

National Institute of Mental Health

Human Subjects Research Protections Toolkit



Advocate

SECTION

2

Tools



- Advocate Preparation
- Assessment Forms
- Monitoring Guides
- Evaluation of the Researcher



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8.1.19

Introduction

A human research protection program (HRPP), in part, aims to protect human research subjects. The National Institute of Mental Health (NIMH) protects potentially vulnerable **SUBJECTS** with **ADVOCATES** who support the individual subject as well as educate and advise **RESEARCHERS**.

This NIMH Toolkit for Human Subjects Research Protections is based on the NIMH's experience conducting research with potentially vulnerable subjects. Our aim is to help research organizations assess, implement, and refine appropriate levels of human subjects protections during all phases of research (submission of the initial protocol to the Institutional Review Board [IRB] through subject transition out of the protocol). Research organizations need to tailor these practices to suit their own standards and legal and policy requirements.



SUBJECTS
ADVOCATES
RESEARCHERS

Section 2: Advocate Tools provides tools and samples which can be adapted for specific protocols and for individual organizations implementing a human subjects protections program for potentially vulnerable subjects.

Email: nimhhspu@mail.nih.gov

Disclaimer: This NIMH Toolkit does not incorporate state or local law or organizational policies, nor does it address possible applicable federal law or speak to regulatory interpretation of 45 C.F.R. § 46. It does not address specifics for a particular type of protocol or IRB requirements. This Toolkit is the opinion of the NIMH intramural program and is subject to change.



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A protections program may include the following tools. An affirmative answer to any of the questions below indicates which tools to consider for integration into a protocol.

For example, if a new protocol includes a potentially vulnerable population and is more than minimal risk, the Institutional Review Board (IRB) or researcher may consider requiring a capacity assessment and consent monitoring.



Capacity Assessment

- Does the protocol include a potentially vulnerable subject population?
- Is the protocol more than minimal risk, without a prospect of direct benefit, and/or requires complex procedures?
- Is the subject's capacity expected to change over time?



Ability to Assign a Surrogate Decision-Maker Assessment

- If the potential subject without consent capacity does not have an identified surrogate, does organizational policy allow the potential subject to assign one?



Surrogate Decision-Maker Assessment

- Does the protocol allow for surrogate decision-maker consent?



Consent Monitoring

- Does the protocol include a potentially vulnerable subject population?
- Is the protocol more than minimal risk, without a prospect of direct benefit, and/or requires complex procedures?



Assent Monitoring

- Does the protocol include a potentially vulnerable subject population?
- Is the protocol more than minimal risk, without a prospect of direct benefit, and/or requires complex procedures?
- Does the protocol include adult subjects without consent capacity?
- Does the protocol allow for the enrollment of minors?



Subject Monitoring

- Is this an inpatient or longer-term protocol?
- Does the protocol include a potentially vulnerable subject population?
- Is the protocol more than minimal risk and/or requires complex procedures?
- Is the subject's capacity expected to change over time?
- Is symptom worsening expected?



The researcher requests an assessment by contacting the advocate.

The researcher provides the following information:

- Date, time, and location of the assessment(s)
- Potential subject's name
- Type of assessment(s) requested (e.g., capacity assessment, ability to assign a substitute decision-maker assessment, surrogate decision-maker assessment)
- Protocol number
- Potential subject's preferred language
- Interpreter services scheduled
- Copy of the consent
- Access to the protocol, if needed
- Risk level of the research
- Benefit level of the research
- Confirmation the researcher obtaining consent is approved by the Institutional Review Board (IRB) to do so

For capacity assessments, confirm

- The researcher educated the potential subject about the protocol.
- The potential subject was given an explanation of the upcoming assessment(s).

For protocols allowing surrogate consent, confirm

- The surrogate decision-maker is authorized to consent to the research (e.g., review by legal counsel of the potential subject's guardianship order, advance directive [AD], durable power of attorney [DPA] for healthcare, or living will documents).
- The potential subject and the surrogate decision-maker were given an explanation of the upcoming assessment(s).
- The surrogate decision-maker will be present for the consent process.

The advocate schedules the assessment allowing adequate time to create an unhurried environment.



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 preferred 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 and family (if present), explain the advocate's role, and address their 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.

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

Capacity Assessment: Protocol-Specific

Advocate Tools

These responses have been created for an NIMH Alzheimer's Disease protocol. You must create expected responses to reflect your protocol. This tool is clinically derived. It is not validated.

Assess



2.4

Instructions for NIMH Clinical Research Advocates (CRAs)

CRAs must be trained before administering this assessment.

Prepare for the assessment

- Use two trained CRAs to assess the potential subject. Use one CRA if circumstances dictate (e.g., the potential subject is highly anxious).
- Designate one CRA as the interviewer. Both CRAs are raters, and each rater completes a copy of the assessment form.
- Allow observers only when necessary.

Administer the assessment

- Explain the purpose of the assessment. Inform the potential subject you will take notes during the interview.
- The format of the interview is conversational and does not require the questions to be read verbatim.
- The domain descriptions (Understanding, Appreciation, Reasoning, Choice) are for your reference. Do not read them aloud.
- If the potential subject gives the expected information, check the box and proceed to the next question. If not, provide the prompt. You may need to ask clarifying questions.
- If the potential subject clearly does not have capacity, stop this assessment and transition to the next assessment if necessary (e.g., *Ability to Assign a Surrogate Decision-Maker*).

