Capacity Assessment in Practice

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Ability to Consent Assessment Team

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National Institute of Mental Health

Disclaimer

- The views expressed in this presentation are my own and do not represent the position or policy of the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), Department of Health and Human Services (DHHS) and/or the United States federal government.

NIH National Institute of Mental Health

Objectives

1) Current events within National Institute of Mental Health (NIMH) and the Office of the Clinical Director (OCD)

2) Describe the role of the Human Subjects Protection Unit

3) Increase understanding of how capacity assessments may be conducted within NIMH/NIH

4) Share the HSPU Algorithm

5) Highlight 2 protocols and 2 cases for discussion

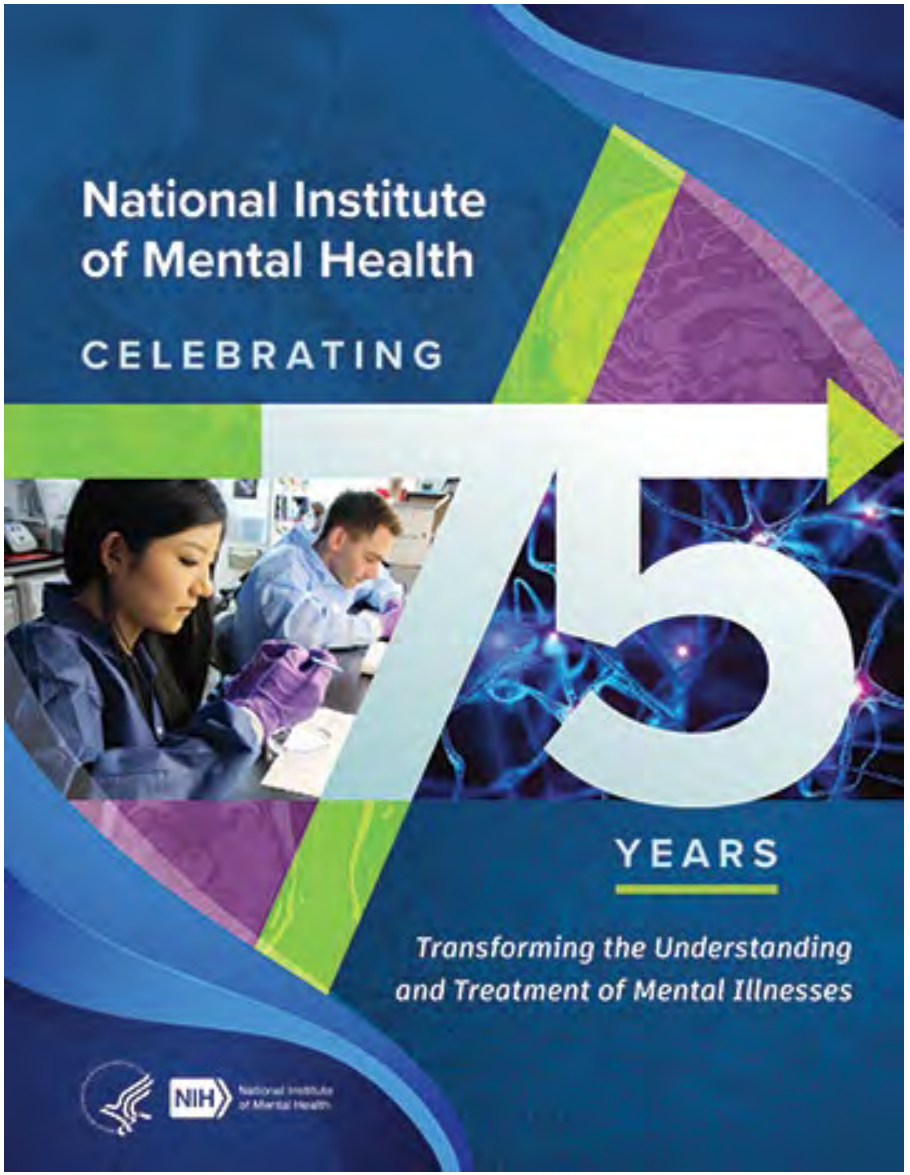
6) Identify the "Points to Consider" and Outcomes

7) Provide Resources

"For 75 years, NIMH has been at the forefront of mental health research. Our mission is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. The institute's influence is widespread; NIMH-supported research has played a pivotal role in advancing our understanding of the brain, developing groundbreaking treatments and therapies, and improving the quality and availability of mental health care."

