MINUTES Institutional Review Board November 10, 2009

Present: Garrett Milam (Chair), Lisa Ferrari, Grace Kirchner, Mary Rose Lamb, Julia Looper, David Lupher, Petra Perkins (Community Member), and David Moore

The meeting was called to order at 8:20 a.m. Chair Milam reviewed the planned agenda for the meeting and also announced that the Director of the Office of Institutional Research (OIR) would be present for the planned discussion of the University Policies for Survey Design and Administration.

INTRODUCTION OF NEW COMMUNITY MEMBER

The first order of business was to introduce the new community member to the IRB, Petra Perkins. Petra's background, qualifications, and interest in serving on the IRB were briefly discussed, and she was welcomed by the rest of the Board.

PROTOCOL REVIEW

1. Protocol 0910-002

The Board raised the following questions and requests for revision/clarification:

- (1) A sample recruitment/sign-up sheet or script was absent from the protocol and should be included.
- (2) Greater clarification is needed regarding the recruitment strategy, including more specific inclusion/exclusion criteria for participants in the study and strategies for ensuring that the minor participants or their parents do not experience coercion to take part in the study.
- (3) A letter of support from the Principal of McCarver Elementary School is needed.
- (4) Greater clarification is requested regarding the researchers' plans regarding the level and nature of participation in the monthly meetings held at the school.
- (5) Board members expressed some concerns about maintaining confidentiality and security of data, with the current proposal to store data on laptop computers. One suggestion for implementing a higher level of security was for the researchers to store data on password-protected flash/USB drives, which could then be stored in locked file cabinets when not being used.
- (6) Although negative reactions to the research participation may be unlikely, it is requested that the researchers be prepared to offer referrals (e.g., for counseling), in the event that any participants experience psychological distress in the course of their participation in the study.
- (7) It may be advisable for the researchers to add boilerplate language in the consent form which notes the limits of confidentiality regarding disclosure of child abuse.
- (8) It is requested that the researchers replace the categorization of "no risk" with "minimal risk" in the consent form, and that they note the potential risks of

- participating in the study (e.g., potential sadness or discomfort, even if these reactions are unexpected).
- (9) Since, minors can not legally give "consent," the researchers should use the term "Assent" on the document given for minors' approval to participate in the study.

Action: The study was unanimously approved (8-0), pending the revisions requested.

2. Protocol 0910-003

The Board raised the following questions and requests for revision/clarification:

- (1) The proposal needs to be reviewed by an IRB designate before being submitted to the full IRB.
- (2) The researcher will likely need to obtain IRB approval from Seattle University, given that she is a student there.
- (3) Board members expressed concerns about an inherent conflict of interest with this study as currently proposed, given the investigator's status as an employee at the University of Puget Sound. To resolve this issue, it was suggested that the researcher either: (a) attempt to collect data at another university (where she is not employed), or (b) enlist someone else to collect the data (preserving her ability to analyze the data).
- (4) Practical concerns were also raised about the researcher's ability to recruit participants for this study.

Action: the committee unanimously decided to deny approval of the study (8-0) but agreed to notify the investigator of the need to address the issues noted above, before the Board would be able to consider approving a revised protocol.

OTHER ORDERS OF BUSINESS

Discussion of the drafted Policies for Survey Development and Administration

The Director of the Office of Institutional Research (OIR) joined the meeting at 8:55 to discuss questions and issues regarding this drafted policy statement. Several issues were discussed, as noted below.

- (1) It is unclear what the sequencing would be for proposals that would require both IRB and OIR approval. It was recommend that a clear flow chart or decision tree be added to the policy, to clarify requirements and sequencing for submitted proposals.
- (2) Given the significant overlap between IRB and OIR requirements, the question was raised whether the OIR would accept a standard IRB protocol, perhaps with an additional cover sheet addressing any issues not covered by the standard IRB format.

- (3) In regards to the statements in the policy regarding IRB review, it was suggested that the policy statement add a comment noting that both the researcher, *as well as the University*, may incur legal liability if the treatment of survey recipients is unethical.
- (4) The question was raised regarding how the policy would be distributed, once a final version was approved. In addition to the strategies suggested by the Director of the OIR (including a copy in the HR policy section on the University website, new webpage on the OIR site, campus-wide Email once the policy is official, and annual Email reminder of the policy), it was also recommended that a link to the policy also be added to the IRB webpage.
- (5) The Board recommended that a stronger statement appear in the policy regarding the personal responsibility of researchers when using external survey tools (e.g., SurveyMonkey), and that this statement be made more upfront, clear, and explicit. Specific precautions or safeguards might include ensuring that data are encrypted and that participants' Emails or ISPs are not connected to their survey responses.

Action: The Director of the OIR will make the suggested revisions and resubmit the policy to the IRB for review and final approval.

The meeting was adjourned at 9:15 a.m.

Respectfully submitted,

David Moore