



Ancillary Studies Evaluation Subcommittee (ASES)
Meeting Minutes

Meeting: November 11, 2013

Present: Chhavi Chadha, Bess Dawson-Hughes, Michael Lewis, Taso Pittas, Richard Pratley, Patricia Sheehan

Absent: Cyrus Desouza, Philip Raskin, Cliff Rosen (sent comments ahead of time), Myrlene Staten (sent comments ahead of time), Anne Peters (excused), David Robbins (excused)

1. Review of Letter of Intent - Drs. Robbins and Weinstock (AS13-07)

The primary reviewer presented the LOI and summarized its strengths and weaknesses. The secondary reviewer provided additional comments. Committee members were then invited to discuss the LOI. The committee members felt the proposed ancillary study was worthwhile and would like to invite Drs. Robbins and Weinstock to submit a full application. For review of the full application, a statistician will be invited as an ad hoc committee member to assist in the review. In the full application, the committee would like to see the following areas addressed:

- scenarios of sample size calculations (i.e. what kinds of changes could be detected with varying sample sizes)
- clarification of processing procedures and burden on coordinators (will coordinators need to mix stool before aliquoting?)
- based on the proposed design, the goal is to collect as many samples as possible, but only a subset (based on sample size calculations) will be run. Once the sample size is achieved, will stool collections stop? What will be done with the remaining samples?

2. Ancillary Study Policy revisions

The policy was revised to add a statement regarding the length of the LOI and application approval period. There were not enough committee members present to approve the policy, but modifications based on discussions will be made, and a revised version will be circulated to committee members for review.

Next Meeting: Monday, December 9, 2013 at 3:00 pm EST