



Ancillary Studies Evaluation Subcommittee (ASES)
Meeting Minutes

Meeting: January 13, 2014

Present: Chhavi Chadha, Cyrus Desouza, Michael Lewis, Taso Pittas, David Robbins, Cliff Rosen, Patricia Sheehan, Myrlene Staten

Absent: Bess Dawson-Hughes (excused), Anne Peters, Rich Pratley, Philip Raskin

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

Dr. Robbins left the call for the review of this application (in conflict as the PI)

This application was submitted in follow-up to the approved LOI to look at the human gut microbiome in its relation to vitamin D and diabetes.

The subcommittee expressed the following concerns:

1. more detail needs to be provided on the feasibility of sample storage and transport to minimize the burden on participants
2. suggest revising the aims as follows:
 - aim 1: investigate the gut microbiome in those who progress to diabetes as compared to those who do not (observational)
 - aim 2: investigate the effect of vitamin D on change in gut microbiome (intervention of vitamin D)
 - aim 3: if vitamin D shows a protective effect on diabetes, investigate the modifying effect of changing gut microbiome by vitamin D on progression to diabetes
3. revision of the aims may require a revised sample size calculation

All subcommittee members voted in favor of approving the application with the suggested changes and pending statistical review.

Statistical review (completed after meeting on 1/15/2014): statistical methods are appropriate with no further comment.

2. Review of LOI - Dr. McGrath (AS13-07)

Dr. Pittas left the call for the review of this LOI (in conflict as a co-investigator)

This LOI proposes to investigate the effect of vitamin D on adverse neuropsychiatric outcomes.

The subcommittee expressed the following concerns:

1. the instrument used may not be appropriate for this population (not validated in US populations, more frequently used for epidemiological studies). Consider using a different instrument that is validated in the US in a diabetes population.
2. revise specific aims to narrow focus to a few outcomes (such as depression and dementia)

All subcommittee members felt the proposal was worthwhile, but needed additional work for reconsideration.

3. Review of application status report - Dr. Ceglia (As12-01)



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The investigator has no plans to re-submit for funding. She plans to submit an application to ASES in the future to use stored samples.

Next Meeting: Monday, February 10, 2014 at 3:00 pm EST