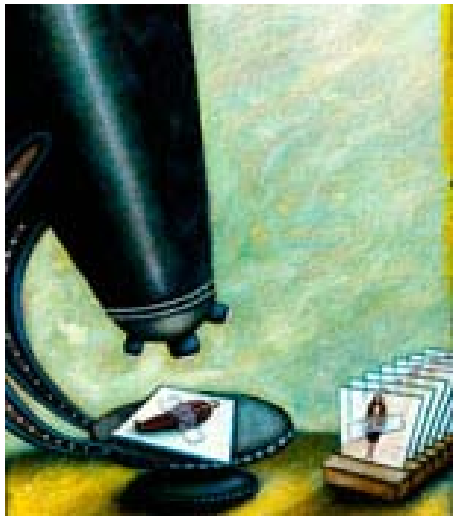
Ethics and Clinical Inquiry

Ethics and Clinical Enquiry



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Objectives

- ✓ Describe the role of the Institutional Review Board (IRB)
- ✓ Discuss the difference in human subjects' review and institutional oversight between a QI project and a research study
- ✓ Identify the required elements of informed consent and how the informed consent protects human subjects in research

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Which best describes your role in research?

- Care for patients on clinical trials or supervise staff who care for patients on clinical trials
- Educate staff about clinical trials
- Coordinate protocols and care for patients on clinical trials
- Other

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What is your practice setting?

- Hospital/Academic Medical Center
- Corporate/Industry
- Private Practice
- Other

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How we got where we are today . . . . .

Historical Perspectives

What can we learn from our past?

How can we have impact?

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The Good, the Bad, and the Ugly

Walter Reed
Yellow Fever
Cuba 1900

Nuremburg Code, WWII
1946

Drug Amendment Act
1962

Declaration of Helsinki
1964

The Belmont Report
1979

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Belmont Report – Informed Consent & Institutional Review Boards

- Respect for Persons → Informed Consent
- Beneficence → Risk-Benefit Assessment
- Justice → Selection of Subjects

Childress (2005)

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Institutional Review Board (IRB)
Roles & Responsibility

How research ethics live and breathe through the IRBs

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Institutional Review Board

- Overview of Responsibilities
  - Formally charged with reviewing and approving biomedical and behavioral research
  - Conducts initial reviews of the research for approval
  - Conducts reviews of modifications to prior approved research
  - Conducts continuing reviews of approved research
  - May suspend or terminate approved research that is not being conducted in accordance with IRB requirements

(45 CFR Part 46.108)

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Institutional Review Board

- Committee Members
  - How does committee member representation promote adequate review?
- Protocol Review
  - Hypothesis to be tested – scientifically valid, properly designed protocol
  - Rationale for number of subjects
  - Subject selection criteria – selection is equitable
  - Justification for use of vulnerable subjects
  - Is there unnecessary exposure to risk?
  - Consent procedure

Human Subject Review – QI or Research?

What are the differences in the review of a QI project or a research project?

What does this mean for you?

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Human Subject Review – QI or Research?

- Evidence Based Practice (EBP)
  - Integrating the best evidence from studies and patient care data combined with patient preference to change the delivery of healthcare
- Quality Improvement (QI)
  - Designed to improve processes or practices
- Research
  - Findings are generalizable, the purpose is to generate new knowledge

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What type of review is required?

Full Board Review

- Goes to the IRB – review by committee members, approval may occur at that time
- Board may ask for experts to attend if additional information is needed
- Most Boards have a variety of experts as members

Expedited Review

- Doesn't mean "quick" review, must meet all determinations required for approval
- Doesn't go to the full Board, the IRB Chair or Co-Chair may review

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What type of review is required?

Exempt Review

- Little or no risk to human subjects
  - Educational, behavioral, social science
  - Anonymous educational tests, surveys, interviews, or observations
  - Collection or study of existing data, documents, records where the information recorded cannot identify the subjects

When in doubt . . . . .

