

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that all Investigators meet the following requirements to conduct human subjects research under the jurisdiction of the DOH IRB.

II. Authority

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

III. Supportive Data

- A. DOH IRB Policy, "Institutional Oversight of Assurance"
- B. DOH IRB Policy, "Activities Subject to IRB Jurisdiction"
- C. DOH IRB Policy, "Investigator and Key Study Personnel Conflicts of Interest"
- D. World Health Organization, "Guidelines for Good Clinical Practice"

IV. Definitions

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

V. Procedures

- A. As described in DOH IRB Policy, "Institutional Oversight of Assurance", DOH's Federalwide Assurance (FWA) with the Federal government specifies that all human subjects research that is conducted by or under the direction of any employee or agent of DOH or covered entity, in connection with his or her institutional responsibilities must be reviewed by the DOH IRB.
- B. All DOH employees or agents of DOH will have reviewed the ethical principles of *The Belmont Report*, Federal and State laws and regulations, institutional policies and procedures, DOH IRB policies and procedures, and if applicable, Good Clinical Practice standards when conducting human subjects research. Additionally, they will have completed the required training (initial and continuing education) for the ethical conduct of human subjects research (See IRB Policy, "Investigator and Key Study Personnel Training").
- C. Conflict of Interest. The protection of human research participants requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the IRB will


consider conflict of interest issues in its deliberations of applications

- D. All individuals conducting human subjects research must be adequately qualified and, if necessary, licensed relevant to the scope and complexity of the research conducted.

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



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Secretary, Department of Health

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Date