|  |
| --- |
| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving Adults with Impaired Decision Making Capacity. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure). * 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 submits this completed checklist to the IRB office. The IRB Office retains this checklist in the protocol file.
* 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, one of the following two options may be used:
1. The IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist or equivalent does not need to be completed or retained.
2. The IRB reviewer(s) completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office retains this checklist in the meeting files.
 |
|  |
| 1. Minimal Risk1 Research (All must be “Yes” or “N/A”)
 |
| [ ] Yes [ ]  No | The research involves no more than minimal risk to adults with impaired decision-making capacity. |
| [ ] Yes [ ]  No [ ] N/A | For research sponsored/funded by the Dept. of Defense, the research does not involve human beings as *experimental subjects*.2 (N/A if not DoD sponsored/funded.) |
| [ ] Yes [ ] No [ ]  N/A | Assent from the subject, in addition to obtaining consent from the legally authorized representative (LAR), will be required of the following: (N/A if a waiver of consent has been granted. If Yes, one of the following must be checked.)[ ]  All subjects [ ]  All subjects who have the cognitive ability to be assented consistent with the protocol (or application) specifications [ ] None of the subjects [ ]  Other - specify:      |
| [ ]  Yes [ ]  No [ ]  N/A | The consent document includes a signature line for the LAR3 and consent is required in accordance with Spectrum Health policy. (N/A if a waiver of consent has been granted.) |
| 1. Research Involving Adults with Impaired Decision Making Capacity in Which There is Anticipated Direct Benefit to the Subject (All items must be “Yes”)
 |
| [ ]  Yes [ ]  No | One of the following is true: **(Check box that is true)**[ ]  Subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context.[ ]  The objectives of the trial cannot be met by means of study of subjects who can give consent personally. |
| [ ]  Yes [ ] No | Risks to subjects are reasonable in relation to anticipated benefits to subjects.*Provide protocol specific findings justifying this determination:*       |
| [ ]  Yes [ ]  No | The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. |
| [ ]  Yes [ ]  No | Subjects will be particularly closely monitored. |
| [ ] Yes [ ]  No | Subjects will be withdrawn if they appear to be unduly distressed. |
| [ ]  Yes [ ]  No | The proposed plan for the assessment of the capacity to consent is adequate.*Provide protocol specific findings justifying this determination:*       |
| [ ] Yes [ ]  No | The subject will be informed about the research to the extent compatible with the subject's understanding. |
| [ ] Yes [ ]  No | Assent will be required of the following: (One of the following must be checked)[ ]  All subjects [ ] All subjects who have the cognitive ability to be assented consistent with the protocol (or application) specifications [ ] None of the subjects [ ] Other - specify:      |
| [ ] Yes [ ]  No | The consent document includes a signature line for the LAR and consent is required in accordance with Spectrum Health policy. |
| [ ] Yes [ ] No | If capable, the subject will sign and personally date the written informed consent. |
| 1. Research Involving Adults with Impaired Decision Making Capacity in Which There is NO Anticipated Direct Benefit to the Subject (All items must be “Yes”)
 |
| [ ]  Yes [ ] No | The research bears a direct relationship to the decisionally impaired subject’s condition or circumstance.  |
| [ ]  Yes [ ]  No | The objectives of the trial cannot be met by means of study of subjects who can give consent personally.*Provide protocol specific findings justifying this determination:*       |
| [ ]  Yes [ ]  No | The research presents a minor increase over minimal risk.*Provide protocol specific findings justifying this determination:*       |
| [ ]  Yes [ ]  No | The negative impact on the subject’s well-being is minimized to the extent possible.*Provide protocol specific findings justifying this determination:*       |
| [ ]  Yes [ ]  No | Subjects will be particularly closely monitored. |
| [ ]  Yes [ ] No | Subjects will be withdrawn if they appear to be unduly distressed. |
| [ ] Yes [ ] No | The proposed plan for the assessment of the capacity to consent is adequate.*Provide protocol specific findings justifying this determination:*       |
| [ ] Yes [ ] No | The subject will be informed about the research to the extent compatible with the subject's understanding.*Provide protocol specific findings justifying this determination:*       |
| [ ] Yes [ ] No | Assent is required of the following: (One of the following must be checked)[ ]  All subjects [ ]  All subjects who have the cognitive ability to be assented consistent with the protocol (or application) specifications [ ]  None of the subjects [ ] Other -specify:      |
| [ ] Yes [ ] No | The consent document includes a signature line for a legally authorized representative and consent is required in accordance with Spectrum Health policy. |
| [ ] Yes [ ] No | If capable, the subject will sign and personally date the written informed consent. |