PHACS Publication Policy
(08/06/19)

I. PURPOSE

A major goal of the Pediatric HIV/AIDS Cohort Study (PHACS) is the dissemination of study findings through high quality presentations and publications. To realize these ends, PHACS has established this publication policy. The policy confirms PHACS's commitment to collaboration, equity, excellence, and timeliness in the publication of study findings and deliberations. It ensures that the data generated in this project are available for comprehensive and valid analysis by both the PHACS investigators and their non-PHACS scientific collaborators.

II. OWNERSHIP OF THE RESEARCH

The PHACS Scientific Leadership Group (SLG) will retain custody of and have primary rights to PHACS data and specimens during the life of the award and two years subsequent to the PHACS's termination, subject to government rights of access consistent with current HHS and NIH policies. Whereas the SLG holds the rights to their intellectual property, the PHACS Executive Committee (EC) is the controlling body of resources within PHACS. Both the SLG and the EC will work in tandem regarding the data developed and its usage. Any proposal to use data generated by a PHACS study protocol must be approved by both the SLG and the EC.

For collaborative studies initiated outside of PHACS, the Data and Operations Center (DOC) 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 Memorandum of Agreement (MOA) or a data sharing agreement will be executed prior to study initiation. The PHACS EC will review and approve any such MOA/data sharing agreement.

For PHACS participants who were previously enrolled in PACTG/IMPAACT studies, participant consent to share data between PACTG/IMPAACT and PHACS has been requested as part of the PHACS consenting process. A data transfer agreement pertaining to the transfer of data from multiple PACTG/IMPAACT protocols to PHACS has been secured (PACTG/IMPAACT protocols to PHACS). PHACS has oversight of the 219/219C database and all repository samples. The 219c repository is a unique asset, with many samples obtained prior to the HAART era. Proposals which utilize 219c data and/or repository specimens do not need approval by IMPAACT unless IMPAACT data and/or specimens are also included. The PHACS/219C Steering Committee will review all proposals utilizing 219c data and/or repository specimens and may submit an evaluation and recommendation to the reviewing committees. The PHACS Coordinating Center will provide a copy of such proposals to the PHACS/219C Steering Committee prior to the scheduled reviews.

III. RESEARCH AGENDA DEVELOPMENT AND APPROVAL

1. Generation of the Research Agenda

The functions of the Principal Investigator (PI) of the Coordinating Center (CC), as Chair of the SLG, include identifying, in conjunction with the EC and the SLG, the key topic areas and directions for the study, determining the best approaches to addressing them, ensuring that the resources are available to answer them and overseeing the scientific productivity of the study. In conjunction with the PI of the DOC, the PI of the CC will ensure the highest quality and rigor of the scientific performance of the study and oversee site performance. The PI of the CC will serve as chair of the EC and the SLG, and will direct the activities of the CC.

2. Priority of Analyses

The EC is the final arbiter of the order in which PHACS analyses occur following recommendations of the SLG. In making this judgment, the EC will consider:

- the importance and urgency of the study question,
- the input from the PHACS working group (WG) chairs regarding workload
- the input of the DOC regarding the complexity of the analysis, and
- the level of network resources required.

IV. ANALYSIS AND MANUSCRIPT DEVELOPMENT AND TIMELINE

This section details the steps involved in the process of proposing a substudy or data analysis within PHACS and producing a manuscript for publication. These steps are outlined in Figure 1.

1. Study Capsule

Proposals may be submitted by PHACS investigators as well as non-PHACS investigators; non-PHACS investigators must work closely with one or more PHACS investigators in the development of their proposal. The proposing investigator(s) develops a Study Capsule, a brief description of the proposed research with objectives.

The text of the capsule (excluding cover page and references) can be no longer than 3 pages (8.5 x 11 inches, 0.5-inch margins, single spaced, font no smaller than Ariel 11. Capsules that don't meet these requirements will be returned to the author. If the lead investigator has a previously approved capsule/concept sheet, their progress in producing the final manuscript in a timely manner (according to the timeline in the Publications Policy) will be considered in the review of the new capsule. On the cover page, the lead investigator should discuss their plan (and timeline) for finishing any uncompleted work.

The capsule should include the following elements:

- Cover page
    - Study title
    - Lead investigator and co-investigators
    - PHACS Working Group
- Major study objectives
- Significance
- Study population
- Exposure and outcome measures
- Analysis plan and estimated sample size required (e.g., 20-40 or >100; a formal sample size calculation not required)
- Resources required
    - Estimated budget and funding source
    - Estimate of resources and time (FTE) needed by CBEAM statistician
- Collaborating networks (if appropriate)
- Scientific Impact
    - Please include a brief statement of the impact this sub-study or data analysis would have on science, guidelines, and/or patient care
- References

The lead investigator should work with a DOC epidemiologist/statistician early in the process of developing a capsule. The DOC epidemiologist/statistician can help ensure that the primary scientific objectives are clearly developed, the study design is appropriate, and that a brief preliminary feasibility assessment is incorporated. It also allows PHACS to identify the appropriate statistical and epidemiologic leaders early in the process. The proposing investigator is responsible for ensuring that all named co-investigators have agreed to participate and have reviewed the capsule before submission. If you are not able to identify a DOC epidemiologist/statistician prior to submitting the capsule, the WG co-chairs will identify one for you if the capsule is approved.

For a capsule to move forward for Concept Sheet (CS) development, it must relate to the current scientific research agenda of the PHACS protocols. All investigators are encouraged to utilize the PHACS monitoring, administrative, and surveillance reports as much as possible in the development of their capsule. If additional preliminary analysis and data are needed, the proposing investigator should contact the WG co-chairs and epidemiologist/statistician if identified, who will aid with additional analytic and design assistance. The proposing investigator will be responsible for developing the basic study objectives, significance and background literature to enable the WG to determine if the capsule should move ahead to a concept sheet.

