CHECKLIST: Cognitively Impaired Adults		
NUMBER	DATE	PAGE
HRP-417	1/9/2015	1 of 3

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 cognitively impaired adults as subjects. 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 attaches this checklist to CHECKLIST: Non-Committee Review (HRP-402). 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 convened IRB completes the corresponding section of the TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations and the IRB Office retains this checklist in the protocol file.

Veterans Administration (VA) research must meet the criteria in Section 3.
All other research must meet the criteria in Sections 1 or 2.

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.
☐	If capable, the subject will sign and personally date the written informed consent.

2	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 legally authorized representative.
☐	If capable, the subject will sign and personally date the written informed consent.

3	Veterans Administration (VA) research involving cognitively impaired adults (Check if "Yes" or "N/A". All must be checked)
☐	Individual are presumed to have decision-making capacity unless it has been documented by a qualified practitioner in the individual's medical record in a signed and dated progress note that the individual lacks capacity to make the decision to participate in the proposed study, the individual has been ruled incompetent by a court of law, or the investigator will consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the informed consent process. *Provide protocol specific findings justifying this determination:*
☐	Individuals, who because of a known condition, are at high risk for temporary (e.g., head trauma) or fluctuating (e.g., schizophrenia) lack of decision-making capacity will be evaluated by a qualified practitioner (who may be a member of the research team), to determine the individual's ability to provide informed consent. If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a legally authorized representative must provide informed consent. If the subject regains decision-making capacity, the investigator or designee must repeat the informed consent process with the subject, and obtain the subject's permission to continue with the study. *Provide protocol specific findings justifying this determination:*
☐	One of the following is true: (Check box that is true) ☐ The research presents no greater than Minimal Risk to the subject ☐ There is a greater probability of direct benefit to the subject than direct harm ☐ The research is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition. *Provide protocol specific findings justifying this determination:*
☐	One of the following is true: (Check box that is true) ☐ The disorder leading to the individual's lack of decision-making capacity is being studied and the study cannot be performed with only persons who have decision-making capability. ☐ The subject of the study is not directly related to the individual's lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the study). *Provide protocol specific findings justifying this determination:*
☐	The study includes appropriate procedures for respecting dissent. Subjects will not be forced or coerced to participate even if a legally authorized representative has provided consent. *Provide protocol specific findings justifying this determination:*
☐	If feasible, the practitioner will explain the research to the prospective subject even when the legally authorized representative gives consent. *Provide protocol specific findings justifying this determination:*
☐	The study includes appropriate additional safeguards. *Provide protocol specific findings justifying this determination:*
☐	Legally authorized representatives will be well informed regarding their roles and obligations to protect the proposed subject. *Provide protocol specific findings justifying this determination:*
☐	Legally authorized representatives will be told that their obligation is to try to determine what the proposed subject would do if the subject could consent, or if the proposed subject's wishes cannot be determined, what they think is in the proposed subject's best interest. *Provide protocol specific findings justifying this determination:*
☐	The consent of a legally authorized representative will only be obtained when the proposed subject is unable to consent. *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:*
☐	Assent will be obtained from: (One of the following must be checked) ☐ All subjects. ☐ Some subjects, specify: ☐ None of the subjects
☐	Adequate provisions are in place for a re-consenting process for participants with fluctuating decision-making capacity or those with decreasing capacity to give consent. ("N/A" if subjects will be unable to re-consent.) *Provide protocol specific findings justifying this determination:*