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

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

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Disclaimer

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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](http://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)
for the Evaluation of the Informed Consent Process

Instructions

This OSCE is used to evaluate a researcher’s ability to obtain informed consent from a potential subject who is eligible to participate in a specific protocol. Evaluation involves (in person or virtually) the consent process between researcher and the real or mock potential subject. The researcher is evaluated on:

- Professionalism
- Interpersonal and communication skills
- Required consent elements

The researcher begins the consent discussion with a self-introduction or explanation of the evaluator’s presence. For example:

“My name is __________ I am going to review the informed consent with you. The person accompanying me is evaluating me and will talk to us as we go along. However, my focus is on making sure you have all the information you need to make a decision about participating in the research.

The researcher reviews the consent form. For each section, the evaluator checks one of the following:

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 is missed) and notes feedback and observations in the comment section.

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 necessary improvement.

Interpersonal and Communication Skills

1. Presentation style
   a. Presents in an organized way with sufficient detail
   b. Uses nonverbal nonverbal
   c. Avoids reading content verbatim
   d. Is alert and appropriate
   e. Is direct and empathetic
   f. Allows sufficient time for discussion including reasons why one might want to participate

   Comments

Interpersonal and Communication Skills (cont.)

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

   Comments

Professionalism

1. Introduces self and role
2. Maintains privacy during interview
3. Promotes subject well-being during interview
4. Utilizes nonverbal cues of question
5. Limits number of responses
6. Allows involvement of significant other as appropriate

   Comments

General Requirements for Informed Consent

Basic consent elements
1. A statement that the study was research
2. A statement that participation is voluntary
3. An explanation of the purpose of the research
4. The expected duration of the subject’s participation
5. A description of the procedures to be followed
6. Identification of procedures that are experimental
7. A description of risks and discomforts
8. An explanation of any benefits to the subject or others
9. A discussion of appropriate alternative procedures or courses of treatment that might be advantageous
10. A statement that the confidentiality of records will be maintained
11. An explanation about compensation
12. An explanation about available medical treatments for a research-related injury

Comments

Objective Structured Clinical Examination (OSCE) for the Evaluation of the Informed Consent Process

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 adjustments in future consents (e.g., a prompt is required for an element, did not have a copy of the consent form for the subject).
3. Needs improvement. Missed multiple elements or required multiple prompts (e.g., did not explain assumptions/misunderstandings). Reviewing assumptions/misunderstandings with the consent form and/or the subject.

Comments

Interpersonal and Communication Skills

1. Presentation style
   a. Appears to be well organized and conversational
   b. Utilizes a conversational manner
   c. Avoids reading consent verbatim
   d. is clear and audible
   e. Clearly states the reason for discussion
   f. States sufficient time for discussion

Circle one:
1. Meets expectations. Demonstrated all elements in a way that facilitated comprehension, including having several forms prepared.
2. Meets expectations with recommendations. Demonstrated elements with minor exceptions (e.g., required at least three prompts, missed non-verbal cues, smiled).
3. Needs improvement. Required prompts for multiple elements (e.g., researcher did not ask the consent form, did not ask the subject, did not give time for discussion, explained or affirmed to other signs). Reviewing forms and interpersonal skills.

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

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
- Ensure 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, NIH HSFP 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 (D) (3), 2018.
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](http://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

HSPU Capacity Assessment Algorithm

1. Researcher educates potential participant about the protocol
2. HSPU administers capacity assessment
3. HSPU determines
   - Potential participant is ABLE to give informed consent
     - Researcher obtains informed consent
   - Potential participant has QUESTIONABLE ABILITY to give informed consent (Difficulty in 1-2 domains)
     - To pursue surrogate consent, if allowed by protocol
   - Potential participant is UNABLE to give informed consent (Difficulty in multiple domains or severe difficulty in 1 domain)
     - Not to enroll potential participant in protocol
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

*Next-of-kin (NOK)

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.

- Researchers will enroll potentially vulnerable populations as subjects
- Anticipated protocol is more than minimal risk and there is no prospect of direct benefit
- Anticipated research is controversial

Enhanced protections plans may be initiated by:

- Researcher request
- Organizational policy decision
- IRB requirement
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