Subject: Procedure for Obtaining Assent/Dissent by Children or Cognitively Impaired Adults Who Lack Decision-Making Capacity

Procedure:
The purpose of this procedure is to outline the process for obtaining assent and dissent in children and cognitively impaired adults who lack the capacity for decision-making for participation in research activities.

I. Investigator Responsibilities.
A. The Investigator will provide a description of the targeted study population as instructed in the "Application for Human Research." When the targeted population includes children or cognitively impaired adults who lack decision-making capacity, the Investigator will also provide a detailed description on how assent and dissent will be obtained and documented, or request consideration of a waiver of assent and dissent
B. When the research participant population includes children or the cognitively impaired the Investigator will provide additional information for children and/or for cognitively impaired participants.
C. The Investigator will draft the assent documents and may utilize the assent template located on the HRPP Website at http://www.mc.vanderbilt.edu/irb/.
D. The Investigator will provide plans for assessment and documentation of examples of behaviors demonstrating assent and dissent in the targeted populations.
E. The Investigator will obtain permission from the child’s parents or legal guardians in conjunction with assent requirements. Documentation of permission from the child’s parents or legal guardians is provided by their signature and date on the informed consent document.
F. Permission must also be obtained for research participants who are cognitively impaired and/or lack decision-making capacity from the individual’s legally authorized representative unless a waiver of informed consent has been granted by the IRB. Permission will be documented by the legally authorized representative’s signature and date on the informed consent document.

II. IRB Committee Responsibilities.
A. The IRB Committee will review research involving children and cognitively impaired adults who lack decision-making capacity to determine whether assent and dissent is:
1. Required of all participants in the proposed research; or
2. Required on a case-by-case basis, when in the Investigator’s opinion, the individual is able to comprehend the proposed research purpose and associated activities and procedures.
B. The IRB Committee will also consider granting a waiver of assent in circumstances in which the targeted population does not have the ability to comprehend the proposed research purpose and associated procedures.
C. The IRB Committee will consider granting a waiver of assent in circumstances in which the research holds out the prospect of direct benefit that is important to the health or well-being of the participant and is available only in the context of the research.
D. The IRB shall take into account the age, maturity, and psychological state of the participants involved to determine if and when assent is required and the method of documenting assent.
E. The IRB will review the Investigator’s plan for assessment of the research participant’s ability to provide assent and dissent and determine if the plan is appropriate. The IRB will make recommendations for additional requirements, when necessary.

F. The Reviewers will complete the “Reviewer Comment Form for Cognitively Impaired Population” and/or the “Reviewer Comment Form for Children.”

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will complete a pre-review of the initial study submission involving children or cognitively impaired adults who lack decision-making capacity for the inclusion of assent and dissent plans, or a request for a waiver of assent and/or dissent in these targeted populations.

B. If the plan for assent and dissent is not included in the initial submission, the RCA will request additional information from the Investigator.

C. The RCA will pre-review the assent documents assuring that each has been presented in an age appropriate language for children and in simple lay language for the cognitively impaired adults who lack decisionmaking capacity. The RCA will forward recommendations for revisions to the Investigator.

D. The RCA will assign the study to Reviewers who have the expertise in the area of the proposed research and the population targeted. If a member with those qualifications is not a regular Committee member, an expert consultant will be sought.