

## **I. PURPOSE**

A major goal of the Pediatric HIV/AIDS Cohort Study (PHACS) network and its affiliated studies is the dissemination of its research findings from approved Concept Sheets (CS) related to the health of children born to mothers living with HIV across their lifespan, from to young adulthood, along with health outcomes of their mothers and caregivers. The PHACS Network is committed to high standards and clear expectations in the preparation, review, and approval of abstracts, presentations for scientific conferences, and manuscripts for submission to peer-reviewed journals. This policy specifies the criteria for authorship, timeline for manuscript development, and policies and procedures for review and approval of manuscripts, abstracts, and presentations.

All manuscripts related to PHACS-affiliated studies and substudies must be approved by the Publications Committee (PC) prior to submission. All abstracts must be approved by the Scientific Leadership Committee (SLC) prior to submission. Submission of an abstract to a conference without prior PHACS approval is inconsistent with the spirit of collaborative research and may result in denial of access to data and a cessation of collaborative support.

In addition, manuscripts, abstracts and conference presentations utilizing PHACS and/or HOPE data and/or specimens which were supported by non-PHACS funds (e.g. an investigator obtained an R01, R21, etc.) must likewise be reviewed and approved by the PC or SLC, as appropriate, and will be held to the same timelines as noted in this policy. Investigators who use any PHACS funding or resources for their study (e.g., data or repository specimens, site support, lab support) must acknowledge PHACS (see “PHACS Acknowledgements” section).

Appendix IV provides a summary of the email address and website links needed for specific tasks discussed throughout the Publication Policy.

## **II. MANUSCRIPT DEVELOPMENT AND TIMELINE**

### **1. Writing Team**

The lead investigator of the CS may choose to establish a core writing team including at least the first author (if not themselves), the lead epidemiologist/statistician, the analyst, and a senior author. This team will work closely together during the process including cleaning data, evaluating validity of data, coding variables, and defining exposures, outcomes, confounders and effect modifiers. Small group calls and periodic full writing team calls should be scheduled during this time and throughout the process of analysis and drafting of the manuscript.

The Epidemiologic and Statistical Core (ESC), which may have already offered reviews while the CS was in development, offers optional, ongoing consultations to investigators leading CS’s to overcome methodological challenges or implementation of novel techniques throughout the

analyses ([phacs.esc@fstrf.org](mailto:phacs.esc@fstrf.org)). If appropriate, consultations on the use of novel methods will be conducted in a forum open to all ESC members to expand the use of these methods to other PHACS analyses. The lead investigator is responsible for organizing all calls with the help of the Scientific Administrative Core (SAC) as needed ([phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu)).

## **2. First Author Responsibilities for Manuscript**

The first author is responsible for writing the first draft of the manuscript and selecting the journal for manuscript submission, with input from the core writing team. The epidemiologist and/or statistician will contribute to the analytic methods section, tables and figures, and interpretation of results. The first author is encouraged to circulate a *complete* first draft manuscript to the writing team within three months of receiving the final analysis report (**Figure 1**). Writing team members should read and comment on the complete first draft within 2 weeks of receipt or notify the first author if more time is needed.

## **3. Complete Draft of Manuscript**

The complete draft of the manuscript should include the following with the order as specified by the target journal:

- A cover page including
  - The list of authors in the order the first author wishes them to appear in the manuscript. If this hasn't been decided, then provide an alphabetical list of authors and their affiliations
  - The proposed journal
  - Funding source(s) (PHACS-affiliated studies and substudies funding; generally the PHACS standard funding statement)
- Abstract
- Introduction
- Methods
- Results
- Discussion
- Acknowledgments (including PHACS acknowledgements. See Section 4)
- Funding statement (see Section 4)
- References
- Tables
- Figures (if applicable)

## **4. Acknowledgements and Funding Statement**

All manuscripts must include the appropriate acknowledgments section and a funding

statement, both of which can be found on the PHACS website<sup>1</sup>. In addition to these PHACS statements, authors should also include acknowledgement and funding statements for independently funded substudies specifying the substudy grant award number and any additional acknowledgements specific to the substudy. All PHACS manuscripts must also acknowledge any local site grants that supported the development of the manuscript. Care should be taken to only attribute PHACS funding to manuscripts that are supported by PHACS.

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 Scientific Administrative Core (SAC). However, note that some journals require individuals to provide approval for use of their name in the acknowledgements that are specific to the manuscript and journal. The PHACS SAC 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<sup>1</sup>. In addition, for papers which are more methodologic in nature and do not include PHACS data (or only include previously published results), but include one or more investigators whose efforts on these methodologic papers are supported by PHACS, an exception may be made to instead provide a link to the acknowledgments section on the PHACS website<sup>1</sup> rather than including the full acknowledgments section in the paper itself.

