Capacity to Provide Informed Consent in Research

Carol Squires, LCSW
National Institute of Mental Health
Office of the Clinical Director
Human Subjects Protection Unit (HSPU)
Ability to Consent Assessment Team (ACAT)

National Institute of Mental Health

Human Subjects Protection Unit (HSPU)

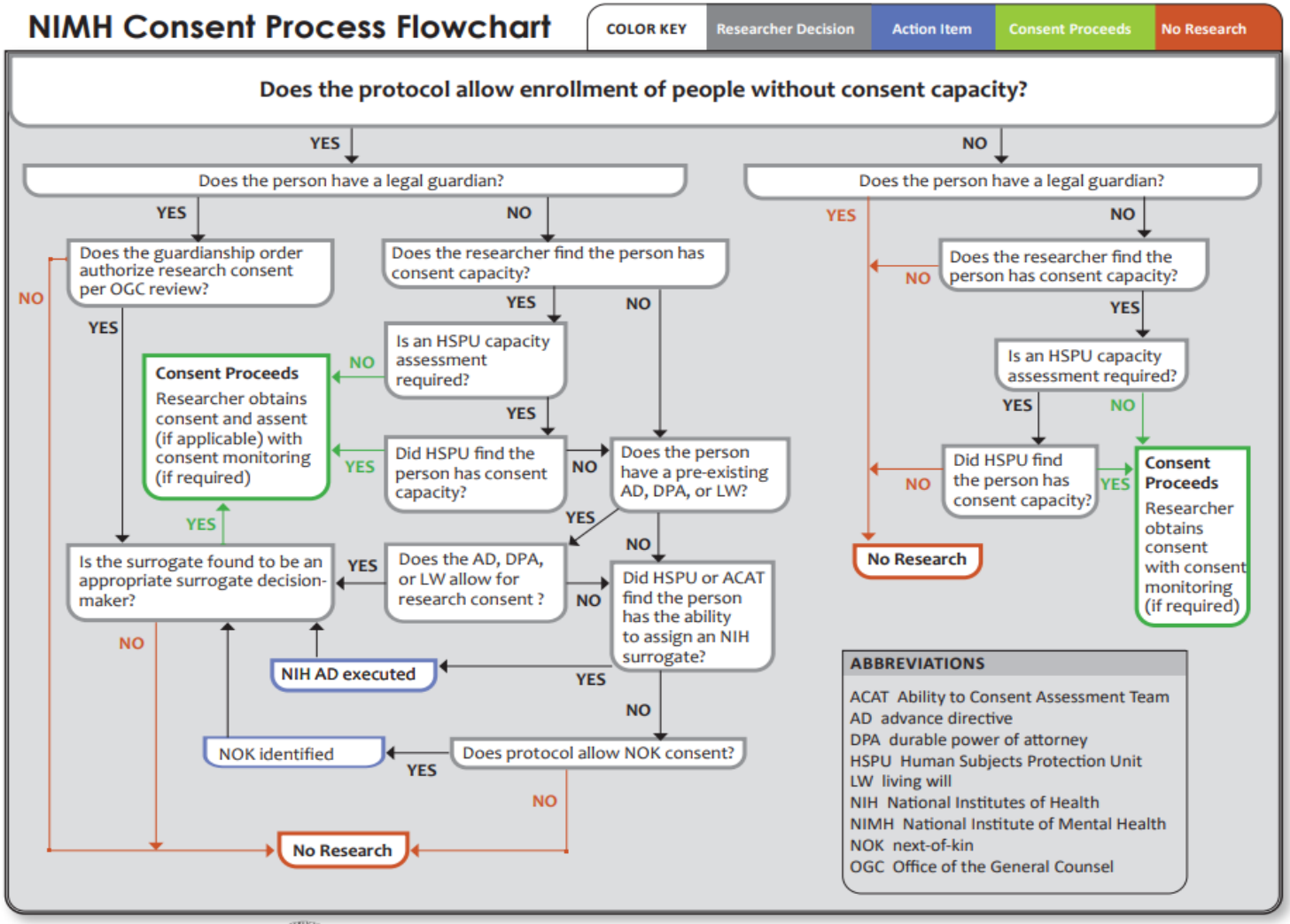
- What is the NIMH HSPU?
  - NIMH Office of the Clinical Director www.nimh.nih.gov/hspu
  - Clinicians independent of research
  - Ability to Consent Assessment Team (ACAT)

