PRC Steering Committee Administrative Meeting Minutes

Friday, February 26, 2016
9:00 AM- 11:00 AM
Location: St. Peter's University Hospital

Present

Columbia: Ron Wapner, Michelle DiVito, Sabine Bousleiman, Mary Talucci, Cynthia Gyamfi, Caroline Torres, Vilmarie Carmona, Cande Ananth, Kirsten Cleary, Stephanie Lynch
Christiana: Tony Sciscione, Carrie Kitto, Jennifer Nava
Drexel: Lauren Plante, Cheryl Tocci (phone), Damien Croft (phone), Brandi Leopaldo, Marge Sherwood, Sarah Foster, Nahidah Rahman, Shontrcal Cooper
Lehigh Valley: John Smulian, Joanne Quinones, Sagan Loburak, Terry Kloiber (phone)
NYP-Queens: Dan Skupski, Phyllis August (phone), Madhavi Madalvi, Rosalyn Chan, Susan Ingenito
Rutgers: Todd Rosen, Christina Duzyj-Buniak, Shama Khan, Mayra Cruz Ithier, Guadalupe Herrera-Garcia, Diana Sanchez, Analia Albuja
Saint Peter's: Angela Ranzini, Ed Guzman, Tracy Vitale, Michelle Falk, Shoan Davis, Clara Perez
Virtua: Ron Librizzi
Winthrop: Wendy Kinzler, Tony Vintzileos, Christine Stanganelli
Not present: Matt Hoffman, Karin Fuchs, Shailen Shah

I. Administrative

Agenda Topic	Discussion- Actions- Next Steps
Approval of 11/6/2015 Meeting Minutes	1. Will approve electronically.
PRC Administrative Business Michelle DiVito	1. Introduction of new Program Manager, Stephanie Lynch. 2. Reviewed 2016 MFMU/PRC meeting schedule. Next meeting May 20th at Lehigh Valley. 3. Reviewed MFMU/PRC Coordinator Conference Calls –they are the 4th Friday of the month. Next one is changed to Wednesday, March 23rd 10-12 due to Good Friday. Site Coordinators were asked if the 4th Friday of the month does not work to please let us know.
Central IRB Michelle DiVito	1. Status of sites and agreement: • NYP-Queens and CCHS did not provide initial feedback. • SPUH – signed then rescinded due to legal review. • Drexel, Lehigh, Virtua, Winthrop and Rutgers – all reviewed and sent back comments. Columbia will send back Reliance Agreement along with SOP's to the sites for signature. 2. All 5 sites that responded had their comments addressed – particularly regarding the indemnification clause, which is standard in all Columbia service agreements. 3. Ron discussed the Central IRB is needed and it will be discussed further at the May meeting. If sites do not sign the Reliance Agreement they may not be able to stay in the consortium.
GSK Feasibility Discussion Michelle DiVito / Discussion	1. Sites that have agreed to do this study: CUMC, Lehigh, NYP-Queens, Rutgers, SPUH and Virtua. 2. Can any of the sites feasibly do the GSK study? Are sites prepared to commit to the study? Sites have been challenged with CHAP. GSK will take a lot of time screening (24/7) and require research staff coverage for up to 48 hours to follow the study protocol, PK levels, etc. GSK is not willing to pay for on-call at this time. There will be a lot of screening, not many eligible patients and staff on-call for this study to be successful. **ACTION:** The PRC has agreed not to move forward with this study unless GSK is willing to pay for on-call and if so the PRC will re-evaluate. **NOTE:** GSK 722 ARIOS infant follow-up study requires the PI to be a neonatologist. This is not being handled as a PRC project.
CHAP Update Kirsten Cleary	1. CHAP invoicing will be done like MFMU invoicing. UAB has sent Columbia reports with itemized capitation payments due each site. The reports will be sent to each site by Stephanie. Sites will have to verify the reports then send to their business person for invoicing. 2. Kirsten reviewed the most recent protocol changes. These changes are IRB approved at all PRC sites. 3. We need one enrolled patient per site per week to meet the recruitment goals. The numbers are increasing: 4 enrolled in October 2015 and 11 in February 2016.

	4. Calls were conducted with some of the sites having trouble enrolling. 5. Dr. Tita is willing to come to any site to do Grand Rounds. 6. Main recruitment barriers are: patients are too far along and the BP thresholds. 7. UAB has proposed Protocol modifications including modify BP screening to align with BP measurement routinely used and include mild HTN up to 160/105. 8. Discussion regarding the protocol modifications: screening patients with higher clinical BP patients and eliminating the 5 minutes rest. 9. Ron stated the consortium reported to have 2,500 CHTN patients a year. He also reminded everyone that patients will not come to you. You have to go find the patients. Columbia reported a low refusal to consent rate, approximately 10%.

