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| The purpose of this checklist is to provide support for IRB members or the IRB Chair or Vice Chair following the HRP-314 - WORKSHEET - Criteria for Approval when both of the following are true:   1. The research involves cognitively impaired adults as subjects, AND 2. The research involves a consent process or other intervention or interaction with the cognitively impaired subject(s).   This checklist must be used for all reviews where a consent process is required per the protocol, or where interventions or interactions will be required with the subjects (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure). This checklist does not need to be used for reviews where the research qualifies for waiver or alteration of consent processes per **HRP-410 – CHECKLIST – Waiver or Alteration of Consent Process,** and where there will be no interventions or interactions with the subjects.   * For initial review and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Research Compliance Administrator completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Research Compliance Administrator attaches this checklist to the “Submit Pre-Review” activity. The IRB Chair, Vice Chair, and/or Convened IRB reviews the checklist to confirm the criteria have been met. The IRB Office (HRPP/HSPO) retains this checklist in the protocol file. | | |
| **IRB Number:** | |  |
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| All other research must meet the criteria in Sections 1 or 2. | | |
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| 1. Research Involving cognitively impaired adults with anticipated direct benefit to the subject (Check if “Yes”. All must be checked) | | |
|  | 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.  *Provide protocol specific findings justifying this determination:* | |
|  | Risks to subjects are reasonable in relation to anticipated benefits to subjects.  *Provide protocol specific findings justifying this determination:* | |
|  | The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.  *Provide protocol specific findings justifying this determination:* | |
|  | The trial is not prohibited by law.  *Provide protocol specific findings justifying this determination:* | |
|  | Subjects will be particularly closely monitored.  *Provide protocol specific findings justifying this determination:* | |
|  | Subjects 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.  *Provide protocol specific findings justifying this determination:* | |
|  | The subject will be informed about the research to the extent compatible with the subject’s understanding.  *Provide protocol specific findings justifying this determination:* | |
|  | Assent will be obtained from: **(One of the following must be checked)**  All subjects.  Some subjects, specify:        None of the subjects | |
|  | The consent document includes a signature line for a Legally Authorized Representative (LAR). | |
|  | If capable, the subject will sign and personally date the written informed consent. | |
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| 1. Research involving cognitively impaired adults with NO anticipated direct benefit to the subject (Check if “Yes”. All must be checked) | | |
|  | Subjects 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 subjects who can give consent personally.  *Provide protocol specific findings justifying this determination:* | |
|  | The foreseeable risks to the subjects are low.  *Provide protocol specific findings justifying this determination:* | |
|  | The negative impact on the subject’s well-being is minimized and low.  *Provide protocol specific findings justifying this determination:* | |
|  | The trial is not prohibited by law.  *Provide protocol specific findings justifying this determination:* | |
|  | Subjects will be particularly closely monitored.  *Provide protocol specific findings justifying this determination:* | |
|  | Subjects 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.  *Provide protocol specific findings justifying this determination:* | |
|  | The subject will be informed about the research to the extent compatible with the subject’s understanding. | |
|  | Assent will be obtained from: **(One of the following must be checked)**  All subjects.  Some subjects, specify:        None of the subjects | |
|  | The consent document includes a signature line for a LAR. | |
|  | If capable, the subject will sign and personally date the written informed consent. | |