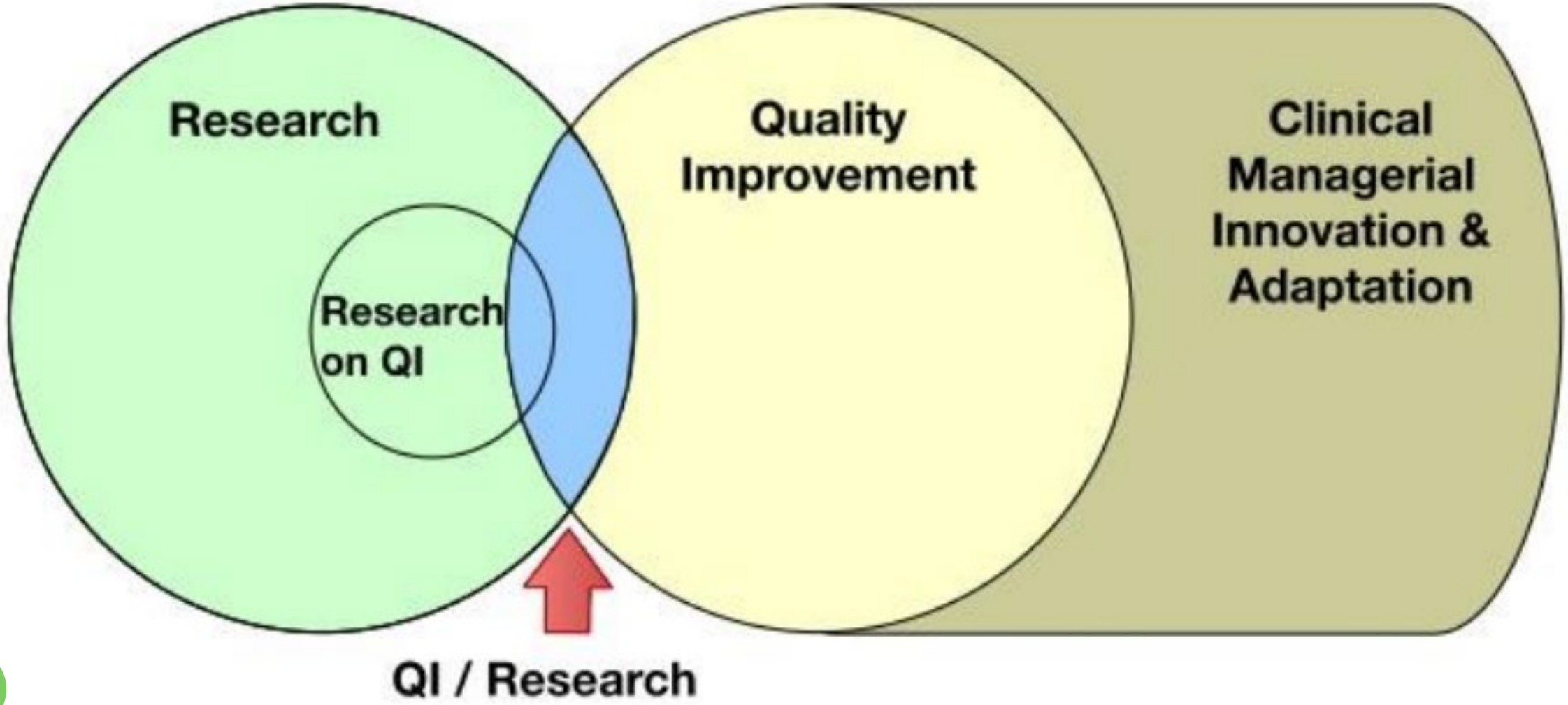
Similarities between HSR and QA/QI

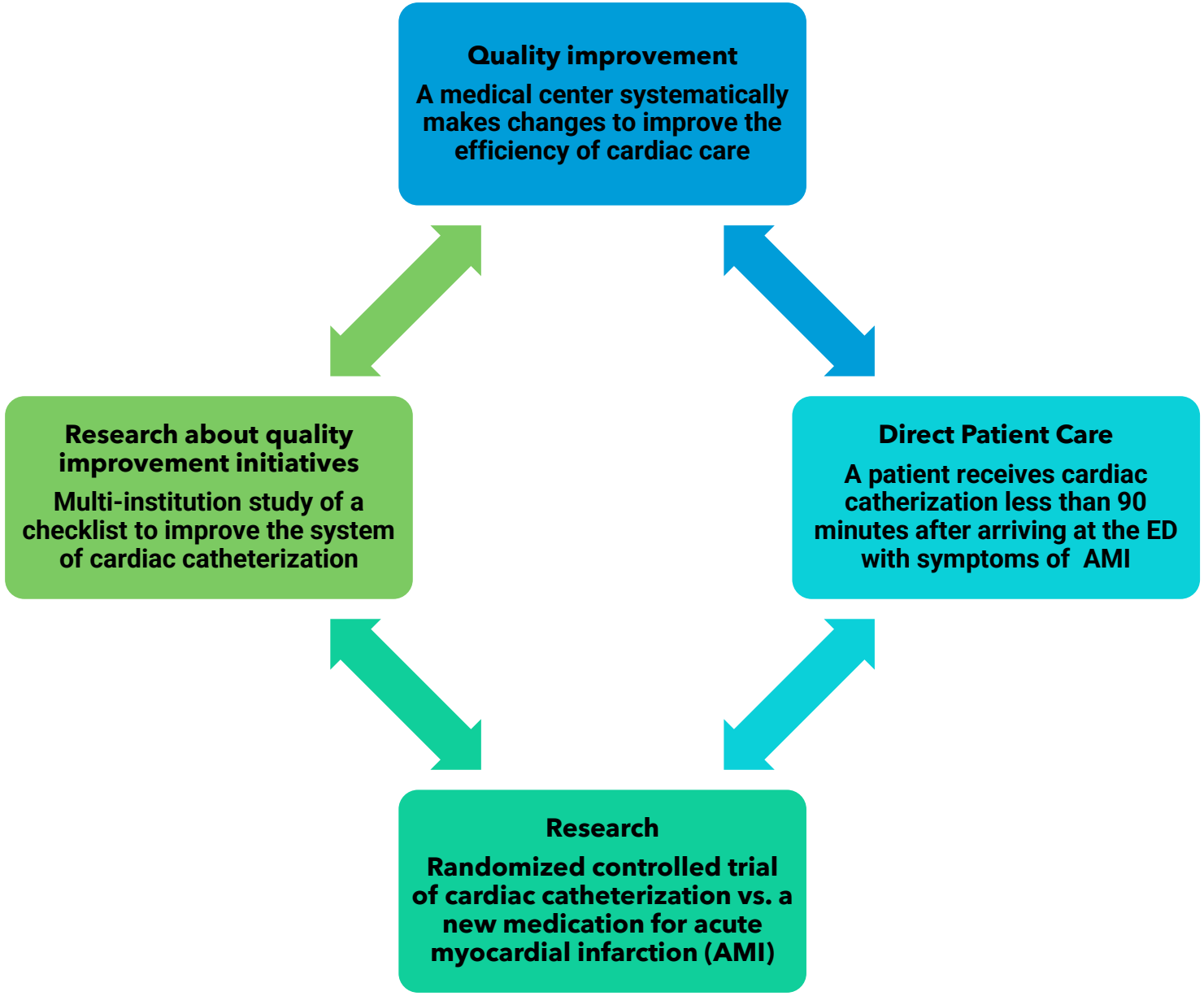


Are there overlaps between HSR and QA/QI?

- Yes!
  - A QI project might be HSR
- For Example:
  - The research team introduces an **untested clinical intervention** to both improve quality of care AND to collect information about patient outcomes that will **contribute to scientific evidence** to determine how well the **intervention achieves its intended results**.
    - There is an intervention that is intended to change or alter some aspect of care
    - There is the collection of data to evaluate the intervention
    - The intention it to generate generalizable scientific knowledge

Intersection of QI and Research




Quality improvement
A medical center systematically makes changes to improve the efficiency of cardiac care
Direct Patient Care
A patient receives cardiac catherization less than 90 minutes after arriving at the ED with symptoms of AMI
Research
Randomized controlled trial of cardiac catheterization vs. a new medication for acute myocardial infarction (AMI)
Research about quality improvement initiatives
Multi-institution study of a checklist to improve the system of cardiac catheterization

When QA/QI is not research

When the purpose is to assure known quality not to develop or contribute to generalizable knowledge

When the project presents no additional risks to patients

When it is used to evaluate optimal functioning of an organization

For internal auditing processes only

Designed to bring about immediate improvements in health delivery in a defined setting, such as a single department or division.