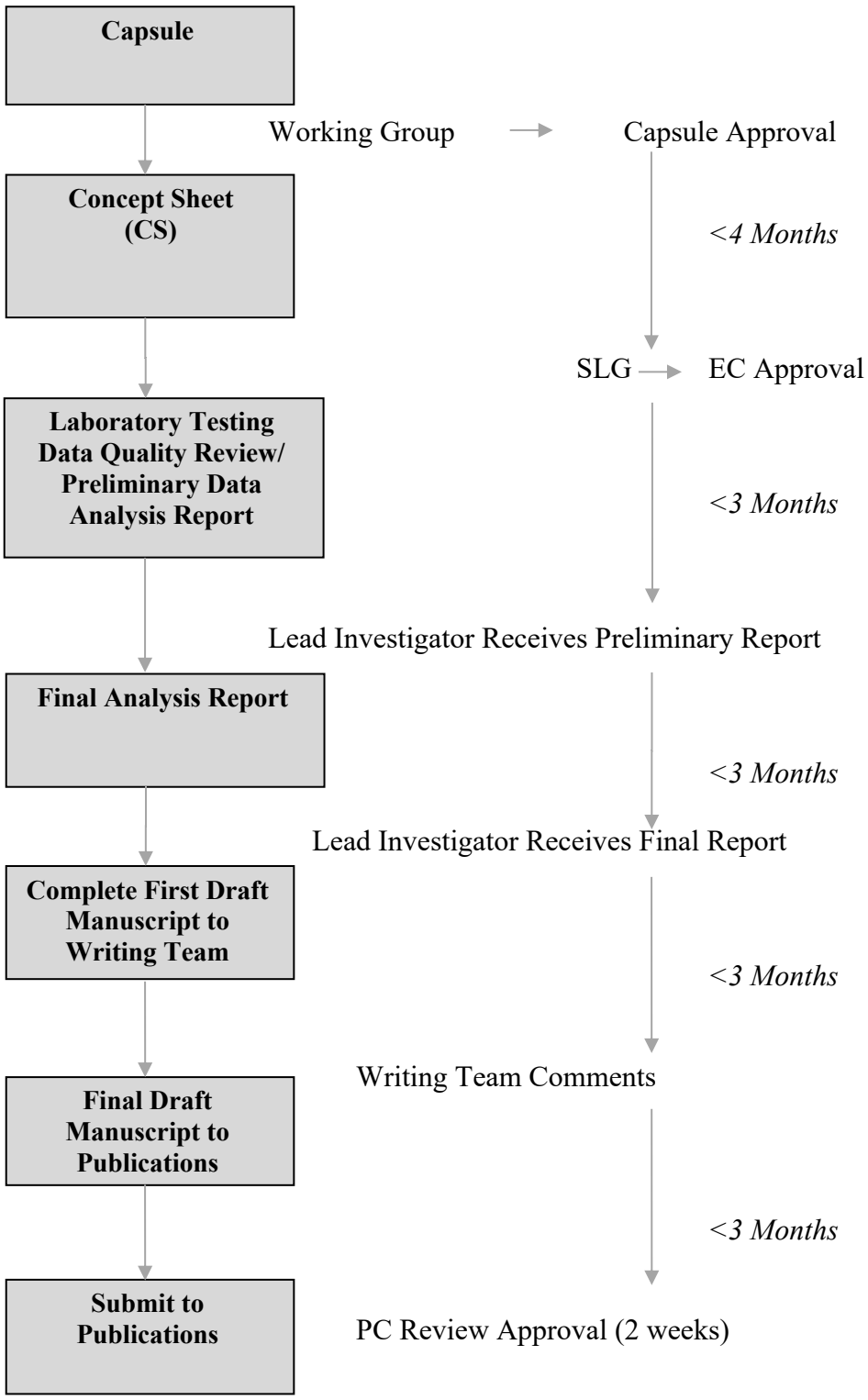
Capsule Review Process:

1. The proposing investigator submits the capsule to the chairs of the appropriate WG (PHACS Working Groups) in electronic form, copying the CC (PHACSCC). Capsules which address the objectives and/or outcomes of several WGs should be submitted to all appropriate WGs. One will be designated as the lead WG by the WG chairs.
2. The chairs of the WG receive the capsule and after preliminary review may 1) reject the capsule; 2) request revision of the capsule; or (3) request a review and vote by the WG for approval. The proposing investigator presents the capsule on the WG call and the WG votes on it. A capsule is approved by a majority vote of voting members. In some cases, the WG may indicate that scientific input from another working group is advisable, especially if the expertise on the outcomes and/or main exposures are in another working group. Investigators who submit similar capsules will be encouraged to work together. Upon approval, the WG chairs will submit the approved capsule as a concept sheet and its appropriate reviews to the CC (PHACSCC).

2. Concept Sheet (CS)

Once the WG approves a capsule, the study moves to CS development. In general, the development of a CS should take no more than four months to complete (Figure 1). It will generally follow the same outline recommended for a capsule but will include greater detail, particularly regarding the study design, the data analysis plan, sample size calculations, and budget. Please see **APPENDIX III** entitled "Development of a Protocol Concept Sheet (PCS) or Data Analysis Concept Sheet (DACS)."

FIG 1: MANUSCRIPT DEVELOPMENT TIMELINE*



** The guidelines may change subject to the need for additional laboratory testing, the need for any additional data collection or verification, or the workload of the DOC.*

The lead author will establish a CS writing team to include the second author (generally the epidemiologist/statistician) and senior author, as well as other interested members identified as the capsule was approved. Please see **APPENDIX I/II** for a summary of first author and co-author responsibilities. The WG co-chairs can assist in identifying an epidemiologist/ statistician if one is not already involved. Additional CS team members may be encouraged to participate to address deficiencies in expertise identified as CS development progresses, including expertise in specific clinical or conceptual areas, exposure or outcome assessment, study design or analytic methods (e.g. the use of causal modeling).

The lead author is responsible for conceptualizing the CS, including defining the study question(s) and associated hypotheses and conducting a review of the literature. The lead investigator will also write the first draft of the CS, with the epidemiologist/statistician contributing to the analysis and power calculations sections. In addition, the lead author (with assistance from the CC) will set up calls of the writing team. All team members should be named in the CS at this point.

Once the CS has been approved by the CS writing team, the lead author should send it to the appropriate WG for review. The WG will discuss the CS and vote on it. Once WG approval is obtained, the CS should be sent by the lead investigator to the CC (PHACSCC) for SLG review. The submission should include the Concept Sheet checklist. Please see **APPENDIX VII** entitled "PHACS Concept Sheet Author Checklist." The PHACS Coordinating Center will let the investigator know the date it will be reviewed by the SLG. The CS will be reviewed by the SLG on their next call, if possible, provided it is received at **least ten working days** before the SLG conference call (2nd Monday of each month). The lead author must join the call to summarize the CS and answer questions regarding the reviews. A ballot will be sent after the call to the SLG voting members and decision will be made by a majority of votes cast. The vote will also include prioritization score of the concept sheet.

A CS that is approved by the SLG must also be reviewed by the EC. EC approval is by a majority of votes cast, with particular consideration given to the budget. Additionally, the EC

will determine the prioritization of the CS among all approved concept sheets. The CC will convey the priority score to the WG chairs and how the CS fits into the existing workload.

The CC will notify the lead author of the results of both the SLG and EC votes within seven working days of the EC call. With approval by the EC to begin the project, the CC will send the lead author a copy of the PHACS Publication Policy. The lead author will be required to acknowledge receipt of the policy and agree to abide by the timeline and the policy.

3. Amending Concept Sheets

In some cases, an approved concept sheet (CS) may need an amendment. The writing team of the CS will develop the written amendment in the form of a CS. The title of the amendment should include the original CS number.

Similar to the original CS the amendment should include:

- complete rationale
- background
- objectives
- study population
- analysis plan
- indication of the resources needed

Once the amendment is drafted it should be reviewed and approved by the appropriate working group where the original CS was approved. The working group will assign reviewers and if possible the reviewer of the original CS should be enlisted to review the amendment. The reviewers should be requested at least a week before the working group call, if possible.

Once the CS amendment is approved by the working group, the amendment is sent to the PHACS Coordinating Center for dispersal to the SLG for review and vote. When submitting the amendment include both the original concept, with the new additions highlighted, plus the amendment itself.

