



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.

Eligibility: These Pilot Program funds are intended primarily for PHACS-affiliated investigators who wish to apply for PHACS discretionary funds, which were required to be made available by the PHACS grant RFA, in order to advance the aims of the PHACS protocols. Non-PHACS investigators may also apply, but at least one PHACS-affiliated investigator must be included on the proposal team, and data that can be collected by PHACS sites must be used. For non-PHACS investigators, the PHACS Scientific Administrative Core (SAC) will support collaboration or co-endorsement agreements with other research networks, as appropriate. Applications may not include any foreign components (e.g. international investigators or institutions).

Funding: PHACS plans to award between 1-3 (initial and continuation) projects for pilot studies using PHACS data, specimens, or infrastructure. Typically, individual awards will be under \$100,000 (total cost – 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). Applicants are advised to notify the SAC prior to submitting a proposal that totals more than \$100,000 (total cost) per year.

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: Applications due: February 1, 2022
Notification of Award: March 31, 2022
Funding Start Date: August 1, 2022

Submission of Proposals: Proposals must be submitted to PHACS (PHACS@hsph.harvard.edu) no later than 11:59 PM EST on Tuesday, February 1, 2022 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 11 point 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 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 scientific agenda
- Major study objectives
 - Aims and hypotheses
- Study population
 - For each aim:
 - Include PHACS cohort (e.g. SMARTT, AMP Up/Lite, etc.) or sub-study (e.g. oral health, HPV) and inclusion and exclusion criteria. (Information about PHACS study and substudy protocols maybe 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
- Analysis plan
 - For each aim, write an analysis plan including 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
- Scientific impact
 - A brief statement of the impact this sub-study or data analysis would have on science, guidelines, and/or patient care
- 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 C. 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 12 month period and a summary total.

The initial period of performance for this round of applications will be 8/1/22 – 7/31/23. Unless prior approval has been granted, 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 team leader or member of an already approved PHACS capsules or concepts, 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:

- Significance of proposed research
- Scientific merit and rigor of proposed research strategy and methods
- Feasibility and relevance to the PHACS mission and scientific agenda
- Likelihood of success in the funding period
- Feasibility of timeline
- Appropriateness of the budget

Reporting Requirements:

- Awardees will be required to summarize their research progress by May 1, 2023.
- 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 should 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.