

Minutes from 6.26.2014

Call to order - 3:34pm / Adjourned -

Present: Bess Dawson-Hughes, Saul Malozowski, Anastassios Pittas, David Robbins, Patricia Sheehan, Myrlene Staten

1. Newsletter:

Sent out as an attachment. Will be provided to sites to send or give to randomized participants as well as screeners. 3 issues/year

Tufts IRB - minor edit

EC - approved

Newsletter will be sent to sites to run by their IRB as take it or leave it. No changes will be made.

Content - want to keep fresh, if you come across newsletter worthy items please send to CC.

Next Issue Ideas:

Holiday theme (how to manage the holidays)

Staying active as weather gets colder

Have next note from leadership (on the front page) come from someone from NIDDK (Judy?)

2. Reports

Were sent out on Wednesday

56 this month with 11 ready to randomize and 11 more may be eligible - pending lab results

Tulane:

1 person with study drug has been unresponsive and not willing to come back for an end of study visit

1 person who had a baseline visit is willing to be seen at Pennington

Take Tulane off graphs and add as a footnote (officially not closed) - end of next week.

Florida:

Bringing people in but nothing is happening (14 screenings), 3 ready for baseline

if they have a bad ratio they may be bringing people in who not at high risk. If they are already using the diabetes risk score, perhaps they need to raise the threshold.

Nebraska:

Had a horrible month as far as ratios

3. DSMB

Letter of DSMB

Change graphs to reflect recruitment start date of December.

We will have 2 versions (DSMB and sites version). Plan is to use both versions for the next couple of months and then switch to just DSMB version (state date of December).

Have to provide DSMB with numbers every month - use updated recruitment date version.

Edits to letter:

We were over optimistic.

Robbins - Surprised and disappointed, rather make it seem like the study is better because of them ... remove surprised and disappointed.

Myrlene - rather than surprised and disappointed show we don't think we're doing that bad.

Saul - vent displeasure, strength of scientific rationale.

Decision - delete sentence

Myrlene/Cliff - remove paragraph on relying on OGGT

Saul - all vices are difficult to kill, in earnest this is unfeasible, uncharted territory, first study using this approach.

Taso - we're making the point that this is a new approach, so relying on OGGT goes against this method being phased out. This was not budgeted for, would need more time, money and resources.

Myrlene - some believe OGGT is the way to go. Keep it in the back pocket until we start getting conversion rates. We don't know how close we are.

Decision - sentence removed, keep in the back of our minds, may need it later.

Modified contrast with DPP to avoid diminishing DPP value.

4. Payments for Sites / Motivate Sites

Taso will be sending out notice to the sites to try to explain differences between year 1 and 2.

Despite efforts to explain budget, people still don't understand. You get 40% of your year 2 budget regardless.

Ways to motivate sites and keep them excited?

True Blue - encourage sites to nominate someone from their team to be in next newsletters.

Additional rewards - means more to sites, recognition

Based on NIH rules, don't know how to reward people.

Do not want it to sound like honorarium.

Recognition Award - retention, merge site staff retention into it.

Participants retained because of RC.

Action: [Taso] - ask administrator if there is a way to phrase this/how to lump legitimately.

Robbins - photograph and biography (yes planning to do)

Give recognition at investigators meeting.

Plan is to mention in next newsletter and have it start in July.