Institutional Review Board
October 11, 2007

Present: Roger Allen, Jim Evans, Marsha Gallacher, Tatiana Kaminsky, Sally McCoy, Garrett Milam, David Moore, Sarah Moore, Karim Ochosi, Ray Preiss, Ann Wilson

Review of Senate Charges: Allen provided board members with the Senate charges to the 2007-2008 IRB. The board reviewed and briefly discussed each charge.

1. "Continue to monitor protocols and maintain and manage records for research involving human subjects." This charge is the primary function of the IRB so no further discussion was warranted.
2. "Post and monitor upgraded IRB information on the webpage for IRB researchers." The guidelines document has been revised and is pending approval of the full board before being placed on the webpage. Sarah Moore reported that Jimmy McMichael is updating the names of current board members, meeting times and protocol submission deadlines for this academic year and will be making those changes in the near future.
3. "Work with new Associate Dean and IRB liaison with the administration and discuss administrative duties for the IRB liaison that ease the secretarial work of the Chair." This is in process. Allen and Sarah Moore have met with Jimmy McMichael regarding streamlining the recordkeeping and archiving of protocols. McMichael was invited to attend today's meeting but was unable to due to illness. He will be invited to the next meeting.
4. "Determine the possibility of an electronic IRB stamp for approved consent/assent forms." This issue was addressed and board members felt that the current system that requires a physical stamp on all consent forms is most appropriate at this time and in keeping with the practices of most other IRBs.
5. "Explore the possibility of creating a web-space where IRB approved UPS research studies can post flyers for recruitment of human subjects." Board members generally agreed that a space dedicated to posting such information would probably not be utilized by the campus community. Instead, the board plans to dedicate space on the current IRB page to providing links to departmental sites where such information can be posted.
6. "Consider the scope and mechanism of IRB review in light of national professional and disciplinary standards." (See discussion below.)

Status of Search for New Developments in IRB Involvement in Social Science Research: Preiss distributed a document from the Center for Advanced Study entitled "Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep". He reported that he learned of the existence of this document from Suzanne Holland who was the Senator who originally brought the issue to the attention of the Faculty Senate. Preiss pointed out that this document is a white paper "conversation" and does not reflect policy changes that are federally mandated. The group involved in preparing this document consisted of ethicists and others with an interest in social science research rather than individuals who have actual responsibility for monitoring the protection of human subjects. Preiss questioned whether the Senate has the ability to give a charge to alter the way in which the IRB operates given that IRBs were created by a federal mandate and are subject to federal regulations rather than a university's own set of guidelines. Preiss stated that he felt that the university might be better served by hiring a consultant to review our IRB's guidelines and practices to see how they compare with others instead of trying to make changes based on the sentiments expressed in the white paper. Allen offered to summarize the discussion and inform the Senate on issues related to the federal mandate related to the creation and role of IRBs in the annual report to the Senate in the spring. Wilson proposed that Allen suggest that Senators who are interested in understanding more about

the federal regulations and IRB oversight visit the IRB training website provided by NIH http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp . It was also suggested that Department Designates talk to their respective departments about their role since protocols that meet the criteria for either exempt or expedited review do not require full board review and that may also help alleviate some of the concerns expressed.

Reconsideration of Allowing Michigan State University (MSU) to be the IRB of record for the College Board Study: Allen provided copies of the protocol that was submitted to the MSU IRB as well as a copy of the approval letter from the MSU IRB. The board unanimously approved (11-0) to allow MSU's IRB oversight of this project consistent with their guidelines. The approval letter from MSU that the approval is good for a period of one year ending on February 26, 2008. Allen will inform George Mills that UPS will allow the MSU IRB to have oversight over this project but that he (Mills) will need to make sure that he obtains a copy of the extension of the approval from MSU to continue the study beyond the current expiration date and that he submits documentation of the approval extension to the Office of the Associate Dean for archiving.

Protocol Reviews:

#0708-001 Board members raised several issues related to the lack of information in the protocol regarding exclusion criteria and participant safety as well as mechanisms for participant recruitment and additional details that needed to be included in the consent form such as procedures for maintaining confidentiality and storage of data. The language in the consent form also needs to be simplified. **ACTION:** The board voted (11-0) to approve the protocol with modifications. Once the modifications have been made, Allen will review the revised protocol and send the approval letter.

#0708-002 Board members raised several issues related to the lack of information in the protocol regarding exclusion criteria and participant safety as well as mechanisms for participant recruitment and additional details that needed to be included in the consent form such as procedures for maintaining confidentiality and storage of data. The language in the consent form also needs to be simplified. **ACTION:** The board voted (11-0) to approve the protocol with modifications. Once the modifications have been made, Allen will review the revised protocol and send the approval letter.

Consideration of Registration with the Office for Human Research Protections: This agenda item was tabled due to lack of time.

Discussion/Approval of website changes: This agenda item was tabled due to lack of time.

The meeting was adjourned at 12:05 p.m.

Respectfully submitted,

Ann Wilson