



The Pediatric HIV/AIDS Cohort Study (PHACS) Emerging Research Pilot (ERP) Program

Goal: To investigate new scientific questions arising during the course of [PHACS studies](#), as well as previously identified scientific questions, which align with the PHACS scientific agenda but were unable to be funded in the current grant funding.

The following are high priority areas for funding:

- Evaluating short and long-term effects of antiretroviral and HIV exposures
- Understanding biological mechanisms of antiretroviral therapy and its adverse outcomes
- The impact of social and structural determinants of disparities and/or inequities on the health of PHACS participants and their families
- Studies that result in actionable findings with the potential for an immediate impact on the community of people living with or affected by HIV

Eligibility: Pilot Program funds are intended primarily for PHACS-affiliated investigators seeking PHACS discretionary funds in order to advance the aims of PHACS network study protocols. Non-PHACS investigators may also apply, but at least one PHACS-affiliated investigator must be included on the proposal team, and data or samples that can be collected or have already been collected by PHACS sites must be used. For non-PHACS investigators, the PHACS Scientific Administrative Core (SAC) will work to execute collaborative agreements with other research networks or institutions, as appropriate. Applications may not include any foreign components (e.g. international investigators or institutions).

Funding and Budget: PHACS plans to offer initial funding or offer continued funding for projects in process for up to 3 awards which propose the use of PHACS data, specimens, and/or infrastructure. Individual awards will be under \$100,000 total (direct + indirect costs) per year for 1 or 2 years; this translates to approximately \$60,000 direct cost depending on institutional Facility & Administration costs. For 2-year awards, the 2nd year of funding will be contingent on progress in year 1. The budget may not include salary support for the lead investigator(s), but may include effort for research assistants or technicians.

The PHACS SAC will limit the number of active ERPs that involve subcontracts with the PHACS clinical sites. Those are typically projects that plan to collect new data from participants. We will aim to award no more than one new project per year of this type.

Period of Performance: Emerging Research Pilots are intended to be short-term projects. Therefore, the SAC will issue primarily 12-month awards but will also accept proposals planned for up to 24 months. The SAC will issue a combination of initial and continuation awards depending on the year of the project and the progress of the first year's project, if applicable.



Key Dates:

- Intent to Submit (name and affiliation of investigator and proposed title of research project) Due: Wednesday, February 1, 2023
- Applications Due: Wednesday, March 1, 2023
- Notification of Award: Monday, May 1, 2023
- Funding Start Date: Tuesday, August 1, 2023

Submission of Proposals: Proposals must be submitted to PHACS

(PHACS@hsph.harvard.edu) no later than 11:59 PM EST on Wednesday, March 1, 2023 with the subject line heading of “Emerging Research Pilot Application.”

Application Format: The application should utilize NIH proposed formats of margins no less than 0.5 inches, Arial 11point font, and single spacing. Other content and formatting details include:

I. Section A: Title Page (1 page):

- Study Title
- Applicant information, including names and contact information (institution, address, telephone, e-mail) of lead investigator(s) and co-investigators.
- PHACS Working Group(s) or Task Force(s) that lead investigator(s) belong to (primary and others) when appropriate.

II. Section B. Abstract

- Abstract of the proposal – 30 lines maximum

III. Section C. Research Proposal (maximum 8 pages):

Please include the following information:

- Background and significance
- Feasibility and relevance to PHACS [mission](#) and scientific agenda
- Major study objectives
 - Aims and hypotheses
- Study population
 - For each aim:
 - Include PHACS cohort(s) (e.g. SMARTT, AMP Up/Lite, etc.) or substudy (e.g. oral health, HPV) and inclusion and exclusion criteria. (Information about PHACS study and substudy protocols may be found on the PHACS website [here](#)).
 - Clinical site selection (include necessary and preferred criteria if not all sites will be included)
- Study design
 - For each aim:
 - Describe the study design (e.g. cross-sectional, longitudinal, case-cohort) and define exposure(s), outcome(s), potential confounders, effect modifier(s)
 - If new data will be collected (e.g. examination, surveys, laboratory assays) indicate proposed assessments and how they will be obtained



- If existing specimens will be utilized, please indicate which types and timepoints at which they were collected
- Analysis plan
 - For each aim, write an analysis plan including, but not limited to descriptive statistics and details for models that will be fit for univariable and multivariable analyses
 - Sample size/power calculations
 - For each aim, provide sample size, power calculations, or detectable differences for each main exposure on each outcome
- Study timeline, if appropriate, and estimated timeframe for completion of analysis
- Impact statement on public health:
 - Specifically, how the proposed research will have impact or potential impact on science, clinical guidelines, and/or patient care, as well as on the greater community of people living with or affected by HIV
- Resources required
 - Estimate of resources and time (FTE) needed by PHACS statisticians and/or epidemiologists (e.g. 10% of analyst time for 6 months). This does not require additional budgeting.
 - Training needs/capacity (data collection, assessments) if applicable
- Collaborating networks (if appropriate)
- Tables/Figures (if applicable)

IV. **Section D. Appendices:** The following items should be included as Appendices:

- Appendix 1: References
- Appendix 2: Applicant's NIH Biosketch
- Appendix 3: Letters of Support (1-2)
- Appendix 4: Budget and Justification: Using the attached templates, please provide a budget and justification for the entire funding period (total costs = \$ per year). If requesting more than 12 months of funding, submit separate budgets for each 12month period and a summary total.

The period of performance for applications will be 8/1/23 – 7/31/24. Project budgets should be less than \$100,000 total costs per year (see Funding section above). Please note any outside resources that are available to applicants that may contribute to the success of their project; e.g., institutional support, grant or foundation support. If the application is selected for funding, additional institutional budget and administrative documents will be required.

- Appendix 5 (as applicable): If the applicant is a lead investigator of an already approved PHACS capsule or concept, please describe how the investigator's time will be divided between the multiple projects and provide anticipated timelines for each.



The following criteria will be utilized in the review of applications:

- Importance of proposed research
- Clarity of presentation
- Feasibility
- Scientific merit and rigor of proposed research strategy and methods
- Potential for impact on science, clinical guidelines, patient care, or the greater community of people living with or affected by HIV
- Alignment with PHACS mission and the mission of one of the PHACS Working Groups or Task Forces: <https://phacsstudy.org/Our-Research/Areas-of-Focus>.
- Alignment with PHACS priority areas as stated above
- Likelihood of success in the funding period
- Appropriateness of the budget

Reporting Requirements:

- Awardees will be required to submit an interim research progress report by May 1, 2024.
- A final research and expenditures report will be required within three months after the end of the funding period.
- Awardees will be expected to present their progress during a PHACS network meeting.
- Investigators must acknowledge PHACS support and grant number P01 HD103133 on any publications resulting from the Emerging Research Pilot support.

Please contact PHACS@hsph.harvard.edu with any questions or for further information.