PRC Steering Committee Administrative Meeting Minutes

Friday, May 20, 2016
9:00 AM- 11:00 AM
Location: Lehigh Valley Hospital

Present
Columbia: Ron Wapner, Michelle DiVito, Sabine Bousleiman, Mary Talucci, Cynthia Gyamfi, Caroline Torres, Cande Ananth, Kirsten Cleary, Stephanie Lynch
Christiana: Matthew Hoffman, Tony Sciscione, Carrie Kitto
Drexel: Lauren Plante, Cheryl Tocci, Damien Croft, Rachel Danis, Shontreal Cooper
Lehigh Valley: John Smulian, Joanne Quinones, Terry Kloiber
NYP-Queens: Dan Skupski, Phyllis August (phone), Jaslyn Maurer
Rutgers: Todd Rosen, Shama Khan, Mayra Cruz Ithier
Saint Peter's: Angela Ranzini, Ed Guzman (phone), Tracy Vitale
Virtua: Ron Librizzi
Winthrop: Wendy Kinzler
Not present: Karin Fuchs, Shailen Shah, Anthony Vintzileos, Christina Duzyj Buniak

I. Administrative

Agenda Topic	Discussion- Actions- Next Steps
Approval of 11/6/2015 and 2/26/2016 Meeting Minutes	1. 11/6/2015 and 2/26/2016 meeting minutes approved.
PRC Administrative Business Stephanie Lynch	1. Reviewed 2016 MFMU/PRC meeting schedule. Next meeting 7/29 at Drexel University. Outlook invites will be sent for the upcoming meetings. 2. Reviewed MFMU/PRC Coordinator Conference Calls –they are the 4th Friday of the month. Next one is June 24th 10-12. 3. All FY15 Partial Refund Invoices have been received and all but one signed off. All payments will go out shortly. 4. Invoices will be sent out in the next few weeks for membership dues for FY17. **ACTION:** Send refunds to each site Send sites invoices for FY17 Membership dues
Central IRB Stephanie Lynch	1. Reliance Agreements have been sent to every site and requested returned and signed by 5/31/16. 2. Reviewed the Central IRB Process and the 3 SOP's. 3. Several sites have asked about charges for the Central IRB: Currently the Columbia IRB only charges for Industry Sponsored Trials which is paid by the Sponsor. This is left vague in the agreement because NIH and OHRP are moving fast towards mandating a single IRB and with it, the possibility that NIH-supported trials receive some support as well. **ACTION:** All sites must send back signed Reliance Agreements by 5/31/16
GSK Discussion Michelle DiVito	1. GSK approached Todd Rosen at the start-up meeting and wants the PRC involved. 2. There have been ongoing challenges with communicating with GSK and resolving budget issues. 3. GSK will present the study later today for everyone. **ACTION:** Sites - If GSK agrees to the budget we have requested (including on-call payment) sites will be asked to make final decisions on whether they can feasibly participate
PRC Composition Michelle Divito	1. Lehigh Valley announced they are no longer participating in the PRC. 2. Discussion between PI's regarding whether to add a site or not. 3. Current finances need to be reviewed prior to deciding if it is necessary to add one. 4. Jefferson and UPENN are interested, Houston as well but they are not local and everyone agreed to keep any additional sites local. • It was brought up that Jefferson is smaller however all clinic patients and this may be beneficial for research. 5. Discussed creating a new committee-"Strategic Growth Committee" or possibly add this to the current Finance Committee. Role of the Strategic Growth Committee: review impact from a financial perspective, process for adding new sites including choosing potential sites and the application process. • Some potential ways to add sites discussed: fill out an application to have an idea of the sites research infrastructure and/or have the potential site PI presents his/her site to the PRC.

	ACTION: Proceed with Strategic Growth Committee formation and report back to the Steering Committee.

