Subject: Procedure for Research Conducted at International Performance Sites

I. Investigator Responsibilities.
   A. It is the Investigator's responsibility to provide the following to the IRB for international performance sites "engaged" in research:
      1. An Office of Human Research Protections (OHRP) approved Federalwide Assurance (FWA) for the foreign institution or site, if federally funded;
      2. An OHRP registered local IRB/IEC approval letter for the proposed research if an IRB/IEC exists;
      3. A translated informed consent document encompassing all of the required elements of informed consent in the language appropriate to the location of the research, with an English language version of the exact content. The qualifications of the translator must be included in the IRB application or amendment form (See HRPP Policy IV.B); and
      4. Adequate information and materials are provided to evaluate local research context in the location in which the proposed research will be conducted.
   B. It is the Investigators responsibility to provide to the IRB the following for international performance sites "not engaged" in research:
      1. IRB/IEC Approval or Letters of Cooperation.
         (a) When the foreign institution or site has an established IRB/IEC, the Investigator must submit to the IRB 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; or
         (b) When the foreign institution or site does not have an established IRB/IEC, the Investigator must submit to the IRB a letter of cooperation demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.
      2. It is the responsibility of the Investigator and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research;
      3. A translated informed consent document encompassing all of the required elements of informed consent in the language appropriate to the location of the research, with an English language version of the exact content must be submitted to the IRB for review and approval. The qualifications of the translator must be included in the IRB application or amendment form; and
      4. Adequate information and materials are provided to evaluate local research context in the location in which the proposed research will be conducted.
      5. It is the responsibility of the 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.).
   C. The Investigator is responsible for providing to the IRB any reports of correspondence with the foreign institution or site and appropriate documentation of data and safety
measures throughout the course of the study, including serious and unexpected adverse events and unanticipated problems to participants or others (e.g. a breach of participant confidentiality resulting in local ramifications).

II. IRB Committee Responsibilities.
   A. The IRB Committee must demonstrate that it has obtained necessary information about the local research context through written material or discussions with either Committee Members knowledgeable of the local context or appropriate expert consultants. The level of local knowledge required is based on the degree of risk presented by the research. Extra considerations may include the following to enhance human research protections:
      1. The economic prosperity of the area;
      2. The influence of local officials on the population;
      3. Whether the country or area allows foreign visitors;
      4. The nature of the procedures conducted (some may not allow invasive procedures such as in poorer regions);
      5. The literacy rate of the area;
      6. The local legal rights of the population;
      7. How complaints will be reported and to whom;
      8. The relevance of the research to the area’s health needs;
      9. The possibility of including officials from the area in the monitoring of the research; and
      10. The growth rate of sociology and medicine in that area.
   B. The IRB Committee will review the consent process taking into consideration the following additional issues:
      1. Disclosure of scientific and medical facts to individuals who may be unfamiliar with and distrustful of the concepts;
      2. Differences in cultural and societal norms;
      3. Differences in the role of women in society;
      4. Differences in the role of family and community in the consent process;
      5. Multiple local languages; and
      6. Literacy level.
   C. The IRB Committee must assure that adequate provisions are outlined for data and safety monitoring keeping in mind that some foreign Ethics Committees may not require continuing review of approved research.
   D. IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the foreign performance site’s IRB/IEC determination, or letter of cooperation, as applicable.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will pre-review the proposed research according to applicable HRPP policies and procedures.
   B. The RCA will assure the required documents are present for adequate review by the IRB Committee.
   C. The RCA will provide guidance to the Investigator as needed (e.g., finding a translation service, verifying OHRP IRB registration and FWA approval for the foreign site).