

## **Appendix H International Research**

Research in foreign countries presents special concerns regarding the rights and welfare of human participants. In general, the IRB accepts the standards of the location in which the research is taking place, unless those standards violate the basic principles of ethical human participants research. Investigators must understand the context of the locality in which they are conducting their research and must communicate that understanding to the IRB in writing. In addition, the following issues apply to international human participants research:

- All human participants research in foreign countries must be reviewed by the full IRB, regardless of the nature of the research.
- All materials, including consent forms, must have English language translations included with the protocol.
- In localities where English is not the primary language, all materials presented to subjects must be understandable to them. An authority in the native language must provide documentation that the translated materials adequately convey the content of the English language version presented to the IRB.
- Documentation of permission from local authorities is generally required before approval can be granted.
- To expedite the review process, the investigator is asked to provide the name of an individual(s) who has knowledge and/or experience in conducting research in the particular location of study.
- Where research involves minimal risk to subjects, the IRB will obtain necessary information related to the research context through written materials from the investigators or others, and/or discussions with appropriate consultants.
- Where research involves greater than minimal risk to subjects, the IRB will obtain the federally required information through written materials, personal knowledge on the part of one or more IRB members, discussions with consultants in person or via electronic means, and in interchange between the IRB and elements of the local research context, etc.
- If the project involves an international institution that is engaged in research ① the institution must have a federal-wide assurance on file with The Office for Human Research Protections. Otherwise, SUNY New Paltz will not be permitted to conduct research in conjunction with that institution.
- In certain circumstances, a Memorandum of Cooperation may be required.

Further information can be found on the following web page:

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/ass-intl.htm> and  
45CFR46.101 (g) and (h), <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

**Please note: Additional time is needed when reviewing international research since the IRB may need to consult with an expert in that area for local context information.**

① An institution becomes “engaged” in human subject research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45CFR46.102(d), (f)]