Procedure

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: IX.D.1
Section: Vulnerable Populations
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Procedure for Special Categories of Research: Cognitively Impaired

Procedure:
This procedure provides guidance on the special ethical and regulatory considerations of cognitively impaired individuals involved in human subjects research under the jurisdiction of the Human Research Protections Program (HRPP).

I. Investigator Responsibilities.
   A. The Investigator will submit supplemental information with any new study submission in which cognitively impaired participants will be a target population for research activities.
   B. The research plan should address the following considerations:
      1. A rationale as to why it is necessary to include this population;
      2. A description of potential benefits to this population;
      3. A justification for the use of institutionalized individuals, if applicable;
      4. A description as to why non-institutionalized individuals could not be used;
      5. A description of the research as it pertains to the institutionalization, if applicable;
      6. A justification of any plan to hospitalize participants or extend their hospitalization for research purposes;
      7. A description of the procedure for determining capacity for decision-making of the individuals;
      8. A description as to how individuals will be protected in the event they lose their capacity to consent and their capacity to withdraw;
      9. A description of the methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered;
     10. A description as to how permission will be obtained and documented from the legally authorized representative, if applicable;
     11. A process for consulting with the participant’s health care provider, when applicable; and
     12. A description of any research procedures that may likely interfere in the participant’s ongoing therapy or regimes.

   C. An Investigator should not solicit consent of a participant who lacks decision-making capacity without intending to take his/her wishes seriously. In situations where the potential benefits of the study are such that the physicians and legally authorized representative would enroll the participant regardless, and the participant’s capacity is so diminished that he/she could not understand the ramifications of not participating, the participant should simply be told what is planned and should not be deceived.
      1. A request of waiver for consent should be submitted to the IRB for determination (See HRPP Procedure IV.C.1).
      2. Should a situation exist in which the target population lacks decision-making capacity either through trauma, life-threatening condition, or coma, the Investigator may submit a request for surrogate consent (See HRPP Policy IV.A).

   D. The Investigator must present an informed consent document to the IRB for review containing the appropriate amount of information for the participant to make an informed decision. If, in the opinion of the Investigator, a complete informed consent document is not appropriate, a waiver or alteration of informed consent should be requested including...
a rationale for the alteration.

E. Once approved, the Investigator may proceed with consent of the participant and/or legally authorized representative as outlined in HRPP Policy IV.A, unless a waiver has been granted.

F. If the research will involve institutionalized participants and depending on whether the performance site is “engaged in research”, a letter of IRB approval or a letter of cooperation from the institutional official from that site must be submitted to the IRB for review and approval.

II. IRB Committee Responsibilities.

A. The IRB Committee must review the proposed research taking into consideration all applicable policies and procedures, as well as the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the participant. In addition, the IRB must be sure that additional safeguards are in place to protect the rights and welfare of these participants.

B. The effects of separation from supportive family or friends, of disruption in schooling or employment, and the question of responsibility for bearing any additional costs should be carefully considered by the IRB.

C. When determining whether the participants are capable of providing consent, the IRB shall take into account the decision-making capacity of the study population. This determination may apply to all participants to be involved in the study, or on a case-by-case basis, as deemed necessary by the IRB.

D. The methods in which the full IRB Committee approves a new study submission will be followed. In addition to determining whether the study meets criteria 45 CFR 46.111 for approval, the Primary Reviewer must also complete the “Reviewer Comment Form for Cognitively Impaired Population” to assure that adequate provisions and documentation of such provisions have been made for this population.

E. The Committee may not review or make a determination regarding studies involving the cognitively impaired, as a target population, unless it has sufficient expertise in the ethical, clinical, and psychosocial issues impacting this population. Therefore, a Committee member who is knowledgeable about and experienced in working with these subjects must be in attendance at the convened meeting or an expert consultant who has this knowledge must be consulted by the IRB. When the IRB Committee renders its determination it will include:

1. Requirements for determining the decision-making capacity of the target population or on a case-by-case bases, or a rationale why this requirement will be waived; and

2. Appropriate methods for assuring the amount of information contained in the consent documents is appropriate for the target population and the legally authorized representative, when necessary.

F. When institutionalized individuals are involved in research, the IRB must verify that the institution has granted approval for the research to take place at that site. Depending on whether the performance site is “engaged in research”, a letter of IRB approval or a letter of cooperation signed by the Institutional Official is required.

III. Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will verify that supplemental information is completed as part of the initial study documents.

B. The RCA will conduct a pre-review and take into consideration the capacity of the participants in the proposed research when pre-reviewing the informed consent documents.

C. Notifications requesting pre-review changes to the informed consent documents are to be sent to the Investigator by the RCA.
D. Once the pre-review revisions are received from the Investigator, the RCA will place the new study on the next available Committee agenda, assign Reviewers with the appropriate expertise and assure appropriate materials are available. Reviewers are electronically notified once assigned.