



Ancillary Studies Evaluation Subcommittee (ASES)
Meeting Minutes

Meeting: September 8, 2014

Present: Chhavi Chadha, Bess Dawson-Hughes, Cyrus Desouza, Michael Lewis, Taso Pittas, Cliff Rosen, Patricia Sheehan, Myrlene Staten

Absent: Sangeeta Kashyap, Rich Pratley (sent comments), Philip Raskin, David Robbins

Meeting Minutes

1. Review of Application – Dr. Gunstad (AS14-05)

This application proposes to assess the impact of prediabetes on neurological disorders and the effect of vitamin D in attenuating cognitive decline.

The subcommittee was appreciative that Dr. Gunstad took all the recommendations of the subcommittee regarding the LOI and modified his application as appropriate.

The following concerns were brought up:

- Regarding feasibility, this proposed study couldn't begin before mid-summer of 2015. By mid-fall of 2015, recruitment should be drawing to a close. The investigator's ability to enroll 400 D2d participants as they enter D2d will depend upon all sites agreeing to participate. At this point, their willingness to do so is unknown. It is important to quickly contact all of the sites to assess their willingness to participate. The contact list of site PIs is attached separately.
- Regarding the normal volunteers, it is important to ensure that:
 - a) they are matched on demographics *as well as* clinical characteristics associated with glucose intolerance
 - b) don't have glucose intolerance at entry
 - c) whether they develop glucose intolerance during the 3-yr follow-up is documented
- Regarding the identification of normal volunteers, will they undergo an OGTT to ensure they do not have pre-diabetes? And to ensure they have not progressed to diabetes?
- Regarding the recruitment normal volunteers, the subcommittee suggests that you consider using D2d study screen failures (due to low A1c, etc.) to control for regional variation and seasonality. It would be worth seeing if sites would be willing to do this when you are in contact with them about participating. If sites are not willing to take on this burden, you could then consider drawing healthy controls from the Cleveland Clinic population.
- The subcommittee recommends that participants be compensated \$20 per survey for their participation.

The application was approved for the PI to go forward with a grant application, taking the above comments into consideration, pending Steering Committee review.

Next Scheduled Meeting: Monday, November 10th, 2014 at 3:00 pm EDT