



## Director's Message: New Pilot Recipient

We just completed a very successful site visit, which included Drs. Walla Dempsey, Ruth Florese, Mark Challberg, and Swee Teo from the NIH/NIAID, and have now submitted our third NIH progress report. Two of our studies, Longitudinal CMV and Valacyclovir PK, will be starting within the next few weeks. Also, our third CPIC Pilot Project has been awarded to Carol Kao, MD, an Assistant Professor of Infectious Diseases at Washington University in St. Louis. She will work under the mentorship of Drs. Stephanie Fritz and Juliane Bubeck-Wardenburg on her project entitled *Staphylococcus aureus*  $\alpha$ -toxin antibody response in maternal-infant dyads. Dr. Kao's CPIC funding will allow her to enroll pregnant women in their third trimester and follow infants until 12 months of life. By collecting cord blood, serial culture swabs, and parental data, this study will provide novel insight into the role maternal antibodies play in the development of postnatal *S. aureus* immunity. Given the significant healthcare burden of *S. aureus* infections and continued trend for increasing antibiotic resistance, findings from this study will inform the development and utilization of novel anti-*S. aureus* therapeutics to prevent infant and childhood infections. We wish Dr. Kao success as her research progresses!

Stay safe and well –  
David

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## CPIC Partners with Herpes Cure Advocacy

Herpes Cure Advocacy (HCA) has joined CPIC as a new patient advocacy group working to prevent neonatal herpes. HCA is a grassroots, membership-based international organization of more than 14,000 patient advocates, with the goal of cure, treatment, and prevention for HSV types 1 and 2. Recent advocacy from HCA has led to the first-ever national strategy and strategic plan from the Office of the Assistant Secretary for Health for the treatment and prevention of herpes in the FY 2022 budget.

HCA recently launched a Neonatal Herpes Advocacy Task Force to provide community for impacted families; engage with stakeholders, physicians, and scientists; and create change to better protect American families from neonatal herpes. The kickoff meeting will be held 9/14 at 6pm EST. Families, clinicians and professionals, policy workers, and advocates for change are all welcome. To register and receive an email confirmation with instructions to join the meeting, click [here](#). For more information, please visit the [HCA website](#).



## Protocol Status

- 1) The Neonatal EV Sepsis protocol is active at 28 sites, with 8 subjects enrolled. We encourage all activated sites to continue working with their local treating teams to identify possible subjects for enrollment.
- 2) The Valacyclovir PK protocol version 2.0 was approved by the FDA to proceed. The IRB submission, MOP and eDES development are being finalized with EMMES and our study start-up meeting is scheduled for August 24<sup>th</sup>.
- 3) The Longitudinal CMV protocol version 1.0 is final and the study start-up meeting is set for August 30<sup>th</sup>. The eDES development is being finalized with the DMCC.
- 4) Letemovir PK study design has been reviewed by the DMID Clinical Science Review Team. We have initiated development of the full protocol and ICF and anticipate study initiation toward the end of 2022.

## CPIC Seminar Series

We welcome James H. Willig, MD, MSPH as the new Director of the CPIC Career Enhancement Core and Scholars Program. Dr. Willig is the Associate Dean of Clinical Education in the UAB School of Medicine and Professor of Infectious Diseases in the Department of Medicine. His research interests in quality improvement and medical informatics have found expression in both research into quality issues in HIV primary care and the design of software to enhance research and education. Dr. Willig is already taking an active role with our Scholars and finding opportunities for synergy with UAB's Center for Clinical and Translational Science (CCTS). We look forward to his continued input and guidance.

### 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

## Administrative and Financial Updates

Year 3 is coming to a close August 31, 2022! Please invoice for maintenance funds and subject fees provided in your Year 3 (9/1/21-8/31/22) subawards. If you have any questions about this process, direct them to Sarah Dowdy ([sdowdy@uabmc.edu](mailto:sdowdy@uabmc.edu)).

For those sites that will proceed with set-up of the newest study, DMID 22-0013 Retrospective Follow-up CMV Infection, amendments adding new funds to the Year 3 subaward will be requested. New funds may be calculated to cover costs until the end of the grant year, 8/31/22, to ensure that sites can invoice for the full amount. Additional funding will be provided with the Year 4 subawards after UAB receives the next year's budget Notice of Award.

The NIH has announced that the next RDCRN Grant Funding Cycle will begin 1 year later than previously expected. This means that CPIC has the opportunity to take a no cost extension, extending our funds (and work) into a 6th year. CPIC intends to apply for the no cost extension, moving our grant end date to 8/31/25. We expect to have adequate funds for our CPIC sites in Year 6, considering the pandemic-related slowdowns we experienced in Years 1 and 2.

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 (DHA) request from CCHMC. This agreement is between your institution and CCHMC. Direct any questions about the DHA to [rd.dmcc@cchmc.org](mailto:rd.dmcc@cchmc.org).

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