The Informed Consent Process: The Good, the Bad & the Ugly

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5/5/22

National Institute of Mental Health

Disclaimer

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

Objectives

- Introduce the NIMH HSPU
- Identify what contributes to a successful informed consent discussions and what are potential pitfalls
- 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

Human Subjects Protection Unit (HSPU)

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

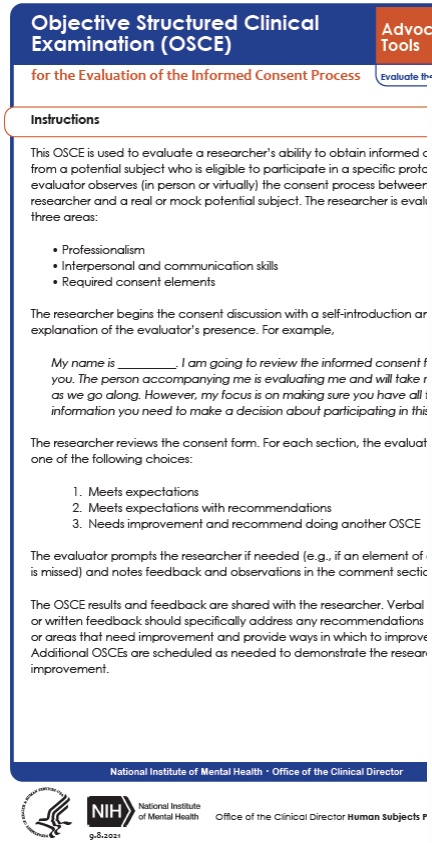
HSPU Functions

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

Obtaining IC – How Are We Doing?

NIMH Model

- New investigators and trainees are required to attend Elements of a Successful Consent Training
- Complete an OSCE for the Evaluation of the Informed Consent Process
- This model has been
  - Replicated by other ICs,
  - Requested by the IRB for trainees
  - Used by research groups as part of a corrective action plan



Objective Structured Clinical Examination (OSCE)

Advocate Tools

Evaluate the Researcher

for the Evaluation of the Informed Consent Process

Instructions

This OSCE is used to evaluate a researcher's ability to obtain informed c
from a potential subject who is eligible to participate in a specific protc
evaluator observes (in person or virtually) the consent process between
researcher and a real or mock potential subject. The researcher is evalu
three areas:

- Professionalism
- Interpersonal and communication skills
- Required consent elements

The researcher begins the consent discussion with a self-introduction ar
explanation of the evaluator's presence. For example,

*My name is _____. I am going to review the informed consent f
you. The person accompanying me is evaluating me and will take r
as we go along. However, my focus is on making sure you have all
information you need to make a decision about participating in this*

The researcher reviews the consent form. For each section, the evaluat
one of the following choices:

1. Meets expectations
2. Meets expectations with recommendations
3. Needs improvement and recommend doing another OSCE

The evaluator prompts the researcher if needed (e.g., if an element of
is missed) and notes feedback and observations in the comment sectic

The OSCE results and feedback are shared with the researcher. Verbal
or written feedback should specifically address any recommendations
or areas that need improvement and provide ways in which to improve
Additional OSCEs are scheduled as needed to demonstrate the researc
improvement.

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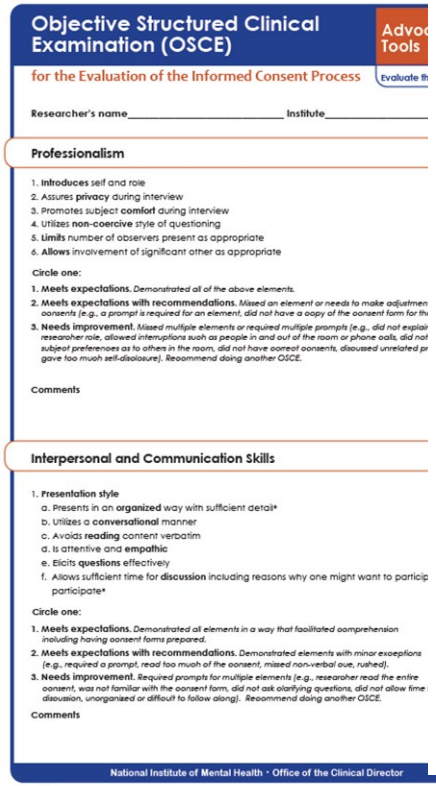