Rate the responses

During the assessment

- Complete **Rater's Comments**. Enter comments, concerns, and recommendations. Note when prompting is required.
- Complete **Rater Scale**. (Question 9 has no scale.) These numbers are not tallied as a score. Indicate the level of understanding by marking the appropriate description:
 - 1 = Understands
 - 2 = Has partial understanding
 - 3 = Does not understand

After the assessment, without the potential subject present

- Complete the **Global Impressions** section. Indicate ability to give informed consent by marking the appropriate description:
 - A ABLE**
 - B QUESTIONABLE ABILITY**
 - C UNABLE**
- Resolve any differences between raters to determine an outcome.
- **Interviewer only:** enter the outcome and plan on the form.
- Document the outcome and plan according to organizational policy.

The CRA or researcher, as appropriate, informs the potential subject of the outcome.

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Capacity Assessment: Protocol-Specific

Advocate Tools

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Assess



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Examples of capacity assessment outcomes and plans

A ABLE

- Researcher may obtain consent
- Recommend the researcher remind the subject that if he later changes his mind about participating that decision will be respected

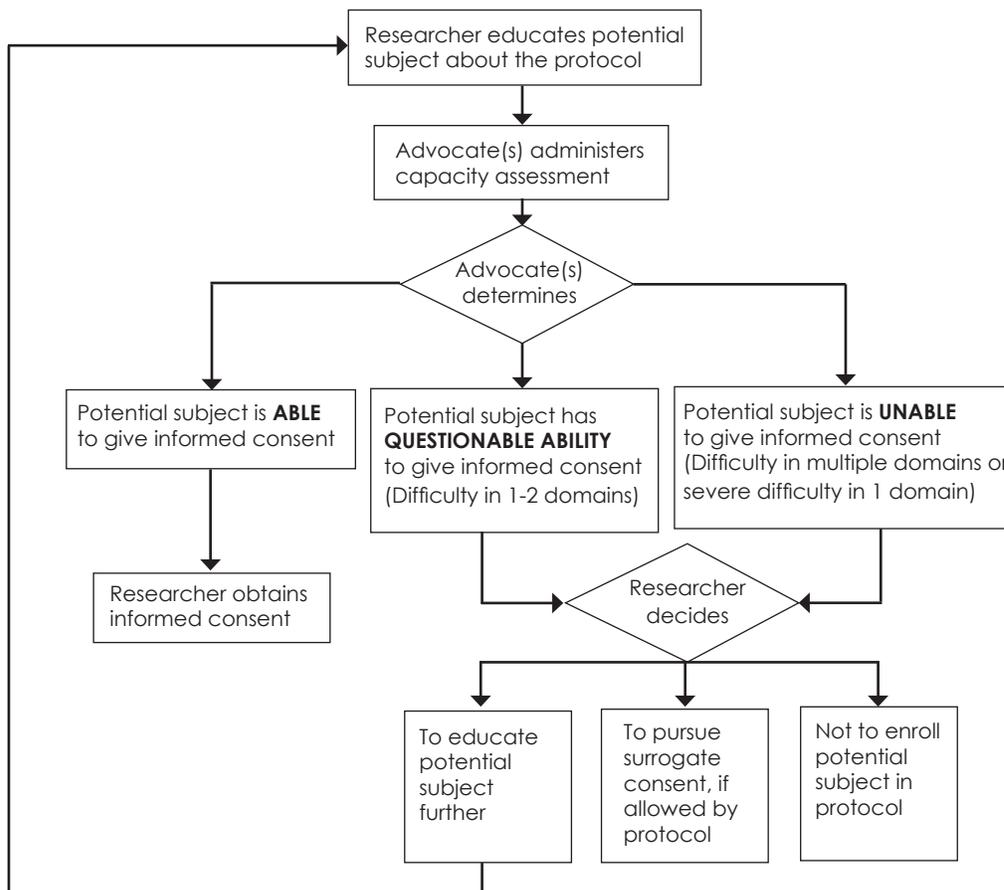
B QUESTIONABLE ABILITY

- Recommend further education in domains where difficulty was noted
- Re-assess

C UNABLE

- Researcher may pursue surrogate consent as allowed in this protocol
- Assess ability to assign a surrogate decision-maker
- Assess appropriateness of the surrogate

Capacity assessment algorithm



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Capacity Assessment: Protocol-Specific

Advocate Tools

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Assess

Protocol number _____ Date _____

Potential subject _____ Age _____

Interviewer _____ Rater _____

Is there a legal guardian? _____



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UNDERSTANDING *of disclosed information about the nature of the research project and its procedures**

1. What is the purpose of this research and who is being studied?

- Expected: To evaluate people with signs and symptoms of Alzheimer's Disease and determine whether they qualify for other studies

Prompt: *The purpose of this study is to evaluate people with signs of memory loss to see if they qualify for other studies.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

2. What are some of the things you will be asked to do during this study?

- Expected: Tests, such as blood draws, brain scans (MRI and PET), and cognitive testing

Prompt: *During the study the researchers will ask you to do brain scans, blood draws, and paper-and-pencil tasks.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

