Informed Consent and Nurses

Lyndi Lahl, R.N., M.S.
Division of Education and Development
Office for Human Research Protections
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Outline

- Regulatory requirements: informed consent
- Process for obtaining informed consent
- Nurse as subject advocate

Federal Regulations and Policy

45 CFR 46 - Basic DHHS Policy for Protection of Human Research Subjects - Subpart A


- HHS regulations based on federal funding of research
Additional Regulations for Protection of Human Subjects

- Subpart B - Pregnant Women, Human Fetuses, and Neonates
- Subpart C - Prisoners
- Subpart D - Children

Informed Consent

- Ethical Principle: Respect for persons
- Definition Informed Consent

Basic Elements

- Research
  - Purpose
  - Duration
  - Procedures
- Alternatives
- Confidentiality
- Compensation for Injury
- Whom to Contact
- Right to Refuse or Withdraw
- Benefits
**Additional Elements**

Unforeseeable Risks  | Termination of Participation
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Number of Subjects  | Informing of New Findings
Additional Costs  | Consequence of Withdrawal

**The Consent Process**

- Full disclosure
- Adequate comprehension
- Subject's voluntary choice to participate
- Sufficient opportunity
- Minimize coercion or undue influence

**Obtaining Consent**

- Adults
  - legally competent
  - incompetent
- Minors
  - affirmative agreement
  - parental permission
  - state laws- age of majority
Consent Language
- Understandable language
  - written consent form
  - "short" form
  - Exculpatory language

Administrative Considerations: Informed Consent
- Who obtains
- Required signatures
- Use of correct document

Special Considerations: Informed Consent
- Reconsenting subjects
- Third party issues
- Tiered consent
Subject Advocate Duties

- Facilitate legally effective informed consent
- Ensure research conducted as per IRB approved protocol

Challenges for Subject Advocate

- Knowledge
- Conflict with others

Overcoming Challenges

- Familiar with:
  - pertinent regulations
  - institutional policies and procedures
  - sponsor requirements
  - protocol
  - Effective communication