EC Minutes from 10/16/14

Present: Bess Dawson-Hughes, Anastassios Pittas, Patricia Sheehan, Myrlene Staten, Jim Ware

Central Lab
Central Lab will be open both Mondays during their holiday break.
Sites should avoid doing visits on Tuesdays because they will have to wait until the following Monday to ship. These samples will arrive outside the shipping window if they do not arrive overnight.

Action: [CC/site call] need to make it clear to sites that they should not schedule visits on Tuesday during CC/site calls.

Pennington PI Change
Dr. George Bray is retiring and proposed Dr. Daniel Hsia as his replacement. Change needs to be approved by NIDDK and EC.

EC members present approved. Need to run by Saul.

Planning of Publications

Last meeting PPS reviewed subcommittee's policy and tried to improve by adding sections on funding and analytical support. EC and PPS will brainstorm ideas for potential topics/ manuscripts. Need to decide who will need to apply formally for these topics/manuscripts. Publications will be prioritized based on target date. Lead author and writing group will not be final until PPS and EC approves.

Hemoglobinopathy
No formal updates on hemoglobin variance issue. NIDDK had a discussion with the DSMB. NIDDK decided that knowledge of variance is important to subjects because it could affect their A1c values at other laboratories providing clinical care. NIDDK proposed informing all subjects with a hemoglobin variance, provide them with a one page info sheet and refer them to their PCP. Judy talked to the chair of the DSMB who thought that was acceptable.

Action: [CC] develop a one page information handout for sites to provide to participants with a hemoglobin variance. Sites will have to run by IRB.
*NIDDK website was designed for patients and has really good language.

Reports
28 randomized as of 10/16
87 screenings
63 baselines

New Sites:
Baltimore - first screening on Monday
Kaiser - first screening Monday

Cleveland Clinic - delay with IT searching EMR. EMR list did not have A1c but has been requested. Starting with employee database.

Tennessee - Taso is somewhat optimistic. They said soon 7000 letters will go out to people with prediabetes or who meet the criteria which is better than using the RMV. Letters are coming from the healthcare group, no intention to follow-up.

Action: [CC/Tennessee site call] Myrlene suggest having their IT include PCPs in the EMR report so Karen Johnson will know where most potential participants are coming from and can approach those PCPs to follow-up.

Investigator's Meeting
Need to discuss how to maintain recruitment.
Presentation boards

- Scavenger hunt with questionnaire
- What can you take away and carry-out when you get back?

Action: [CC] will provide a flushed out agenda draft for next week.

RRS – Recruiting Hispanics
Myrlene - not confident in Hispanic recruitment. Sites are not willing to try.

Taso - site are struggling in general so they're not putting extra effort into recruiting Hispanics. Make it more direct. How do you plan to try to recruit Hispanics?

Bess - wait until the Investigator's meeting. Tracking # of Hispanics enrolled by site may have a motivating effect.

Myrlene - may help with recruitment seeing sites are not actually trying now. Discussion at Investigator's meeting. Reach out to doctors who have bilingual speaking staff. Doctors may have medical records.

Need to view this population as an untapped resource.

Katherine Tucker from Northeastern University is heavily involved in Puerto Rican recruitment. Perhaps, Katherine or someone from her team is willing to present either at the Investigator's meeting or on an RRS call.