

Institutional Review Board Minutes  
September 12, 2006

Members present: Allen, Evans, Finney, Kaminsky, McCoy, Ochosi, Preiss, Wilson, Woodward

The meeting was opened at 4:00 PM in Wyatt 326

1. Election of chair and secretary.
  - Faculty Senate representative Bill Haltom attended the first part of the meeting and called for nominations for IRB chair. Allen nominated McCoy who accepted the nomination. No other members were nominated. McCoy was elected chair of the Board. Senator Haltom left the meeting.
  - Kaminsky volunteered to act as secretary for the Fall semester. This position will be discussed again at the beginning of Spring semester.
2. Permanent meeting time
  - The IRB will meet the first Thursday of the month from 4:00 to 5:00 pm. If there are additional protocols needing review, the Board may meet the third Thursday of the month from 4:00 to 5:00 as well. Finney will arrange a meeting room.
3. Community representative
  - Discussion about possible resources for locating a community representative. Ochosi to follow up with some participants from an exercise science program, Kaminsky to ask faculty from occupational therapy for ideas, Woodward and Preiss to follow up about recruiting a retired lawyer to act in this position. Wilson to discuss the possibility with her husband.
4. Decision about whether to review study
  - Discussion by the Board about a large study that involves a faculty member acting as a coordinator. The question was raised about whether or not the UPS IRB should review the protocol or waive jurisdiction. Since the study does not involve UPS facilities, participants in the study will not be affiliated with UPS, and the investigators being coordinated are also not affiliated with UPS, the Board decided to waive jurisdiction.
5. Review of Protocol #0607-001
  - The following issues were raised by members of the Board:
    - More information is requested about who the research assistants are and how they will be trained.
    - In the health questionnaire, there are questions about participant drug and alcohol use. Are these questions necessary? If so, the Board would like further justification for inclusion of these questions. If these questions are retained, participants should be notified on the consent form that they will be asked about illegal behavior. A statement at the beginning of the

questionnaire clarifying that participants are free to disregard any questions they don't want to answer is also recommended.

- The protocol states that filling out the questionnaires is anticipated to take 45 minutes. The Board wondered if this estimate was low and questioned how the time requirement was determined. Is this based on pilot testing?
- There was extensive discussion about the described use of blood pressure monitoring. A clearer explanation of the protocol is needed. How will participants be positioned? Will they be told not to move? Why is it necessary to take blood pressures every minute? There was some concern by the Board that this will lead to physical discomfort or even injury for participants, especially if they have underlying physical conditions such as peripheral vascular disease. There was also some concern that repeated blood pressures with such little recovery time will lead to false readings of elevated blood pressure. One member of the Board pointed out that a stress response will lead to elevations in blood pressure lasting as long as 25 minutes, so less frequent monitoring should be sufficient to track changes in blood pressure due to stress. If the investigators still feel that blood pressure monitoring every minute is necessary, the Board would like further evidence as to the safety and scientific necessity of this protocol.
- The Board suggested that the investigators revise downward the requirements for blood pressure. The American Heart Association has recently changed the guidelines for what is considered hypertension.
- Consistent with some of the concerns about injury with repeated blood pressure monitoring, the exclusion criteria should be revised to include people with peripheral vascular diseases, such as Raynaud's Disease.
- More information about protection of videotapes is needed. Where will videotapes be stored? How long will they be kept before they are destroyed? Will images be used for scientific presentations? This information needs to be included in both the protocol and the consent.
- Will instructors be asking for volunteers in their own classes? If so, the Board recommends other studies be described at the same time to avoid the possibility of coercion.
- By a unanimous vote (9-0), the Board did not approve the protocol in its present form. It will be sent back to the investigators for reconsideration and revision.

#### 6. Review of Protocol #0607-002

- The following issues were raised by members of the Board:
  - The consent forms still list the MultiCare IRB as a contact for participants. This needs to be removed since MultiCare did not consider the protocol.
  - The assent form needs to have a minor rewording change. It currently states that the parent or guardian "wants" the child to participate in the study. The wording will be changed to a phrase that does not have the risk of coercion.
- The protocol was approved by unanimous vote (9-0), pending the above revisions.

The meeting was adjourned at 5:00 PM.

Respectfully submitted,  
Tatiana Kaminsky, IRB Secretary