I. PURPOSE

A major goal of the Pediatric HIV/AIDS Cohort Study (PHACS) network is the identification and evaluation of impactful scientific research questions related to the health of children born to mothers living with HIV across their lifespan, from infancy to young adulthood, along with health outcomes of their mothers and caregivers. To support this goal, PHACS has established this research development policy. The policy confirms PHACS's commitment to collaboration, equity, excellence, and timeliness in the review and conduct of scientific research. It also specifies that multiple stakeholders, including clinical and neuropsychological researchers, statisticians and epidemiologists, site coordinators, community representatives, and others affiliated with the PHACS network are all valued members of the research process. It ensures that the data generated in this project are available for comprehensive and rigorous analysis by both the PHACS investigators and their non-PHACS scientific collaborators.

II. GENERATION OF THE RESEARCH AGENDA

The PHACS research agenda is advanced by the development of research proposals by members of a PHACS scientific Working Group (WG) or Task Force (TF), which are reviewed and approved by the relevant WG and then by the Scientific Leadership Committee (SLC). The SLC also defines and implements the scientific agenda of the PHACS network by suggesting topic areas of importance and by reviewing and approving concept sheets (CS) for data analysisor substudies which require additional funding (e.g. grants or supplements). It also oversees the scientific productivity of the PHACS network. The SLC includes representatives from all stakeholders mentioned above, in order to inform and guide the research process. Both scientific and participant priorities drive the PHACS research agenda.

III. CAPSULE DEVELOPMENT AND REVIEW PROCESS

1. Capsule development

The first step in proposing a PHACS data analysis or substudy CS is for the lead investigator to develop a PHACS capsule, a brief description of the proposed research, which includes its significance, objectives, and feasibility (Figure 1). A capsule must relate to the current scientific research agenda of the PHACS-affiliated studies and substudies[1]. A PHACS capsule should be developed with the aim of producing a single manuscript, or at the most two manuscripts if based on a single set of analyses. Both PHACS and non-PHACS investigators may develop a capsule. In the latter case, the lead investigator will work with a PHACS investigator to develop the capsule. If the capsule is not already associated with a specific WG (or TF), the PHACS Data Resources Core (PHACS@hsph.harvard.edu) will identify the appropriate primary WG for the capsule and facilitate communication with the WG chairs. PHACS occasionally creates Task Forces (TFs) to focus on specific scientific objectives. While capsules may be developed within a TF, they must be reviewed and approved by the appropriate WG. If a capsule addresses the scientific agenda of more than one WG, the primary WG Co-Chairs should ask the other appropriate WG to provide a secondary review.

If the lead investigator is not an epidemiologist/statistician in PHACS, the lead investigator of the capsule must work with an epidemiologist/statistician in the PHACS Data Resources Core (DRC) early in the process of capsule development to ensure that the primary scientific objectives are clearly developed, the study design is appropriate, and that a brief preliminary feasibility assessment is incorporated. The WG chairs can help identify a DRC epidemiologist orstatistician, who is usually a member of the WG.

To familiarize themselves with the available data, investigators are encouraged to utilize the PHACS annual administrative and complications monitoring reports and the data collection instruments in the development of their capsule. These documents are accessible through the PHACS website[2]. If the lead investigator needs additional supporting data, they can discuss this with the epidemiologist/statistician or the WG Co-Chairs. The proposing investigator will be responsible for developing the capsule with input from the DRC epidemiologist/statistician and any other study team members. The proposing investigator is responsible for ensuring that all named co-investigators have agreed to participate and have reviewed the capsule before submission.

2. Capsule requirements

The text of the capsule (excluding cover page and references) should be no longer than 4 pages (excluding references) (8.5 x 11 inches, 0.5-inch margins, single-spaced, font no smallerthan Arial 11). The WG Co-Chairs will return a capsule to the lead investigator if it does not meet these requirements and needs shortening.

