

This work is licensed under a [Creative Commons Attribution-NonCommercial-ShareAlike License](https://creativecommons.org/licenses/by-nc-sa/4.0/). Your use of this material constitutes acceptance of that license and the conditions of use of materials on this site.



Copyright 2006, The Johns Hopkins University and Holly Taylor. All rights reserved. Use of these materials permitted only in accordance with license rights granted. Materials provided "AS IS"; no representations or warranties provided. User assumes all responsibility for use, and all liability related thereto, and must independently review all materials for accuracy and efficacy. May contain materials owned by others. User is responsible for obtaining permissions for use from third parties as needed.



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Assessment of Risks and Benefits

Holly Taylor, MPH, PhD
Johns Hopkins University

Framework for Ethical Analysis

- ◆ Beneficence
 - Moral requirements
 - Do no harm
 - Maximize benefits/minimize harms
 - Practical applications
 - Study design
 - Assessment of risks and benefits

Topics to be Covered

- ◆ Principle of beneficence
- ◆ Study design
 - What is research?
- ◆ Assessment of risks and benefits
 - Risks
 - Benefits
 - Balancing



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section A

Principle of Beneficence

Definition/Theory

- ◆ Central to health professions
- ◆ Different views of beneficence
 - Frankena
 - Beauchamp and Childress

Definition/Theory

- ◆ Beauchamp and Childress formulation

Definition/Theory

- ◆ Principle of utility
 - Beneficence at core
 - Maximizing principle
- ◆ Ethic of care
 - Relationships

Principle of Beneficence

- ◆ Applied to research ethics
 - Study design



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section B

What is Research?

What is Research?

- ◆ “Research—a systematic investigation including research development, testing, and evaluation designed to contribute to generalizable knowledge.”

What is Research?

- ◆ “Human subject—a living individual about whom an investigator conducting research obtains . . .
 - (1) data through intervention or interaction with the individual, or
 - (2) identifiable private information.”

What is Research?

- ◆ Distinguishing research from practice

Research vs. Practice

1. What is the goal of the investigator?
 - Local or generalizable
2. Is there intent to publish the results?
 - Journal requirements

Research vs. Practice

3. How did the investigator come to know/interact with the patient/client?
 - Stranger?
4. Will usual care be changed or manipulated?

Research vs. Practice

5. How novel is the care or intervention?
 - Does it deviate from standard practice?
6. Will there be systematic data collection?

Research vs. Quality Assurance

◆ Criteria 1

- “Initiative should be regulated by research regulations if the majority of patients are not expected to benefit directly from the knowledge to be gained.”

Research vs. Quality Assurance

◆ Criteria 2

- “If the majority of patients are likely to benefit from knowledge to be gained, initiative should be reviewed and regulated as research if participants would be subjected to additional risks or burdens beyond the usual clinical practice to make its results generalizable.”

Research vs. Quality Assurance

Initiative	Criteria 1	Criteria 2	Research?
ICU Chart Review	No Benefit	N/A	Yes
Satisfaction Survey	Benefit	No Burden	No
CCU Catheter Comparison	Benefit	Burden	Yes

Source: Casarett, Karlawish, Sugarman. JAMA 2000 283 (17): 2275-80)

Research?

- ◆ If activity is determined to be research:
 - Federal guidelines apply
 - Must be reviewed by an IRB



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section C

Assessment of Risks and Benefits

IRB Responsibility

- ◆ Risks to subjects are minimized
- ◆ Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably be expected to result

Risk Concepts

- ◆ Risk—probability and magnitude of some future occurrence of harm
- ◆ Harm—injury, setback to interests
- ◆ Risk assessment

Risk Concepts

RISK ASSESSMENT

Magnitude

Major

Minor

Probability
High
Low

1	2
3	4

Risk Concepts

- ◆ Uncertainty—lack of predictability
- ◆ Risk perception—perceptions based on personal experience/attitudes/psychology
- ◆ Relative risk

Risk Concepts

- ◆ Minimal risk—“Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of itself than those encountered during daily life or during the performance of routine physical and psychological examinations or tests.”