3. What are the most significant risks to you during this study?

- Expected: Discomfort from the blood draws, intravenous catheter placement, radiation exposure, and claustrophobia while in the scanner(s)

Prompt: *The possible risks associated with this study include discomfort during blood draws, IV placement, minimal radiation exposure, and claustrophobia while lying in the scanner.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

4. What benefits might you receive as a result of participating in this study?

- Expected: No direct benefit

Prompt: *This study will not treat your symptoms. By participating you may help others in the future.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____



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Capacity Assessment: Protocol-Specific

Advocate Tools

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Assess



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APPRECIATION *of the effects of research participation (or failure to participate) on subjects' own situations**

5. How is being in this study different from going to your regular doctor?

- Expected: This research does not provide ongoing clinical care.
- Expected: Your regular doctor will treat your symptoms.
- Expected: You would not do research tasks such as the PET scan for clinical care.

Prompt: *There are differences between participating in research versus receiving regular medical care in the community. This research does not treat your memory problems. Your regular doctor provides continuous treatment and medicine.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

REASONING *in the process of deciding about participation, focusing on subjects' abilities to compare alternatives in light of their consequences**

6. Based on what we discussed, why are you interested in participating in this study?

- Expected: Raters assess whether the subject is able to use information from questions 1-5 to decide on participation in this protocol (e.g., I know this study won't benefit me, but I want to learn more about Alzheimer's and contribute to future treatment).

Prompt: *The information we have discussed will help you decide whether to participate in this study.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

7. What would you do for treatment if you decide not to participate in this study?

- Expected: Continue care in the community

Prompt: *There are alternatives to participating in this study, including continuing care with your regular doctor.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

CHOICE *expressing a choice about research participation**

8. Whose decision is it to enter this study?

- Expected: Mine

Prompt: *Research participation is voluntary. It is your choice to participate or not at any time during the study.*

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____



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Capacity Assessment: Protocol-Specific

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Assess



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9. Have you decided to enroll in this study? Yes No

Please tell us why _____

What would happen if you choose not to participate in this study?

Rater's Comments _____

10. How would you let us know if you wanted to stop participating in this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

GLOBAL IMPRESSIONS

- A **ABLE** to give informed consent at this time
- B **QUESTIONABLE ABILITY** to give informed consent at this time
- C **UNABLE** to give informed consent at this time

Identify any specific concerns for each domain.

Understanding _____

Appreciation _____

Reasoning _____

Choice _____

Signature of Rater _____

INTERVIEWER ONLY: Raters' final determination

- A **ABLE** to give informed consent at this time
- B **QUESTIONABLE ABILITY** to give informed consent at this time
- C **UNABLE** to give informed consent at this time

PLAN _____

*Paul S. Appelbaum and Thomas Grisso, *MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)* (Sarasota, FL: Professional Resource Press, 2001), 1. Domain names and definitions used with permission.



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Capacity Assessment: Generic

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Assess

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2.9

Instructions for NIMH Clinical Research Advocates (CRAs)

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Prepare for the assessment

- Use two trained CRAs to assess the potential subject. Use one CRA if circumstances dictate (e.g., the potential subject is highly anxious).
- Prior to the assessment, determine the expected responses for each question.
- Designate one CRA as the interviewer. Both CRAs are raters, and each rater completes a copy of the assessment form.
- Allow observers only when necessary.

Administer the assessment

- Explain the purpose of the assessment. Inform the potential subject you will take notes during the interview.
- The format of the interview is conversational and does not require the questions to be read verbatim. You may need to ask clarifying questions.
- The domain descriptions (Understanding, Appreciation, Reasoning, Choice) are for your reference. Do not read them aloud.
- If the potential subject gives the expected information, proceed to the next question. If not, provide a prompt and re-ask the question.
- If the potential subject clearly does not have capacity, stop this assessment and transition to the next assessment if necessary (e.g., *Ability to Assign a Surrogate Decision-Maker*).

Rate the responses

During the assessment

- Complete **Rater's Comments**. Enter comments, concerns, and recommendations. Note when prompting is required.
- Complete **Rater Scale**. (Questions 12-14 have no scale.) These numbers are not tallied as a score. Indicate the level of understanding by marking the appropriate description:
 - 1 = Understands
 - 2 = Has partial understanding
 - 3 = Does not understand

After the assessment, without the potential subject present

- Complete the **Global Impressions** section. Indicate ability to give informed consent by marking the appropriate description:
 - A ABLE**
 - B QUESTIONABLE ABILITY**
 - C UNABLE**
- Resolve any differences between raters to determine an outcome.
- **Interviewer only:** enter the outcome and plan on the form.
- Document the outcome and plan according to organizational policy.

The CRA or researcher, as appropriate, informs the potential subject of the outcome.

