

EC Minutes from 10.23.14

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

RRS Co-Chair, Dr. Bray is retiring.

EC nominates Dr. Brodsky from Maine and Miranda Ouellette from Kansas as co-Vice Chairs.

Action: [Patty] ask Vanita what she thinks about making Dr. Brodsky and Miranda co-Vice Chairs.

Reports

44 – randomized this month as of 10/23

608 – total randomizations

23 awaiting randomization

40+ awaiting baseline results

Cleveland - 1 screening, 3 more scheduled

Baltimore - Monday screening postponed

Kaiser - 2 scheduled, 11 thru first phase of screening, does a combined screening/baseline visit

There is activity for almost every site which is encouraging.

UTSW - screened 4, 3 in for baseline, received 3+ online questionnaire submissions

Patty, Paul and Ellen have been explaining to site that if they have a ratio of 4:1 and a goal of 6 randomizations/month, they need to screen 24 people/month.

D2d needs to screen more participants.

Missed visits:

Eventually plan to split table (number missed vs. number that came back)

Myrlene – would like to see who has missed 2+, 3+ , etc. visits

Only one site has missed 2 visits so far.

Action: [CC] [enhance](#) table

Hemoglobinopathy

Saul - DSMB crafting email when they return

Agreed to telling everyone with a hemoglobin variance and providing them a handout.

Current handout incorporates all EC comments.

False hemoglobin → inaccurate/incorrect/not reliable/unreliable

Correct or true reading → accurate

Machine → method

David Robbins – the central lab is not running standards of hemoglobin S, C, E etc. Strengthen the language that this is preliminary; this should be confirmed by a repeat test at your primary care doctor.

Action: [EC] send additional comments to Patty.

[CC] separate traits onto 3 separate sheets.

Investigator's Meeting Agenda

Working draft looks good.

Action: [NIDDK] invite Judy.