

EC Minutes from 1.6.15

Meeting called to order-4:05pm/ Adjourned-5:08pm

Present: Saul Malozowski, Anastassios Pittas, David Robbins, Patricia Sheehan, Myrlene Staten, James Ware.

Reports

- 65 randomized for the month of December.
- 6 Randomized for month of January so far.

Proposal to deal with Glycemia discrepancy

- *Challenge:* BAS-RAN is not good (60%), and has not changed at all in the last 6 months vs. first 6 months of 2014. This is a waste of resources at the sites and central lab, need radical change.
- *Proposal:* At SCR visit, sites send A1c and FPG to the central lab to assess eligibility.
-If participant qualifies;
 - Enter SCR A1c (which is done at central lab) as the BAS A1c value.
 - At BAS visit, do OGTT to get FPG, 30-min values and 2hPG. Do not repeat A1c at BAS visit.
- Pilot: To assess eligibility, 2 sites (Tufts, Nebraska) are sending A1c and FPG done at the SCR visit to the central lab.
- **Action:** CC will collect more data and report back about pilot at the next EC meeting.

Protocol Changes- remove lower BMI limit

- *Proposal:* Lower the BMI exclusion criterion to 18.5, either for all participants or at least for Asians because they develop diabetes at lower BMI.
- **Action:** CC will send out survey and review responses.

Site Expansion

- Denver: IRB submitted
- Kansas: Expanding to Truman participants