PRC Steering Committee Administrative Meeting Minutes
Friday, May 19, 2017
1:00 PM- 4:00 PM
Location: Virtua Health and Wellness Center

Present
Columbia: Ron Wapner, Michelle DiVito, Sabine Bousleiman, Mary Talucci, Cynthia Gyamfi-Bannerman, Cande Ananth, Kirsten Cleary, Alex Friedman, Stephanie Lynch
Christiana: Matt Hoffman, Tony Sciscione, Carrie Kitto, Kelly Ruhstaller
Drexel: Lauren Plante, Cheryl Tocci, Brandy Leopanto-phone, Marge Sherwood-phone
NYP-Queens: Dan Skupski, Rosalyn Chan, Susan Ingenito, Jessica Scholl, Ajini Cherian
Rutgers: Todd Rosen, Shama Khan, Christina Duzyj Buniak, Mayra Cruz-Ithier
Saint Peter's: Kristy Palomares, Tracy Vitale, Sol Otarola
Virtua: Ron Librizzi, Jillian Stanley, Jenny Schott
Winthrop: Wendy Kinzler, Jolene Muscat, Kim Byrnes-phone
Temple: Laura Goetzl
Guest: Jennifer Jury McIntosh, DO, MS- Medical College of Wisconsin

Not present: Shailen Shah, Damien Croft, Ed Guzman, Phyllis August

I. Administrative

Agenda Topic	Discussion- Actions- Next Steps
Approval of 2/3/2017 Conference Call Minutes	1. 2/3/2017 conference call minutes approved.
Finance Committee Update Stephanie Lynch	1. FY16 refunds have been sent to every site. **ACTION:** Let us know if you have not received your refund.
Strategic Growth Committee Todd Rosen	1. Rutgers-New Jersey Medical School had applied to be part of the PRC. Todd Rosen is interested in having them added as a PRC site and fall under the same administrative oversight of Rutgers-RWJMS. He is going to discuss the implications internally at Rutgers to see if it is possible to have them as a site with the Rutgers-RWJMS site. **ACTION:** Todd Rosen is going to look into the implications of having Rutgers-New Jersey Medical School as a site. If feasible, he will present a proposal to the Strategic Growth Committee.
Data Repository Committee Update Matt Hoffman	1. We have had several calls to determine a pilot study with data from Columbia, Christiana and Rutgers. One study was suggested but determined to not fit the criteria needed for pilot data. **ACTION:** Schedule a call to discuss a potential pilot study for the data repository.
Central IRB Working Group Update Stephanie Lynch/Michelle Divito	1. Reviewed working group discussion regarding the local context review for each protocol (review of local laws/policies). This has been an issue at the local IRB offices which has caused significant delays and duplication of effort at some sites. 2. Two recommendations from the working group: -Find out the policy at every site for using Commercial IRB's and which commercial IRB's each site works with currently. -Meet with the Columbia CIRB to suggest modifications to the current process in order to decrease the local context review requirements at the sites. 3. Commercial IRB status at sites: CUMC and CCHS do not work with commercial IRB's at this time. All other PRC sites work with commercial IRB's (mostly for Industry studies). 4. Fees for local context review: some sites are requiring it and some not. **ACTION:** Set up a meeting with the Columbia IRB office to discuss the local context review and the possible use of commercial IRB's for PRC projects in the future.

