MINUTES Institutional Review Board March 23, 2010

Present: Lisa Ferrari (presiding over the meeting, in Chair Milam's absence), Grace Kirchner, Mary Rose Lamb, Julia Looper, David Lupher, Petra Perkins, and David Moore

The meeting was called to order at 8:05 a.m.

Announcements: (1) Given Garrett Milam's absence, the committee will defer the planned discussion of a possible appeal process for rejected protocols. (2) The review of the University's research misconduct policy will likewise be taken up next meeting when the Chair of the committee is present. (3) The agenda for the present meeting was reviewed, which involved reviewing the 4 submitted protocols (presented below). (4) Lisa noted that Garrett Milam had submitted detailed feedback to her for all of the reviewed protocols in advance of the meeting, which she would incorporate in the committee's deliberations.

Orders of Business:

1. Deliberation on Protocol 0809-015 (Modification). Note: Julia Looper, the Principal Investigator (PI) for this protocol and Co-PI for the next protocol reviewed, was present for questions and then recused herself and left the room before the committee deliberated and voted on these two protocols.

The committee did not raise any issues or questions for this protocol.

Action: M/S/P The protocol was unanimously approved (6-0) as written, with no changes requested.

- **2. Deliberation on Protocol 0910-012**. Key issues and questions included the following:
 - The researchers should specify the department or office in which files will be stored at the University in the Consent Form.
 - Although not a condition for approval, the committee wondered whether there are any established minimum security standards for data encrypted flash drives in research, which were proposed to be used in this particular study. The committee asked if Co-PI Looper would be willing (in her role as member of the IRB) to investigate any such published standards, so that the IRB could attempt to ensure compliance, where appropriate.

Action: M/S/P The protocol was unanimously approved (6-0), pending the requested revision above regarding file storage.

- **3. Deliberation on Protocol 0910-010**. Key issues and questions included the following:
 - If there are students who do not wish to participate in the study, the question was raised as to whether they would have the option of receiving traditional English training or whether they would still be required to participate in the theatrical language training. Particularly if this option is not available at the given school, the researcher and/or school officials should be sure to communicate this fact well in advance to prospective students, in order for them to make an informed decision about the conditions of enrolling in the program.
 - A number of questions were raised regarding the cultural "transportability" of the research project, including the extent to which some constructs may or may not generalize to Vietnamese culture. However, the consensus seemed to be that these questions related more to methodological issues rather than ethical concerns and that the risk posed to participants is indeed minimal.
 - The researcher should specify how long records will be kept, where these will be stored (i.e., in Vietnam or at the University of Puget Sound), and who will have access to these records.
 - A concern was raised about the use of the word "test" for the researcher's survey of attitudes, in that this label may inadvertently convey to Vietnamese students that there are right or wrong answers. It is recommended that this be replaced with a word that, when translated, has the meaning of "survey" or a similar term that suggests that there are indeed no right or wrong answers for these particular questions (in contrast to the test of language skills).
 - The researcher should define more clearly what she means by keeping the data "strictly confidential," especially for this sample of participants who may be unfamiliar with this concept.
 - Although perhaps unlikely, the question was raised whether Vietnam had any specific requirements or procedures that need to be followed for the conduct of research. It is recommended that the researcher examine whether there are any relevant governmental regulations that need to be followed in order to avoid any potential problems when carrying out the study.
 - One of the 2 letters of approval from the schools was not signed and instead only included a typed name. A signed letter is requested. This letter can be faxed or scanned and emailed.

Action: M/S/P The protocol was unanimously approved (7-0), pending the requested revisions.

- **4. Deliberation on Protocol 0910-011**. Key issues and questions included the following:
 - The protocol was not reviewed by a departmental designate before being submitted to the IRB. As a function of this oversight, there were several

issues and problems with the protocol, varying from minor to more substantive.

• The protocol was briefly discussed and some of the more substantive issues were highlighted.

Action: M/S/P The committee unanimously determined (7-0) that no action could be taken on this protocol, given the substantial revisions necessary before the protocol could be considered ready to be reviewed for approval by the full board. The committee decided to charge departmental designate and IRB member David Moore with the task of forwarding key issues and concerns regarding the protocol to the PI. The protocol will then need to be reviewed again by the full board before IRB approval can be given. Lisa Ferrari stated that she would contact the Associate Dean's office to report that the researcher has made a "good faith" effort to seek IRB approval, so that she might still be eligible to apply for summer research funding.

The meeting was adjourned at 9:10 a.m.

Respectfully submitted,

David Moore