

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to assure that adequate provisions are made for soliciting the assent and dissent of children and cognitively impaired adults who lack decision-making capacity.

II. Authority

A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

A. *The Belmont Report*

B. 45 CFR 46, Subpart D

C. 21 CFR 50, Subpart D

D. DOH IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent"

E. DOH IRB Policy, "Special Categories of Research: Children"

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. **Children:** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. According to Florida State law, the legal age for consent is 18 years of age.

C. **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 as determined by reasonable medical judgment. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

D. **Dissent:** An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

- E. Legal Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
- F. Legally Authorized Representative: An individual, judicial, or other body authorized under applicable law to grant permission on behalf of a prospective participant for participation in research activities.
- G. Parent: A child's biological or adoptive parent.
- H. Permission: The agreement of parents or legal guardians to the participation of their child or ward in research.


V. Procedures

- A. In instances where the participant is not legally capable of giving informed consent (e.g., minors) or where the participant is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the participant when, in the judgment of the IRB, the participant is capable of providing assent.
- B. In determining whether participants are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the participant involved. This judgment may be made for all participants to be involved in research under a particular protocol, or for each participant, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a 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, the assent of the participant is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with IRB Policy.
- C. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

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

06/29/05

Date