

Capacity to Consent to Research Participation

OHRP Research Community Forum

July 28, 2015

University Park, Illinois

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IT'S HOW MEDICINE SHOULD BE®

Personal Inventory

- Take a few minutes to consider what your thoughts / opinions are about capacity to consent to research
 - Write your thoughts / opinions down and put away until the end of the presentation
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Disclosure

- There are no financial conflicts of interest to disclose

Disclosure

- Advance Practice board certified psychiatric nurse who has conducted research of serious mental illness throughout career
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Anecdote

- Advance Practice board certified psychiatric nurse who has conducted research of serious mental illness throughout career
- A psychiatrist who prescribes the newest treatments, states that research should not be conducted with psychiatric patients
- Many illnesses have no curative treatment and supportive treatments have limited efficacy

Objectives

- Discuss capacity to consent
 - Briefly review the concept of informed consent in human subject research
 - Identify concepts and controversies of capacity to consent to research
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Competence

- Competence is a legal determination of a person's ability to understand and react
- It is determined by a judge

(Black's Law Dictionary, 2nd Edition)

Capacity

- Capacity is a functional determination
- Capacity is an important indicator of an individual's ability to exercise autonomous choice

(Janicak, 1980)

Cognitive

- The mental action or process of acquiring knowledge and understanding

Informed Consent

- Nuremberg code – IFC
 - Belmont Report - Respect for Persons - requires considerations of autonomy and the protection of those with diminished autonomy
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Informed Consent

- 45 CFR 46.116 & 21 CFR 50.20

Informed Consent process provided in language understandable to the subject or representative

NBAC

- National Bioethics Advisory Commission
 - 1996 to 2001
 - Commissioned by President Clinton
- Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity
 - Report, March 1999
- “identification of the population of persons with mental disabilities at risk of decisional incapacity”

Diagnosis

- “population of persons” = Diagnosis
- **Diagnosis does not determine capacity to consent and thus is not a determinant of diminished capacity**

Controversies

- All research that includes populations that are at risk should assume lack of capacity to consent
- There should not be any research with these populations
- Should LARs be allowed to consent, if so when, who?
- Should a special committee be created to review this type of research

Anecdote

Story of Malcolm

Ass+U+Me

- Prospective adult participants with impairments to functional abilities (capacity) are presumed to be capable of providing consent to enroll and participate in a research study unless there is a substantial evidence that they are not capable
- Presence of a condition that leads to diminished functional abilities should not be assumed to indicate lack of capacity to consent

Stigma

- Labeling particular groups at risk for lacking decisional capacity or as incapable of making a voluntary choice reinforces stigma or stereotypes, when in fact members of such groups are frequently diverse and function as well as so-called healthy volunteers...even when at risk...

Anecdote

Story of the Son of the Czars

Stigma

- The assumption of lack of capacity based on a diagnosis engenders stigma
 - May prevent participation in research
 - May prevent subjects in other research from additional safeguards
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Illinois Mental Health & Disabilities Code

- (405 ILCS 5/2-100 (a))

No recipient of services shall be deprived of any rights, benefits, or privileges guaranteed by law, the Constitution of the State of Illinois, or the Constitution of the United States solely on account of the receipt of such services.

Illinois Mental Health & Disabilities Code

- (405 ILCS 5/2-101)

No recipient of services shall be presumed legally disabled, nor shall such person be held legally disabled except as determined by a court

So, If Not Diagnosis?

- What then?
- It is essential to assess the capacity to consent of all potential subjects (Craven, 2010).

Anecdote

MD is diagnosed with a brain tumor

Parents of a critical young child in ER

So, If Not Diagnosis?

The need for additional safeguards does not depend on why adults are unable to consent, only that they are unable to consent (Wendler, 2001)

Safeguards

- Level of risk to the subject should be a factor in determining participation in the research by those who lack capacity to consent.

Safeguards

- Consider the risk of decisional impairment in the study population
- Describe how capacity to consent will be assessed
- In the absence of capacity, who will act as proxy?
- Will the capacity be reassessed?