Dr . Josh Gordon, Director of NIMH

Source:
https://www.nimh.nih.gov/sites/default/files/documents/NIMH-Celebrating-75-Years-508.pdf



Supporting the NIMH Mission:
The Human Subjects Protection Unit (HSPU)

- ***What is the Human Subjects Protection Unit (HSPU)?***
  - NIMH under the auspices of the **Office of the Clinical Director (OCD)**
  - Clinical Research Advocates (**CRA**s)
  - Clinicians and consultants independent of research
  - Members of the Ability to Consent Assessment Team (ACAT):
    NIH CC Bioethics Consult Service + HSPU= ACAT
  - Provide training, education and other functions support to the NIMH Mission

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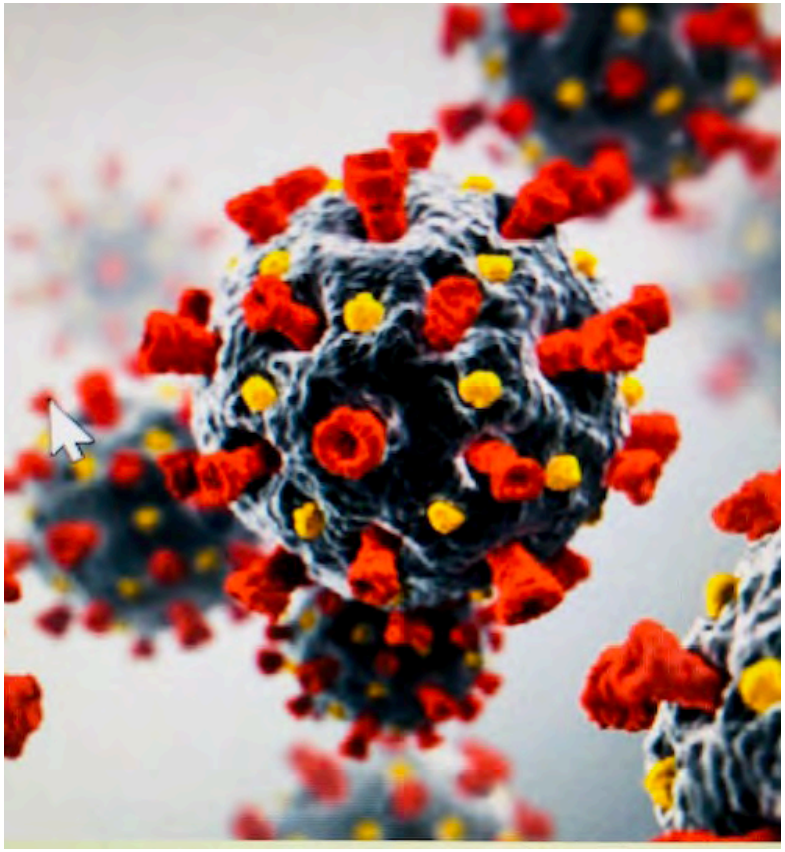
Awarded the U.S. DHHS Secretary's Commendation

NIMH: The Coronavirus Pandemic

- ***Last month, Dr. Maryland Pao received the U.S. Department of Health and Human Services Secretary's Commendations for her part in NIH's response to COVID-19.***
- ***Dr. Pao initiated and oversaw for all NIH staff mental health and mental wellness programs to help deal with the challenges of the pandemic; understand what was happening with their and their children's mental health; and respond with education and support to the needs for mental health assistance for NIH employees and their families.***



- 3D illustration of coronavirus. Credit: www.istockphoto.com/portfolio/ BlackJack3D.

