The Institutional Review Board

The Structure and Function of the Institutional Review Board (IRB)

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Objectives

• Discuss the role of the Institutional Review Board (IRB) in human subjects research

• Examine the differences and similarities between QI, EBP and Research

• Compare the different levels of IRB review

• Identify the different IRBs at UCLA and the types of studies they review
The Role of the Institutional Review Board

The IRB is made up of scientists and nonscientists “established to protect the rights and welfare of human research subjects recruited to participate in research activities …”


http://www.hhs.gov/ohrp/archive/irb/irb_chapter1.htm
The Role of the Institutional Review Board

How does the IRB protect human subjects?

The IRB reviews:

• The ratio of risk to benefit for research participants
• The equitable selection of subjects
• Proper consent process
• How well is participant informed of:
  • Risks and benefits
  • Their rights as participants (i.e. participation is voluntary)
• Continue to monitor safety of subjects after they are enrolled

(http://www.yale.edu/hrpp/members/roles.html)
Human Subjects

Who are the human subjects commonly involved in nursing research?
What is Research

• The IRB reviews all research involving human subjects

• Research is a systematic investigation, which includes research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

(DDHS, 2009)
Systematic Investigation

Systematic investigation is a rigorous problem solving process with specific steps aimed at testing a hypothesis.

- Typical steps in the research problem solving process include:
  - Identify problem or question
  - Review Literature
  - Clarify problem - what is purpose?
  - Define terms and concepts
  - Define population (strict inclusion/exclusion criteria)
  - Identify research design (road map)
  - Data collection procedures
  - Collect data
  - Analyze data
Generalizable Knowledge

What is generalizable knowledge?

• Shared Knowledge - the outcomes draw conclusions which are generalizable beyond a single individual or sample to a larger population with similarities

• Generalizability - based on a rigorous systematic approach which includes the design and method of the project
Quality Improvement (QI), Evidence-Based Practice (EBP) and Research?

Definitions of QI, EBP, and Research

- QI - "systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings"

- EBP - "the practice of nursing in which the nurse makes clinical decisions on the basis of the best available current research evidence, his or her own clinical expertise, and the needs and preferences of the patient"

- Research - "systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge"

(Baily, Bottrell, Lynn, Jennings, 2006; Mosby’s dictionary of medicine, nursing & health professions, 2009)
What is the intent?

- **QI** - "analyze data to improve systems related to processes and outcomes (i.e. cost, productivity, quality)."

- **EBP** - "analyze existing data for purposes of ranking evidence that is used to answer a burning clinical, educational, or administrative question that guides practice."

- **Research** - "validate and refine existing data or generate new knowledge to influence nursing practice, systems, and policies."

(Shirey et al., 2011)
Quality Improvement or Research?

Ethical Justification

• QI - Considered an expectation by society for clinical practice to continuously improve
  • Due to the collective enterprise of health care delivery, patients are expected to participate in QI initiatives to help improve the quality of care

• Research - Ethically justified by weighing risks to individual versus societal benefits from the development of new knowledge
  • Publication and dissemination of new knowledge is one way that society benefits from research

(Baily, Bottrell, Lynn, Jennings, 2006)
Quality Improvement or Research?

Indicators that project may benefit from IRB review

- Activities pose greater than minimal risk

- A fixed clinical protocol is used that may not be altered by the caregivers and staff

- Activities objective is **NOT** to improve safety or care that will be sustained over time

- There is randomization of participants

- Collection and analysis of identifiable patient information
## Quality Improvement or Research?

