The Informed Consent Process

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Overview

- Evolution of informed consent
- Two senses of informed consent
- Process of informed consent
- Relevant regulations
- Challenges
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

Schloendorff v. Society of New York Hospitals, 1914
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 as 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
Human Radiation Experiments

- 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
- Relevant regulations
- Challenges
Autonomous Authorization

- Ethical principle of respect for persons
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
- Relevant regulations
- Challenges
Informed Consent Process

Threshold
- Decision-making capacity
Informed Consent Process

- For research with populations likely to lack adequate decision-making capacity:
  - Work with IRB
  - Formal evaluation of capacity
Informed Consent Process

Threshold
- Decision-making capacity
- Voluntariness
Informed Consent Process

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

**Information**
- Disclosure
- Understanding
Clarify Terms

- “Medical experiments” vs. “medical studies”
- “Clinical investigation” vs. “clinical trial”
Informed Consent Process

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

**Information**
- Disclosure
- Understanding

**Authorization**
- Indication of agreement
- Consent forms:
  - Consistent with disclosure
  - Readable
Consent vs. Assent

- Consent = informed, voluntary decision to participate, culminating from a process of disclosure and understanding
- Assent = expression of willingness
Overview

- Evolution of informed consent
- Two senses of informed consent
- Process of informed consent
- Relevant regulations: 45 CFR 46, Parts 116 & 117
- Challenges
Relevant Regulations

45 CFR 46

Part .116 - Requirements for consent
- Required elements to be disclosed
- Conditions for waiver of elements of consent

Part .117 - Documentation
- Requirements for documentation of consent
- Conditions for waiver of documentation of consent
Required Elements of Consent

- Nature of the proposed intervention:
  - purpose of the research
  - duration of participation
  - procedures to be followed
  - procedures which are experimental
Required Elements of Consent

- Nature of the proposed intervention:
  - purpose of the research
  - duration of participation
  - procedures to be followed
  - procedures which are experimental

- Potential risks and benefits

- Alternative procedures

- Protection of confidentiality
Required Elements of Consent

■ For research involving greater than minimal risk: compensation and treatment, if any, for possible injury
■ Contact information
■ Assurance that participation is voluntary
Additional Elements Where Appropriate

- Unforeseeable risks
- Termination of participation
- Costs to subjects
Additional Elements Where Appropriate

- Unforeseeable risks
- Termination of participation
- Costs to subjects
- Consequences of withdrawal
- New findings
- Number of subjects
Conditions for Waiver of Required Elements

1. Minimal risk;
2. Would not adversely affect the rights and welfare of the subjects;
3. Could not be practically carried out without the waiver; AND
4. Subjects provided with additional information after participation.
Requirements for Documentation

- **Written consent**
  - embodies required elements
  - signed by the subject or the subject’s legally authorized representative

- **Short form**
  - states the required elements have been presented orally
  - witness needed
  - IRB approves summary
  - signed by witness
  - copy of short form and summary to subject
Conditions for Waiver of Required Documentation

1. The only record linking the subject to research would be the consent document, and the principal risk relates to breach of confidentiality;
Conditions for Waiver of Required Documentation

1. The only record linking the subject to research would be the consent document, and the principal risk relates to breach of confidentiality; Or,

2. No more than minimal risk and involves no procedures for which consent is required outside of the research context.
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Challenges to the Process of Informed Consent

- Recommendations, persuasion vs. coercion
Challenges to the Process of Informed Consent

- Recommendations, persuasion vs. coercion
- Research with minors
Summary

- *Respect for persons* is manifest in the expectations of informed consent process.
- US regulations emphasize the need for *written informed consent* and the elements to be included in the consent process.
- When aimed at enhancing protection of subjects, *modifications* to the informed consent process can be authorized by the IRB.