# Capacity Assessments at the National Institute of Mental Health (NIMH)

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# Disclaimer

The views expressed in this presentation are my own and do not represent the position or policy of the NIMH, NIH, DHHS, or US government

# Human Subjects Protection Unit (HSPU)

- What is the Human Subjects Protection Unit (HSPU)?
  - NIMH Office of the Clinical Director
  - Clinical Research Advocates (CRAs)
  - Clinicians independent of research
  - Ability to Consent Assessment Team (ACAT)
    - HSPU
    - NIH CC Bioethics Consult Service

# HSPU Functions

- Provide protection and advocacy
- Assess, develop, and implement protections
- Assist in the application of regulations and polices
- Provide education

# Human Subjects Protection Unit (HSPU)

The NIMH created the HSPU to address the need for a systematic approach to assess potential research participants whose ability to consent may be uncertain.

HSPU provides

- Capacity to consent assessments
- Ability to assign a surrogate decision-maker assessments
- Appropriateness of the surrogate assessments
- Consent and assent monitoring
- Subject monitoring
- Informed consent training
- Evaluation of the investigator to obtain informed consent

# Consent Capacity

## Capacity

- Capacity refers to a one-time clinical judgment of a potential participant's ability to give informed consent.
- Does not refer to the ability to understand legal rights and responsibilities and the possession of authority to make legal decisions.



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# HSPU Capacity Assessments

Capacity assessments may be initiated by




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# HSPU Capacity Assessments

- HSPU creates and administers tools two types of capacity assessments*
  - **Protocol-Specific Capacity Assessment**
    - is used when a protocol requires participants to be formally assessed
    - is created in advance
    - expected responses to questions have been developed
  - **Generic Capacity Assessment**
    - is used as a guide for the unexpected enrollment of cognitively impaired individuals
    - consists of generic questions
    - respondent answers are expected to be appropriate to the protocol in question.

*Examples can be found in the **NIMH Human Subjects Research Protections Toolkit**, Section 2. at www.nimh.nih.gov/hspu

# HSPU Capacity Assessments

These tools:

- Are clinically derived and have not been validated.
- Assess four domains through a series of 9 to 11 open-ended questions.
- Are administered by two evaluators.
- Consist of tailored questions related to each domain.*
  - **understanding** of the potential participant's personal situation study specific procedures
  - **appreciation** of the effects of study participation on the potential participant
  - **reasoning** of why the potential participant wants to be in research
  - **choice** expressing a choice about research participation

*Domain definitions from Paul S. Appelbaum and Thomas Grisso, *MacArthur Competence Assessment Tool for Clinical Research* (*MacCAT-CR*) (Sarasota, FL: Professional Resource Press, 2001).



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# HSPU Capacity Assessment Tool

Subject _____ Age _____ Date _____

Interviewer _____ Rater _____

Is there a legal guardian?_____ Is there a DPA?_____

• **UNDERSTANDING** *of disclosed information about the nature of the research project and its procedures*[1]

1. **What is the purpose of this research?**

- ☐ Expected: To learn more about schizophrenia or other neuropsychiatric illnesses
- ☐ Prompt: *What is the disorder or illnesses being studied in this research?*

- ☐ Expected: To study subjects on and off medications
- ☐ Prompt: *Will researchers need to study participants on and off medications?*

Rater's Comments _____

1 ____ 2 ____ 3 ____

2. **What are some of the important things you will be asked to do?**

- ☐ Expected: Tests, such as blood draws and cognitive testing
- ☐ Prompt: *What are some of the tests?*

- ☐ Expected: Medication withdrawal, take placebo
- ☐ Prompt: *Will you stop taking your medications?*

- ☐ Expected: Imaging, such as MRI, PET scans
- ☐ Prompt: *Will you be asked to do brain scans?*

Rater's Comments _____

1 ____ 2 ____ 3 ____

3. **What are the most important potential risks to you during this study?**

- ☐ Expected: Symptom worsening
- ☐ Prompt: *What might happen while you are not taking your regular medication?*

