



Director's Message: Research and Upcoming EAC Visit

Even as we move away from RSV and flu season, CPIC remains busy. We are preparing for our third External Advisory Committee (EAC) meeting later this month and will provide updates with what we learn during the visit and how it may shape our plans moving forward. While we finish up as much of our current research as possible, we are also looking toward our next 5-year cycle. The new RFA for the U54 Rare Diseases Clinical Research Consortia was just released ([PAR-24-206](#)) with a deadline of August 13th, and we are already thinking about how it will be structured and what exciting new studies we can add to our portfolio. As with the current award, the new RFA also requires an Administrative Core, a Pilot/Feasibility Governance Core, a Career Enhancement Core, and 2-4 Clinical Research Projects (with one focused on increasing understanding of a disease, such as a natural history study). If the budget will allow it, we would like to submit four projects, one of which will be completing the Letermovir PK study. We are also considering treatment studies of neonatal herpes and enteroviral sepsis, as well as a foray into the world of congenital syphilis. If you have suggestions or input, please let me know. More information will be provided as this comes into greater focus.

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:

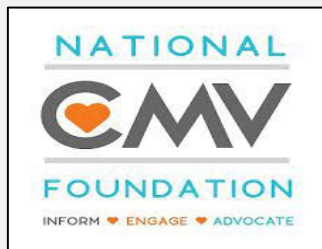
Sarah Dowdy, MPH
sdowdy@uabmc.edu

Career Enhancement
Administrator:

Melissa McBrayer, MEd
mmcbrayer@uabmc.edu

Pilot Program Administrator:

Cheryl Perry, PhD, MPH
cherylperry@uabmc.edu



Stop CMV Act Legislation Introduced

The National CMV Foundation is excited to announce that bipartisan federal legislation has been introduced in the US Senate and House to improve early detection and research for congenital cytomegalovirus (cCMV)! The Stop CMV Act authorizes funding to states for hospitals and other healthcare entities caring for infants to administer congenital CMV tests and encourages state healthcare agencies to prescribe standards and procedures for the administration of these tests. The bill also creates grant programs to provide funds to administer CMV tests, improve cCMV data collection systems, and assist in cCMV education and training. Lastly, it advances NIH research for screening techniques, diagnostics, prevention, vaccines, and treatments. Click to view the [Senate](#) and [House](#) versions of the bill.

Here's how you can help:

- Contact your legislators to ask them to co-sponsor The Stop CMV Act. [Info and templates available here.](#)
- Support our advocacy work by [making a donation.](#)
- [Volunteer](#) to meet virtually with Congressional staff.



Protocol Status

- 1) The Neonatal EV Sepsis protocol v3.0 (6/27/23) is active at all 31 sites, with 43 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 9 sites. Others are encouraged to submit ICFs and site activation documents to the UAB CU. It has 12 subjects enrolled, and 7 with PK data collected.
- 3) The Retrospective/Longitudinal cCMV protocol v3.0 (3/24/23) is active at 17 sites, with 20 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 Letermovir PK protocol v2.0 (2/13/24) is active at 1 site (0 enrolled). Others are encouraged to submit ICFs and site activation documents to the UAB CU.

CPIC Scholar Update

CPIC Scholars held a specific aims review session on February 16th. Drs. David Kimberlin, Andi Shane, and James Willig served as reviewers to provide personalized feedback for the specific aims pages of four CPIC Scholars.

On May 3rd at noon central, Dr. Matt Might, Hugh Kaul Endowed Chair of Precision Medicine, Professor of Internal Medicine, and Professor of Computer Science will present "Precision ID in the Age of Artificial Intelligence".

Administrative and Financial Updates

Our 4th budget year began September 1, 2023. All sites have received their subaward amendments for Year 4 (9/1/23 to 8/31/24). 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.

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

CPIC 2024 Pilot and Feasibility Program

Keep in mind that the CPIC Pilot and Feasibility Program's brief pre-applications are **due April 15th**. We plan to fund one yearlong award of up to \$30,000 in direct costs. The RFA is available [online](#). Questions may be directed to Cheryl Perry (cherylperry@uabmc.edu), Pilot Program Administrator.

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