II. Committee Updates

Agenda Item	Discussion- Actions- Next Steps
Data Repository Committee Matt Hoffman	1. No updates
Financial Oversight Committee Michelle DiVito	1. No updates
Steering Committee Only Discussion Ron Wapner	1. Ron led a discussion with the all PI's regarding Lehigh Valley PI's continuing to attend the PRC meetings without participating in any projects. Unanimously all PI's agreed to allow them to continue to attend the meetings. 2. Discussed adding sites and how potential sites will be determined. St. Barnabas and Jefferson were discussed as potential sites. 3. Tony Sciscione suggested we should have a year-end report. 4. All PI's agreed to a Strategic Growth Committee **ACTION**: Year-end report needs to be created Form the Strategic Growth Committee

III. The administrative component of the meeting was adjourned. Next meeting is on July 29th, 2016 at Drexel University.

PRC Science Meeting Minutes

May 20th, 2016
12:30 PM- 4:00 PM

Location: Lehigh Valley Hospital

I. Presentations

Study	Discussion and Comments
Update: AWARE Trial Grant Tony Sciscione	1. Tony reported we did not receive the approval from the NICHD to submit over the $500,000 limit for the 4/15/16 submission. We are submitting June 5th each site needs to submit some new paperwork due 5/23. We are still waiting on paper work from several sites. **ACTION**: Sites that have not submitted their grant paperwork have until Monday 5/23 to do so.
Vaginal Progesterone to decrease recurrent preterm delivery in women on 17-OHPC Cynthia Gyamfi-Bannerman	1. Not yet resubmitting. 2. Reviewing randomization and timeline.
Update: ALPS Follow Up Submission Cynthia Gyamfi-Bannerman	1. Follow-up of children from the ALPS Study (MFMU) 2. Looking for a pediatric pulmonologist to add to the grant 3. Plan resubmission for the July 5th, 2016 cycle
Updates: **Genetics and Abruption** **HPV and Preeclampsia** Cande Ananth	1. R01 Genetics and Abruption – Plan for R01, 7/5/16 submission date. 38th percentile last submission. We have permission from NICHD to submit this large grant application for July. This is the last possible submission since the NICHD will not fund large grants going forward. 2. HPV and Preeclampsia- (Collaboration with Maged at UTMB) Submitting as a new June R01 cycle with UTMB. • Revised the sample size to 16,000 screened and 800 cases / 800 controls (1600 enrolled).
Presentation: "Does the cerebroplacental ratio predict adverse obstetrical outcomes in low risk pregnancies?" (CPR Study) Mayra Cruz-Ithier	1. Background on Cerebroplacental ratio. • 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 6. Informed consent will be obtained **Action:** Follow-up with sites to see who is interested in participating. Mayra will work on a draft protocol to circulate **Concerns**: No funding