The capsule should include the following elements:

- Cover page, including
    - Study title
    - Lead investigator and co-investigators
    - PHACS primary WG, and TF or secondary WG if appropriate
- Background and Significance including a summary of the background literature
- Major study objectives
- Study population*
    - Inclusion and exclusion criteria
    - Estimated overall estimated sample size, commenting on feasibility
- For each aim
    - Brief study design (e.g. cross-sectional, longitudinal, case cohort)
    - Exposure and outcome measures
- Scientific, public health, and community impact
    - A brief statement of the impact this sub-study or data analysis could have 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
    - Funding source, if not PHACS
    - Estimate of resources and time (FTE) needed by DRC statisticians or epidemiologists (e.g. 10% of analyst time for 6 months)
- Collaborating networks (if relevant)
- Key references (not included in page count)

*Note: The capsule does not need an analysis plan or formal sample size/power calculations unless it is a methods proposal

3. Capsule Submission

The proposing investigator submits an electronic version of the completed capsule to the chairs of the primary WG. Capsules that address the objectives and/or outcomes of several WGs should be submitted to one or more secondary WGs either at the same time or after review in the primary WG. When the capsule is submitted to the primary WG Co-Chairs, the lead investigator should include a list of ongoing PHACS concept sheets on which they are the lead investigator and provide a projected timeline for completion to ensure that the investigator has the necessary time to devote to all of their projects.

4. Capsule Review Process

The Co-Chairs of the WG will receive the capsule and after preliminary review, they may 1) reject the capsule if it does not fit into the PHACS Scientific agenda or does not meet length/formatting requirements; 2) request a revision of the capsule; or (3) proceed with a review of the capsule at a WG group meeting. If approved for review, the WG chairs will assign two reviewers, one clinical and one methodologic, usually from the WG to review the capsule. The proposing investigator will present a brief (10-15 minute) summary of the capsule on a WG call and the two reviewers will each present their brief review (5-10 minutes) followed by a groupdiscussion. The HECC Director and Associate Director are added to all WG email listservs to benotified about WG calls when capsules will be discussed, so that the HECC leadership can attend the call. After the call, WG Co-Chairs will send out a ballot to the WG members. A capsule is approved by majority of votes cast. In some cases, the WG Co-Chairs may decide that scientific input from another WG is advisable, especially if the expertise on the outcomes and/or main exposures are in another WG. Investigators who submit similar capsules will be encouraged to work together. If the capsule has also been submitted to a secondary WG, the Co-Chairs of the secondary WG will decide if a formal review and vote are necessary. They should share all written reviews with the primary WG Co-Chairs and the lead investigator. After the capsule is approved the lead investigator will receive the Concept Sheet checklist (Appendix1). Although the opportunity for discussion of a capsule on a WG call is strongly encouraged, in rare cases in which there is a time constraint or scheduling difficulties, WG Co-Chairs maychoose to have a capsule reviewed by WG members by email.

5. **Capsule sent to Health Education and Community Core (HECC) and Epidemiologic and Statistical Methods Core (ESC)**

After the primary WG approves the capsule (and after input on a secondary WG call if applicable), the lead investigator will complete the ESC/HECC Design Review form directly on the PHACS website and upload the approved capsule[3] within one week of capsule approval by the WG. When an author submits the ESC/HECC Design Review form, it will be forwarded to the HECC leadership (Director and Associate Director) and to the ESC Leadership for review. Both the HECC and the ESC should send their reviews to the proposing investigator and the Co-Chairs of the primary WG within 2 weeks of the capsule being uploaded to the website.

HECC review of approved capsules: The HECC, including members of the Community Task Force, will provide a written review of all capsules according to an established checklist of criteria (Appendix 3). The HECC leadership may offer the lead author (or the lead author may request) an opportunity to present the capsule on an HECC Core call or to send a summary (written or video) in lay language about the proposed research. In those cases, the HECC leadership will support the author in creating a list of questions to get feedback on issues important for the community perspective. The HECC and/or Community Task Force review may include the following: relevance of study aims for community members' lives and alignment with PHACS' mission; appropriate contextualization of research topic with regards to social and structural determinants of health; clarity of personal, social, and structural factors that race, sex, and gender identity are proxy for; additional co-variates or confounders to consider; potential limitations of data; inclusion of the full spectrum of PHACS participants or justification if not; the burden of new proposed data collection (if any) on study participants and clinical site staff; and a community ranking of priority of the proposal. The HECC review will be summarized in written form by HECC Leadership and sent to the originating WG Co-Chairs and lead investigator within 2 weeks of the capsule being uploaded to the website in order to be considered in the development of the CS.

ESC review of approved capsules: The ESC Leadership will review the submitted capsule and email the investigator with any comments on the capsule and to advise whether it should goto the full ESC. This should occur within two weeks of the capsule being uploaded to the website. If the lead investigator is requesting specific methodologic expertise, the lead investigator along with the capsule statistician/epidemiologist can arrange a phone conversationwith the ESC Leadership to discuss design and analytic issues (phacs.esc@fstrf.org). ESC leadership may also propose a discussion at an ESC Design Review meeting.

