

Call to order - 12:03 pm / Adjourned 1:45 pm

Present: Maine, Tufts, Duke, South Carolina, Florida, Atlanta, New York, Northwestern, Tennessee, Tulane, Pennington, Health Partners, Baylor, Nebraska, UT Southwestern, LA, Stanford, Ware, Central Lab, NIDDK

1. Recruitment Review

14 baselines this week, 33 eligible for baseline

All sites are screening besides Phoenix (IRB approval in early February).

Study PI emphasized efforts at recruitment. Now that the holidays are over, sites need to intensify recruitment efforts. Study wide, we need to randomized 100 participants/month.

Generally, sites (e.g., Health Partners) have been successful in convincing potential participants to limit their vitamin D intake to 1,000 IU but are worried that 3 months is a long time to wait before bringing the individual back for a screening visit (loss of interest).

ACTION: A proposal was made to have volunteers taking 1000 to 2000 units/day wait only 8 week. This change will be proposed to the DSMB at end of January.

2. Review and Approval of Revised Protocol

-Site-specific glycemia algorithms and an increased BMI range (24-42) were approved by the DSMB

-There was consensus that in order to offer physicians flexibility, the physical exam may take place directly before randomization instead of at baseline. This will be incorporated in the revised protocol.

-Emesis is not listed as a potential side effect of the OGTT and it will be added in the protocol and template.

ACTION: SC members to email CC by the next day if they don't approve the new protocol.

ACTION: If there are no emails to the contrary, the revised protocol (version 1.5) will be considered approved and will be distributed to the sites for IRB approval.

3. Study Design Paper Proposal

-Proposals for manuscripts need to be approved by the SC so investigators are aware of what others are doing and to allow investigators with expertise in a certain proposal the opportunity to become a co-author.

-Reviewed steps to submission: A ready-for-submission manuscript is sent to PPS, if approved the manuscript is sent to SC to read and approve before the paper can be submitted.

ACTION: SC members will review Dr. Pittas's study design paper proposal and email any votes of rejection to the CC, no response will be counted as approval.