Risk Concepts

Minimal Risk

- ◆ Implications for . . .
 - Consent
 - Enrollment of vulnerable populations

Risk Concepts

Minimal Risk

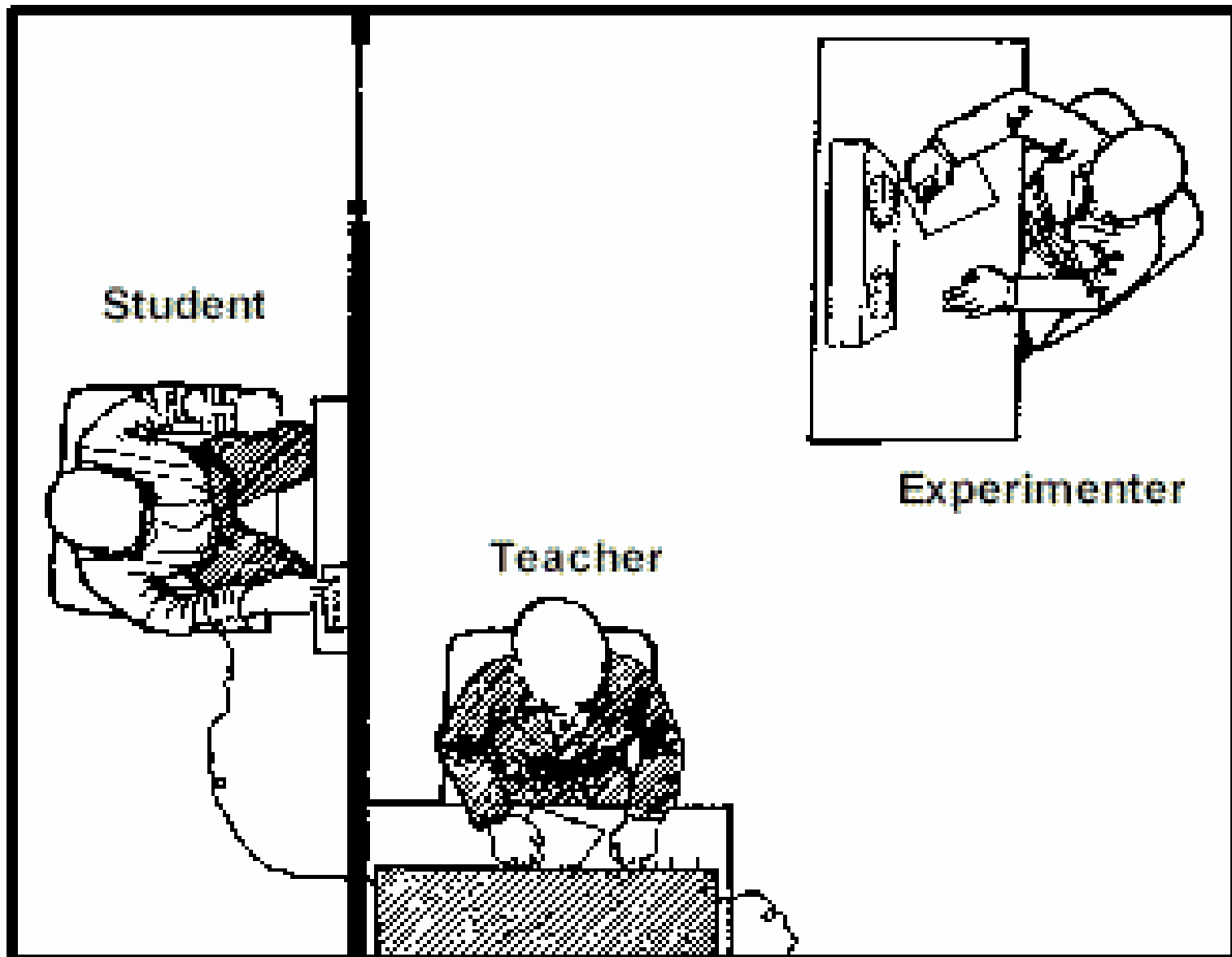
- ◆ Therapeutic vs. non-therapeutic

Individual Risk

- ◆ Physical
 - Bodily injury
 - Healthy volunteer vs. patient
 - Early testing
 - Delay
 - Related to RCT