Examples:

***accumulating statistical data for monitoring and clinical performance assessment,**

***assessing community-based outreach programs for the delivery of health care**

*** evaluating billing practices**

Human Subjects Research  Quality Improvement: Which one is it?

1. Purpose: Systematic Investigation designed to develop or contribute to generalizable knowledge
2. Starting point: Knowledge seeking is independent of routine care and intended to answer a question or test a hypothesis
3. Design: Plan, do, study, act leading to abandonment of a process or implementation of a process
4. Benefits: Directly benefits a process, system or program and may or may not directly benefit patients
5. Risks: may put subjects at risk
6. Participant role: Participate as a part of standard of care or update of processes.
7. Endpoint: improve a program, process or system
8. Analysis: methodology may serve to statistically prove or disprove a hypothesis
9. Adoption of results: Results rapidly adopted into local care delivery
10. Effect on program or practice: Findings are not generally expected to immediately impact or change practice
11. Publication/presentation: practitioners are encouraged to share systematic reporting of insights but not obliged to.

1. Research
2. Research
3. Quality improvement
4. Quality improvement
5. Research
6. Quality improvement
7. Quality improvement
8. Research
9. Quality improvement
10. Research
11. Quality improvement

What else is considered Not Human Subjects Research (NHSR)?

We know this

- Program evaluation, quality assurance review, or quality improvement projects.
  - Limited to:
    - Program evaluation
    - Quality assurance or quality improvement activities that evaluate, assure, or improve performance within a department, classroom, or hospital setting.
    - There should be no intent to alter or control the evaluation for research purposes

But what else is there?

- Case report or series with no more than 3 patients, describing an interesting treatment, presentation, or outcome and not subject to FDA approval.
  - HIPAA or other state and local laws may apply
- Journalistic or documentary activity including oral history. May be reported in any medium: print, documentary video, online magazine.
- Research involving ONLY deidentified or coded private information or specimens if one of the following conditions are met
  - The investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigator under any circumstances
  - There are written policies and operating procedures for a repository or data management center that have been IRB approved and that prohibit the release of the key to investigators

Publishing requirements for QA/QI

Be sure to describe your project as QI/QA Evidence-based practice rather than human subjects research

Do not state that you received IRB approval. State that it was determined by the IRB to be QI/QA/Evidence-based practice

You can disseminate your findings publicly, but findings are not intended to be generalizable

There is value in presenting these projects to discuss potentially effective models, strategies, assessment tools or to provide quality benchmarks

IRB approval cannot be obtained retroactively. Be sure to submit to the IRB prior to starting a project to assure that you are proceeding in the most ethical manner.

Case Examples

Example #1: QA/QI or Research?

- Data will be used internally to develop an implementation protocol.
- Investigators will evaluate the use of nares swabs for de-escalating antibiotics in pts. with pneumonia.
- The use of nares swabs has been utilized in several other healthcare systems to limit/decrease the exposure to antibiotics since 2010. Implementing this practice and updating Carilion processes will improve patient care and bring Carilion clinical practices up to current standards.

QA/QI

Example #2: QA/QI or Research?

- Current American Academy of Pain Medicine and American Society of Anesthesiologists guidelines do **not indicate a standard of care** for PCA pumps in the pain management guidelines.
- CMC has set the pump default for the dose request light cord to come on only when a dose is available. CMC initially determined to keep the dose request cord light on, but this was not based on any data, **as there is no standard of care for pump light settings.** At this time nursing can change the settings from the CMC default at the bedside upon patient or family request.
- The objective of this investigation is to determine whether having the visual cue of a light from the dose request chord, when a dose is due, as the default setting increases the number of doses the patient requests.

Research

Example #3 Is it QA/QI or research?

