Institutional Review Board December 13, 2007

Present: Roger Allen, Jim Evans, Marsha Gallacher, Sally McCoy, Garrett Milam, David Moore,

Sarah Moore, Ray Preiss, Ann Wilson

Visitor: Jimmy McMichael, Office of Associate Deans

Meeting times for spring semester: The IRB will meet the second Thursday of each month from 9:00 a.m. – 10:00 a.m. at a location to be determined. The regular meeting dates for spring will be February 14, March 13, April 10 and May 8. Protocols are due to the Office of the Associate Deans no later than two weeks before the meeting. Therefore, the protocol submission deadlines for spring semester are January 31, February 28, March 27 and April 24.

Protocol Reviews:

#0708-004

This protocol is actually a request for renewal and a modification of a protocol which was approved in AY 2006-2007. Rather than assigning a new protocol number, this protocol should be cataloged under its original number. Jimmy McMichael will add the information from today's deliberations to the protocol that is archived in the Office of the Associate Deans. The researchers will be asked to describe the procedure that they will use to provide resources or referrals for appropriate management of any distress that might arise from recalling past traumatic events.

ACTION: The board voted (9-0) to approve the protocol with the minor modifications listed above. Modifications will be sent to Roger Allen for final review and approval. Roger Allen also agreed to applaud the researchers for requesting the modification in a timely manner.

#0708-005

The way in which the medical questionnaire will be used needs to be clarified, i.e., any "YES" responses will exclude a person from participation. Minor changes in wording on the consent form were recommended as were minor changes in the recruitment script that the researchers plan to use.

ACTION: The board voted (8-0 with one abstention) to approve the protocol with the minor modifications listed. Modifications will be sent to Ann Wilson for final review and approval.

#0708-006

The intervention described in the protocol is for a different type of exercise than is listed. The researcher needs to include copies of the specific questionnaires to be used in the protocol so that the items can be reviewed by the board. The board raised several concerns regarding the safety of the proposed intervention and how the participant's anonymity will be preserved. In addition there were several other questions that the board was unable to answer from the materials provided. **ACTION:** The board voted (9-0) that it was unable to make a determination on this protocol based on the information provided. The researcher will be asked to revise and resubmit the protocol addressing the specific questions that were raised in the deliberations.

#0708-007

The board was unable to determine specifically what the intervention is for this protocol. The researcher needs to include the specific questions that will be asked of the participants and to clarify the procedures that will be used. In addition,

there were several other questions that the board was unable to answer from the materials provided.

ACTION: The board voted (9-0) that it was unable to make a determination on this protocol based on the information provided. The researcher will be asked to revise and resubmit the protocol with a complete description of the intervention and a literature-based justification for the merit of the project.

#0708-008

The board had difficulty determining what the study was attempting to pilot test. In addition there were concerns regarding the appropriateness of interviewing employers of participants regarding certain dimensions of his or her job performance. The risks to participants, particularly with respect to interviewing employers need to be clarified. The consent form contains potentially coercive language in the project description. In addition, the description in the consent form may influence the way in which participants respond during the study. The letters of support for this protocol need to be submitted on company letterhead and need to be specifically for this particular protocol.

ACTION: The board voted (9-0) that it was unable to make a determination on this protocol based on the information provided. The researcher will be asked to revise the protocol in a way that minimizes the risk of potential liability and other issues associated with interviewing employers about job performance.

#0708-009

The board had difficulty understanding the specific aim of the study. Concerns were also expressed regarding the appropriateness of interviewing employers about certain dimensions of an individual's job performance. The consent contains several items that are irrelevant to informed consent and refers to "the author, which is presumed to be the person conducting the interviews, which is confusing. The letters of support for this protocol need to be submitted on company letterhead and need to be specifically for this protocol.

ACTION: The board voted (9-0) that it was unable to make a determination on this protocol based on the information provided. The researcher will be asked to revise the protocol in a way that minimizes the risk of potential liability and other issues associated with interviewing employers about job performance.

#0708-010

The board had difficulty understanding the specific aim of the study. The absence of an adequate literature review made it difficult to understand what the research question is and how this study is justified. The consent form needs to be reworded so that the description does not include the proposed benefits of the study and that personal pronouns are used appropriately. The information regarding study procedures and data collection should be removed from the risks and benefits section of the consent form.

ACTION: The board voted (9-0) that it was unable to make a determination on this protocol based on the information provided. The researcher will be asked to revise the protocol by including an adequate literature review and a clear description of the specific aims of the study as well as make significant revisions to the consent form.

Additional January Meeting: Given the number of protocols that will be sent back to the researchers for revision, the board voted to hold an additional meeting on January 31 at 9:00 am to review any protocols from this group that are submitted two weeks prior (January 17).

Addition of additional consent form examples to website: Given that the example consent forms that will be added to the IRB webpage when it is revised in the future do not contain a representative example for a phenomenological study, the board will seek to add one. Ann Wilson and Roger Allen will bring examples for review at the February meeting.

Respectfully submitted,

Ann Wilson