

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that members will review all human subjects research activities under the Department of Health's jurisdiction.

II. Authority

A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

A. 45 CFR 46

B. 21 CFR 50, 56, 312, and 600

C. IRB Policy VII.C, "IRB Member Conflicts of Interest"

IV. Definitions

Not Applicable.

V. Procedures

A. Committee Members

The mission of the DOH IRB is to protect the rights and welfare of human research subjects recruited to participate in research activities conducted by DOH Investigators or funded or supported by the DOH (See: policy "IRB jurisdiction") through ethically responsible and scientifically valid research, continuous education of the research community, monitoring of research activities, and compliance with the federal regulations and institutional policies and procedures.

1. Committee members have an understanding of basic ethical principles, the regulatory requirements, and the mechanics of serving on the IRB.
2. Committee members conduct prospective and continuing review of proposed research activities according to Department of Health and Human Services (DHHS) regulations 45 CFR 46, Food and Drug Administration (FDA) regulations 21 CFR 50 and 56 and when applicable, other Federal, State and local laws, and institutional policies and procedures including the IRB policies and procedures.
3. Committee members evaluate the research proposal for both scientific and scholarly merit. This includes consideration of research design, statistical power, equitable subject selection process, etc.

4. Committee members identify any conflicts of interest prior to the review of research activities and bring this to the attention of the Administrative Staff for reassignment.
5. Committee members obtain guidance or additional information in order to conduct an adequate study evaluation. This may include the request of an additional reviewer or consultant with expertise in the area of research under review (e.g., a Psychiatrist consultant may be asked to review a study that requires a "wash-out" period followed by intervention with investigational or novel agents in a population that has a high likelihood of enrollment of subjects that are or may become cognitively impaired).

B. Consultants and Ad Hoc Reviewers

1. Consultants and ad hoc reviewers are held to the same standards as those described above.
2. A consultant may serve as an ad hoc reviewer when expertise in a specific area is needed. The consultant may not be able to attend the meeting, but is expected to provide a written review of the research. This could be a narrative or could be captured on the reviewer's comment form.
3. The consultant may attend the meeting to participate in the review and discussion, however; the consultant may not count toward quorum or vote.
4. A Committee member or Administrative Staff may request a written review from an expert consultant and may also request they attend the meeting for participation in the discussion.

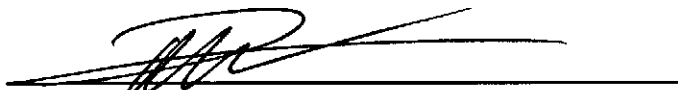
C. Investigational Drug Services (IDS) Reviewer

1. IDS reviewers evaluate the research proposal for compliance with FDA regulations for the storage, dispensing, handling, and disposal of investigational and FDA-approved drugs, agents, and biologics.
2. The IDS assures the PI complies with FDA regulations, IDS policies and procedures, IRB policies and procedures, and FDA audits.
3. All adverse events reviewed at full Committee that involves drugs, agents, or biologics are reviewed by the IDS representative.

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