Decision-Making Capacity and Consent

Achieving Excellence in DoD HRPP:
Taking an Active Role

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Learner Objectives

1. Describe four factors that affect or alter individual’s decision-making capacity

2. List three types of subjects whose decision-making capacity may be affected or altered, and methods to address this

3. Describe two strategies for assessing potential research subjects’ decision-making capacity
Ethical Framework

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
April 18, 1979
The Belmont Report

Ethical Principle Related to Informed Consent Process and Decision-Making Capacity

- **Respect for Persons**
  - Treat individual with autonomy
  - Protect individuals with diminished autonomy
    - possible ‘over protection’?

Informed consent process
- to degree possible, give opportunity to choose what happens - or not - to them
Regulatory Framework

...legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

32 CFR 219.116
Elements of informed consent

Informed consent and decision making

- Information
- Comprehension
- Voluntariness - Choice

The Belmont Report 1979
Elements of informed consent and factors in decision making

Information

Factors
- Who presents
- What is presented
- When presented
- Where presented
- How presented
Elements of informed consent and factors in decision making

Comprehension

Factors
- Reading, seeing, or hearing ability
- Language - level & appropriateness
- Maturity
- Cognitive ability

Informed consent and decision making
Elements of informed consent and factors in decision making

Voluntariness - Choice

Factors
- Who is involved
- When decision made
- Social-cultural context

Informed consent and decision making
What is Decision-Making Capacity?

Is...

an individual’s ability to make a decision about whether to participate in research

Is not...

“competence” of an individual in the legal sense as determined by court
Decision-Making Capacity

Factors affecting decision making capacity

- Situational
- Organizational structure & relationships
- Social & cultural context
- Potential Decisional impairments
Decision Making

Factors affecting decision making

**Situational**
- Pregnant women*
- Pre-surgery or procedure
- Emergency medical situation
- Abusive or violent situations
- Prisoners*

* DoDD 3216.02 implements the additional requirements of 45 CFR 46 Subparts B and C
Decision Making

Organizational structure & Relationships
- Student-teacher
- Employee-employer
- Military chain of command*
- Mentor-mentee

* DoDD 3216.02 describes additional requirements
Decision Making

Factors affecting decision making

Social & cultural context
- Children
- Parent-child relationship
- Family structure
- Native American tribes
- International populations

* DoDD 3216.02 implements the additional requirements of 45 CFR 46 Subpart D
Factors affecting decision making

Potential Decision-making Impairments
- Durable – Down syndrome
- Progressive diseases or disorders
- Mental illness or disorders
- Neurological disorders
  - PTSD, TBI
Other factors to consider...

**State Laws**

- Legally Authorized Representative (LAR)
  - Not defined in 32 CFR 219
  - Many states have not defined LAR (rare exceptions)

- Legal Age of Majority
  - Generally 18 years of age: also 19 & 21
What would you decide?

“Teens Having a Blast”
You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.
What would you decide?

“Butter or Bullets?”

You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.
What would you decide?

“Senior Shots”

You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.
What would you decide?

“Baby on Board”
You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.
Assessing Decision-Making Capacity
Early thoughts....

“On occasion, it may be suitable to give some oral or written tests of comprehension.”

The Belmont Report 1979
Assessing Decision-Making Capacity

- Independent assessment
- UCSD Brief Assessment of Capacity to Consent (UBACC)
- MacArthur Competence Assessment Tool (MacCAT-CR)
- Affirming no dissent
- Methods: oral & written
- Other methods
- 2-step consent
- Post-consent written test
- Standardized cognitive tests
Affirming no dissent

- Least comprehensive approach
- Usually a leading yes-no question
  - Do you have any questions?
- Presumes understanding
Assessing Decision-Making Capacity

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- Other methods
- Standardized cognitive tests
2-step consent

• Adds time for potential subject:
  - to consider information
  - talk with family, friends, others

• Sets stage for “conversation” between potential subject and researcher
Assessing Decision-Making Capacity

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- 2-step consent
- Post-consent written test
- Standardized cognitive tests
- Other methods
Post-consent written test

