PRC Steering Committee Administrative Meeting Minutes
Friday, November 4, 2016
1:00 PM- 4:00 PM
Location: Columbia University

Present
Columbia: Ron Wapner, Michelle DiVito, Sabine Bousleiman, Mary Talucci, Caroline Torres, Cande Ananth, Kirsten Cleary, Stephanie Lynch
Christiana: Matt Hoffman, Carrie Kitto, Amy Staples, Ashley Vanneman, Kelly Ruhstaller
Drexel: Lauren Plante-phone, Cheryl Tocci,
NYP-Queens: Dan Skupski-phone, Rosalyn Chan, Susan Ingenito, Jessica Scholl
Rutgers: Todd Rosen, Shama Khan, Christina Duzyj Buniak, Mayra Ithier-Cruz
Saint Peter's: Angela Ranzini, Tracy Vitale
Virtua: Ron Librizzi, Ann Marie Palantik
Winthrop: Wendy Kinzler, Jolene Muscat, Kim Byrnes-phone

Not present: Cynthia Gyamfi, Shailen Shah, Damien Croft, Ed Guzman, Phyllis August, Tony Sciscione

I. Administrative

Agenda Topic	Discussion- Actions- Next Steps
Approval of 9/7/2016 Conference Call Minutes	1. 9/7/2016 conference call minutes approved.
PRC Administrative Business Stephanie and Michelle	1. Review of SC voting reviewed: - If a site investigator is absent from a Steering Committee meeting and/or absent from an Administrative Board vote, he/she may appoint an alternate investigator to attend the meeting and vote in his/her place with the approval of the SC chair. -If replacing an Investigator then the CV must be submitted for approval by the SC chair. 2. Reviewed the 2017 in-person meeting schedule dates and locations. 3. PRC membership fees have been received from the following sites: NYPQ, Rutgers RWJ, Virtua, Winthrop. -all other sites confirmed prior to the meeting that Columbia will receive the payment shortly.
Central IRB Update Stephanie Lynch	1. All Reliance Agreements are fully executed. 2. The CIRB process was reviewed with the Coordinators in the morning meeting. 3. CIRB Study Updates: -Illumina - IRB approved. -Site specific information and consents will be sent to sites in the next week. -GSK - waiting for IRB comments from the initial meeting on 10/26/16.
MOMPOD Update Michelle Divito	1. Reviewed this is the Metformin study – it received a score of 10 and funding was cut. 2. We resolved the indirects and the first $25,000 with each site. 3. Pharmacy costs are an issue. Pharmacy fees were not included for all PRC sites – only 1 site was budgeted. We would have to manage the pharmacy as a single site. Columbia does not have a distribution license but perhaps another site is able to distribute study drug. -Randomization and blinding of study drug are still being worked out at UNC. 4. We are waiting for the final Protocol to see if we can manage randomization and distribution of drug as 1 site for all the PRC sites. 5. Capitation will not be cut due to additional funding and re-budgeting. **ACTION:** Ask your pharmacy if they have a distribution license.

II. Committee Updates

Agenda Item	Discussion- Actions- Next Steps
Strategic Growth Committee Todd Rosen	1. RFA and Application updates reviewed: -Sent to NJ Perinatal Society email distribution list. -Uploaded to the PRC website. -Email/calls to Jefferson, Carnegie Group - Mount Sinai. -Communicated interest to date: Rutgers-New Jersey Medical School and St. Barnabas. -Suggestions: Geisinger, Temple, Hershey Reading and Yale. 2. Applications are due 12/1. 3. We will schedule another committee call early December. 4. Some expressed concern with Yale being too far and outside of suggested PRC geographical location. It was also mentioned this would be far to travel for QA. Decision was made to reach out to Yale to see if they are interested. 5. Future Committee recommendations will include: reviewing applications, guidelines for approving a site and criteria for final decision. **ACTION:** Christina will contact Yale. Todd will look up contacts for Temple and Hershey and reach out to UPENN.
MQIP Update/ Data Repository Committee Update Matt Hoffman	1. Review of MQIP status per site: Columbia – changing vendors –will participate in the future. Drexel – planning on installing Cerner in future and will participate. Rutgers – has matched their system with the MQIP data dictionary. St Peters – not participating at this time. Winthrop – not participating at this time. NYP-Queens – not participating at this time. Virtua - installing Stork 2015 – possibly participation in the future. Christiana – waiting for data to be sent. 2. MQIP-Steve Hasley is still working on the Data Sharing Plan. 3. Christina had a call with GE and MQIP to review Rutgers data dictionary and the feasibility of being a viable site for MQIP. Discussions are ongoing with GE and Rutgers. **ACTION:** Please contact Matt Hoffman or Stephanie Lynch when you are able to participate.
Finance Committee Update Michelle Divito	1. FY16 financials show a $7,249.00 refund. 2. A finance committee call is being scheduled to review and approve the FY16 financials. **ACTION:** Finance Committee call to be scheduled.

