

## Demystifying the IRB Process

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## Session Objectives

1. Attendees will describe issues to consider in determining if a project should be considered a research activity
2. Attendees will describe the process of IRB review and responsibilities post-approval

## Regulations

- ▶ Federal – Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46; “Common Rule” (\$ = regulations)
- ▶ State of Washington
- ▶ Institutional Review Board

## State of Washington

- ▶ Revised Code of Washington (RCW) covers records used for research and confidentiality of medical, psychiatric, and educational records  
Uniform Health Care Information Access & Disclosure

## Institutional Review Boards

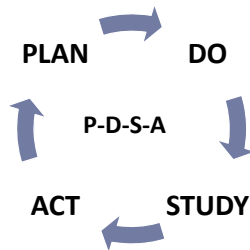
- ▶ UW Human Subjects Division
  - ▶ UW policies
  - ▶ Cooperative agreements with other agencies (e.g. GHC, SMC, VMCC)
  - ▶ <http://www.washington.edu/research/hsd/index.php>
  - ▶ 206-543-0098
- ▶ Other Institutional Examples
  - ▶ Swedish Medical Center IRB (206) 215-2536
  - ▶ Seattle Children's Hospital IRB  
<http://www.seattlechildrens.org/research/support-services/institutional-review-board/>
  - ▶ VA Puget Sound Health Care System

## What is Research?

**Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge**  
**CFR 46.102(d)**

### QI is not “research lite”

Must ensure through systematic monitoring that only positive outcomes occur



### How does quality improvement differ?

- ▶ HIPPA: “health care operations means ...conducting quality assessment and improvement activities... **provided that the obtaining of generalizable knowledge is not the primary purpose of any studies**”
- ▶ “Systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings” (Lynn 2007)
- ▶ To improve health care quality and outcomes through local innovations and adaptation in the processes and systems of care

### Ways research projects may differ from QI:

- Testing of issues that **go beyond current knowledge based on science and experience**, such as new treatments
- **Random allocation** of patients into different intervention groups to enhance confidence in differences that might be obscured by nonrandom selection
- **Deliberately delayed or ineffective feedback of data** from monitoring the implementation of changes, especially if this is done to avoid biasing the interpretation of data
- Involvement in key project roles of researchers who have **no ongoing commitment to improving the local care situation**, even if others in the team do have professional commitments to it
- **Funding, sponsorship or substantial participation by parties outside the clinical setting** or organization in which the activity takes place

### Quality Improvement May Require IRB Approval

- ▶ Quality improvement is strictly intra-mural
- ▶ Quality improvement compares standard care practices
- ▶ IRB approval typically needed if findings will be disseminated
- ▶ Quality improvement typically doesn't require consent
- ▶ Gray areas when investigator is nursing staff or nursing manager
- ▶ Rule of thumb: Is there an intervention or an interaction with a living person that would not be occurring in some other fashion but for this activity?
  - ▶ If the answer is YES, requires IRB review.

Always get another opinion.  
Don't ASSUME.

### If It's Research...Rights of Subjects

- ▶ Treated professionally with dignity, respect
- ▶ How they were identified as potential subject
- ▶ Voluntary participation, withdrawal
- ▶ Confidentiality/anonymity
- ▶ Questions answered
- ▶ Informed consent
  - ▶ Assent

### Potential Issues to consider when planning to publish QI

- There are no specific guidelines on the level of oversight authors are required to demonstrate
- Many organizations require IRB review – particularly if there are identifiable data (even reported as %)
- If there is intent at the beginning of a **minimal risk** QI project to publish – IRB approval should be sought (note – the IRB may decide that review is not necessary)
- Post-QI - IRB approval – confidentiality of patient data (even if reporting as percentages) – IRB approval may ensure patient safety was upheld and that HIPPA rules were adequately reflected

Morris PE, Dracup K. Editorial: Quality improvement or research? The ethics of hospital project oversight. *Am J Crit Care*, 2007, 16(5), 424-426.

### Case Study Discussions



"These machines sure are life savers, doc. The noise annoyed me right out of my coma."

### Levels of Review

- ▶ Certificate of Exemption
- ▶ Minimal Risk Review "Expedited" (Subcommittee)
- ▶ Full IRB Committee review

### Exempt Studies

- ▶ "Exempt" does not mean there isn't review. Application and permission are needed.
- ▶ 6 categories: Educational, survey, interview, observation, existing data EXCEPT if subject identifiable AND responses could place at risk AND information is sensitive
- ▶ What doesn't qualify
  - ▶ Research with protected vulnerable populations
  - ▶ FDA regulated
  - ▶ More than minimal risk
  - ▶ Use of PHI in WA state without subject authorization or consent

### Exempt Study Examples

- ▶ Live interview (no recording) about diabetes teaching format preferences
- ▶ Evaluation of food preferences among patients with renal failure
- ▶ Anonymously returned survey about teamwork and collaboration and how impacts patient care
- ▶ Implementation and evaluation of educational program to help nurses better identify delirium