Presentation: CHAP Update Kirsten Cleary	1. Kirsten reviewed CHAP recruitment goals and the most recent UAB CHAP enrollment reports. Enrollment goals are not being met. 2. We need one enrolled patient per site per week to meet the PRC recruitment goals. 3. Kirsten reviewed the screening process and barriers at each site. Some barriers mentioned may be less of an issue with the new protocol, i.e., screen failures with the OMRON BP device. • Dr. Plante mentioned this study is labor intensive 4. Protocol v1.4 reviewed • CCHS, Drexel, NYP-Queens and Virtua have received IRB approval • Columbia is approved but waiting for stamped consent • Rutgers, St. Peters and Winthrop still waiting for IRB approval **ACTION:** Goal for each site is to screen at least 2 patients per week and enroll 1 patient per week
Presentation: "PH III retosiban Program – NEWBORN-1 & ARIOS Overview" Dr. Kathleen Beach, Dr. Lauren McKain and Jessica Jolly	1. Presentation began with lengthy regulatory history of how the Protocol has evolved. Ron asked they please present the study and the Protocol as it is now. 2. Newborn I Overview: Randomized, Double-Blind, Multicenter, Phase III Study Comparing the Efficacy and Safety of Retosiban Versus Placebo for Women in Spontaneous Preterm Labor • 48 hours of tx • All patients will receive corticosteroids • MgSO4 is permitted • Inclusion/Exclusion reviewed • 6 phases of the study: 1) Screening, 2) Inpatient tx (4 blood draws), 3) Post-Infusion Assessment, 4) Delivery, 5) Maternal Post-Delivery, 6) Neonatal Medical Record Review (need neonatologist involved) 3. ARIOS: Follow-up Study to Assess Long Term Safety and Outcomes in Infants Born to Mothers Participating in Retosiban Treatment Studies • 5 year follow-up beginning after final assessment (28 days following estimated date of delivery) 4. Dr. Wapner expressed concerns regarding the lack of responsiveness from GSK, turnover of staff, delays in negotiations, lack of follow-up and communication. He indicated that we are willing to continue negotiations but only if we are able to deal directly with decision makers and get final answers on proposed budget. **ACTION:** Michelle is working with GSK on the budget. If GSK agrees to the budget including on-call payment an email will be sent with the details and sites will have to decide whether or not they will participate.
Update: "Antioxidants to Prevent Placental Abruption: A RCT in High Risk Women" Cande Ananth	1. Presenting this RCT as a concept proposal to the upcoming MFMU steering committee meeting on July 21-22, 2016 **ACTION:** None at this time - Possible R01 in the future
Update: "Risk of preterm delivery after cesarean"- Cande Ananth	1. Ananth reported he has the data and is working on the analysis.
Presentation: "Antenatal Corticosteroids for Term Scheduled Cesarean: an RCT" Cynthia Gyamfi-Bannerman	1. 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. Primary Outcome: NICU/Special Care Nursery (SCN) admission for

	respiratory distress. 5. New Details: • 37-38 weeks • 1 dose v. 2 dose v. saline placebo • Test all for hypoglycemia • 2 year ND outcomes with Bayley or ASQ screen • Reviewed sample size calculations 7. Sample size: 4,100 8. Comments/Questions to follow-up: • Who would give injection? • Interim analysis will be needed • Need permission for large grant from NHLBI • NPRC sites • Would all sites need a research pharmacy? **ACTION:** Cynthia is working through the logistics and NHLBI and will update at next meeting.
Update: "Morbidly adherent placenta project" Dan Skupski	1. Need to know what sites are interested in participating. **ACTION**: Send an email to find out who is interested in participating. Dan will create a draft protocol to circulate.
Updates on New Opportunities Ron Wapner	1. SMART-Not all sites use Panorama. You can participate if you use this test at your site. It was mentioned that the test used is dependent on what the insurance company dictates. **ACTION:** Send an email to find out who wants to be contacted by the local rep to move forward with the study. 2. MOMPOD- UNC did not budget for all PRC sub sites so the indirect costs are not funded for the first $25,000. We need to figure out a way to pay for the indirect costs due to Columbia on the first $25,000 for each sub site –either with PRC reserve funds or if UNC can find the funds, depends on how much of their budget is cut. Waiting on budget information from UNC. **ACTION:** Send the Protocol to the sites for review. 3. Illumina – Working on a budget and CTA. Capitation is $525 with $9,500 start-up costs and indirects per site. This will be a Central IRB project. **ACTION:** Send protocol to sites
Presentation: "The Maternal Quality Improvement Program" Steve Hasley	1. Background on quality metrics reviewed. 2. Goal of MPIQ is to create a national clinical data registry focused on maternal and neonatal outcomes of childbirth. • The primary goal is feedback to participating practices, to enable continuous quality improvement. • Data will also be aggregated and analyzed at the national level. 3. Funded by ASA and ACOG 4. Engaging vendors: Epic Stork, Cerner, etc 5. Looking for Beta test sites – small pool of volunteer institutions • Need to know what Vendor – some engaged and some not o Epic Stork and others committed to building electronic documentation that directly feeds the registry structured data. • At this point it has not been discussed if sites will be able to generate own reports. **ACTION**: Send PowerPoint slides to all to review. Email all sites to see what Vendor they use and if they are willing to be a Beta Site.

II. Scientific meeting was adjourned. Next meeting July 29th, 2016 at Drexel University.