4. Drafting of the Manuscript

Once the SLG and EC approve the CS, the working WG chairs will tell the investigator when the data cleaning and analysis can begin. For a CS that requires new laboratory testing to be performed (i.e., New Works Concept Sheets), data analysis will not proceed until the results of the testing are available in the PHACS database.

The lead author may choose to establish a core writing team including at a minimum the lead author, epidemiologist/statistician and a senior author. This team will work closely as the process of cleaning, evaluating validity of data, coding, defining exposures, outcomes, confounders and effect modifiers takes place. Small group calls and periodic full writing team calls should be scheduled during this time and throughout the process of analysis and drafting the manuscript. The lead author is responsible for organizing all calls with the help of the CC.

In some cases, a face-to-face meeting of the core members or of the entire writing team may be beneficial, either as part of the regular PHACS meetings or in an ad hoc fashion. Assistance with organizing these meeting should be requested through the CC.

Generally, within three months from EC approval of the CS and when the data required to conduct the analysis are available, the lead investigator should receive a preliminary analysis report from the CS epidemiologist/statistician. The lead investigator may share the preliminary analysis report with the core or full writing team at their discretion. Any issues regarding completeness of data or data quality that could result in a revised data analysis plan will be addressed at this point. Once these issues have been addressed, a final data analysis plan should be agreed upon. In general, the lead investigator should receive a final analysis report, which includes a draft statistical methods section and tables from the CS epidemiologist/statistician, within six months from when the analyses began (Figure 1). Delays may occur if there are data quality issues that require extensive site queries or if the analysis requires use of repository samples. In these cases, the writing team may be unable to meet the six-month goal.

The lead author is responsible for writing the first draft of the manuscript, with the epidemiologist/statistician contributing the statistical methods section, tables and figures. Within three months of receiving the final analysis report, the lead author should circulate a *complete* first draft manuscript to the writing team (Figure 1). The proposed journal should be indicated. The draft should include the following:

- A cover page listing authors and their affiliations
- An abstract
- Introduction, methods, results, and discussion sections
- Acknowledgments
- References
- Tables
- Figures (if applicable)

We encourage the writing teams to read and comment on draft manuscripts within 2 weeks of receiving a draft. A final manuscript should be sent to the Publications Committee (PC) [PHACS PUBLICATIONS] by the lead author within three months of the circulation of the first draft (Figure 1). The version submitted to the PC should be formatted for submission to a specified journal and accompanied by a participant summary **APPENDIX IV** below and a completed Manuscript Submission Checklist **APPENDIX VI**. This timeline allows the writing team six months to complete the writing of the manuscript, and a total of 17 months from the time the working group approved the capsule to submission of the final manuscript to the PC. The responsibility of manuscript approval has been delegated to the PC by the EC.

Guiding Principles for the Timely Production of Manuscripts:

1) Approved capsules that have not led to an approved CS within 6 months of approval by the SLG should be re-reviewed by the SLG or its designate with an explanation of the delay and a new timeline.
2) In general, a concept sheet (CS) should result in a single manuscript, published in a high-impact journal and with high public health and/or scientific impact.
3) Lead investigators with a previously approved capsule/concept sheet should complete the final manuscripts or demonstrate timely progress in completing the manuscripts before leading a new project.
4) Approved CS's will not undergo analyses beyond those specified in the approved concept sheet without re-review of the concept sheet and a plan for further analyses by the SLG.
5) A CS team with at least one published/accepted manuscript wishing to conduct further data analyses for another publication must submit for review a new capsule/CS describing the new data analysis plan.
6) For CSs with a completed analysis report but a delayed manuscript (as defined by publications committee policy and publications committee reviews), the writing team should provide the publications committee with a timeline for submission of a final manuscript. If this cannot be completed in a reasonable period of time (as specified by the Publications Committee), a new first author will be identified by the publications committee in consultation with the WG chairs, PHACS leadership, and the writing team as appropriate.
7) Any CSs without a final analysis report that have been inactive for >1 year (as assessed by the publications committee) will need to be re-reviewed by the leadership and SLG before further analysis can be performed.
8) Data analyses required for the development of an external grant application will require an approved capsule. Requests must be made long enough in advance (generally 8-12 weeks) to allow sufficient time to complete the analyses.

9) Resubmission of a grant utilizing PHACS data must be approved by the SLG after the initial review comments have been incorporated. A request for additional analyses for the resubmissions must be approved by the leadership and SLG.

5. Abstracts for Conference Presentations

In general, abstracts written for presentation at scientific meetings will be based on the data analysis report used to produce the manuscript. An author's request for use of resources to produce an abstract prior to completion of the final data analysis report for manuscript development must be approved by the EC. Analytical work for a primary manuscript will not be halted to produce data for an abstract unless clinically critical information has been uncovered, which requires timely dissemination.

Authors whose abstracts are accepted by the respective conference in which the abstract is submitted must inform the CC (PHACSCC) of that acceptance. Additionally, accepted abstract presentations should be sent to the CC (PHACSCC) which will then send them to the SLG for FYI and final comments.

6. Deviations from the Recommended Manuscript Development Timeline

The PC will ensure that manuscript development proceeds according to the expected timeline (Fig 1). The PC reviews the status of all manuscripts in development on its monthly conference call. The committee determines if significant variance exists between the recommended timeline and the progress of each manuscript. If there are delays in any part of the process, the first step will be for the PC Chair to request in writing that the lead author address the nature of the delay and provide the PC with a plan and revised timeline for completing the manuscript. The WG co-chairs will be copied on these communications. In most cases, the delays will be considered a natural part of the process of research (for example, extensive data cleanup and site queries, the need to obtain missing data, laboratory data, unexpected findings or feedback that may require additional analyses, workload of the epidemiologist/statistician, reprioritization of analyses, etc.).

The status of all CS should be reviewed and updated on the appropriate WG call. The WG co-chairs will update the PC on the status of each CS monthly. The PC will notify the WG co-chairs and lead author if their CS is experiencing delays (see Figure 1 for timeline) and the lead author may request a deadline extension from the PC. The results of the PC's review of extension request will be communicated to the lead author and the WG chairs. A revised timeline will be distributed to the writing group. Changes in the timeline will be documented on the CS and capsule tracking sheet maintained and updated monthly by the DOC.

If the manuscript writing team fails to meet their revised timeline without a reasonable explanation, the PC reserves the right, in collaboration with the WG co-chairs and with approval of the EC, to recommend a new lead author to assume leadership of the writing team. The new lead author will follow the timeline outlined above. Adjustments to the original timelines may be needed depending on the status of the manuscript. The new lead author must continue to report monthly to the working group on the progress of the manuscript.

If, in the opinion of the WG chairs or lead author, an individual writing team member's performance is below expectations (see **APPENDIX I**, "Lead Author Responsibilities"), the lead author will attempt to address the issue with the individual. If mutual agreement cannot be achieved, the lead author will refer the matter to the PC for management and will provide specific suggestions for resolution of the matter.

