

Institutional Review Board Minutes  
October 5, 2006

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

The meeting was opened at 4:03 PM in Wyatt 326

1. Timeliness in getting materials to Board members.
  - The Board discussed ways to speed the process of getting proposals to the members for review. Finney will follow up with Jimmy McMichael in the Associate Dean's office about getting packets copied and sent to members immediately after they are submitted for review.
2. Tracking projects that have been approved
  - We need to have a way of following up annually on projects that have been approved so that renewals or terminations of these studies are being completed. McCoy asked if there was a way to have a system with email reminders asking researchers about whether or not they need to renew their projects. Allen offered to create a database of protocols that are approved this year to facilitate this process.
3. IRB Stamp
  - Discussion about getting a stamp created that can be used on protocols, flyers, consents that are approved by IRB. This would ensure that the final approved forms are the ones being used in studies. McCoy will follow up on getting stamp created.
4. Minutes approval process
  - Minutes will be sent out electronically after the Board meetings. Board members will review minutes and send changes to the secretary as necessary. After changes are made, the minutes will be approved by the Board members electronically. This will speed the process of getting minutes approved and posted since the Board only meets once a month.
  - Minutes from September 12<sup>th</sup> meeting approved.
5. Review of Protocol #0607-001 - Revised
  - The co-investigators attended the IRB meeting. The following topics were discussed:
    - The Board still had some concerns about the frequency of blood pressure monitoring. There was a question about the cumulative effect of monitoring every minute and whether or not this would allow arterial refilling. According to the co-investigators, they will use the "Smart Cuff." This system adjusts the maximal inflation to the participants' blood pressures. It takes approximately 25 seconds for the blood pressure to be taken, with 35 seconds of recovery time. One of the Board members

stated that the literature says that it takes one to two minutes for vessels to refill, so questioned whether or not monitoring every minute is accurate. The co-investigators said that they will be using change scores rather than absolute values of blood pressure so did not think this was an issue.

- One of the co-investigators also stated that this was her sixth study with this blood pressure monitoring technique. She has not had issues with safety with her other studies. In one of her studies, she had 248 participants. Only two asked for blood pressures to be stopped. The co-investigators also stated that they will tell all participants that blood pressure monitoring can be stopped if the participants are uncomfortable with it.
- There was some discussion about positioning for accurate blood pressure monitoring, which is especially important when screening potential participants for inclusion in the study. If participants are not positioned correctly, false high readings may be obtained.
- The co-investigators left the meeting. The revised protocol was reviewed. The Board felt that the co-investigators had addressed all of the concerns that were raised by the Board.
- By a unanimous vote (9-0), the Board approved the revised protocol.

#### 6. Community representative:

- Ochoi knows three people interested in serving as community representative. He had information on two of the three people. The first is a UPS alumnus, has taken courses in medical ethics, has lived in 23 countries, and has worked in banking. The second is the retired executive director of a newspaper. Wilson knows one person interested in serving. He is a sixth grade teacher. Kaminsky, Preiss, Woodward had no luck in locating potential representatives
- After some discussion, the Board decided to ask each person to send a brief (one page) description of his/her qualifications. In return, the Board will send each person a brief (one page) description of the IRB, including duties of the community representative. It is hoped that the person chosen will serve for more than one year. McCoy will create the description of the IRB.
- Upon receiving the information about each candidate, the Board members will choose one to serve as community representative. If possible within the time frame between now and the next meeting, the Committee members will be asked to vote via email on one of the three people who responds to the email inquiry. The Board would like the decision to be made so that the individual selected might attend our next meeting date (November 2<sup>nd</sup>).

#### 7. HIPAA

- McCoy raised the question of Health Insurance Portability Accountability Act (HIPAA) compliance. There are federal requirements for consent forms for studies that look at medical documents. The Board needs to be knowledgeable and compliant with these requirements. Allen and Wilson volunteered to research this further and educate the Board members.

8. IRB website (<http://www2.ups.edu/dean/irb/index.shtml>)
- A “frequently asked questions” document was started last year. Preiss has compiled what was done last year and will send it to the Board for review. Preiss and Woodward will work on updating the IRB website, including adding the FAQ document, checking to make sure that the designated information is accurate, and updating meeting times. There was some discussion about who acts as webmaster for the Board. Changes that need to be made need to be sent to Jimmy McMichael in the Associate Dean’s office so that the website can be updated.
  - Discussion was also initiated about making sure the guidelines document is updated. Every member of the Board needs to read through the guidelines that are currently posted on the website. Any changes that need to be made will be addressed in future meetings.

9. New Business

- McCoy mentioned that some IRBs require anyone submitting an application to go through an online training course. She would like all Board members to complete the training course. She will send the link to all Board members.
- Ochosi brought up a question about classroom labs and activities and whether or not we needed to give approval for those activities (such as conducting experiments in the community as a classroom activity). He stated that it would be nice if there was a document with protocols for these situations. Wilson asked if some models of these documents exist. Ochosi will search for some examples and bring them to the next meeting.

The meeting was adjourned at 5:05 PM.

Respectfully submitted,  
Tatiana Kaminsky, IRB Secretary