II. Study Updates

Agenda Item	Discussion- Actions- Next Steps
Illumina Update Stephanie Lynch	1. Presented current enrollment numbers: CUMC: 5 CCHS: 2 Rutgers: 1 St. Peter's: 2 Winthrop: 1 NYP/Q: 2 Virtua: 0 2. Screening was discussed, specifically the enrollment of 'controls'. The Sponsor is asking to enroll 'controls' close to the 'cases'. Many sites reported it is difficult to screen for controls because they are outpatient and staff are looking at inpatients for cases. -Screening questions from the sites regarding eligible patients: "How long do we have to enroll a patient once they become eligible?" and "Can we enroll patients on Fri/Sat/Sun and hold the specimen until Monday to ship?" 3. "Low blood volume' issue with specimens discussed. When using a butterfly collection set you have to draw a discard tube first or use a vacutainer to draw the blood instead of a butterfly. 4. Invoicing: please send invoices. **ACTION:** Stephanie will follow-up with the Sponsor for the answers to the questions raised.
GSK Update Stephanie Lynch	1. The study has been terminated due to feasibility. 2. We are exploring what payments sites are entitled based on start-up work. **ACTION:** Stephanie will follow-up with sites regarding invoicing.
MOMPOD Update Michelle Divito	1. UNC has indicated that the PRC sub-sites would be able to participate if we are able to arrange for all sites to utilize a central pharmacy and manage all data through Columbia (to enable the DCC to only interact with one organization thereby limiting expense for DCC management). We have explored using a central pharmacy. The cost is prohibitive given the limited funds available for pharmacy and capitation. 2. UNC has indicated that if they are able to add sites, they will first consider our PRC sites **ACTION:** None at this time.
Progenity Update Stephanie Lynch	1. Delay in start-up due to the Sponsor notifying us of ICF changes regarding the use of specimens in the future. Currently waiting for IRB approval of the revised consent for Columbia and the master consent for Christiana. **ACTION:** Local context review documents will be sent to Christiana once IRB approved. SIV's will be scheduled.
Novavax-RSV Vaccine Study Update Stephanie Lynch	1. CUMC and Winthrop participating. Only sites in NY were able to start this year due to timing and the RSV season. Next year other sites can be added. 2. Currently waiting on IRB approval –working on the pending items from the IRB meeting. 3. Contract/budget negotiations in progress. **ACTION:** Local context review documents will be sent to the sites once IRB approved.

III. The administrative component of the meeting was adjourned. Next meeting is on September 8, 2017 at Rutgers - RWJMS.

PRC Science Meeting Minutes
May 19, 2017
1:00 PM- 4:00 PM

Location: Virtua Health and Wellness Center

I. Presentations

Study	Discussion and Comments
Update: " Vaginal Progesterone to decrease recurrent preterm delivery in women on 17-OHPC" Cynthia Gyamfi	1. This grant is a PRC and NPRC submission with plans to resubmit in July 2017. Cynthia will be reaching out to all sites to make sure they are still interested in participating. 2. Currently working on revisions to the grant. 3. Tracy Manuck is multiple PI for this submission. **ACTION:** Grant paperwork will be sent to sites to complete and send back.
Update: "The AWARE RCT: Activity in women at Risk for Early Delivery and Neonatal Morbidities" Tony Sciscione	1. Presented the project to the MFMU subcommittee for the TOPS Study. -Potentially this project can be an ancillary to TOPS and PROSPECT (MFMU projects). 2. MFMU PI call on June 19th – Tony will present the AWARE RCT to the Steering Committee for approval/vote. 3. Outside funding will be sought through another institute – possibly the National Institute of Nursing Research (NINR). **ACTION:** None at this time. Resubmission is being planned.
Presentation: "The epigenetic impact of in utero opioid exposure on Generation Z" Ruth Landau, MD	1. Reviewed study design and sample collection. - This study is designed to evaluate the impact of prescribed opioids used for pain relief during pregnancy on neonatal DNA methylation processes and neonatal clinical outcomes. -We want to examine the hypothesis that *in utero* exposure to opioids permanently alters gene regulation in the exposed neonates and may impact their pain behaviors and susceptibility to opioid tolerance and addiction later in life. 2. Study Procedures: -20 cases (on opioids) and 20 matched controls needed -saliva, hair and meconium collection -data collection -opiod intake questionnaire **ACTION:** Email sites to see if who is interested in participating.
CHAP Study Update Kirsten Cleary and Mary Talucci	1. Mild Chronic HTN Pragmatic RCT. 2. Sample size 4700. 3. Reviewed enrollment updates. -663 overall enrolled as of last report 5/17/17. -Enrollment by Center – PRC 162 enrolled. 4. Study News: UAB sends out the Pulse Newsletter and looking into sites using social media. UAB has created a Facebook page for CHAP. CUMC is working on creating a CHAP Facebook page-more details will be shared as we work on the process. 5. DSMB updates – no safety or ethical concerns, currently allowing patients to deliver outside study sites and the sample size reduction is still under review. Next DSMB meeting is in 10/17. 6. Ancillary proposals are due to UAB by June 8th. Mary mentioned the possibility of an ancillary on compliance. Kirsten has an idea she plans to submit. 7. CHAP QA – Mary Talucci briefly discussed the last CHAP QA. The