7. Participant Summary

A Participant Summary for the general public must be developed for all PHACS-related Publications and abstracts. The first author will develop the summary using **APPENDIX IV** entitled: **Participant/Lay Summary Guidelines for PHACS Authors**. The authors should ensure that the summary:

- Communicates the relevance of the study's findings for the general public (what is the "takeaway"?);
- Is succinct and clear (following guidelines in **APPENDIX IV**); and,

- Is written in plain language at an appropriate reading level for a lay audience. (8th grade reading level is suggested).

The participant summary will be submitted, per the Guidelines and Checklist for Manuscript Submission (**APPENDIX V**), to the PC for approval with submission of the final manuscript. A manuscript will not undergo PC review and approval until a participant summary has also been submitted.

8. Authorship

All manuscripts and conference abstracts shall indicate that authors are writing on behalf of the Pediatric HIV/AIDS Cohort Study; i.e. PHACS should be included as the last entry of the authorship listing ("…for the Pediatric HIV/AIDS Cohort Study"). Exemptions to this requirement may be requested from the PHACS EC.

The PHACS study policy regarding authorship reflects the published policy of the International Committee of Medical Journal Editors (ICMJE) (ICMJE Recommendations). Note that some journals place a limit on the total number of authors.

Listed authors must have made a substantial contribution to the work and should meet ALL FOUR of the following criteria:

1. Substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published/presented; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

To further clarify, within PHACS, it is expected that authors

1) participate in the writing group calls;

2) provide feedback to the lead author on all draft and final versions within the timeframe that is requested by the lead author; if they are unable to do so, the co-author should request a reasonable extension or remove themselves from the writing team.

All designated authors must meet all of the above criteria. All who meet these criteria should be identified as authors, if possible. Those who do not meet all criteria should be included in the acknowledgements.

The author list, though not necessarily the order, should be shared with the team early on in the writing process. The authorship order should be determined during the manuscript writing process as the lead author assesses the cumulative contributions of each member.

Since PHACS is a large epidemiologic study requiring substantial input regarding the design and analysis of each concept sheet, the concept sheet epidemiologist/statistician will generally be the second author except in cases when they are the lead or senior author. Often, these complex analyses will require two epidemiologists/statisticians to fully address all aspects of the analysis. In establishing authorship, consideration should be given to the additional contribution of the second epidemiologist/statistician.

The authorship list should be shared with the entire writing group. Other writing team members' placement on the author list is most often contingent on participation and contributions, as noted by the lead author, or alphabetical, if participation is equal among team members. Authorship should be discussed by the writing team early in the process so that all understand how decisions were/are made. Changes can be made but authors need to be informed of changes.

If there are disagreements regarding the author order or author membership, a discussion should first happen between the concerned author and the lead author in consultation with the

core writing group team; it is recommended that this not occur over email. If the concerned author and the core writing group team cannot come to an agreement, then the full writing team should be consulted. If the full writing team cannot come to an agreement, the WG leadership should be brought in to help the team come to a resolution. Most, if not all disagreements should be resolved within the writing group team and WG leadership. If this fails, discussion should be brought to the PC. The PC will, upon consultation with the writing team members and WG leadership, bring a recommendation to the EC for a vote. Every effort should be made to conduct a respectful, collaborative, non-punitive, and transparent process to resolve disputes, should they occur. All involved parties should be allowed to participate in pertinent discussions to reach a satisfactory resolution.

9. Acknowledgements and Funding Statement

All manuscripts must include an acknowledgments section and a funding statement. PHACS acknowledgements and funding statements have been developed and posted on the PHACS website (Publications Policy Documents).

The lead author must use these PHACS EC approved statements rather than drafting their own. They are updated annually by the PHACS DOC. For sub-studies funded independently, the acknowledgments section should be modified to include the grant award number.

Some journals require written approval by all individuals listed in the acknowledgements section. These approvals have been obtained and are kept on file at the PHACS DOC (PHACSDOC). However, note that some journals require individuals to provide approvals for use of their name in the acknowledgements that are specific to the manuscript and journal. The PHACS DOC is unable to obtain these manuscript- and journal-specific approvals. In these cases, a general PHACS acknowledgements section that does not include specific names can be used.

Manuscripts developed from research studies involving federal funding at a site (e.g.

Pediatric Clinical Research Center) must acknowledge any local grant that supported the manuscript.

10. NIH Clearance

If any author is from the NIH, the manuscript must be submitted for internal NIH approval prior to submission to a journal. It will be the responsibility of the NIH co-author(s) to obtain their institute's approval and communicate the expected timeline and result to the lead author.

V. REVIEW AND APPROVAL OF ABSTRACTS, PRESENTATIONS AND MANUSCRIPTS

1. Abstracts, Presentations, Posters, and Manuscripts from PHACS-funded Studies

All abstracts and manuscripts related to PHACS studies/protocols must be approved by the PC (for publications) or the SLG (for abstracts) and then sent to NICHD project scientist by the lead author for notification prior to submission. (For the purpose of this policy, NICHD notification is understood to mean submission of the actual abstract, to prepare the institute for inquiries). Submission without prior approval is inconsistent with the spirit of collaborative research and may result in denial of access to data and a cessation of collaborative support. The review and approval process is as follows:

Abstracts: (revised 10.18.18)

Following approval by the writing team, an abstract to be submitted to a meeting or conference should be sent to the CC by the lead investigator for review by the SLG. A minimum of six working days are required for the review and approval of an abstract. It is recommended that the abstract be submitted earlier than this to allow the team adequate time to respond to the SLG comments.

The CC will distribute the abstract to voting members of the SLG and simultaneously appoint a

reviewer from among the members of the Publications Committee, with copies of the abstract also sent to all members of the Publications Committee. The designated reviewer will send their review to the CC within three working days, indicating whether the abstract is suitable and appropriate for submission and including any suggestions as appropriate.

The reviewers' comments and recommendations will then be immediately distributed to the voting members of the SLG and the membership of the Publications Committee. The voting members of the SLG should submit their approval or disapproval of the abstract and any comments to the CC within 4 working days of their initial receipt of the abstract, leaving 2 days for the CC to distribute the results of the vote and the writing team address any concerns. With the agreement of the reviewer, a simple majority of votes cast by voting members of the SLG is required for approval of the abstract.

A disagreement as to whether an abstract will be submitted will be resolved by the Chair of the Executive Committee with consultation with the PI of the DOC, the Co-PI of the CC, and the NICHD Project Scientist or designee. Once an abstract is approved for submission, a final copy will be sent by the CC to all members of the SLG, the Publications Committee, and NICHD project scientist to allow the institute to prepare for inquiries.

Additionally, if the approved abstract is not accepted by the conference designated by the author when originally submitted for Publications Committee review. The author can resubmit the same abstract to another conference without having to re-submit the abstract for Publications Committee review, further it is the authors responsibility to notify the PHACSCC if they are resubmitting the same abstract to a different conference.

