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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval (HRP-314) when research involves individuals with potential or actual impaired decision-making capacity as participants (including cognitively impaired adults). This checklist must be used for all initial reviews and for any other review where the determination changes.   1. For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer upload this checklist in the Submit Designated Review activity in ETHOS. 2. For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The IRB Analyst uploads this checklist in the Submit Committee Review activity in ETHOS. | | | |
| **IRB Number:** | | |  |
| **Protocol Name:** | | |  |
| **Investigator:** | | |  |
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| All research must meet the criteria in Sections 1, 2 or 3. Complete Section 4 if applicable. | | | |
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| 1. Research involving adults with the potential for impaired decision-making capacity to consent (diminished, absent, or fluctuating capacity to consent regardless of whether those adults are cognitively impaired). (Check if “Yes” or “N/A”. All must be checked.) | | | |
|  | | Potential participants who are assessed as having impaired decision-making capacity (diminished, absent, or fluctuating capacity) to consent are excluded from the research. | |
|  | | To determine who should be excluded from the research, one of the following plans is in place:  For research involving greater than Minimal Risk, the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) or another validated tool appropriate to the context of the research (or other validated tool deemed more appropriate for the population participating in the study) will be utilized to determine whether participants are capable of providing consent for themselves.  *Provide protocol specific findings justifying this determination:*  For research involving Minimal Risk, the UCSD Brief Assessment of Capacity to Consent (UBACC) or another validated tool appropriate to the context of the research (or other validated tool deemed more appropriate for the population participating in the study) will be utilized to determine whether participants are capable of providing consent for themselves.  *Provide protocol specific findings justifying this determination:* | |
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| 1. Greater than Minimal Risk research involving adults with impaired decision-making capacity to consent (diminished or absent capacity to consent). (Check if “Yes” or “N/A”. All must be checked) | | | |
|  | There is anticipated direct benefit to the participant.  There is no prospect of direct benefit to the participant. NOTE: Participants lacking capacity to consent at the time of initial enrollment cannot be included in study activities that pose greater than minimal risk of harm to the participant. The IRB may allow their participation in study activities that pose minimal risk if such a modification would not jeopardize the scientific merit of the study.  *Provide protocol specific findings justifying this determination:* | | |
|  | One of the following is true: **(Check box that is true)**  Participants have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual participant that is unavailable outside the research context.  The objectives of the trial cannot be met by means of study of participants who can give consent personally.  *Provide protocol specific findings justifying this determination:* | | |
|  | Risks to participants are reasonable in relation to anticipated benefits to participants.  *Provide protocol specific findings justifying this determination:* | | |
|  | The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.  *Provide protocol specific findings justifying this determination:* | | |
|  | The research is not prohibited by law (See [HRP-111](https://drive.google.com/open?id=0B7644h9N2vLcTTF3dEhlMFJtQUU) and [HRP-112](https://drive.google.com/file/d/0B7644h9N2vLcay1CVm1GblIxcms/view?usp=sharing)).  *Provide protocol specific findings justifying this determination:* | | |
|  | Participants will be particularly closely monitored.  *Provide protocol specific findings justifying this determination:* | | |
|  | Participants will be withdrawn if they appear to be unduly distressed.  *Provide protocol specific findings justifying this determination:* | | |
|  | The proposed plan for the assessment of the capacity to consent is adequate. The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) or another validated tool appropriate to the context of the research (or other validated tool deemed more appropriate for the population participating in the study) will be utilized to determine whether participants are capable of providing consent for themselves.  NOTE: Submission of the MacCAT-CR or UBACC assessment form do not have to be uploaded in the IRB submission. Translation of the assessment tool is not required unless the assessor will conduct the assessment in the participant’s language. See Investigator Manual (HRP-103) for further details.  *Provide protocol specific findings justifying this determination:* | | |
|  | The participant will be informed about the research to the extent compatible with the participant’s understanding.  *Provide protocol specific findings justifying this determination:* | | |
|  | Assent will be obtained from: **(One of the following must be checked)**  All participants.  Some participants, specify:  None of the participants, provide rationale | | |
|  | If assent will be obtained, specify the process for documentation:  Investigator will document assent in the consent signature block.  Other (NOTE: The protocol needs to describe the process of assent documentation):  Participants will be unable to assent to participation. | | |
|  | The consent process includes a plan for involving a legally authorized representative (LAR) and the consent document includes a signature line for a (LAR). | | |
|  | | | If capable, the participant will sign and personally date the written informed consent.  **N/A.** The participant(s) will not be capable of doing so. | |
|  | If the research involves participants whose capacity to consent may fluctuate.  Individuals with fluctuating capacity to consent will be included from the research (Complete Section 4).  Individuals with fluctuating capacity to consent will be excluded from the research. | | |
