

# It's Not Research It's Quality Improvement

Mark J. Fox CHC,CHPC,CHRC  
Privacy and Research Compliance Officer

Thora Johnson, Partner, Orrick

June 2022



1

## Quality Improvement Defined?

- The Agency for Healthcare Quality and Research defines quality improvement as “the framework used to systematically improve the ways care is delivered to patients.”
- The Common Rule does not define quality improvement activities.



2

## Definition of Research

- The Common Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”



3

## Definition of Human Subject

- The Common Rule defines human subjects as “individuals’ about whom an investigator (whether professional or student) conducting research:
  - Obtains 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.”



4

## The Intersection of HIPAA

- Quality improvement is also not defined under HIPAA but falls under the definition of health care operations.
- Human subject is not defined by HIPAA.
- The definition of research under HIPAA is the same as the definition under the Common Rule.



5

## Application of Research Definition to Quality Improvement Activities

- Does the activity meet the definition of Research?
- Are human subjects involved?
- Does an exemption apply?
- Is the activity federally funded or does institutional policy require IRB review?



6

## No Definitive Exemption for QI

- Although a quality improvement exemption was discussed in the latest notice of proposed rulemaking for the Common Rule, the exemption was not included in the final rule.
- You must rely on existing exemptions when evaluating potentially exempt human subject research.



7

## Exemption 4

- “Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:



8

## Exemption 4

- (i) The identifiable private information or identifiable biospecimens are publicly available;



9

## Exemption 4

- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;



10

## Exemption 4

- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or



11

## Exemption 4

- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq."



12

## Is this activity Research?

- An emergency department collects door to EKG time to monitor guideline adherence to the established benchmark of ten minutes from the time the patient enters the emergency department until the EKG is evaluated by a physician.



13

## Is this activity Research?

- The respiratory therapy department monitors patients who experience prolonged ventilation.
- Prolonged ventilation is defined as assisted by a ventilator for greater than twenty- four hours following coronary artery bypass graft surgery.
- The respiratory therapist collects a defined set of process indicators on all prolonged ventilation patients.



14

## Is this activity Research?

- The respiratory therapy department monitors patients who experience prolonged ventilation.
- Prolonged ventilation is defined as assisted by a ventilator for greater than twenty- four hours following coronary artery bypass graft surgery.
- The respiratory therapist completes retrospective chart reviews to determine the variables that led to prolonged ventilation for purposes of determining unknown factors that lead to prolonged ventilation.



15

## Is this activity Research?

- The Medical staff department maintains a physician reappointment profile.
- The reappointment profile collects performance indicators collected by other systems within the hospital.
- The reappointment profile is used to determine eligibility for continued privileges.



16



## Is this activity Research?

- A heart failure clinic is introducing a new decision support tool to aid physicians in determining guideline directed medical care.
- The clinic will evaluate how physicians interact with their patients using the tool
- Physicians will be randomized into a control and intervention group where the intervention group uses the tool.



17

## Navigating the Differences

- The line between research and quality improvement continues to be extremely grey.
- One must carefully evaluate the activity to determine if the activity meets the definition of human subject research.



18



AMERICAN  
COLLEGE *of*  
CARDIOLOGY®

---

*Advancing Heart Care Worldwide*

