

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to review, approve, and provide guidance on the special ethical considerations when cognitively impaired participants are involved in human subjects research.

II. Authority

- A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

- A. *The Belmont Report*
- B. Am J Psychiatry 155:11, November 1998, "Guidelines for Assessing the Decision-Making Capacities of Potential Research Subjects with Cognitive Impairment"
- C. The Office of Human Subjects Research (OHSR), National Institutes of Health, Information Sheet #7, "Research Involving Cognitively Impaired Subjects: A Review of Some Ethical Considerations"
- D. DOH IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent"
- E. DOH IRB Policy, "Waiver of Informed Consent for Human Subjects Research or Exception of Informed Consent Requirements for Emergency Research"

IV. Definitions

- A. **Assent:** An individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- B. **Cognitively Impaired:** Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.
- C. **Dissent:** An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

V. Procedures**A. IRB Review and Approval of Research Involving Cognitively Impaired Participants**

1. Because cognitively impaired individuals may have diminished autonomy that may limit their capacity to provide consent or their ability to withdraw, research involving cognitively impaired participants should be reviewed and approved through consideration of the DOH IRB policies and the special considerations as determined by the *Belmont Report*, Federal and State regulations, and guidance documents.
2. The DOH IRB must review all research in which cognitively impaired individuals will be considered as participants to assure that the Investigator has provided additional safeguards to protect the rights and welfare of this vulnerable population.
3. The IRB must consider the degree of cognitive impairment of the participant, the level of risk, and the prospect of benefit to the individual participant.

B. Requirements for Evaluating Decision-Making Capacity for Cognitively Impaired Participants

1. The IRB must find that appropriate provisions are made for determining the participant's ability to provide consent or their ability to withdraw, through evidence of one or more of the following pertaining to the individual:
 - a. The ability to make a choice;
 - b. The ability to understand relevant information;
 - c. The ability to appreciate the situation and its likely consequences; and
 - d. The ability to manipulate information rationally.

C. Determination of Capacity to Consent or Ability to Withdraw

The determination of capacity to consent or ability to withdraw may be made through a standardized measure or consultation with another qualified professional. The IRB must approve the process for making such a determination.

1. Because the capacity to consent or the ability to withdraw may fluctuate, the IRB must evaluate the process for continued verification of understanding and willingness to participate.

- a. The consent procedures should describe a plan for protecting individuals who may lose their capacity to provide consent or their ability to withdraw while participating in research activities (e.g., use of an ombudsman).
 - b. The IRB may require that an outside witness observe and confirm the consenting process.
2. For participants who lack decision-making capacity, the permission of the individual's legally authorized representative is required and assent should be obtained from the participant (See DOH IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent").
 3. In research situations where there is the potential for direct benefit to the participant, the IRB may waive the requirement to obtain assent. However, permission from the legally authorized representative must be obtained.
 4. Even where the IRB determines that the individuals are capable of consenting or withdrawing, the IRB may still waive the consent requirements under the circumstances described in the DOH IRB informed consent policy (See DOH IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent").
 5. The IRB must also review and approve the appropriate consent documents with the required elements of consent written in a language understandable to the participant.

D. Appropriate Provisions for Legally Authorized Representative Consent

When it is determined by the Investigator that the participant lacks decision-making capacity, the IRB must find that appropriate provisions are made for soliciting the permission of each individual's legally authorized representative unless the criteria are met to approve a waiver of informed consent (See DOH IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent").

E. Institutionalized Participants

1. The IRB must consider the rationale and justification for involvement of institutionalized participants, including an explanation as to why non-institutionalized individuals could not be used.
2. Research proposals where involuntarily institutionalized subjects are to be included shall also be reviewed consistent with additional criteria as specified in IRB Policy on Prisoners.


F. Composition of IRB when Cognitively Impaired Participants are Involved in Research

1. When reviewing research involving cognitively impaired participants, the IRB Committee will include into its composition one or more individuals who are knowledgeable about and experienced in working with the cognitively impaired.
2. When the study requires review by the full IRB Committee, it must meet the special composition requirements when conducting reviews for initial review, continuing review, protocol amendments, and reports of adverse events or unanticipated problems when the research involves cognitively impaired individuals.


VI. History Notes

This is a new policy. The Office of Statewide Research, Ethics and Human Research Protections Program are responsible for this policy.

VII. Signature Block with Effective Date



John O. Agwunobi, M.D., M.B.A., M.P.H.
Secretary, Department of Health



Date