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

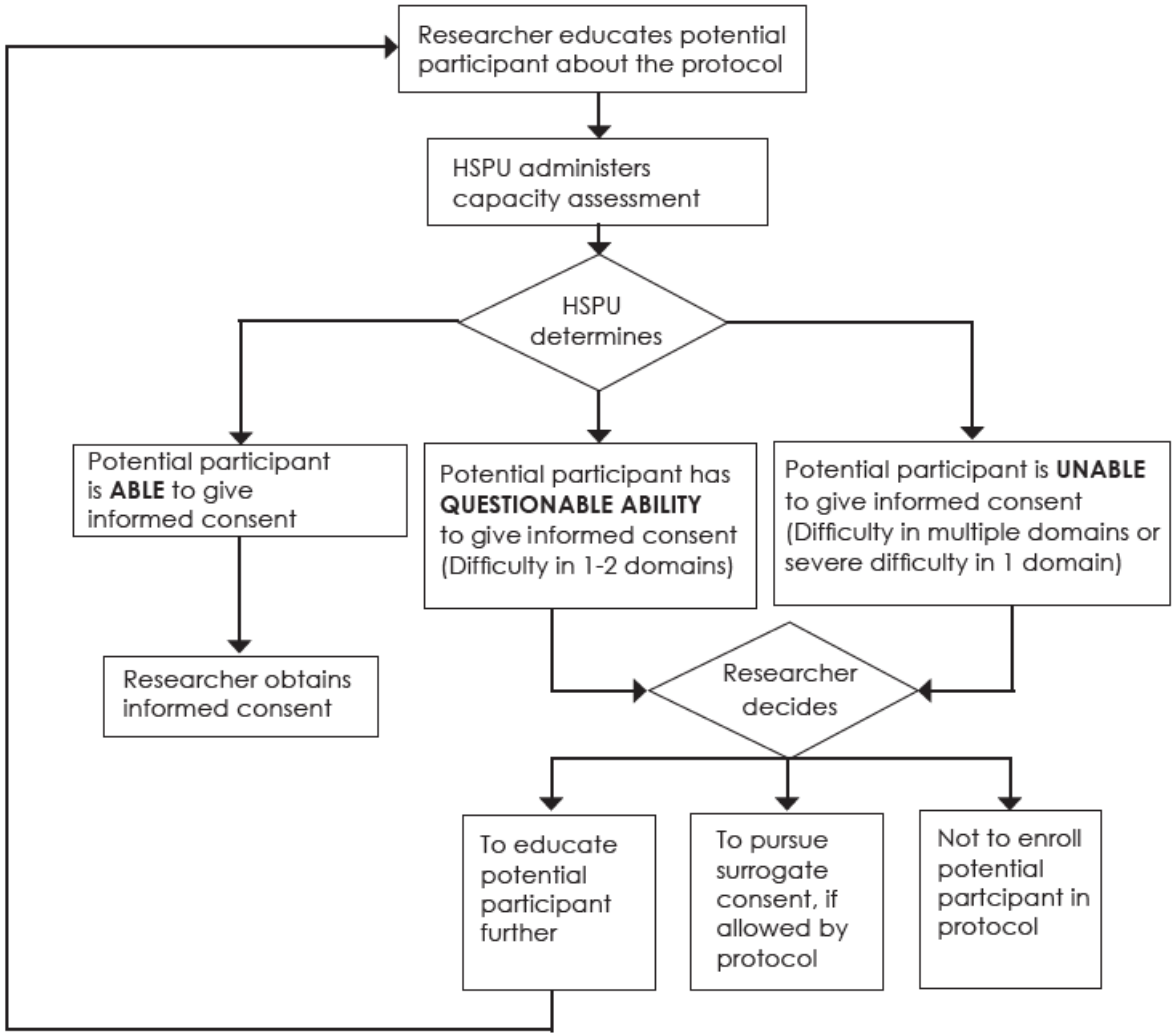
Objectives

- Know the consent capacity process
- Review how to assess for consent capacity
- Identify what contributes to the capacity assessment process going well and what are potential pitfalls
- Identify things to consider when enrolling potentially vulnerable populations

NIMH Consent Process Flowchart



HSPU Capacity Assessment Algorithm



Capacity Assessments

- Participants must have capacity to provide informed consent
  - Clinical judgement
  - Formal process which may include HSPU or ACAT

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 individuals who may not have consent capacity
- 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
Note this NIMH Toolkit will be updated Summer 2022

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 which may lead to further 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).

