

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that Investigators conduct human subjects research in accordance with Federal, State and institutional rules, regulations, and policies, and IRB policies and procedures.

II. Authority

A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

A. *The Belmont Report*

B. 45 CFR 46

IV. Definitions

A. **Assurance:** A contract or agreement that establishes standards for human research as approved by the Office for Human Research Protections (OHRP).

B. **Institutional Review Board (IRB):** A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

V. Procedures

A. Human Subjects Protection

1. The DOH IRB policies and procedures are designed to protect the rights and safety of human research participants based on the ethical principles of *The Belmont Report*.
2. It is the Investigator's responsibility to be knowledgeable regarding the roles and responsibilities as an Investigator. With each initial submission to the IRB the Investigator, Department, Division, or Office Director are required to sign an Assurance Statement affirming that they agree to uphold the protection of the rights and safety of human research participants through adherence to Federal, State, and local laws, institutional rules, regulations and policies, and DOH IRB policies and procedures.
3. The Investigator assumes responsibility for compliance with all Federal, State, and local laws, institutional rules, regulations and policies, and DOH IRB policies and procedures related to research involving humans and, if applicable, to the Good Clinical Practice Guidelines as adopted by the Food and Drug Administration (FDA) available at <http://www.fda.gov/oc/gcp/default.htm>.

4. The Investigator is the ultimate protector of the participant's rights and safety. Each Investigator is obligated to be personally certain that each participant is adequately informed and freely consents to participate in the research. The Investigator must personally assure that every reasonable precaution is taken to reduce risks to the participants.
5. The Investigator may not initiate any research involving humans without prior IRB review and approval. In addition, the Investigator may not amend or change an approved protocol without prior IRB review and approval, except where necessary to eliminate apparent immediate hazard to the participant.

B. Investigator Training

1. It is the responsibility of each Investigator to complete initial and *annual* DOH IRB human research protections training requirements and to remain up-to-date with Federal, State and local laws, institutional rules and regulations, and DOH IRB policies and procedures, and compliance expectations.
2. It is the responsibility of each Investigator to assure that other Investigators and key study personnel who are responsible for the design and conduct of the research are adequately trained in human research protections and assure completion of continuing education requirements.

C. Investigator and Key Study Personnel Conflicts of Interest

1. It is the Investigator's responsibility to disclose all actual or perceived conflicts of interest as defined by institutional policy to the DOH IRB for review to assure full disclosure to participants in human subjects research of the potential conflict.
2. It is the Investigator's responsibility to assure all actual or perceived conflicts of interest as defined by institutional policy are reviewed and a determination rendered by an Ethics Committee and that the outcome of such review is submitted to the DOH IRB, prior to initiation of the research.

D. Congruence with Funding Proposals

1. It is the responsibility of the Investigator to assure that the IRB application is consistent with the proposal for funding for extramural or intramural support.
2. The Investigator should act as a liaison between the IRB and the research sponsor.

E. Supervision and Auditing of Research Process

1. It is the responsibility of each Investigator to assure that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of Florida and the policies of the Department of Health. The Investigator must assure adherence to the study protocol and monitor the informed consent process. The Investigator must also assure there are appropriate facilities and resources to conduct the research.
2. It is the responsibility of the Investigator to regularly review his or her research processes and address any deficiencies identified.
3. It is the responsibility of the Investigator to conduct and document auditing of research activities on a regular basis.
4. It is the responsibility of the Investigator to audit external performance sites routinely, assuring adequate staff, resources, and pharmacy practices.

F. Confidentiality

1. The conditions for maintaining confidentiality of the participants' research records are required for the life of the data.
2. Research conducted with Food and Drug Administration (FDA) regulated articles must be kept in accordance with current FDA regulations.
3. The Investigator must also assure participant privacy and confidentiality according to HIPAA guidelines, Institutional and IRB policies and procedures.

G. Additional Requirements for Activities Involving Vulnerable Populations

1. The IRB must review and approve the use of a vulnerable population in research activities. Special considerations are provided in the Federal regulations and the DOH IRB policies and procedures for the following populations:
 - a. **Pregnant Women, Human Fetuses, Neonates, and Transplantation of Fetal Tissue.** For research activities involving pregnant women, human fetuses, neonates and transplantation of fetal tissue, the Investigator must assure that all requirements are satisfied and adequate provisions have been made for monitoring the informed consent process.
 - b. **Prisoners.** If a participant becomes a prisoner after enrolling in a research study, the Investigator is responsible for immediately reporting this situation in writing to the IRB. The Investigator must cease all interactions or interventions with the prisoner-participant until approval has been received from the DOH IRB and the

OHRP. All research activities involving the use of prisoners as participants require both DOH IRB approval and OHRP approval.

