|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Overview.**  Investigators must specify for their project what constitutes an acceptable level of capacity and identify the key information that must be understood by a participant before allowing participation in the research protocol. Because the levels of understanding, appreciation, and reasoning abilities required may vary with the degree of study risk, researchers should specify these levels beforehand.  **Instructions.**  Complete this form for assessing capacity to consent with the MacCAT-CR. Review the comprehensive assessment to determine whether the participant has the capacity to consent to research. An assessor should attempt to share information in other ways if a potential participant has does not understand the information at first. Then follow with selective questioning on the items that did not achieve a full score. The second attempt of sharing information should not be targeted directly at the information a participant didn’t understand nor share all the information over again. Assessment notations in **red** suggest that the participant may not have capacity to consent to research, even after multiple attempts to share the information in other ways. | | | | | |
| **IRB Number:** |  | | | | |
| **Participant Name/ID:** |  | | Initial Assessment of Capacity  Ongoing Assessment of Capacity | | |
| **Assessor Name:** |  | | **Assessment Date:** |  | |
|  | | | | | |
| 1. Understanding: A participant’s ability to recall information in their own words. | | | | | |
| Provides adequate information about the purpose of the study.  “I just shared a lot of information with you and I want to be sure that I explained the study clearly. Can you tell me in your own words about what I have just shared with you?” | | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score:1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | | | **Notes:** |
| Provides adequate information about the duration of study.  If the participant has not mentioned already, ask “How long will the research project last?” | | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score:1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | | | **Notes:** |

|  |  |  |
| --- | --- | --- |
| Identifies the most important study activities or procedures.  1. Activity / Procedure Click or tap here to enter text.  2. Activity / Procedure Click or tap here to enter text.  3. Activity / Procedure Click or tap here to enter text.  If the participant has not mentioned already, ask “What sorts of things will be done with people who agree to be in the study?”  If some key activities or procedures are not mentioned, ask “What else might be done with people who agree to be in the study?” | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score:1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  Score: 0 | **Notes:** |
| Explains how the research study differs from ordinary treatment.  “Can you tell me your understanding of what I just said?”  “There are important differences between research and treatment that you should understand. The goal of research is to learn new things in order to help groups of people in the future. The goal of treatment is to help you get better or to improve your quality of life. Doctors can make changes to your treatment plan as needed.  If applicable, clarify whether there are research parts and treatment parts of the study. | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score:1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | **Notes:** |
| Explains how research methods, such as randomization, blinding, and placebo affect individualized care of a participant.  “Can you tell me your understanding of what I just told you?”  “Will all the people in the study get the experimental treatment?”  “How will it be decided what each of the people in the study will receive?”  “Who will know what each of the people in the study is receiving?” | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | **Notes:** |

|  |  |  |
| --- | --- | --- |
| Identifies potential benefits of participation, if any, to the participant or others.  **Study Specific Benefits (if any)**  1. Potential Benefit Click or tap here to enter text.  2. Potential Benefit Click or tap here to enter text.  3. Potential Benefit Click or tap here to enter text.  “Can you tell me in your own words about what I have just said?”  “What might doctors learn about this research study?”  “In what way might people who volunteer be better off by being in this research study?” | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | **Notes:** |
| Identifies potential risks or discomforts of participation, if any, to the participant or others.  **Study Specific Risks (if any)**  1. Potential Risk Click or tap here to enter text.  2. Potential Risk Click or tap here to enter text.  3. Potential Risk Click or tap here to enter text.    “Can you tell me in your own words about what I have just said?”  “What are the potential side effects that you might experience if you participate in this study?”  “What pain or other uncomfortable things might happen if you participate in this study?” | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | **Notes:** |
| Recognizes participation in the research is voluntary and can stop at any time.  “Can you tell me your understanding of what I just told you?”  “What will happen if a person says that they do not want to participate?”  “What happens if someone wants to change their mind about participating in the study after it has already started?” | Recalls the content, fairly clear version of what was shared.  MacCAT-CR Score: 2  Recalls some content, but suggests that understanding is uncertain, even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 1  Does not recall the content or clearly inaccurate, or distorts its meaning, unrelated response even after assessor makes efforts to share information in other ways.  MacCAT-CR Score: 0 | **Notes:** |

|  |  |  |
| --- | --- | --- |
|  | | |
| 1. Appreciation: A participant’s ability to acknowledge how they themselves will be affected by a decision to participate in the research study. Assessments noted in red suggest that the participant may not have capacity to consent to research. | | |
| Recognizes the difference between research and clinical care.  “Do you believe that you have been asked to be in this study primarily for your personal benefit?”  Then ask, “What makes you believe that this was/wasn’t the reason you were asked?” | Acknowledges he or she is being recruited for a valid reason unrelated to personal benefit from being in the study.  MacCAT-CR Score: 2  Acknowledges being recruited for reasons both related and unrelated to potential personal benefit or solely for potential personal benefit but has a plausible explanation as to why.  MacCAT-CR Score: 1  Acknowledges being recruited for reasons solely for potential personal benefit but does not have a plausible explanation as to why or provides unrelated response to the question asked. Or provides unrelated response.  MacCAT-CR Score: 0 | **Notes:** |