- Get help in determining whether or not you need IRB approval
- Request for determination from an IRB
- Useful resources to help determine

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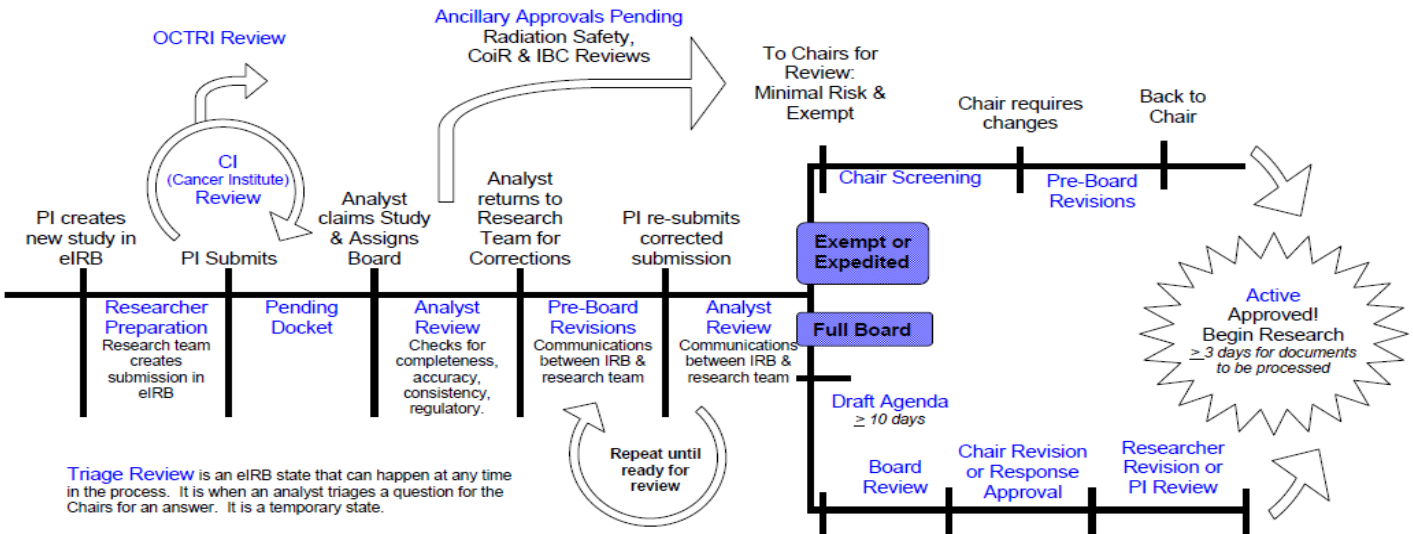
Research/QI Differentiation Tool (Kring 2008)

Question	Research	Quality Improvement
Which phrase best describes the purpose of your project?	To generate new knowledge	To improve internal processes, practices, costs or productivity
Who will most likely benefit from your project?	Future patients (or other targeted population) mostly will benefit	Most of the subjects that participate in the study, as well as future patients will benefit
Could your project be done with participants outside your setting?	Yes, having participants outside the setting would add strength to the project	No, having participants outside the setting would not makes sense
Will your findings change practice/	Will change practice slowly over time, often after multiple studies validate the results	Will practice change in my setting immediately

IRB Review – piece of cake!

General Overview of: OHSU IRB Initial Review Process



Triage Review is an eIRB state that can happen at any time in the process. It is when an analyst triages a question for the Chairs for an answer. It is a temporary state.

Documents Pending is an eIRB state indicating that the IRB is waiting for documents.

BLUE TEXT = eIRB State
Use the link below to see descriptions of all **states**.
http://www.ohsu.edu/xd/research/about/integrity/irb/upload/IW-Guide-to-Study-Status-v1.pdf

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Informed Consent

"Informed consent is widely recognized as the cornerstone of ethical clinical research"
(Steinbrueck, 2010)

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Informed Consent for Research vs. Surgical or Procedural consent

Procedural Consent

- Information based on known procedures, common understanding
- Information given that a reasonable person would wish to know in order to make a decision
- Known risks vs. benefits, and alternatives

