Advocate Preparation
• Assessment Forms
• Monitoring Guides
• Evaluation of the Researcher
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.

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.

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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.
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 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

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.
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

Researcher educates potential subject about the protocol

Advocate(s) administers capacity assessment

Advocate(s) determines

Potential subject is ABLE to give informed consent

Potential subject has QUESTIONABLE ABILITY to give informed consent
(Difficulty in 1-2 domains)

Potential subject is UNABLE to give informed consent
(Difficulty in multiple domains or severe difficulty in 1 domain)

Researcher decides

To educate potential subject further

To pursue surrogate consent, if allowed by protocol

Not to enroll potential subject in protocol

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

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Potential subject is UNABLE to give informed consent
(Difficulty in multiple domains or severe difficulty in 1 domain)

Researcher decides

To educate potential subject further

To pursue surrogate consent, if allowed by protocol

Not to enroll potential subject in protocol
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 ______
Capacity Assessment: Protocol-Specific

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.

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 ___________
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 ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
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).
- 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.
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

1. Researcher educates potential subject about the protocol
2. Advocate(s) administers capacity assessment
3. Advocate(s) determines
4. Potential subject is **ABLE** to give informed consent
5. Researcher obtains informed consent
6. Potential subject has **QUESTIONABLE ABILITY** to give informed consent (Difficulty in 1-2 domains)
7. Potential subject is **UNABLE** to give informed consent (Difficulty in multiple domains or severe difficulty in 1 domain)
8. Researcher decides
9. To educate potential subject further
10. To pursue surrogate consent, if allowed by protocol
11. Not to enroll potential subject in protocol

This tool is the NIMH Generic Capacity Assessment. It is a basic format to use when an unanticipated assessment need arises. You must create expected responses to reflect the protocol. This tool is clinically derived. It is not validated.
# Capacity Assessment: Generic

This tool is the NIMH Generic Capacity Assessment. It is a basic format to use when an unanticipated assessment need arises. You must create expected responses to reflect the protocol. This tool is clinically derived. It is not validated.

<table>
<thead>
<tr>
<th>Protocol number</th>
<th>Date</th>
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<tbody>
<tr>
<td>Potential subject</td>
<td>Age</td>
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<tr>
<td>Interviewer</td>
<td>Rater</td>
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<td>Is there a legal guardian?</td>
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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 _______
Capacity Assessment: Generic

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__________________________________________________________

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

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
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

- Confident that the potential subject cannot understand A page 2.14 → Potential subject cannot assign a surrogate; no further assessment.
- Unsure whether the potential subject can understand A page 2.14 → Raters complete assessment Parts A through E.
- Confident that the potential subject does understand A page 2.14 → Raters complete assessment Parts B through E.

**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.


**Ability to Assign a Surrogate Decision-Maker Assessment**

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 do 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? ____________________________
Part B Choose a surrogate decision-maker

**Yes**

Is there someone you trust to make decisions with you about this study?

Who is that? __________________________ Is _____ with you?

If no, explore with the potential subject whether this person can be available during the research.

Who usually helps you to make decisions when you visit a doctor?

If no one, explore further. If the potential subject does not go to a doctor, ask about the dentist, school, work, etc. Ask for more explanation. If a surrogate cannot be identified, the potential subject may not be able to participate.

**Questions about the named person**

- How does _____ usually help you with decisions? ______________________
- Does _____ help you to understand what the doctor wants to do? _____
- Does _____ make decisions for you? ____________________________
- Do you think that _____ makes good decisions for you? ____________
- If no, why not? ____________________________
- Do you ever disagree with _____ about what you should do? ____________
- What happens? ____________________________
- Do you want _____ to help make important decisions with you about this study? ____________________________
- Have you ever gone to a doctor’s appointment and refused to do something _____ wanted you to do? ____________________________
- How did _____ respond? ____________________________
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.
Surrogate Decision-Maker Assessment

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.

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? ________________________________
Surrogate Decision-Maker Assessment

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?
Surrogate Decision-Maker Assessment

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.

- 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?
Surrogate Decision-Maker Assessment

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?
Surrogate Decision-Maker Assessment

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?
Surrogate Decision-Maker Assessment

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

• Surrogate understands risks, benefits, and alternatives

• Surrogate has evidence that participation is consistent with X’s values/preferences/interests

• Surrogate is comfortable/willing/able to serve as substitute decision-maker

Additional comments

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
# Consent Monitoring Checklist

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.

## 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).

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*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.
### Consent Monitoring Checklist

#### 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.
Subject Monitoring Guide

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)

for the Evaluation of the Informed Consent Process

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.
## Objective Structured Clinical Examination (OSCE)

**for the Evaluation of the Informed Consent Process**

Examinee name __________________________ Institute __________________________

### Professionalism

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Unacceptable</th>
<th>Acceptable</th>
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</thead>
<tbody>
<tr>
<td>1. <strong>Introduces</strong> self and department/institute affiliation</td>
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<tr>
<td>2. <strong>Assures</strong> privacy during interview</td>
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<tr>
<td>3. Promotes subject <strong>comfort</strong> during interview</td>
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<tr>
<td>4. Utilizes <strong>non-coercive</strong> style of questioning</td>
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<tr>
<td>5. <strong>Limits</strong> number of observers present as appropriate</td>
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<tr>
<td>6. <strong>Allows</strong> involvement of significant other if subject desires</td>
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</table>

Other comments

### Interpersonal and Communication Skills

1. **Presentation style**
   a. Utilizes a **conversational** manner |   |   |
   b. Avoids **reading** content verbatim |   |   |
   c. Attentive and **empathic** |   |   |
   d. Elicits **questions** effectively |   |   |
   e. Allows sufficient time for **discussion** |   |   |

Other comments

2. **Body and verbal language**
   a. Maintains **eye contact** |   |   |
   b. Utilizes subject’s preferred **language**, appropriate to education level |   |   |

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

Required Basic Consent Elements*

Informed consent process includes

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

Examinee signature_________________________________________ Date________

Examiner signature_________________________________________ Date________