Quality Improvement: To IRB, or Not to IRB, That Is the Question

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Objectives

• Describe an IRB, quality improvement activities, and human subject research

• Identify how quality improvement activities and human subject research intersect

• Describe an ethical oversight process for quality improvement activities
What is an IRB?

The IRB is an established administrative body mandated by federal regulations to assure that appropriate steps are taken to protect the rights and welfare of human research subjects recruited to participate in research activities.

The IRB’s function is derived from the DHHS Regulations, Title 45 of the Code of Federal Regulations Part 46 (45 CFR 46) = The Common Rule

(Department of Health and Human Services [DHHS], 2018)
Design Definitions

What is Human Subject Research?
“systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”

What is Quality Improvement?
Systematic, data-driven activities designed to target immediate improvements in health care delivery or outcomes in a local setting

(DHHS, 2018, p.6)  
(Mormer & Stevans, 2019; Stiegler & Tung, 2017)
# Research vs. QI: Key Differences

<table>
<thead>
<tr>
<th></th>
<th>Research</th>
<th>Quality Improvement</th>
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<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Develop or contribute to generalizable knowledge</td>
<td>Improve a process or performance of established standards</td>
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<td><strong>Outcome</strong></td>
<td>Generalizable</td>
<td>Relevant to single site</td>
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<td><strong>Benefits</strong></td>
<td>May or may not benefit subjects</td>
<td>Benefits a process or program and usually benefits patients</td>
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<td><strong>Risks</strong></td>
<td>May put subjects at risk</td>
<td>Low risk to subjects, may have privacy concerns</td>
</tr>
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<td><strong>Methods</strong></td>
<td>Strict protocol</td>
<td>Protocol may need modifications over time</td>
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<tr>
<td><strong>Results</strong></td>
<td>Answer a research question or hypothesis</td>
<td>Improves or creates process/system/program to improve delivery of care, safety, satisfaction</td>
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(Fiscella et al., 2015; Mormer & Stevans, 2019)
DHHS does not define what constitutes “generalizable knowledge.” Lack of clarity requires IRBs to interpret the definition of research and distinguish boundaries of QI and human subject research.

When projects share elements of QI and human subject research, ethical concerns and regulatory oversight become entangled.

(Lee et al., 2016)
Quality Assurance and Quality Improvement Projects

CUHSR Application

- Pilot new application with nursing department for QA/QI projects starting fall 2019 to provide ethical oversight
- Reviewed by CUHSR committee chair
- Determines if project is research or QA/QI
- Human interaction at or below minimal risk
Ensure basic human protections

- Consent process
- Autonomy
- Truthfulness (risks/benefits)
- Protection of privacy
- HIPAA
- Data access and security

Developed by Dr. Andrew Struhbar, PhD, PT
Chair Committee on the Use of Human Subjects in Research
References


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