## **5. Final Draft of Manuscript**

The first author is encouraged to complete the final manuscript within 2 months of completing the first draft (**Figure 1**). The final version must be approved by all authors before being sent to the PC and include all elements stated above. The final version submitted to the PC must be formatted correctly for the intended journal following the journal guidelines and include a Community Research Summary.

## **6. Community Research Summary**

The first author of any PHACS-related publication must write a Community Research Summary intended for distribution to the PHACS sites and community advisory boards. The Community Research Summary will be submitted to the PC with the final manuscript. The authors should ensure that the summary achieves the following:

- Communicates the relevance of the study's findings for the general public (what is the "takeaway"?);
- Is succinct and clear (following guidelines in **APPENDIX I**, Community Research Summary Guidelines for PHACS Authors); and,
- Is written in plain language at an appropriate reading level for a lay audience (6<sup>th</sup> to 8<sup>th</sup> grade reading level is suggested).

### **III. AUTHORSHIP GUIDELINES**

#### **1. Role of First Author**

The lead investigator of a CS is generally the first author on the manuscript, but the lead investigator may designate another member of the team to be first author. The first author is responsible for writing the first draft of the manuscript and producing the final manuscript, submitting the final manuscript to the PC, and then to the journal. The core writing group team will work with the first author on subsequent drafts of the manuscript while later, more complete versions should have the input of all CS team members. Junior investigators taking the lead on manuscripts should be provided with appropriate mentorship from the senior author. Of note, some journals do limit the number of authors.

#### **2. Contribution of Authors**

The authors of a manuscript and the sequence of authorship should reflect the relative contribution of each individual in the design, analysis and conduct of the study as well as the drafting and revising of the manuscript. PHACS authorship policies are consistent with the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* developed by the *International Committee of Medical Journal Editors (ICMJE)*<sup>2</sup>. Based on ICMJE criteria, authorship credit should be based on the following 4 criteria:

- 1) Substantial contributions to: conception and design; **or** acquisition of data; **or** analysis and interpretation of data; and
- 2) Drafting the article or revising it critically for important intellectual content; and
- 3) Final approval of the version to be published; 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.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria but have contributed substantially should be acknowledged in the manuscript. In addition to being accountable for the parts of the work they did, the first author should be able to identify the parts for which each co-author is responsible. In addition, authors should have confidence in the integrity of the contributions of their co-authors. These authorship criteria are intended to limit authorship to those who deserve credit and can take responsibility for the work.

It is expected that PHACS manuscript and abstract authors will participate in writing group calls and provide feedback to the lead author on all draft and final versions within the timeframe that is requested by the first author. If they are unable to do so, the co-author should request a reasonable extension from the first author or remove themselves from the writing team. In case of a dispute regarding an individual writing team member's performance, the first author will discuss the matter with the Working Group (WG) Co-Chairs, and if necessary with the PC.

### 3. Inclusion of PHACS in Author List

All manuscripts and conference abstracts shall indicate that authors are writing on behalf of the Pediatric HIV/AIDS Cohort Study or HOPE study, as applicable. If the manuscript relies on PHACS data then it is expected that the network be listed on the authorship masthead as the last entry of the authorship listing (“...for the Pediatric HIV/AIDS Cohort Study”). On occasions when an exemption to this requirement is needed, the authors must request approval from the PHACS PC.

### 4. Authorship List and Order

The first author should share the author list, though not necessarily the order with the team early in the writing process. It is suggested that the first, second, third, and senior author be identified early in the process. Ultimately, authorship order should be determined by the first author on the final draft of the manuscript based on the cumulative contributions of each member to the final manuscript and the research process. Authorship order for an abstract submitted to a conference may differ from the final manuscript.

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

If there are disagreements regarding the author order or author membership, a discussion should first happen between the concerned author and the first 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 Co-Chairs of the appropriate Working Group (WG) 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 may, upon consultation with the writing team members and WG Co-Chairs, bring a recommendation to the SLC for a majority vote. Every effort should be made to conduct a respectful, collaborative, and transparent process to resolve disputes, should they occur.

## **IV. SUBMISSION OF FINAL MANUSCRIPT TO THE PUBLICATIONS COMMITTEE**

### **1. Publication Costs**

**The first author is responsible for any publication costs.** In the event that they are not able to cover publication costs, before submission, the author can request that PHACS cover the cost. The PC will review the request and ask for final approval by the LG. PHACS has the option of either agreeing to cover this cost, or requesting that the lead author consider another appropriate journal without publication fees.

## 2. Submission Requirements for Review by the PHACS Publications Committee

After all co-authors have reviewed and signed off on the final manuscript, the first author will send the following items to the PC via [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) for review and approval prior to journal submission. All of these documents must be sent, and the indicated requirements fulfilled for the manuscript to be reviewed by the PC (**APPENDIX II: PHACS MANUSCRIPT AUTHOR CHECKLIST**).

