PRC Steering Committee Administrative Meeting Minutes
Friday, February 3, 2017
1:00 PM- 4:00 PM
Location: Drexel University

Present
Columbia: Ron Wapner, Michelle DiVito, Sabine Bousleiman, Mary Talucci, Caroline Torres, Cande Ananth, Kirsten Cleary, Alex Friedman, Stephanie Lynch
Christiana: Tony Sciscione, Carrie Kitto, Ashley Vanneman, Kelly Ruhstaller
Drexel: Lauren Plante, Cheryl Tocci, Brandy Leopanto, Marge Sherwood
NYP-Queens: Dan Skupski, Rosalyn Chan, Susan Ingenito, Jessica Scholl, Ajini Cherian
Rutgers: Todd Rosen, Shama Khan, Christina Duzyj Buniak
Saint Peter's: Kristy Palomares, Tracy Vitale, Michele Falk
Virtua: Ron Librizzi, Erin Obermeier, Amy Glasofer
Winthrop: Wendy Kinzler, Jolene Muscat, Kim Byrnes-phone

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

I. Administrative

Agenda Topic	Discussion- Actions- Next Steps
Approval of 11/04/2016 Conference Call Minutes	1. 11/4/2016 conference call minutes approved.
Finance Committee Update Stephanie Lynch	1. FY16 financials show a $6,125.00 refund. **ACTION:** Refund invoice instructions will be sent to all sites.
Strategic Growth Committee Todd Rosen	1. Temple has been recommended by the Committee to move ahead with the application process. -Dr. Goetzl is presenting 'Temple' today at 12:30. -Steering Committee will vote on adding them as a site later in the day. 2. Rutgers-New Jersey Medical School also applied. Todd Rosen has reached out to them to let them know that although they are a different site they fall under the same administrative oversight of Rutgers. We will look into possibly having them as a subsite under the Rutgers-RWJMS site in the future. 3. We had a call with UPENN to discuss the PRC. They are thinking about it and may apply next time. **ACTION:** If the Steering Committee approves at the vote later today, Temple will be offered membership.
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. We are still unsure how the data will be shared for research. 3. Ron W. mentioned why don't we create our own database then possibly share with MQIP in the future? Christina agreed. **ACTION:** A data committee call will be set up to discuss plans with Matt Hoffman.

II. Study Updates

Agenda Item	Discussion- Actions- Next Steps
MOMPOD Update Michelle Divito	1. The only option for having all sites participate at this time is to have them function as one entity which would require contracting with a pharmacy that would be able to serve all PRC sites. The preliminary assessment of this option appears to not be feasible from a financial perspective. UNC has agreed to contact us if they wish to add additional centers and will consider PRC sites before reaching out to others. **ACTION:** None at this time.
Progenity Update Stephanie Lynch	1. Sent for Central IRB approval. 2. Negotiating the contract and budget. 3. Columbia and Christiana only-most other sites are already participating. **ACTION:** None at this time.
Novavax-RSV Vaccine Study Update Stephanie Lynch	1. A Phase 3, Randomized, Observer-Blind, Placebo-Controlled, Group-Sequential Study to Determine the Immunogenicity and Safety of a Respiratory Syncytial Virus (RSV) F Nanoparticle Vaccine With Aluminum in Healthy Third-trimester Pregnant Women; and Safety and Efficacy of Maternally Transferred Antibodies in Preventing RSV Disease in Their Infants -this is a new study and the Sponsor has already contacted all the PRC sites by email to complete a questionnaire. This needs to be completed before the Sponsor will contact you for the next steps. - Purpose of this study is to determine the efficacy of maternal immunization with the RSV F vaccine against symptomatic RSV lower respiratory tract infection (LRTI) with hypoxemia through the first 90 days of life in infants - All maternal subjects will receive a single intramuscular (IM) injection on Day 0 with the assigned test article, the RSV F vaccine or placebo. Study participation for maternal subjects will span approximately nine (9) months from the first dose, ending six (6) months post-delivery. Study follow-up for infant subjects who are consented will span approximately one (1) year post-delivery. **ACTION:** Sites need to respond to the email, complete the questionnaire and let the Sponsor know if they are interested. Resend the email to each site.