- ☐ Expected: Possibility of not returning to baseline functioning
- ☐ Prompt: *Is it possible that you may not return to your current condition after being off meds?*

- ☐ Expected: Possibility of becoming a danger to self/others
- ☐ Prompt: *Is it possible that you could become a danger to yourself or others?*

- ☐ Expected: Radiation exposure during PET, possible claustrophobia during MRI
- ☐ Prompt: *What are some of the risks of imaging scans?*

Rater's Comments _____

1 ____ 2 ____ 3 ____


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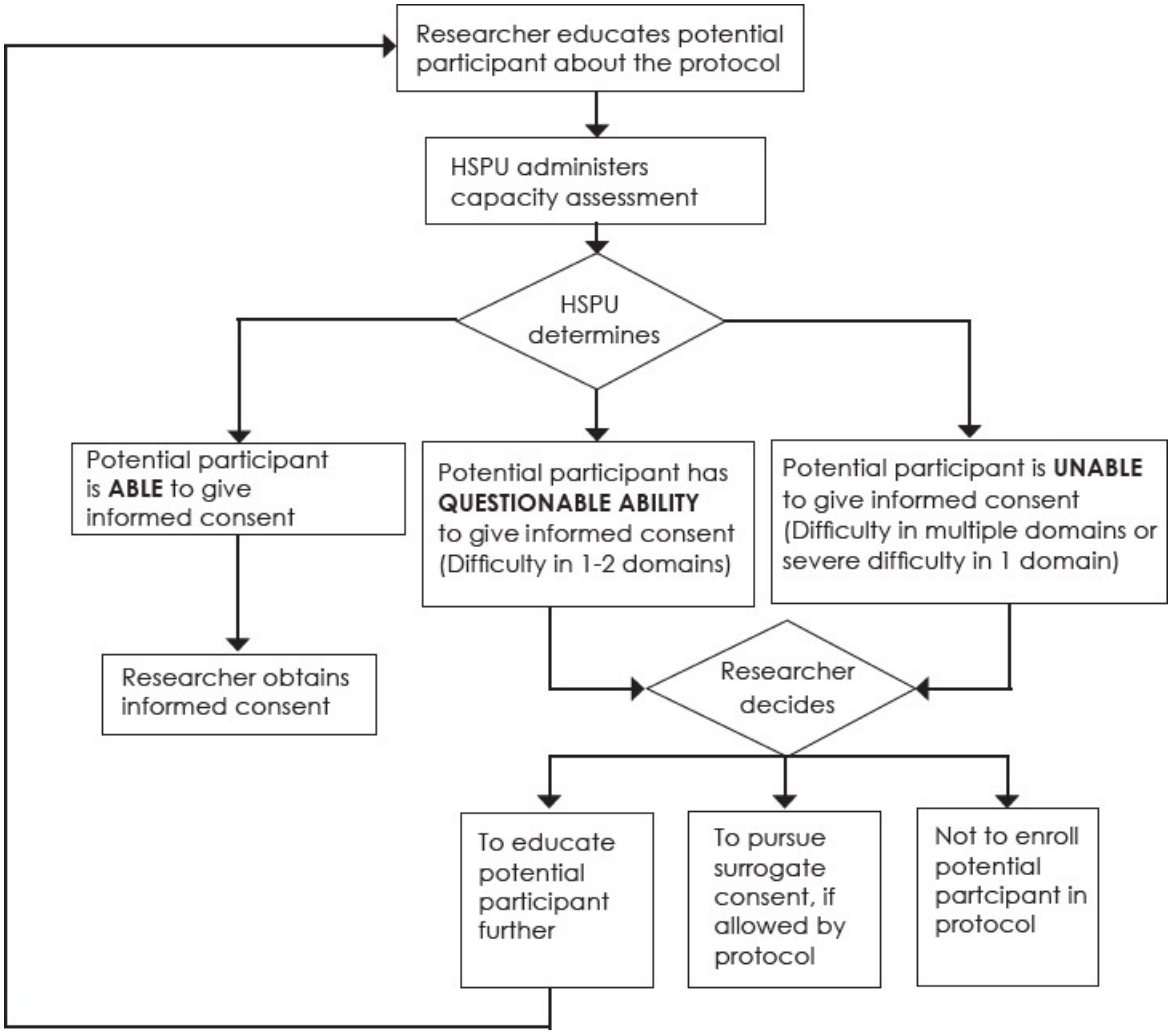
# HSPU Capacity Assessment Algorithm