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Examples of capacity assessment outcomes and plans

A ABLE

- Researcher may obtain consent
- Recommend the researcher remind the subject that if he later changes his mind about participating that decision will be respected

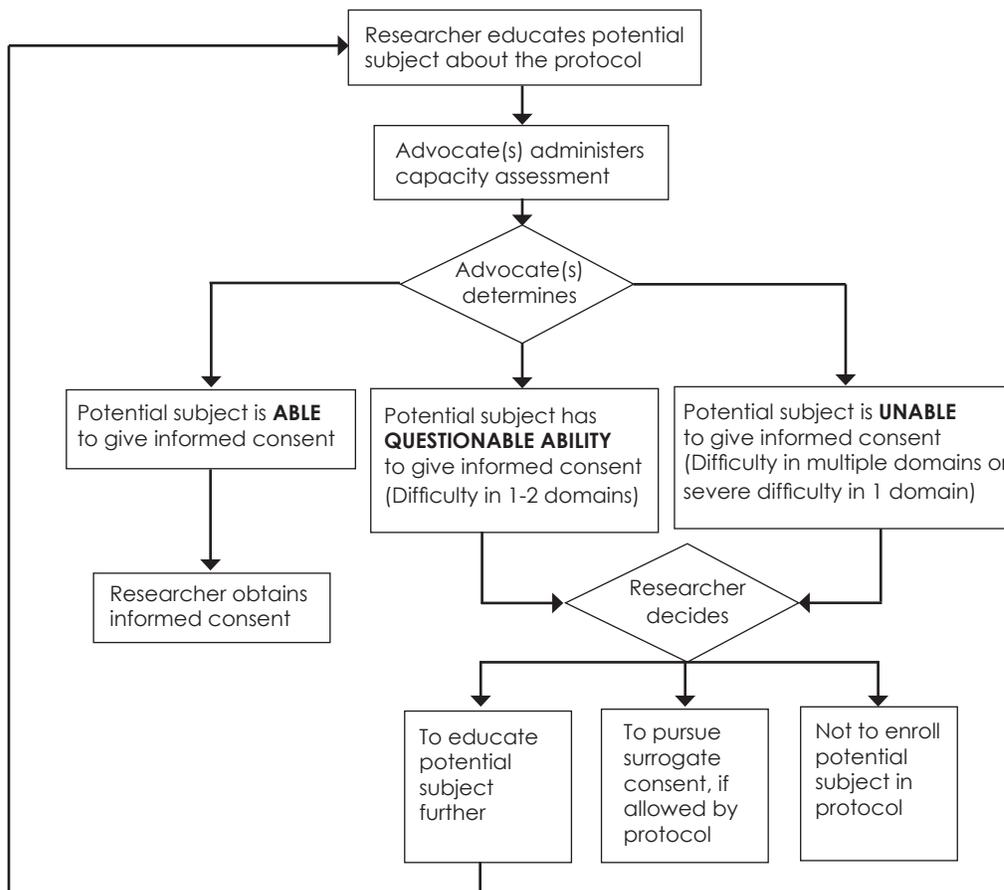
B QUESTIONABLE ABILITY

- Recommend further education in domains where difficulty was noted
- Re-assess

C UNABLE

- Researcher may pursue surrogate consent as allowed in this protocol
- Assess ability to assign a surrogate decision-maker
- Assess appropriateness of the surrogate

Capacity assessment algorithm



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Protocol number _____ Date _____

Potential subject _____ Age _____

Interviewer _____ Rater _____

Is there a legal guardian? _____



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UNDERSTANDING *of disclosed information about the nature of the research project and its procedures**

1. What made you decide to come here?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

2. What are the researchers attempting to learn with this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

3. What are some of the things you will be asked to do during this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

4. What are the most significant risks to you during the study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

5. What benefits might you receive as a result of participating in this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

APPRECIATION *of the effects of research participation (or failure to participate) on subjects' own situations**

6. How is being in this study different from going to your regular doctor?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

7. How will being in this study affect your routine?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____



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Capacity Assessment: Generic

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REASONING *in the process of deciding about participation, focusing on subjects' abilities to compare alternatives in light of their consequences**

8. What are the alternatives to participating in this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

9. Based on what we discussed, why are you interested in participating in this study?

Raters assess whether the subject is able to use information from questions 1-5 to decide on participation in this protocol (e.g., I know this study won't benefit me, but I want to learn more about my illness and contribute to future treatment).

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

CHOICE *expressing a choice about research participation**

10. Whose decision is it to enter this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

11. How would you let us know if you wanted to stop participating in this study?

Rater's Comments _____

Rater Scale 1 _____ 2 _____ 3 _____

12. Have you decided to enroll in this study? Yes No

13. Please tell us why _____

Rater's Comments _____

14. What would happen if you choose not to participate in this study?

Rater's Comments _____

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GLOBAL IMPRESSIONS

- A ABLE** to give informed consent at this time
- B QUESTIONABLE ABILITY** to give informed consent at this time
- C UNABLE** to give informed consent at this time

Identify any specific concerns for each domain.

Understanding _____

Appreciation _____

Reasoning _____

Choice _____

Signature of Rater _____

INTERVIEWER ONLY: Raters' final determination

- A ABLE** to give informed consent at this time
- B QUESTIONABLE ABILITY** to give informed consent at this time
- C UNABLE** to give informed consent at this time

PLAN _____



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Ability to Assign a Surrogate Decision-Maker Assessment

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This tool assumes assent is required. Adapt the tool according to your protocol requirements (e.g., assent is not required) and organizational policy. This tool is clinically derived. It is not validated.

Assess



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Background

Some adults who are unable to consent for themselves and do not have a previously assigned surrogate or legal guardian may still be capable of assigning a surrogate through an advance directive (AD). This tool describes a process for assessing a potential subject's ability to assign a surrogate and the steps for obtaining surrogate consent and potential subject assent (if required).