ESC Design review meetings take place monthly with additional meetings scheduled as needed. All members of the ESC and the lead proposing investigators will be encouraged to attend and provide input as part of the design review. Online meeting platforms will be utilized toensure a collaborative discussion among researchers at diverse locations. The design review will involve a discussion of the study objectives and the planned design and analyses. It will focus on broad areas such as identifying the most efficient design to address study objectives, selecting valid analysis techniques, identifying supplementary or sensitivity analyses to ensure that results support study conclusions, and identifying important study limitations. The ESC mayidentify the need for novel analytic methods (e.g. machine learning, bioinformatics, and causal inference). ESC staff from the HSPH Bioinformatics and Microbiome Analysis Cores will attend design

review meetings when needed and inform studies with high dimensional –omics data. They will inform study design and analyses and identify validated end-to-end bio/microbiome informatics tools, large-scale visualization methods, and computing requirements. The design review will result in a clear plan for the development of concept sheets. If the capsule team does not yet have a methodologist with needed expertise, the ESC can assign someone who would take part in the analysis and be included as a co-author on the manuscript.

IV. CONCEPT SHEET (CS) DEVELOPMENT AND REVIEW PROCESS

1. Concept sheet timeline

Once the primary WG approves a capsule, the proposed study moves to CS development. In order to most efficiently use PHACS analytic resources, a PHACS concept should be developed with the aim of producing a single manuscript; on occasion, a single set of analyses may result in a maximum of two manuscripts. In general, development of a CS should take no more than four months after the capsule is approved (Figure 1).

2. Concept sheet requirements

In addition to the elements included in the capsule, the CS will include more detail on the study design, a complete analysis plan, sample size calculations, estimation of time for analytic support, and a budget when requesting discretionary funding from PHACS, if available, or when applying for PHACS Emerging Research Pilot funding. When writing the CS, the lead investigator should assemble the full research team (See #4. Below) and consider the reviews by the WG(s), TF, ESC, and HECC. They are encouraged to schedule a meeting with the HECC if they need clarification or wish to discuss issues raised in the review at phacs.hecc.leadership@fstrf.org. If the team needs additional assistance on any design or analytic issues, which may also include novel design issues, new analytic methods, or high dimensional data analysis, the epidemiologist/statistician and the lead investigator can contact the ESC for input phacs.esc@fstrf.org.

The CS document should be formatted as 8.5 x 11 inches, 0.5-inch margins, single-spaced, witha font no smaller than Arial 11. While there is no page limit, CS are typically 7-10 pages excluding references. When writing a CS in the format of a grant, this length can be extended tothe standard page limit for the grant mechanism. For example, R01 grants are typically up to 13 pages for specific aims and research strategy.

The CS should include the following elements:

- Cover page including
  - Study title
  - Names of the lead investigator(s) and co-investigators with authorship order for first, second and last
  - PHACS Primary WG and TF or other WG when appropriate
- Background and significance including a summary of the background literature
- Major study objectives

- Aims and hypotheses

- Study population
  - For each aim:
    - Include PHACS cohort (e.g. SMARTT, AMP Up/Lite, HOPE, etc.) or substudy (e.g. oral health, HPV) and inclusion and exclusion criteria
    - Clinical Site selection (include necessary and preferred criteria if not all sites will be included. (See section 6 below)

- 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, etc.) indicate proposed assessments and how and where will be obtained

- Analytic section
  - 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

- Accrual timeframe, if appropriate, and estimated timeframe for completion of analysis

- Timeline, milestones and deliverables

- Scientific, public health, and community impact: A discussion of the impact this sub-study or data analysis could have 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
  - Funding source, if not PHACS
  - Estimate of resources and time (FTE) needed by the statisticians and/or epidemiologists (e.g. 10% of analyst time for 6 months)
  - Training needs/capacity (data collection, assessments) if applicable
  - Budget with justification when requesting discretionary funding from PHACS, PHACS Emerging Pilot Research funds, or indication if outside funding will be sought (e.g. R01)

- Collaborating networks (if appropriate)
- Key references

3. Lead investigator responsibilities

The lead investigator is responsible for conceptualizing the CS, including contextualizing the significance of the study, defining the study question(s) and associated hypotheses, and conducting a review of the literature. The lead investigator will schedule and lead calls with the writing team to develop, refine, and finalize the CS, taking into account the suggestions from the team members, and the WG, HECC, and ESC reviews. They will also write the first draft of the CS, with the epidemiologist/statistician contributing to the study design and power calculation sections.