Research consent

- A common understanding does not exist – seeking new knowledge
- Since volunteering they may wish to know considerably more about the risks – since procedure is neither necessary for their care nor fully understood

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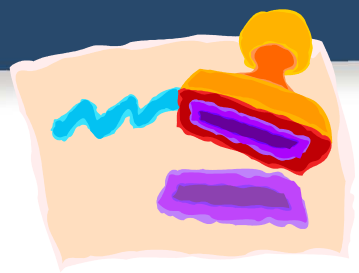
Informed Consent



- Voluntary choice of an individual to participate in research
  - based on an accurate understanding of it's purposes, procedures, risk, benefits, alternatives and any other factors that may affect a person's decision to participate.
- Provides initial and ongoing patient education about the clinical trial
- Informed consent is a continuing and ongoing process, no rubber stamping
- Consent is obtained prior to all research activities or procedures

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Informed Consent

- Research consents are specific to the protocol, to be written at an eighth grade reading level.
  - Basic elements that are required by HHS
  - May include HIPPA consent if appropriate
  - May include specific consent for genetic research
  - How do we know if our subjects understand the consent?

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The Consent Document Must Include:

- Statement that study involves research.
- Purpose of research and expected duration.
- Description of procedures, identification of procedures which are experimental.
- Reasonably foreseeable risks.
- Description of alternative procedures and the statement that research participation is voluntary.
- Benefits to subject , if any.
- Statement that describes how or if personal health information will be protected and that the FDA may review the records.
- Explanation whether compensation and medical tx available if injury occurs
- Contact for questions about research, rights, and research-related injury

(45 CRF, part 46.116)

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Additional Elements of the Consent Form:

- Information about risk to a fetus
- Circumstances when the investigator may terminate the subjects participation without the subjects consent.
- Any additional costs to the subject
- Consequences of subject's decision to withdraw from a study and procedures for early termination.
- Statement about any new finding about the research that may be shared with the participant that may affect their desire to participate.
- The number of subjects participating in this study.

(45 CRF, part 46.116)

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Different Paths to the Same Destination

(Steinbrueck, 2010)

- A thin elderly gentleman
- A young mother
- An anatomy professor with his teenage son

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Informed Consent - Issues

- The study team must obtain written informed consent *prior* to *any study related procedure*
- Allow subjects enough time and opportunity to decide whether to participate and ask questions
- The subject must re-sign the consent if the study and consent are modified in a way that affects their participation while they are active in the study
- Therapeutic Misconception
- Compensation, incentive vs. coercion

