

**I. Policy**

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that all investigators and key study personnel conducting human subjects research under the jurisdiction of the DOH IRB complete initial and annual human research protections training.

**II. Authority**

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

**III. Supportive Data**

- A. DOH IRB Policy, "Investigator Qualifications"
- B. DOH IRB Policy, "General Responsibilities of Investigators"
- C. National Institutes of Health (NIH) policy, "Required Education in the Protection of Human Research Participants" June 5, 2000 (Revised August 25, 2000) available at <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>
- D. Collaborative IRB Training Initiative (CITI) Training: <http://www.citiprogram.org>
- E. "Category Definitions," Carnegie Foundation for the Advancement of Teaching <http://www.carnegiefoundation.org/>

**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. The June 5<sup>th</sup>, 2000 NIH Guide Notice mandated all key study personnel involved in NIH funded human subjects research must have formal instruction in human research protections. This policy has been embraced by many federal agencies, and is recommended by accrediting organizations. Therefore, all DOH IRB human research investigators and key study personnel must complete the following initial and continuing education requirements and provide certification of completion to the DOH IRB:
  - 1. Initial Training via the Collaborative IRB Training Initiative (CITI). This internet-based course in human research protection and bioethics is

available at no cost and designed specifically for all personnel that have a significant involvement in the planning, conduct, and analysis of any scientific activity that employs human research participants. The course consists of training modules that are divided into two tracks: Biomedical Research and Social/Behavioral Research. The learning objectives of the CITI course are:

- a. To provide an understanding of the historical perspectives, ethical principles, and Federal regulations associated with the conduct of research with human participants;
  - b. To provide a clear understanding of what constitutes informed consent and how it must be applied in research involving humans;
  - c. To provide basic information on the regulations and policies governing research with investigational drugs, biologics, and devices;
  - d. To provide a clear understanding of the ethical issues and Federal regulations in force during the conduct of Social/Behavioral research, records based research, and genetics research with human participants; and
  - e. To provide Investigators conducting research at VA facilities a clear understanding of the special procedural and regulatory policies for human research at VA research facilities.
2. Annual Training. Investigators and key study personnel with open protocols are required to document completion of one hour of continuing education each year, which may include any of the following:
- a. Completion of one additional CITI module, not including modules already completed;
  - b. Attendance at education sessions conducted by the Office of Statewide Research;
  - c. Attendance at national or regional conferences on human subjects protections such as those conducted by Public Responsibility in Medicine and Research (PRIM&R) or the Office of Human Research Protection;
  - d. Attendance at continuing education on research involving human subjects provided by professional associations
  - e. Attendance at continuing education on research involving human subjects provided by the researcher's academic institution,

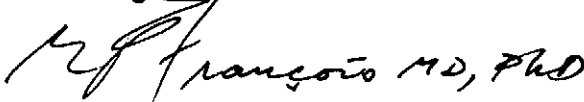
institutions with an accredited human research protection program, or institutions that satisfy the Carnegie criteria as either a Doctoral/Research Exclusive or Inclusive institution (see: <http://www.carnegiefoundation.org>)

- B. An Investigator's Handbook will serve as a resource manual for researchers that will assist Investigators in smoothly navigating the IRB process and adhering to the Federal regulations and IRB policies related to human research protections. The manual is located on the IRB website.
- C. All Investigators and key study personnel conducting research involving humans at the DOH are encouraged to review the core training materials including the DOH Federalwide Assurance, the DOH IRB policies and procedures, the Belmont Report, and the Federal regulations including 45 CFR 46, 21 CFR 50 and 56. Links to this information plus links to other federal agencies (e.g., National Institutes of Health, Food and Drug Administration, Office of Human Research Protections, etc.) governing human subjects research are available at the DOH IRB website <http://www.doh.state.fl.us/execstaff/irb/>.
- D. The IRB will send mass e-mail notifications, limited to a mailing list of all Investigators and key study personnel that have active studies, to alert them of pertinent IRB issues or decisions that may impact their research.

#### 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

4/3/06

Date