Beyond the Facts: Appreciation as a Goal in Informed Consent

Emphasis on Process of Consent

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Basis for Consent
Basic Ethical Principles of The Belmont Report

1. Respect for Persons
   1. Individuals must be treated as autonomous agents.
   2. Persons with diminished autonomy are entitled to protection.

2. Beneficence
   1. Do not harm.
   2. Maximize benefits/ minimize harm

3. Justice
   1. Fairness in opportunity
   2. Fairness in distribution of risk and benefit
Challenge of Informed Consent

• Research is a systematic investigation through a standard, consistent protocol.

  The informed consent document describes the universal participation in any protocol.

• But each participant is an individual with individual reactions, experience, learning styles, families, and cultures.

  The process of informed consent individualizes the fit between the participant and the protocol.
What is necessary to make Informed Consent

**Informed and Consenting**

- **Investigator/ Study Staff**
  - Full disclosure of the purpose, risks/benefits, procedures, alternatives, repair and compensation
  - Understandable presentation
  - Individualized clarifications
  - Anticipatory exploration

- **Capacity of the person**
  - Cognitive and language ability
  - Attention/learning availability
  - Judgment
  - Access to alternatives
  - Ability to question
  - Ability to refuse (coercion)
  - Resources to participate

**Process**
From Information to Process

• Fostering Appreciation
  – Sponsor consent document = manual for all
  – Appreciation = individual interface with the protocol
    • Individual impact of demand
    • Individual implication of the risks
• Applying anticipatory exploration/guidance
  – Projection of circumstances across time (visual time lines)
  – Identification of potential problems, concerns
  – Plans to support participation
Promoting Appreciation

- Visual aids – e.g., personalized time line- translated protocol calendar into real time
- Guided consideration of risks: Which of these is most concerning?
- Guided considerations expectations: What is most important to you and your family?
- What are the barriers to participation; misgivings about research?
- Set up ongoing communication.
- Review phases against personal master calendar.
- Review risk and adverse event experience.
- Review experience beyond the outcome measures
- Review other sources of information.
Research in Life Timeline

September
  Screening – over 2 days for total 8 hr

October
  Start drug or placebo
  Q week blood draws
  2 MRIs - 14 days apart

November
  Continue drug/placebo

December
  Cognitive testing at
  12 Weeks of drug
  2 8-hour test days
  2 MRIs 14 days apart
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Okay but not last 2 weeks
School starts 9/14
Okay if early appts Yes-at-7.
Okay - Halloween Dance Sleepover

Yikes - exams + Winter break 12/11 -
College Visit Not going to work!
**Doctor:** “I need to tell you that a heart stent for stable coronary artery disease won’t prevent a heart attack, won’t prolong your life, won’t treat the inflammation that causes heart attacks, and often leads to more heart operations including bypass grafts that require sawing open your chest and sewing veins from your leg to your coronary arteries. ... Or you could adopt a whole food diet of vegetables, fruit, whole grains, nuts and seeds.”

**Patient:** “Golly, doc. Whole foods? Isn’t that kinda drastic?”
Process of Informing about Risks

– The medical term
– The experience – what are the early signs
– What action to take
– In what time frame
– Resources
Critical Questions

• What concerns you most about this project?
• How will this affect your life?
• What will be the most difficult part for you? How will you manage?
• Considering the visits, appointments, what will be the most difficult?
• What would be the most helpful for you?
Effect of Emphasizing Process /Appreciation

• Consent process takes longer
  – More than one session
  – More training for consenting
• Risk of more refusals
• Potential advantages
  – Fewer deviations
  – Fewer withdrawals
  – Greater senses of participation
Sentinel Points

• Process of informed consent individualizes the research experience
• Anticipating the demands and the consequences supports informed consent
• Process of informed consent encourages participation