III. The administrative component of the meeting was adjourned. Next meeting is on May 19, 2017 at Virtua Medical Group.

PRC Science Meeting Minutes
February 3, 2017
1:00 PM- 4:00 PM

Location: Drexel University

I. Presentations

Study	Discussion and Comments
Presentation: "Temple University" Laura Goetzl, MD, MPH	1. Dr. Goetzl reviewed OB volume and demographics -@ 3,000 deliveries a year -Co-I is Wadia Mulla, MD – MFM and Genetics -currently have a full-time study Coordinator: Sarmina Hassan -research infrastructure: EPIC, research space and 24 hour pharmacy, off-hour coverage with fellows/nurses **ACTION:** Vote and let Dr. Goetzl know the results as soon as possible.
Update: "The AWARE RCT: Activity in women at Risk for Early Delivery and Neonatal Morbidities" Tony Sciscione	1. Discussed randomized trial vs. observational cohort. -Todd Rosen and Cynthia Gyamfi-Bannerman are in favor of an observational cohort-no need for a randomized trial. 2. Discussion continued regarding crossover, enrolling only high risk participants, will an observational study give us the information we want to obtain? -sites agreed that observational is the best option, although compliance may be an issue. When the sites were asked, most were split with some Dr's at each site still prescribing bedrest and some not. -It was agreed compliance may be an issue. Will need to be convincing in the grant that Dr's still prescribe bedrest. 3. Cynthia Gyamfi-Bannerman has a study at Columbia using the 'fitbit'. Per Tony Sciscione the 'fitbit' is not validated and the Actigraph for the AWARE study is more robust and validated. **ACTION:** None at this time. Resubmission is being planned.
Update: " Vaginal Progesterone to decrease recurrent preterm delivery in women on 17-OHPC"- Cynthia Gyamfi	1. This grant is a PRC and NPRC submission. 2. Working on revisions and resubmitting. 3. Tracy Manuck is multiple PI for this submission. **ACTION:** Follow-up call scheduled in a few weeks.
Updates: **Genetics and Abruption** **HPV and Preeclampsia** Cande Ananth	1. RO1 Genetics and Abruption – Large grant application. Unable to submit for a large grant now. Impact score was 31-overall science was ok but questioned the value and benefit to study such a rare issue. 2. HPV and Preeclampsia- (Collaboration with Maged at UTMB) not funded. Scheduling a call to discuss other options. Overall this was not interesting to the reviewers. **ACTION:** None at this time.
CHAP Study Update Kirsten Cleary and Mary Talucci	1. Mild Chronic HTN Pragmatic RCT. 2. Sample size 4700. 3. Reviewed enrollment updates. -499 overall enrolled as of last report 1/28/17. -enrollment by Center – PRC 127 enrolled. 4. DSMB updates – sample size reduction is still under review. 5. Protocol v1.5 modifications: streamline the pragmatic BP's and no more OMRON BP's at follow-up visits. -reviewed new algorithm for screening/enrollment.

	5. Capitation modifications 12/1/16. -A capitation increase is anticipated: $2,000 per patient ($1800 + $200 incentive for meeting targets). 6. CHAP QA – Mary Talucci discussed the results of the second CHAP QA - Areas of improvement: Regulatory / PI documentation / protocol violations or deviations Late & missing forms / study drug discrepancies -Areas that continue to need improvement Medical record discrepancies Data discrepancies / GCP issues / incomplete headers - Common issues: source documentation/medical record discrepancies, keying errors, GCP issues with the case report forms including heading and signature errors. -Calls will be set up with sites to discuss QA results. **ACTION:** Schedule QA calls with sites.
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. - Nulliparous women between the ages of 18 and 45 36 weeks of gestation or later -2 additional U/S measurements (approx. 5 mins) -Sample size: 3,000 -Providers are blinded -Paper CRF's will be sent to Rutgers 2. Start-Up -There will be a central Webinar training for the sites. - Brief PowerPoint for sonographers to review prior to acquiring U/S. measurements for the study. 3. This has been submitted to the Central IRB for approval. 4. QA will be done remotely. 5. Data entry will be done centrally at Rutgers. 6. Sites participating in addition to Rutgers: Winthrop, Virtua, St. Peter's, NYP-Q and Columbia. (CCHS and Drexel are not participating). 5. Data sharing agreements will be sent to the sites as a work order. **ACTION:** Once IRB approved local context reviews will be sent to the sites.
Presentation: "Morbidly Adherent Placenta: A Retrospective Cohort Study" Dan Skupski	1. MAP study has been submitted for Central IRB approval. 2. All data, including U/S images, will be coded by the site and sent to New York Presbyterian/Queens (NYP/Q) encrypted. -The U/S images will be stored on a disc and shipped to NYP/Q 3. All sites are interested in participating. 4. Data sharing agreements will be sent to the sites as a work order. - Included in the Protocol: The data may be shared with the Perinatal Research Consortium (PRC) member sites for future research purposes. **ACTION**: Once IRB approved local context reviews will be sent to the sites.
Presentation: "Racial/Ethnic BMI Nomagrams Across Gestation" William S. Vintzileos	1. William Vintzileos is an MD candidate at George Washington University. 2. William provided background information regarding the associations between BMI, as well as excessive and suboptimal weight gain during pregnancy and adverse outcomes. 3. Study Objective: the study objective is to establish BMI nomograms across gestation by various racial/ethnic groups. - seeking collaboration with PRC and assistance for any existing database and statistical analysis. 4. Ron Wapner mentioned the Fetal Growth Study data should have all the data he is looking for. **ACTION:** Ron will work with Ananth to obtain the Fetal Growth Data for William's study.

Central IRB Discussion Stephanie Lynch	1. Summarized the central IRB process. 2. Illumina study central IRB status – to date no local context reviews have been IRB approved at Columbia CIRB. 3. Discussed some of the challenges with the Central IRB process. - Timing of Central IRB approval -Timing of sending Protocol Specific Information Form (PSIS) to sites -Delays at the site conducting the local context review -Information Form – after a call with the Rutgers IRB some of the suggested modifications from Rutgers will be incorporated into the next Protocol Specific Site Information Sheet (PSIS). -Consent language -Duplication of efforts – sites are requiring IRB applications in order to sign the local context review. Rutgers reported they have to complete a facilitative review application to submit the local context review to their IRB. -Fees for local context review: some sites are requiring it and some not. 4. Sites reported that the local context review requires a full review of the protocol which is time consuming. Amy Glasofer mentioned this is not the way the National Cancer Institute (NCI) CIRB is set up. They do not require the IRB review/signature for each Protocol. 5. Need to form a working group to discuss the issues and strategize solutions. Jolene Muscat, Amy Glasofer and one of the staff at Rutgers have agreed to be on the working group. **ACTION:** Solicit others to the working group and set up a call.
Illumina Study Status Update Stephanie Lynch	1. The Sponsor is waiting for all sites to have IRB approval. We need to submit the local context reviews for approval as soon as possible. **ACTION:** All sites need to send local context reviews to CIRB for approval.
GSK Study Status Update Stephanie Lynch	1. GSK has master CIRB approval. **ACTION:** Send the local context reviews to sites when received from the CIRB.

II. Scientific meeting was adjourned. Next meeting May 19th at Virtua Medical Group.