Institutional Review Board Minutes
November 2, 2006

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

The meeting was opened at 4:01 PM in Wyatt 326

1. Timeliness in getting materials to Board members.
   - This was much improved this month and materials were received in a timely fashion. No further action needed.

2. Tracking projects that have been approved
   - Allen is working on a database for tracking projects that have been approved this year.

3. IRB Stamp
   - McCoy has ordered the stamp. It will be here in a couple of weeks. All forms (e.g. consents and flyers) that are approved by the IRB will be stamped in the future.

4. Minutes approval process
   - Meeting minutes from October 5th were approved via email, but this took a little while. In the future, minutes will be sent out electronically with a 72 hour deadline for feedback. If a response is not received within 72 hours, the secretary will assume members approve the minutes and will submit them for posting online.

5. Updating the IRB website
   - Preiss has an updated list of IRB designates. These will be sent for inclusion on the website.
   - Blood borne pathogen protocol will be included on the website.

6. Community member of the IRB
   - Two of the community members who were interested in serving on the IRB submitted personal statements. The Board considered the statements and discussed the candidates.
   - Marsha Gallacher will be the community representative and will attend IRB meetings starting on December 7th, 2006.

7. HIPAA statement was created by Wilson and Allen. This statement needs to be included on the consent forms for studies that access medical information of participants. The statement was approved by the Board. This is the HIPAA statement:

APPROVAL TO USE AND SHARE HEALTH INFORMATION

Federal and state laws require care providers to protect the privacy of your health information. Volunteering to participate in this study means that your health information that relates to this study may be collected, used and shared to carry out the study. This includes health information about you that was collected prior to, and in the course of the study. Information may be collected from you by interviews or from your medical records. Examples of the health information that may be collected include, but are not

limited to, personal information (such as name, address, gender, age, etc.), your medical history, personal habits, and physical tests and measures.

By signing this consent form, you are authorizing the research team to have access to your study-related health information. The research team includes the investigators listed on this consent form only. Your health information will be used only for the study purpose(s) described in this research consent form. Your health information will be shared, as necessary, with any other person or agency as required by law. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

By signing this study consent, you are authorizing the research team to use and share your study-related health information until the end of the research study. The study records will be confidentially shredded for your security when storage is no longer required.

You may withdraw your approval to use and share your study related health information at any time by contacting the Principal Investigator in writing. If you withdraw this approval, you may no longer participate in this study. The study related health information that has already been collected may still be used to preserve the integrity of the study, including a disclosure to account for your withdrawal from the study. However, the use or sharing of future health information will be stopped.

8. Review of Protocol #0607-004 was done via email. Revisions were suggested to the researchers. The researchers have completed the revisions and the protocol has been approved.

9. Review of Protocol #0607-005
    - The following topics were discussed:
        - The researchers state that they have the support of Pierce County and the City of Tacoma. Letters of support need to be submitted to the Board.
        - There was some discussion about the language in the consent form. The Board felt that the language needs to be changed to reflect that participants are being invited to join the study. Right now, the language sounds as if the participants are expected to join the study. This is especially important given the vulnerable nature of the population. There was also a concern that the language is very sophisticated in the consent form. The reading level needs to be modified downward.
        - Person first language is recommended for the consent form. For example, rather than saying “homeless individuals,” the consent form should state “individuals who have been homeless.”
        - The Board requests acronyms be spelled out on the interview guide. This will help the Board assess the personal nature of the questions.
        - Since medical information is being collected, the HIPAA statement needs to be included on the consent form.
        - The Board requests more information about the follow up survey mentioned in the consent form by the researchers
        - In the cost and payment section of the consent form, a statement should be made about the participants not needing to pay to be in the study.
        - Need to include statement in the consent form about when personal information will be destroyed.

- Need to tell participants that they will receive the Safeway gift card even if they withdraw from the study.
- If researchers do plan to tape record conversations with participants, that information needs to be included in the consent form.
- More information is requested about how potential participants will be approached to avoid the possibility of coercion.
- In the risk part of the consent form, the researchers need to state more clearly that records can be subpoenaed given the sensitive nature of some of the information that is being collected.

- The Board agreed to send the above recommendations to the researchers and consider a revised protocol after it is submitted to the IRB.

10. Review of Protocol #0607-006

- This protocol, as submitted, had many areas of concern and needs more global scrutiny by the faculty advisor in addition to extensive revision, correction, and clarification by the students. The following topics were discussed, though there are other issues that are not mentioned here that need to be carefully considered by the faculty advisor prior to this protocol being resubmitted:
  - Student phone numbers should not be listed on the consent form, especially when those numbers require participants to make a long distance phone call. The department number should be listed instead.
  - Need a statement of support from the faculty advisor.
  - Many typos in the consent form (both for the adolescent and for the parent). These need to be fixed.
  - The consent form states that teammates will be present at the first session. The Board was unclear about the reasons for this and whether or not it is necessary.
  - The researchers need to state what will happen if injury to participants occurs. What will be done to prevent injury?
  - The consent form states that "other faculty" will have access to data. Who are the other faculty and why do they need to have access to the data?
  - More information is needed about how participants will be recruited. In addition, if the purpose of the study is to compare boys and girls, how will researchers recruit to ensure that there are a similar number of participants of each gender?
  - If participants will be videotaped, information about this needs to be in the consent, including how videotapes will be protected, how they will be used, and when they will be destroyed.
  - The researchers state that information that is not pertinent to the study will be stored for five years then destroyed. Why will this information be collected in the first place if it is not pertinent? What will happen with information that is pertinent to the study?
  - Benefits listed in the consent form need to be more closely examined. The Board was unsure if the researchers will in fact be educating participants about the importance of the non-kicking leg during goal kicking. If this education will not be occurring, the statement about this as a benefit needs to be removed.
  - Print consent form on UPS letterhead

- The Board agreed to send the above recommendations to the researchers and consider a revised protocol after it is submitted to the IRB.

11. Review of Protocol #0607-007
    - The following topics were discussed:
        - Some discussion about participant burden. This is a continuation of previous research that has been done. Participants have been willing to complete daily data collection for other studies, so this was determined to not be an issue.
        - Recommendation was made to place data sheets in a sealed envelope each day so that the participant cannot refer to them again. This may help to ensure independent daily data collection.
        - A few typos were found on the consent form that need to be corrected.
        - Discussion about venous blood collection being more accurate than fingertip prick. If possible, this method of blood collection would be beneficial.
        - There was also some discussion about estrogen having an effect on thyroxine. If the participant is taking birth control pills, this may have an impact on the data.
    - The protocol was passed by a unanimous vote (7-0) with the minor revisions noted above.

12. Discussion on Protocol #0607-008
    - The protocol was not thoroughly discussed due to time constraints. Several points were raised that will be shared with the researchers:
        - More details needed about when participants will be debriefed since deception is needed for this study.
        - If recruitment of participants will take place in clinics, there may be other IRB's that need to be consulted.
        - Remove the word "additional" under the costs section of the consent form.
        - Print consent form on the UPS letterhead
    - The protocol will be discussed further on December 7th.

13. Training for department designates.
    - Some discussion about the departmental designate role in the IRB process. The Board felt that some of the errors being seen on IRB protocols should be addressed by department designates prior to protocols being submitted for full review. IRB may request that designates have some training. This will be discussed further.

14. Board members are asked to read the IRB guidelines for the next meeting. Notes need to be made about what needs to be updated. Wilson has already started making notes about point H on page 4 of the guidelines.

The meeting was adjourned at 5:00 PM.

Respectfully submitted,
Tatiana Kaminsky, IRB Secretary