- c. **Children.** For research activities involving children, the Investigator must assure that all requirements are satisfied. The Investigator is responsible for assuring parental consent, as well as child assent/dissent, in accordance with the determinations of the DOH IRB.
 - d. **Cognitively Impaired.** Individuals who are or who may become decisionally impaired may have diminished autonomy that may limit their capacity to provide consent. Therefore, the Investigator is responsible for assuring that informed consent is conducted in accordance with the determinations of the DOH IRB.
2. The IRB may also determine that other target populations identified in the research proposal are "vulnerable" in particular types of research; and may impose additional protections not outlined in the Federal regulations.

H. Amendments and Requests for Changes in IRB Application

It is the responsibility of the Investigator to not deviate from the IRB approved research activities until the Investigator has received written approval from the IRB.

I. Informed Consent

1. The Investigator must assure that the performance of the informed consent process is congruent with IRB policy and Federal regulations.
2. The Investigator may delegate obtaining informed consent to a member of his or her study team. However, the Investigator is responsible for monitoring the informed consent process and assuring copies of the consent documents have been provided to participants while keeping the original on file.

J. Unanticipated Problems Involving Risk to Participants or Others

The Investigator must report to the IRB, Data and Safety Monitoring Boards, sponsors and appropriate Federal agencies any unanticipated problems involving risks to participants or others that occur in the course of the research.

K. Continuing Reviews

1. All approved research proposals, with the exception of those which qualify for exemption in accordance to 45 CFR 46.101 and 21 CFR 56.104(d) must receive continuing review at intervals appropriate to the degree of risk as determined by the IRB.

2. Continuing review must be conducted not less than once per year. The Investigator must assure that continuing review applications are submitted in a timely manner so that their review occurs prior to their expiration date. The Investigator acknowledges that the Federal regulations do not allow a grace period.
3. Continuing review must be substantive and meaningful. Therefore the Investigator must submit a comprehensive summary of the research activities and progress since the last continuing review, which would include a summary of adverse events and unanticipated problems, amendments, results of literature searches, publications, etc. The Investigator is responsible for being aware of the current literature in his/her field of study to assure participants are no longer placed at risk if additional risks have been identified or no benefit has been proven.

L. Research Records

1. At a minimum, Investigators must maintain research records for at least three (3) years from the date the research is closed with the DOH IRB.
2. All research records must be accessible for inspection and copying by authorized representatives of the IRB, Federal regulatory agency representatives, and the department or agency supporting the research.
3. Beyond three years, requirements for record retention vary with the type of research conducted and provisions of the Investigator's funding source. It is the Investigator's responsibility to have a clear understanding of the retention requirements of a sponsor.
4. All Health Insurance Portability and Accountability Act (HIPAA) related documentation must be maintained for at least six (6) years from the date of the last use or disclosure of the Protected Health Information (PHI).
5. If for any reason there is a change in PI on a protocol, then the DOH IRB must be notified. The Investigator may either have another Investigator assume Principal Investigator responsibilities, close any research studies with the IRB, or take the research studies to the new location. The Investigator must also notify in writing to the DOH IRB the plan for either destroying the data or transferring the data to another Principal Investigator.

M. Use of Investigational Drugs and/or Investigational Devices

The Investigator is responsible for obtaining the Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA in accordance with Federal regulations.

N. Additional Institutional Committee/Institution Approvals

1. It is the responsibility of the Investigator to seek review and approval from any other required DOH Committees or other Institutions (universities, hospitals, school districts) as required and provide documentation to the DOH IRB, prior to the initiation of any research.
- O. Federalwide Assurances (FWA), Memos of Understanding (MOU), Other IRB Approvals, and Letters of Cooperation
1. It is the Investigator's responsibility to assure that the proper approvals and agreements are in place prior to the commencement of research. This includes research at performance sites, "engaged" or "not engaged," that are not a legal entity of the DOH or covered entity.
 2. The Investigator is responsible for submitting copies of all IRB approvals or letters of cooperation, whichever is applicable, for all performance sites indicated in the IRB Application that are not a legal entity of the DOH or covered entity.
 3. The Investigator must assure that each performance site indicated in the IRB Application as "engaged" in research, has a *current* FWA and IRB approval, not just initially but throughout the conduct of the research.
 4. If the DOH IRB has agreed to serve as the IRB of Record for a performance site "engaged" in research as evidenced by an executed MOU, it is the Investigator's responsibility to assure that the MOU is current and that he/she upholds the terms and conditions defined within the MOU.

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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Secretary, Department of Health

06/29/05

Date