### Minimal Risk

- ▶ Minimal risk = probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than **those ordinarily encountered in daily life** or during the performance of routine physical or psychological examinations or tests
- ▶ No vulnerable groups
- ▶ Nothing sensitive\*
- ▶ No video recordings or pictures\*

### Examples of Minimal Risk Studies

- ▶ Audio-recorded interviews with nurses to determine how define and manage fever across settings
- ▶ Focus groups with health care providers to determine facilitators and barriers to provider order entry system implementation
- ▶ Factors influencing unstageable pressure ulcer healing

### HIPAA: Health Insurance Portability and Accountability Act

- ▶ Must obtain written authorization from patient to use or disclose protected health information.
- ▶ Patients must be informed of their rights regarding health care information.
- ▶ Normal access to medical information as part of your job **does not** provide permission for research usage.

### Use of Health Information Without Explicit Consent (aka Waiver of Authorization)

- ▶ No more than minimal risk from disclosure
- ▶ Waiver does not adversely affect privacy rights and welfare
- ▶ Research could not practicably be conducted without the waiver
- ▶ Research could not practicably be conducted without access to the health information
- ▶ Privacy risks consistent with benefit.
- ▶ Plan to protect identifiers from disclosure
- ▶ Plan to destroy identifiers at earliest opportunity
- ▶ Assurance that protected health information would not be reused

So You Need to Submit a Human Subjects Application....What Now?

### Human Subjects Training and COI

- ▶ Ethical Conduct of Research with Human Subjects; Protection of Human Subjects in Research Training
  - ▶ In Person
  - ▶ Online Courses (CITI, NIH)
  - ▶ Special requirements
    - ▶ DoD
    - ▶ Refresher
- ▶ Conflict of Interest Review

### Putting together the Application

- ▶ Make sure you start with the correct form type
  - ▶ Correct version if paper-based
- ▶ Include a copy of everything that is a contact with subject:
  - ▶ Recruitment materials (Information sheets, letters to subjects, scripts for phone or in-person contact, flyers, advertisements)
  - ▶ Consent/assent
  - ▶ Instruments
- ▶ Letters of cooperation
- ▶ Proposal or study procedure manual, if applicable.

### Do's and Don'ts of Recruitment

- ▶ Avoid use of "cold calls", "cold contacts"
- ▶ Use an intermediary for live contact
- ▶ Use a script
- ▶ Subject self-nomination - provide adequate information describing study for self-screening
- ▶ Don't reveal an unknown condition or diagnosis in the recruitment materials or consent
  - ▶ "We're interested in talking with women who are dying of breast cancer"
- ▶ Don't use project titles, return addresses, etc. that threaten confidentiality.
  - ▶ "Addicted Nurses Study"
  - ▶ "When Nurses Don't Care"

### Assure Identity for Phone Calls

- ▶ Don't launch into a phone recruitment call without first assuring the identity of the person; don't break confidentiality.
- "Hi, this is Lottie from the UW Study of Persons Who Practice S & M calling for Troy."

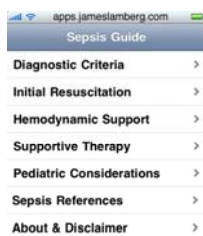
### Do's and Don'ts for Screening

- ▶ Do get permission before screening potential subjects  
"If it's OK with you, I'd like to ask a few questions to make sure the study is right for you. This will take about 5 minutes. I'll be asking about ..... You can refuse to answer any questions."
- ▶ Do state what you will do with screening information if subject declines or is screened out?
- ▶ More than basic information requires oral consent (Do you consume more than 5 alcoholic drinks each day?)

### Do's and Don'ts of Consent

- ▶ Do follow the template for the agency
- ▶ Do ensure the reading level is appropriate for the audience
- ▶ Do explain time commitment, what is involved
- ▶ Do give examples of any sensitive content you may be asking about
- ▶ Don't forget to include actual date when any recordings will be destroyed; or data will be delinked from codes.

### Case Exemplars



### What Happens at the IRB?

- ▶ Before IRB: Departmental Review
- ▶ At the IRB
  - ▶ Logging in application and committee assignment
  - ▶ Initial administrative review
  - ▶ Review and Determination
    - ▶ Can be iterative process



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Exempt Application: Investigator Responsibilities post-approval

- ▶ Exempt status is granted for 5 years, is non-renewable.
- ▶ Use Consent and Recruitment materials stamped "approved"
- ▶ Ensure enroll only the number of subjects approved
- ▶ Know policy regarding allowable modifications to exempt if any.
  - ▶ E.g. UW: "minor" are allowable, and don't require resubmission; "substantive" requires new application.

Minimal Risk and Full Review: Investigator Responsibilities

- ▶ Use Consent and Recruitment materials stamped "approved"
- ▶ Ensure enroll only the number of subjects approved
- ▶ Any revisions must be approved first, by modification
- ▶ Report any adverse events, unanticipated problems, protocol violations and deviations to the IRB
- ▶ Submit status report annually for renewal
- ▶ Close out study when complete