

**I. Policy**

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to render motions/determinations according to Federal regulations and Florida law.

**II. Authority**

A. Chapter 381.86, Florida Statutes, Institutional Review Board

**III. Supportive Data**

A. Florida Public Law Chapter 116, The Public Records Act (Sunshine Law)

B. 45 CFR 46

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

**V. Definitions**

Not Applicable.

**VI. Procedures****A. Motions****1. Approval with no changes**

An approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 and no changes to the research application are recommended.

**2. Approved Pending Review and Approval by the Chairperson or His/Her Designee**

An approved pending status is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 and the modifications required by the full Committee are such that they only require simple concurrence by the Investigator. The application is approved if, on review, the modifications have been made by the Investigator and confirmed by the Chairperson or his/her Designee. If any modifications have not been made, or additional modifications have been made that were not requested, the Chairperson or his/her designee refers the study to full Committee, unless the Committee specifically asked for clarification of factual errors.

**3. Deferred**

A deferral is granted if the study does not meet the criteria for approval as defined in 45 CFR 46.111 or the IRB Committee recommends substantial revisions to the IRB Application, Sponsor's Protocol, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit ratio without the completed revisions.

4. Tabled

A study that lacks sufficient information to conduct an adequate review at the full Committee review level may be tabled pending receipt of the requested information.

5. Tabled due to Lack of Time

A study that is unable to be reviewed at the Committee meeting due to lack of time. The study is then placed first on the following meeting's agenda.

6. Administrative Hold

A currently approved study may be placed on hold by the IRB Committee, when the Committee requires additional information. Additionally, the IRB Chairperson or his/her designee may also place the study on Administrative Hold when more information is needed. The determination may be made and lifted at the level of review for which the study qualifies.

7. Sponsor-Imposed Suspension

A sponsor-imposed suspension is when the IRB receives written notification that the sponsor has suspended the research study. This will be acknowledged by the IRB Committee, Chairperson or his/her Designee when the appropriate level of review determines the suspension is appropriate. The IRB may impose additional criteria for suspension, if needed, to protect the participants from potential harm.

8. Suspension for Cause

A currently approved study is suspended for cause when evidence of a possible increase in risk to participants or non-compliance by the Investigator has been determined by the IRB. Suspensions for cause are made under full Committee review procedures.

9. Expiration

A currently approved study is expired when continuing review has not been conducted and approved prior to the study's expiration date.

10. Termination for Cause

A currently approved study may be terminated if the study is not being conducted in accordance with the IRB policies, is not in compliance with Federal regulations, and/or has been associated with unexpected serious harm to participants. Terminations for cause are made under full Committee review procedures.

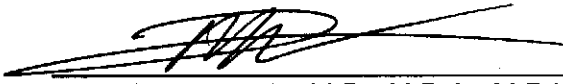
**B. Voting**

1. Members must vote either in favor (affirmative) or against (negative) regarding a protocol. Under Florida law (Ch. 119), a vote of "abstention" can only be recorded if there is a conflict of interest. Under federal regulations IRB members declaring a conflict of interest must recuse themselves and be absent during discussion and voting. Therefore, DOH IRB members with a conflict of interest must recuse themselves and the remaining members must vote either in favor or against the protocol.

**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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John O. Agwunobi, M.D., M.B.A., M.P.H.  
Secretary, Department of Health

06/29/05  
Date