Objective Structured Clinical Examination (OSCE)

Advo Tools

Evaluate th

for the Evaluation of the Informed Consent Process

Researcher's name_____ **Institute**_____

Professionalism

1. **Introduces** self and role
2. Assures **privacy** during interview
3. Promotes subject **comfort** during interview
4. Utilizes **non-coercive** style of questioning
5. **Limits** number of observers present as appropriate
6. **Allows** involvement of significant other as appropriate

Circle one:

1. **Meets expectations.** *Demonstrated all of the above elements.*
2. **Meets expectations with recommendations.** *Missed an element or needs to make adjustmen consents (e.g., a prompt is required for an element, did not have a copy of the consent form for th*
3. **Needs improvement.** *Missed multiple elements or required multiple prompts (e.g., did not explair researcher role, allowed interruptions such as people in and out of the room or phone calls, did not subject preferences as to others in the room, did not have correct consents, discussed unrelated pr gave too much self-disclosure). Recommend doing another OSCE.*

Comments

Interpersonal and Communication Skills

1. **Presentation style**
   a. Presents in an **organized** way with sufficient detail*
   b. Utilizes a **conversational** manner
   c. Avoids **reading** content verbatim
   d. Is attentive and **empathic**
   e. Elicits **questions** effectively
   f. Allows sufficient time for **discussion** including reasons why one might want to particip participate*

Circle one:

1. **Meets expectations.** *Demonstrated all elements in a way that facilitated comprehension including having consent forms prepared.*
2. **Meets expectations with recommendations.** *Demonstrated elements with minor exceptions (e.g., required a prompt, read too much of the consent, missed non-verbal cue, rushed).*
3. **Needs improvement.** *Required prompts for multiple elements (e.g., researcher read the entire consent, was not familiar with the consent form, did not ask clarifying questions, did not allow time discussion, unorganized or difficult to follow along). Recommend doing another OSCE.*

Comments

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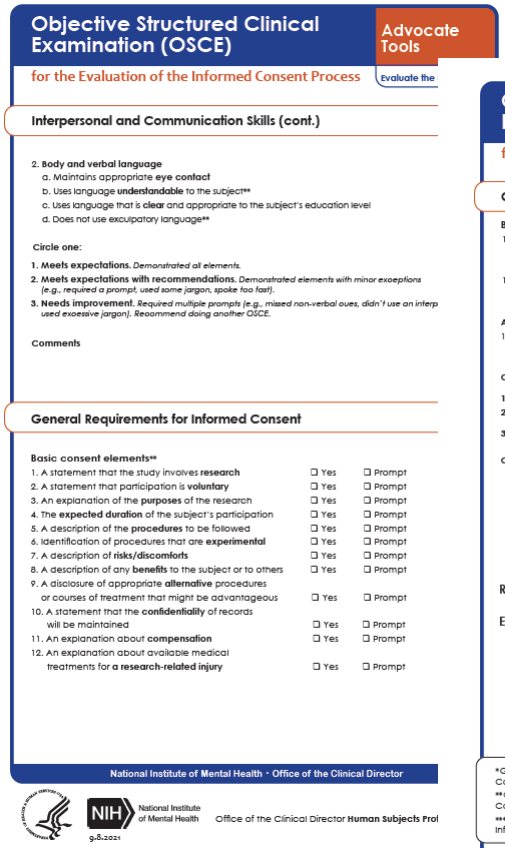

Objective Structured Clinical Examination (OSCE)

Advocate Tools

for the Evaluation of the Informed Consent Process

Evaluate the

Interpersonal and Communication Skills (cont.)