- Final manuscript
  - Manuscripts submitted to the PHACS PC should be “submission-ready”—in the format required by the target journal and containing all of the components required by the PHACS project.
  - For ease of review, a single MS Word 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.
  - Any PHACS-related manuscripts must include “for the Pediatric HIV/AIDS Cohort Study” at the end of the author list (see above under section III, bullet 3). The appropriate acknowledgement sections (for AMP, AMP Up Series, SMARTT, TERBO Brain and/or HOPE) taken from the PHACS website<sup>1</sup> 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.
- PDF or a link to the journal’s guidelines for manuscript submission
- Community Research Summary (see APPENDIX I)
- Completed Manuscript Submission Checklist (APPENDIX II)

## 3. NIH Clearance

If any author is from the NIH, the manuscript must be submitted for internal NIH approval prior to submission to a journal. The final version may be submitted to NIH at the same time it is submitted to the PC. 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 first author.

## **V. REVIEW OF MANUSCRIPTS**

### 1. Review by the PHACS Publications Committee

The SLC has delegated authority for review and approval of PHACS-related manuscripts to the PC. Manuscripts that are ready to be submitted to a journal should be sent to the PC via [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu). After receiving the manuscript, the Co-Chairs of the PC will appoint a clinical and a methodological reviewer based on the content of the submission. The designated reviewers should complete their reviews within 5 business days and submit them to

[phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) using the Manuscript Review Form (**Appendix III**). They may also send the manuscript itself including their comments or edits, although the latter is not required.

The received reviews will be circulated to all members of the PC for comments on the manuscript. If both reviewers have approved the manuscript for submission and do not request a revision, and if there are no objections from the members of the PC within two working days, the manuscript will be considered approved by the PC. The PC administrator will notify the first author of approval or requested revision of the manuscript and include the manuscript submission checklist with reviews and the manuscript with suggested edits, if provided. The goal is to have the manuscript review process completed within 14 days of submission to the PC.

If the reviewers have concerns and do not approve the manuscript in its present form, or the PC members or Co-Chairs note concerns regarding the manuscript during the two day time period for review, these concerns will be discussed by email or on a call among PC members. The PC Co-Chairs may request that the reviewers, lead author or other authors join the discussion to answer questions. This may take an additional 2-5 days. Finally, the administrator of the PC will send an email to the first author requesting resubmission of the manuscript to the PC after addressing the concerns. In the email, the administrator will include the reviews, suggested edits and comments on the manuscript if provided, and the disposition indicated on the Manuscript Review Form. The first author will send the revised manuscript to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu). After the first author receives final approval of the revised manuscript by the PC, it can be submitted the manuscript to the journal.

## **2. Appeal of Unfavorable SLC/PC Decisions**

The appeal process can be invoked when the authors of a manuscript and the SLC 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 PHACS Leadership Group and the decision will be made by a majority vote.

## **3. 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 PC via [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) 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 the PC.

## **4. Post-Journal Submission**

The first author, in consultation with the writing team, may take action without further review by any PHACS committee in the following situations:

- 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.

If the manuscript undergoes substantial revisions following a journal review the manuscript should be resubmitted to the PC for approval.

## 5. Post-Journal Acceptance

When the manuscript is accepted for publication, the first author should notify the PC via [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu).

The SAC and the Health Education and Communication Core (HECC) will work with the first author to formulate a press release (if appropriate) and to put the Community Research Summary submitted with their manuscript into the appropriate format. Community Research Summaries will be reviewed and approved by the first author and by at least one CAB member before they are considered final. The PC will select final summaries to be graphically presented in English and Spanish, which will be disseminated to the entire PHACS network via email and posted to the PHACS website for public access<sup>3</sup>.

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 or shortly after publication. If the journal does not deposit the article, it is the first author's responsibility to deposit the article. The first step of this process is to submit the manuscript to the NIH Manuscript System (NIHMS)<sup>4</sup>. Manuscripts will initially be given an NIHMS #, and then formatted and sent to the lead author for approval, prior to being given a PMCID. Failure to obtain a PMCID number for an NIH-funded manuscript can result in delay or withdrawal of NIH funding for PHACS.

## 6. Journal Requirements for Data Sharing

Some scientific journals require studies to make the data used in their published manuscripts available upon request by interested investigators. The PHACS network supports such data sharing practices for published articles in journals that have this requirement, when feasible. For these journals the lead author must first confirm with the PC via [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) that the data from their specific manuscript can be made publically available, as there may be some restrictions. If approved by PHACS, the lead author can inform the journal that investigators interested in obtaining the data can complete a request form on the PHACS website<sup>5</sup>. This link can be placed in the publication. The completed request form will be reviewed by the PHACS PC. If approved, the investigator will be sent a de-identified dataset.

