

Institutional Review Board
April 10, 2008

Present: Roger Allen, Jim Evans, Lisa Ferrari, Tatiana Kaminsky, David Moore, Ray Preiss, Ann Wilson

The meeting was called to order at 9:00 a.m.

Student recruitment for drug trial database: Roger Allen reported that he was advised that a group called the Charles River Clinical Associates was in the SUB recruiting students to add to their database for future drug trials. This activity was taking place without the knowledge or approval of the IRB. He contacted the Charles River group and told them that all activities of this nature needed to be reviewed and approved by the university's IRB. Allen has asked the group to suspend this activity at UPS. In addition, he requested that all students from UPS who agreed to be added to the database while the group was on campus be removed.

A question was raised as to how other comparable institutions deal with this type of activity on their campuses. Lisa Ferrari agreed to follow up on that. Ray Preiss suggested that the university attorney be consulted for an opinion on this type of activity as well.

Department designate reports: Department designate reports on the status of protocols that have been reviewed and approved this academic year need to be submitted to Roger Allen by April 25th so that the information can be included in the annual report to the Faculty Senate.

Protocol Reviews

- 0708-014 The researcher's plan to use UPSID is problematic because that is an identifier that can be linked directly to a specific participant. The researchers will need to clarify why that information is needed. The researchers will need to clarify the differences between anonymity and confidentiality in the protocol and on the consent form. A question was raised as to the reason for needing to contact the Disabilities Specialist to "verify" the information provided by the participants. **ACTION:** The board voted (7-0) to approve the protocol with modifications. Allen will provide the researcher with detailed information and will review the revised protocol to ensure that all of the concerns have been addressed.
- 0708-015 The recruitment flyer should have an additional clause that states that participants must have a diagnosis of restless legs syndrome and have no other medical problems that would prevent them from safely participating in a low level exercise program. There is also one typographical error in the protocol and one formatting error in the consent form. **ACTION:** The board voted (6-0 with 1 abstention) to approve the protocol pending correction of the flyer and errors mentioned above.
- 0708-016 This protocol was a resubmission from March. (Please see discussion in minutes regarding protocol 0708-013.) While the researcher has attempted to address some of the issues that were raised by the board initially, there are still a significant number of concerns about the current protocol. Given the sensitive nature of the project and the issues related to subject recruitment and confidentiality that have not been addressed, the board is unable to complete its review.

ACTION: The board voted (7-0) that it was unable to make a determination on this protocol. The researcher will be asked to revise and resubmit the protocol addressing the specific questions that were raised in the deliberations. If the researcher chooses to resubmit the protocol with revisions, the researcher will be asked to appear at the meeting in person to address any remaining questions that the board may have.

0708-017 The survey instrument that will be used is an adaptation of an instrument that was published previously and needs to be referred to as a modified form rather than as the original instrument. Minor errors on the consent form were noted.
ACTION: The board voted (7-0) to approve the protocol with minor modifications to the protocol and consent form as described above.

The meeting was adjourned at 9:55 a.m.

Respectfully submitted,

Ann Wilson