Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: V.C.1
Section: Records, Documentation, and Fees
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: March 19, 2004
Revision Dates: January 26, 2009; July 1, 2015

Subject: Procedure for Development, Approval, and Maintenance of Policies and Procedures

Procedure:
This procedure outlines the process for the development, approval, and maintenance of the HRPP policies and procedures.

I. Investigator Responsibilities.
   A. The Investigator will review all HRPP IRB policies and procedures as part of the required initial training for conducting human subjects research at Vanderbilt University. Current policies and procedures are located on the HRPP website at http://www.mc.vanderbilt.edu/irb/ under "Policies & Procedures".
   B. It is the responsibility of the Investigator to routinely view the HRPP website for new or revised HRPP policies and procedures.
   C. The Investigator will contact an HRPP Regulatory Compliance Analyst (RCA) or the HRPP Process Improvement Team for clarification of policies and procedures, when needed.

II. HRPP Administration Responsibilities.
   A. The HRPP Process Improvement Team will routinely view the OHRP and FDA websites for issuance of guidance documents, changes in regulations, and determination letters.
   B. A member of the HRPP Process Improvement Team will attend HRPP staff meetings and Optimization Committee meetings if applicable to obtain guidance on necessary revisions of policies and procedures.
   C. The HRPP and the Office of General Council will maintain a joint relationship to discuss changes and assist with interpretation of federal, state and local regulations affecting HRPP policies and procedures.
   D. The HRPP Process Improvement Team will provide educational sessions to the IRB Committee members and staff regarding HRPP policies and procedures, as well as updates or revisions in a timely manner.
   E. The HRPP Policy and Procedure Committee is responsible for the development and maintenance of HRPP policies and procedures as directed by the HRPP Director.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will use the HRPP policies and procedures posted on the HRPP website when processing research activities.
   B. The RCA may consult with the HRPP Process Improvement Team for guidance in applying the HRPP policies and procedures.
   C. If the RCA notices that a policy or procedure is inaccurate or out of date, the RCA should bring it to the attention of their Team Leader or the HRPP Director who will communicate to the Chair of the HRPP Policy and Procedure Committee, or they can communicate it directly to the Chair of the HRPP Policy and Procedure Committee. It is all HRPP staff's responsibility to keep the HRPP policies and procedures current and applicable to the daily processes.