The ability to assign a surrogate

- Does not require consent capacity for research
- Ideally, requires that potential subjects be able to understand the unique nature of research as different from other activities
- Requires that potential subjects be able and willing to choose whom they want to make research decisions with them

A surrogate may have the authority to make decisions for a specific protocol or a range of protocols. Assigning a surrogate does not commit the potential subject to participation or non-participation in a protocol.

Prior to obtaining surrogate consent, the appropriateness of the surrogate should be assessed.

Process

To assign a surrogate, the potential subject should

- A. Understand that
 - The goal of the research is to learn something that may help others
 - Some or all of the research procedures may offer no chance of individual benefit
 - Research procedures can involve discomfort and risk
 - Decisions about research participation and the procedures done as part of the research will be made by the surrogate
 - The potential subject retains the right to say no to research participation or to specific procedures
- B. Be able to identify a person to make decisions for them while in a protocol



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Ability to Assign a Surrogate Decision-Maker Assessment

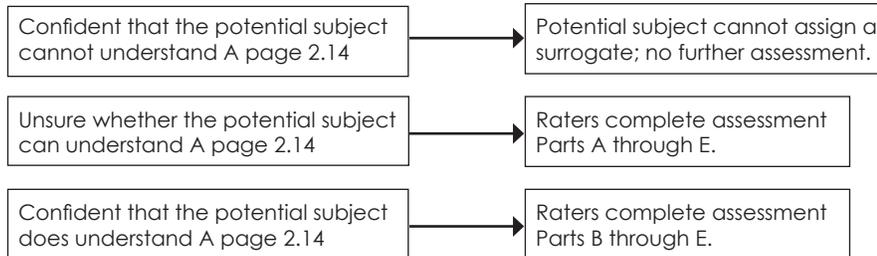
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Assess

This tool assumes assent is required. Adapt the tool according to your protocol requirements (e.g., assent is not required) and organizational policy. This tool is clinically derived. It is not validated.

In many cases, the assessment of a potential subject's ability to assign a surrogate will occur shortly after the potential subject was determined not to have the capacity to consent to research.

Based on the capacity assessment, if the raters are



Instructions

- Use one or two independent, trained raters to administer the assessment.
- One rater is designated the interviewer and completes the form.
- Ideally, raters are familiar with the specific protocol, the study population, and any information available about the potential subject.
- The assessment is conducted in a private space, with the fewest observers present, and without the potential surrogate (as appropriate).
- Document the assessment outcome according to organizational policy.



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Ability to Assign a Surrogate Decision-Maker Assessment

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Assessment

Potential subject _____ Date _____

Interviewer _____ Rater _____

Raters must be trained before administering this assessment. The following is a guide to help determine a potential subject's ability to assign a surrogate and includes items to be considered that may go beyond the legal requirement. The interviewer should omit questions or probe more deeply depending on the discussion and circumstances specific to each assessment.

Begin the assessment with a brief introduction. For example

You have been invited to be part of a research study. I am here to discuss who you would like to make decisions with you about enrolling.

Part A Probe understanding of the nature of research

What we do in research is different in an important way from what happens when you see a doctor somewhere else. We are doing studies to learn something that might help other people and may not help you get better.

- *Does that make sense?* _____
- *Can you tell me in your own words what we are trying to do through this study?* _____

Some of the things we are doing in this study may be similar to what your doctor at home does (insert something specific from the protocol, e.g., taking blood or having an x-ray). These things can sometimes hurt or pose some risks (insert something specific from the protocol, e.g., infection or nausea).

- *Does that make sense to you?* _____
- *How do you feel about doing things that may have risks or discomfort to try to help other people?* _____
- *Is it OK if researchers ask you questions to learn something that might help others?* _____
- *Are you willing to (insert something specific from the protocol, e.g., have blood drawn or take medicine) that wouldn't help you so that we could learn something that might help others?* _____



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Ability to Assign a Surrogate Decision-Maker Assessment

Advocate Tools

Assess

This tool assumes assent is required. Adapt the tool according to your protocol requirements (e.g., assent is not required) and organizational policy. This tool is clinically derived. It is not validated.

