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**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, Institutional Review Board, *Florida Statutes*
- B. Rule 64H-2.001, Institutional Review Board, *Florida Administrative Code*

**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. Signature Block with Effective Date**

  
\_\_\_\_\_  
Ana M. Viamonte Ros, M.D., M.P.H.  
State Surgeon General  
Florida Department of Health

12-16-10  
\_\_\_\_\_  
Date

**V. Definitions**

See DOHP 400-11.1, "Definitions".

**VI. Protocols**

- A. Outcomes

The Department has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants.

- B. Personnel
  - 1. EHRPP Staff

2. IRB Board Members
  3. Principle Investigators
  4. Research Staff
- C. Competencies
- Research Ethics education
- D. Areas of Responsibility
1. The Office of Public Health Research, Ethics and Human Research Protections Program is responsible for this policy
  2. All individuals involved with the Human Research Protections Program understand and apply their obligation to protect the rights and welfare of research participants.

## VII. Procedures

### A. Institutional Commitments

DOH's Assurance will be maintained in the office of the Director of Public Health 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 State Surgeon General serves as the Institutional Official responsible for DOH's Assurance. It is the State Surgeon General'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. The State Surgeon General is responsible for ensuring the independence of the IRB and others responsible for the oversight of research. The State Surgeon General delegates responsibility for administration of the program to the Human Research Protection Administrator designated in the Department's Assurance. This individual is an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.
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 when they are engaged in research under the jurisdiction of the DOH IRB (See DOHP 400-1.2, "Activities Subject to IRB Jurisdiction").

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) for federally-funded research, or equivalent protections to all proposed research in which the Department of Health is engaged 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), U. S. Environmental Protection Agency Regulations (40 CFR 26), or 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.
  6. No research in which the Department is engaged may be approved by DOH Officials or others that has not been previously approved by the DOH IRB.
- B. Structure of the Institutional Review Board
1. The IRB Committees are appointed by the State Surgeon General. 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 DOH IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding Memorandum of Understanding.
  2. The Department of Health's Assurance presently designates two OHRP-registered IRB Committees. 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 human participants.
  2. Through the review process, the IRB has the authority to approve, require modifications to secure approval or disapprove research.

3. The IRB has authority to suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.
  4. The IRB has the authority to observe, or have a third party observe, the consent process and the conduct of research.
  5. 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.
- D. Process to ensure that research does not commence until the research has obtained all required approvals. Researchers complete a worksheet, "Research Site and Program Support" to ensure that:
1. Researchers have created an application for review by the DOH IRB prior to submission of grant applications; IRB review is not required prior to submission of grant applications. (See DOHP-57.1 "Grant Application Review and Approval Process".)
  2. Approval of Bureau Chiefs, Division Directors, or Office Directors is obtained by researchers prior to IRB review of research involving central office programs.
  3. A data use agreement is obtained by the researcher prior to IRB review of research involving DOH registries.
  4. Approval of the Administrator or Director is obtained by researchers prior to IRB review of research involving County Health Departments by completing the "Research Site and Program Support" worksheet.
  5. Approval of the Medical Director or CEO is obtained by researchers prior to IRB review of research involving A.G. Holley State Tuberculosis Hospital.
  6. Researchers provide a copy of the contract or funding agreement prior to IRB review.
- E. Process to respond to attempts to influence the IRB or others responsible for the oversight of research
1. To ensure decisions of the IRB are impartial, DOH does not tolerate attempts to sway, pressure, manipulate, or otherwise influence the decisions of the IRB.
  2. Persons aware of attempts to influence the IRB, or who have questions or concerns, may report this to an IRB Chair, IRB Administrator, the Human

Research Protection Administrator designated in the Department's Assurance, the Director of the Office of Public Health Research, Deputy Secretary, or State Surgeon General.

3. Reports of undue influence will be investigated by the Human Research Protection Administrator designated in the Department's Assurance, in coordination with the program attorney and senior leadership. If the allegation involves the Human Research Protection Administrator, then the Director, Office of Public Health Research will be responsible for the investigation.

**VIII. Distribution list**

All individuals involved with the Human Research Protection Program  
All individuals conducting research involving Florida Department of Health  
Florida Department of Health Leadership

**IX. History Notes**

Revised 10/21/2010