



CPIC eBrief

Congenital and Perinatal Infections Consortium

January 2020



Welcome to the CPIC eBrief!

We are excited that CPIC will soon begin implementing our research projects as part of the Rare Diseases Clinical Research Network (RDCRN). As we begin the work of our Consortium, we want to distribute important information and updates to all sites in a consistent and concise way. We will have monthly calls with PIs and study teams to discuss protocols once the studies are active, but will use this eBrief format to share additional information. Please note that each issue will include the status of our four research projects, as well as updates related to the Career Enhancement Core and the Pilot and Feasibility Core. We will also include contact information for key personnel, as well as any relevant regulatory or financial updates.



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Director's message

I am pleased to report that we have been making great progress and are slightly ahead of our timeline. We finalized Version 1.0 of our Neonatal EV Sepsis natural history protocol and will be distributing it to sites in the near future. We have also been notified that the Data Management and Coordinating Center (DMCC) will be using this protocol to pilot test serving as the single IRB (sIRB) for RDCRN sites. This is especially exciting for us, because it would allow us to redirect some of the funding earmarked for IRB fees to our site research teams. We will share more information on this process as soon as we establish the division of responsibilities between the DMCC personnel and CPIC Central Unit staff, but please be on the lookout for requests for regulatory information in the near future.

The CPIC Executive Committee has also been exploring a couple of exciting opportunities for research collaboration. One is a future research project in collaboration with the Primary Immune Deficiency Treatment Consortium (another member of the RDCRN) related to SCID babies and involving assessment for acquisition of CMV. Another ongoing discussion, initiated during ID Week, involves our participation in an international CMV registry. Both of these opportunities would add value to the CPIC and to the larger RDCRN, and may be suitable for funding through NIH supplements.

CPIC Research Sites



Protocol Status

- 1) Neonatal EV Sepsis had Version 1.0 finalized on 12/27/19 and is almost ready to be distributed to sites. We should be on target to begin by April/May 2020.
- 2) Valacyclovir PK protocol development is 80% complete. Though scheduled to be completed by 2/29/20, it should be ready by early February.
- 3) Longitudinal CMV protocol development is slated for 3/1/20 – 8/30/20.
- 4) Letemovir PK protocol development is scheduled for 3/1/21 – 8/30/21. It was planned to begin later to provide more flexibility for the budget.

Financial Update on Subawards:

We are working with sites to complete “base” subawards and amendments as the protocols and related budgets are completed for each of the planned studies. Please make sure we have contact information for your site’s administrative contact so that we can work with them to get agreements in place as soon as possible.

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
1-877-975-7280 or 1-205-934-5316

Career Enhancement Core (CEC)

Led by Michael Mugavero, MD, MHSc, this Core’s purpose is to develop the next generation of rare diseases researchers through didactic and experiential training. Initially, sites will identify early-stage investigators to apply for selection as CPIC Research Scholars. Though Scholars do not receive funding, they will benefit from career enhancement opportunities such as a CPIC Seminar Series and travel awards and be eligible to apply for mini-sabbatical, immersion research experiences. Scholars will identify mentors at their institutions and will work on at least one CPIC protocol. A call for Scholar applications will go out in February, with applications due in March and selection in April. More information will be distributed to site PIs soon.

Pilot & Feasibility Core (P&F Core)

Directed by Rich Whitley, MD, the CPIC P&F Core has \$30,000 per year in Years 2-5 of the grant to fund at least one pilot award. Awards will favor early stage investigators and can be supplemented with institutional funds. The CPIC Executive Committee will select a focus area for the upcoming RFA within the next month, so that a call for applications can be distributed by mid-March. Each site PI will receive the RFA and will be asked to distribute it to those who might be interested and to publicize it via relevant websites and publications. The application process will require an initial LOI (pre-application), with the most promising applicants selected to submit full applications in May. The earliest start date for awards is September 1.

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