Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: I.A.1
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: October 1, 2003
Revision Dates: May 28, 2004; January 23, 2009; September 8, 2009; May 21, 2010; June 30, 2010; May 1, 2016

Subject: Procedure for Institutional Oversight of Assurance

Procedure:
This procedure outlines the VUMC Institutional Review Board responsibilities in maintaining the Vanderbilt's Assurances.

I. Investigator Responsibilities.
   A. The PI is responsible for acquiring the appropriate knowledge regarding human participant protections, ethics, federal regulations, training, and monitoring to conduct his/her proposed research.
   B. The PI must assure that his/her key study personnel are adequately trained and knowledgeable regarding human participant protections, ethical considerations, and federal regulations applicable to the proposed research.
   C. The PI is responsible for complying with the training, monitoring, and human participant research guidance as outlined in the Assurances and HRPP policies and procedures.

II. IRB Committee Responsibilities.
   A. The IRB Committee reviews all research activities and documents its findings regarding ethical considerations, scientific merit, adherence to federal regulations and IRB policies and procedures.
   B. The IRB Committee must review and monitor ongoing research for adherence to the federal regulations and IRB policies and procedures.

III. Regulatory Compliance Analyst Responsibilities.
   A. The RCA participates in ongoing auditing and monitoring activities to assure adherence to the federal regulations.
   B. The RCA participates in the revisions of the HRPP policies and procedures as applicable.

IV. HRPP Administration Responsibilities.
   A. All information provided under the Assurances must be updated at least every 60 months, even if no changes have occurred, in order to maintain active Assurances approved by OHRP.
   B. Amendments to the Assurances are to be reported promptly to OHRP. This includes changes to IRB Committee rosters and the addition or deletion of an IRB Chairperson or legally recognized entity of VUMC.
   C. VUMC will maintain policies and procedures reflecting the current practices of the IRB in conducting reviews and approvals under its Assurances.
      1. These policies and procedures will be maintained and kept current by the HRPP. They will be re-reviewed at least every 60 months. All revision dates will be listed under the revision date for each policy and procedure.
      2. Changes in policy are determined by the IRB Optimization Committee. As appropriate, policies and procedures are developed and revised by the HRPP Policy and Procedure Committee.
      3. All policies are to be approved by the Institutional Official and the HRPP Medical Director at VUMC.
      4. All procedures are to be approved by the Institutional Official and the HRPP Medical Director at VUMC.
V. Annually, the HRPP budget will be reviewed by the Associate Vice Chancellor for Research, the HRPP Medical Director and the HRPP Director and modified as necessary to accommodate the volume and type of research reviewed, space, facilities and staff. The budget then undergoes a thorough review process by the Department of Finance.

VI. The IO and HRPP administration meet every other week to evaluate the resources needed for the operations and functions of the HRPP. These meetings are used to assess and evaluate performance metrics such as turnaround times (Measures of Success), type of submission summaries, staff satisfaction, and customer feedback to assure the HRPP has adequate resources and tools. Action plans for improvement are developed to improve processes and are reviewed and approved by HRPP administration. Process improvement activities are evaluated using the Plan, Do, Study, Act (PDSA) cycle method. All changes are tracked as data over time and either acted upon or abandoned depending on if the change shows an improvement.