Posters and Slide Presentations for Public Research Conferences:

To maintain consistency among PHACS posters and to increase the profile of the study, PHACS maintains poster and slide templates (available on the PHACS website Publications Policy Documents), which all PHACS authors should use. The lead author is responsible for developing the poster. Drafts should be circulated to all co-authors four weeks prior to the conference for posters and 10 days prior for presentations. Co-authors should be given 1 week to

respond with comments.

The final version must be sent to the WG and SLG two weeks prior to the conference for posters and 3 days prior for presentations. These notifications are for informational purposes--no comments or corrections will be solicited at that time from these groups. The PHACS DOC can review and edit an investigator's poster or presentation to provide feedback on the graphics and layout. To take advantage of this service, please move all of the above timelines back by one week to allow for an additional week after the poster or presentation has been finalized for review. The lead author is responsible for printing the poster.

Slide Presentations for Other Audiences:

PHACS investigators who wish to present PHACS research findings which have been previously published or presented publicly (not just at a PHACS meeting) at a meeting (and thus previously approved by the SLG and/or EC) can do so without obtaining further approval. Such presentations should include only the material which has been previously presented. As a courtesy, it is recommended that the first author of previous presentations to be included be notified and acknowledged. PHACS should be acknowledged in any such presentations.

Presentation of PHACS research findings which have not previously been published or presented publicly require approval by the SLG. The draft presentation should be sent to the SLG at least 15 working days prior to presentation.

Manuscripts:

A manuscript should be submitted to the Publications Committee (PC) through the Coordinating Center (PHACS Coordinating Center) by the lead author for final approval after review and sign off by all co-authors. The following should be included with the submission: a Participant *Summary* (**APPENDIX IV**); *PHACS Guidelines and Checklist for Manuscript Submission* (**APPENDIX V**) and a complete *PHACS Manuscript Author Checklist* (**APPENDIX VI**). The chair of the PC will appoint two reviewers based on the content of the submission. The designated reviewers should complete their reviews of the manuscript within 6 business days and submit them to the Coordinating Center. If both reviewers have approved the manuscript for submission, the manuscript and the two reviews are sent to the Publications Committee with a 24-hour window for comments. The reviews are concurrently sent to the lead

author of the manuscript. The chair of the PC may approve submission of the manuscript based upon these reviews after the 24-hour period. The lead author is notified of approval for submission by the CC. If the reviewers have concerns, the manuscript, the reviews, and any comments from members of the PC are distributed to the PC and discussed by email or on a call. The chair of the PC may request that the reviewers, lead author or other authors join the discussion to answer questions. If a revision of the manuscript is requested by the PC, final approval of the revised manuscript by the reviewers and Chair of the PC is required. Notification of final approval for submission will be sent to the lead author by the Coordinating Center.

2. Expedited Review

In certain instances, such as when an author must meet a submission deadline for a journal special edition, the PC may grant an expedited review. Any request to deviate from the full review policy must be submitted to the Chair of the EC by the writing team with a justification for the deviation. An expedited review will only be granted for compelling reasons. Expedited reviews will be conducted by a subcommittee composed of the chair and vice-chair of the SLG/PC and, as appropriate, the NICHD project scientist, and the PI of the DOC. This subcommittee will have the authority to approve an abstract or manuscript for submission.

3. Appeal of Unfavorable SLG/PC Decisions

The appeal process can be invoked when the authors of an abstract, presentation, or manuscript and the SLG or PC fail to reach agreement on the terms under which they can authorize the publication/presentation of study findings. In this event, the decision will be appealed to the EC. The decision of the EC by majority vote of voting members will be binding.

VI. POST-JOURNAL SUBMISSION

Once a manuscript is submitted to a journal, the first author should forward a copy of the submitted version to the CC (PHACS Coordinating Center). The CC will forward it to the SLG and EC for informational purposes.

The following circumstances do not require further review by any PHACS committee:

- A manuscript is accepted provisionally with required or recommended changes or additions.
- A journal invites a revised draft of the same article.
- An article is rejected and is being submitted to another journal with minimal changes.

In these instances, the lead author, in consultation with the writing team, may take action without further PHACS review. A copy of the revised submitted manuscript should be forwarded by the lead author to the PC. The CC will forward it to the SLG and EC for informational purposes only.

If journal reviewer feedback indicates a need to reformulate the essential components of the analyses before the manuscript can be resubmitted or submitted to another journal, the team must submit a request for the proposed additional analyses to the WG. If the additional analysis is extensive, the WG chairs will request approval by the SLG and EC. Manuscripts with substantially-modified analyses and/or conclusions must be resubmitted to the PC for re-review. It is the responsibility of the writing team to differentiate between alterations which reflect mere editorial changes and those which essentially modify the analyses and/or conclusions of the study previously approved by the PC.

VII. POST-JOURNAL ACCEPTANCE

When the manuscript is accepted for publication, the lead author should notify the PHACS Coordinating Center (PHACSCC) and the PHACS Health Education and Communication Publicity Committee (PHACS HECC). The Publicity Committee will work with the lead author to formulate a press release (if appropriate) and to put the participant summary submitted with their manuscript into the appropriate format. Summaries will be reviewed and approved by the lead author and by at least one CAB member before they are considered final. Final summaries will be translated into Spanish, disseminated to the entire PHACS network via email and will be

posted to the PHACS website.

Since PHACS publications are NIH-funded, they are required to be deposited in PubMed Central (PMC) and have a PMC reference number (PMCID). Many journals will deposit the article during publication. If the journal does not deposit the article, the responsibility reverts to the lead author. For more information, see NIH Submission Methods

VIII. ABSTRACTS, PRESENTATIONS, AND MANUSCRIPTS FROM NON PHACS-FUNDED STUDIES

Abstracts, presentations, and manuscripts from studies utilizing PHACS data and or specimens, whose investigators are supported by non-PHACS funds (R01s, R21s, etc.) must be reviewed and approved as outlined by the PC and will be held to the same timelines as noted in this policy. Investigators who use any PHACS funding or resources for the study (e.g., data or repository specimens, site support, lab support) must acknowledge PHACS (see "PHACS Acknowledgements" section).

IX. DEPARTING INVESTIGATORS

Departing investigators or staff who are no longer affiliated with the PHACS Network can submit a proposal for authorship on abstracts and/or papers to the working group. The investigator or staff must meet all of the guidelines for authorship described in this publications policy.

X. SITE-SPECIFIC DATA PRESENTATIONS

Data presentations being formally submitted to regional or national meetings which are descriptive of local activities or data collected at a single site through activities supported by PHACS should be approved by the SLG. Similarly, submissions for consideration for peer-reviewed publication, even if only descriptive of local PHACS-funded activities, should be formally reviewed and approved as a PHACS manuscript.

When a presentation/manuscript is being considered for submission to a meeting or publication, the investigators determine if it uses only site-specific data that was not collected using PHACS funds (no pooled Network data), does not relate specifically to the primary or secondary objective of PHACS, and required no DOC resources. If these conditions are met, the presentation/publication is permitted and does not require PC or SLG approval. If these conditions are not met, the presentation/publication requires approval by the SLG. As courtesy expected among cooperative research network investigators, the SLG and EC should be notified of such studies prior to submission for publication or meeting presentation and receive a copy of the final publication. This informs the SLG and EC of similar studies and prepares it for questions from the public or other scientists.