4. Team members

In addition to the team members listed on the capsule, the lead investigator may add additional members to the team. The CS must include an epidemiologist/statistician from the DRC (if not the lead), interested members of PHACS, and others as appropriate, it is recommended that at least one site coordinator and one CAB member is included on the writing team. Additional CS team members outside of PHACS may include an investigator with expertise in specific clinical or conceptual areas, including laboratory expertise, exposure or outcome assessment, study design, or analytic methods (e.g. the use of causal modeling, high dimensional data analysis).

5. Subset of PHACS clinical sites

If the proposed study will be using a subset of the PHACS clinical sites, particularly for a grant submission, the CS should include site selection criteria (both necessary criteria and preferred criteria).

- Minimum and maximum number of sites and number of participants per site
- Specific participant populations (e.g., school program, specialty clinic)
- Availability of specific testing (e.g., functional MRI)
- Staffing and site requirements (existing staff expertise and availability, space, capacity, funding needs for additional staff)
- Existing site partnerships or facilities; (e.g. locale, etc.)

6. Concept Sheet Submission and Review by the Working Group(s) (WGs)

After the final version of the CS is approved by the CS writing team, the lead investigator will send the CS to the WG Co-Chairs for review. Generally, this will be the WG in which the capsule was developed (primary WG). Feedback can also be requested by the CS team from a secondary WG as well, without need for a formal review and/or a vote. The Primary WG Co-Chairs will select one clinical and one methodologic reviewer, generally from the WG and often

the same reviewers of the capsule, to provide a brief written review of the CS. Subsequently, the lead investigator and the reviewer(s) will each give a brief presentation on a WG call followed by group discussion. A ballot to approve the CS will be sent to WG members after the call; a majority of votes cast is required for approval. For concepts initially developed within a Task Force (TF), reviewers may be drawn from among TF members, but each CS must be formally reviewed and approved by the primary WG. If the CS is not approved and requires further revisions, the lead investigator will resubmit the CS to the WG after making the appropriate changes with team input. Although providing an opportunity for discussion of a CS on a WG is strongly encouraged, in rare cases in which there is a time constraint or scheduling difficulties, a CS may be reviewed by WG members by email at the discretion of WG Co-Chairs.

7. PHACS related grants and supplements

If the investigator is planning to submit a grant (e.g. to NIH, a private foundation, a pharmaceutical company, etc.) or a supplement to the PHACS P01 or HOPE for the intended research, the format of the CS can be written in the format of a grant/supplement application as long as it contains all of the elements of a CS as described above. If not already included as part of the grant, a separate attachment should indicate PHACS resources required for completion of the grant aims.

The grant draft must be approved by the WG as a CS prior to submission to the funding organization. Ideally the grant will be reviewed by the SLC prior to submission to the funding agency. However, if there are time constraints a letter of support may be provided by the PHACS Leadership noting that final support is contingent on SLC approval.

8. Concept Sheet Submission and Review by the SLC

Once the CS is approved by the WG and requested revisions made, the lead investigator will send the CS and the Concept Sheet checklist (Appendix 1) to the Scientific Administrative Committee (SAC) (PHACS@hsph.harvard.edu). The checklist reminds the lead investigator to include specific elements in the CS, including PHACS resources required, any new data collection or testing, use of repository samples, and outside collaborations, and to address any time constraints (e.g. grant application, dissertation, etc.). The CS must be received by the SAC at **least 21 working days** prior to an SLC conference call (which generally occur 1-2 times per month). The investigator will receive an email from PHACS@hsph.harvard.edu indicating the date on which they will present the CS to the SLC. The selected presentation date will depend on the SLC agenda.

