Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: I.G
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: September 25, 2007
Revision Dates: February 11, 2010; November 5, 2012; May 1, 2016

Subject: Use of Collaborative Models of IRB Review to Facilitate Review Time and Effort

Definitions:
1. **Federalwide Assurance (FWA):** A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).
2. **IRBchoice:** An electronic resource which allows sharing of documents and reviews as well as documentation of ceded review.
3. **IRB of Record:** An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an agreement, designating the relationship.
4. **Local Research Context:** Knowledge of the institution and community environment in which human subjects research will be conducted.

Policy:
It is the policy of the VUMC IRB to allow sharing of IRB reviews and/or review documents such as minutes, comments, and any other approved documents to facilitate another IRB’s review, or to use another IRB’s minutes, comments, and approved documents to facilitate its review.

I. This policy is limited to multi-center clinical trials which are:
   A. Minimal risk; or
   B. Greater than minimal risk which have identified an external data and safety monitoring board which is responsible for review of all adverse events in conjunction with the local investigator’s assessment of the event as well as local IRB review.
   C. Reviews of industry supported research will only be shared with Sponsor’s approval.

II. **Shared Initial Review by Another Institution.**
   A. The VUMC IRB reviews all submitted materials at the level for which it qualifies including but not limited to the protocol, investigator’s brochure, IRB application, consent document(s), initial committee’s review minutes or comments (if applicable) and any other pertinent materials applicable to the assessment of the risk-potential benefit profile of the project.
   B. The VUMC IRB conducts all subsequent reviews according to the HRPP Policies and Procedures listed in section III.
   C. Each IRB remains the IRB of record for its respective site.

III. **Shared Initial Review by the VUMC IRB.**
   A. The VUMC IRB reviews all submitted materials at the level for which it qualifies according to HRPP Policy.
   B. Upon completion of its review, the approved documents and meeting minutes or reviewer comments if expedited review are provided to all subsequent reviewing institutions.
   C. The VUMC IRB conducts all subsequent reviews according to the HRPP Policies and Procedures listed in section III.
   D. Each IRB remains the IRB of record for its site.
IV. Ceded Reviews.
A. The VUMC IRB may arrange with another FWA-holding institution to cede review process via IRBchoice or other arrangement.
B. Initial and subsequent reviews are conducted at the level for which it qualifies by the IRB of record for that study and in accordance with the MOU arrangements between entities.

References:
www.irbchoice.org