	main focus was to look at the HP17 form (outcome report). There have been a lot of questions about this form and how to complete it. Overall sites are doing well and showed improvement. **ACTION:** Email sites the ancillary proposal form. All sites continue to increase enrollment.
Presentation: "Morbidly Adherent Placenta: A Retrospective Cohort Study" Dan Skupski	1. IRB approved at all sites. 2. Reviewed hypothesis of the study and classic and subtle signs of MAP. 3. Sites are asked to identify appropriate cases by querying your U/S database program. Acceptable scans may need to be reviewed by a PI or fellow. 4. Reviewed the status of potential cases per site. 5. Trice will present Tricefy – an U/S cloud to send the U/S images to for the study. **ACTION**: All sites need to identify cases for the study. If questions about eligible images contact Dan Skupski.
TRICE for the MAP Study Wilson Gottschild	1. Tricefy - the U/S cloud. -share U/S images -archive images safe and secure -secure/data encrypted -HIPAA compliant – labeled with study ID -mobile access -installed in approx. 20 minutes (internet browser does not matter) -Main account for those reading the U/S images. Sub accounts for all the sites. 2. $500 per site for the MAP study (for 500 studies) -Could PRC reserve funds be used to fund this? **ACTION:** Schedule a finance call to discuss using PRC funds for Trice.
Presentation: "Does the cerebroplacental ratio predict adverse obstetrical outcomes in low risk pregnancies?" (CPR Study) Mayra Cruz-Ithier	1. All sites are IRB approved. 2. Work orders have been sent to the participating sites: Winthrop, Virtua, St. Peter's, NYP-Q and Columbia 3. Central Webinar training on 5/23 at 12pm. This will be recorded for those unable to attend. 4. Brief PowerPoint for sonographers has been sent out to review prior to acquiring U/S measurements for the study. 5. QA will be done remotely. 6. Data entry will be done centrally at Rutgers. **ACTION:** Webinar training for research staff on 5/23 at 12 pm.
Presentation: "Fetal and Neonatal Neuronal Exosomes" Laura Goetzl, MD, MPH	1. Discussed areas of opportunity: -In-utero infection – CMV, Zika, Toxoplasmosis -Exposure to medications – General Anesthesia -Exposure to drugs – Opioids and NAS -Exposure to hypoxia 2. Background information presented on neuronal exosomes. 3. Reviewed CMV, Zika, Toxoplasmosis, Anesthetic exposure, Opiod exposure, hypoxic encephalopathy. 4. Pilot data presented and discussed feasibility (including: incidence, detection and sample collection) 5. Discussion: PRC sites interested in any/all of the areas presented, new pilot data is needed (specimens with outcomes) before applying for funding. Determine process and next steps. **ACTION:** Form a working group of those interested in moving this ahead.
Presentation: "Validation and optimization of maternal early	1. Reviewed background: '. . . the early warning signs of impending maternal collapse went unrecognized.' 2. Maternal Early Warning System (MEWS) initiated 8/2013 at Columbia.

warning systems" Alexander Friedman, MD, MPH	-500 consecutive admissions reviewed starting 6/2015. -Conclusions from data: -Relatively high "screen positive" rate. -Some vital sign parameters perform better than others. -Majority of clinically relevant alerts were for hypertension. 3. PRC Study Concept: Prospectively evaluate obstetric hospitalizations and collect data on maternal vital signs and other potential triggers. -Intervention: -Some or all centers would implement a maternal alert system. -Before/after maternal outcomes data would be measured. -Study Design: Include PRC sites – 5 year study. **VOTE**: Majority=Yes to move forward **ACTION:** Present at the next PRC meeting with more details regarding study design and budget. Possible Fall R01 submission.

II. Scientific meeting was adjourned. Next meeting September 8 at Rutgers-RWJMS.