

PRC Steering Committee Administrative Webinar Meeting Minutes

Wednesday, September 7, 2016

1:00 PM- 4:30 PM

Location: Conference Call/Webex

Present

Columbia: Ron Wapner, Michelle DiVito, Sabine Bousleiman, Mary Talucci, Caroline Torres, Cande Ananth, Kirsten Cleary, Stephanie Lynch

Christiana: Tony Sciscione, Carrie Kitto, Amy Staples, Kelly Ruhstaller

Drexel: Lauren Plante, Cheryl Tocci

NYP-Queens: Dan Skupski, Madhavi Malladi

Rutgers: Todd Rosen, Shama Khan, Christina Duzyj Buniak

Saint Peter's: Angela Ranzini, Tracy Vitale

Virtua:

Winthrop: Wendy Kinzler, Deborah Whitfield

Not present: Cynthia Gyamfi, Shailen Shah, Anthony Vintzileos, Damien Croft, Ron Librizzi, Matt Hoffman, Ed Guzman, Phyllis August

I. Administrative

Agenda Topic	Discussion- Actions- Next Steps
CHAP SC Call	<ol style="list-style-type: none"> 1. Alan Tita led the CHAP Steering Committee call. <ul style="list-style-type: none"> -Reviewed current enrollment numbers – specifically Columbia, Penn and Drexel had record enrollment numbers for the month. -Discussed NHLBI request for a Corrective Action Plan – UAB has received remediation plans and will submit their plan to NHLBI. -CHAP sample size – decreasing the sample size is in discussion. No final approval as of yet.
CHAP Update Stephanie and Kirsten	<ol style="list-style-type: none"> 1. PRC enrollment update <ul style="list-style-type: none"> -4 enrolled in the past week: 2 Columbia, 1 Drexel, 1 Winthrop -91 enrolled total for the PRC 2. Screening numbers reflect increased activity at all the sites. <ul style="list-style-type: none"> -all sites have screened patients in the past few weeks, multiple new screenings and pending screenings. -the screening table presented shows the correlation between increased screening numbers which equal increased enrollment. 3. Overall 335 enrolled into CHAP. 4. PRC enrolled 15 in August: 7 CUMC, 1, CCHS, 5 Drexel and 2 Rutgers. 5. Reminder of the CHAP Virtual Grand Rounds on 9/14 at 12:30 PM. <p>ACTION: All sites increase screening and enrollment. Reach out to private physician offices.</p>
CHAP QA Michelle Divito	<ol style="list-style-type: none"> 1. Mary completed her QA of one randomly selected subject per site. <ul style="list-style-type: none"> -Review includes: eligibility criteria, consents and consent documentation, protocol adherence, adherence to study timelines, data forms compared to the data entry system and source document verification to data forms/data entry. 2. CHAP QA revealed multiple errors specifically: <ul style="list-style-type: none"> -Source documentation - medical record discrepancies -Source documentation – other record discrepancies (worksheets) -Keying errors -Missing forms 3. Reviewed each site with the number of errors per category. 4. Sites are provided immediate feedback from Mary. 5. Michelle asked all sites to review their subject forms/data for accuracy. 6. There will be a repeat QA in October on 2 randomly selected subjects. 7. Coordinators will have an educational session on Sept. 23rd during the monthly PRC Coordinator Call. 8. All sites were asked if they have questions. Todd Rosen was interested in talking to Mary about the QA results at Rutgers. <p>ACTION: Sites are to review all their data for accuracy.</p>

