

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that all significant financial interests be reported to the IRB for review to assure protection of the rights and welfare of participants in human subjects research.

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"

IV. Definitions

- A. **Individual Conflict of Interest:** A circumstance such that any action or decision in which an individual is substantially involved with the research may have direct or predictable effect on a financial interest of the individual, spouse, minor child, or organization in which the individual serves as an officer, trustee, partner or employee.
- B. **Key Research Personnel:** The Principal Investigator and all individuals responsible for the design or conduct of the study.
- C. **Immediate Family Member:** Spouse, parent, child or legal representative
- D. **Significant Financial Interest:** Any of the following financial interests of any key research personnel, or his or her immediate family, in aggregate. (The thresholds described below apply to the aggregate ownership of a key research personnel and his or her immediate family. For example, if an Investigator, his/her spouse, domestic partner and dependent children own together \$10,000 or five percent worth of equities in the sponsor). The thresholds do not apply to the combined ownership of all Investigators:
 - 1. Compensation whose value could be affected by the study outcome.
 - 2. A proprietary interest in the tested product included but not limited to, a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.
 - 3. Any equity interest in the sponsor or product whose value cannot be readily determined through reference to public prices (e.g., ownership interest or stock options).
 - 4. Any equity interest in the sponsor or product that exceeds \$10,000 or five

percent ownership interest.

5. Significant payments or other compensation with a cumulative value of \$10,000 made directly by the sponsor as an unrestricted research or educational grant, equipment, consultation fees, honoraria, or other payment.

V. Procedures

Investigators must report conflicts of interest using the "Conflict of Interest" form.

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