Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: IF
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: IRB of Record

Definitions:
1. Coordinating Center: An institution, department, or center, which agrees to be responsible for the conduct, administrative, or coordinating functions of a multi-center research project.
2. IRB of Record: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution. A Memorandum of Understanding is required designating the relationship.
3. Memorandum of Understanding (MOU): A formal agreement between VUMC and another institution that identifies the VUMC Institutional Review Board as the IRB of record for that institution.
4. Performance Site(s) Engaged in Research: A performance site becomes "engaged" in human subjects research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human subjects research when it receives a direct federal award to support the research.

Policy:
The policy establishes the provisions under which the VUMC Institutional Review Board (IRB) will serve as the IRB of Record for an external site engaged in research.

I. IRB of Record
   A. Differences between "coordinating center" and "IRB of Record."
      1. When the VUMC IRB serves as the IRB of Record, it is accepting the responsibility of oversight of the conduct of the research for a particular site. The details of such an agreement are outlined in an MOU.
      2. A "coordinating center" of a multi-center trial is responsible for assuring that IRB approval is granted at the participating sites prior to the initiation of the research at that site. It is important to note that even when an Investigator serves as the "coordinating center," the VUMC IRB is not the IRB of Record. The coordinating center assumes responsibility for assuring that the participating site has received IRB approval at its sites.
      3. Under rare circumstances, the VUMC IRB may be requested to serve as the IRB of Record for a participating site of a multi-center trial in which a VU or VUMC Investigator is serving as the "coordinating center." The participating site may either not have an IRB of Record, or due to other circumstances, may request the VUMC IRB to serve as their IRB of Record for that particular study at that particular site.

II. Memorandum of Understanding (MOU).
   A. An executed MOU is the only method by which the VUMC IRB serves as the IRB of Record for a site, which is not a legal entity of VUMC.
   B. The VUMC IRB will not accept an "IRB Authorization Agreement" or an "Unaffiliated Investigator Agreement" (listed on the OHRP website). All agreements for the VUMC IRB to serve as the IRB of Record for a performance site “engaged” in research must be detailed in an executed MOU.
   C. A MOU between the relevant parties will outline specific provisions and responsibilities for each party entering into the agreement.
   D. Basis for VUMC IRB to serve as the IRB of Record.
1. The performance site engaged in research does not have an IRB of Record and will rely solely on the VUMC IRB for review of human subjects research activities; or
2. The performance site engaged in research may or may not have an IRB of Record, but will rely on the VUMC IRB for a specific research project.

E. Conditions for VUMC IRB to serve as the IRB of Record.
   1. The research shall be conducted in collaboration with VU or VUMC; and
   2. The Investigator must be a full-time faculty member at VU or VUMC.

F. The performance site engaged in research requesting VUMC IRB to serve as the IRB of Record must:
   1. File a Federalwide Assurance (FWA); and
   2. Conduct the research in accordance with the terms and conditions specified in the MOU.

G. The Investigator must provide all necessary information pertaining to local research activities conducted at external sites in accordance with HRPP policies and procedures.

H. The VUMC IRB and external site will maintain an approved Federalwide Assurance (FWA) and provide verification of such during the negotiation of the MOU.

I. The Investigator will be responsible for payment of the negotiated fees as established in the MOU.

J. The Investigator and external site will abide by all HRPP policies and procedures including accessing HRPP Website at http://www.mc.vanderbilt.edu/irb/ to view any revisions and/or updates.

K. Investigators will comply with all oversight activities deemed appropriate by the IRB, federal oversight agencies and/or federal funding agencies at all sites (e.g., monitoring, auditing).

References:
45 CFR 46