Procedure

Subject: Procedure for General Responsibilities of Investigators

Procedure:
This procedure outlines the general responsibilities of Investigators conducting research involving humans.

I. Investigator Responsibilities.
   A. The Investigator will obtain knowledge regarding federal, state, and local laws and regulations, institutional policies, HRPP policies and procedures, the ethical principles of The Belmont Report, and Good Clinical Practice (GCP) Guidelines, if applicable, prior to conducting research involving humans.
   B. The Investigator will assure protection of the participant's rights and safety by adequate design and conduct of research, as well as oversight of all research processes and procedures and other research personnel involved in research activities.
   C. The Investigator will apply for IRB review and approval according to HRPP policies and procedures prior to conducting human subjects research.
   D. The Investigator will complete the required human subjects training through the Collaborative IRB Training Initiative (CITI). Instructions and access to training is available on the HRPP Website at http://www.mc.vanderbilt.edu/irb/. The Investigator will assure that all key study personnel (KSP) have completed the required human subjects training prior to IRB submission of research applications. In addition, the Investigator will participate and assure that all KSP participate in continuing education at least annually as required by HRPP policy.
   E. The Investigator will respond to all IRB requests for additional information in regards to verifying knowledge training, and resources adequate to perform research involving human participants.
   F. The Investigator will assure that required approvals from other university committees or institutions are granted prior to beginning research activities.
   G. The Investigator will assure the proper handling, storage, and dispensing of all investigational agents and when not using the services of the Investigational Drug Service (See HRPP Procedure XI.B.1 for proper procedure).
   H. The Investigator will disseminate new information regarding the use of FDA agents in research to participants as he/she becomes aware.

II. IRB Committee Responsibilities.
   A. The IRB Reviewer will assure the Investigators and key study personnel have adequate knowledge processes, personnel, and facilities to conduct human subjects research according to federal, state, local laws and regulations, ethical principles of The Belmont Report, and GCP guidelines, if applicable.
   B. The IRB may request from the Principal Investigator (PI) additional documentation to assure the Investigators and key study personnel have adequate knowledge, processes, personnel, and facilities to conduct human subject research under the jurisdiction of the IRB.

III. HRPP Regulatory Compliance Analyst (RCA) responsibilities.
   A. The RCA will offer guidance on federal, state, and local laws and regulations governing human subjects research to Investigators and key study personnel as needed.
   B. The RCA will stay abreast of current federal, state, and local laws and
regulations governing human subjects research and act as a resource to the IRB Committee in its review and determinations of human subjects research

C. The HRPP will provide educational opportunities in human research protections for Investigators and KSP.