



CPIC eBrief

Congenital and Perinatal Infections Consortium

October 2020



Director's Message: Research & Training Accomplishments

We are pleased to announce that our Neonatal EV Sepsis protocol is active at 12 sites. In addition, we are hopeful that our Valacyclovir PK and Longitudinal CMV protocols will be initiated by late 2020 or early 2021. The Valacyclovir PK study synopsis was reviewed by the NIAID/DMID Clinical Science Review Committee on 10/20 and received favorable feedback. Full comments are expected soon, clearing the way for protocol development and selection of the 5 sites. More on site selection to follow.

In addition, we want to congratulate Dr. Nitin Arora, recipient of our inaugural CPIC pilot award! His research interest and the funded project are described below. Our Scholar Program has also accepted its first applicants, who are beginning to take advantage of CPIC training opportunities. Though many potential Scholars are busy responding to the current COVID-19 pandemic, we are hopeful that this cohort will continue to grow over time as COVID-19 responsibilities decline. More information, including a link to Scholar Program information and application materials, is featured on the following page.

Stay safe and well –
David

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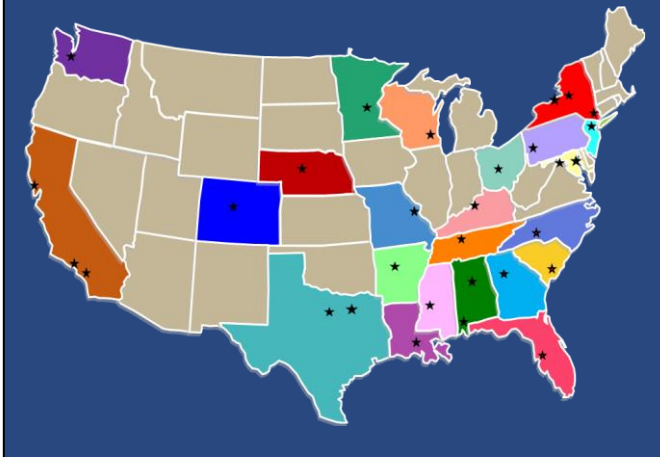


First CPIC Pilot Recipient

We are pleased to announce that the recipient of our inaugural CPIC Pilot Award is **Nitin Arora, MD, MPH**, an Assistant Professor at UAB in the Department of Pediatrics, Division of Neonatology. He will work with Drs. Virginia Duncan, Ona Faye-Petersen, Suresh Boppana, and William Britt on his project entitled *Impact of human cytomegalovirus (HCMV) on placental morphology and neonatal outcomes in primary and non-primary infected pregnancies*.

Dr. Arora's long-term research goal is to gain an understanding of perinatal vertical and postnatal horizontal transmission of pathogens. This project will allow him to quantify histopathological findings of HCMV placental infection and use them to establish a non-biased scoring system to assess pathological changes in the placenta. The scoring will then be combined with spatially-oriented transcriptomics to extend observations into more refined measures of tissue damage and dysfunction.

CPIC Research Sites



Protocol Status

- 1) The Neonatal EV Sepsis protocol has been activated at 12 sites, with others to come on board as subawards are executed and IRB approvals obtained. There are no subjects enrolled to date.
- 2) Our Valacyclovir PK protocol has been reviewed by the DMID, as detailed above in the Director's Message. We expect to initiate this study in late 2020 or early 2021.
- 3) Longitudinal CMV protocol development is a bit delayed, with anticipated study initiation in late 2020.
- 4) Letemovir PK study design is being discussed ahead of schedule, although study initiation is still anticipated for late 2021, due to the structure of our 5-year budget.

CPIC Scholar Program

We have recently accepted our first two Scholars: **Craig Bierle, PhD** and **Keerti Dantuluri, MD, MPH**. Dr. Bierle, from the University of Minnesota, is a molecular virologist interested in how TORCH pathogens cause infection at or circumvent the maternal-fetal interface (Mark Schleiss, MD, mentor). Dr. Dantuluri, from Levine Children's Hospital, is interested in epidemiologic research and gaining knowledge about clinical research implementation (Amina Ahmed, MD, mentor).

This program is open to late-stage fellows and early stage faculty, and is currently [seeking additional applicants](#).

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

Administrative and Financial Updates

The last day to send in invoices for Year 1 (9/1/19–8/31/20) is October 30, 2020. However, we request your invoices ASAP to ensure you receive funds for your work in Year 1. We have now begun Year 2 (9/1/20–8/31/21) of our CPIC grant and we are working diligently to provide updated sub-awards to each site. If you haven't received your draft sub-award, these will be coming to you shortly. We expect Year 2 sub-awards to include funds to continue studies initiated in Year 1. Further into Year 2, we will provide funding amendments to begin the Valacyclovir and Longitudinal CMV studies.

Reminder – Since CPIC will utilize Cincinnati Children's Hospital Medical Center (CCHMC) REDCap database services for the Neonatal EV Sepsis 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. Also, please note that we will be using a Data Management and Coordinating Center (DMCC)-provided tool – Complion – for our eRegulatory binder.

How to Cite CPIC in Publications

All publications about research resulting from the use of CPIC resources are required to: 1) cite both CPIC and the DMCC awards and 2) comply with the [NIH Public Access Policy](#). We suggest wording such as: "Research was supported by the National Institutes of Health (NIH) under award numbers U54AI150225 and U2CTR002818. Content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

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