Human research conducted outside of the United States must conform to the same ethical standards, university policies, and regulatory standards to which research conducted within the United States is held. International research must be conducted in accordance with applicable Michigan State University (MSU) policies for the conduct and review of human research, regardless of the location of the research. See the Human Research Protection Program (HRPP) Manual 4-1 “Applicability.”

Investigators are responsible for complying with laws or requirements relevant to their human research activities. Visit the U.S. Office for Human Research Protection (OHRP) website for compiled information on international requirements. For information regarding clinical trials in developing countries visit the National Bioethics Advisory Commission (NBAC) publications. Investigators should be aware that research determined exempt from the U.S. regulations by the MSU IRB may still be subject to requirements at the foreign country. The MSU’s Office of the General Counsel will be consulted as needed if questions arise regarding applicability of laws to human research activities. For example, when research is conducted outside the jurisdiction of the United States (i.e., international research), the MSU Office of the General Counsel will be consulted as appropriate to determine whether any relevant laws apply to the conduct of the research. MSU’s Office of the General Counsel will also be contacted to resolve potential conflicts of law (e.g., between federal / national law and other internationally applicable laws).

In addition to obtaining MSU Institutional Review Board (IRB) approval, if there is a local ethics board (e.g. local IRB, Independent Ethics Committee, or equivalent) in the country or at the international institution where the research will be conducted, review of the human research protocol by the local ethics board may be required by the country or international institution or may be required by the MSU IRB. A list of international IRB’s registered with OHRP may be found on the OHRP web site.

The IRB may also require that the investigator identify and consult with a local expert or community leader prior to submitting the IRB application. The local expert or community leader would be asked to provide information on the cultural experience of the locale where there is no equivalent ethics board or group or as appropriate. This local expert should be a person who lives or has lived in the foreign country so that the investigator may incorporate the local expert’s input into the research so that it is designed in such a way that it is sensitive to the cultural norms while demonstrating cultural understanding and sensitivity. The investigator would be responsible for identifying and recruiting such
as individual and for obtaining the individual’s input prior to submitting the application to the IRB. The IRB may require a statement from the expert or the CV as part of the review process. For research reviewed at the expedited or full board review level, the IRB may require, when appropriate, documentation of such review by the local ethics board, or description of how local approval or support of the research will be obtained. The MSU IRB will also coordinate and communicate directly with the local ethics board as appropriate.

Consent is a process, not just a form, and in international research the consent process may present additional challenges. Consideration must be given to the consent process, including taking into account the literacy level of the subjects and the cultural norms. Consent must be obtained in a language that is comprehensible to the subjects. The consent form or oral consent script and instruments provided to the IRB must include the English translation and should also include the native language versions when practicable. If research will be conducted in a country where there may be a number of different languages and cultures, the researcher should consider how to address this in advance and obtain consent documentation in all the languages that might be encountered. If there is a possibility that an unanticipated language or comprehension problems will be encountered, the investigator should describe this in the IRB application so that a plan to handle these contingencies can be developed.

The additional considerations for international research will be included as part of the IRB review processes, including at the time of initial review, continuing review, and review of modifications. Complaints will be handled in accordance with HRPP Manual 9-4 “Subject Complaints,” unanticipated problems involving risks to subjects or others will be handled in accordance with HRPP Manual 9-1 “Unanticipated Problems Involving Risks to Subjects or Others,” and noncompliance will be handled in accordance with HRPP Manual 9-2 “Noncompliance.” When reviewing complaints, unanticipated problems involving risks to subjects or others, and noncompliance, additional consideration will include as appropriate potential language and cultural differences and the MSU IRB will coordinate with the local ethics board as appropriate. Additional expertise may be obtained as part of any of the IRB review processes (e.g. initial, continuing, modifications, complaints, noncompliance, unanticipated problems involving risks to subjects or others, post approval monitoring) when needed. See HRPP Manual 5-4 “Additional Expertise” for process to obtain additional expertise.

When the IRB performs post approval monitoring on a project that is conducted internationally, additional considerations may be incorporated as part of the post approval activity. For example, investigators may be asked to complete a survey or answer questions as part of the post approval monitoring to identify any potential issues or concerns related to the research being conducted internationally.