

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that the composition of IRB Committees be in accordance with Federal regulations.

II. Authority

- A. Chapter 381.86, Florida Statutes (F.S.), Institutional Review Board

III. Supportive Data

- A. 45 CFR 46.107
- B. 34 CFR 350 and 356
- C. OHRP IRB Guidebook
- D. OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002
- E. DOH IRB Policy, "Special Categories of Research: Children"
- F. DOH IRB Policy, "Special Categories of Research: Prisoners"
- G. DOH IRB Policy, "Special Categories of Research: Pregnant Women, Human Fetuses, and Neonates"
- H. DOH IRB Policy, "Cognitively Impaired Individuals in Research"

IV. Definitions

- A. Agent: Any individual (employee or contractor) authorized to act on behalf of the Department of Health.

V. Procedures

- A. Composition of Institutional Review Boards

Each IRB must include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and one member who is not affiliated with DOH (i.e. not a family member or spouse of an employee, not recently retired, not a contractor or vendor providing goods or services). The non-scientist and non-affiliated member may be the same individual.

- 1. Ex Officio and Administrative Members

- a. Ex officio members, administrative members, invited guests or expert consultants do not have voting privileges.

- b. Ex officio and administrative members on the IRB may include the following:
- (1) Persons who are automatically members by virtue of the position held; and
 - (2) Persons necessary to the Committee by virtue of special knowledge or area of expertise (e.g., expert consultant).

B. Membership Selection

Selections for IRB Committee member voting positions and Chairpersons for the IRB Committees are made by the Secretary of Health based upon the specific needs of the IRB Committee, e.g. medical specialty, diversity, non-scientist, non-affiliated, etc.

1. The Assistant Director for Ethics and Human Research Protections in collaboration with the Director for the Office of Statewide Research recruits volunteers as needed, seeking advice from IRB Committee Chairpersons, IRB Committee Members, Division Directors, Bureau Chiefs, and others in making recommendations to the Secretary.
2. Decisions for selecting Committee members are made to assure that the IRB Committees retain diversity while maintaining regulations for required individuals to serve on the Committee.
3. Committee Chairs and Vice Chairs are selected as highly respected individuals from within or outside the institution, fully capable of managing the IRB and matters brought before it with fairness and impartiality.
4. The IRB Committee Rosters are posted on the DOH IRB website at <http://www.doh.state.fl.gov/ExecStaff/IRB/>.

C. Number of Members

The IRB Committees are required to have a minimum of five members each, with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the DOH or involving DOH resources or clients.

D. Alternates

Trained alternates formally listed on the IRB roster may vote in place of an absent voting member. Alternates are assigned according to their scientific or non-scientific status, as indicated on the Committee member rosters, and in accordance with the area of expertise required for adequate review. Meeting minutes must document when an alternate member replaces a voting member.

E. Qualifications of IRB Members

1. The IRB Committee membership must be:
 - a. Sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel; and
 - b. Able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice;
2. Additionally IRB Committee Members and Chairpersons must:
 - a. Be committed to the workload;
 - b. Understand the required time commitment;
 - c. Come to meetings prepared for discussion;
 - c. Be committed to the institution's goals for human research protections;
 - d. Possess good communication skills;
 - e. Be able to act as a facilitator;
 - f. Be willing to contact Investigators to discuss issues and initiate solutions prior to the meeting; and
 - g. When applicable have,
 - (1) Strong clinical expertise; and/or
 - (2) Research experience

F. Annual Review of Membership Needs

Composition of the membership of the IRB Committees should be adequate in light of the anticipated scope and complexity of research activities, the types of subject populations likely to be involved, and the size and available resources of the DOH. The IRB Administration conducts an annual review of IRB membership for composition and appropriateness.

G. Term of Service

1. Committee Members

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- a. Committee members are requested to serve a minimum of two years.
- b. Committee members are requested to serve as an alternate member at the completion of their term.

2. IRB Chairs

- a. Chairs are normally requested to serve one year as a Committee member prior to assuming the role of Chair.
- b. Chairs are requested to serve a minimum of three years including a minimum of one year as Chair.
- c. Chairs are requested to serve an additional year as a Committee member at the completion of their term to serve as a mentor for the newly selected Chair to promote consistency and continuity. In addition, this will provide a resource for the newly selected Chair and Committee members on historical perspectives, rationale for decisions made regarding policy, and meeting facilitation skills.
- d. Chairs are requested to serve as an alternate member at the completion of their term.

H. Required Expertise for Review of Research Involving Vulnerable Populations

1. Research Involving Children

An IRB Committee considering a protocol involving children as participants should:

- a. Assess its needs for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities; and
- b. Consider inclusion of one or more individuals who are knowledgeable about and experienced in working with children. To fulfill this requirement, the IRB Committee may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members.
- c. When reviewing proposed research on handicapped children or mentally disabled persons sponsored by the US Department of Education, the DOH IRB must also include a member with the expertise in the area of this population as described in the US Department of Education's regulations at 34 CFR 350 and 356.

2. Research Involving Prisoners

Federal regulations require that the IRB Committee membership be

modified if it is to review research involving prisoners. Therefore, if any IRB Committee will review research involving prisoners, at least one voting member of the IRB Committee shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

3. Research Involving Pregnant Women, Human Fetuses and Neonates Representative

The IRB Committee considers all applicable Federal regulations regarding research with this population and requests review by an expert, as needed.

4. Research Involving Cognitively Impaired Participants

The IRB Committee may include, if necessary, at least one member with expertise in the area of the cognitively impaired population when reviewing studies with this population or studies in which the participants may become cognitively impaired throughout the course of the research.

I. Additional Appropriate Expert Consultants

On a case-by-case basis, the IRB Committee may request review by an individual with competence in an area not represented by the Committee membership.

J. IRB Committee Member and Chair Performance Evaluations

1. Committee members and Chairs complete a self-evaluation annually which includes the following:

- a. Knowledge and application of the Federal regulations;
- b. Knowledge and application of IRB policies and procedures;
- c. Participation in Committee meeting discussions;
- d. Interaction with Investigators and study contacts; and
- e. Completion of educational requirements.

2. The Assistant Director, Office of Statewide Research, Ethics and Human Research Protections and other staff shall perform an ongoing assessment of the IRB Committee members and Chairs based on observations made during the IRB Committee meetings, and provide feedback individually to the member to enhance and promote growth in their performance as an IRB Committee member.

K. Reporting Changes in IRB Membership

The IRB Administration is responsible for reporting any amendments or changes to the IRB roster to OHRP prior to the initiation of such changes.

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

Date