III. The administrative component of the call was adjourned. Next meeting is on February 3, 2017 at Drexel University.

PRC Science Meeting Minutes

November 4, 2016
1:00 PM- 4:00 PM

Location: Columbia University

I. Presentations

Study	Discussion and Comments
Update: "The AWARE RCT: Activity in women at Risk for Early Delivery and Neonatal Morbidities" Michelle Divito on behalf of Tony Sciscione	1. Grant scored a 33/20th percentile. (previously was a 34) 2. Summary statement has been reviewed. 3. Ananth reported there is a need to find a strategic way to defend both trials in a single application. 4. Plan is to resubmit. **ACTION:** None at this time. Resubmission planned sometime next year.
Update: " Vaginal Progesterone to decrease recurrent preterm delivery in women on 17-OHPC"- Stephanie Lynch on behalf of Cynthia Gyamfi	1. This grant is a PRC and NPRC submission. 2. No changes to the Protocol. 3. Plan is to revise and submit in 2/2017.
Presentation: "Prospective Collection of Whole Blood Specimens in Pregnant Women" (Illumina, Inc) Stephanie Lynch	1. Illumina asked we consider participating in this new project. (RGH-015 Project Oban) 2. Primary Objective: to collect whole blood specimens and clinical data from pregnant women for research and development for molecular assays. 3. Key points: - Viable pregnancy 8 weeks 0 days -Only exclusion is maternal blood transfusion -Blood draw can be different than the day of consent -Samples to Illumina within 5 days of blood draw (can be kept at site for max of 72 hours) 4. Offering $800 a subject 5. Plan is to submit for FDA approval. 6. PI's discussed there are multiple similar studies and some PRC sites are already participating with other companies. Progenity is another company with a study looking to enroll similar patients and they are presenting later at this meeting. 7. Decision at this time is to defer until reviewing all projects recruiting similar patients. **ACTION:** Inform Illumina that we are deferring at this time and will get back to them later if the PRC is interested in participating.
Presentation: "Does the cerebroplacental ratio predict adverse obstetrical outcomes in low risk pregnancies?" (CPR Study) Mayra Cruz-Ithier	1. Study Protocol was distributed prior to the meeting. 2. Objective is to determine whether the cerebroplacental ratio (CPR) can predict adverse obstetrical outcomes in low risk pregnancies. -assessing placental deficiency. -if abnormal values are seen it may predict bad outcomes. 3. Informed consent will need to be obtained. 4. Sites interested at this time in addition to Rutgers: Winthrop, Virtua, St. Peter's, NYP-Q and Columbia. (CCHS and Drexel are not participating). 5. Next steps: Finalize the Protocol, develop CRF's and ICF. **ACTION:** Central IRB submission. Mayra will work with Ananth on the power analysis. Will need Data Use Agreements.
CHAP Study Update Kirsten Cleary	1. Mild Chronic HTN Pragmatic RCT. 2. Sample size 4700. 3. Reviewed enrollment updates: -latest enrollment curve - 44% of expected.

