Institutional Review Board
October 20, 2010

Present: Lisa Ferrari, Andrew Gardner, Julia Looper, Mary Rose Lamb, Elise Richman, Alexa Tullis

The topic under discussion during this meeting was whether the University of Puget Sound should require IRB approval for any research that would be done outside the United States. Before the meeting Julia Looper compiled a selection of documents from other universities (attached) to give us an idea of what other institutions are doing. We noted that many institutions required approval of the IRB or equivalent body in the country where the research was to be done before submission to the IRB at the home university of the researcher. Ferrari noted that obtaining approval of the research project might be involve a conflict of interest for local experts who might well be involved in the project.

We then moved to discussing reasons that students in particular should be required to receive approval from the Puget Sound IRB. Ferrari reported the experience of a professor emerita who found that when students went to foreign countries to pursue research projects on their own (that is, not associated with a university in the country where the research was to be done) they often had little understanding of the local customs and norms. This ignorance could be a problem for both student and research subjects. Gardner noted that researchers always start out being culturally ignorant and insensitive but they learn rapidly from mistakes made.

We came back to considering what our institutional role should be in regulating or approving international research. Gardner noted that the guidelines of the other institutions that we reviewed had flexibility built into them. He suggested that we be similarly flexible in our requirements. Tullis suggested that we add information to our guidelines to inform researchers about things to consider as they prepared for doing research abroad and what the IRB would expect to see in their protocols. Looper suggested that we allow an appendix to the protocol, something beyond the current five page limit, in which researchers could address the issues of doing research in a foreign country. Looper volunteered to draft a statement about international research for inclusion in the handbook.

Gardner asked for clarification of exactly what the changes would cover. Would research that would be classified as "exempt" if done here would still be exempt? Ferrari suggested that the Board review the criteria for a protocol to be considered expedited, that there might be issues that should be considered. Further, we would not ask for IRB approval of any research done overseas as part of an approved study abroad program. Those programs should have approval processes of their own. Nor would the changes affect class studies. These requirements would affect those students doing summer research.

Then we considered how disseminate information about changes to require IRB approval for overseas research. Looper pointed out that we need a campus-wide understanding of the issue. Tullis suggested that a link to the policy be placed in all campus grant (UEC, summer research, etc.) applications. Gardner proposed adding an additional check on the IRB cover sheet to direct those doing research

abroad to check the policy. Ferrari noted that this was another reason to be serious about revising both the handbook and the website.

Finally, Gardner reported on CITI certification. One of the other issues that we have been dealing with this year is the requirement by both the NIH and NSF for training in research ethics for undergraduates as well as principal investigators. Students in the School of Physical Therapy already meet this requirement by doing the on-line training offered by the NIH. Gardner is certified by the Collaborative Institutional Training Initiative (CITI). This is an electronic venue for certification for human subject research. It has a few advantages over the NIH training. First, it consists of a series of modules that can be customized for the needs of a particular institution. Second, it contains a strong set of modules that are devoted to social and behavioral research. While the NIH training is appropriate for those doing medical research, it is often not the best choice for those doing social research. The drawback of using CITI for training in dealing with human subjects is that it charges a fee to institutions to participate, currently $2000 per year.

Respectfully, if belatedly, submitted,

Mary Rose Lamb

Code of Federal Regulations; **TITLE 45**, **PART 46 PROTECTION OF HUMAN SUBJECTS**

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

Emory:

- If conducting overseas research include local IRB submission/approval or at least a cultural context letter

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International Research

Social and behavioral science research is going global, and this presents a whole host of issues that researchers and IRBs need to grapple with. One is informed consent — how to tailor it to different cultures and the differences in obtaining it from individuals in those cultures. This is done on a case-by-case basis, as the Office of Human Research Protections (OHRP) hasn't yet had the resources to provide solid guidance on this.

Tanya Broesch, a graduate student at Emory University who conducts cognitive psychological research in Fiji, finds that it's well worth the time and energy to educate the IRB as to why, for certain rural populations, verbal consent is much more culturally appropriate (and thereby more likely to yield accurate data) than is written consent. The research participants find signing documents strange, Broesch says, and she is working with her IRB to include verbal consent in her protocol.

Another thing to get a head start on is approval from the local research institution. Jeff Victoroff, University of Southern California, conducts biobehavioral research in Gaza, and he advises researchers to identify a local university or research entity with an IRB to host the

research (in his case, it was the Gaza Community Mental Health Programme). One should make sure that the entity has a U.S. Federal-Wide Assurance (FWA; proof that it complies with U.S. standards for ethical review). If not, you can assist the local IRB in getting an FWA by referring to the OHRP rules (http://www.hhs.gov/ohrp/assurances/assurances_index.html#international).

