**CPIC 2023 Pilot and Feasibility Program**
**Request for Applications**

## Purpose

The mission of the Congenital and Perinatal Infections Consortium is to reduce the morbidity and mortality of rare viral infections such as congenital cytomegalovirus (CMV) disease, neonatal herpes simplex virus (HSV) infection, and neonatal viral sepsis caused by enteroviruses (EVs) and the related human parechoviruses (HPeVs). Focus on rare congenital and perinatal viral infections is unique in the current Rare Diseases Clinical Research Network (RDCRN), and we have grouped these diseases together because of their pathogenic potential in the neonatal population and the current and future opportunities to intervene meaningfully to improve outcomes. Though antiviral therapeutic agents with activity against each of these viruses already exist (CMV, HSV) or are in varying stages of clinical development (EV, HPeV), all of these viral infections cause substantial morbidity and mortality; collective consequences include developmental and motor delays, neurologic morbidity, visceral organ damage, hearing and vision loss, respiratory and cardiac complications, septic shock, and death. The opportunity to ameliorate disease impact (or drastically decrease the number who progress from infection to disease, in the case of neonatal HSV) for the pediatric population and their families forms a common purpose among Consortium researchers.

For this call for pre-applications, the CPIC Executive Committee has decided on a broad request for projects related to rare pediatric congenital or perinatal infections. Animal models will not be considered, per NIH guidelines. We plan to fund at least one yearlong award of up to $30,000 in direct costs. Applicants are encouraged to seek co-sponsorship of pilot awards with other institutional entitles, research networks, pharmaceutical companies and other stakeholders. If co-sponsorship is secured, the total award may exceed $30,000 in direct costs. Applicants are encouraged to collaborate with other CPIC and/or RDCRN sites and stakeholders.

## Eligibility

This program is primarily intended to support full-time faculty who are early-stage investigators (see NIH definition). Faculty with previous or active K-awards are eligible and are encouraged to apply. Past CPIC pilot applicants are also encouraged, but subsequent applications should be “new” submissions. Postdoctoral fellows are eligible if a faculty appointment will be made on or before September 1, 2023. If this is the case, the applicant must include a letter from their Department Chair confirming their status.

Applications will also be accepted from established investigators with a previous history of funding with justification of eligibility. Established investigators are eligible if the proposed research represents a major shift from his/her scientific portfolio to date. By providing an Eligibility Statement within the Pre-Application, established PIs have the opportunity to comment on how the proposed aims represent a major shift in science.

## Application Process

The CPIC P&F Program involves a two-phased application process: a Pre-Application and a Full Application. This funding announcement includes the instructions and guidelines for both Pre-Application and Full Application submissions.

**Phase One: Pre-Applications**

All proposals should represent the ideas of the Principal Investigator directly. Pre-Applications should be emailed as a single pdf document to Cheryl Perry (cherylperry@uabmc.edu) by 5pm on April 17th. Pre-applications will be scored using the NIH 9-point scale. Applicants receiving the best scores will be invited to submit Full Applications by May 1st.

Pre-Applications should be no more than 2 pages, and be submitted with the PI's 5-page NIH biosketch. The 2-page application must include the following:

- PI name and degree/s, email address and phone number
- Institution and department/division of PI's appointment
- PI's anticipated rank at time of award (i.e., Assistant Professor)
- Gender and race/ethnicity of PI
- Declaration of eligibility (2-3 sentences on how the PI meets the eligibility criteria)
- Name of proposed mentor/s
- Project title
- Research Plan – see organization below. Please note if project includes work with any partnering institutions or stakeholder groups.

The Research Plan should be organized as follows:

1. **SIGNIFICANCE**
   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - Provide a clear and concise description of the goals of the research.

2. **INNOVATION**
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - Describe any refinements to or novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation or interventions.

3. **APPROACH**
   - Be sure to include explicit statements of aims and corresponding hypotheses.
   - Describe the overall strategy, methodology and analyses to be used to accomplish the specific aims of the project.

4. **REFERENCES CITED** (NOTE: References do not count toward the 2-page limit.)
   - Provide a bibliography of all references cited. Each reference must include the names of all authors, the article and journal title, book title, volume number, page numbers, and year of publication.

The pre-application must use a font size no smaller than 11 point and spacing of no more than 6 lines per vertical inch. Figures can be smaller but must be legible at 100%. Margins should be no smaller than one-half inch.

Pre-Application Review Criteria

Pre-applications will be assigned an Impact Score (NIH 9-point scale) corresponding to the overall scientific merit of the proposal taking into account the proposed project, approach and investigator qualifications. Applications will also be assessed for PI eligibility, alignment of

project with CPIC goals, and potential to improve diagnosis, clinical trial readiness, and/or treatment for congenital or perinatal diseases.

**Phase Two: Full Applications**

Full applications will not be accepted without invitation. Letters requesting full applications will be emailed by May 1st. The letter of invitation will include feedback on the mentor(s) selected and suggestions for how to incorporate Consortium resources and stakeholder input. It will also include recommendations for any additional partnerships that might strengthen the research project prior to submission and will remind applicants of the support provided by the RDCRN Data Management and Coordinating Center (DMCC). In cases where projects could benefit from additional collaborator involvement, the P&F Core Director or members of the Selection Committee will connect applicants with potential partners. Applicants will also be encouraged to confer with the CPIC biostatistician, Inmaculada Aban, PhD. She will work with statisticians at partner sites to ensure that study design and methodology are appropriate for all projects submitted as full applications.

