

Institutional Review Board
March 5, 2009

Present: Lisa Ferrari, Marsha Gallacher, Tatiana Kaminsky, David Lupher, Garrett Milam, Karim Ochosi, Ann Wilson

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

Protocol Reviews

0809-009 The board members request clarification from the researcher in the following areas:

- 1) Delineate/describe the specific role of each individual listed as a co-investigator on the protocol.
- 2) Clarify whether participants must complete the entire study in order to receive the cash payment or whether the payment will be made at the end of each session.
- 3) Clarify whether a person can decline participation in the study and still remain in the group.
- 4) Clarify how the information will be kept confidential if identifying information such as participant name appears on written material related to the study.
- 5) Clarify the need for and nature of protected health information that will be gathered about participants as a condition of inclusion in the study.

In addition, the board made several suggestions regarding changes in the language and order of items on the consent form.

ACTION: The board voted 7-0 to approve the protocol pending the chair's receipt of the revised protocol that addresses the concerns listed above and a revised consent form.

0809-010 Given the level of risk described for this study, the board members request clarification from the researcher on the following issues:

- 1) Clarify the specific data that will be collected from the maximal and submaximal tests in a way that non-exercise scientists can understand.
- 2) Clarify the role of each of the researchers listed on the protocol and describe precisely how the student researcher will be supervised during the testing of the participants.
- 3) Describe the steps that will be taken to minimize risks associated with participation in the study.
- 4) Specify the ways that the researchers will assist participants who may experience a medical emergency or adverse reactions as a result of the testing.

The language in the consent form needs to be modified so that a person without an exercise science background can understand what he/she will be asked to do if he/she agrees to participate. In addition, the language should remind the participant that he/she is doing this voluntarily and is "being asked" or "invited to"... rather than being "required to" perform certain tasks.

In addition, the board suggests that the researchers consider having the faculty advisor rather than the student researcher provide the introduction/participant recruitment to avoid the potential risk of coercion.

ACTION: The board voted 7-0 to return the protocol to the researchers with a request to address all of the issues listed above and resubmit to the full board for consideration at a future meeting.

0809-004 This protocol, which was reviewed previously, was resubmitted with modifications. The board determined that the consent form needs further revision in the project description to reflect what the participants will be asked to do rather than what the study will entail. In addition, the letter to the students needs to be proofread before it is sent.

ACTION: The board voted 7-0 to approve the protocol pending the chair's receipt of a revised consent form.

0809-011 The board discussed this protocol briefly and determined that it was not presently in a form that could be reviewed or approved. Therefore, it will be returned to the researcher with no action from the board. The researcher will be instructed to consult and follow the guidelines posted on the IRB web page.

Revisions to IRB Guidelines Document: The board voted 7-0 to allow the following changes to be made to the IRB Guidelines Document:

- 1) Researchers should send one physical copy of the protocol to the Office of the Associate Deans prior to the published deadline. [The current guidelines require 10 copies of the protocol be submitted.] This will require changes in Sections 5 and 12 of the document as well as page 12.
- 2) Researchers should submit letters of support/cooperation/collaboration if they are working with an outside agency. This change should be reflected in the protocol preparation section of the guidelines document.

Department Designate Training: Ann Wilson has agreed to provide or assist with training designates from departments who use the IRB for student and/or faculty research on a regular basis. The purpose of the training is to help ensure consistency of the review process and to answer questions related to the role and responsibilities of the department designate. The board discussed specifically inviting designates from the following departments to attend: OT, PT, Exercise Science, Psychology and Comparative Sociology. Garrett will follow up with Ann to try and get this scheduled before the end of the semester.

The meeting was adjourned at 10:55 a.,m.

Respectfully submitted,

Ann Wilson
Secretary