Source: https://www.nimh.nih.gov/research/research-conducted-at-nimh/scientific-director/office-of-clinical-director/key-personnel

What else does HSPU do?

Provide	Additional layers of protection and advocacy
Assess, develop, and implement	Assess, develop, and implement human subject protections for research participants
Consultation	Assistance in the application of regulations and polices
Support	Education, training and research related to human subject protections

Human Subjects Protection Unit (HSPU)

The NIMH OCD established the HSPU to provide protections for potentially vulnerable populations in research.

Within NIMH, there was a need for a systematic approach to assess potential participants who may lack decision-making capacity to consent to research.

Additional assessments and roles evolved. Currently, the HSPU conducts:

- Capacity to provide informed consent assessments "Capacity Assessments"
- Ability to assign a Legally Authorized Representative (LAR) assessments
- Appropriateness of the LAR assessments
- Consent and assent/dissent monitoring
- Subject monitoring
- Consultation regarding regulations and policies related to human subjects' protections
- Informed consent training
- Education and evaluation of the quality of informed consent for investigators

What is 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.

An individual's capacity to provide informed consent can be compromised by:

- **Anxiety**
- **Panic**
- **Depression**
- **Delirium**
- **Psychosis**
- **Medical illness**
- **Substance abuse**
- **Cognitive difficulty**
- **Dependency upon those who provide treatment**

HSPU Capacity Assessments

Capacity assessments may be initiated by

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

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HSPU Capacity Assessments

These tools:

- Are clinically derived and have not been validated.
- Assess four domains through a series of open-ended questions.
- Are typically 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).

A Snapshot of the 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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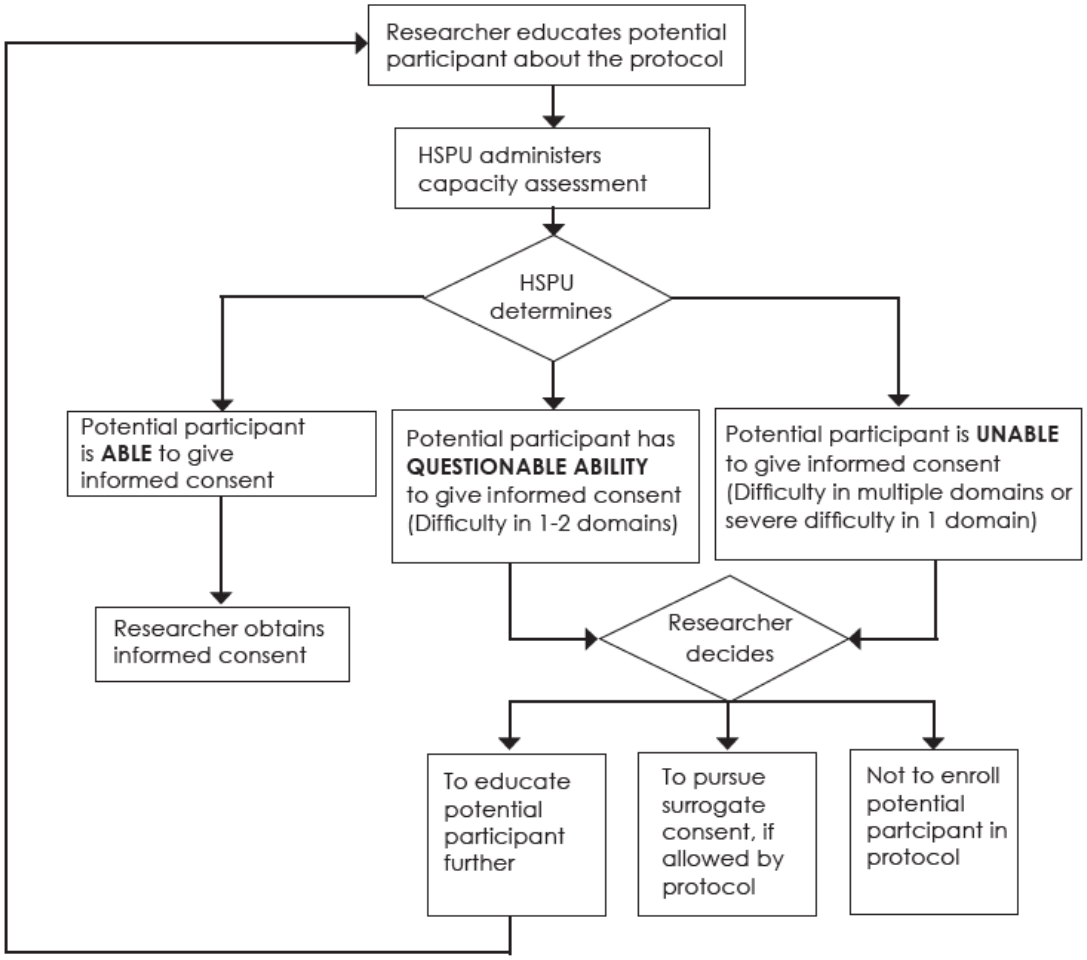
HSPU Capacity Assessment Algorithm