II. Committee Updates

Agenda Item	Discussion- Actions- Next Steps
Data Repository Committee Matt Hoffman	1. No updates
Financial Oversight Committee Michelle DiVito	1. All sites paid dues for FY16. FY15 refunds are due back to the sites in the amount of $5,097. 2. Ended with $57,345 balance - 20% will go into reserve ($11, 469) 3. Remaining FY15 cash balance is $45, 876/9 = $5,097 refund per site. 4. Stephanie will contact sites to obtain invoices to process the refunds.
Steering Committee Discussion Ron Wapner	1. Ron led a discussion with the site PI's regarding challenges of working with sites that conduct research through a central office rather than in the department 2. John Smulian shared his challenges and experiences with using a central office.

III. The administrative component of the meeting was adjourned. Next meeting is on May 20th, 2016.

PRC Science Meeting Minutes

February 26, 2016
12:30 PM- 4:00 PM

Location: Saint Peter's University Hospital

I. Presentations

Study	Discussion and Comments
Presentation: "Developing a Test for Detection of Neonatal Sepsis" Yiping Han	1. Background: • Culture-independent technology detects more microbial species in AF and CB than the conventional culturing methods. • More poly-microbial infections are detected by the culture-independent methods. • Species previously unrecognized to be associated with PTB were identified. • F. nucleatum, a common oral anaerobe, is one of the most prevalent species in intrauterine infection associated with PTB and EONS. 2. Objective is to further develop the Culture-Independent technology for detection of neonatal sepsis • Prospective study: 1-2,000 term and preterm patients at delivery • Samples to be collected: Maternal saliva, neonatal cord blood (both whole blood and serum should be collected from artery and vein for comparative analysis) • Data to be collected: Patient demographics, placental histology from preterm births, culture results, neonatal outcomes (mortality rate, NICU, neonatal sepsis, RDS, BPD) 3. Discussion: How long to process specimens? Very quickly, under an hour and store in -20. Placenta histology – not always good clinical exams-basically they want to know chorio **Vote:** Unanimous Yes –interest in hearing more
Update: Strict Activity Restriction (SAR) **Now the AWARE Trial** Tony Sciscione	1. Name change -AWARE Trial: The **AWARE** RCT: **A**ctivity in **W**omen **a**t **R**isk for **E**arly Delivery and Neonatal Morbidities 2. Resubmitting with April 15th deadline. A few changes: did not want to use just preterm birth as an outcome so neonatal morbidities will be added and the short cervix criteria was 2.0 and now is < 2.5 cm's for the high risk patients. 3. Co-enrollment with the MFMU APPS Protocol was brought up as a concern. 4. R01 Letter for approval to exceed $500k in DC for this grant will be submitted next week. 5. See Harpers Magazine link: https://harpers.org/archive/2015/12/the-bed-rest-hoax/
17-P, Short Cervix, and Preterm Delivery Submission Cynthia Gyamfi-Bannerman	1. Not yet resubmitting 2. Need to review the OPPTIMUM study publication. The study used vaginal progesterone for preterm birth.
Update: ALPS Follow Up Submission Cynthia Gyamfi-Bannerman	1. Awaiting written critiques from NHLBI and planning re-submission in July
Updates: **Genetics and Abruption** **HPV and Preeclampsia** Cande Ananth	1. R01 Genetics and Abruption – Large grant approval to be submitted. Plan for RO1, 7/5/16 submission date. 2. HPV and Preeclampsia- (Collaboration with Maged at UTMB) 1st submission not scored, 2nd submission 39th percentile. Plan is to revise and resubmit a new application in June R01 cycle with UTMB.

Presentation: "Creating Father-Engaged Perinatal Setting" Diana T. Sanchez	1. Background: • Early father involvement: recent studies reveal that fathers' involvement may be critical to maternal and infant health. • Father-engaged medical settings (EMS): Incorporate father inclusive cues, create and provide fathering materials, train nurses to engage fathers during the visit. 2. Study participants: • 120 unmarried fathers and their partners (120 mothers) • Recruited from the Ultrasound Clinic Waiting Room at RWJUH for T1 and T2 (approximately 3 weeks after birth) in exchange $40 each ($80 per couple). • Only moms who want fathers involved (invited for T2) • Retention through monthly 3 min surveys in exchange for monetary compensation 4. Rutgers is using internal funding. **Action:** Diana is looking for feedback regarding the study and funding to add sites. All PRC sites are interested.
Presentation: "Does the cerebroplacental ratio predict adverse obstetrical outcomes in low risk pregnancies?" (CPR Study) Mayra Cruz-Ithier	1. Background on Cerebroplacental ratio. • CPR is currently been used as a predictor of adverse pregnancy outcomes and assessment of well-being in fetus diagnosed with fetal growth restriction. • Some studies have suggested the use of CPR as an alternative approach for appropriately grown fetuses suffering from placental insufficiency, therefore failing to reach their growth potential. 2. Objective is to determine whether the cerebroplacental ratio (CPR) can predict adverse obstetrical outcomes in low risk pregnancies. 3. Study Proposal: (288 subjects needed, screen 3,000) • Prospective observational design • Assess CPR in low risk pregnancies • Review inpatient records • Assess for association between CPR and obstetrical outcomes 4. Primary Outcome: Rate of cesarean section for non- reassuring fetal heart tracing. 5. Inclusion criteria: Nulliparous patients, scheduled ultrasound at 36 weeks gestation and beyond, delivery to occur at PRC hospital **Action:** Vote is tabled until Mayra sends an email with additional details and questions. **Concerns**: Asking for a waiver of consent, no funding
Presentation: "Antioxidants to Prevent Placental Abruption: A RCT in High Risk Women" Cande Ananth	1. Background: • Common pathophysiological mechanisms for preeclampsia, IUGR, and abruption is "Ischemic Placental Disease". • Oxidative stress results from an imbalance between pro-oxidants and antioxidant capacity. • Vitamin E helps to prevent oxidative stress, which is characterized by an excess of free radicals coupled with decreased antioxidants. 2. Study Hypothesis: Among women with history of ischemic placental disease, combined vitamin C-E supplementation in the first trimester will reduce the risk of placental abruption in the subsequent pregnancy. 3. Aims: • To evaluate if prophylactic administration of combined vitamin C-E daily therapy initiated at <13 weeks is associated with placental abruption • To evaluate if maternal smoking (at randomization) modifies the association between prophylactic administration of vitamin C-E daily initiated at <13 weeks and placental abruption 4. Primary Outcome: Risk or recurrence of placental abruption 5. Study Design: Multicenter, double-blind, placebo controlled trial 6. Eligibility: Multiparous women with ischemic placental disease in a previous pregnancy, singleton gestation, entry to prenatal care (and randomization) in the first trimester (<13 weeks).

