

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to have jurisdiction over all human subjects research subject to its Assurance.

II. Authority

A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

A. *The Belmont Report*

B. 45 CFR 46, 160 and 164

C. 21 CFR 50 and 56, 312, 812

D. Terms of Assurance, Office of Human Research Protections, Department of Health and Human Services (DHHS)
(<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>)

E. Guidelines for Defining Public Health Research and Public Health Non-Research, Centers for Disease Control and Prevention, October 4, 1999.
<http://www.cdc.gov/od/ads/opspoll1.htm>

IV. Definitions

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

B. Clinical Investigation: Any experiment that involves a test article and one or more human subjects and is subject to requirements for submission to the Food and Drug Administration.

C. Food and Drug Administration (FDA): The United States government office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with humans.

D. Human Subject: A living individual about whom an Investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual or the individual's identifiable private information or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

1. Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.

2. Interaction: Includes communication or interpersonal contact with a subject or their private identifiable information.
 3. Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.
 4. Test article: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.
- E. Memorandum of Understanding (MOU): A formal agreement between the Department of Health and another institution that identifies the Department of Health Institutional Review Board as the IRB of record for that institution.
- F. Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.
- G. Research: Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
- H. Human Subjects Research: Any research that involves humans as subjects and any clinical investigation.
- I. Office of Statewide Research: The office responsible for research and human research protections at the Department of Health.

V. Procedures

- A. Review and Approval of Human Subjects Research.
1. All human subjects research, and all other activities, which in part involve human subject research, which is funded or supported by the Department of Health, must be reviewed and approved by the Department's Institutional Review Board. Studies receiving 100 percent federal funding and for which the Principal Investigator is not a DOH employee are exempt from this policy. However, this does not imply, in any way, that the study itself is exempt from IRB review and approval.
 2. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has

reviewed and approved the research.

3. It is the responsibility of the Institutional Official or Assistant Director, Office of Statewide Research or IRB Administrator to determine what activities constitute "human subjects research."

B. Scope of Authority

The Department of Health's Assurance with the Federal government defines its jurisdiction over the review of human subjects research. The DOH IRB must review all human subjects research if one or more of the following apply:

1. The research is sponsored (funded) in whole or in part from state appropriations to DOH;
2. The research is conducted by or under the direction of any employee or agent of DOH in connection with his or her official responsibilities;
3. The research is conducted using any property or facility of the DOH;
4. The research involves DOH clients;
5. The research involves the use of non-public information maintained by the DOH;
6. The research is conducted in accordance with an Assurance filed with the Office of Human Research Protections (OHRP) in which the DOH IRB is designated as the IRB of record through an established Memorandum of Understanding.

C. Review of Research Involving Data Collected for Non-Research Purposes

1. If after data are collected for non-research purposes, an Investigator wants to access the data with the intent of conducting research, IRB review and approval may be required prior to accessing the data for research purposes.
2. If an Investigator begins a non-research project and later finds that the data gathered could contribute to generalizable knowledge, the ultimate decision regarding classification lies in the intent of the project. If the primary intent is to generate generalizable knowledge, the project is research. If the primary intent is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research. If the primary intent changes to generating generalizable knowledge, then the project becomes research, and it is important that the Investigator submit a proposal to the IRB for review and approval prior to release of such information.
3. Because there are no universally accepted or completely specified criteria

for determining when data collected for non-research purposes is being used for research, projects are reviewed on a case-by-case basis.

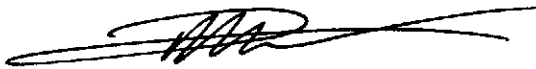
D. Failure to Submit a Project for IRB Review

1. The implications of engaging in activities that qualify as research that is subject to IRB review without obtaining such review are significant. In addition to disciplinary action or other action that the Institutional Official may take, the results from such research may not be published or presented unless IRB approval had been obtained prior to collecting the data.
2. Investigators who request approval to continue human subjects research that was not previously reviewed or to use research data that was collected without IRB approval face the possibility that the IRB will administratively withdraw or request the PI to administratively withdraw the application, as the IRB cannot give post-hoc approval to research projects.
3. The IRB may not approve applications where the Investigator has attempted to circumvent IRB policies and procedures regarding human subjects research by collecting data as non-research and then applying to use them as existing data. It is therefore in the Investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

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