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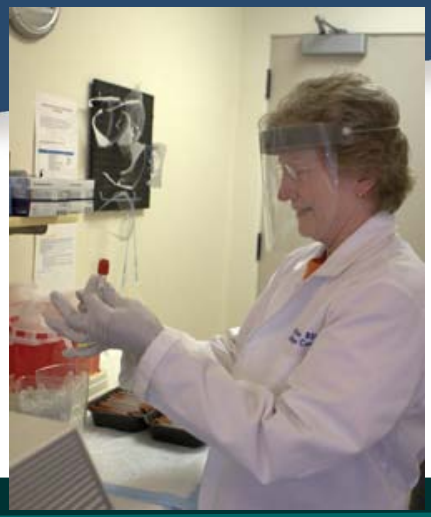
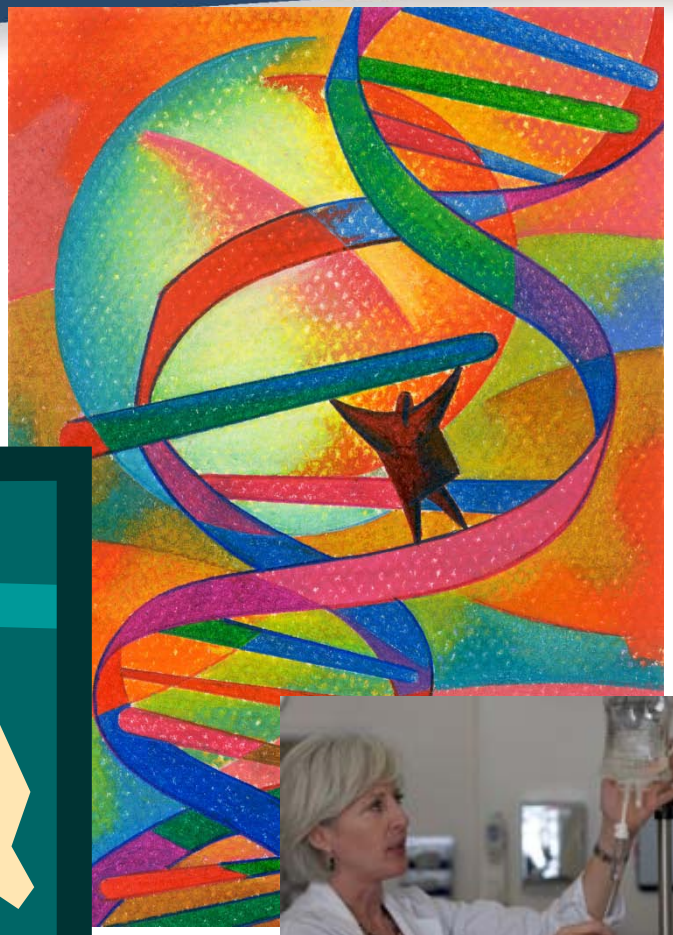
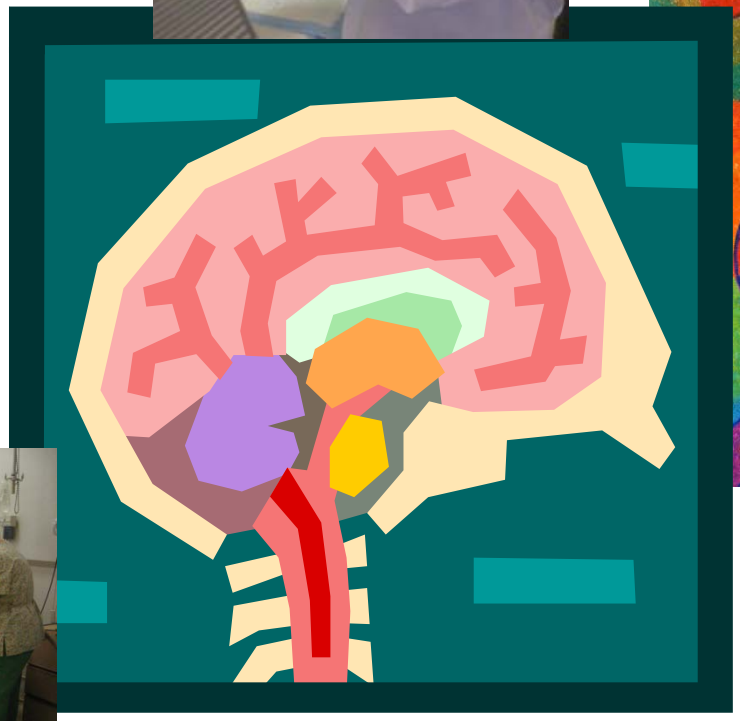
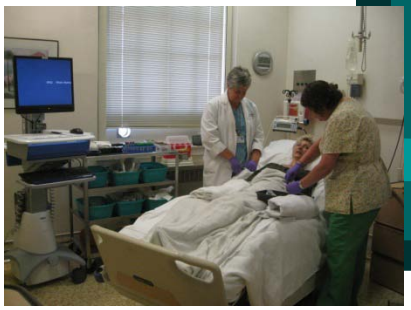
Let’s wrap up - Ethics and your role









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Evolving ethical considerations

- Innovative therapies test existing regulations
- Human stem cell research
- Genetics

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Our roles as nurses in the protection of human subjects

- Continuing our education regarding clinical research
- Role in the ongoing informed consent process
  - You are a key participant in this process
- As investigators, nurse scientists
- As RN's taking care of patients enrolled in trials
  - Code of Ethics for Nurses
- ANA: Nurses role in ethics and human rights position statement

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