The SAC will select a clinical and a methodologic reviewer (Appendix 2). Each of these two reviewers will score the CS on scientific merit, public health impact, and research advantage of PHACS. Scores range from 1 (highest) to 5. The SAC will additionally ask for a third review from the HECC, which will solicit input from its members (Appendix 3). The reviewer will score the CS based on feasibility to participant and site staff, impact of proposed research on people living with or affected by HIV, and the priority PHACS community members have given the topic.
Scores range from 1 (highest) to 5. On the SLC call, the lead investigator or their alternate will give a brief presentation (~10 minute) summarizing the CS using the SLC Concept Sheet Presentation Template[4]. Each reviewer will be allotted 5 minutes. The lead investigator will respond to reviewer comments, and then the session will be open for general discussion. The

CS will have been distributed to all SLC members for review at least 5 days in advance of the SLC call so that a robust discussion is possible. The WG Co-Chairs may also comment on the CS.

A ballot will be sent after the call to SLC voting members and a decision will be made upon receipt of votes from a quorum of SLC voting members (at least two-thirds must submit votes). When a quorum is attained, the CS will be approved if at least two thirds of the SLC members who submitted a ballot, after excluding abstentions, voted to approve the CS. Each SLC voting member will also include prioritization of the concept sheet based on the overall PHACS Scientific agenda (high, moderate, low). The SAC will notify the lead investigator and the primary WG Co-Chairs of the ballot result, generally within ten working days of the SLC call. With approval by the SLC to begin the project, the SAC will send the lead author a copy of the PHACS Publication Policy. The lead investigator will be required to acknowledge receipt of the policy by email to the SAC and agree to abide by the timeline and the policy. If the CS is for a grant or supplement, the investigator must obtain a letter of support from the PHACS Leadership Group.

9. Initiation of PHACS Concept Sheet Analyses

The date of initiation of analysis for the CS will be set by the DRC with input from the SLC reviews and prioritization will be based on the following criteria.

- Urgency of the study question and whether it addresses the primary aims of PHACS Importance
- Workload of epidemiologists/statisticians/analysts
- Complexity of the analysis
- Level of network resources required

10. Amending Previous Concept Sheets

There are times when an amendment to an existing CS must be submitted to the WG and the SLC for review, generally pertaining to CSs approved several years ago for which an initial manuscript was already published. The investigator may submit an amendment to complete analyses on the remaining aims or they may wish to make modifications to the existing aims. They must contact the WG chairs to discuss whether the remaining aims or modifications are relevant to the current WG's scientific agenda. If they are, the investigator will develop a written amendment in the form of a CS with the same elements as any CS, referring back to the approved CS. The title of the amendment should include the original CS number. This will be reviewed by the WG as with any other CS. Once the CS amendment is approved by the WG, the amendment is sent to the SAC (PHACS@hsph.harvard.edu) to relay to the SLC for review and vote. When submitting the amendment, the investigator must include both the original concept with the new additions highlighted, plus the amendment itself.

If the investigator wishes to add aims to an existing CS that are not related to the original aims,it is best to submit a new capsule and CS following the previously mentioned guidelines.

V. OWNERSHIP OF THE RESEARCH AND SPECIMEN USE

The PHACS Scientific Leadership Committee (SLC) will retain custody of and have primary rights to PHACS data and specimens during the life of the award and for two years following the termination of the PHACS network, subject to government rights of access consistent with current NIH policies. The SLC not only holds the rights to the PHACS intellectual property, but also is the controlling body of resources within PHACS. Any proposal to use data generated by a PHACS-affiliated study protocol must be approved by the SLC. In addition, use of specimens generated by a PHACS-affiliated study protocol must be approved by the Operations Committee(OC), unless the proposal concerns the use of the last remaining specimen of a particular type for a participant or requires additional funding, in which case the Leadership Group (LG) must review and approve.

Data use and material transfer agreements: For collaborative studies initiated outside of PHACS, or for which the analysis will be conducted outside of the Data Resources Core (DRC), the DRC will negotiate any PHACS rights to data and authorship with the executive bodies of collaborating networks or studies or with collaborating investigators external to PHACS. A Data Use Agreement (DUA) and/or a Materials Transfer Agreement (MTA) will be executed prior to study initiation as needed. The HSPH Office of Sponsored Programs Administration (SPA) will support the creation, negotiation and execution of any DUAs. MTAs will be drafted and executed in collaboration with the Harvard Office of Technology Development (OTD). For thosewith questions about the DUA or MTA process, please contact the DRC via PHACS@hsph.harvard.edu.

