

# **Geroscholars Seminar:** **Research Informed Consent in** **Cognitively Impaired Older Adults**

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# Objectives

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- **Identify elements of decisional capacity**
- **Distinguish consent vs. assent vs. absence of objection**
- **Describe approaches to evaluating capacity of older adults to consent to participate in research**
- **Recognize opportunities for research related to consent in elders with cognitive impairment**

# Challenges for geriatric research

- **Absence of federal guidelines on research consent of cognitively impaired adults**
- **Maryland and California introduced restrictions on research involving cognitively impaired elders**
- **NIH convened a conference to explore solutions**
- **Alzheimers Association and others have proposed approaches to provide adequate protection for cognitively impaired research participants**

Alzheimer Dis Assoc Disord 18:171-175, 2004

Karlawish JHT. N Engl J Med 348:1389-1392, 2003

# Examples of cognitive domains that may be impaired

May be affected in dementia or MCI:

- memory (amnesia)
- language (aphasia)
- recognition (agnosia)
- performing motor activities (apraxia)
- initiation/executive function (abulia)
- visual-spatial function

# Dementia: Diagnostic Criteria

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- **Memory loss, plus...**
- **Impairment in at least one other cognitive domain (speech, recognition, praxis, etc)**
- **Interferes with function**

# Mild Cognitive Impairment: Criteria

- MCI, amnestic type
- MCI, non-amnestic type
- Impairment beyond normal for age and education
- Usually retains normal...
  - Perception
  - Judgment
  - Reasoning skills
  - Ability to perform ADLs

# Epidemiology of MCI

- Over age 70 yrs, prevalence is 12%
- Increased incidence of Alzheimer Disease by 3-4X
  - 10-15% annual incidence in patients w/ MCI
  - 1-2% annual incidence w/out MCI
- Important target for research
- Poses challenge for informed consent

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**Diagnosis of Dementia or MCI  
(or psychosis or other mental  
disorders) does not determine  
or predict decisional capacity**



# Elements of Decisional Capacity

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**Informed consent for treatment or research requires the ability to**

- 1. Understand relevant information**
- 2. Appreciate the nature of the situation AND its consequences**
- 3. Reason by manipulating information**
- 4. Express or communicate a choice**

# Concept of sliding scale for threshold of decision-making capacity

- **Decisional capacity is a dimensional concept (i.e., there is a continuum of cognitive capacity)**
- **Must define a threshold for capacity to consent to a specific treatment or research protocol**
- **Threshold is adjusted based on level of risk or benefit**
  - **Higher risk warrants higher bar for cognitive capacity**
  - **Minimal risk may allow consent w/ lower cognitive ability**

# **When an individual is found incapable of giving consent: Definitions of Assent**

- **National Commission for Protection of Human Subjects Research: “an authorization by a person whose capacity to understand and judge is somewhat impaired by illness or institutionalization, but who remains functional”**
- **Common Rule: “affirmative agreement to participate in research”**

**NCPHSR. Report and Recommendations: Research Involving those Institutionalized as Mentally Infirm. Washington DC: Dept of Health Education and Welfare, 1978**

# Ethical principle behind assent

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- Goal is to preserve autonomy to the extent possible
- Need alternative for those not capable of giving informed ***consent***
- ***Assent*** maximizes opportunities for the individual to remain involved in the consent process

# **Suggested Standards for Assent to Research Participation**

## **Potential subjects required to**

- 1. Know what procedures will be performed**
- 2. Choose freely to undergo those procedures**
- 3. Communicate their choice unambiguously**
- 4. Be aware of right to withdraw**

**NCPHSR. Report and Recommendations: Research Involving those Institutionalized as Mentally Infirm. Washington DC: Dept of Health Education and Welfare, 1978**

# Absence of Objection

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For those who lack capacity to consent *or* assent, the ***absence of objection*** is sufficient to allow participation if the research

1. is relevant to the subject's condition
- and
2. poses no more than minimal risk

# Informed Consent Procedures in Maryland AL Study

## 3-step process for assessing decisional capacity:

1. Ask facility staff if resident is routinely making his/her own medical and financial decisions
2. Contact the family member or legal representative who routinely represented the resident's interest in interacting with the facility
3. Interview the resident using unstructured questions to assess decisional capacity  
(ability to understand, appreciate, reason, and express a choice)

# Practical Considerations

- IRB's may require a structured test of the subjects understanding of key elements of consent
- Short quiz (3-5 questions) administered during consent process may be used to establish
  - Understanding
  - Appreciation (of situation and consequences)
- Patient representative (proxy) may be
  - Legal guardian or person w/ power of attorney
  - Next of kin
  - Informal surrogate decision-maker



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**Questions  
And  
Discussion**