Meeting the Ethical Challenges of Obtaining Informed Consent

Jeremy Sugarman, MD, MPH, MA
Berman Institute of Bioethics
Johns Hopkins University
Baltimore, Maryland USA
Disclosures

• I serve on Merck KGaA’s Bioethics Advisory Panel and Stem Cell Research Oversight Committee; Quintiles Ethics Advisory Panel; and have consulted with Novartis on bioethical issues.

• I am on the faculty at Johns Hopkins University.
Objectives

1. Discuss the evolution of informed consent practices for clinical practice and research.
2. Explain the ethical underpinnings for consent.
3. Describe approaches to meet the ethical goals of consent in practice.
Overview

• Evolution of informed consent
• Two senses of informed consent
• Process of informed consent
The Evolution of Consent

For Medical Treatment
• Patient litigation
• Laws and regulations

For Research
• Early consent practices
• Infamous research
Medical Treatment and The Right to Liberty

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

• Recognized as important for research with volunteers

• Not necessarily free and voluntary
Yellow Fever Experiments

• Conducted in Cuba following the Spanish-American War
• Written consent in English and Spanish
• Consent was witnessed
Yellow Fever Experiments

Ethical Difficulties

• Excessive compensation

• No ability to withdraw
Infamous Research

- Tuskegee Syphilis Study
- Nazi experiments
- Deception research
- Jewish Chronic Disease Hospital
- Human radiation experiments
Human Radiation Experiments

• Thousands of experiments conducted during the Cold War
• Most conducted without informed consent
• Researchers sought to minimize risks
• Consistent with the norms at the time, physicians decided about enrolling their patients in research
Overview

• Evolution of informed consent
• Two senses of informed consent
  – Autonomous authorization
  – Social rules of consent
• Process of consent
Two Senses of Informed Consent

• Autonomous authorization
• Social rules of consent
Autonomous Authorization

• Ethical principle of respect for persons
• Right to liberty
Two Senses of Informed Consent

• Autonomous authorization
• Social rules of consent
Social Rules

• Consent of minors
• Special forms
• Witnesses
Overview

• Evolution of informed consent
• Two senses of informed consent
• Process of informed consent: Beyond consent forms
Informed Consent Process

Threshold

- Decision-making capacity
Informed Consent Process

Threshold
- Decision-making capacity
- Voluntariness
Informed Consent Process

Information
- Disclosure

Threshold
- Decision-making capacity
- Voluntariness
Informed Consent Process

Information
- Disclosure
- Understanding

Threshold
- Decision-making capacity
- Voluntariness
Informed Consent Process

**Information**
- Disclosure
- Understanding

**Threshold**
- Decision-making capacity
- Voluntariness

**Authorization**
- Indication of agreement
- Consent forms:
  - Consistent with disclosure
  - Readable
Concluding Comment

*Respect for persons* is manifest in the expectations of a meaningful informed consent process.