APPENDIX I

Lead author responsibilities:

- Contact CC, working group chairs and/or PHACS investigator to discuss initial idea and draft the capsule.
- Submit capsule to WG and present on WG call.
- Form concept sheet writing team, including identification of epidemiologist/statistician and senior author.
- Lead the writing of the concept sheet.
- Decide author order (in collaboration with writing team).
- Plan/schedule calls to discuss the analysis, summarize and share decisions made during calls with the writing team.
- Address questions about the analysis from the co-authors (in partnership with the epidemiologist/statistician).
- Monitor participation of writing team members; consult directly with co-authors who fail to participate to discuss their continued participation.
- Write the first draft of the manuscript and distribute to the writing team for their review; provide a timeframe within which team members should provide feedback.
- Communicate with co-author regarding any decisions not to incorporate substantial feedback.
- Provide updates on the writing group's progress on WG calls, reporting issues causing delays and a revised deadline if there are acceptable delays.
- Track the manuscript development timeline and inform the writing team of upcoming deadlines.
- Ensure all co-authors approve the final draft of the manuscript before PC submission.
- Submit the approved manuscript to a journal; respond to reviewer comments (with input from the epidemiologist/statistician if appropriate).
- Ensures manuscript is deposited in PubMed Central (PMC) and has a PMC reference number (PMCID) within the required timeframe.

APPENDIX II

Co-author responsibilities

- Actively participate in conference calls, email discussions and writing/editing the concept sheet and manuscript.
- Respond to emails from the lead author within the time frame provided; if unable to respond within the timeframe, either request a reasonable extension or remove themselves from the writing team.
- Sign-off on the manuscript prior to PC review; participate in the revision of the manuscript as necessary following journal review.

APPENDIX III

Development of a Protocol Concept Sheet or Data Analysis Concept Sheet

Following approval of a capsule, the proposing investigator(s) develop(s) a Concept Sheet (CS) that includes the following components (in page/line numbering format):

- Study title
- Proposing investigator(s)
    - Lead investigator
    - Team members
- Study objectives and aims
    - Brief study overview and objective
    - Aims and/or hypotheses
- Study rationale/background
- Study design
- Study population with inclusion and exclusion criteria and data set required if applicable (for a DACS)
- Interventions or evaluations, if applicable
- Analytic section
    - Analysis plan
    - Sample size estimate
- Feasibility section detailing required PHACS resources and collaboration with other networks if applicable.
- Proposed assessment measures (in an appendix) if developed in a pilot study or if the measures have limited use in children or youth if applicable.
- Training needs/capacity (for intervention, data collection, procedure) if applicable
- Budget with budget justification
- Accrual timeframe or timeframe for completion of analysis for a DACS.

If the proposed study will be using a subset of the PHACS clinical sites, the CS should include:

- Site selection criteria (obligatory and desirable)

    Attach an appendix describing criteria necessary or desirable for site selection and

external constraints (e.g., school program, specialty clinic, detention center). Minimum and maximum number of subjects per site; minimum and maximum number of sites. Rationale/basis for site restriction that may include but not be restricted to: Staffing (existing staff expertise and availability, space, capacity, funding needs for additional staff), existing site partnerships or facilities, locale, etc.

If a team has specific site preferences, in addition to the above, the appendix must include: 1) their request in writing with a justification addressed to the Executive Committee and 2) statements from the PHACS site PIs at those preferred sites stating their interest, availability of staff, and immediate availability of the populations required for the proposed study. Final site selection will occur once the protocol is completed.

If needed, a CS team may request a consultation review with members of the SLG to discuss issues related to development of the proposed concept before the full CS is submitted to the SLG for formal review and vote.

Proposing investigators or the working group co-chair(s) should submit the CS to the Coordinating Center (CC) in electronic form.

The CC distributes the CS to the SLG for review.

- The CC assigns one clinical review and the DOC assigns one statistical review within 3 days of receipt of the CS. Occasionally outside reviewers may be consulted at the discretion of the SLG. Reviewers provide a written review of the CS to the CC within 6 business days. The reviewers are sent *Criteria for PHACS SLG Review of Concept Sheets and Protocols* **(APPENDIX X)**. A CS is reviewed on the basis of scientific merit, feasibility, priority relative to the core protocol objectives (AMP or SMARTT), and placement within the PHACS Network's scientific agenda. The written review should include major and minor points (if any) and comments on each of the CS content areas listed above as appropriate. All specific recommendations and comments should refer to a specific page and line number when applicable. Reviews are sent to the CC for distribution to the investigators and the SLG.

- When reviews are completed, the CS is included on the agenda of the next monthly SLG conference call. SLG members will review the CS and the evaluations prior to the call.

- The proposing investigator(s) present(s) a brief overview of the CS on the SLG conference call, and the two SLG reviewers present their evaluations, and other SLG

members may offer additional comments or feedback. Discussion with the SLG may ensue, and the proposing investigator(s) will have an opportunity to clarify and discuss issues and answer queries and concerns.

- The proposing investigator(s) then leave the conference call and the SLG may further discuss the CS if needed. Following the call, the CC distributes an e-mail ballot for SLG voting members to vote to 1) approve or disapprove the CS to move forward to be developed into a protocol, and, if approved, to 2) approve or disapprove a recommendation to the EC for requested PHACS resources, including site selection if appropriate. An approval vote of two-thirds of eligible voters is required to approve a CS and to approve a recommendation to the EC concerning the requested resources. SLG members are not eligible to vote if they are a proposing investigator or collaborator on the CS under review. If approved and no revisions are required, the CS moves forward to the next step in the review process. If the CS is approved but revisions are requested by the SLG, the SLG will specify if the reviewers alone can approve the revised CS (for minor modifications), or if full SLG review is required (for major modifications). If the latter occurs, revisions are made and the CS is resubmitted to the CC within three weeks of notification of the results of the review. The CS is then submitted to the SLG for full re-review and an approval vote as above.

- The CC forwards the approved CS and written comments from the SLG (including recommendation on use of resources and participating sites to the EC for approval. The CS is included on the agenda of the next EC conference call. The EC chair presents the CS, reviews, and SLG recommendation. Following the call, the CC distributes an e-mail ballot to voting EC members to approve or disapprove the CS resource recommendation. A simple majority vote is required for approval.

Once a concept sheet proposing a sub-study or nested study is approved by the SLG and EC, the protocol team is formed and protocol development is initiated. Once a Data Analysis Concept Sheet (DACS) is approved, the analysis/writing team is formed and the analysis initiated.

Full Protocol Development

In general, the protocol chair will be the person proposing an approved CS.

- When the CS is approved for protocol development, a protocol team is organized which will generally include the proposing investigators, a SLG liaison if the proposing investigators are from outside the PHACS Network, a Protocol Specialist from the DOC, a PHACS site PI, and a Study Coordinator. Other investigators including site PIs, Study Coordinators who desire to devote time and effort to the development of the protocol may contact the protocol team directly regarding their involvement through a written communication outlining their proposed contribution. CAB input on developing protocols is solicited as appropriate.

