Minutes from 4/17/14 Meetings

Present: Bess Dawson-Hughes, Saul Malozowski, Anastassios Pittas, Clifford Rosen, Patricia Sheehan, Myrlene Staten - Guest: Michael Lewis

Call to order - 12:03pm / Adjourned - 1:00pm

1. Screening to Baseline Variability
Some sites (e.g. Northwestern) have extremely tight windows of for eligibility because the FPG and A1c at SCR and BAS move in opposite directions. During the SC meeting it was proposed that fasting glucose could be repeated for participants that only missed eligibility criteria by a few points but otherwise qualified.
*[Ware] previously expressed concerns with repeating single values
[Patty] implement such a change in EDC would be difficult, but not impossible.
[Lewis] would require significant changes in Central Lab procedures. Dr. Lewis highlighted that internal quality control at the central lab is excellent.
Additional information is needed on this topic.
What types of tubes are sites using at screening visits?
What assay type are sites using? Glucose oxidase vs. Hexokinase - Central Lab uses hexokinase assay.

Conclusion: Do not allow the repeat of just fasting glucose at this point.

Actions: develop document to share with sites on this topic
[Patty] ask Dr. Lewis to write up assay type multiple choice questions that can be sent to sites. Express to sites that internal quality control at the central lab is excellent (not the problem).
[Taso] write up on how Tufts is handling this challenge.

2. Updates
191 - randomized; 35 - April; 11 - pending; 58 - potential baselines
Same sites are doing poorly. Tulane understands its situation is serious.

Action:
[Erica] update EMR section of RRC to include a sample "opt out" letter.

3. Investigator's Meeting
GRADE is holding October 27th-30th for meeting.
*Follow-up: Doodle poll was sent out to PIs to determine a new date to hold the Investigator's meeting. Best day appears to be November 17, 2014

[Myrlene] can hold meeting outside of Bethesda if savings is substantial (20%).

4. New Sites
Baltimore - submitted proposal, letter of support and budget. Vanita will be the PI and will have a Co-I in Baltimore (Stuart Levine). Will be looking to hire an RC and RA in Baltimore who will be trained by Hyattsville staff and follow the same procedures as the Hyattsville site. Site will have access to EMR and can generate letters from PCP. Believe they can enroll 100 participants.
*[Saul] add satellite sites as a successful method in RRC
[Patty/Myrlene] push back on budget

[Myrlene] can Vanita physically be there as necessary, especially during start-up?

Action:
[Patty] work out budget and discuss Vanita's availability --> Approved

Washington State University - submitted application, letter of support and budget. Believe they can enroll 150 participants.
*[Taso] more realistically can enroll 75. Have done a lot of studies but have not enrolled large numbers.
[Myrlene] would like to see a true EMR search, similar to Baltimore.
Action:
[Patty] ask site to perform a true EMR search using Baltimore criteria.

Cleveland Clinic - only have good data for the Stampede trial (bariatric surgery); only enrolled 70% of their target. Site has EMR experience and are allowed to send letters through PCP but want to call patients instead.
*[Taso] likes that the PI is not experienced, believes they will perform above average!
[Myrlene] would like them to query their EMR using Baltimore's criteria.

Kaiser (Portland) - Patty talked to site and they are excited - expect to have their application next week.

Action:
[Patty] write follow-up email to all sites so all question/concerns are addressed for next week's meeting.