	<p>-September PRC Coordinator call will include education session on quality and documentation GCP's.</p> <p>-Mary will complete a QA in October of 2 subjects at each site.</p>
Approval of 5/20/2016 Meeting Minutes	<ol style="list-style-type: none"> 5/20/2016 meeting minutes approved.
PRC Administrative Business Stephanie Lynch	<ol style="list-style-type: none"> Next in-person MFMU/PRC meeting is 11/4 at Columbia. A draft 2017 meeting schedule was presented with discussion. <ul style="list-style-type: none"> -In-person meetings are preferred. -Avoid summer meetings in July/August. -A new draft meeting schedule for 2017 will be circulated. <p>ACTION: Stephanie and Sabine will revise the 2017 meeting schedule and send it out to for feedback.</p>
Central IRB Stephanie Lynch	<ol style="list-style-type: none"> All Reliance Agreements have been fully executed except St. Peter's (one issues to resolve) and CCHS (waiting for final signature). We are requesting every site provide us with their local policies and procedures on research involving human subjects. We will provide training sessions for the Coordinators in the future to work through this process. <p>ACTION: Each site must send their local IRB policies on research involving human subjects to Stephanie.</p>
Illumina Stephanie Lynch	<ol style="list-style-type: none"> Working on Central IRB Submission. Working on the centralized process with the Sponsor for: CDA, CTA and budget. <ul style="list-style-type: none"> -CTA and budget are close to being finalized. -CDA – may need to have individual CDAs. Still a work in progress. Will have the Protocol out to all for review as soon as possible. -Sponsor has asked we delay IRB submission until they send us an amended Protocol which they are currently working on. This study is looking for patients with preeclampsia and fetal growth restriction and matching controls. One time blood collection and data collection. Sample size is up to 240 enrolled. <p>ACTION: Need to resolve CDA and send sites the Protocol.</p>
SMART Stephanie Lynch	<ol style="list-style-type: none"> CUMC and St. Peters are participating. Rutgers and Virtua are having calls with Natera to discuss participating. <ul style="list-style-type: none"> -Rutgers had a call but not interested in participating because of insurance/billing concerns. -Virtua has not had a call with Natera.
GSK Study Michelle Divito	<ol style="list-style-type: none"> CUMC, Rutgers and NYPQ are participating. Working on Central IRB submission. Finalizing the budget and contract. <ul style="list-style-type: none"> -It continues to be challenging working through the budget and contract with PPD (CRO). -Working on finalizing the budget for the on-call payment and what is needed for continued payment of on-call funding, i.e., one patient enrolled, etc. <p>ACTION: Finalize the budget and CTA and share the final budget with sites. Submit for Central IRB approval.</p>
MOMPOD Michelle Divito	<ol style="list-style-type: none"> We resolved the indirects and the first \$25,000 with each site. We had a call with Kim Boggess at UNC and she is looking for additional funding to support the project. NIH decreased funding and the capitation may be decreased to \$400 per patient. CUMC has decided they will not participate if the capitation is cut. <p>ACTION: Sites interested should review the protocol and decide whether or not they can participate if the capitation is decreased. We will ask sites for a final decision once we hear more about the capitation.</p>

II. Committee Updates

Agenda Item	Discussion- Actions- Next Steps
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<p>Strategic Growth Committee Todd Rosen</p>	<ol style="list-style-type: none"> 1. Reviewed the Strategic Growth Committee (SGC) first conference call details: <ul style="list-style-type: none"> -Reviewed finances-committee agreed 9 sites are ideal. -How to find sites - RFA proposed. -Committee members were asked to review the PRC application and provide feedback. 2. Draft RFA and Application reviewed. 3. Suggested key dates were reviewed: <ul style="list-style-type: none"> -Post the application 10/1/16 -Due Date 12/1/16 -Possible presentations at 2/2017 meeting -Membership beginning 7/1/2017 4. Future Committee recommendations will include: reviewing applications, guidelines for approving a site and criteria for final decision. 5. Need SC approval for: 9 sites, RFA, application and revised bylaw wording. 6. Discussion on announcing the RFA and key dates included: <ul style="list-style-type: none"> -Suggestion to change the date getting back to applicants from Jan 1, 2017 to a later date due to the Holiday. -How to send out the RFA -need to determine a list of potential sites and possibly have the PI's reach out to the site with the RFA and application. <p>ACTION: Send the RFA and application to all for feedback and approval. Set up a committee call after the feedback is received.</p>
<p>Data Repository Committee Matt Hoffman/Stephanie Lynch</p>	<ol style="list-style-type: none"> 1. No updates 2. MQIP - No updates
<p>Financial Oversight Committee Michelle DiVito</p>	<ol style="list-style-type: none"> 1. No updates

III. The administrative component of the call was adjourned. Next meeting is on November 4th, 2016 at Columbia University.

PRC Science Meeting Minutes

September 7, 2016

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I. Presentations

Study	Discussion and Comments
Update: “Antioxidants to Prevent Placental Abruption: A RCT in High Risk Women” Cande Ananth	1. Dr. Ananth presented the concept proposal at the July 2016 Steering Committee Meeting of the MFMU, and the concept was voted down (2 in favor and 12 against). The next steps are to assess feasibility to submitting the proposal to the NIH other funding organizations. ACTION: None at this time - Possible R01 in the future
Update: “Risk of preterm delivery after cesarean”- Cande Ananth	1. Dr. Ananth received the data from Dr. Hoffman (Christiana Care), analyzed the data, and the abstract has been submitted to the SMFM for consideration.
Presentation: “Morbidly Adherent Placenta: A Retrospective Cohort Study” Dan Skupski	1. A draft protocol was circulated prior to the call. 2. Dr. Skupski presented a summary of the protocol. -Retrospective cohort. -Sites will need to: -identify patients -gather images and outcome information -need 3 MFM specialists to review images – Dr. Duzyj-Buniak is interested 2. Ananth sent feedback and offered to have a call to discuss the protocol. 3. All sites are interested in participating (last poll after 5/16 meeting). 4. Next steps: refine the protocol, work on IRB submission, and discuss data use agreements. ACTION: Dr.’s Skupski and Ananth will set up a time to discuss the protocol.

II. Scientific call was adjourned. Next meeting November 4th, 2016 at Columbia University.