Minutes from 4/24/14 Meetings

Present: Saul Malozowski, Anastassios Pittas, Patricia Sheehan, Myrlene Staten

Call to order - 12:04pm / Adjourned - 1:10pm

1. Potential Sites
Washington State and Cleveland Clinic are working on getting EMR search results following MedStar's search criteria as requested.
MedStar (Baltimore) - approved
Action: Ask Bess and Cliff to complete evaluation forms for Washington State and Cleveland Clinic.

Kaiser
Investigator Experience - not a lot with intervention studies but very motivated (career wise), has experienced research coordinators and has the support of her colleagues.
Site projected to enroll 160 participants; site has access to EMR and a good plan of how they will go about using it.
Cost/participant: 160 participants = $8,000/participant (lower range of current sites)

Patty - feels better about Kaiser than Washington State or Cleveland Clinic
Myrlene - work through budget but approve

Cleveland Clinic
Investigator Experience - young, motivated and has slightly more experience than LeBlanc through studies in bariatric surgery (Stampede) and was a Co-I in Accord. Enrollment rate around 70%.
Access to Epic EMR and employee health database (5,000) which they claim to have used in previous studies (waiting on EMR search results).
Taso - main issue is whether they can really use EMR and employee database.
Action: Ask site to explain how they plan to reach out to employees and those qualified from EMR search.
Cost/participant: $11,900 (average range of current sites)

Washington State
Investigator Experience - done lots of different studies and has experience RCs
Plan to send letters through Rockwood Clinic, community outreach and EMR.
Enrollment rate between 57-87% with very small enrollment sizes.
Myrlene - EMR number look estimated (waiting on EMR search results)
Action: Ask site to explain how they plan to use EMR.

2. Recruitment
Over 200 randomized; 49 - April; 22 waiting to be randomized
Shining sites in April: BI, Nebraska, Stanford, Duke, Maine
*Tennessee - screened 8
HealthPartners - picking up
Poorly performing sites are still the same.

How to motivate sites?
CC received some negative feedback to site memos.
Dr. Robbins described the memo as harsh and un-motivating.

3. Reporting Averse Events - Expected vs. Unexpected
Patty - clearly defined in DSMP (pg 3 & 4), if it not specifically listed in DSMP it is considered to be unexpected. Unexpected should not require expedited reporting unless it is also possibly, probably or definitely related to the intervention or study (a UAP).
Myrlene - need to cover this topic again with SOS and SC.