Subjects With Impaired Decision-Making Ability Checklist

Research Involving Adult Subjects with Impaired Decision-Making Skills with Anticipated Direct Benefit to the Subject (all must be checked)

- ☐ One of the following is true:
  - ☐ Subjects have a disease/condition for which the research provides the prospect of direct benefit that is not available outside the research context
  - ☐ The objectives of the research cannot be met by studying subjects who have the decision-making ability to provide consent
- ☐ The investigator is knowledgeable about the condition and any level of impairment that is likely to be present in the subject population
- ☐ The risks to subjects are reasonable in relation to anticipated benefits to subjects
- ☐ The ratio of anticipated benefits to risks is at least as favorable to the subject as that presented by available alternative approaches
- ☐ The research procedures are not prohibited by law
- ☐ The subjects will be closely monitored
- ☐ Subjects will be withdrawn if they appear to be unduly distressed
- ☐ Subjects will be informed about the research to the extent compatible with their understanding
- ☐ Assent will be documented and obtained from some or all of the subjects to the extent compatible with their understanding (and signed assent is used whenever possible)
- ☐ The plan for the assessment of the capacity to consent/assent is adequate
- ☐ Signed informed consent will be provided by a legally authorized representative (LAR)
- ☐ If applicable, the protocol includes a plan should the subject regain or develop the ability to provide consent, such that the subject's consent will be obtained for any future research procedures (the consent of the LAR would become invalid)

Research Involving Adult Subjects with Impaired Decision-Making Skills with NO Anticipated Direct Benefit to the Subject (all must be checked)

- ☐ Subjects have a disease/condition for which the purpose of the research procedures are intended
- ☐ The objectives of the research cannot be met by studying subjects who have the decision-making ability to provide consent
- ☐ The investigator is knowledgeable about the condition and any level of impairment that is likely to be present in the subject population
- ☐ The foreseeable risks and any negative impact on the subjects' well-being are minimal
- ☐ Procedures are in place to minimize risk
- ☐ The research procedures are not prohibited by law
- ☐ The subjects will be closely monitored
- ☐ Subjects will be withdrawn if they appear to be unduly distressed
- ☐ Subjects will be informed about the research to the extent compatible with their understanding
- ☐ Assent will be documented and obtained from some or all of the subjects to the extent compatible with their understanding (and signed assent is used whenever possible)
- ☐ The plan for the assessment of the capacity to consent/assent is adequate
- ☐ Signed informed consent will be provided by a legally authorized representative (LAR)
- ☐ If applicable, the protocol includes a plan should the subject regain or develop the ability to provide consent, such that the subject's consent will be obtained for any future research procedures (the consent of the LAR would become invalid)