	-enrollment by Center – PRC 104 enrolled. -quarterly recruitment chart over the past year. -enrollment vs. screening chart – the more you screen the more you enroll. 4. DSMB updates: -Request for sample size reduction under review. -Increased effort needed regardless to meet milestones. -Mean GA at randomization 15 weeks-earlier screening may aid recruitment. -Protocol Deviations. 5. Reviewed the proposal to increase enrollment and UAB response: -Advance approximately 2 months of the screening budget ($140,000) and pay it back gradually over 1 year from earned capitation. -A capitation increase is anticipated: $2,000 per patient ($1800 + $200 incentive for meeting targets). 6. Reviewed monthly enrollment average over the past year compared to each sites delivery volume. 7. Discussion – need to see patients sooner, work on accessing private patients, Todd mentioned working with St. Peter's to enroll patients in a larger private practice (the practice is ok with CHAP but patients cannot enroll in other studies). Ron W. mentioned perhaps they could share an FTE to enroll patients. Winthrop is currently utilizing a volunteer to help find patients at the private practices. Virtua is unable to put research staff in the private offices however the Grand Rounds Webinar was helpful. **ACTION:** All sites need to work on increasing screening and accessing private office patients.
Presentation: "Morbidly Adherent Placenta: A Retrospective Cohort Study" Dan Skupski	1. A revised protocol was circulated prior to the call. -Ananth reviewed and Dr. Skupski agreed to change the criteria – nullips are excluded. -Retrospective cohort. -Sites will need to: -identify patients. -gather images and outcome information. 2. Need 1 additional MFM specialists to review images (currently Dan Skupski and Jessica Scholl at NYP/Q). 3. All sites are interested in participating. 4. Need to figure out how images will be transferred from sites to NYP/Q. A suggestion was to contact GE to see if they can assist and possibly provide some funding for the project. 5. Next steps: refine the protocol and data elements to be collected, work on IRB submission, discuss data use agreements and contact GE. **ACTION**: Dr.'s Skupksi will reach out to GE. Central IRB submission, work on Data Use Agreements.
Presentation: "Whole Blood Specimens Collection from Pregnant Subjects" Rachel Allen, MS, CGC-Progenity	Rutgers brought this study to the meeting to see if other PRC sites are interested. 1. Reviewed the protocol summary: -obtain whole blood specimens from pregnant subjects to be used for development of prenatal assays to assist on the screening for fetal genetic abnormalities, infectious and other diseases, and blood group typing through detection of circulating cell-free DNA extracted from maternal plasma. -viable singleton pregnancy -confirmed CVS or amnio -Offering $2,500 per sample for infectious disease and blood group antigen cohorts. -Offering $5,000 initial visit and $2,500 subsequent visits for T21, T18, T13, sex chromosome abnormality and microdeletions. - If patient is high risk and not confirmed (there is specific criteria for this sample) the offer is $500 payment. -Patient compensation is a $100 gift card per visit. 2. Site Initiation visits will be done remotely. 3. This is not tied to any commercial use. 4. Sites will need to complete a 6 page CRF and submit the clinical report 5. All sites are interested in moving forward. Need CDA's at each site. ****St. Peter's is already participating. Ron asked that all PRC sites bring studies to

	the consortium. **ACTION:** Contact Progentiy and let them know we are interested and start working on CDA's at all the sites.
Update "Antenatal Corticosteroids for Term Scheduled Cesarean: an RCT" Stephanie Lynch on behalf of Cynthia Gyamfi	1. On hold until ALPS follow-up is started.
Illumina Study Status Update Stephanie Lynch	1. CTA is fully executed with Columbia. - Work orders will be sent to the sites from Whitney Meeks –CUMC CTO. -Reviewed the study budget. 2. CIRB – central IRB approval and Columbia approval. 3. Columbia had their SIV on 11/2/16. 4. SIV is approximately 3 hours with 1 hour needed with the PI. 5. Site qualification visits will be needed at Rutgers and NYP/Q. **ACTION:** Process work orders at each site, send Protocol specific information sheet and consent forms to each site for local review and complete regulatory paperwork for the Sponsor.
GSK Study Status Update Stephanie Lynch	1. CUMC, Rutgers and NYPQ are participating. 2. Contract and budget have been negotiated and working on signatures. -Reviewed the budget. 2. Protocol has been submitted to the Central IRB. 3. Collecting regulatory documents from every site. **ACTION:** Process work orders at each site once fully executed at Columbia, send Protocol specific information sheet and consent forms to each site for local review (once CIRB approved) and complete regulatory paperwork for the Sponsor.

II. Scientific call was adjourned. Next meeting February 3rd at Drexel University.