## Institutional Review Board December 11, 2008

Present: Roger Allen, Lisa Ferrari, Marsha Gallacher, Tatiana Kaminsky, David Lupher, Garrett Milam, David Moore, Ann Wilson

Garrett Milam called the meeting to order at 10:00 a.m.

Following a brief discussion of the number of protocols that needed to be reviewed, and the fact that several of them are student projects with the same faculty mentor, the board decided review them in a different order than they were received. The order below indicates the order in which each protocol was reviewed.

## PROTOCOL REVIEWS

0809-006

The board commented that the protocol was well-written and therefore, easy to review. A few minor wording changes were suggested on the consent form. **ACTION:** The board voted (8-0) to approve the protocol pending the chair's receipt of a revised consent form.

0809-007

Board members voiced concerns regarding the wording in the sample invitation to participate that the primary investigator provided. Suggestions included updating the sample back page (that will be attached to the electronic survey) to reflect the current study in terms of dates, etc., providing a separate statement to participants regarding resources available to assist them with issues related to drug or alcohol abuse and a clarification of the requirements necessary to be eligible for the prize drawing at the end of the study.

**ACTION:** The board voted (8-0) to approve the protocol pending the chair's receipt of the revised invitation to participate.

NOTE: The following protocols were discussed together since they were all student projects With a common faculty advisor and since all presented with similar issues and concerns.

0809-003 0809-004 0809-005 0809-008

Each one of these protocols needs a support statement from the faculty advisor. The statement should specify if the proposed research is independent or a requirement for a course. A brief biographical sketch of the advisor/mentor should also be included. The biographical information submitted by the student researchers should include information such as course work completed that qualifies the students to conduct the research.

Each protocol needs to have a description that justifies the reason for the research and a purpose that clearly articulates a specific research question. In justifying the research, the board would like to see evidence that the investigators have reviewed the literature in the area in which they intend to do research.

The board suggests that the faculty advisor consider requiring the students to complete the tutorial on the role and function of IRBs to gain an appreciation of the importance placed on the protection of human subjects. The tutorial can be accessed at: <a href="http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp">http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp</a>

Following a lengthy discussion, it was determined that each of the protocols listed above need significant revision before they can be reviewed by the full board. Therefore, these protocols will be returned to the student researchers with a letter indicating that. In addition, the IRB chair will provide specific recommendations to the faculty advisor/research mentor for these students. Students will be invited to resubmit their protocols for review early in the spring semester.

Meeting time for spring term: IRB meetings will take place the second Thursday of the month at 10:00 a.m. beginning in February. The board will consider having a January meeting on either January 15 or January 22 if there are protocols to review.

The meeting was adjourned at 11:05 a.m.

Respectfully submitted,

Ann Wilson