Minutes

I. Welcome Comments (no minutes to be reviewed at this meeting)

II. Initial review of new full board project IRB#14-021 (557901-1) “The Effect of Moderate-And Vigorous-Intensity Physical Activity on Food Intake Regulatory System and Glucose Metabolism in Young Normal Weight and Obese Male Subjects” submitted by Dr. Alireza Jahan-Mihan.
   - IRB members were given prior shared access to the project documents within IRBNet (IRBNet ID: 557901-1).
   - Background
     • Project determined to be full board because of the use of vigorous exercise which is not allowable under exempt or expedited review. The PI also described death as a potential risk to participation.
     • Participants will include UNF students who have been screened and determined to be at low risk of health complications
   - The PI Dr. Jahan-Mihan attended a portion of the meeting along with one of his Co-I’s Dr. Magyari. They provided clarity about some items and were informed that they will be asked to address some review items in the near future.
   - Discussion: Committee Review included, but was not limited to, evaluation of the following issues:
     • Subject Recruitment – additional information needed about recruitment techniques. Several reviewers also felt that the advertisement for the research overemphasized the reward and should be adjusted. Several IRB members also remarked that they thought they saw the recruitment flyer up in some of the colleges. When the PI was asked about this he indicated that he had not begun recruitment and the flyers were for an informal meeting or another research project pertaining to a similar topic.
     • Consent Procedures and Documents – the consent document was determined not to contain all of the regulatory requirements in 45 CFR 46.116. Additionally, it contains outdated and potentially inaccurate information that will need to be adjusted. One IRB member initially had concerns about student researchers conducting consent procedures without supervision. However, the PI informed the IRB that a PI or Co-I would be present during all consent procedures. This assurance was sufficient to alleviate the reviewer’s concerns. The PI will also be asked to confirm that all participants will be given a copy of the consent document to keep for their records (45 CFR 46.117). One reviewer also felt that it was not clear in the
consent that participants would be responsible for conducting seven finger sticks on themselves. Seven is a lot and it might affect whether individuals choose to participate in the research if they were aware of the requirements. Some additional clarity with regard to procedures will be needed in the consent document.

- Investigator and personnel training: The protocol includes references to conducting ECGs on participants. However, these procedures are not clearly outlined in the protocol application. Additionally, it is not clear if the study personnel are qualified to conduct such ECG procedures. PI later said that he did not plan on conducting ECG readings. Clarity about this is needed in the protocol documents.

- Equitability of Participant Selection – the PI is planning to limit his study population to males only. Because the federal regulations require the selection of subjects to be equitable (45 CFR 46.111), the PI will be asked to provide a justification for this exclusion criterion. When asked about this at the meeting, the PI indicated that males and females differ with regard to food intake and hormones and the next study will most likely examine effects on women. Additionally, he indicated that it is often difficult to find women who are obese and exercising but not dieting. The IRB agreed that women should be included in the study if possible. If the PI would like to limit the study to males only, a justification for that exclusion criterion will need to be included in Attachment A.

- Privacy of Participants – additional information about the extent of privacy for participants will be requested. If possible, research personnel who are the same sex as participants should be paired for Bod Pod data collection. Additional information about the Bod Pod procedures with respect to privacy will also be requested.

- Screening Procedures – more clarity is needed about how participant risk will be calculated during the screening process. Additional information is also needed about the timing of screening activities compared to informed consent procedures and what will happen to the screening data if an individual doesn’t agree to participate in the research. Finally, there seems to be information on the screening questionnaire that may not apply to the participant population. The PI will be asked to adjust the screening tool to reflect information that will be collected for this study.

- Risk/Benefit Ratio – Because the risks are considered more than minimal and benefits should outweigh risk, more information is needed about societal benefits in order to determine that the benefits outweigh the risk.

- Because breakfast is an important part of the study, the PI will be asked to consider providing breakfast to participants if possible. Breakfast procedures should be included in the calculation of time cost for participants.

- Participant Safety – More information about emergency procedures is needed.

- Inconsistency in Protocol Documents – there is some conflicting information between study documents regarding time duration and other study details. The PI will be asked to adjust the information so it is consistent throughout.

- One reviewer thought that it would be best if the study was conducted in a medical environment where the researcher could access resources that could be lifesaving to participants in case of a serious adverse event. However, because the participant population will be limited to only those who are at minimal risk, the reviewer decided that this was not a requirement.
- The reviewers were not concerned about incomplete disclosure and determined that debriefing would not be required.
- Due to time constraints, the IRB was not able to specifically discuss every item in the pre-review (although most were discussed in detail). The lead reviewer made the final determination about the review items based on the IRB discussion and the pre-review.

- **Vote:**
  - Approve after the identified minor review comments have been addressed (8 of 8 voted in favor of this outcome)
  - Revisions will not have to come back to the full board because the lead reviewer was given authority to review revised documents to ensure revisions addressed. If all revisions sufficiently addressed, the lead reviewer was given the authority approve the revised materials.

**IRB Projects Approved since last convened meeting:**

**Original Approvals**

**Exempt**

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<td>Dinsmore, Daniel</td>
<td>3/26/2014</td>
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<td>14-022 (545623-1)</td>
<td>Doster, Jennifer (FA: Scheirer)</td>
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<td>13-110 (542450-2)</td>
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<td>14-018 (516334-3)</td>
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**Contingent Approvals**

NONE

**Amendment Approvals**

**Exempt**

NONE

**Expedited**

NONE

**Full Board**

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Contingent Amendment Approvals
NONE

Extension Approvals
NONE

Conditional Extension
NONE

Contingent Extension Approvals
NONE

Extension & Amendment Approvals
NONE

Waived

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Class Project Waivers
NONE