



Ancillary Studies Evaluation Subcommittee (ASES)
Meeting Minutes

Meeting: January 12, 2015

Present:, Bess Dawson-Hughes, Cyrus Desouza, Michael Lewis, Taso Pittas, Rich Pratley, David Robbins, Cliff Rosen, Patricia Sheehan, Myrlene Staten

Absent: Chhavi Chadha, Sangeeta Kashyap, Philip Raskin

Meeting Minutes

1. Review of Letter of Intent – Dr. Huffman (AS14-07)

This application proposes to investigate the relationship between vitamin D and markers of DNA damage.

Overall, this is a novel idea that answers a valid question that is a unique area of interest. It does not increase the burden on participants, though it does utilize stored samples.

The following concerns were brought up:

- The subcommittee requests further explanation on the selection of whole blood as opposed to plasma as part of your request and if the study would be compromised by using plasma rather than whole blood for the telomere analyses.
- The subcommittee would like assurance that your investigative team will have the needed expertise in genetics to execute this study.
- The subcommittee expressed concern regarding request for the relatively large volume of 1.7 ml of serum, noting that some of the measures are already being done as part of the parent study: A1c, FGP, and 25(OH)D. Clarification requested for volume of serum required.
- The proposal required a D2d co-investigator who might be interested in joining your project as a co-investigator. Dr. Cyrus Desouza expressed interest.
- It is not clear that there would be statistical power to conduct subgroup analyses (e.g., minority subgroups) as proposed.
- The PI indicated an intended application submission date of Feb 5. She was given the option of an expedited review, but decided to instead aim for a July submission.

The application was approved for the PI to go forward with the ASES application, taking the above comments into consideration.

Next Scheduled Meeting: Monday, February 9th, 2015 at 3:00 pm EDT