

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed according to the criteria described in the Federal regulations.

II. Authority

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

III. Supportive Data

- A. 45 CFR 46.101(b)
- B. 45 CFR 46.401(b)
- C. DOH IRB Policy, "Non-Human Subject/Non-Research Determination"
- D. OHRP Compliance Activities: Common Findings and Guidance -7/10/2002 Item #30
- E. OHRP Guidance: Coded Private Information - 8/10/2004

IV. Definitions

- A. Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. According to Florida State law, the legal age for consent is 18 years of age.
- B. Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

VI. Procedures

- A. Full Committee Eligibility
 - 1. An Investigator may request a particular type of review, but the final determination is made by the Institutional Official or designee.
 - 2. A full IRB Committee must review studies not qualifying for IRB review under the exempt or expedited categories.
 - 3. The IRB has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

- B. IRB Quorum Required for Full Committee Review**
1. The IRB Committee may only review proposed research at a convened meeting at which a quorum is present. A majority of the voting members of the IRB Committee are present, including at least one member whose primary interests are in nonscientific areas.
 2. IRB meetings are not convened if a nonscientist is not present.
 3. No official actions take place at a meeting where a majority of the voting members are not present.
 4. Should the Committee meeting lose quorum (e.g., those with conflicts being excused, early departures, loss of all non-scientists), the meeting is terminated from further votes until the quorum is restored.
 5. Wherever possible, IRB Committee meetings take place with all participating IRB members physically present. However, circumstances sometimes warrant conducting IRB meetings via telephone conference call. OHRP will recognize as "convened" those IRB meetings conducted via telephone conference call, provided that each participating IRB member:
 - a. Has received all pertinent material prior to the meeting to allow adequate time for review and the request of additional information, if needed; and
 - b. Can actively and equally participate in the discussion of all protocols (i.e., each member can hear and be heard by all other participating members).
 - c. The minutes of such meetings clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance; initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).
 6. No IRB Committee member may participate in the IRB Committee's initial or continuing review of a project in which the member has conflict of interest. If a conflict exists, the Committee member can provide information requested by the IRB Committee but cannot be present for the discussion and the vote.

C. Required Review

1. Substantive review of standard protocols takes place at convened meetings. Applications undergoing review are individually presented and discussed at a convened meeting of the IRB Committee.
2. In conducting the full IRB Committee review, the majority of the Committee must agree that materials are in sufficient detail to determine the study meets criteria 45 CFR 46.111 and if applicable, 21 CFR 56.111 or 38 CFR 16.111 for approval:
 - a. Risks to subjects are minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
 - b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB Committee should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
 - c. Selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
 - d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Federal and State regulations and Institutional policies and procedures including the IRB;
 - e. Informed Consent will be appropriately documented, in accordance with, and to the extent required by the Federal and State regulations and Institutional policies and procedures including the IRB;
 - f. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;

-
- g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- h. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The IRB Committee must determine if additional safeguards need to be included in the study to protect the rights and welfare of these subjects;
- i. When appropriate, the need for ancillary care, additional monitoring, counseling, and social support are provided; and
- j. When appropriate, the Informed Consent Document should include the additional elements of informed consent.
- k. The full IRB Committee determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the last date of IRB approval. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of the research occurs on or before the date when IRB approval expires. The following factors are taken into consideration when determining the appropriate review interval, but are not limited to:
- (1) Involvement of vulnerable populations;
 - (2) Research conducted internationally;
 - (3) Involvement of recombinant DNA or other types of gene transfer protocols;
 - (4) Use of waiver of informed consent procedures, (e.g. surrogate consent);
 - (5) Classified research;
 - (6) Research for which participants would be exposed to additional risks, e.g. breach of confidentiality, phase I studies, disproportionate number or severity of adverse events;
 - (7) Previous Administrative Holds or Suspensions of the research due to compliance, record-keeping or other concerns; and/or


(8) Recommendations from other Institutional committees

3. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting the criteria for approval by the full IRB Committee.
4. All research approved by the full IRB Committee is conducted in accordance with all applicable Department of Health policies and procedures.
5. The decisions and requirements for modifications by the IRB Committee are promptly conveyed to the Investigator. Written notification from the IRB of a decision to disapprove a protocol is accompanied by the IRB Committee's reasons for the decision and an invitation for reply by the Investigator, either in person or in writing.

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