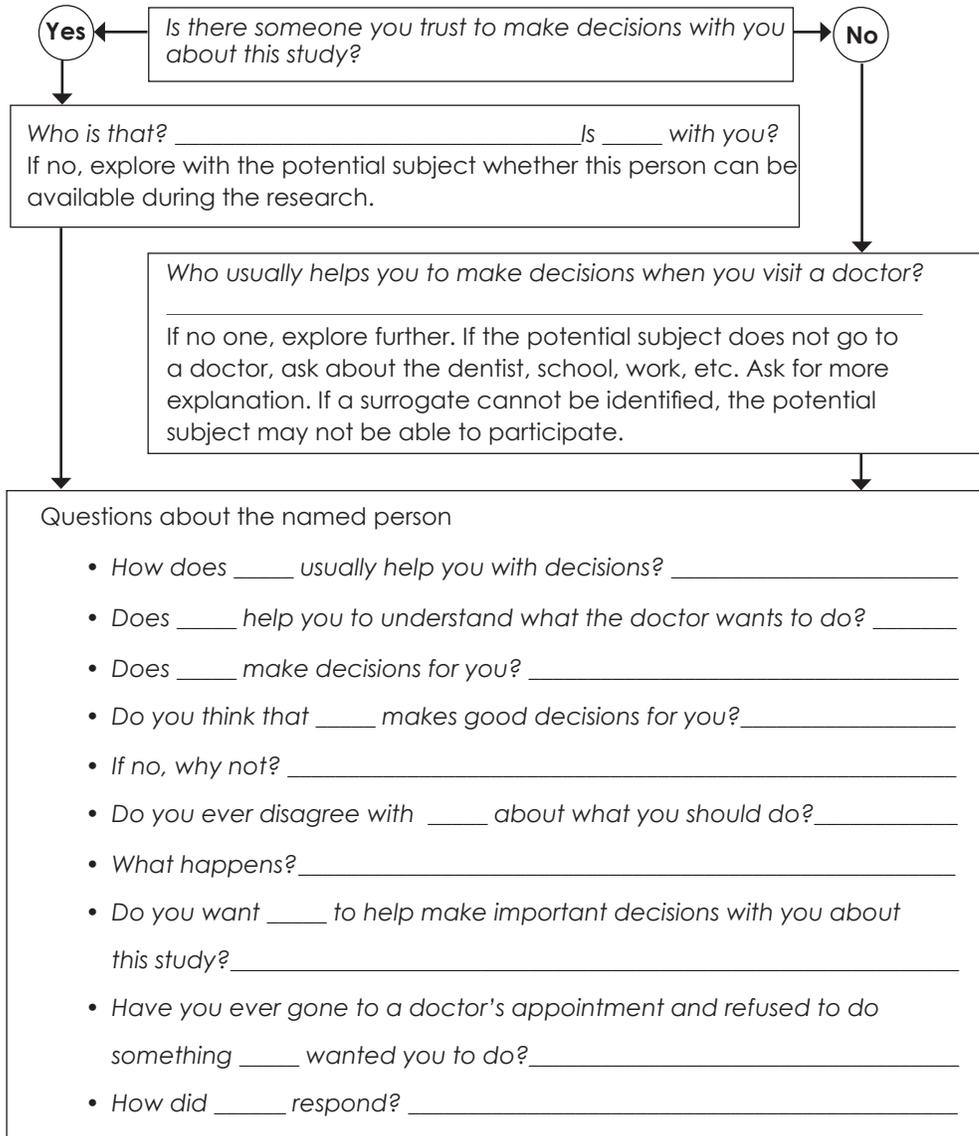


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Part B Choose a surrogate decision-maker



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Ability to Assign a Surrogate Decision-Maker Assessment

Advocate Tools

Assess

This tool assumes assent is required. Adapt the tool according to your protocol requirements (e.g., assent is not required) and organizational policy. This tool is clinically derived. It is not validated.

Part C Additional questions

Please remember that you can say no to something you do not want to do.

- Is there anything you can think of that you would not want to do or have done while you are here? _____
- Is there anything that has been discussed that you are worried about?

- Have you talked with _____ about what you might be willing or not willing to do here? _____
- How would _____ know if you did not want to do something? _____
- Can you talk to _____ about what you would and would not want to do? _____

Part D Research questions

Would you like _____ to make decisions for you

- Only for the study that we are talking about today
- For research more generally

This discussion may include different types of research (e.g., minimal risk, no prospect of direct benefit, etc.).

Part E Document

- Provide assessment outcome to researcher and surrogate as appropriate.
- If the potential subject is found able to assign a surrogate, complete the appropriate document (e.g., AD).
- Document assessment outcome according to organizational policy.

If the potential subject is found able to assign a surrogate, administer the *Surrogate Decision-Maker Assessment* to evaluate the appropriateness of this person to serve as the potential subject's research surrogate.



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Surrogate Decision-Maker Assessment

Advocate Tools

This tool uses a basic format. You must adapt your tool according to your protocol requirements and organizational policy. This tool is clinically derived. It is not validated.

Assess

Surrogate name _____ Date _____

Relationship to potential subject _____ Protocol number _____

Type of surrogate _____

Interviewer _____ Rater _____

Instructions

- Administer this assessment after a surrogate decision-maker has been identified by legal and/or organizational procedure.
- Raters must be trained before administering this assessment.
- This assessment is administered by one or two independent raters.
- One rater is designated the interviewer.
- The interviewer should omit questions or probe more deeply depending on the discussion and circumstances specific to each assessment.
- A rater documents the assessment outcome according to organizational policy.
- In this assessment, surrogate = the surrogate decision-maker;
X = the potential subject.

Domain 1 Does the surrogate understand that the protocol involves research?

Finding: Sufficient Insufficient

Goal: Determine whether the surrogate understands that research is different from clinical care. The surrogate should understand that an important goal of research is to benefit others. The surrogate should also understand if the research is non-beneficial.

Sample questions:

- *What is the study about?* _____
- *What procedures are involved?* _____
- *Are you aware that some procedures are for research to help others in the future and may not benefit X?* _____
- *What do you think about that?* _____



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Surrogate Decision-Maker Assessment

Advocate Tools

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Assess



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Domain 2 Does the surrogate understand the risks, benefits, and alternatives?

