To IRB, or Not to IRB

Outline
- Institutional Review Boards
- Purpose
- Federal Policy
- QI versus Evidence Based Practice versus Research
- Strategies for Success

Types of MSN Projects
- Systematic review of the literature
- Evidence-based initiative projects
- Quality improvement projects
- E-portfolios
- Population health interventions
- Educational interventions
- Traditional thesis
- Survey data
- Research assistant activities/experiential learning

Purpose of IRB
- Act as the advocate for human subjects involved in research studies
- Protection of research subjects
  - Risk
  - Privacy and confidentiality
  - Informed consent
- Uphold the Policy for the Protection of Human Subjects, Title 45 Part 46 (Department of Health and Human Services, 1981)

Federal Policy (Common Rule)
- Federal policy outlining human research subjects protection
- Divided in 5 subparts:
  - A: basic policy for protection of human research subjects
  - B: additional protections for pregnant women, human fetuses and neonates involved in research
  - C: additional protections pertaining to biomedical and behavioral research involving prisoners as subjects
  - D: additional protections for children involved as subjects in research
  - E: registration of institutional review boards

Federal Policy
- Policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency
- Federalwide Assurance (FWA)
  - Extension of the federal regulations to all research with human subjects, regardless of the source of funding, or lack thereof
Human Subject

- A living individual about whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information

Human Subjects

- Intervention
  - Physical procedures by which data are gathered and/or manipulation of subject or subject’s environment
- Interaction
  - Communication or interpersonal contact between investigator and subject
- Private information
  - Behavior that occurs in a context in which an individual can reasonably expect that no observation or recording would take place
  - Information provided for specific purposes by an individual that the individual would reasonably expect not to be made public
- Intervention or interaction that the individual can reasonably expect not to be made public
- Intervention or interaction that is individually identifiable (i.e., the identity of the subject or ability to identify the subject in the information in which the information is collected) in which no observation or recording would otherwise take place

Research

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Levels of IRB Review

- Exempt
- Expedited
- Full

Exempt

- Certain situations of research involving human subjects are exempt from this policy (unless otherwise required by department or agency heads)
Exempt

- Research conducted in established or commonly accepted educational setting involving normal practices
- Regular and special education instructional strategies
- Use of educational tests, survey procedures, interview procedures or observation of public behavior – UNLESS subjects can be identified by the method of data collection or responses could place subjects at risk for liability or could be damaging to the subject in any way

Exempt

- Research involving the collection or study of existing data, document, records, specimens if the sources are publicly available or if subjects cannot be identified by the information collected
- Research involving the examining, studying and/or evaluating public benefit or service programs
- Taste and food quality evaluation and consumer acceptance studies

Exempt

- List of categories provided by the Office for Human Subjects Protections
  http://www.hhs.gov/ohrp/policy/expedited98.html
- No more than minimal risk to subjects
- Minor changes in previously approved research the approval period (1 year or less)
- Minimal risk
  - the probability and magnitude of harm or discomfort are no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Expedited Review

- Vulnerable populations
- Greater than minimal risk to subjects
  - Use of deception
  - Exposure of behaviors that require mandatory reporting
  - Child abuse
  - International studies
  - FDA jurisdiction

Full Board Review

- IRBs need to comply with the Federal policy
- BUT they have the authority to make requirements above and beyond the policy recommendation
- ALSO...
  - Each IRB writes their own procedures for:
    - Conducting initial review
    - Reporting findings and actions to the PI and institution
    - Determining if projects require more frequent review
    - Verification process for renewals
    - Reporting and approval of amendment to IRB approved research
    - Reporting of unanticipated risks or noncompliance with the policy
    - Suspending or terminating approval

Why all the variation?

- Research (systematic investigation designed to produce generalizable knowledge) involving human subjects (through interaction or intervention obtaining identifiable private information)
  - If not, Common Rule does not apply.

To IRB or Not

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Confusion

- QI versus research
- Research = generalizable knowledge = IRB
- Publication = generalizable knowledge?
- QI is valuable and needed – but don’t tell anybody!

- Most agree that publication ≠ research
- OHRP
  - Publishing QI does not make it research
- HIPAA
  - Not well designed to deal with research issues
  - Different definitions regarding personal information (PI) versus identifiable private information

The QI Conundrum

- Is QI research?
- Do QI projects need to go before the IRB?
- What if QI projects are published/presented?

QI vs. EBP vs. Research

QI

- Data-driven systematic approach by which individuals work together to improve specific internal systems, processes, costs, productivity, and quality outcomes within an organization

EBP

- Problem-solving approach that integrates a systematic search for and critical appraisal of the most relevant evidence (may or may not be research based) to answer a burning clinical, education, or administrative question

Research

- A scientific process that validates and refines existing knowledge and generates new knowledge that directly and indirectly influences nursing practice or health systems
- The scientific process is systematic and methodical
**Strategies for Success**

**Challenges**

- The Ethical Argument
- Multiple Models for Approval Processes: Research or QI
  - Single IRB review at either the University or System Stakeholder
  - Multiple reviews at both University and System Stakeholder
  - Corporate IRB
  - Paying for IRB approval
- Few institutions with Quality Councils that review projects
- Lack of streamlined methods to identify exempt and expedited research
- Publication conundrum
Hastings Center (2007): QI Ethical Issues

- QI & Research warrant different oversight processes
- Organizations should develop models of internal management of QI
- Some (but not most) QI activities are also research activities that may require IRB review
- QI practitioners, researchers & OHRP need to develop practical rules to identify the overlap activities that require IRB review.
- Publication does not distinguish QI from research as QI can produce insights that are useful to others and should be shared through publication and other means

Building Capacity

- Knowledge and Education
  - Reinforce key distinctions between QI and Research
  - Identify and provide resources
- Organizational Assessment and Context
- Stakeholder Engagement
  - Academe: Faculty and Students, IRB board (chair, members)
  - Health Care Systems: Executive Leadership, IRB, Quality Council

Resources

- National Quality Strategy
  - http://www.ahrq.gov/workingforquality/
- The Commonwealth Fund (2010)
  - The Ethical Review of Health Care Quality: Findings from the Field
- National Center for Nursing Quality
  - http://www.nursingworld.org/MainMenuCategories/ThePracticeofProfessionalNursing/PatientSafetyQuality
- Institute for Healthcare Improvement
  - http://www.ihi.org

Strategies to Facilitate IRB Processes

- Develop Quality Improvement Boards/Councils
- Establish Written Policy
- Decision Trees
- Create Checklists

Develop Quality Improvement Boards

- http://www.thehastingscenter.org/Research/Archive.aspx
- http://www.ahrq.gov/workingforquality/
- http://www.ihi.org
- http://ora.research.ucla.edu/OHRPP/Pages/QualityImprovement.aspx
Reasons for IRB review of QI Projects

- Grant Funding
- Use of random sampling techniques: control vs intervention
- Need to assure standard of care is being met for QI work
- Multisite projects
- No process for QI/Failed checklist – Determination of Human Subject Research Form
- Publication issues– still shows up on a few checklists/websites
Recap: QI Key Distinctions

- Systematic, data-guided initiatives to improve clinical care, operations, patient safety, services or program
- QI uses existing knowledge to improve health care outcomes or processes within a local institution or setting
- Ensure that the standard of care is being met - No control groups
- Non random samples
- HIPAA: QI (but not research) is included in health care operations and specifically exempt from the requirements for specific written permission
- Describe effort at protecting data confidentiality and privacy
- Intent to publish or present the data is acceptable