(Alzheimer Association, 2004)

Interventions

- Evaluate capacity (understanding) of all subjects during the consent process; request subject describe study & risks
- If a higher risk study, use an objective method to evaluate; MMSE
- If the risk of loss of capacity during research, have a pre-determined process
- Reassess capacity throughout a study

Interventions

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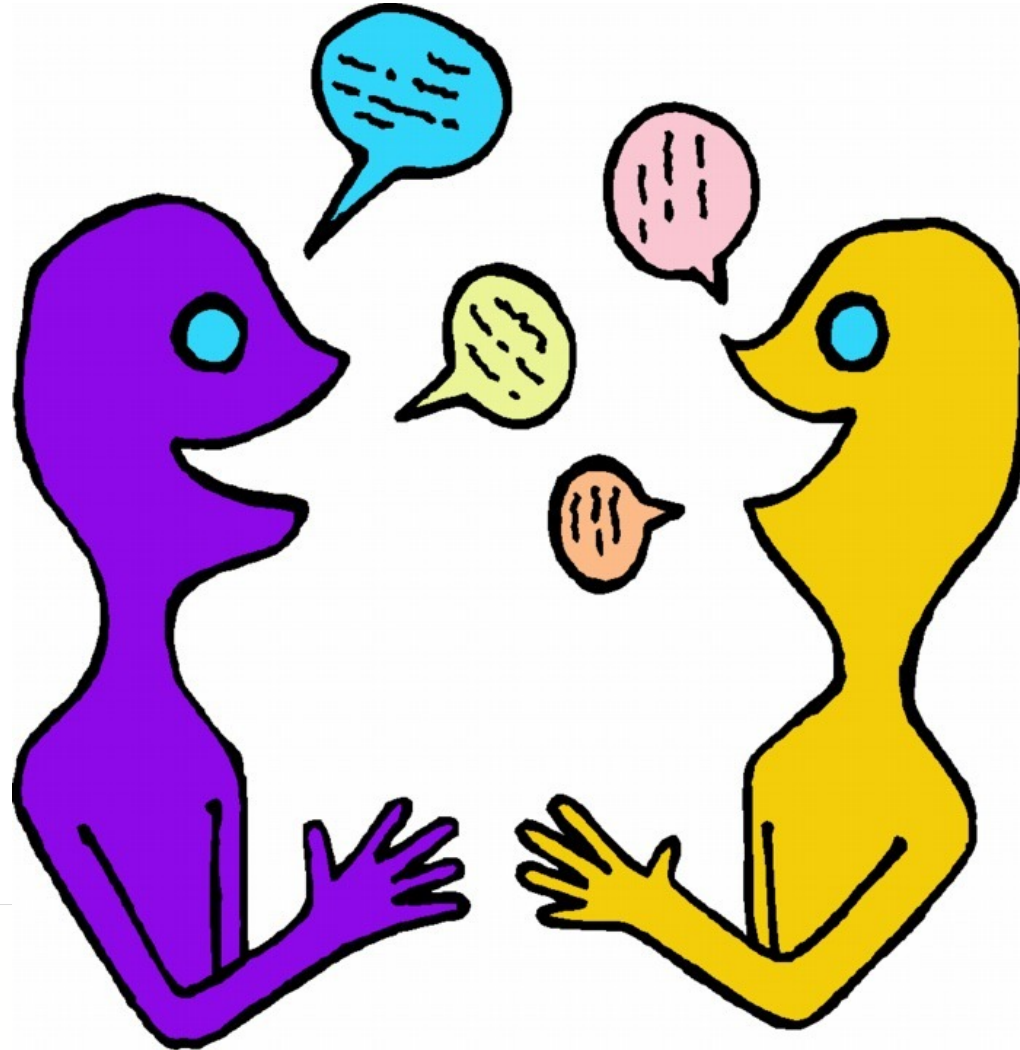
Interventions

- Have a site SOP for how you assess capacity in general
 - Include at what point a third party assessment would be required
 - If a LAR is used, when would you consent subject
 - As always, balance risks to benefits
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Personal Inventory

- Look at your thoughts / opinions that you wrote at the beginning of the presentation
 - Are they any different
 - Let's discuss changes

Questions / Discussion



References

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