Finding: Sufficient Insufficient

Goal: Determine whether the surrogate understands the risks and appreciates the likelihood that X could be hurt as a result of research participation.

Sample questions:

- *Is there any chance X could be hurt or something bad could happen from the research?*

- *What could happen, and how likely is it?*

- *If something did happen, how would this affect X?*

Goal: Determine whether the surrogate knows the potential benefits of the protocol. If the protocol offers no prospect of direct benefit, the surrogate must understand this.

Sample questions:

- *What is the chance that X will benefit from being in the study?*

- *In what way might X benefit?*

- *Is there a chance that the study will not benefit X?*

Goal: Determine whether the surrogate knows the alternatives to research participation and that enrolling X in the protocol is voluntary.

Sample questions:

- *What would X do if X did not enroll in the study?*

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Surrogate Decision-Maker Assessment

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Assess

- Can you decide not to enroll X?

- If X enrolls can you withdraw X at any time?

Domain 3 Does the surrogate have sufficient evidence that participation in the protocol is consistent with the potential subject's values and preferences?

Finding: Sufficient Insufficient

Goal: Determine whether the surrogate is sufficiently familiar with X and X's medical history to be making decisions on X's behalf now.

Sample questions:

- What do you know about X's medical history (e.g., doctors, treatments, procedures, and hospitals)?

- Have you talked to X about participating in research? When?

Goal: Determine whether the surrogate will appropriately involve X in decision-making, will respect X's dissent when appropriate, and will involve others in decision-making if appropriate.

Sample questions:

- How do you and X make decisions together (if applicable)?

- How does X usually make decisions about treatment?

- Do you and X ever have disagreements about medical care?



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Surrogate Decision-Maker Assessment

Advocate Tools

Assess

This tool uses a basic format. You must adapt your tool according to your protocol requirements and organizational policy. This tool is clinically derived. It is not validated.

- How have you resolved differences of opinion in the past?

- Can X say no to things X does not like?

- Is there anyone you would consult in making decisions about X who knows about X's values?

Goal: Determine whether the surrogate knows if X has preferences or values that are consistent with research participation.

Sample questions:

- How willing is X to do things that pose risks?

- Does X think it's important to help others?

- Do you think X would want to help others through research?

- What makes you think that X will be OK with research participation?

Goal: Determine whether the surrogate will consider X's relevant preferences, values, and interests and will make the choice that X would have made, if that is clear, or base the decision on X's best interests.

Sample questions:

- What would help guide your decision about enrolling X?

- What decision would X make?

- Why do you think that?



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Surrogate Decision-Maker Assessment

Advocate Tools

This tool uses a basic format. You must adapt your tool according to your protocol requirements and organizational policy. This tool is clinically derived. It is not validated.

Assess

- How would you know if X did not want to participate in the study?

Domain 4 Is the surrogate appropriate, able, and willing to serve as an advocate?

Finding: Sufficient Insufficient

Goal: Evaluate whether the surrogate is appropriate, able, and willing to advocate for X's interests when interacting with the research team.

Sample questions:

- Do you feel comfortable making decisions for X?

- If not, what makes you uncomfortable?

- What would make you say no to X participating in the research?

- Is there a chance that you might benefit from having X participate in this study?

- Are you willing to serve as a surrogate for X?

- Are you available to serve as a surrogate for X?



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Surrogate Decision-Maker Assessment

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This tool uses a basic format. You must adapt your tool according to your protocol requirements and organizational policy. This tool is clinically derived. It is not validated.

Assess



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Closing questions

- Do you have any questions?

- Was there anything you were told about the study that was unclear?

- Have your questions been answered?

- Is there anything else you would like to know?

- If you have any issues that come up in the future, or if there is something you become less comfortable with, please feel free to call me (provide contact information).

Summary of findings

- | | | |
|---|-------------------------------------|---------------------------------------|
| • Surrogate understands protocol involves research | <input type="checkbox"/> Sufficient | <input type="checkbox"/> Insufficient |
| • Surrogate understands risks, benefits, and alternatives | <input type="checkbox"/> Sufficient | <input type="checkbox"/> Insufficient |
| • Surrogate has evidence that participation is consistent with X's values/preferences/interests | <input type="checkbox"/> Sufficient | <input type="checkbox"/> Insufficient |
| • Surrogate is comfortable/willing/able to serve as substitute decision-maker | <input type="checkbox"/> Sufficient | <input type="checkbox"/> Insufficient |

Additional comments _____



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Consent Monitoring Checklist

Advocate Tools

Monitor



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This checklist is a tool to use with the potential subject or surrogate decision-maker to assure all parts of the consent process are completed.

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Before the consent

- Assure the consent and/or assent discussion takes place in a quiet, private space.
- Assure the correct version of consent and/or assent is used.

During the consent

- Pay attention to non-verbal communication.
- Observe the potential subject's understanding of the information presented. If the potential subject does not understand, know the next steps to take (e.g., consider stopping and moving to a capacity assessment).
- Assure all required consent elements* are reviewed and discussed by the researcher and the potential subject. Additional situational elements may be required.†
 - Purpose of the research
 - Participation is voluntary
 - Expected duration of participation
 - Protocol procedures
 - Potential risks and discomforts
 - Potential benefits
 - Identification of experimental procedures
 - Alternative treatments
 - Confidentiality including exceptions (e.g., mandated reporting)
 - Research related injury
 - Compensation
 - Researcher contact information
 - A statement on the collection of identifiable private information or identifiable biospecimens
- Ask whether the potential subject has any further questions or concerns.
- Ask whether the potential subject wants to participate in the research.
- Confirm the researcher, the potential subject, and the witness sign the correct version of consent and/or assent document(s).

