

**I. Policy**

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that informed consent be documented in writing as determined in the IRB review and approval process.

**II. Authority**

A. Chapter 389186, 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. Legally Authorized Representative: A court appointed guardian or conservator, a Durable Power of Attorney for Health Care (DPAHC) or a Health Care Decision Maker.

B. Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

C. Short Form Consent: A written informed consent document that summarizes the required elements of informed consent to be presented orally to the participant or his or her legally authorized representative.

**V. Procedures****A. Three Options for Documentation of Informed Consent**

1. The IRB may approve procedures for documentation of informed consent that involve either:
  - a. A written consent form signed by the participant;
  - b. A short form written consent with oral presentation; or
  - c. In limited circumstances, a waiver of the signed written consent form.

Each of these options is described in detail below.

2. It is the responsibility of the IRB Committee to determine which of the procedures described below is appropriate for documenting informed consent in research applications that it reviews. Generally, only Option One will be appropriate.

**B. Option One: Written Consent Form Signed by the Participant or Legally Authorized Representative.**

1. In most circumstances, the IRB should require that informed consent is documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative.
2. This consent form must embody the required elements of informed consent required by IRB Policy IV.A, in addition to any applicable additional elements that are required by the Federal regulations. This form may be read to the participant or the participant's legally authorized representative. However, the Investigator should allow the participant or the legally authorized representative adequate opportunity to read and consider the consent document before it is signed. A copy of the document must be given to the person signing the form.
  - a. The written informed consent document should embody, in language understandable to the participant, all the required elements necessary for legally effective informed consent (See IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent").
  - b. Participants who do not speak English should be presented with an informed consent document written in a language understandable to them.

**C. Option Two: Oral Presentation Using Short Form**

1. As an alternative to standard written informed consent documents, oral presentation of informed consent information may be used. In such cases, the participant must be provided with both:
  - a. A short form written informed consent document stating that the required elements of consent (See IRB Policy, Legally Effective and Prospectively Obtained Informed Consent) have been presented orally to the participant or the participant's legally authorized representative; and
  - b. A written summary of the information that is presented orally.
2. **Witness Required.** A witness to the oral presentation is required. The witness must sign and date both the short form written informed consent document and a copy of the written summary.
3. The participant or the legally authorized representative must sign and date the short form written consent document.
4. The person obtaining consent (e.g., the Principal Investigator) must sign and date a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.
5. **Participants Who Do Not Speak English**
  - a. It is preferable that the written informed consent documents for non-English speaking participants embody, in a language understandable to the participant, all the required elements necessary for legally effective informed consent.
  - b. Alternatively, the regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the participant must be given copies of the short form informed consent document and the summary. When this procedure is used with participants who do not speak English, the following are required:
    - (1) The oral presentation and the short form written informed consent document should be in a language understandable to the participant;
    - (2) The IRB-approved English language informed consent document may serve as the summary; and

- 
- (3) A witness who is fluent in both English and the language of the participant should be present.
  - c. The IRB Committee must review and approve all foreign language versions of the informed consent document or the short form informed consent documents prior to use.
  - d. Expedited review of these versions is acceptable if the convened IRB Committee has already approved the research study, the full English language informed consent document, and the English language version of the short form document.
- D. Option Three: Waiver of Documentation
1. The IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all participants if the IRB finds either:
    - a. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (*Note: When the IRB waives the requirement for documentation under this condition, each participant must be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern*); or
    - b. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
  2. In cases in which the documentation requirement is waived, the IRB may require the Principal Investigator to provide participants with a written statement regarding the research.
- E. No Verbal Consent. Verbal agreement to participate in a research study is not permitted unless the documentation or process of informed consent is waived by the IRB.
- F. Use of Facsimile or Mail to Document Informed Consent
1. The IRB may approve a process that allows the informed consent document to be delivered by mail or facsimile to the potential participant or the potential participant's legally authorized representative and to conduct the consent interview by telephone when the participant or the legally authorized representative can read the consent document as it is discussed.
  2. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

**G. Standard Surgical Consent Documents**

1. Standard surgical or medical treatment consent documents may be used in lieu of specific research informed consent documents but they must include all the elements of consent as required by DOH policy (See IRB Policy, "Legally Effective And Prospectively Obtained Informed Consent") and Federal regulations for standard research consent documents, in addition to applicable additional elements, and must be approved by the IRB prior to its use for research.
2. Reliance on such documents for research generally requires a formal waiver of consent in accordance with Federal Regulations and DOH IRB Policy.

**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