|  | If appropriate, one or more of the following requirements:  Independent monitors will be appointed to assist with various aspects of the study  A participant advocate, such as a member of the target population or family member thereof, or an employee of an organization that advocates for the target population;  An individual with expert knowledge of the relevant psychological or physical condition who will monitor the consent of participants capable of providing it as well as the assent of participants incapable of consenting and the consent of their LARs; or  A health care professional, to serve as a consultant to participants and their LARs  Consent auditor assigned by HRPP Quality Assurance (QA)  Use of the [Participant Contact Card Template](https://research.umn.edu/units/hrpp/education-training/order-print-participant-materials)  Use of [participant-facing brochures](https://research.umn.edu/units/hrpp/education-training/order-print-participant-materials)  No additional requirements are needed. | | |
|  | If appropriate, other enhancements to the consent process are needed, such as:  Auditing of the consent meeting through live observation or observation of a video recording;  Use of a witness to the consent process and documentation in the consent signature block  Other:  No additional enhancements are needed for this study. | | |
|  | For **Greater than Minimal Risk** research without direct benefit to the research participant(s), participants who previously provided consent may be eligible to continue participation after the loss of capacity to consent. The IRB should consider the following to determine whether study participation should be allowed to continue in some or all of the activities.  N/A  The following must be true for studies that have been previously approved by the IRB:  The participant has not expressed a desire to withdraw.  An adult participant had previously provided consent when deemed capable to do so or the participant was enrolled when a minor and the only condition that has changed is the participant has reached the age of a majority.  The remaining study activities are minimal risk or represent only a minor increase over minimal risk.  The following conditions may also be considered by the committee to allow continued participation:  Remaining study activities that represent greater than minimal risk can be eliminated or modified for the participant without jeopardizing scientific merit. Identify which activities will be eliminated or modified:  The participant understood his/her condition could lead to diminished decision-making capacity, this was discussed with the participant and he/she expressed a willingness to continue/complete the study with consent provided by an LAR. | | |
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| 1. Minimal Risk research involving adults with impaired decision-making capacity to consent (diminished or absent capacity to consent). (Check if “Yes” or “N/A”. All must be checked) | | | |
|  | Participants have a disease or condition for which the procedures involved in the research are intended.  *Provide protocol specific findings justifying this determination:* | | |
|  | The objectives of the trial cannot be met by means of study of participants who can give consent personally.  *Provide protocol specific findings justifying this determination:* | | |
|  | The negative impact on the participants’ well-being is minimized and low.  *Provide protocol specific findings justifying this determination:* | | |
|  | The research is not prohibited by law (See [HRP-111](https://drive.google.com/open?id=0B7644h9N2vLcTTF3dEhlMFJtQUU) and [HRP-112](https://drive.google.com/file/d/0B7644h9N2vLcay1CVm1GblIxcms/view?usp=sharing)).  *Provide protocol specific findings justifying this determination:* | | |
|  | Participants will be particularly closely monitored.  *Provide protocol specific findings justifying this determination:* | | |
|  | Participants will be withdrawn if they appear to be unduly distressed.  *Provide protocol specific findings justifying this determination:* | | |
|  | The proposed plan for the assessment of the capacity to consent is adequate. A version of the UCSD Brief Assessment of Capacity to Consent (UBACC) or another validated tool appropriate to the context of the research (or other validated tool deemed more appropriate for the population participating in the study) will be utilized to determine whether participants are capable of providing consent for themselves.  NOTE: Submission of the MacCAT-CR or UBACC assessment form do not have to be uploaded in the IRB submission. Translation of the assessment tool is not required unless the assessor will conduct the assessment in the participant’s language. See Investigator Manual (HRP-103) for further details.  *Provide protocol specific findings justifying this determination:* | | |
|  | The participant will be informed about the research to the extent compatible with the participant’s understanding. | | |
|  | Assent will be obtained from: **(One of the following must be checked)**  All participants.  Some participants, specify:  None of the participants, provide rationale | | |
|  | If Assent will be obtained, specify the process for documentation:  Investigator will document assent in the consent signature block.  Other **(NOTE: The protocol needs to describe the process of assent documentation):**  Participants will be unable to assent to participation. | | |
|  | The consent document includes a signature line for a legally authorized representative. | | |
|  | If the research involves participants whose capacity to consent may fluctuate, complete Section 4 below.  Individuals with fluctuating capacity to consent will be included in the research (Complete Section 4).  Individuals with fluctuating capacity to consent will be excluded from the research. | | |
|  | If appropriate, other enhancements to the consent process. Specify:  No additional enhancements are needed for this study. | | |
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| 1. Research involving adults with impaired decision-making capacity to consent (fluctuating capacity to consent). (All must sections be completed) | | | |
|  | Participants’ capacity to consent over the course of the study will be periodically re-evaluated.  *Provide protocol specific findings justifying this determination:* | | |
|  | The study team has a plan to discuss with the participant the role of the LAR prior to study enrollment or during study participation depending on the nature of the fluctuating capacity to consent.  *Provide protocol specific findings justifying this determination:* | | |
|  | Individuals identified as potential LARs will be involved in the entire consent process each time capacity to consent is re-evaluated.  *Provide protocol specific findings justifying this determination:* | | |
|  | Participants will be asked to document their wishes regarding future participation in the study if their capacity changes over time.  *Provide protocol specific findings justifying this determination:* | | |