Hierarchy of LARs*

- Legal guardian (court appointed, must be reviewed by OGC)
- Agent for durable power of attorney (DPA)
  - Outside
  - NIH Form 200 http://intranet.cc.nih.gov/medicalrecords/forms/forms-advance.html
- Next-of-kin (NOK)

*Presentation on Policy 403 can be found on the IRBO website https://irbo.nih.gov/confluence/download/attachments/36241835/403%20.%20Presentation%20-%20Research%20Involving%20Adults%20Who%20Lack%20Capacity%20to%20Consent.pptx?version=1&modificationDate=1607371587359&api=v2

Ability to Assign an NIH DPA/AD (Form 200)

- Do you need ACAT to assess the subject's ability to assign an NIH DPA? (https://policymanual.nih.gov/3014-403)
- In most cases, everyone is offered the opportunity to complete an NIH DPA/AD. It assumed they have the capacity to do so unless reason to think to think otherwise. (E.g., if a potential participant does not have consent capacity)
- At the CC, the Ability to Consent Assessment Team evaluates whether an adult who is unable to consent to research has retained the ability to execute a DPA. If at a non-CC NIH site, contact your IC leadership for policies and guidance

Validity of the LAR

- Who will assess the validity of the LAR & how? (https://policymanual.nih.gov/3014-403)
  - Policy requires the confirmation of the validity of the LAR. The LAR is someone who:
    - Is permitted consistent with the risk/benefit category made by the NIH IRB
    - Is permitted consistent with the hierarchy
    - Has the capacity to consent to the research; and
    - Is able to represent the wishes or best interests of the subject.
    - Ensure that the LAR will be available, ideally present, at the time of research consent

Capacity Assessments Go Well When:

- The participant and potential LAR know what to expect
- OGC and investigator have reviewed the guardianship or outside DPA paperwork (respectively)
- There is enough time for all necessary assessments which have been scheduled in advance when possible
- Investigator finds out how participant and LAR make decisions outside of NIH
- Assent is clear
- Documentation is done properly

Capacity Assessments – Common Pitfalls

- Investigator not knowing if protocol allows for LAR
- Not explaining process ahead of time
- Not obtaining necessary documents and having them reviewed
- Assessments occur after the consent is signed
- Not educating the participant to the protocol
- Not re-assessing
- LAR not identified or available
- Poor communication with team re: LAR
- Not understanding the hierarchy of LARs

Considerations for Research with Potentially Vulnerable Participants

- Guardians
- Minors aging up and do not have consent capacity
- Additional protections and assessments
- Determine who administers the assessments
- Policy vs protocol
- Ongoing consent

Case Example 1

- B is an adult who presents at the CC to participate in a MIOMR, NDB dementia study
- Day before study, the investigator calls B to educate her about the study and finds she understands the study
- Study allows LAR consent
- B is accompanied by her adult daughter whom she has assigned as her DPA
- Study requires HSPU capacity assessment
- HSPU determines she does not have capacity at time of assessment
- Daughter shares that B is also eligible to enroll in a MR longitudinal study with another NIH institute.

How do we proceed?

Case Example 2

- C has schizophrenia and is enrolled in a minimal risk screening protocol on the i/p unit to determine eligibility for a MMR, NDB, double blind, placebo controlled study with accompanying PET/MRI studies.
- Nursing provides education about the higher risk study, prior to HSPU capacity assessment
- LAR consent is not permitted
- HSPU determines C does not have capacity at this time. C indicated some reservation about participating.

What are next steps?

Contact Information

HSPU Clinical Research Advocates

Katherine W. Todman, LCSW-C, LICSW, LCSW	301-496-8782
Carol J. Squires, LCSW	301-402-6845
Julie Brintnall-Karabelas, LCSW-C	301-402-6787

HSPU	301-232-2984
HSPU pager/SPOK	102 11158
HSPU email	nimhhspu@mail.nih.gov
ACAT after hours: call the page operator ask for Bioethics attending on call	301.496.1211

NIMH Toolkit for Human Subjects Protections

www.nimh.nih.gov/hspu