- Procedures for protocol development depend upon whether the protocol is to be developed within the PHACS Network or within a collaborating network:
    - If protocol development is to be within the PHACS Network, a Protocol Specialist will be assigned to assist in full protocol development including full detailing of study procedures, visit schedules, timelines, IRB materials, and data monitoring safety issues. Please refer to the PHACS Procedure for Protocol Development, Approval, and Implementation for details of this process.
    - If protocol development is to be within a collaborating network, issues of logistical support will be negotiated with the appropriate network. A Memorandum of Understanding (MOU) will be signed by the PIs of both Networks and by the protocol chair.

- The PHACS Network is committed to the most efficient development of the studies that it endorses and therefore, the performance of the protocol team is monitored closely by the EC. Reassignment of a protocol chair could be considered by the EC if there is lack of leadership or an inattention to timelines during protocol development, protocol implementation, or manuscript production. Records will be kept on how protocol concept plan development proceeds and what precedents are set each year of the study. These will be reviewed and the policy amended as needed annually.

APPENDIX IV

PARTICIPANT/LAY RESEARCH SUMMARY GUIDELINES FOR PHACS AUTHORS

A Participant Summary is a brief description of the highlights of a manuscript written for the general lay population. In PHACS, authors are asked to create a participant summary to accompany their manuscripts so that we are able to disseminate findings to our participants and CAB members.

When to submit a participant summary:

The first author should submit a participant summary based on the final manuscript. It should be submitted along with the manuscript to the PHACS Publications Committee for review. Manuscripts will not be approved for submission unless they are accompanied by a participant summary.

Contact:

The Director of Health Education and Communication will be listed as the contact on the participant summary and will respond to basic inquiries. However, when necessary, some inquiries will be forwarded to the authors.

Please feel free to reach out to Claire Berman, Director of Health Education and Communication (cberman@hsph.harvard.edu), for assistance as you are drafting the summary. Once you receive notification that your paper will be published, please contact Claire and she will work with you to transfer this content to the participant summary template.

Formatting and Language Guidelines:

- Organize according to the sections outlined below.
- Write short sentences and use plain language.
- Define technical/medical jargon using plain language.
- Adhere to the recommended length outlined for each section.

Complete the fields using plain language – the way you'd explain something to a patient. The text should be at a roughly 6th - 8th grade reading level. This is the average reading level of U.S. adults and the OHRP-recommended reading level for informed consent materials.

Please confirm the reading level of your participant summary before submitting to the Publications Committee. Microsoft Word has a proofing feature under options where you are can run readability statistics on your summary. Remember that including more technical words (even if they are defined) may raise the reading level in Microsoft Word but may not reflect the true reading level. If your summary includes a lot of medical jargon, please aim for a Microsoft Word reading level of 10th grade or below.

Participant Summary Sections – Please fill out each section for your manuscript and include the section headers.

Paper citation: Include the concept sheet number and the paper citation.

> *For instance:* C079. Rough, K., et al. (2015). Dramatic decline in substance use by HIV-infected pregnant women in the United States from 1990 to 2012.

Plain Language Title: This can read like a news headline and should convey the main message and/or group that the research was about.

> *For instance:* Decrease in Drug and Alcohol Use During Pregnancy from 1990 to 2012 in Pregnant Women Living with HIV.

Background: 2 – 3 sentences about how/why this particular study was done. Why was this an important research question to pursue?

> *For instance:* In the early 1990s, studies found that a number of women with HIV used alcohol and drugs during pregnancy. Drug and alcohol use during pregnancy can hurt mothers and their infants. We wanted to see whether drug and alcohol use during pregnancy has changed over time for women with HIV. Understanding this change over time helps us respond to pregnant women's current health needs.

Who participated: 1 – 3 sentences describing the characteristics of the participants in your study for context. These may include: number of participants, caregiver/participant status, age, PHACS protocol (SMARTT/AMP/AMP Up) or other study affiliation, HIV status, pregnancy status, etc.

> *For instance:* 4,408 pregnant women with HIV participated. Some women were from SMARTT, and some women were from another similar study called the Women and Infants Transmission Study.

What we did: 2 – 3 sentences describing the study methodology in simple terms, which may include particular tests you performed, which factors/populations you compared, etc.

> *For instance:* We looked at how the percentage of pregnant women using drugs and alcohol changed over time. We compared our findings in women with HIV to rates of substance use in pregnant women in the general U.S. population.

What we found: 2 – 4 sentences describing the main findings of your study that would be particularly relevant to caregivers and study participants. Feel free to use bullet points if preferred.

> *For instance:* Women's use of drugs and alcohol during pregnancy decreased substantially from 82% in 1990 to 23% in 2012. By 2005, the pregnant women in our study were similar to other pregnant women in the U.S. in terms of how many used alcohol, marijuana, cigarettes, heroin, and cocaine. We found that women who had used drugs or alcohol *previously* during pregnancy were five times more likely to use them in *later* pregnancies.

What we learned: 2 – 3 sentences describing the main takeaway from your study – how should/will your results be useful for individuals, in clinical practice, or for research? Do the results mean anything for a participant or caregiver's day-to-day life or for their clinical care?

> *For instance*: There is no evidence that having HIV puts pregnant women at higher risk

for substance use. Programs to further reduce substance use during pregnancy in women with HIV should focus on women who have used drugs and alcohol in past pregnancies.

Final thoughts: Is there anything in particular we haven't already asked that should be emphasized throughout the lay summary?

APPENDIX V

Guidelines for Submission of Manuscripts for Review by the PHACS Publications Committee

1. The PHACS SLG has delegated authority for review and approval of PHACS-related manuscripts to the PHACS Publications Committee. Manuscripts ready to be submitted to a journal should be sent via email to the PHACS Coordinating Center (PHACS Coordinating Center). The PHACS Publications Committee will identify at least 2 reviewers for each manuscript and will discuss the reviews prior to making a decision regarding approval for submission to a journal.

2. Manuscripts submitted to the PHACS Publications Committee must be "submission-ready"—in the format required by the target journal and containing all of the components required by the PHACS project.

3. For ease of review, a single MS Word (preferred over pdf) file should be submitted containing the title page, coauthors and affiliations, corresponding author, abstract, manuscript body and correctly formatted references, and tables. If necessary, figures may be submitted separately.

4. Any PHACS-related manuscripts must include "for the Pediatric HIV/AIDS Cohort Study" at the end of the author list. If any of the authors are from NIH, the manuscript must be submitted for NIH approval prior to journal submission.

5. The appropriate acknowledgement section (for AMP or SMARTT), taken from the PHACS website (PHACS Acknowledgement) must be included. Some journals also require that funding sources be listed on the title page, and if so the funding statement included on the PHACS website should be used.

