Demonstrating Respect & Enhancing Trust: Mastering the Informed Consent Process

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Objectives

Name and describe key components of informed consent

List steps in the informed consent process

Define therapeutic misconception

Understand the *process* of consent

Learn to discuss research participation with potential participants demonstrating respect, honesty and transparency with the goal of enhancing trust and understanding

Understand that while the *content* of consent changes, the *process* is similar for each protocol

Informed consent

What it IS NOT:

A legal release

A document to limit institutional liabilities

A formality for research

A one-time event

What it IS:

An interactive process between participant and researcher

A process done at every point in the study

Acknowledgment of a person's autonomy

Why obtain consent for research?

Requirements
- IRB Policies
- Office of Human Research Protection (45 CFR part 46)
- FDA Requirements (21 CFR 50.20)
- Belmont Report (1979)
- Declaration of Helsinki (rev. 2008)
- AMA and other professional codes of ethics

Ethical rationale
- Demonstrates respect for person
- Establishes trust between researcher and participant
- Demonstrates honesty and transparency

Consent matters to research participants

What influences participants?

Risks – physical and financial

Benefits
- Hope for therapeutic effect
- Access to health services, information, learning

Incentives

Referral source

Helping others (altruism)

Contributing to science
- Less important for most research participants

Trust/distrust of health care system and research establishment

Research

≠

Medical Practice

Key components of informed consent

Basic components

1. Study involves research, purpose and description of procedures
2. Risks
3. Benefits
4. Alternatives to research
5. Participation voluntary, participants may withdraw at any time
6. Extent of confidentiality
7. Medical treatments available in the event of injury
8. Contact information – participant receives copy of consent form

Additional components

1. Risks are unforeseeable
2. Additional costs
3. Consequences of withdrawal
4. Termination of participation by the investigator
5. Approximate number of participants in study
6. Significant new findings will be provided

Institution-specific requirements

For more than minimal risk research, you MUST include this statement VERBATIM (unless Sponsor's contract differs):

"If you believe that the research procedures have resulted in an injury to you, immediately contact Dr. [the PI] or the Study Coordinator (see first page). Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation."

Key steps in consent process

1. Disclosing information
   - This is research
   - Purpose of research
   - What will happen to participant
   - Benefits, risks and burden
   - Confidentiality
   - Conflicts of interest
   - Other institutional requirements

Key steps in consent process (continued)

2. Assessing decision-making capacity
   - Determining participant's ability to reason and comprehend
3. Explaining free choice
   - Voluntariness
     - Compensation to participants
     - Freedom to withdraw
   - Agreement

Beginning the consent process

Introduction - why are you here?

- *"I'd like to talk to you about possibly volunteering for a research study"*

Explain the purpose of the research

- *"We are trying to find out if a new drug for your condition could work"*

Emphasize experimental, investigational

- *"We are trying to learn more about your condition. We hope that by completing this study that we will be able to better understand..."*

What will happen to participant?

Randomization, controls, placebo, blinding *if applicable*

- *"If you volunteer, you will have a 50-50 chance of getting the experimental treatment and a 50-50 chance of getting a "sugar pill" or placebo.*
- *Nobody, including your doctors, will know if you have the experimental or the placebo pill."*

Expectations

- *"You will be asked to come in every month for extra blood tests. We do more blood tests to see what effect the study might be having on you."*

Benefits, risks and burden

Direct benefits:

Something of health-related, psychosocial, or other value to a participant (not monetary incentive)

- *"You may learn more about your diabetes"*

Avoid talking about the possible benefit of the "new treatment"

- Therapeutic misconception
- *"There may be no benefit to you at all"*

Benefits, risks, and burden (continued)

Risks:

"Some of the possible side effects from this study are..."

- Drug side effects
- Anxiety from survey questions

Include uncertainty of risks/harms

- *"Because it is new, we don't really know all the possible good or bad things the drug could do"*

Include risk of a breach of confidentiality of health information

- *"Although we try to protect your private information, there is a chance your privacy could be violated"*

Benefits, risks, and burden (continued)

Burden:

Inconvenience

- *"The questionnaire takes about 20 minutes to complete"*

Pain (e.g., muscle biopsy, blood draw)

Cost (transportation, time off work)

- *"You will have to come more often for visits and tests"*

Techniques to assess comprehension

Assess understanding: *"talk back" method*

Avoid yes/no questions ("Do you understand?")

Ask participant to paraphrase

- *"I want to make sure that I have not bombarded you. So, I want to ask you a few questions that will help me make sure you understand what we have been discussing."*
- *"Can you tell me what this research is about and what we are asking of you? "*
- *"Can you tell me, in your own words, about the risks associated with this study?"*

ABCs of informed consent

When: Before any research procedures
Where: Environment
How: Avoid technical language

Be sensitive to culture, literacy, and timing of disease diagnosis

Prevent misunderstanding
- Open-ended questions
- Talk-back method

Process

Start with an interview
- Choose a private quiet location
- Explain research in simple terms
  - Emphasize participation is voluntary
  - Describe study activities
  - Disclose risks and benefits
  - Describe alternatives

Process

Explain difference between research and clinical treatment
- How randomization occurs
- Clinical equipoise
  - Researcher does not know which intervention is best
  - Participant may or may not benefit
- Alternative options
- Participant may withdraw at any time

Process

Use consent document as a script for discussion, include required elements
- Confidentiality
- Study Termination
- Who to contact in event of injury
- Withdrawal and consequences of withdrawal

Encourage the participant to ask questions

Check the participant's understanding

Ethical Concerns

No coercion or undue influence

Therapeutic misconception

Determining decisional capacity

Language and cultural issues

Conflict of interest

Adjust consent process

High risk research (e.g., gene therapy, sham surgery)

Vulnerable participants

- Serious condition without standard treatment options
- Impaired decision-making capacity
- Students
- Prisoners
- Children
- Pregnant women

Summary

Consent is a *process* - not a document

Obtaining valid consent (or refusal) to participate in research requires knowledge *and* skills

- Knowledge of regulations and elements of consent
- Communication skills, listening and "translating"

Adjust for culture, literacy, and timing of disease diagnosis