2. **Body and verbal language**
   a. Maintains appropriate **eye contact**
   b. Uses language **understandable** to the subject**
   c. Uses language that is **clear** and appropriate to the subject's education level
   d. Does not use exculpatory language**

Circle one:

1. **Meets expectations.** *Demonstrated all elements.*
2. **Meets expectations with recommendations.** *Demonstrated elements with minor exceptions (e.g., required a prompt, used some jargon, spoke too fast).*
3. **Needs improvement.** *Required multiple prompts (e.g., missed non-verbal cues, didn't use an interp used excessive jargon). Recommend doing another OSCE.*

Comments

General Requirements for Informed Consent

Basic consent elements**

1. A statement that the study involves **research**	❑ Yes	❑ Prompt
2. A statement that participation is **voluntary**	❑ Yes	❑ Prompt
3. An explanation of the **purposes** of the research	❑ Yes	❑ Prompt
4. The **expected duration** of the subject's participation	❑ Yes	❑ Prompt
5. A description of the **procedures** to be followed	❑ Yes	❑ Prompt
6. Identification of procedures that are **experimental**	❑ Yes	❑ Prompt
7. A description of **risks/discomforts**	❑ Yes	❑ Prompt
8. A description of any **benefits** to the subject or to others	❑ Yes	❑ Prompt
9. A disclosure of appropriate **alternative** procedures or courses of treatment that might be advantageous	❑ Yes	❑ Prompt
10. A statement that the **confidentiality** of records will be maintained	❑ Yes	❑ Prompt
11. An explanation about **compensation**	❑ Yes	❑ Prompt
12. An explanation about available medical treatments for **a research-related injury**	❑ Yes	❑ Prompt

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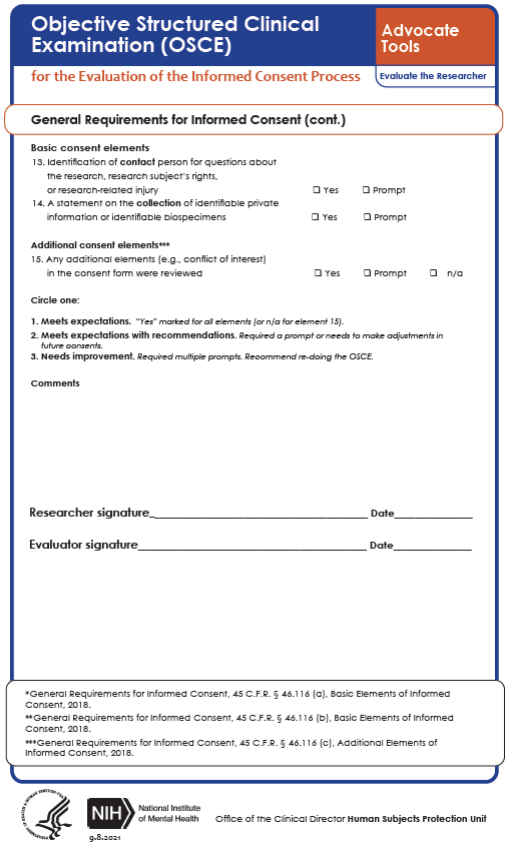

Objective Structured Clinical Examination (OSCE)

Advocate Tools

for the Evaluation of the Informed Consent Process

Evaluate the Researcher

General Requirements for Informed Consent (cont.)

