



Director's Message: Focus on Research

I hope everyone is staying healthy and had time to celebrate and relax a bit over the holidays. We have selected 13 institutions to participate in our Valacyclovir study and will be distributing that protocol later this month. The Neonatal EV Sepsis study continues to recruit. UAB recently enrolled a subject who was on ECMO due to EV sepsis – so it's out there, even with this being winter. In addition to our research, we are beginning to prepare for our first External Advisory Committee (EAC) meeting in early March. Since we will likely discuss our upcoming competitive renewal application, we would appreciate it if sites could share suggestions for building on current projects or for new projects that are related to our areas of interest. That way, we can make the most of our time with the EAC and receive feedback on our future plans. We will also be presenting information on current projects and on our career enhancement activities and our pilot program. We will keep you posted on what we learn during the EAC visit and how it may impact our plans moving forward. Finally, all sites should be receiving weekly updates from the RDCRN that detail opportunities within the larger network. Please let us know if you are not receiving these, and we can run interference from our end to make sure that you do.

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Stay safe and well –
David



Universal Newborn CMV Screening

CMV is a public health issue and newborn screening saves lives. Early identification, diagnosis, and intervention can prevent long-term disability and may improve the quality of life of children and their families. The National CMV Foundation will continue to advocate for universal screening of newborns at the federal level through the Recommended Uniform Screening Panel (RUSP), the national guideline. Most states also have their own process for evaluating which diseases are included on their newborn screening panels even if CMV is added to the RUSP.

We're excited to announce that Minnesota is slated to become the first state to enact universal newborn CMV screening. On January 11, 2022, the MN Newborn Screening Advisory Committee voted 16-3 in favor of adding congenital CMV to the state bloodspot panel. If this recommendation is endorsed by the state Commissioner of Health, Minnesota will begin plans to implement the addition of CMV to its newborn screening program. Congratulations to our parent advocates, ardent supporters, and state sponsors for your perseverance!



Protocol Status

- 1) The Neonatal EV Sepsis protocol has been activated at 26 sites, with 2 subjects enrolled. We ask all activated sites to work with their virology labs and neonatology teams to identify possible subjects for enrollment.
- 2) We are preparing for a pre-IND meeting with the FDA for the Valacyclovir PK protocol and will resubmit the IND soon. We are preparing central IRB documents and will send out the protocol later this month.
- 3) Longitudinal CMV protocol development has been delayed but is now underway. We anticipate study initiation in mid-2022.
- 4) Letemovir PK study design has been finalized and is currently under review at the NIH. Study initiation is still on track for the first half of 2022.

Scholar Series

The next CPIC Seminar, "Protocol Development and Implementation," will be presented Friday, February 18 at noon (CST) by David Kimberlin, MD, CPIC principal investigator, and Professor and Co-Director of the Division of Infectious Diseases in the UAB Department of Pediatrics. Scholar seminars are open to all CPIC investigators, study team members, associated trainees, and students. Join us by [Zoom](#).

Visit <https://rdcrn.org/cpic/scholars> to find out more about becoming a CPIC Scholar. Scholar designation provides access to training opportunities through the NIH Rare Diseases Consortium Research Network and funds for travel to meetings and mini-sabbatical experiences.

Links

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



CPIC is supported by the UAB Central Unit located at:

The University of Alabama at Birmingham
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Administrative and Financial Updates

We are in the 2nd quarter of Grant Year 3, which began 9/1/21. All sites have received their Year 3 Subawards to fund work between 9/1/21 and 8/31/22. Please invoice for maintenance funds and any subject fees. If you have any questions about this process, direct them to Sarah Dowdy sdowdy@uabmc.edu.

Data Hosting Agreements Required for Enterovirus Sepsis Study – 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. Your site should have received a Data Hosting Agreement request from CCHMC. This agreement is between your institution and CCHMC. Direct any questions about the DHA to rd.dmcc@cchmc.org.

Revamped CPIC Website Content Now Available

When you get a chance, please check out the new content on our CPIC website: <https://rdcrn.org/cpic>. Use the left side navigation bar for information on our research, our patient advocacy group, CPIC programs, and more. Our revamped site is now more user friendly, with a focus on information that is most useful to lay audiences. If you have any feedback or suggestions for additional content, please contact Cheryl Perry (cherylperry@uabmc.edu).

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