### TABLE 1.

Differentiating Research From a QI Project

<table>
<thead>
<tr>
<th></th>
<th><strong>Quality Improvement Project</strong></th>
<th><strong>Research</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intent</strong></td>
<td>Apply known solutions to a limited problem</td>
<td>Discovery of new information creates generalizable knowledge to be applicable at more than 1 institution</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Less rigorous, theoretical framework not included, speaks to problem at hand</td>
<td>Rigorous, theoretical framework, adheres to accepted designs</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>A single setting and situation</td>
<td>Single or multiple settings</td>
</tr>
<tr>
<td><strong>Timeline</strong></td>
<td>Shorter</td>
<td>Longer</td>
</tr>
<tr>
<td><strong>Benefit</strong></td>
<td>Subjects in the project and institution where the project was conducted</td>
<td>Greater scientific community and clinicians, generalizable to greater populations and institutions</td>
</tr>
<tr>
<td><strong>Outcome measurement</strong></td>
<td>Statistical analysis is optional</td>
<td>Statistically appropriate measures</td>
</tr>
<tr>
<td><strong>Extraneous variables</strong></td>
<td>May acknowledge but not controlled</td>
<td>Variables are controlled and measured</td>
</tr>
<tr>
<td><strong>Generalizable findings</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Plan for dissemination</strong></td>
<td>Internal newsletters, flyers, posters</td>
<td>External publication, podium presentations</td>
</tr>
<tr>
<td><strong>Oversight</strong></td>
<td>Institution where the project is conducted</td>
<td>Institution, IRB, government agencies</td>
</tr>
<tr>
<td><strong>Subject risk</strong></td>
<td>None or minimal</td>
<td>Varies, risk-to-benefit ratio must be considered</td>
</tr>
<tr>
<td><strong>(risk also includes use of protected health information)</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Informed consent</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>IRB</strong></td>
<td>Not always</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviations: IRB, institutional review board; QI, quality improvement.
Different Levels of IRB Review

• Full Board Review
• Expedited Review
• Exempt Review
Full Board Review: (IRB Committee)

Required when greater than minimal risk to subjects

In addition, full board review may be required if:

1) Subjects are randomized

2) Participants are questioned on sensitive topics such as sexual behavior, alcohol use, drug use
Expedited Review: (Chair/ Vice Chair)

Minimal Risk to Subjects (Reviewed by Chair or Vice Chair)

• In addition to being of minimal risk to the subject, the procedures in the research must fall within one of seven Department of Health and Human Services (DHHS) expedited review categories:

1. Clinical studies of drugs and medical devices can be expedited if the drug or device is approved by the FDA and is not used experimentally

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture if certain conditions are met

3. Collection of biological specimens for research purposes by noninvasive means such as hair and nail clippings

(UCLA OHRPP, 2011)
Expedited Review (cont'd)

4. Collection of data through noninvasive procedures routinely used in clinical practice (i.e. ultrasound, echocardiography)

5. Research involving materials that are collected solely for non research purposes such as medical treatment or diagnosis (i.e. data, documents, records, or specimens)

6. Collection of data from voice, video, digital, or image recordings

7. Data on group characteristics or behavior such as perception, communication, cultural beliefs, social behavior

(UCLA OHRPP, 2011)
Exempt Review

Exempt - very little or no risk to subjects
(reviewed by IRB staff)

• Categories of research that qualify for exemption
  1. Normal education practices and settings
  2. Anonymous educational tests, surveys, interviews, or observations
  3. Collection or study of existing data that is available publically or is recorded in a manner that would prevent identification of subjects either directly or indirectly (address, account number etc…)

(UCLA OHRPP, 2011)
The Different IRBs at UCLA

1) **North General Campus** - reviews research from the College of Letters & Science and the Professional Schools.

2) **South General Campus** - reviews social-behavioral research in areas such as public health, quality of care, quality of life, health prevention and health education research.

3) **Medical IRB 1** - reviews general and internal medicine, infectious diseases, and ophthalmologic research.

4) **Medical IRB 2** - reviews oncology and hematology research.

5) **Medical IRB 3** - reviews neuroscience, neurology, psychiatric, drug abuse, dental research, and related behavioral science research.

(UCLA OHRPP, 2011)
Summary

• The IRB protects human subjects involved in research through various mechanisms

• Differentiating QI, EBP and Research based on intent, generalizability, and risk to participants

• The three level of IRB review based on the level of risk to subjects

• UCLA has five different IRBs divided between the social behavioral IRB and the various medical IRBs
References

References (cont'd)


Questions or Comments?

THE IRB WAS TAKING TOO LONG SO I DID THE SURVEY WITHOUT APPROVAL.

WRONG! YOU CAN'T BYPASS THE IRB!