



## Director's Message: Moving Forward with Research

I am pleased to report that, as more and more people are getting vaccinated for COVID-19, life is beginning to return to normal. For CPIC, this means our returning to the office on May 10<sup>th</sup> and a renewed focus on regular meetings and updates. Though COVID has had a significant impact on all researchers, probably none have been affected more than those of us working in infectious disease research.

I am grateful to everyone in our Consortium who has continued to participate in remote meetings and conference calls during this busy and difficult time. As our responsibilities lighten, we hope for a renewed focus on our CPIC research projects and substantial progress toward advancing the understanding of rare congenital and perinatal viral infections to reduce disease burden.

Stay safe and well –  
David

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## A Message from our Patient Advocacy Group Partner

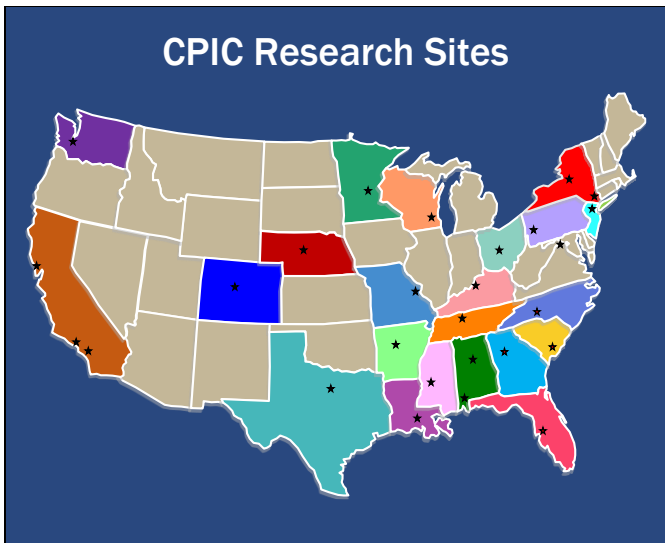
Cytomegalovirus (CMV) is a global public health issue and arguably the most common preventable cause of neonatal disability in the United States. A congenital CMV diagnosis can be incredible daunting; our parents are often overwhelmed or ill-prepared.

The CMV community is frustrated by the perceived lack of progress in prevention education, newborn screening, treatment and vaccine development. In 1999, a CMV vaccine was assigned the highest priority for vaccine development by the Institute of Medicine. Industry cites a lack of public awareness for vaccine delay.

We view our partnership with CPIC as an opportunity to advance the field and improve the lives of children and families afflicted by congenital CMV. Parents would like medical providers to consider the following about the impact of congenital CMV on families:

- Congenital CMV is not rare. It is common and serious.
- Discuss simple CMV prevention techniques during prenatal visits, when women are already making behavioral changes.
- Screen every baby at birth; early intervention IS treatment and is more cost-effective in optimizing long-term outcomes.

Every baby deserves the best possible start! Learn more at [NationalCMV.org](http://NationalCMV.org).



## Protocol Status

- 1) The Neonatal EV Sepsis protocol has been activated at 20 sites, with others to come on board as subawards are executed and IRB approvals obtained. There is 1 subject enrolled to date.
- 2) Our Valacyclovir PK protocol is currently under review by the DMID and the RDCRN. We expect to finalize this protocol in mid-2021.
- 3) Longitudinal CMV protocol development is a bit delayed, with anticipated study initiation in mid-2021.
- 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 Resource

As part of a broader effort to provide additional opportunities for engagement and learning across the Career Enhancement Committee (CDC), an [RDCRN CEC folder](#) has been created in Box and currently stores several documents, R25 webinars, etc. This folder is meant to serve as a resource for young investigators and scholars. [Click here](#) for a step by step visual for accessing the RDCRN CEC folder.

CPIC continues to accept Scholar applications from [late-stage fellows and early-stage faculty](#). Scholar designation provides access to training and funds for travel to meetings and mini-sabbatical experiences (as allowed).

## Administrative and Financial Updates

We are more than halfway into our Year 2 budget cycle (9/1/20–8/31/21). Please invoice for maintenance funds and any subject fees. Invoices should be submitted at least quarterly per the terms of your subaward. Due to pandemic delays, we now expect funding for the Valacyclovir and Longitudinal CMV studies to be initiated later this year. Please email Sarah Dowdy ([smdowdy@ped.s.uab.edu](mailto:smdowdy@ped.s.uab.edu)) with any subaward questions.

Update on Data Use Agreements – CPIC utilizes REDCap database services through the RDCRN's Data Coordinating Center at Cincinnati Children's Hospital Medical Center (CCHMC) for its Neonatal EV Sepsis study. CCHMC intends to establish a Data Use Agreement (DUA) with each site to formalize this transfer of data. However, the CCHMC DUA template and process is undergoing revisions at this time. If your site has not yet established a DUA with CCHMC, please watch for updated information and a future request.

## 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 7<sup>th</sup> Avenue South  
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1-877-975-7280 or 1-205-934-5316

## CPIC Featured in RDCRN Newsletter

A feature article on CPIC was included in a recent RDCRN *Spotlight on Rare Diseases Newsletter*. Please take a look and feel free to share it over your social media channels:

- [Blog post](#)
- [Facebook](#)
- [Twitter](#)
- [LinkedIn](#)

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