Basic consent elements

13. Identification of **contact** person for questions about the research, research subject's rights, or research-related injury	❑ Yes	❑ Prompt	
14. A statement on the **collection** of identifiable private information or identifiable biospecimens	❑ Yes	❑ Prompt	

Additional consent elements***

15. Any additional elements (e.g., conflict of interest) in the consent form were reviewed	❑ Yes	❑ Prompt	❑ n/a

Circle one:

1. **Meets expectations.** *"Yes" marked for all elements (or n/a for element 15).*
2. **Meets expectations with recommendations.** *Required a prompt or needs to make adjustments in future consents.*
3. **Needs improvement.** *Required multiple prompts. Recommend re-doing the OSCE.*

Comments

Researcher signature_____ **Date**_____

Evaluator signature_____ **Date**_____

*General Requirements for Informed Consent, 45 C.F.R. § 46.116 (a), Basic Elements of Informed Consent, 2018.
**General Requirements for Informed Consent, 45 C.F.R. § 46.116 (b), Basic Elements of Informed Consent, 2018.
***General Requirements for Informed Consent, 45 C.F.R. § 46.116 (c), Additional Elements of Informed Consent, 2018.

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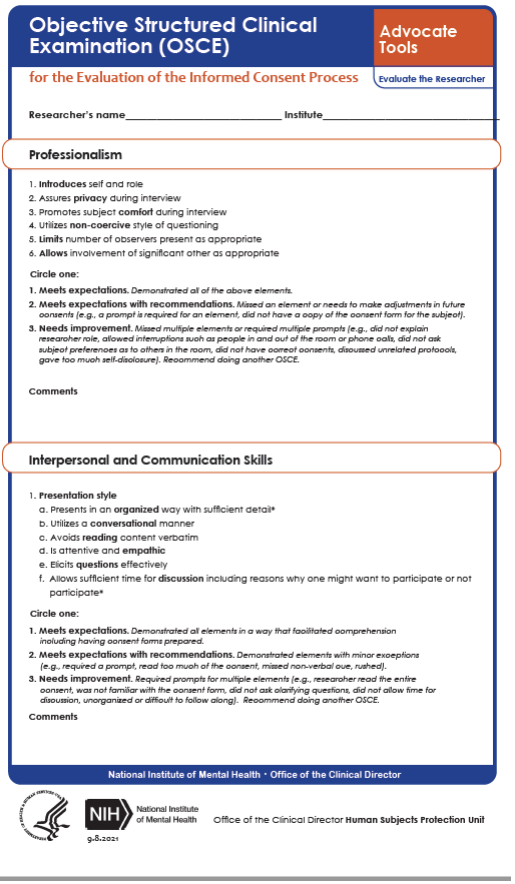

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Comments

Successful Consents

- Are discussions
- Are individualized
  - Health literacy
  - Previous participation
- Have a copy of the consent form for participant to follow along
- Allow time
- Are clear about who is giving consent
  - Participant or LAR
  - If a minor, one or both parents