Sharing data from PACTG and/or IMPAACT studies: For PHACS participants who were previously enrolled in PACTG/IMPAACT studies, participant consent to share data between PACTG/IMPAACT and PHACS is requested as part of the PHACS consenting process. An agreement pertaining to the sharing of data from multiple PACTG/IMPAACT protocols with PHACS is in place. PHACS has oversight of the 219/219C database and all repository samples. Proposals which utilize only 219c data and/or repository specimens do not need approval by IMPAACT. However, proposals that use data and/or repository specimens from both 219/219C and another PACTG/IMPAACT study require approval by both PHACS and IMPAACT.

VI. REFERENCES

1 PHACS Website After logging in, go to Documents/Study Documents, and then select the study folder

2 PHACS Website After logging in, go to Documents/Study Documents, then select the study folder (e.g. SMARTT, AMP Up Series), and go to Study Reports for the available Administrative and Complications reports

3 PHACS Website After logging in, go to Our Research/Resources for Researchers, and then click the link ESC & HECC Design Review Form

4 PHACS Website After logging in, go to Documents, then Analyses/Templates and Guidelines, and select SLC Concept Sheet Presentation Template

VII. INQUIRIES

For questions, please email phacs.pm@fstrf.org

FIGURE 1: Capsule and concept sheet development and recommended timeline

DELIVERABLES	PROCESS	TIMELINE
CAPSULE	Lead Investigator develops & sends capsule to WG Co-Chairs Working Group (WG) reviews and approves capsules Lead Investigator sends approved capsule to HECC/ESC	No timeline " w/in 1 week
CONCEPT SHEET (CS)	Lead Investigator: • Develops CS with team • Works with Stat/epi • Incorporates HECC comments • Works with primary WG to review/approve CS • Sends CS to SLC for review • Presents CS on SLC • Addresses SLC comments	≤4 months since capsule approval
LAB TESTING & DATA REVIEW	Conducts lab assays	Varies
	Analysis Team checks data quality and sends queries	1-2 months
PRELIMINARY ANALYSIS REPORT	Analysis Team: • Performs preliminary data analysis • Sends preliminary report to lead investigator	≤4 months from data availability
FINAL DATA ANALYSIS REPORT	Analysis Team: • Performs final data analysis • Sends final report to lead investigator and team	≤4 months from prelim. report
FIRST DRAFT MANUSCRIPT	Lead Investigator: • Works with writing team to write first draft of manuscript • Additional analysis may be required.	≤3 months
FINAL MANUSCRIPT	Lead Investigator: • Incorporates team comments and finalizes manuscript • Receives approval from team of final manuscript • Writes participant summary	≤2 months
PUBLICATIONS COMMITTEE (PC) REVIEW	Lead investigator: • Sends final manuscript, author checklist & participant summary to PC	
	Publications Committee Review: • Approves and gives recommendations/comments	10 Working Days
MANUSCRIPT SUBMISSION TO JOURNAL	Lead investigator submits manuscript to journal	

APPENDIX 1

PHACS CONCEPT SHEET AUTHOR CHECKLIST

Concept Sheet Title:
Lead Author:
Working Group(s):
Date concept sheet submitted to phacs@hsph.harvard.edu:

Note: The information you provide below will be used by the Scientific Leadership Committee during the review yourconcept sheet. Please click on the checkbox next to your chosen responses. Submit your concept sheet and the completed checklist to **PHACS@hsph.harvard.edu**.

Resources Required:

☐ Please confirm that the concept sheet includes an estimate of Harvard biostatistician/epidemiologist resources required (e.g. 10% of a statistician for 3 months).

New data collection or testing

Does the concept sheet propose the collection of new data or testing of repository samples?

☐ No
☐ Yes → Please confirm:
  ☐ The concept sheet includes a budget and budget justification for the PHACSresources required to conduct the study.
  ☐ The budget indicates the proposed source(s) of funding (i.e. whether theauthor will pursue external funding or is requesting support from PHACS).

Repository Samples:

Does the concept sheet require specimens from the PHACS repository?

☐ No
☐ Yes→ Please confirm:
  ☐ The concept sheet clearly states the type and number of specimens
  ☐ required.
  The concept sheet indicates where testing of the samples will be conducted(a material transfer agreement (MTA) and/or Data Use Agreement (DUA) will be required).

Collaborations:

Is the concept sheet a collaborative project with individuals, networks, or laboratories outside ofPHACS?

☐ No
☐ Yes→ → Please confirm:
  ☐ The concept sheet states whether the writing team proposes to have some orall of the data analyses conducted by individuals who are not based at the PHACS DRC

☐ The concept sheet states whether a DUA is required?