	7. Sample size: Sample size per arm = 1,925 subjects, 3,850 subjects total **ACTION:** Vote=majority yes to move forward. Ananth will present to MFMU Network. (Possible RO1 in the future)
Presentation: "Antenatal Corticosteroids for Term Scheduled Cesarean: an RCT" Cynthia Gyamfi-Bannerman	1. Background: • Cesarean delivery is one of the most common surgical procedures • Absolute risk of respiratory morbidity is low • Relative risk of respiratory morbidity is 2-3 fold higher-compared to SVD • Retention of fetal lung fluid in cesarean delivery 2. Research Question: Among infants of women delivered by scheduled cesarean between 37 0/7 to 39 6/7 weeks gestation, does administration of antenatal betamethasone decrease the rate of special care nursery admission for respiratory distress over placebo? 3. Hypothesis: Women of infants delivered by cesarean exposed to antenatal betamethasone within the week prior to delivery will be less likely to be admitted to the NICU for respiratory distress than unexposed infants. 4. Inclusion Criteria: Singleton gestation, 37 0/7 – 39 6/7 weeks, scheduled cesarean for any indication, delivery expected >24 hours, <7 days 5. Study Design: Prospective, randomized, double-blind, placebo-controlled trial of betamethasone or an identical placebo for women with singleton gestations scheduled for cesarean at 37-39 weeks. 6. Primary Outcome: NICU/Special Care Nursery (SCN) admission for respiratory distress. 7. Sample size: 4,100 **ACTION:** Vote=majority yes to move forward RO1 for June
Presentation: "Health Incentives to Improve Maternal Health Outcomes" Yukiko Washio	1. Background: Substance Abuse in Pregnancy • Approx. 30% of prenatal substance use among socioeconomically disadvantaged women. • Up to 80% of substance-using women able to abstain from at least one substance during pregnancy. • Cigarette smoking, as the most common substance used, with the poorest short and long-term cessation rates. 2. Incentive based intervention: use of incentives to promote health behavior • Smoking and drug abstinence • Weight reduction • Physical activity • Adherence with medication regimens • Health service utilization • Increase Breastfeeding (BF) 3. Further Development: • NICHD RO1-cost effectiveness study, community structuring for sustainability • NICHD R21-mobile application to track and case manage BF, monthly incentives, African American moms **ACTION:** None right now, informational to see who is interested in the future
Updates on New Opportunities Ron Wapner	1. SMART-Which sites are using Panorama testing now? **ACTION:** send Ron an email 2. MOMPOD-Funded. This is a randomized clinical trial of insulin plus placebo versus insulin plus metformin for the treatment of overt T2DM complicating pregnancy. Women will be randomized between 10 weeks 0 days and 20 weeks 0 days' gestation and followed until delivery. (Enrollment: randomize 1,334 women) **ACTION:** None. Waiting for more details. No capitation rate yet. 3. Illumina – moving forward with PRC sites. Objective: Conduct a limited prospective collection of whole blood samples in pregnant women with a diagnosis of preterm preeclampsia in addition to samples from one reference group to aid in the development of a NGS-based assay to detect molecular markers associated with preterm preeclampsia. **ACTION:** None. More details to come.

Update: "Morbidly adherent placenta project" Dan Skupski	1. Waiting for the central IRB before moving ahead.
Update: "Risk of preterm delivery after cesarean"- Cande Ananth	1. Waiting for signed DUAs. Once signed, can get the study going.

II. Scientific meeting was adjourned. Next meeting May 20th, 2016 at Lehigh Valley Health Network.