|  |  |  |
| --- | --- | --- |
| Recognizes that participating in research may not result in personal benefit (i.e. improve their health or condition).  “Do you believe that you could be assigned to the \_\_\_\_ (experimental drug or sugar pill)?”  Then ask, “What makes you believe that this could/ couldn’t happen in your case?” | Acknowledges the idea that the research procedures, not personal needs, will determine which intervention he or she will be assigned to (i.e. experimental vs. non-experimental intervention).  Uncertain about whether the research procedures or personal needs, will determine which intervention he or she will be assigned to (i.e. experimental vs. non-experimental intervention).  Indicates that personal needs will determine assignment to the intervention, but has a plausible explanation for why this might be the case.  Believes personal needs will determine which intervention he or she will be assigned to (i.e. experimental vs. non-experimental intervention). Does not have a plausible explanation as to why this might be the case. Or provides unrelated response. | **Notes:** |
| Recognizes that deciding not to participate or withdrawing from the research study is a personal decision.  “What do you believe would happen if you were to decide not to be in this study?”  Then ask, “What makes you believe that this would happen?” | Acknowledges that a decision to stop now or later will not adversely affect him or her, such as the care they already receive from the hospital or clinic.  Uncertain about whether a decision to stop now or later will not adversely affect him or her, such as the care they already receive from the hospital or clinic.  Believes a decision to stop now or later will adversely affect him or her, such as the care they already receive from the hospital or clinic, but has a plausible explanation as to why this is the case.  Believes a decision to stop now or later will adversely affect him or her, such as the care they already receive from the hospital or clinic. Does not have a plausible explanation as to why this might be the case. OR offers a response that is unrelated to the question or unintelligible. | **Notes:** |

|  |  |  |
| --- | --- | --- |
|  | | |
| 1. Reasoning: A participant’s ability to compare alternatives in light of their consequences, including the ability to draw inferences about the impact of the study on the participant’s daily life. Assessments noted in red suggest that the participant may not have capacity to consent to research. | | |
| Ability to express a choice to participate or not want to participate in the research study.  “As you know, you have been invited to participate in this research study. Do you think you are more likely to want to participate in this study or not want to participate?” | Communicates a choice (to or not to participate).  Communicates more than one choice (to or not to participate), seems uncertain or ambivalent.  Does not communicate a choice (to or not to participate). OR offers a response that is unrelated or off topic. | **Notes:** |
| Logically shares their opinion as to why they have decided to participate or decline to participate in the research study.  “You mentioned you are more (likely to or not to) participate in this research study. Tell me a bit more about your thoughts on why (you want to or not want to) participate.”  If an additional prompt is needed, ask “Can you share more about…” | Responds in the form of a rational comparison of at least two options, such as “I’d prefer not to participate because if I did, I would miss my … or I want to participate because I want to help researchers learn more about this disease...” A response can be related to or not related to the alternative options shared during the conversation.  Shares a comparative statement, but does not describe a consequence, such as “It will be better if I stay out of the study.”  Does not share any reasonable or specific comparative statements or consequences when explaining a choice, even after being asked directly whether there were any more reasons why a choice they made seemed best. | **Notes:** |
| Appropriately compares the advantages and disadvantages of more than one alternative to participating in the study.  “I shared with you information about some of the possible benefits (if any) and risks of participating in this research study such as [high level summary of key information]. What are some ways that these could affect your everyday activities if you participate in this research study?”  If a prompt is needed, as, “How might (restate a benefit or risk) affect your everyday life?” | Mentions at least two reasonable everyday consequences related to the risks or possible benefits (if any) discussed in the conversation.  Mentions only one reasonable consequence when explaining a choice, which may be related to or not related to the alternative options shared during the conversation.  Does not share any reasonable consequences when explaining a choice, even after being asked directly whether there were any more reasons why a choice they made seemed best. | **Notes:** |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | |
| 1. Expressing a choice: A participant’s ability to express a choice to participate in the research study. Assessments noted in red suggest that the participant may not have capacity to consent to research. | | | |
| Decision to participate aligns with the potential participant’s reasoning, taking into account their interests and understanding of the research study.  “You mentioned that you were (likely or not likely) interested in participating in this research study. What do you think now that we have discussed everything? What would you like to do?” | | Participant’s final choice follows logically from their own reasoning, based upon their responses.  It’s not clear whether the choice follows logically from the participant’s own reasoning.  Participant’s choice clearly does not follow logically from subject’s own reasoning. | **Notes:** |
|  | | | |
| 1. Overall Assessment of Capacity to Consent to Research: Based upon the assessor’s conversation with the participant, the following assessment was made in regards to the participant’s capacity to consent to this research study. | | | |
|  | Potential participant has capacity to consent to this research study.  Assessment documentation (checked) in sections 1-4 suggest that the participant has adequate understanding, appreciation, and reasoning skills for this research study.  Participant’s final choice follows logically from their own reasoning, based upon their responses.  Considerations for ongoing evaluation of capacity for the duration of the study:  Re-evaluation of capacity should follow IRB approved protocol procedures.  Increase frequency of re-evaluation of capacity, beyond the IRB approved protocol procedures (see Notes). | | **Notes:** |
|  | Potential participant does not have capacity to consent to this research study.  Primary capacity concerns relate to (see Notes):  Understanding  Appreciation  Reasoning  Expressing a Choice  Considerations for participation in this research study:  Cannot be included per inclusion/exclusion criteria of the research protocol.  May be included in the study with the permission from and involvement of the participant’s legally authorized representative | | **Notes:** |
|  | Potential participant may or may not have the capacity to consent to this research study.  Primary capacity concerns relate to (see Notes):  Understanding  Appreciation  Reasoning  Expressing a Choice  Further evaluation is needed (see Notes) | | **Notes:** |