



Director's Message: Ending Year 2 with New Pilot Award

As we resume normal operations, we just submitted our second NIH progress report, detailing challenges related to the COVID-19 pandemic and our efforts to get our research and career development efforts back on track. Moving forward, we are pleased to announce that our second CPIC Pilot Award recipient is Craig Bierle, PhD, an Assistant Professor at the University of Minnesota in the Department of Pediatrics, Division of Infectious Diseases. He will work with Dr. Mark Schleiss on his project entitled *T cells and cytomegalovirus-associated immunopathology*. Dr. Bierle's CPIC funding will allow him to analyze T cell specificity toward viral and paternal antigens and to develop next generation sequencing methods to study T cell receptor diversity in guinea pig (GP) samples. Successful completion of his project will allow Dr. Bierle to show the maternal and fetal immune response to congenital GPCMV infection and the role of T cells in placental immunopathology after intrauterine viral infection. We wish him success as his research progresses!

Stay safe and well –
David

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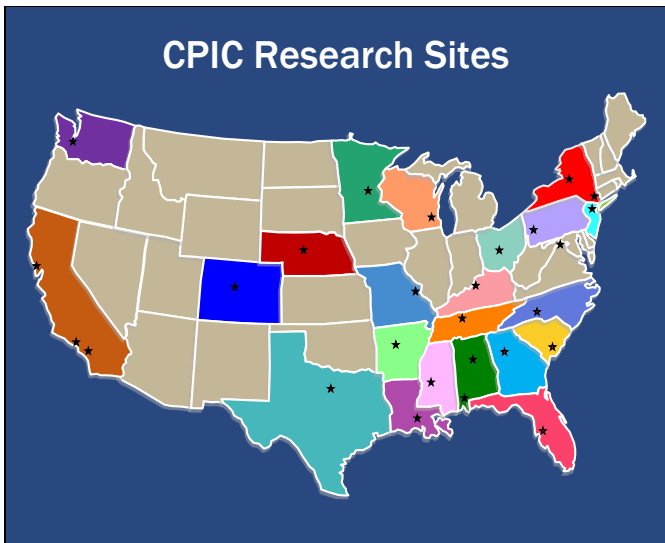
A Patient Advocacy Group Partner Message

Cytomegalovirus, or CMV, is the most common infectious cause of birth defects in the US. Every year, 30,000 infants are born with CMV and at least 6,000 have or develop permanent disabilities such as hearing loss, intellectual deficits and vision abnormalities.

Despite high prevalence and serious consequences, only 9% of women have heard of it. It is uncommon for women to be counseled about the risks of CMV transmission. In fact, according to a federal survey, less than half of OB-GYNs tell pregnant patients how to avoid CMV, even though women are commonly advised to take every imaginable precaution against listeria, toxoplasmosis, Zika, and now COVID-19.

The American College of Obstetricians and Gynecologists previously encouraged counseling for pregnant women on how to avoid CMV transmission but reversed its policy in 2015, saying “patient instruction remains unproven as a method to reduce the risk of congenital CMV infection.”

In 2019, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists updated their practice guidelines to provide guidance on the prevention of maternal CMV infection during pregnancy. Last week, the Society of Obstetricians and Gynaecologists of Canada followed suit and updated their recommendations, highlighting that serious outcomes due to congenital CMV may be mitigated.



Protocol Status

- 1) The Neonatal EV Sepsis protocol has been activated at 23 sites, with 1 subject enrolled to date. As we are approaching enterovirus season, we are asking all activated sites to ramp up their screening activities.
- 2) Our Valacyclovir PK protocol is currently under review by the DMID and the RDCRN. We expect to finalize this protocol in mid-2021.
- 3) Longitudinal CMV protocol development is a bit delayed, with anticipated study initiation in late 2021.
- 4) Letemovir PK study design has been discussed ahead of schedule and study initiation is still on track for late 2021 or early 2022.

CPIC DSMB Presentation

CPIC Scholars and other interested learners are invited to attend a Zoom presentation, "DSMB: Role of the Chair," by Richard Whitley, MD, distinguished professor in the UAB Division of Pediatric Infectious Diseases.

Dr. Whitley was 1 of 12 experts of the federally appointed COVID-19 Vaccine Data and Safety Monitoring Board, or COVID-19 DSMB, who were responsible for the safety, integrity and scientific validity of the US trials for vaccine makers Moderna, Janssen and AstraZeneca. This presentation will be held on Wednesday, 7/28 from 2-3pm (CT). Click [here](#) to join (Meeting ID: 2059342424, Passcode: SOCRA).

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

Administrative and Financial Updates

The end of the grant year (8/31/21) is approaching! Please invoice for maintenance funds and any subject fees as soon as possible. Direct any questions to Sarah Dowdy smdowdy@peds.uab.edu.

We are happy to report that the annual RPPR was submitted to NIH on June 30th. We look forward to receiving our Year 3 Notice of Award around September. Due to pandemic-related delays in our first two years of the grant, we expect to request carry-forward of funds in order to push all our CPIC studies ahead in Year 3. Carry-forward is NOT automatic for this grant.

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.

New Simplified CPIC Scholar RFA

The Career Enhancement Core is seeking interested fellows and early-stage faculty to be designated CPIC Scholars. While this designation does not include salary support, Scholars may note their status as a CPIC Rare Diseases Scholar on their CVs. Participation in this Program also makes Scholars eligible to request CPIC funds to attend meetings or participate in mini-sabbatical research experiences. Applications are due 8/15/21. Click [here](#) to download the RFA.

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