MINUTES
Institutional Review Board
April 20, 2010

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

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

Announcements: Garrett reviewed the agenda for the meeting, which included review of 3 new protocols and 1 re-submission, followed by a discussion of the University's Research Misconduct Policy.

Orders of Business:

1. **Deliberation on Protocol 0910-011 (Re-submission).**

   The committee briefly discussed the revised protocol and raised only 1 remaining issue, namely that the committee would like to see language added to the protocol regarding what researchers will do if it comes to light that some participants (or prospective participants) are homeless themselves. Although the committee does not anticipate the level of risk to such participants to be of concern, several members thought that this could be an issue for the schools and felt that the principal investigator should clarify how this situation would be handled.

   Action: The protocol was unanimously approved (7-0) pending approval letter(s) from the schools, which will need to be submitted to Associate Dean Lisa Ferrari.

2. **Deliberation on Protocol 0910-013**. Key issues and questions included the following:

   - The protocol is incomplete in its present form (several missing items or pieces of information are noted below).
   - It is unclear how the researcher plans to administer the survey (e.g., what survey tool or medium he plans to use).
   - It is unclear how the researcher will ensure anonymity or confidentiality, especially given that it is possible to identify or track IP addresses or other identifiers via the internet.
   - The researcher's appraisal that the proposed survey is non-sensitive in nature seems inconsistent with the focus on criminal activity or potentially criminal activity (depending on the specific jurisdiction).
   - The researcher needs to submit for IRB review the recruitment materials or advertisements that he plans to use for the study (in the various languages of the target participants), as well as a list of the websites where he plans to recruit participants.

- In order to approve the project, the IRB must be able to review the actual survey and cover letter (or other materials) accompanying the survey.
- The researcher should specify the target range of desired participants (even if this range is a broad estimate of the minimum and maximum number accepted).
- The researcher needs to specify how and where data will be stored and for what duration. Likewise, he needs to specify how the security of data (electronic and otherwise) will be maintained.
- The researcher should clarify how study materials will be translated into the necessary languages spoken by prospective participants.

Action: The vote was unanimous (7-0) that the researcher will need to revise and resubmit the proposal to the Full Board.

3. **Deliberation on Protocol 0910-014**. Key issues and questions included the following:

    - Clarification and greater specificity is requested regarding the exclusion criterion for ongoing litigation (e.g. Will involvement in any type of litigation whatsoever serve as grounds for exclusion?). An added concern was how researchers would identify ongoing litigation for prospective participants, as this was not mentioned in the screening survey submitted to the IRB.
    - In the Risks section of the Consent Form, the researcher should add a comment about potential pain/discomfort during the intervention/testing itself (e.g. "You may experience an increase in pain during functional tests"). In this same section on the Consent Form, the committee requests that the researcher re-label the risk level as "minimal."
    - Please specify the specific department or location where data will be stored.

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

4. **Deliberation on Protocol 0910-015**. Key issues and questions included the following:

    - The affiliation with the University of Puget Sound (and perhaps physical therapy) should be added to the flier advertising the study.
    - Two revisions are requested in the Consent Form: (1) The researcher should clarify that participation or refusal to participate in the study will not affect the care/treatment participants' receive at UPS, either currently or in the future; (2) the researcher should insert an explicit disclaimer that participation in the study does not guarantee the opportunity or preference for participants to become a patient in Dr. Hastings' private practice. In addition to inserting the latter disclaimer, it is requested that the contact person for the research project communicate this same information to prospective participants (e.g.

"Participation in this study does not imply ongoing treatment with Dr. Hastings").

Action: The committee unanimously (7-0) approved the study, pending the requested revisions.

5. **Review of the University Research Misconduct Policy**.

   The Board identified several areas of the Research Misconduct Policy that are in need of revision and it plans to develop specific recommendations to the PSC regarding how to proceed at the May 11 meeting.

6. **Additional Announcement.**

   Lisa Ferrari announced that Dean Bartanen has suggested that starting next year, the IRB should meet 2 times per month—with one meeting devoted to the review of protocols and the other meeting to deal exclusively with administrative charges. A brief discussion of this followed, and the Committee unanimously agreed that the IRB would indeed meet 2 times per month starting the following academic year.

The meeting was adjourned at 9:05 a.m.

Respectfully submitted,

David Moore