- An organization has been receiving complaints from patients that they have been having problems with customer service and patients have had trouble contacting the ambulatory care practice, gaining entry, and using the services of the practice.
- The organization implemented the “plan-do-study-act” process as outlined below
    1. Confirmed suspected problems by gathering more information
    2. Examined the data and developed a new measure for gathering data
    3. Set goals and formulated actions for improvement
    4. Implemented those actions for improvement
    5. Assessed the progress and refined the actions for improvement
    6. Monitored the actions for sustainability.

QA/QI

Example #4 Is it QA/QI or Research?

- The investigators want to obtain a better understanding of the best duration of oral cephalosporin therapy for patients with uncomplicated pyelonephritis.
- The investigators develop a protocol that will evaluate the difference between a short duration (7-9 days) and a longer duration (10-14) days to determine non-inferiority of the shorter duration.
- One group of patients will receive the 7-9 day dose and another group will receive the 10-14 day dose. Results will be compared across groups. In order to reach statistical significance they will have to recruit 200 patients into each group.

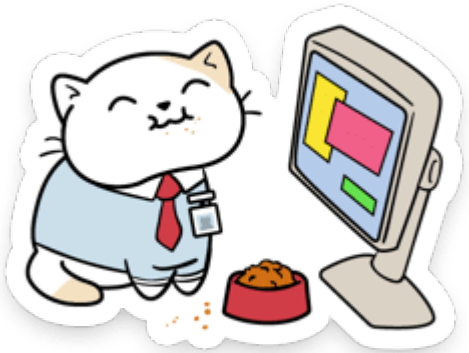
Research

I understand the differences, now what?

- NHSR projects do not need formal IRB determination
- Use a secure shared drive for data storage such as REDCap or SPARC
- HIPAA for healthcare information use still applies
- Additionally:
  - Propose your project at your department level.
  - Feel free to contact IRB staff for help or recommendations.
  - If it is unclear whether a project is QA/QI or research, it should be submitted to the IRB for determination through the PRIS3M system.

If it is research, follow this process

1. Complete required CITI training modules
2. Consult with the Health Analytics Research Team (HART) if you need data extracted from medical records
3. Complete and submit the R&D Department level review form signed off by the department chair
4. Submit the IRB Application with PI and department chair signoff
5. Collaborations between Virginia Tech and Carilion should be discussed very early on in the process
6. Watch for contact from the IRB with recommendations, changes, or stipulations to the protocol

