Subject: Procedure for Knowledge of Local Research Context

Procedure:
This procedure outlines the process for the collection, submission, and review of sufficient information regarding local research context for research within the jurisdiction of the VUMC Institutional Review Board.

I. Investigator Responsibilities.
   A. The Investigator will obtain documentation of the necessary information required under the DHHS regulations for verification of local research context when the proposed research will be conducted in an area geographically removed from the VUMC IRB, 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.). This documentation should include:
      1. The anticipated scope of the outside institution’s involvement in the research activities;
      2. The types of participant populations likely to be involved;
      3. The size and complexity of the institution;
      4. Any Institutional commitments, regulations, and/or applicable laws specific to the outside institutions;
      5. Standards of professional conduct and practice at the outside institution;
      6. The method for equitable selection of subjects;
      7. Method for protection of privacy of subjects;
      8. Method for maintenance of confidentiality of data;
      9. Language(s) understood by prospective participants;
     10. Method for minimizing the possibility of coercion of undue influence in seeking consent;
     11. Safeguards to protect the rights and welfare of vulnerable participants; and
     12. Determination and, specifically, documentation that provisions to protect the privacy of participants and maintain confidentiality of data are adequate.
   B. The Investigator is responsible for addressing local research context at each continuing review interval.
   C. The Investigator must promptly report to the IRB any changes in the local research context that may influence or alter the risk/benefit ratio.

II. IRB Committee Responsibilities.
   A. The IRB Committee must have the experience and expertise necessary to review and make determinations regarding local research context. This may be achieved through:
      1. Submission of sufficient documented information regarding local research context by the Investigator;
      2. Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended, direct experience with the research institution, its subject populations, and its surrounding community; and/or
      3. The Committee may request a written review by a consultant(s) knowledgeable of the local research context. The consultant may then be invited to participate (either physically or through audiovisual or telephone conference) in the convened meeting of
The IRB.

B. The IRB must demonstrate that it has obtained the necessary information about the local research context through compliance with required standards. These standards include the following:

1. Minimal risk. When the research involves minimal risk to the subjects, the IRB should demonstrate that it has obtained necessary information about the local research context through written materials or discussion with appropriate consultants.

2. Greater than minimal risk without intervention/interaction with participants. When the research involves greater than minimal risk to the participants but the local research context involves no intervention or interaction with participants and the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality, the IRB should:
   a) Demonstrate that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants and necessary information under DHHS regulations described above in I.A; and
   b) Determine and specifically document that provisions to protect the privacy of subjects and maintain confidentiality are adequate.

3. Greater than minimal risk with intervention/interaction with participants. When the research involves greater than minimal risk and the Investigator and/or key study personnel will have interaction or intervention with the participants or the risk associated with the local research context is broader than the potential harm resulting from a breach of confidentiality, the IRB should demonstrate that it has obtained necessary information about the local research context through one or more of the following mechanisms or through other mechanisms deemed appropriate by OHRP for the proposed research and local research context:
   a) Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended, direct experience with the research institution, its subject populations, and its surrounding community;
   b) Participation (either physically or through audiovisual conference) by one or more appropriate consultants in a convened IRB meeting. Such consultant(s) should have personal knowledge of the local research context, such knowledge having been obtained through extended, direct experience with the research institution, its subject populations, and its surrounding community. The consultant(s) may participate in the discussion and provide a recommendation but they are not a voting member;
   c) Prior written review of proposed research by one or more appropriate consultant(s) (see 3.b. above), in conjunction with participation (either physically or through audiovisual conference) by the consultant(s) in convened IRB meetings, when such participation is deemed warranted either by the consultant(s) or by any member of the IRB. The consultant(s) may participate in the discussion and provide a recommendation but they are not a voting member; and/or
   d) Systematic, reciprocal, and documented interchange between the IRB and elements of the local research context. Such interchange should include:
      (1) Periodic visits to the research site, occurring several times per year, by one or more IRB members in order to obtain and maintain knowledge of the local research context, including the research institution, its subject populations, and its surrounding community;
      (2) Periodic discussion with appropriate consultants knowledgeable about the local research context;
      (3) Regular interaction with one or more designated institutional liaisons; and
      (4) Review of relevant written materials.
C. Local research context must be reviewed at the time of continuing review of the proposal.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will pre-review the submitted research proposal to assure that local research context has been addressed, when applicable.
B. The RCA will assist the Committee with identifying a consultant(s) and will assure distribution of the appropriate review materials, when applicable.
C. The RCA will maintain documentation of local research context and will update the database accordingly.
D. The IRB Compliance Officer may monitor the sufficiency of the information submitted from the Investigator during its random auditing and monitoring activities.