Once the foreign IRB has secured its FWA, you can submit your research proposal to that IRB to make sure that the project conforms with local cultural sensitivities and geographic variants of research ethics. Once approved by the local IRB, you can then submit to your own IRB. If the local foreign IRB has approved your project and has an FWA, the home institution ought to approve pro forma.

Though not new, international social and behavioral research is growing exponentially and researchers and institutions need to work together to figure out the best way to proceed. Sandy Sanford, the Director of Research Subject Protections at George Mason University in Virginia, has overseen a number of international protocols submitted to her campus' IRB. She says that when a Mason student or faculty member wishes to conduct research overseas, the IRB asks the researcher for a contact name of someone familiar with conducting research in the proposed country, to whom it sends a list of questions (modeled after OHRP's) and a copy of the research protocol. This provides the IRB with the OHRP requirement for the IRB to have knowledge of the local research context. When the IRB receives the answers, it then proceeds with the protocol approval. What's key here is knowledge of local context, and the better informed the IRB is, the easier the process will be.

University of Minnesota

IRB Review of International Research

Research conducted by University investigators in foreign countries remains under University purview and guidelines.

While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct of research or for a meaningful consent process.

Special attention should be given to local customs and to local cultural and religious norms in drafting written consent documents or proposing alternative consent formats.

In some instances it may be appropriate for the IRB to waive some or all requirements for written consent.

Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such as waiver. (eg. societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the researcher)

Research projects must have been approved by the local equivalent of an IRB before they are presented to the University IRB.

Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval" before it gives approval.

***Include Appendix K** with IRB applications for international research projects.*

Oklahoma State:

The ever changing and expanding landscape of the university–based research environment is providing an increasing number of opportunities for faculty and students to conduct research in foreign countries. It is important to note that human subject research conducted by OSU investigators in foreign countries remains under the purview of OSU and must be reviewed by the OSU IRB. This poses a challenge to the IRB, because the IRB must evaluate the research based, not only, on Western ethical standards, but also the values and customs of the region where the research is being conducted.

When applying to the IRB for review of research to be conducted internationally, the researcher should address or include the following in the application package (in addition to items required as a standard application):

Location of the research;

For research reviewed at the expedited or full board level, documentation of review by the local equivalent of an IRB, or description of how local approval or support of the research will be obtained;

Description of the consent process;

Translated versions of any recruiting documents, consent documents and instruments/questionnaires/interview questions.

The requirements and customs for documenting informed consent vary widely among cultures. The IRB cannot exempt human subject research conducted in foreign countries from the consent requirements, but in some instances it may be more appropriate for the IRB to waive some or all of the requirements for written documentation of consent, understanding that in some settings, the process of signing the form is very intimidating and may be riskier than the research itself. In the IRB application, researchers should thoroughly explain their proposed method of documenting consent. The explanation should include a description of local customs or social structures in the foreign country, especially if they constrain the typical informed consent process. Researchers should provide participants in foreign sites local contacts so that they may ask questions about the research or about their rights as a research volunteer.

For research expected to be reviewed at the expedited or full board level, researchers must also provide documentation that their research has been approved by the local equivalent of an IRB. The Office of Human Research Protections (OHRP) has complied a listing of the laws, regulations and guidelines that govern human subjects research in many countries around the world. This can be found on the ORHP web site at http://www.hhs.gov/ohrp/international/HSPCompilation.pdf. Where there is no equivalent

board or group, researchers must rely on local experts or community leaders to provide approval.

For assistance in preparing an application for international research, please contact the OSU IRB Manager at 405-744-5700 or beth.mcternan@okstate.edu.

Penn State

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: Social Science IRB: February 15, 2007; Biomedical IRB: February 15, 2007

www.hsph.harvard.edu/hsc/gremap

Yale:

450.2 IRB Responsibilities

IRB Review of Research

The IRB ensures the ethical and equitable treatment of research volunteers and protects the rights and welfare of those who participate in research. For international research involving human subjects, the IRB review must include confirmation of local IRB/IEC approval as applicable, current host institution FWA approval as applicable, and compliance with adverse event reporting and other Yale policies as they apply to human subjects research. For more information, see IRB Policy 100: IRB Review of Research Protocols, and associated Procedures and Guidance.

Knowledge of Local Research Context

In order to approve a protocol being carried out at a foreign site and to make an informed judgment about the level of risk to potential research participants, the Yale IRB must demonstrate that it has sufficient information about the local research context and local law by its review of written material, or through discussions with either IRB members knowledgeable about the local context or appropriate expert consultants. The level of knowledge about the local context and local law required for approval is based on the degree of risk to potential research participants. Higher risk studies require more thorough considerations of local context and inclusion of strategies to mitigate harm than do minimal risk studies.

Informed Consent Process

The Yale IRB will review the consent process, paying special consideration to maintaining sensitivity to local cultural norms and applicable law, including issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in

the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and literacy level.