



IRB GUIDELINE II

International Research Involving Human Participants

These guidelines are prepared as a brief overview of things to consider when conducting research in international settings. The Institutional Review Board (IRB) believes that culturally appropriate procedures are an important aspect of protecting participants in research. Because there are specific rules to be followed when conducting research involving human participants in countries other than in the United States, there are often local customs that are not usually considered in the IRB deliberations. These differences must be brought to the attention of the researcher. The guidelines contained in this document are intended to apprise researchers of the various issues that arise when conducting research with human participants in international settings.

1. When documents are translated into a language other than English, the researcher should provide a copy of the document in English, a copy in the language to be used in the document, and a letter from an individual (e.g., a Penn State faculty member) indicating that the translated version of the document is complete and does not contain information that is not presented within the context of the English version of the document.
2. If the research includes enrollment of children in other countries, the principal investigator is responsible for providing the IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to consent to participation in research, including any medical treatments or procedures if applicable. The IRB may, if it appears advisable, require the submission of an opinion rendered by an attorney from any applicable jurisdiction on age at which an individual can consent to participation in research.
3. If local customs and regulations are such that active parental permission would be culturally inappropriate, the researcher must supply the IRB with proof that such permission is not culturally appropriate. Examples of such proof would be specific regulations (in English and certified to be accurate) that indicate that such permission is not required, an official letter from a ranking official in the country of interest indicating that such permission is not culturally appropriate, or being accompanied to the IRB meeting by another Penn State employee (preferably a faculty member) who can attest to the cultural inappropriateness of the requirement for active parental permission. In those cases where seeking active parental permission for minors to participate in research is culturally inappropriate, a waiver of such permission may be granted at the discretion of the IRB, as long as the research does not place the participants at untoward risk. Regardless, the participants in the research retain the right to discontinue participation, without penalty, at any time during the gathering of data.
4. If a waiver of active parental permission is granted, a letter informing the parents of the research, written at a literacy level that would be understood by the parents, may be required and should be prepared and sent to the parents by the most expeditious method possible.
5. Letters of agreement from the appropriate officials (e.g., government officials, school officials, community officials, Chief Executive Officers, etc.) indicating that the research protocol and any

and all instruments to be used (including any biomedical equipment) have been reviewed and are acceptable to those officials are to be submitted. The certification letter must be on letterhead stationary and carry an original signature.

6. When appearing before the IRB to answer questions about the research, it is helpful if an individual who is familiar with the culture (unless the researcher is recognized as an "expert") can accompany the researcher.
7. If data will be collected by someone other than the researcher, that individual or individuals must be identified and Individual Investigator Agreements signed and IRB training completed. If the data collector(s) will have access to the data, such access must be specified.
8. Specific processes for assuring anonymity and/or confidentiality of all data must be specified, particularly if the analysis will occur away from Penn State.
9. Processes for transporting data from the international location to Penn State, with particular reference to #6 and #7 above, must be specified.

Approved: Biomedical & Social Science IRBs: February 15, 2007