

Minutes
Institutional Review Board
January 14, 2013

Present: Lisa Ferrari, Mita Mahato, Garrett Milam, Andrew Rife (Community Rep.), Kirsten Wilbur

Meeting was called to order at 10:05am by Garrett Milam

Review of Protocol: #1213-007

Concerns were raised in the following areas:

- *Cost to participate*
 - Milam had concerns about the cost to the patient to participate in the study. What are the costs based on and would insurance cover the cost?
- *Clarification regarding the groups*
 - Mahato wanted clarification about group attendance after week 52. Is there a charge for group attendance?
 - Milam wanted the inclusion criteria to be clear regarding who needs approval from their primary care physician. The board was uncomfortable with participants self-reporting. The board recommends that each participant obtain a letter of support/consent from their primary care physician.
- *Length of the study*
 - Ferrari pointed out that the board cannot approve a multi-year study. The researchers will have to submit yearly for renewal.
- *Procedural*
 - Mahato wondered if there needs to be a procedure for what to do if something comes up medically with a participant that affects their participation in the study. Recommend formally including a statement as to if something is discovered in the preliminary testing what the procedure would be.
- *Consent form*
 - The consent form needs clarification regarding attendance and cost to the participant in terms of time commitments and monetary expenses.
 - Also recommend to clarify about what happens to the data collected from the questionnaires.
 - Recommend including the wording “care at this institution.”
 - Recommend including the boiler plate language.
 - Recommend the consent form clarify that the participants will not be taken on as patients by Dr. Rife. The study is separate from any treatment provided by their primary care physician.

Motion on Protocol: A motion was made that Protocol: **Group-based dietary and lifestyle intervention for community –dwelling adults** be approved with minor revisions. Recommend including letter from the participant’s primary care physician, clarify the time and cost commitments and that the consent letter use lay terminology.

The meeting was adjourned at 11am.

Respectfully submitted,

Kirsten Wilbur

