Subject: Research Involving Performance Sites

Definitions:

1. Independent Ethics Committee (IEC): A specifically constituted review body whose responsibility is to ensure the protection of the rights, welfare and safety of research participants. An IEC shares the same composition, and operations as an Institutional Review Board.

2. Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

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 approved Assurance with OHRP. A Memorandum of Understanding is required, designating the relationship, for VUMC to serve as the IRB of Record.

4. 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 and defines the responsibilities for both the VUMC IRB and the other institution.

5. Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

6. Performance Site: A site where research is performed.

7. 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.

8. Performance Sites Not Engaged in Research: A performance site is "not engaged" in human subjects research if its employees or agents do not 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. If a VU or VUMC Investigator or his/her staff, including site personnel contracted by VU or VUMC, performs all research related activities as well as screening, recruiting, or consenting at the performance site, the performance site would be considered "not engaged" in research, unless the non-VU or VUMC performance site releases identifiable private information to VU or VUMC researchers without first obtaining participants’ permission.

Policy:

It is the policy of the Institutional Review Board to assure that appropriate approvals and/or written agreements are completed when human subjects research involves performance sites.

I. Performance Sites "Engaged" in Research.
A. Regardless of financial support or funding, the VUMC IRB must assure that all performance sites "engaged" in research have approval from the IRB of Record for the proposed research to be conducted at the site.

B. The performance site "engaged" in research may have the proposed research reviewed and approved by:
1. Its own Federalwide Assurance designating an OHRP registered IRB/IEC that will review the project; or
2. VUMC IRB provided an approved MOU is on file.

C. Initiation of Research conducted at a performance site “engaged” in research is contingent upon the VUMC IRB receipt and review of the IRB/IEC approval from the “engaged” performance site.

D. It is the responsibility of the IRB of Record and the Assurance holding institution to assure that the resources and facilities are appropriate for the nature of the research under its jurisdiction.

II. Performance Sites "Not engaged" in Research.

A. When performance sites are "not engaged" in research and have an established IRB/IEC, the Investigator must obtain approval to conduct the research at the "not engaged" site from the site's IRB/IEC or provide documentation that the site's IRB/IEC has determined that approval is not necessary for VU or VUMC to conduct the proposed research at the site.

B. When performance sites are "not engaged" in research and the "not engaged" site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional officials are permitting the research to be conducted at the performance site.

C. VUMC IRB approval to conduct research at a performance site is contingent upon receiving documentation of the performance site's IRB/IEC determination, or letter of cooperation, as applicable.

D. It is the responsibility of the VU or VUMC Principal Investigator and the performance site "not engaged" in research to assure that the resources and facilities are appropriate for the nature of the research.

E. It is the responsibility of the VU or VUMC PI and/or the performance site "not engaged" in research to notify the VUMC IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site "not engaged" begins consenting research participants, etc.).

References:
45 CFR 46
21 CFR 50 and 56
OHRP Guidance Document: Notice to Clarify a Requirement in the FWA Form for International (non-U.S.) Institutions Approved by OHRP, July 10, 2006