Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: I.F
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: March 19, 2004
Revision Dates: May 1, 2016; January 25, 2018

Subject: Coordinating Centers (Formerly IRB of Record, see Policy I.G)

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 (Reviewing IRB): An IRB is considered the IRB of Record when it assumes IRB responsibilities for another institution. A reliance agreement or Memorandum of Understanding (MOU) is required designating the relationship.
3. Performance Sites 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 private information for research purposes. Further, a performance site is considered “engaged” in human subjects research when it receives a direct federal award to support the research.

Policy:
It is the policy of the VUMC IRB to review coordinating center activities occurring at VU or VUMC to assess and enhance human subject protections.

I. Coordinating Centers.
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 for oversight of the conduct of the research at a particular site. The details of such an arrangement are outlined in the reliance agreement or 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 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 automatically the IRB of Record. The coordinating center assumes responsibility for assuring that the participating sites have received IRB approval at its sites.
   3. The VUMC IRB may be requested to serve as the IRB of Record for multi-center studies where the Investigator is also serving as the coordinating center. The participating sites may or may not have an IRB but may still request the VUMC IRB serve as the IRB of Record.

II. Lead Investigator/Study Team.
A. The lead investigator and their study team for a multi-center study may act as the coordinating center. Typically, this is the primary recipient of a grant or the Investigator who has initiated or developed the research project being conducted.
B. The lead investigator may delegate this responsibility to an established coordinating center or may contract with an organization to manage the study.