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HSPU Vignette 1: The Protocol

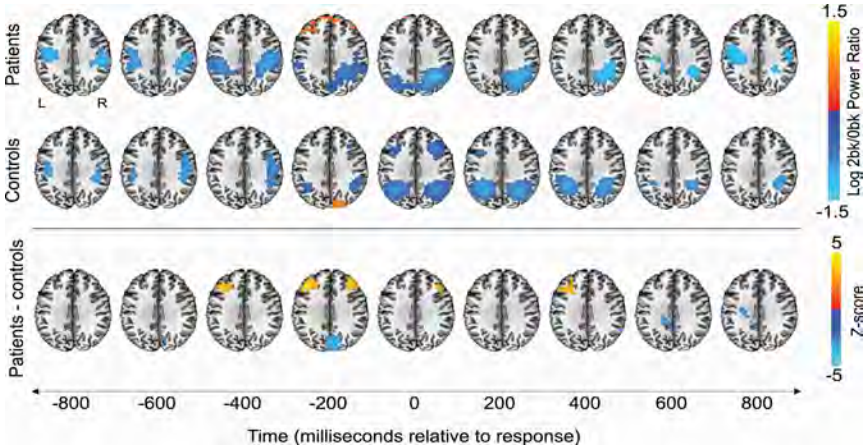
Investigators submit a protocol to the IRB for a study which invites adults diagnosed with schizophrenia to participate in brain imaging and other tests/procedures. The individuals are invited to volunteer for procedures (blood tests, neuropsychological tests, MEG, PET-scans, MRIs etc.). The study has two phases. One phase involves being on antipsychotic mediation and the second phase involves being in a placebo-arm.

- Is a double-blind, placebo-controlled, crossover design
- Lasts approximately 10 weeks
- Requires an inpatient stay of several months
- Does not allow pro re nata (PRN) or other psychiatric medications (anti-depressants or anti-anxiety medication)
- Does not allow for individual therapy during the study (groups and activities offered)
- Following these two phases, or if the participant is withdrawn from the study, the protocol offers standard treatment

Consequently, the IRB determined that the protocol:

- Is more than minimal risk
- Has no prospect of direct benefit
- Does not allow consent by a Legally Authorize Representative (LAR)
- Requires an independent capacity assessment for all participants
- Throughout protocol participation on the inpatient unit, requires ongoing "subject monitoring" by HSPU

In May 2023, Schizophremia Bulletin, Berman et al "Spatiotemporal Alterations in Working Memory-Related Beta Band Neuromagnetic Activity of Patients With Schizophrenia On and Off Antipsychotic Medication: Investigation With MEG," Berman et al.