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# Vignette 1

Investigators submit a protocol to the IRB to study adults diagnosed with schizophrenia through imaging (PET & MRI) both on and off antipsychotic medications. The protocol

- Is a double-blind, placebo-controlled, crossover design
- Lasts 10 weeks
- Requires an inpatient stay
- Does not allow pro re nata or additional medications (e.g., antidepressants)
- Does not allow for individual therapy during the study (groups and activities offered)
- Provides standard treatment after study procedures end (or participant withdraws)

The IRB determined that the protocol

- Is more than minimal risk
- Has no prospect of direct benefit
- Does not allow surrogate consent
- Requires independent capacity assessment for all participants

# Vignette 1

M is a 21-year-old diagnosed in the with recent onset schizophrenia.*

M is treatment naive and is currently experiencing auditory hallucinations and anxiety.

During the capacity assessment discussion held prior to the consent process, M states that she is at the NIMH because she is hearing voices and the doctors would like to take pictures of her brain off and on medications.

M is willing to stay on the inpatient unit but is not able to distinguish that this is for research purposes (e.g., observation, testing, controlled environment) and that otherwise an inpatient stay is not clinically indicated. M is not aware of alternative treatments available to her in the community (e.g., she does not need to enroll in research to be able to start medication, individual therapy). The advocate discusses the difference between research and clinical care with M.

M continues to have difficulty appreciating the difference between the two but is willing to enroll.

Do you think M has capacity to provide informed consent at this time?

*Standard treatment for schizophrenia requires a psychiatric evaluation and generally includes medication, individual therapy, and adjunct supports/therapies.



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# Vignette

**Points to consider**

- alternative standard treatments are available in the community
- level of risk and delay of treatment
- no direct benefit
- difference between research and clinical care.

**Understanding**

**Appreciation**

**Reasoning**

**Choice**

**Possible outcomes?**



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# Vignette 2

Investigators submit a protocol to the IRB to study the signs, symptoms and course of Alzheimer's disease. It is a longitudinal, natural history design involving PET scans (with an investigational ligand) and neuropsychological testing (e.g., memory assessments). Participants current treatment and medications will not be changed. The study requires 2 outpatient visits a year for 5 years.

The IRB determined that the protocol

- Is more than minimal risk
- Has no prospect of direct benefit
- Allows surrogate consent
- Requires independent Capacity Assessment and if needed Ability to Assign a Surrogate Assessment and Appropriateness of the Surrogate Assessment

# Vignette 2

T is a 70-year-old diagnosed with Alzheimer's Disease and is eligible to enroll in this protocol.

During the capacity assessment T states that he understands the researchers are studying dementia and will ask him to participate in PET (with an experimental ligand), MRI scans, and neuropsychological testing. He states will be relying on his spouse to get him to his 5 outpatient appointments as he longer is driving. He also states that he knows that participating in this research will not cure his dementia. He notes that having a strong family history of this disease and concern for his children's greater risk of inheriting it, motivates him to contribute to possible future treatments for others.

Do you think T has capacity to provide informed consent at this time?

# Vignette 2

**Understanding**
**Appreciation**
**Reasoning**
**Choice**

**Points to consider**

- Doesn't involve change in current treatment
- How far apart are the research procedures?
- What if T's capacity changes?

**Possible outcomes?**



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# DISCUSSION



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