

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to uphold its Assurance as filed with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

II. Authority

A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

A. *The Belmont Report*

B. 45 CFR 46, 160 and 164

C. 21 CFR 50 and 56, 312, 812

D. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

E. Terms of Assurance, Office of Human Research Protections, Department of Health and Human Services
(<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>)

IV. Definitions

A. Assurance: A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).

B. Department of Health and Human Services (DHHS): The United States government agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

C. Food and Drug Administration (FDA): The United States government office under the Department of Health and Human Services responsible for implementing regulations (21 CFR 50 and 56) governing pharmaceutical drugs and devices.

D. Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

E. IRB of Record: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an

approved Assurance with OHRP. A Memorandum of Understanding is required, designating the relationship, for DOH to serve as the IRB of Record.

- F. Memorandum of Understanding (MOU): A formal agreement between the Department of Health and another institution that identifies the Department of Health Institutional Review Board as the IRB of record for that institution.
- G. Office for Human Research Protections (OHRP): The United States government office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.
- H. Office of Statewide Research: The office responsible for research and human research protections at the Florida Department of Health.

V. Procedures

A. Institutional Commitments

DOH's Assurance will be maintained in the office of the Director of Statewide Research, and will be available via the DOH IRB website. DOH's Assurance is based on the following commitments:

1. Safeguarding the rights and welfare of human participants in research through the creation of an Institutional Review Board (IRB) is a general policy established in Florida Public Law 381.86. The Secretary of Health serves as the Institutional Official responsible for DOH's Assurance. It is the Secretary's responsibility to exercise appropriate administrative oversight to assure that the Department of Health's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance.
2. DOH employees, contractors, and anyone acting as an agent of the DOH and which comprise its bureaus, divisions, offices, county health departments, and facilities, are subject to the Assurance and this policy. This includes any research for which an Assurance or another formal agreement (e.g., MOU) identifies the DOH IRB as the IRB of record. In addition, any person conducting biomedical and behavioral research on human subjects receiving DOH state funds, using DOH facilities or private data for research purposes, or involving DOH clients in research activities is also subject to this Assurance and this policy. Studies receiving 100 percent federal funding and for which the Principal Investigator is not a DOH employee are exempt from this policy. However, this does not imply, in any way, that the study itself is exempt from IRB review and approval.
3. DOH agrees to uphold the ethical principles of the Belmont Report and apply DHHS regulations (45 CFR 46, including Subparts A, B, C, & D) to

all proposed research which is funded or supported by the Department of Health or which involves DOH clients. The ethical principles set forth in the Belmont Report are:

- a. **Respect for Persons:** Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
 - b. **Beneficence:** Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and
 - c. **Justice:** Fairness in the distribution of research benefits and burdens.
4. DOH agrees to apply additional regulations such as the U.S. Food and Drug Administration Human Subject Regulations (21 CFR 50, 56, 312 and 812), the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants under review.
 5. DOH further agrees to apply additional state laws, such as Florida Public Law 381.86 (Institutional Review Board) and any other relevant state law relating to conduct of research with human subjects.

B. Structure of the Institutional Review Board

1. The IRB Committees are appointed by the Secretary of Health. As such, the IRB serves the DOH as a whole, rather than a particular office, division, bureau, or county health department, and any institution for which the Department of Health IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding MOU.
2. The Department of Health's Assurance presently designates one (1) OHRP-registered IRB Committee. Designation of additional IRB Committees under the Assurance requires prior notification of and approval by OHRP.

C. Responsibilities of the IRB to Provide Oversight for its Assurance Agreement

1. Approval of the IRB is required prior to the initiation of research involving humans.
2. Through the review process, the IRB has the authority to approve, require modifications, disapprove, suspend, or terminate all research activities that fall within its jurisdiction.
3. Research reviewed and approved by the IRB may be subject to review and disapproval by officials of the DOH, or any institution for which the DOH IRB is designated as the IRB of record in accordance with an

Assurance or a signed MOU with the DOH IRB. However, officials may not approve research previously disapproved by the DOH IRB.

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