

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to assure that provisions are made to obtain legally authorized informed consent prospectively from each research participant or permission from his or her legally authorized representative.

II. Authority

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

III. Supportive Data

- A. 45 CFR 46.111
- B. 45 CFR 46.116 and 46.117
- C. 21 CFR 50.24, 50.25 and 50.55
- D. 38 CFR 16 and 17
- E. OHRP Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained (OPRR REPORTS 95-03)
- F. DOH IRB Policy, "Vulnerable Populations"

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. **Health Care Decision-Maker:** In the case of an incompetent individual, or an individual who lacks decision-making capacity, the individual's health care decision-maker is designated in order of preference as one of the following: the individual's court-appointed legal guardian or conservator with health care decision-making authority (e.g., Durable Power of Attorney for Health Care or DPAHC); the individual's health care agent as specified in an advance directive; or the individual's Health Care Decision-Maker.
- D. **Informed Consent:** An individual's voluntary agreement, based upon adequate

knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

- E. **Legally Authorized Representative:** A court appointed guardian or conservator, a Durable Power of Attorney for Health Care (DPAHC) or a Health Care Decision Maker.

V. Procedures

A. Presumption of Informed Consent in Research

The IRB assures that provisions are made to obtain legally effective informed consent prospectively from each research participant, or permission from his/her legally authorized representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with Federal regulations.

B. Presumption that Informed Consent will be Documented

Documentation of informed consent is obtained unless alternate procedures are approved by the IRB. The IRB reviews all informed consent documents to assure the adequacy of the information contained in the consent document, and adherence to Federal regulations regarding the required elements of informed consent.

C. Presumption that Consent will be obtained Prior to Research

Informed consent is obtained from the participant or permission from a legally authorized representative prior to initiating research activities. This includes recruitment and screening procedures.

1. **Children.** For subjects less than 18 years of age their parents or legal guardians are the legally authorized representatives who may grant permission for their participation in research.
 - a. **Parents.** Only the parents may grant permission for their child's participation in research. Assent is to be sought from the child, only after permission has been obtained from the parents. Grandparents and other relatives or caregivers may not grant permission unless they have been granted formal custody of the child by a court. In such cases, the Principal Investigator (PI) must obtain a copy of the court order as evidence of that person's authority to grant permission for participation in research on the child's behalf.
 - b. **Children in State Custody.** Department of Children and Families (DCF) can act as the legally authorized representative for a child in state custody with a court order granting custody provided that it includes specific authorization to enroll the child in research. In

such cases, the PI must obtain a copy of the court order from DCF.

- c. **Mature Minors or Emancipated Minors.** In certain limited circumstances, it may be appropriate to allow a mature minor to consent to participation in a research study in the absence of the permission of a parent or legal guardian if the minor has the sufficient capacity to consent to the procedures involved in the research study. The inclusion of mature minors or emancipated minors in research activities in the absence of the permission of a parent or legal guardian is considered narrowly by a Judge. Further, each situation is judged on a case-by-case basis, and the PI should obtain legal counsel before initiating any research activity including screening. Documentation of those decisions must be included in the research file. Capacity to consent depends upon:
- (1) The age, ability, experience, education, training, and degree of maturity and judgment of the minor. A minor between the ages of fourteen (14) and eighteen (18) may have such capacity, but a minor under the age of fourteen (14) would rarely have such capacity;
 - (2) The conduct and demeanor at the time consent is to be given;
 - (3) The totality of the circumstances;
 - (4) The nature of the proposed research procedures and their risks, probable consequences, benefits, and alternatives to the treatment; and
 - (5) The minor's ability to appreciate the nature, risks, consequences, benefits, and alternatives of the proposed research procedures.
2. **Cognitively Impaired Adult Subjects.** If a prospective adult subject lacks the capacity to consent, his or her legally authorized representative may grant permission, on their behalf, for their participation in research. Family members and close friends are not considered a legally authorized representative for the adult subject unless they have been formally appointed as that person's health care agent or legal guardian or conservator as described below.
- a. For example, a court-appointed guardian or conservator, or someone appointed as an agent for the subject under a durable power of attorney for health care may grant permission for the subject to participate in research. In such cases, the PI obtains a copy of the court order or durable power of attorney as evidence

of that person's authority to grant permission on the subject's behalf.

- (1) **Health Care Agent.** The health care agent is the individual named in a Durable Power of Attorney for Health Care (DPAHC) executed by the subject while the subject had decision-making capacity. The health care agent acts on the subject's behalf to make health care decisions, including enrolling the subject in a research study, when the subject is unable to provide consent.
 - (2) **Legal Guardian or Conservator.** A legal guardian or conservator is a person appointed by a court to make decisions for an individual who has been judicially determined to be incompetent.
 - (3) **Health Care Decision Maker.** When a health care agent, legal guardian or conservator has not been appointed, the use of a Health Care Decision Maker is utilized to obtain permission, only if the research has been approved by the IRB for such use. The Health Care Decision Maker identified to make medical care decisions on the patient's behalf is the individual who makes decisions regarding the patient's participation in IRB-approved research. A Health Care Decision Maker can serve as the legally authorized representative. For non-medical studies, a Health Care Decision-Maker cannot be used; another form of legally authorized representative must consent on behalf of the cognitively impaired adult.
- b. **Research over Extended Periods.** Studies involving subjects who are decisionally-impaired may take place over extended periods of time. The IRB considers whether and when periodic reconsenting of individuals is required to assure that a subject's continued involvement is voluntary. The IRB may require that the Investigator re consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB considers whether and when to require a reassessment of decision-making capacity.

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