Timeline:

☐ Are there any time constraints for the proposed analysis and publication (e.g. preliminary data needed for a grant application, dissertation or thesis)? If so, include a proposed timelineand note external deadlines.

APPENDIX 2

CRITERIA FOR CLINICAL AND METHODOLOGICAL REVIEW OF PHACS SCIENTIFICLEADERSHIP COMMITTEE CONCEPT SHEETS AND PROTOCOLS

When reviewing a concept sheet (CS)/protocol please comment on the following elements of the study listed below, particularly if you have concerns. For CS, provide an overall score in each of the areas, including scientific merit, public health impact, and research advantage of thePHACS group.

Elements of the study

- **Aims and hypotheses** – Clearly defined and relevant
- **Inclusion and exclusion criteria** – Specify an appropriate population.
- **Participant selection** – Appropriate for the aims
- **Exposure(s)** – Clearly defined and appropriate
- **Covariate(s)** – Relevant covariates selected accompanied by clear descriptions
- **Outcomes** - Readily measurable, clinically relevant, and sensitive to the exposures.
- **Stratification procedures/effect modification** (if applicable) – Clear justification anddescription
- **Follow-up** Proper duration of follow-up for a clinically relevant assessment of outcomes.
- **Sample size** - adequate to detect differences between groups that are clinically relevant.
- **Statistical methods** – Appropriate for proper estimation and inference.
- **Monitoring outcomes and safety data** - Proper procedures for monitoring outcomesand safety data to safeguard participants' confidentiality and trial integrity.
- **Safety and ethical** – Appropriate consideration of safety and ethical issues
- **Budget** - Budget is appropriate and reasonable (if applicable).

Overall scores for CS: Please give an overall score for each of the following criteria (score 1-5,1 is the highest rating with few concerns):

Scientific Merit	• Are the hypotheses scientifically sound and answerable by the proposed design? • Will the study design yield the proposed outcomes? • Is the population appropriate for the research? (See Elements of Study Design above)
Public Health and/or Community Impact	• What is the relevance of the concept to our understanding of the problem, and does it lead to advances in management? • What is the feasibility of implementation? • What is the value added to the field, e.g., existing interventions and unmet need? • What is the acceptability by the community?

Research Advantage of the PHACS group	• Does the proposed research benefit from a multi-site, multi-disciplinary collaboration? • Is it likely that the proposed research could be more efficiently conducted outside PHACS?

APPENDIX 3

CRITERIA FOR HECC REVIEW OF PHACS SCIENTIFIC LEADERSHIP COMMITTEE CAPSULES AND CONCEPT SHEETS

Please comment on the elements noted below, particularly if you have concerns:

1. How feasible are any participant-facing aspects of the proposed research, suchas proposing new data collection? What is the time, mental, and/or emotional burden on participants?
2. Is the proposed research investigating a sensitive topic (i.e., stigma, racism,violence, mental health, etc.), and what are ways to protect participants frompotential harms?
3. If data was already collected, are there potential limitations to be aware of (i.e.,limitations of a survey about a stigmatized topic administered by a person vs acomputer, etc.)?
4. What would be the impact of the proposed research on the lives of people livingwith or affected by HIV?
5. Are there additional co-variates or confounders that should be considered ascorrelates or alternative explanations for outcomes?
6. Does the background sufficiently consider and contextualize the potential independent or combined influences of social and/or structural determinants ofhealth, if appropriate?
7. If race, sex, and/or gender identity are included as primary exposures or variables to control for, has the author offered appropriate justification and clearly defined the individual, social, or structural variables that they are a proxy for?
8. Do the proposed research aims align with or depart from the lived experiences of community members? Are they reflective of the mission and values of PHACS? What changes could help bridge any potential gaps?
9. Are all subgroups of participants included? If not, are exclusion criteria justified sufficiently?
10. Has the author offered explicit language to describe populations PHACS works with (i.e., avoiding coded language such as “at-risk youth,” and making the specific risk exposure explicit)? What insights or adjustments to language, if any,can the HECC and Task Force offer?

Overall comments:

Community Task Force Comments (Without Names, Clinical Site Indicated:

Please give an overall prioritization score using the following criteria (score 1-5, 1 best):

HECC Priority	• What priority have PHACS community members given this topic? • Does the proposed work seem feasible from a participant and site staff perspective? • What impact will the proposed research have on the lives of people living with or affected by HIV?