Source: *Schizophrenia Bulletin*, Volume 49, Issue 3, May 2023, Pages 669–678, https://doi.org/10.1093/schbul/sbac178

HSPU Vignette 1: A Case

- M is a 21-year-old male diagnosed with recent onset schizophrenia.*
- M is treatment naïve. M is currently experiencing auditory hallucinations, anxiety and had to stop his college courses due to his sx.
- During the capacity assessment discussion held prior to the consent process, M states that he is at the NIMH because he is hearing voices. M also says, ***"The doctors would like to take pictures of my brain off and on medications…to help me."***
- M confirms he is willing to stay on the inpatient unit but has difficulty distinguishing that this is for research purposes (e.g., observation, testing, controlled environment) and not for primary benefit. M understands the test, procedures and risks.
- The advocates discuss the difference between research and clinical care.
- M has difficulty appreciating the difference between clinical care and research.
- M is not aware of alternative treatments available in the community . He seems confused about whether or not he needs to enroll in this research to be able to start medication. The advocate provides education about the standard treatments* available in the community
- Does M has capacity to provide informed consent at this time? Are there concerns that should be addressd?
- Are there additional questions to explore? What else might be important to highlight?

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

HSPU Vignette 1: Education and Outcome

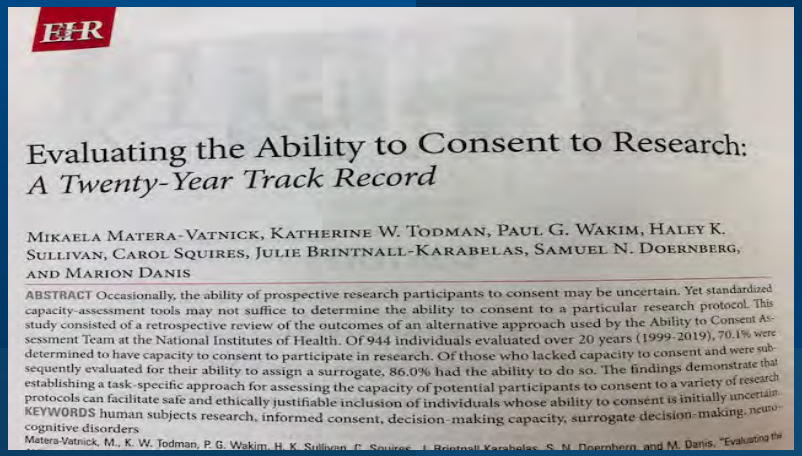
- **Points to consider**
  - Further education about alternatives and the standard treatments available in the community
  - Highlighting the level of risk and the delay of treatment
  - Education that there is no direct benefit
  - Clarification of the differences between research and clinical care.

Recommend Education and Reassess:

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

Outcome?

Ability to Consent Assessment Team (ACAT)


E&R

Evaluating the Ability to Consent to Research: *A Twenty-Year Track Record*

MIKAELA MATERA-VATNICK, KATHERINE W. TODMAN, PAUL G. WAKIM, HALEY K. SULLIVAN, CAROL SQUIRES, JULIE BRINTNALL-KARABELAS, SAMUEL N. DOERNBERG, AND MARION DANIS

ABSTRACT Occasionally, the ability of prospective research participants to consent may be uncertain. Yet standardized capacity-assessment tools may not suffice to determine the ability to consent to a particular research protocol. This study consisted of a retrospective review of the outcomes of an alternative approach used by the Ability to Consent Assessment Team at the National Institutes of Health. Of 944 individuals evaluated over 20 years (1999-2019), 70.1% were determined to have capacity to consent to participate in research. Of those who lacked capacity to consent and were subsequently evaluated for their ability to assign a surrogate, 86.0% had the ability to do so. The findings demonstrate that establishing a task-specific approach for assessing the capacity of potential participants to consent to a variety of research protocols can facilitate safe and ethically justifiable inclusion of individuals whose ability to consent is initially uncertain.