*General Requirements for Informed Consent, 45 C.F.R. § 46.116 (b), 2018. Your IRB may require additional elements.

†General Requirements for Informed Consent, 45 C.F.R. § 46.116 (c), 2018.



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Consent Monitoring Checklist

Advocate
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Monitor



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After the consent

- Encourage the potential subject to ask questions of the researchers throughout the protocol, not just during the consent process.
- Remind the potential subject that a decision to participate may be changed any time, even after signing consent.
- Document the consent process according to organizational policy.
- Give the subject a copy of the signed consent.

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The questions below are suggestions to guide a conversation with the subject about the ongoing research experience. The advocate documents according to organizational policy.

Does the subject know what and how many procedures remain to be done?

How has the experience been so far?

Does the subject have any questions or concerns?

If so, have the questions or concerns been communicated to the team or appropriate persons?

Does the subject want to continue in the research?



Objective Structured Clinical Examination (OSCE)

Advocate Tools

for the Evaluation of the Informed Consent Process

Evaluate the Researcher



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Instructions

The OSCE is used to evaluate an examinee's ability to obtain informed consent from a potential subject who is eligible to participate in a specific protocol. The examiner observes the consent process between the examinee and a real or mock potential subject. The examinee is evaluated in three areas:

- Professionalism
- Interpersonal and communication skills
- Required consent elements

The examinee leads the evaluation by stating

My name is _____. I am going to review the informed consent form with you. The person accompanying me is evaluating me and will take notes 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 this study.

As the examinee reviews the consent, the examiner marks acceptable or unacceptable for each item on the evaluation form.

Example of an acceptable rating

The examinee begins by closing the door, introducing herself, and states the purpose of the consent discussion.

Example of an unacceptable rating

The examinee is unfamiliar with the protocol consent, is reading it verbatim, and is missing the potential subject's non-verbal expression of confusion.

If an element is missed, the examiner reminds the examinee to review the missed element. If an element is not applicable to the protocol being discussed, such as there are no risks, then the person obtaining consent states there are no anticipated risks.

The OSCE results and feedback are shared with the examinee. Verbal or written feedback should specifically address any unacceptable ratings and provide ways in which to improve.

Additional OSCEs are scheduled as needed to demonstrate the examinee's improvement.

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Objective Structured Clinical Examination (OSCE)

Advocate Tools

for the Evaluation of the Informed Consent Process

Evaluate the Researcher

Examinee name _____ Institute _____

Professionalism

- | | | | |
|--|---------------------------------------|-------------------------------------|------------------------------|
| 1. Introduces self and department/institute affiliation | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable | |
| 2. Assures privacy during interview | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable | |
| 3. Promotes subject comfort during interview | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable | |
| 4. Utilizes non-coercive style of questioning | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable | |
| 5. Limits number of observers present as appropriate | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable | <input type="checkbox"/> N/A |
| 6. Allows involvement of significant other if subject desires | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable | <input type="checkbox"/> N/A |

Other comments

Interpersonal and Communication Skills

1. Presentation style

- | | | |
|---|---------------------------------------|-------------------------------------|
| a. Utilizes a conversational manner | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| b. Avoids reading content verbatim | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| c. Attentive and empathic | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| d. Elicits questions effectively | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| e. Allows sufficient time for discussion | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |

Other comments

2. Body and verbal language

- | | | |
|--|---------------------------------------|-------------------------------------|
| a. Maintains eye contact | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| b. Utilizes subject's preferred language , appropriate to education level | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |

Other comments

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Objective Structured Clinical Examination (OSCE)

Advocate Tools

for the Evaluation of the Informed Consent Process

Evaluate the Researcher



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Required Basic Consent Elements*

Informed consent process includes

- | | | |
|--|---------------------------------------|-------------------------------------|
| 1. A statement that the study involves research | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 2. A statement that participation is voluntary | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 3. An explanation of the purposes of the research | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 4. The expected duration of the subject's participation | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 5. A description of the procedures to be followed | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 6. Identification of procedures that are experimental | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 7. A description of risks or discomforts | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 8. A description of any benefits to the subject or to others | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 9. A disclosure of appropriate alternative procedures or courses of treatment | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 10. A description of how confidentiality of records will be maintained | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 11. An explanation about compensation | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 12. An explanation about available medical treatments for a research-related injury | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 13. Whom to contact for questions about the research, research subject's rights, or research-related injury | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |
| 14. A statement on the collection of identifiable private information or identifiable biospecimens | <input type="checkbox"/> Unacceptable | <input type="checkbox"/> Acceptable |

Examinee signature _____ Date _____

Examiner signature _____ Date _____

*General Requirements for Informed Consent, 45 C.F.R. § 46.116 (b), 2018. Additional situational elements are listed in General Requirements for Informed Consent, 45 C.F.R. § 46.116 (c), 2018.

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