Procedure

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: I.G.1
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: February 27, 2017
Revision Dates: January 25, 2018

Subject: Procedure for Use of Single Models to Facilitate Review Time and Effort

Procedure:

I. Investigator’s Responsibilities.
   A. The Lead Vanderbilt Investigator (when Vanderbilt is the IRB of Record) is responsible for:
      1. Complying with existing VHRPP Policies and Procedures;
      2. Assisting in obtaining local context information;
      3. Submitting any local site personnel changes to the VUMC IRB; and
      4. Submitting all relevant documents to the VUMC IRB.
   B. Relying Vanderbilt Investigator (when Vanderbilt is NOT the IRB of Record)
      1. Investigators submit the following to the VUMC IRB when another IRB is serving as the IRB of Record:
         a. All funding information (including a copy of the grant, if available);
         b. Key Study Personnel and their qualifications;
         c. Any basic information about the study type and reviewing IRB;
         d. A description of the study;
         e. All enrollment information for participants at Vanderbilt;
         f. All radiation/radioactive drug procedures and any drugs that will be used in the course of the study, if applicable;
         g. A description of any PHI to be used/disclosed, if applicable;
         h. Any conflicts of interest;
         i. The IRB approved consent including local context information and Vanderbilt-specific language (e.g., HIPAA authorization and subject injury language);
         j. The IRB approved study protocol; and
         k. The IRB approval letter from the reviewing IRB.
      2. Investigators are responsible for submitting the IRB approved updated consent forms and protocols when major amendments occur (See HRPP Policy III.J).
      3. Investigators are responsible for submitting reports of non-compliance and adverse events/unanticipated problems that occur at Vanderbilt (See HRPP Policies II.F and III.J).
      4. Investigators are responsible for submitting all annual enrollment numbers and study status information as a continuing review report.

II. IRB Committee Responsibilities.
   A. Reviewing IRB (when Vanderbilt is the IRB of Record) is responsible for:
      1. Following all Committee Member responsibilities;
      2. Reviewing local context information from relying sites in the context of the study (See HRPP Procedure I.D.1); and
      3. Reviewing site PI changes to ensure qualifications of the local PIs.
   B. Relying IRB (when Vanderbilt is NOT the IRB of Record).
      1. The VUMC IRB conducts the following local ancillary reviews when consistent
with the reliance agreement used:
   a. Key Study Personnel qualifications and compliance with human subjects training, if applicable;
   b. Medicare Qualifying Clinical Trials Analysis, if applicable;
   c. HIPAA authorizations and requests for waiver of authorizations when the IRB of Record will not serve as a Privacy Board for Research; and/or
   d. Human subjects radiation safety.

2. The VUMC IRB will facilitate the following local ancillary reviews:
   a. Conflict of Interest Committee;
   b. Radioactive Drug Research Committee;
   c. Institutional Biosafety Committee; and/or
   d. Vanderbilt Institutional Human Pluripotent Cell Research Oversight Committee.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. Reviewing IRB (when Vanderbilt is the IRB of Record):
   1. The RCA verifies reliance documents in collaboration with the participating site’s IRBs;
   2. Assists the Investigator’s with submissions; and
   3. Verifies and disseminates local context information for the IRB Committee.

B. Relying IRB (when Vanderbilt is NOT the IRB of Record):
   1. The RCA verifies reliance documents in collaboration with reviewing IRBs; and
   2. Assists Investigators with submissions.