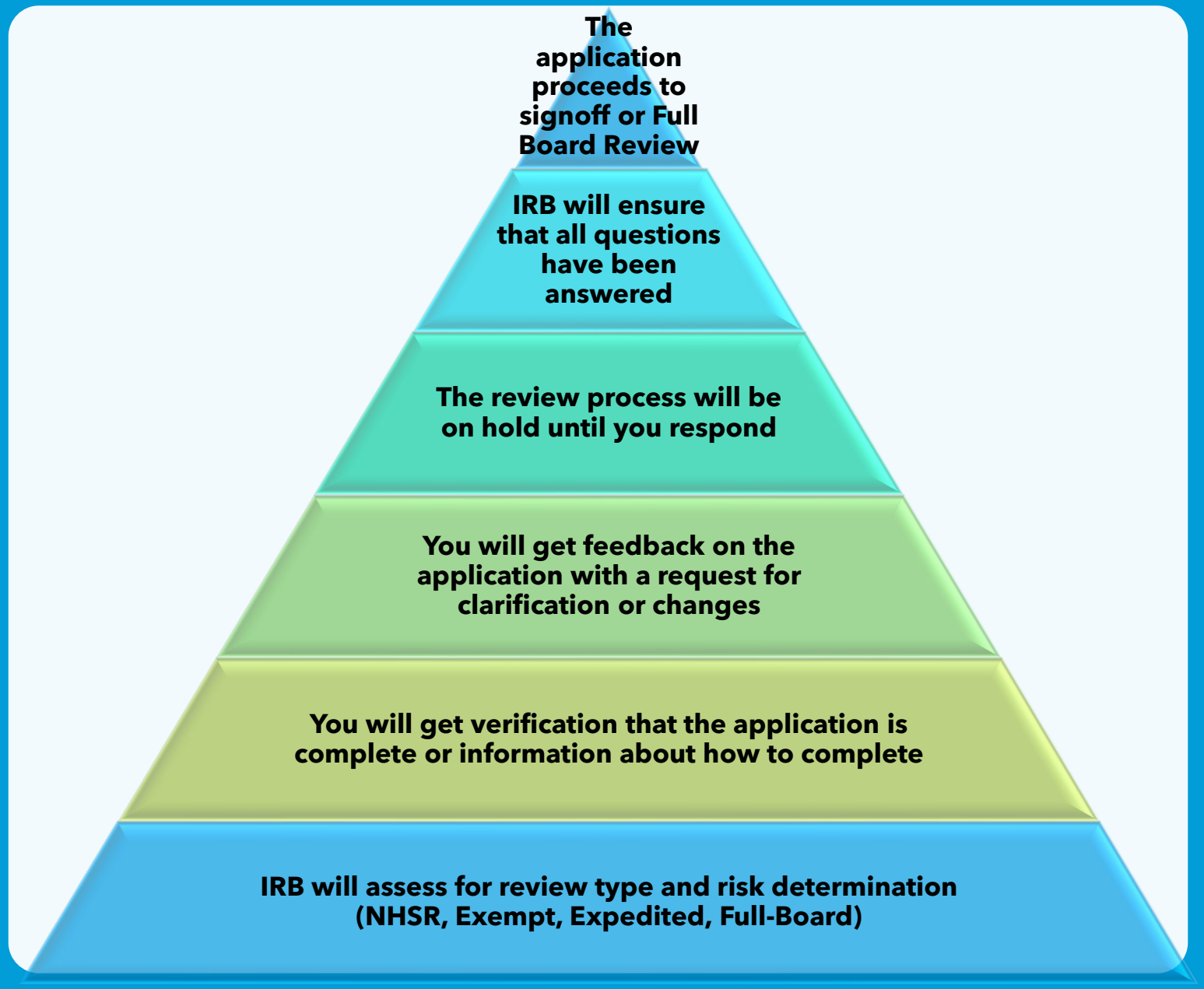


- Research and development is responsible for operational aspects of research such as billing compliance, contracting/budgeting, feasibility analysis, and personnel assignments.
- **Prior to submitting a research proposal to the IRB for consideration investigators must obtain departmental approval via R&D.** This form can be accessed here
- If you require Epic data extraction, biostatistics support, data management (REDcap), Epic research builds, Epic research access, or feasibility volume, contact HART@carilionclinic.org

Institutional Review Board

- Protects the rights and welfare of human research subjects.
- The IRB reviews all research prior to initiation to make a determination of risk, participant accessibility and equity, participant privacy, and participant autonomy.
- The Common Rule and the FDA give IRBs the authority to approve, require modification, or disapprove research activities under their jurisdiction.
- CFR 56.113 (HHS) and 21CFR 56.113 (FDA) authorizes IRBs to suspend or terminate approval or research not being conducted in accordance with IRB requirements or associated with unexpected serious harm.

Pre-review of the submission



Common stumbling blocks for investigators

- **Incomplete CITI training:** Have **ALL** study team members completed the required trainings?
- **Insufficient literature search:** Have you identified a gap or edge in the research? Has this research already been done? Is this a replication study?
- **Intent:** Are you answering a new question, implementing evidence into practice, or improving a process?
- **What is the hypothesis:** How will you know if you have sufficiently addressed the research question?
- **Methodology:** Clearly articulate the differences between standard care and the research plan
- **Data Analysis:** How do you plan to analyze the data and is that the best method for addressing the research question?
- **Risks:** What are they and how will the study team reduce the chances of those things happening?
- **Inattention to detail:** Respond to IRB stipulations, questions, revisions, make sure you have all forms and department signoffs. Don't forget to attach the CV of the PI. Check for consistency, if you change something in one part of the protocol, make sure it is changed at each location where it appears.
- **Failure to respond to feedback**: If the reviewed protocol sits in the queue for too long it will be removed from the system and the team will have to resubmit a new protocol for review.


Questions?
About the presentation?
About your project?

Thank you

Please contact the IRB office if you have questions or need assistance

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