6. **A one-page Participant Summary** must be submitted along with the manuscript, following the guidelines on the PHACS website (under "Analyses: Templates and

Guidelines"). The summary is intended for distribution to the PHACS sites and CAB, and should be written in clear, plain language. Reviewers do not need to ensure the summary is at a specific reading level in Microsoft Word; rather, they should check that the content of the summary is accurate and reflects the main findings of the manuscript. The Director of Health Education and Communication will work directly with authors on reading level once the manuscript has been accepted by a journal. If a summary has previously been prepared for the purposes of a similar abstract and the manuscript results are not substantially changed, then the prior summary can be attached. However, since the participant summary forms the basis of communicating results to the sites and participants, it should be reviewed and updated if necessary to ensure the primary message regarding findings remains consistent.

When submitting a manuscript for review by the PHACS Publications Committee, please complete **APPENDIX VI** "PHACS Manuscript Author Checklist" and forward it with your manuscript to PHACS PUBLICATIONS.

APPENDIX VI

PHACS MANUSCRIPT AUTHOR CHECKLIST

Manuscript Title:

Lead Author:

Working group(s):

Target journal:

Date submitted to Publications Committee:

Checklist for Submission of Manuscripts to PHACS Publications Committee:

☐ All authors have seen this manuscript version and have approved it for submission.

☐ The author list includes "for the Pediatric HIV/AIDS Cohort Study".

☐ If any author is from NIH, the manuscript has been submitted for internal NIH approval (the manuscript must be approved prior to submission to a journal).

☐ The appropriate acknowledgements section has been included (for AMP, SMARTT, or both AMP and SMARTT).

☐ If required by the target journal, funding sources have been included on the title page.

☐ The manuscript is in the format required by the target journal and is in a single MS Word (preferred) or pdf file. (If necessary, figures may be submitted separately.)

☐ A one-page participant summary has been submitted along with the manuscript, following the guidelines on the "Analyses: Templates and guidelines" section of the PHACS website.

APPENDIX VII

PHACS CONCEPT SHEET AUTHOR CHECKLIST

Concept Sheet Title:

Lead Author:

Working Group associated with:

Date concept sheet submitted to PHACS Coordinating Center (via email at PHACS CC):

This template was developed to confirm that concept sheets submitted to the PHACS CC for review by the Scientific Leadership Committee include all information necessary to ensure a complete and thorough SLG review. Please complete this form by inserting a check next to each appropriate and response and submit to the CC with your concept sheet.

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).

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 resources required to conduct the study.

_____ The budget indicates the proposed source(s) of funding (i.e. whether the author will pursue external funding or is requesting support from the PHACS Coordinating Center).

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 the testing of the samples will be conducted.

Collaborations: Is the concept sheet a collaborative project with individuals, networks, or laboratories outside of PHACS?

____ No

____ Yes→ _____ The concept sheet states whether the writing team proposes to have some or all of the data analyses conducted by individuals who are not based at the PHACS Data and Operations Center.

_____ The concept sheet states whether it will require a data sharing agreement and/or materials transfer agreement?

Timeline:

____ Are there any time constraints for the proposed analysis and publication (e.g. concept sheets associated with a grant application, dissertation or thesis)? If so, include a proposed timeline and note external deadlines.

APPENDIX VIII *(updated 05.08.2019)*

Development and Review of Capsules & Concept Sheets

Capsule Sheet Development and Review Process:

1. Capsules should be developed and approved by a PHACS Working Group (WG). Although multiple WGs can be involved in the development of a capsule, one WG should serve as the primary WG.
2. The text of the capsule (excluding cover page and references) should be no longer than 3 pages (8.5 x 11 inches, 0.5-inch margins, single spaced, font no smaller than Ariel 11. Capsules that don't meet these requirements will be returned to the author by the Coordinating Center.
3. If the lead investigator has a previously approved CS, their progress in producing the final manuscript in a timely manner (according to the timeline in the Publications Policy) should be addressed in considering the new capsule by the WG and SLG. On the cover page, the lead investigator should discuss their plan (and timeline) for finishing any uncompleted work resulting from a prior CS.

Concept Sheet Development and Review Process:

4. Once a capsule has been approved by the primary WG, the Concept Sheet (CS) team should be assembled and the team should proceed with CS development.
5. The CS will be reviewed and approved by the primary WG, then the WG co-chairs should send the approved CS to the Coordinating Center.
6. The Coordinating Center will forward the CS to the SLG for discussion and review on their next scheduled call.
7. Once approved by the SLG, the Coordinating Center will forward the CS to the EC for discussion and review on their next scheduled call.
8. Once a CS is both SLG and EC approved the primary CS team should be assembled and the team should proceed with Manuscript development.

APPENDIX IX

Guiding Principles for the Timely Production of Manuscripts:

1. Approved capsules that have not led to an approved CS within 6 months of approval by the SLG should be re-reviewed by the SLG or its designate with an explanation of the delay and a new timeline.
2. In general, a concept sheet (CS) should result in a single manuscript, published in a high-impact journal and with high public health and/or scientific impact.
3. Lead investigators with a previously approved capsule/concept sheet should complete the final manuscripts or demonstrate timely progress in completing the manuscripts before leading a new project.
4. Approved CS's will not undergo analyses beyond those specified in the approved concept sheet without re-review of the concept sheet and a plan for further analyses by the SLG.
5. A CS team with at least one published/accepted manuscript wishing to conduct further data analyses for another publication must submit for review a new capsule/CS describing the new data analysis plan.
6. For CSs with a completed analysis report but a delayed manuscript (as defined by publications committee policy and publications committee reviews), the writing team should provide the publications committee with a timeline for submission of a final manuscript. If this cannot be completed in a reasonable period of time (as specified by the Publications Committee), a new first author will be identified by the publications committee in consultation with the WG chairs, PHACS leadership, and the writing team as appropriate.
7. Any CSs without a final analysis report that have been inactive for >1 year (as assessed by the publications committee) will need to be re-reviewed by the leadership and SLG before further analysis can be performed.
8. Data analyses required for the development of an external grant application will require an approved capsule. Requests must be made long enough in advance (generally 8-12 weeks) to allow sufficient time to complete the analyses.

9. Resubmission of a grant utilizing PHACS data must be approved by the SLG after the initial review comments have been incorporated. A request for additional analyses for the resubmissions must be approved by the leadership and SLG.

APPENDIX X

Criteria for PHACS SLG Review of Concept Sheets and Protocols

Please comment on the "elements of study design" noted below, particularly if you have concerns:

1. Clearly defined aims with relevant hypotheses.
2. Inclusion criteria specifying an appropriate population.
3. Proper subject selection and stratification procedures (if applicable).
4. Clear description of the exposures of interest and covariates.
5. Outcomes that are readily measurable, clinically relevant, and sensitive to the exposures.
6. Proper duration of follow-up for a clinically relevant assessment of outcomes.
7. Adequate sample size to detect differences between groups that are clinically relevant.
8. Proper statistical methods for estimation and inference.
9. Proper procedures for monitoring outcomes and safety data to safeguard participants' confidentiality and trial integrity.
10. Appropriate safety and ethical considerations.
11. The budget is appropriate and reasonable (if applicable).

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

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 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, eg. 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?