

**I. Policy**

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that all conflicting interests of an IRB Committee Member, consultant, and IRB Administrator be declared before review of any research under IRB jurisdiction. IRB Committee Members, consultants, and IRB Administrators with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and may be requested to absent themselves from the meeting during the IRB's deliberative discussion and vote on the affected research.

**II. Authority**

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

**III. Supportive Data**

- A. OHRP Guidance, "Conflict of Interest"  
<http://hhs.gov/ohrp/humansubjects/finaltrn/fguide.pdf>

**IV. Definitions**

- A. Individual Conflict of Interest: A circumstance such that any action or decision in which an individual is substantially involved may have a 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. IRB Committee Member: An individual serving as an IRB Committee Member including Chairs, the IRB Pharmacy reviewers, alternates or expert consultants regardless of voting privileges.
- C. Immediate Family Member: Spouse, parent, child or legal representative
- D. Significant Financial Interest: Any of the following financial interests of any key IRB personnel, or immediate family, in aggregate. (The thresholds described below apply to the aggregate ownership of a key IRB personnel and his or her immediate family. For example, if IRB personnel, their spouse, 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 IRB personnel:
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.

E. Conflicting Interest: IRB Committee Members, consultants and IRB Administrators are considered to have a conflicting interest if they have any:

1. Significant financial interest;
2. Role in the conduct of the research; or
3. Other individual conflict of interest.

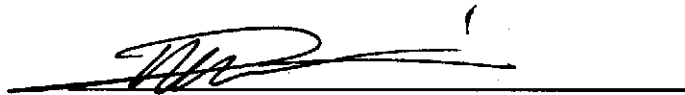
**V. Procedures**

IRB members must report any conflicting interests at the beginning of each IRB meeting.

**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