Individual Risk

- ◆ Psychological
 - Stress, discomfort
 - Disclosure of medical information
 - Deception



*Used with permission of New Life Community Church of Stafford:
<http://www.new-life.net/milgram.htm>*

Milgram Experiment

- ◆ “I observed a mature and initially poised businessman enter the laboratory smiling and confident. Within 20 minutes he was reduced to a twitching, stuttering wreck, who was rapidly approaching a point of nervous collapse.”

Individual Risk

- ◆ Inconvenience
- ◆ Wrongs to personhood

Individual Risk

Individual Risk—Social Risks

- ◆ Risks to reputation/stigma
 - Breaches of confidentiality
- ◆ Economic

Community Risk

- ◆ Readings
- ◆ “Community”
 - Ethnic/tribal
 - Immigrants
 - Marginalized group
 - Minority group
 - Extended family
 - Religious group

Community Risk

Community Risk—Social Risks

- ◆ Stigma
- ◆ Economic
- ◆ Exploitation



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section D

Benefits

Benefits

- ◆ Concept
 - Something of value related to health/welfare

Possible Benefits

Individual Benefit

- ◆ Physical
 - Medical
 - “Inclusion” Benefit
 - Lantos
 - Peppercorn, et al.

Individual Benefit

- ◆ Psychological
 - Hope
 - Altruism
- ◆ Kinship
- ◆ Social

Individual Benefit

- ◆ Economic
 - Access to medical care
 - Monetary

Possible Benefits

Financial Compensation

- ◆ Concerns

Possible Benefits

Financial Compensation

- ◆ Models
 - Market
 - Wage-payment
 - Reimbursement

Benefits

- ◆ Community Benefit
 - Medical
 - Material

Balancing Risks and Benefits

- ◆ Goals
 - Minimize risk
 - Maximize benefit



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section E

*Case Example: Research in the
Emergency Room*

Research in ER

- ◆ **Will patients with severe head trauma benefit from anti-oxidant therapy?**
- ◆ Investigators wish to study whether the drug polyethylene glycol-superoxide dismutase (PEG-SOD) will limit the degree of brain injury suffered by head trauma patients
- ◆ To date, data from animal models and limited human trials demonstrate a possible benefit

Research in ER

- ◆ The study design will randomize patients to receive either one of two possible doses of PEG-SOD or placebo
- ◆ Given the circumstances of the patients' injuries, they are typically unable to give informed consent

Research in ER

- ◆ Furthermore, if the patients are to benefit from PEG-SOD, the investigators must administer the drug expeditiously, within two hours of presentation to hospital

Research in ER

- ◆ Consider risks and benefits
 - Individual
 - Group

Research in ER

- ◆ Consider alternative methods of consent
 - Surrogate
 - Deferred
 - Waiver

Research in ER

- ◆ Consider alternative methods of consent
 - 1996 waiver
 - Life threatening situation
 - Available treatment unproven
 - Valid scientific data necessary

Research in ER

- ◆ Consider alternative methods of consent
 - 1996 waiver
 - Obtaining consent not feasible
 - Participation holds out potential for direct benefit
 - Research could not be carried out without waiver

Research in ER

- ◆ Consider alternative methods of consent
 - 1996 waiver
 - Investigator will try and reach decision-maker
 - IRB approved
 - Protections
 - Subject notified ASAP