

# Distinguishing Quality Improvement from Research

Graduate Medical Education

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# Agenda

- A. Research definition
- B. Quality Improvement definition
- C. QI Determination Checklist

# Research and Quality Improvement Definitions

- **Research:** A systematic **investigation** including research development, testing and evaluation designed to develop or contribute to **generalizable knowledge**. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.[Source: Code of Federal Regulations 45CFR46.102]
- **Quality improvement (QI):** A systematic patterns of **actions** that constantly optimizing productivity, communication, and value **within an organization** in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product. [Source: The Institute of Medicine]

# QI Determination Checklist

- ☐ **Purpose:** Is the activity being conducted intended to contribute to general knowledge in the area of study (and not for the sole purpose of improving HCA processes)?
- ☐ **Funding:** Is the project funded by an entity (such as a sponsor) that makes clear its mission to conduct research or has a commercial interest in the results of the activity?
- ☐ **Scope:** Does it involve interactions or observations that do not routinely occur in patient care (for patients) or everyday life?
- ☐ **Evidence:** Is the evidence provided from this activity needed to support implementing this type of process change?
- ☐ **Project Staff:** Is the activity conducted by staff that does not provide care or is not responsible for the practice change at HCA?

# QI Determination Checklist

- ☐ **Methods:** Does it assign people or specimens to groups (via randomization, samplings, simple assignment, etc.) for simultaneous comparison?
- ☐ **Sample/Population:** Does it involve a sample of populations (patients/participants) who are not ordinarily seen at HCA?
- ☐ **Recruitment:** Is there a formal process planned for recruitment?
- ☐ **Consent:** Does it involve patient/participants undergoing procedures that normally would not be done for their problem?
- ☐ **Benefits:** Does the patients/participants at HCA not directly potentially benefit from it?
- ☐ **Risks:** Does it involve increased risk or burden to the patients/participants (e.g. additional blood draw, fatigue, embarrassment, or giving personal information)?

# Knowledge Test #1:

## QI or Research?

**“Efficacy and safety of novel deflectable guide catheter in coronary sinus cannulation for cardiac resynchronization therapy – a retrospective comparison study”**

**A.** Quality Improvement

**B.** Research

# Knowledge Test #2:

## QI or Research?

**“Reducing Unnecessary Routine Post-Operative CBCs in the Pediatric Intensive Care Unit at Orange Park Medical Center”**

**A.** Quality Improvement

**B.** Research