Subject: Research Conducted at International Sites

Definitions:
1. Assurance: A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).
2. Independent Ethics Committee (IEC): A specially 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.
3. Institutional Review Board (IRB): A specially 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.
4. Local Research Context: Knowledge of the institution and community environment in which human research will be conducted.
5. Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services (DHHS) responsible for implementing the DHHS regulations (45 CFR 46) governing biomedical and social/behavioral sciences research involving human participants.

Policy:
It is the policy of the Human Research Protections Program to assure that adequate provisions are in place for research under its jurisdiction conducted at international sites.

I. IRB Review of International Research.
A. When the foreign institution or site is a performance site “engaged” in research.
   1. The IRB will review all international research utilizing human participants to assure adequate provisions are in place to protect the rights and welfare of the participants.
   2. Because VU and VUMC hold assurances with OHRP, the foreign institution or site must file an Assurance of compliance (FWA) with OHRP, if the study is federally funded.
   3. Approval of research is permitted if “the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46.”
   4. The IRB must receive and review the foreign institution or site’s IRB/IEC review and approval of each study prior to the commencement of the research at the foreign institution or site.
B. When the foreign institution or site is a performance site “not engaged” in research.
   1. When the foreign institution or site has 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 the Investigator to conduct the proposed research at the site.
   2. When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.
3. IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance site’s IRB/IEC determination, or letter of cooperation, as applicable.

4. It is the responsibility of the VU or VUMC Investigator and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.

5. It is the responsibility of the VU or VUMC Investigator and the foreign institution or site to notify the 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.).

II. IRB Considerations for Approval.
A. For federally funded research, approval of research for foreign institutions or sites “engaged” in research is only permitted if the foreign institution or site holds an Assurance with OHRP and local IRB review and approval is obtained.

B. The IRB will consider local research context when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted (See HRPP Policy I.D). The IRB may require an expert consultant to address issues of local research context if the IRB does not have a Committee Member with the expertise or knowledge required to adequately evaluate the research in light of local context.

C. The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document which must be provided by the Investigator, with the credentials of the translator detailed in the IRB application or amendment form (See HRPP Policy IV.B).

III. Monitoring of Approved International Research.
A. The IRB is responsible for the ongoing review of international research conducted under its jurisdiction.

B. The IRB will require documentation of regular correspondence between the Investigator and the foreign institution or site.

C. The IRB may require verification from sources other than the Investigator that there have been no substantial changes in the research since its last review.

References:
45 CFR 46
21 CFR 50 & 56
OHRP, IRB Guidebook, Chapter VI, “Special Classes of Subjects”
The New England Journal of Medicine, Volume 345:139-142, July 12, 2001: “Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries”