Minutes from 4/10/14 Meeting

Call to Order - 12:03pm / Meeting Adjourned - 12:57pm

1. ASES
Ancillary Studies Evaluation Subcommittee is looking to add two research coordinators, preferably from sites not yet represented on the subcommittee, to join as voting members. Investigators were asked to nominate Research Coordinators

2. Investigator's Meeting
Proposed dates: Monday, October 27th or Tuesday, October 28th
*Arrive the night before
Action: [CC] will send out a poll to determine which day works better for most people.

[Dr. Poretsky - Beth Israel] suggested an informal gathering at the 7th Annual Friedman Fellows Symposium on June 14th at the ADA for those who can attend. *Taso will be presenting.
[Dr. Phillips - Atlanta] suggested another informal meeting like last year (dinner).
Action: CC will discuss options

3. D2d Design Paper
CC plans to submit Design Paper to Diabetes Care this week.
Action: [Patty] send manuscript to all authors once it is submitted to Diabetes Care.

4. Updates
180 Randomized; 13 pending
24 Randomized in April (so far)

NIDDK Phoenix - site is on hold

5. Adding Sites
CC is seeking out new sites to start in the new grant year (June 1st).
Some clinics have contacted the CC others were recommended by NIDDK and current site PIs.
We are looking for new sites that have access to a primary care population and EMR.
[Dr. Phillips] D2d should look into VA sites that are in GRADE.
[Dr. Pratley - Florida] will try reaching out to his VA to find a Co-I.
[Dr. Desouza - Nebraska] is it economical to add new sites rather than expand current sites?
Action [CC] will follow up with above options/ideas

6. Central Lab
Some sites such as Northwestern and Nebraska have very narrow windows of screening results that will qualify participants due to A1c and FPG moving in the opposite direction.
[Dr. Neff - Northwestern] three recent baselines have failed because FPG was off by a few points.
[Dr. Chatterjee] participants who only missed FPG by a few points and are eligible for repeat baselines, decline a repeat visit because they do not want to repeat the whole test. Can FPG be re-tested rather than the whole 2hr OGTT?
[Dr. Lewis - Central Lab- overall differences between local and central lab are not large. Site specific algorithms have increased the yield of eligible participants.

Action: [EC] will further discuss issue and take into consideration statistical issues with repeating just a single inclusion criterion.
Notes: Repeat baselines are not economical for sites or central lab and, so far, have not been very effective.

Per participant invoices start at randomization.

7. SOS
D2d has had one SAE so far - muscle strain (spent the night at the hospital), participant withdrew consent and was not randomized. [Unexpected and unrelated]
[Dr. Phillips] defines expectedness as relating to the treatment and in clinical practice.
[Dr. Desouza] even if it is not listed, it is not necessarily unexpected. Nebraska IRB wants unexpected to disease/condition.
[Dr. Neff] at her recent training, expected was defined as a result of the drug and not any underlying conditions.
[Patty] Typically IRBs require local SAEs be reported and all study wide UAPs - unexpected and related. A SAE that is deemed unexpected and unrelated does not require study wide expedited reporting. Sites are currently classifying adverse events as expected or unexpected per the DSMP and MOP.

Note: Site specific memos will be sent out this afternoon. Please review these memos with your staff and return completed form to the CC.