Respect for Persons and Informed Consent

Holly Taylor MPH, PhD
Johns Hopkins University
Framework for Ethical Analysis

- Respect for persons
  - Moral requirements
    - Acknowledge autonomy
    - Protect those with diminished autonomy
  - Practical applications
    - Informed consent
    - Informational privacy/confidentiality
Topics to Be Covered

- Principle of autonomy
- Introduction to informed consent
  - Legal, medical, and research history
- Basics of informed consent
  - Theoretical and practical
- Barriers to informed consent
  - Personal and procedural
Section A

Principle of Autonomy
Principle of Autonomy

- Autonomy
  - Self-rule
  - Free from controlling influence
Principle of Autonomy

- Conditions for autonomy
  - Agency
  - Liberty
- Autonomous action
- Respect for autonomy
Principle of Autonomy

- Autonomous action
  - Intentional
  - With understanding
  - Without controlling influence
Principle of Autonomy

- Respect for autonomy
  - Right to hold views, make choices, take actions
  - Obligations to build capacity

Continued
Principle of Autonomy

- Philosophical roots
  - Kant
  - Mill

Kant

John Stuart Mill
Principle of Autonomy

- Obligations
  - Negative
  - Positive
Introduction to Informed Consent

 Threads of influence
 - Legal precedent
 - Medical practice
 - Research standards
Landmark Cases

- Legal precedent
  - Non-consensual/offensive touching
  - Consent has to be “informed”
  - Professional negligence regarding disclosure of information
  - Reasonable patient standard
Landmark Cases

- Non-consensual/offensive touching
  - Mohr v. Williams (1905)
    - Ear surgery
  - Scholendorf v. Society of New York Hospitals (1914)
    - Examination only

Continued
Non-consensual/offensive touching

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without his patient’s consent commits and assault, for which he is liable.”

Source: Justice Cardoza, decision regarding Scholendorf v. Society of New York Hospitals (1914)
Landmark Cases

- Consent has to be “informed”
  - Salgo v. Leland Stanford Jr. University Board of Trustees (1957)
    - Back surgery

Continued 16
Landmark Cases

- Professional negligence regarding disclosure of information
  - Natanson v. Kline (1960)
    - Radiation treatment
Landmark Cases

- Physicians obligated “to disclose and explain to the patient, in language as simple as necessary to the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body.”

Source: Decision regarding Natanson v. Kline (1960)
Landmark Cases

- Reasonable patient standard
  - Canterbury v. Spence (1972)
    - Back surgery, fall
  - Truman v. Thomas (1980)
    - Pap smear

Continued
Landmark Cases

- Recent cases in the research setting
    - Gene therapy
    - Melanoma
Physician-Patient Relationship

- Hippocratic oath
- Withholding of information justified

Hippocrates
Physician-Patient Relationship

- Truth-telling
  - Medical Ethics (1803)
  - AMA Code (1847)
Physician-Patient Relationship

- Modern medicine
  - Empirical evidence

Louis Pasteur
Physician-Patient Relationship

- Advances in research setting
  - National Commission
History of Research Ethics

- Yellow fever
  - First documented case of consent for research

- Nuremberg
  - Voluntary consent of human subject is absolutely essential
History of Research Ethics

- Declaration of Helsinki
  - Non-therapeutic v. therapeutic research
- Research in international setting
  - Alternative modes of decision making
Section B

Basics of Informed Consent
Basics of Informed Consent

- Theoretical (Beauchamp & Childress)
  - Threshold
    - Competence
    - Voluntariness
  - Informational
    - Disclosure
    - Plan
    - Understanding
Theoretical (Beauchamp & Childress)

- Consent
  - Decision
  - Authorization
Practical Application to Research

- Threshold
  1. Competence
  2. Voluntariness
- Informational
  3. Disclosure
  4. Understanding
- Consent
  5. Decision
Threshold Element

- Competence
  - Ability to perform task
  - Criteria may vary by task
  - Intermittent
Threshold Element

- Competence?
  - Careful review
  - Surrogate decision maker
  - Assent
Threshold Element

- Competence
  - Sliding scale
Threshold Element

- Voluntariness
  - Persuasion
  - Coercion
  - Manipulation
Threshold Element

- Voluntariness
  - Persuasion
    - Influence based on facts
Threshold Element

• Voluntariness
  – Coercion
    • Credible threat (Willowbrook)
    • Undue inducement (person with HIV)
Threshold Element

- Voluntariness
  - Manipulation
    - Informational
    - Of options
Information Elements

- Disclosure
  - Reasonable patient standard
  - Subjective standard
As Required by the Common Rule

- Description of study
- Reasonable risks and discomforts
- Reasonable benefits to individual or to others
- Alternatives to participation

Source: 45 CFR § 46.116
As Required by the Common Rule

- Confidentiality protections
- Compensation for injuries, if any
- Point(s) of contact
- Participation is voluntary

Source: 45 CFR § 46.116
As Required by the Common Rule

- Unforeseeable risk
- Termination of enrollment
- Additional costs
- Consequences of withdrawal
- Notification of new findings
- Number to be included

Source: 45 CFR § 46.116
Other Suggestions for Disclosure

- Invitation to participate
- Explanation as to why approached
- Recommendation to consult others
- Source of funding
- Potential conflicts of interest
Information Element

- Understanding
  - Substantial v. complete
Consent Element

- Decision
- Autonomous authorization
  - Informed
    - Understanding
    - Absence of control
    - Intentionality
  - Legally effective

Continued
Consent Element

“Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator obtained the legally effective informed consent of the subject or the subject’s legally authorized representative …

Source: 45 CFR § 46.116

Continued
...“An investigator shall seek consent only under circumstances that provide the prospective subject of the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion and undue influence. The information that is given to the prospective subject or the representative shall be in language understandable to the subject or the representative.”

*Source: 45 CFR § 46.116*
Basics of Informed Consent

- Obtaining informed consent is a process—
  not an event
Section C

Barriers to Informed Consent
Barriers to Informed Consent

- Patient-centered
  - Age
  - Education
  - Illness
Patient-Centered

- Illness
  - Physician-patient relationship
    - Dependency
    - Passive role in decision making
Patient-Centered

- Illness
  - Enrollment in research for treatment
    - Blurring of line
    - Last hope
Patient-Centered

-Illness
  - Overestimation of medical benefit
    - False belief?
Patient-Centered

• Illness
  – Summary
  • Reassurance
  • Honest accounting of benefit
  • Patient hope
Patient-Centered

- Other
  - Review of form
  - Legal formality
Process-Centered

- Timing of discussion
  - Opportunity to digest information
Process-Centered

- Time allocated to decision making and questions about protocol
  - Engage subject in conversation
Process-Centered

- Readability of consent form
  - Assess literacy
  - Simplify text
  - Supplement form
  - Potential subject review
Process-Centered

- Content of consent form
  - Ask explicit questions

Continued
Process-Centered

- The process selects my best treatment (14%)
- Each patient has exactly the same chance of receiving the drug, or not receiving the drug, as any other participating patient (68%)
- One treatment is given one time, another is given another time (0%)
- The doctor decides which treatment is the right one for me (18%)
Summary

- Potential subjects deserve respect
- Obligations of investigators
  - Information sharing
  - Assessment of understanding
- Consent is a **process**