Subject: Knowledge of Local Research Context

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. **Department of Health and Human Services (DHHS)**: The United States government's agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
3. **Greater than Minimal Risk**: Where the research involves greater than minimal risk (defined below) to subjects, the mechanism of obtaining local research context differs depending on whether the local research context involves intervention or interaction with subjects and whether the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality.
4. **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.
5. **Local Research Context**: Knowledge of the institution and community environment in which human subjects research will be conducted.
6. **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).
7. **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.

Policy:

It is the policy of the Institutional Review Board to obtain sufficient knowledge of the local research context to fulfill its responsibilities under its Assurance, regardless of the geographical location of the research.

I. The VUMC IRB must fulfill the responsibilities under its Assurance with the federal government regardless of its geographic location relative to the Institution and the research. This is particularly critical when the research involves greater than minimal risk to participants or vulnerable categories of participants.

II. When the VUMC IRB is either geographically removed from the site in which the research will be conducted, the VUMC IRB is serving as another institution’s IRB of Record, or when the research involves a distinct subject population (e.g. Amish Community, etc.), the IRB must demonstrate that it has obtained the necessary information about the local research context through compliance with required standards. These standards reflect minimal levels of adequacy. More stringent standards may be required, depending on the nature of the proposed research or the relevant research context.
III. When the IRB wishes to avoid duplication of effort, in accordance with DHHS regulations at 45 CFR 46.114, the IRB may rely on the review of another OHRP Assurance-holding institution.

A. The review arrangement must be approved in writing by OHRP and by appropriate officials of the institutions involved.

B. When relying on another IRB’s review, the VUMC IRB has a responsibility to ensure that the particular characteristics of the local research context are considered, either

1. through knowledge of the local research context by the reviewing IRB (See IRB Procedure I.D.1); or

2. through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other members of its local IRB.

References:
45 CFR 46
OHRP Guidance Document: Knowledge of Local Research Context, July 21, 2000