



CPIC eBrief

Congenital and Perinatal Infections Consortium

April 2020



Director's Message

Well, what a different world we are in now compared with when the first e-Brief came out! I am sure that you and your research teams are working exceedingly hard to respond to the demands that COVID-19 is placing on our healthcare systems, and to maintain, and advance where possible, non-COVID research activities. We have been doing the same at the Central Unit.

This e-Brief will detail the status of our CPIC studies, including the Neonatal Enterovirus study that will be ready to start once the COVID-19 shutdown lifts as well as the other studies that are in varying stages of development. It also will provide new timelines for the educational and pilot funding activities of our Consortium. Once we are through this – and we will be through it at some point! – I have no doubt that this network of collaborators will emerge stronger, more dedicated, and more energetic than ever before. And, given the great things we have already accomplished together over the past years and decades, that will be a really fun period to be entering!

Stay safe and well –
David

Principal Investigator:

David Kimberlin, MD
dkimberlin@peds.uab.edu

Clinical Trials Administrator:

Jill Bailey-Griffin, RN, MSN
jgriffin@peds.uab.edu

Regulatory Administrator:

Susan Branscum
sbranscum@peds.uab.edu

Program

Management/Finance:

Mary Wyatt Bowers, MA
mwbowers@peds.uab.edu
Sarah Dowdy, MPH
smdowdy@peds.uab.edu

Career Enhancement

Administrator:

Melissa McBrayer, MEd
mcbbrayer@uab.edu

Pilot Program Administrator:

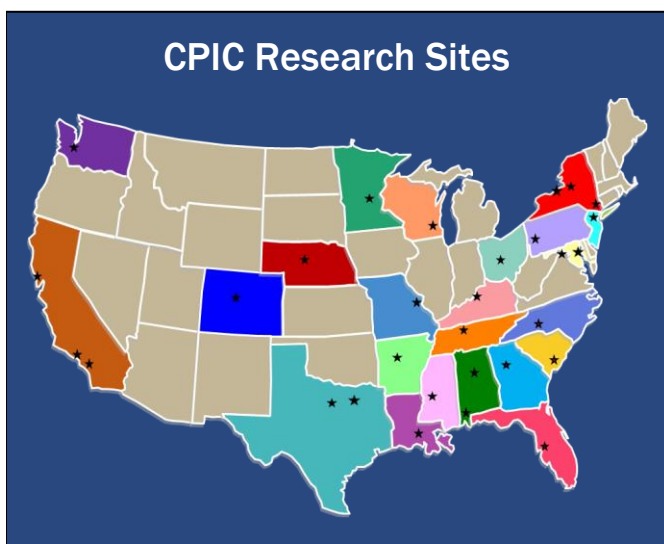
Cheryl Perry, PhD, MPH
cperry@uab.edu



COVID-19 Update

Until mid-March the CPIC Central Unit was operating as usual. Though we are continuing to work on Consortium activities, as detailed in this eBrief, most of us are working remotely and connecting by Zoom or WebEx to continue making progress. We are continuing to bring our 27 other sites on board by executing subawards and are also in the process of finalizing IRB reliance at all sites.

While we are able to prepare things to move forward, we have decided to hold off on the initiation of training opportunities and pilot funding, since that would require redirection of the energy institutions are currently spending battling COVID-19. Once things begin to settle, we will get back on track with these opportunities and should be ready to hit the ground running on our natural history and research protocols.



Protocol Status

- 1) Neonatal EV Sepsis Version 1.0 was distributed to sites on 2/6/20 and the study initiation webinar was held 3/12. The Cincinnati sIRB approval and related documents were distributed on 3/13 for sites to use to prepare their IRB submissions. We anticipate a target start date of late May/early June 2020.
- 2) Valacyclovir PK protocol development is 80% complete. It is now scheduled to be completed by May or June of 2020.
- 3) Longitudinal CMV protocol development is slated for 3/1/20 – 8/30/20.
- 4) Letemovir PK protocol development is scheduled for 3/1/21 – 8/30/21. It was planned to begin later to provide more flexibility for the budget.

Career Enhancement & Pilot Project Updates:

Due to the current focus of infectious disease investigators on COVID-19, we have decided to postpone the initiation of CPIC Scholar selection and distribution of the initial call for Pilot and Feasibility applications. We anticipate that these opportunities may be available in June, but will reassess at that time. We will continue to keep sites informed through these quarterly eBriefs and email communication.

Administrative and Financial Updates

Half of our sites have a fully executed subaward for the first year of their initial protocol, and the remaining subawards are all in process. Amendments will be utilized to provide additional years and funding for subsequent protocols. This is a great time for sites to move their study start-up forward by processing subawards and completing other necessary administrative tasks. Sites may invoice for their start-up costs per the subaward agreements to fund their work.

Administrative Reminder – Since CPIC will utilize Cincinnati Children’s Hospital Medical Center (CCHMC) REDCap database services for the Enterovirus National History study, sites should work to establish a Data Use Agreement (DUA) with CCHMC to formalize this process. Draft DUAs will be provided by the UAB Central Unit in conjunction with each site’s Enterovirus subaward/ amendment.

Links

[Rare Diseases Clinical Research Network \(RDCRN\)](#)



CPIC is supported by the UAB Central Unit located at:

The University of Alabama at Birmingham
Children’s Harbor Building, Suite 303
1600 7th Avenue South
Birmingham, AL 35233
1-877-975-7280 or 1-205-934-5316

CPIC Launches New Website

The CPIC website, as part of the Rare Diseases Clinical Research Network website, is now live! The site contains information about our study team, the diseases we study, our pilot programs, past research on these diseases, and up-to-date news about our consortium (including copies of eBriefs). Content will continue to be updated and added regularly. Check us out at <https://www.rarediseasesnetwork.org/cpic>.

[PROVIDE FEEDBACK](#) | [CONTACT](#)