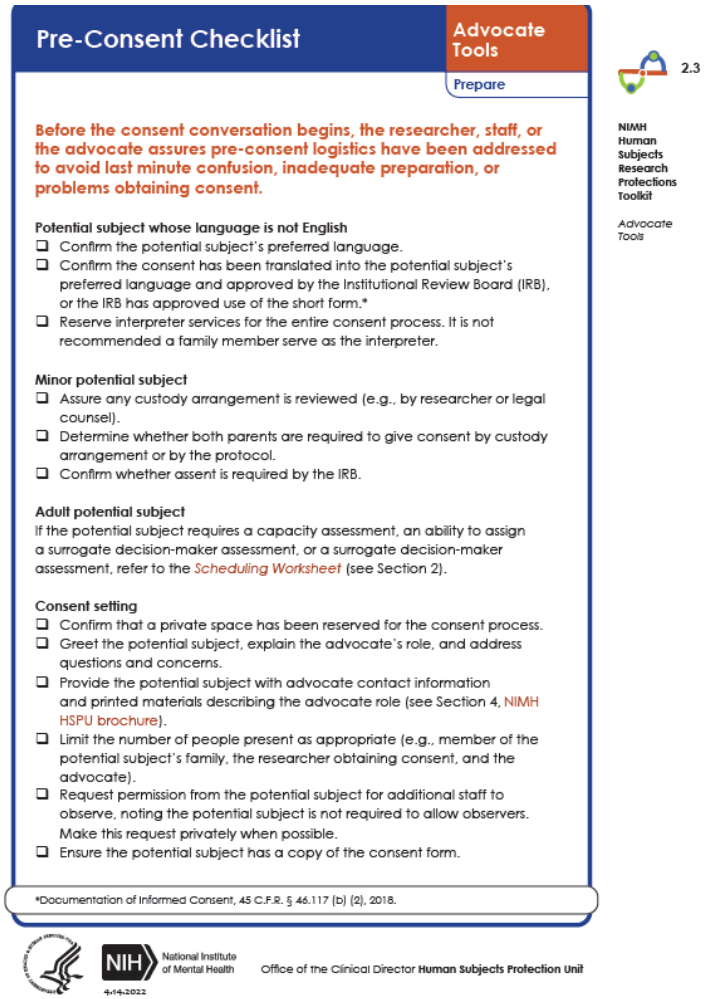
Common Pitfalls - Consent

- Reading
- Time
- Too many people in the room
- Participant doesn’t have a copy of consent to follow
- Not eliciting or answering questions
- Missing or not fully covering required elements
  - Limits of confidentiality
  - Overstating ancillary benefits
  - Identify research contact
  - Research related injuries
- Silence should not be construed as consent
- Documentation

Common Pitfalls - Assent

- Is it required?
- Is there a separate assent form?
- Documentation
- Dissent should be respected
  - Get a Bioethics consult if needed
- Consent at age of majority

Pre-Consent Checklist



Pre-Consent Checklist

Advocate Tools

Prepare

Before the consent conversation begins, the researcher, staff, or the advocate assures pre-consent logistics have been addressed to avoid last minute confusion, inadequate preparation, or problems obtaining consent.

Potential subject whose language is not English

- ❑ Confirm the potential subject's preferred language.
- ❑ Confirm the consent has been translated into the potential subject's preferred language and approved by the Institutional Review Board (IRB), or the IRB has approved use of the short form.*
- ❑ Reserve interpreter services for the entire consent process. It is not recommended a family member serve as the interpreter.

Minor potential subject

- ❑ Assure any custody arrangement is reviewed (e.g., by researcher or legal counsel).
- ❑ Determine whether both parents are required to give consent by custody arrangement or by the protocol.
- ❑ Confirm whether assent is required by the IRB.

Adult potential subject

If the potential subject requires a capacity assessment, an ability to assign a surrogate decision-maker assessment, or a surrogate decision-maker assessment, refer to the *Scheduling Worksheet* (see Section 2).

Consent setting

- ❑ Confirm that a private space has been reserved for the consent process.
- ❑ Greet the potential subject, explain the advocate's role, and address questions and concerns.
- ❑ Provide the potential subject with advocate contact information and printed materials describing the advocate role (see Section 4, NIMH HSPU brochure).
- ❑ Limit the number of people present as appropriate (e.g., member of the potential subject's family, the researcher obtaining consent, and the advocate).
- ❑ Request permission from the potential subject for additional staff to observe, noting the potential subject is not required to allow observers. Make this request privately when possible.
- ❑ Ensure the potential subject has a copy of the consent form.

*Documentation of Informed Consent, 45 C.F.R. § 46.117 (b) (2), 2018.