KEYWORDS human subjects research, informed consent, decision-making capacity, surrogate decision-making, neurocognitive disorders

Matera-Vatnick, M., K. W. Todman, P. G. Wakim, H. K. Sullivan, C. Squires, J. Brintnall-Karabelas, S. N. Doernberg, and M. Danis, "Evaluating the

Our findings show that a careful process of assessing the elements of capacity to consent—understanding, appreciation, reasoning, and ability to communicate a choice—can lead to safe and ethically sound enrollment of many people whose capacity to consent to research is initially unclear.

Source:
https://onlinelibrary.wiley.com/doi/full/10.1002/eahr.500119

Vignette 2: The Protocol

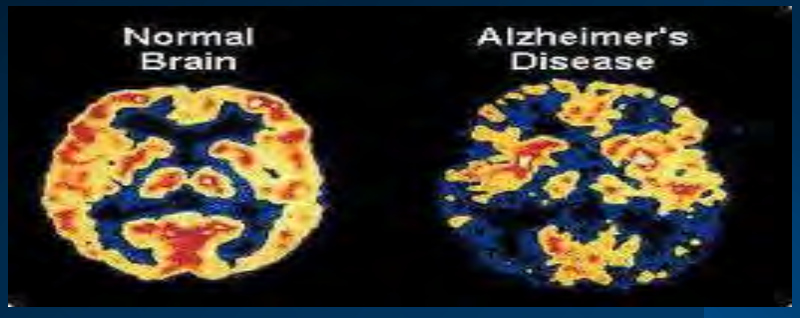


Image source: https://www.midstateradiology.com/radiology-services/neuroradiology/neuroquant/

Investigators submit a protocol to the IRB to study the signs, symptoms and course of Alzheimer's disease.

This 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 5 outpatient visits a year for 2 years.

- **The IRB determined that the protocol:**
  - Is more than minimal risk
  - Has no prospect of direct benefit
  - Allows consent with a legal-authorized representative (LAR)
  - Requires an independent Capacity Assessment and, if needed, Ability to Assign an LAR/Surrogate Assessment and determination of the Appropriateness of the Surrogate Assessment

Vignette 2: A Case

- T is a 62-year-old female with suspected early-onset Alzheimer's Disease and is eligible to enroll in this protocol.
- During the capacity assessment T states that she understands the researchers are studying dementia and will ask her to participate in PET (with an experimental ligand), MRI scans, and neuropsychological testing.
- She shares she will be relying on her spouse to get to the 5 outpatient appointments over the next two years, as he longer is driving.
- She also states that he knows that participating in this research will not cure his dementia.
- She notes that having a strong family history of this disease. She has concern for her children and grandchildren's potential greater risk of inheriting this disease. This is a motivation for her. She wants to contribute to possible future treatments for others.

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

- What may be some additional points to consider?

Vignette 2: Questions and Outcome

- **Points to consider**
  - Doesn't involve change in current treatment
  - What is the length of time between visits?
  - What if the participant's capacity changes?
  - Participant expressed an interest in learning more about the NIH/AD

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

- **Possible outcomes?**

Capacity Assessments and NIH CC Policy:

Policy 403: Research Involving Adults Who Lack Decision-Making Capacity to Consent to Research Participation

This policy describes the requirements for research involving adults who lack the decision-making capacity to consent to research participation.

As per the NIH policy 403, consultation regarding whether an individual is able to provide consent may be obtained by contacting the NIH Ability to Consent Assessment Team (ACAT).

https://policymanual.nih.gov/3014-403

DISCUSSION

To access the NIMH HSPU Toolkit go to….

www.nimh.nih.gov/hspu

In recognition of National Suicide Awareness Prevention Month,

National Institute of Mental Health

Thank you, *for sharing your time today!*