All documents requested must be combined into a single pdf and submitted to Cheryl Perry (cherylperry@uabmc.edu) by 5pm on June 1st. Page 1 should include the PI name, project title and an abstract of no more than 30 lines. Pages 2-5 should include the Research Strategy (see details below). This should be followed by biosketches for the PI, the mentor(s) and any co-investigators, as well as a budget and budget justification.

Research Strategy

The 4-page Research Strategy should be organized as follows:

1. **SIGNIFICANCE**
   - Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
   - *Rigor, Reproducibility & Transparency*: Describe the general strengths and weaknesses of the prior research cited. Consider the rigor of previous experimental designs, use of relevant biological variables, and authentication of key resources.
   - Provide a clear and concise description of the central goals of the project.
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved.

2. **INNOVATION**
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - Describe any refinements to or novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

3. **APPROACH**
   - Be sure to include explicit statements of aims and corresponding hypotheses.
   - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted.

- Describe any strategy to establish feasibility and address the management of any high-risk aspects of the proposed work. Please comment on how this work will set the stage for future, extramural support.
- *Rigor, Reproducibility & Transparency*: Emphasize how the experimental design and methods proposed will achieve robust and unbiased results. Also, explain how relevant biological variables are factored into research designs, analyses, and reporting.
- Include a brief timeline with milestones.

4. **REFERENCES CITED** (NOTE: References do not count toward the 4-page limit.)
   - Provide a bibliography of all references cited. Each reference must include the names of all authors, the article and journal title, book title, volume number, page numbers, and year of publication.

As with the pre-application, full applications must use a font size no smaller than 11 point and spacing of no more than 6 lines per vertical inch. Figures can be smaller but must be legible at 100%. Margins should be no smaller than one-half inch.

Biosketches

Biosketches for the PI, mentor and all co-investigators should follow guidelines for the 5-page NIH biosketch.

Budget and Justification

Applicants may request up to $30,000 in direct costs for a 12-month period. Projects from UAB are not required to budget indirect costs; other CPIC institutions may budget for up to $30,000 in direct costs plus applicable indirect costs. Applicants should utilize the PHS398 Form Page 4: Detailed Budget for Initial Budget Period to submit their budget. Allowable expenses may include personnel, supplies, inpatient/outpatient care costs, and other expenses. Alteration and renovation expenses are not permitted under this mechanism.

All expenses should be well justified. The Budget Justification should be organized as follows:

- PERSONNEL
- EQUIPMENT
- TRAVEL
- OTHER DIRECT COSTS (e.g., supplies, publication costs, consultants)

Please see the NIH Guidelines for more information on what should be included in a detailed budget justification. If funding is not requested in any particular category, please indicate "Not Applicable."

Full Application Review Criteria

Applications will be assigned an Impact Score (NIH 9-point scale) corresponding to the overall scientific merit of the proposal taking into account the proposed project, approach and investigator qualifications.

- **Assessment of Significance.** How well does this proposal address the goals of the CPIC? Will it make a significant contribution to the research base?
- **Assessment of Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will

particularly risky aspects be managed? Is the project feasible for the proposed time frame?

- **Assessment of Investigator and the Research Team.** Are the PI, mentor(s), and other researchers well suited to the project? If Early Stage Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- **Potential for Extramural Funding.** Is it likely that successful completion of this project will provide the preliminary data needed for a competitive, extramural translational research proposal?
- **Overall Impact.** Upon completion of the sections above, applications receive a score (1-9) to indicate the overall scientific merit of this pilot proposal taking into account all review criteria. The score should represent a global view; an application does not need to be strong in all categories to be judged likely to have major scientific impact, and the score does not need to be a mathematical reflection of the sections above.

**Award Notices**

Meritorious applicants will receive a formal notice of award. All funding will be expected to be utilized during the ensuing 12-month period. No-cost extensions may be granted at the discretion of the CPIC Executive Committee and with approval from the NIH. Award recipients will be provided a project management team that meets quarterly to help ensure that progress is consistent with timelines and benchmarks. Funded investigators will also be required to provide information on research productivity annually as part of program evaluation. In addition, pilot recipients will receive the designation of CPIC Scholar, allowing them to participate in quarterly training events and to access mini-sabbatical and travel funds. More information on the CPIC Scholar program is available on the CPIC website: https://rdcrn.org/cpic/scholars.

**Regulatory Approvals**

All lines of investigation supported by this mechanism require appropriate regulatory approvals, such as IRB approval. These approvals must be in place in advance of human subjects work and must remain in good standing throughout study implementation. Funding will not be released until all approvals are received.

**Dates**

Posted Date: 03/13/23

Pre-Application Due Date: 04/17/23

Full Application Invitations: 05/01/23

Full Application Due Date (invitation required): 06/01/23

CPIC Scientific Merit Review: 06/30/23

NIH Review and Approval (if study is Greater Than Minimal Risk or an NIH-defined Clinical Trial): July-August 2023

Earliest Start Date: 09/01/23