



Director's Message: Competitive Renewal & Pilot Recipient

Our team is busy working on CPIC's competitive renewal application, which is due in mid-August. We greatly appreciate your responsiveness to our requests for data, letters, and other information! We will be expanding our consortium to include additional sites in the southwestern US, as well as sites in Canada and the United Kingdom. Proposed research projects include a continuation of our current Ietermovir PK study for symptomatic congenital CMV and addition of: 1) a PK study of the helicase-primase inhibitor IM-250 with acyclovir for neonatal HSV, 2) a PK study of a loading dose of pleconaril followed by maintenance dosing for EV sepsis, and 3) a longitudinal study of congenital syphilis to develop an AI tool to support more accurate diagnosis. I also want to congratulate our newest CPIC Pilot awardee, Megan Pesch, MD, MS, an Assistant Professor of Developmental and Behavioral Pediatrics at the University of Michigan. Her project, entitled *Assessing the longterm harms and benefits of newborn congenital cytomegalovirus screening*, will allow her to collect data from parents and children and to conduct an innovative content analysis of social media accounts. We wish Dr. Pesch success as her research progresses. Finally, we are planning a CPIC working lunch during IDWeek 2024. It is tentatively planned for Friday, October 18th from 12-2pm. We would love to see you there in person (and are exploring remote options as well)!

Stay safe and well –
David

Principal Investigator:

David Kimberlin, MD
dkimberlin@uabmc.edu

Co-Principal Investigator:

Charlotte Hobbs, MD
charlottehobbs@uabmc.edu

Clinical Trials Administrator:

Jill Bailey-Griffin, RN, MSN
jillgriffin@uabmc.edu

Regulatory Administrator:

Susan Branscum
sbranscum@uabmc.edu

Program Management/ Finance:

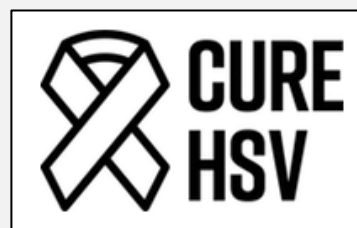
Sarah Dowdy, MPH
sdowdy@uabmc.edu

Career Enhancement Administrator:

Melissa McBrayer, MEd
mmcbrayer@uabmc.edu

Pilot Program Administrator:

Cheryl Perry, PhD, MPH
cherylperry@uabmc.edu



Patient Advocacy Group (PAG) Profiles

A hallmark of the RDCRN is the direct involvement of [Patient Advocacy Groups \(PAGs\)](#). CPIC has two PAGs. Our first is the [National CMV Foundation](#), a nonprofit organization dedicated to preventing pregnancy loss, childhood death, and disability due to congenital CMV. Its programs deliver education to women of childbearing age through digital platforms, strategic partnerships, public health initiatives and grassroots advocacy. It funds early career awards and influences research priorities regarding CMV prevention, treatment and intervention. The Foundation supports a policy agenda targeting prenatal counseling, accelerated research funding, implementation of universal newborn screening and advocacy for a vaccine. Our second PAG is [Herpes Cure Advocacy](#), a nonprofit organization advocating for a cure for Herpes Simplex Virus (HSV-1 and HSV-2), which affects 6 billion people globally who are living with HSV. It provides detailed guidance to promote advocacy; monthly group counseling sessions for those living with herpes; new and clinical research related to the prevention, treatment and cure of herpes; and information on the significant health impacts of herpes.



Protocol Status

- 1) The Neonatal EV Sepsis protocol v3.0 (6/27/23) is active at all 31 sites, with 48 subjects enrolled in Arm 1 (the main study) and 4 in Arm 3 (deceased subjects).
- 2) The Valacyclovir PK protocol v4.0 (3/5/24) has been activated at 10 sites. Others are encouraged to submit ICFs and site activation documents to the UAB CU. It has 14 subjects enrolled, and 7 with PK data collected.
- 3) The Retrospective/Longitudinal cCMV protocol v3.0 (3/24/23) is active at 20 sites, with 36 enrolled. NIAID wants this study completed by August 2025, so we need sites activated and enrolling. Submit tracked ICFs and context documents and complete training ASAP.
- 4) The Letemovir PK protocol v2.0 (2/13/24) is active at 3 sites (0 enrolled). Others are encouraged to submit ICFs and site activation documents to the UAB CU.

CPIC Scholar Update

The Scholars Circle is on hiatus for the summer, but speakers coming this fall include Dr. David Kimberlin (9/20), Ms. Kristen Spytek, CMV parent advocate and CPIC CPAG representative (10/8), and Dr. Charlotte Hobbs, new CPIC co-PI (12/6).

Also, registration is open for 2024 ID Week, held October 16-19 in Los Angeles, CA. Scholars may choose to use CPIC awarded funds for travel to this event. Dr. James Willig, Scholar Director, will meet with Scholars for morning coffee (date TBD) and Scholars may attend the CPIC Annual Meeting. Contact Melissa McBrayer, Program Manager, for more information or with questions.

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
1-205-638-2530

Administrative and Financial Updates

Our 4th budget year comes to an end 8/31/24. We expect to receive our Year 5 Notice of Grant Award in late August. Please invoice for maintenance and subject visit funds. If you have any questions about invoicing for subaward agreements, please direct them to Sarah Dowdy (sdowdy@uabmc.edu).

Data Hosting Agreements Required for EV Sepsis and Retrospective CMV Studies – CPIC utilizes REDCap database services through the RDCRN's Data Coordinating Center at Cincinnati Children's Hospital Medical Center (CCHMC) for these studies. Questions about the DHA should be directed to rd.dmcc@cchmc.org.

Competitive Renewal Reminders

All of our sites have received requests for information needed for CPIC's competitive renewal application. Please be mindful that we have internal deadlines for this application and need to receive all institutional letters of support and facilities/resources information as soon as possible. Questions may be directed to Sarah Dowdy (sdowdy@uabmc.edu), CPIC Fiscal Administrator.

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