• Be sure test questions actually tests understanding and not reading skills

• Can be intimidating - especially if no “conversation” included

• Criteria for “passing” - or failing

• “Over coaching”
Assessing Decision-Making Capacity

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- Methods: oral & written
- Other methods
Standardized cognitive tests

- **Mini—Mental State Examination (MMSE), BECK Depression scales, etc.**

- Tests for specific populations or individuals, or purposes

- Supplement screening or assessment
Assessing Decision-Making Capacity

Methods
-oral & written

Affirming no dissent

Independent assessment
- UCSD Brief Assessment of Capacity to Consent (UBACC)
- MacArthur Competence Assessment Tool (MacCAT-CR)

2-step consent
- Post-consent written test
- Standardized cognitive tests

Other methods
Other methods

- Researcher-initiated alternatives
- Novel approaches
Assessing Decision-Making Capacity

- Independent assessment
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- MacArthur Competence Assessment Tool (MacCAT-CR)

Methods:
- Oral & written
- Affirming no dissent

Other methods:
- 2-step consent
- Post-consent written test
- Standardized cognitive tests
MacArthur Competence Assessment Tool (MacCAT-CR)

- Standardized and validated
- Can be tailored to research protocol
- Takes about 15 – 20 minutes to administer
- Requires trained personnel
- Good general choice

(Appelbaum and Grisso, 1995 & 2001)
Assessing Decision-Making Capacity

- Independent assessment
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Other methods
UCSD Brief Assessment of Capacity to Consent (UBACC)

- 10 item scale
- About 5 minutes to administer
- Easy to use and score
- Identify subjects who may have questionable decision-making capacity
- Can be tailored to research protocol
The 10 questions assess:

- understanding of protocol procedures
  - What is the purpose of the research...
  - Describe some of the risks or discomforts..
UCSD Brief Assessment of Capacity to Consent (UBACC)

The 10 questions assess:

• appreciation of significance of the risks
  - Do you have to be in this study if you do not want to?
  - Is it possible that being in this study will not have any benefit to you?
  - Who will pay for medical care if you are injured....?
UCSD Brief Assessment of Capacity to Consent (UBACC)

The 10 questions assess:

• reasoning

  - What makes you want to consider participating ....?
Assessing Decision-Making Capacity

- Independent assessment
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- MacArthur Competence Assessment Tool (MacCAT-CR)
- Method oral & written
  - Affirming no dissent
  - Other methods
  - 2-step consent
  - Post-consent written test
  - Standardized cognitive tests

Other methods
Independent assessment

Some one outside the research team

- Research personnel
- Clinical personnel
- IRB Chair or member
- Research Subject Advocate
Focus on:

the *process*, not the *document*

*understanding*, not the *signature*
Think outside the box.. to enhance decision-making capacity

“Adult Assent” (AA)

“A picture is worth a 1,000 words…”

“Do the Timeline” (children become adults)

“Informed Consent Check up”

“Guardian Angels”
Closing thought....
April 2001

Ellen Roche - 24 year old technician/healthy volunteer working at a JHU research center - volunteers for research project to study induced airway relaxation by inhalation of hexamethonium, a ganglionic blocker

One day after inhalation, Ellen develops cough and then respiratory distress. She is the third subject to do so.
Ellen died June 2, 2001
Would the following have changed Ellen’s decision to volunteer?....?

Information, Understanding, and Choice

- Hexamethonium is a chemical, not a “medication” and not FDA-approved
- Known toxic effects on humans not found on ‘google’ search (literature review)
- Problems with prior subjects not reported or disclosed to new subjects
- Possible undue influence
For more information

Jeste, et al., *Arch Gen Psychiatry.* 2007:64(8):996-974


Secretary Advisory Committee on Human Research Protections - Subcommittee of Inclusion of Individual with Impaired Decision-making in Research (SIIIDR) Report - October 29, 2007
In appreciation

.....to volunteer human research subjects who give of themselves.

... to IRB members who work diligently without recognition other than self-satisfaction...

...to researchers who respect and protect subjects who volunteer for research...

... to my colleagues for sharing their knowledge, insight, and friendship:
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