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2.3

NIMH Human Subjects Research Protections Toolkit

Advocate Tools

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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

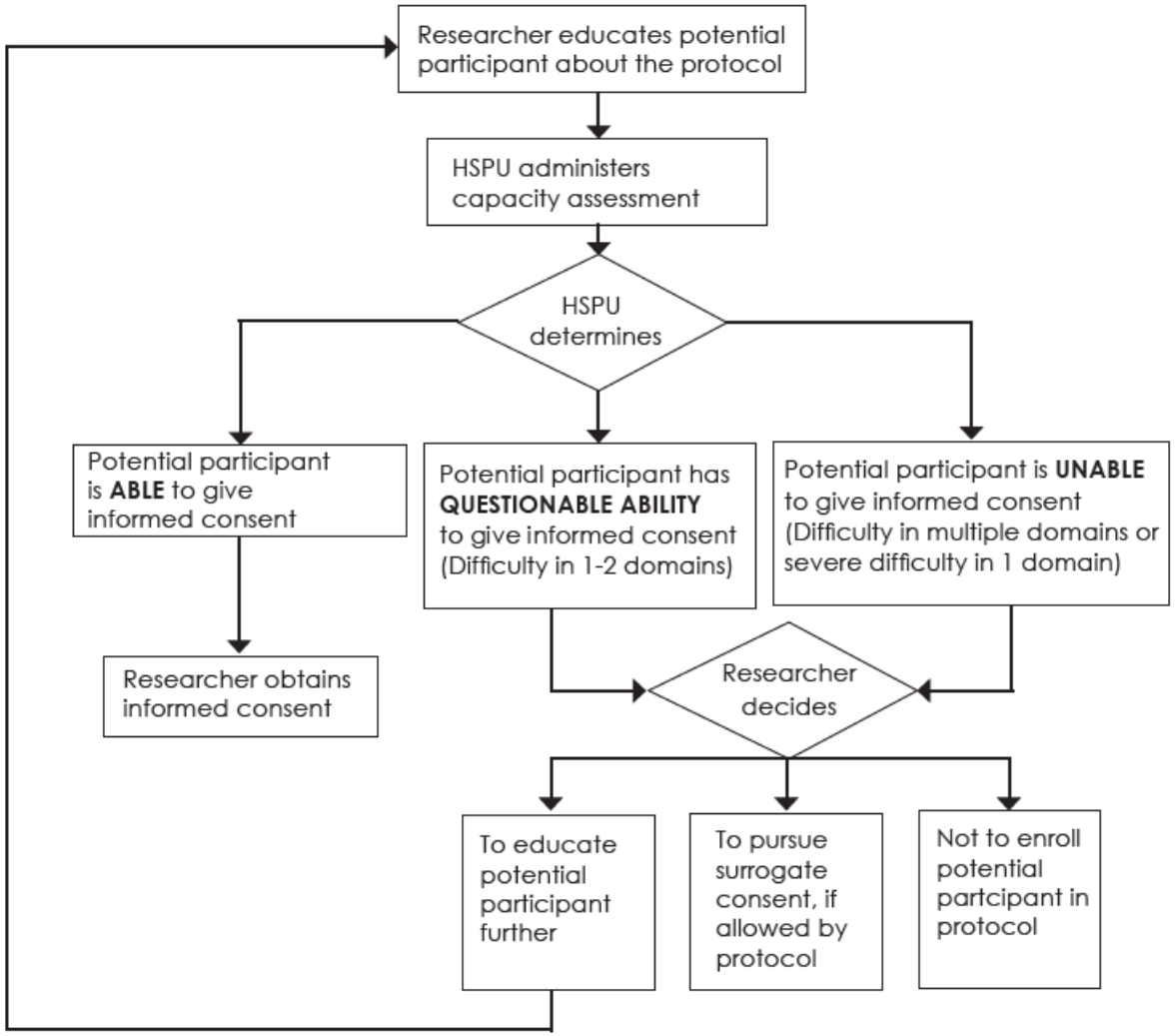
HSPU Capacity Assessments

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).

HSPU Capacity Assessment Algorithm



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

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

Hierarchy of LARs*

- Legal guardian (court appointed)
- 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

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

When to Consider Additional Protections

If any one of the following situations exists, developing a program with specific tools to enhance human subjects protections may be helpful.

Enhanced protections plans may be initiated by

NIMH Human Subjects Research Protections Toolkit

Developing Protections

Contact Information

HSPU Clinical Research Advocates

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