## 7. Deviations from the Recommended Manuscript Development Timeline

The PC will monitor the manuscript development process of all approved CSs to determine if they are proceeding according to the expected timeline (**Figure 1**). On a monthly basis the status of all approved CS's should be reviewed and updated on the appropriate WG call and then this information is summarized and conveyed to the PC. In many cases, delays can occur as part of the ongoing 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). Nevertheless, if the PC determines that there is a significant delay in progress, the PC Co-Chairs will first send an email to the lead author (copying the appropriate WG Co-

Chairs) requesting a written explanation of the nature of the delay and request a plan and revised timeline for completing the manuscript.

The first author may request a deadline extension from the PC. The results of the PC's review of an extension request will be communicated to the first author/lead investigator and the WG Co-Chairs. Changes in the timeline will be documented on the CS/Capsule tracking sheet maintained and updated monthly by the PC administrator.

If the manuscript writing team fails to meet their revised timeline that was agreed upon with the PC, and cannot provide a reasonable explanation, the PC reserves the right, in collaboration with the relevant WG Co-Chairs and with approval of the SLC, to recommend that a new investigator assume leadership of the writing team as first author. The original first author and the writing team will have an opportunity to appeal this decision, and provide a new and final timeline for completion of the manuscript. If the appeal is not successful, the newly identified first author should follow the revised timeline, although adjustments may be needed depending on the status of the manuscript.

## **VI. ABSTRACTS FOR CONFERENCE PRESENTATIONS**

In general, abstracts written for presentation at scientific meetings must be based on the final analysis report for the approved CS aim(s), but may be based on a preliminary analysis report after careful consideration by the core team. Following approval by the writing team, the lead author must submit the abstract to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu).

The SAC Co-Directors will appoint a reviewer from among the members of the PC and that reviewer will send their review to the SAC ([phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu)) within 1-2 working days, indicating whether the abstract is suitable and appropriate for submission and include any suggestions as appropriate. The abstract with the reviewers' comments and recommendations will then be immediately distributed to the voting members of the SLC in the form of a ballot. If the PC review is delayed, the abstract may be sent to the SLC without the review and the PC review sent as soon as it is available.

The voting members of the SLC should submit their approval or disapproval of the abstract and any comments to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) within 3 working days of their initial receipt of the abstract. Two-thirds of voting members of the SLC are required to constitute a quorum and must vote to move forward with the approval process. A minimum of two-thirds of the votes cast (after removing abstentions) must be in favor of the abstract for its approval by the SLC. Within 2 working days, the SAC will distribute results of the vote to the lead investigator. If approved, the investigator may address comments and suggestions received and proceed with submission of the abstract to the meeting. The final submitted abstract should be provided to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) to be sent to all members of the SLC and the PC.

The SLC Chairs in consultation with the Co-Directors of the SAC will resolve any issues regarding an abstract. Authors whose abstracts are accepted must inform the PC ([phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu)) of that acceptance.

## **VII. ORAL AND POSTER PRESENTATIONS OF APPROVED ABSTRACTS**

### **1. Assistance with Presentations**

The PHACS DRC and HECC are available to assist with graphics and layout for an oral presentation or poster. A request for these services should be sent to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) at least 3 weeks before the submission deadline of the conference for an oral presentation and 4 weeks before the submission deadline of the conference for a poster presentation. While the DRC and HECC can provide assistance as described above, they are not responsible for printing the poster.

### **2. Oral Presentations**

For an oral presentation (e.g. Power Point) of an approved abstract, a draft of the presentation should be circulated to all co-authors at least **two weeks** prior to the conference. Co-authors should be given 1 week to respond with comments. Prior to the conference, the final version must be sent to the relevant WG(s) and to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) which will forward it to the SLC. This will be for informational purposes only – no comments or corrections will be solicited at this time from these groups. One of the PHACS PowerPoint templates should be used for all PHACS oral presentations (including those for R01s using PHACS data) for consistency and to increase the profile of PHACS (templates available after logging into the PHACS website, selecting “Documents”, then “Analyses”, then “Templates and Guidelines”). A separate template will be available for HOPE.

### **3. Poster Presentations**

At least **two weeks** prior to the conference, the first author should circulate the draft of the poster using the PHACS template to all co-authors, allowing them 1 week to respond with comments. Prior to the conference, the final version of the poster must be sent to the appropriate WG(s) and to the [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu), which will forward it to the SLC. This will be for informational purposes only as no comments or corrections will be solicited at this time from these groups. It is strongly encouraged that authors use the PHACS PowerPoint poster templates available<sup>6</sup>. The first author is generally responsible for all costs associated with the presentation.

### **4. Presentations of Previously Published or Presented Materials**

PHACS investigators who wish to present PHACS research findings that have been previously published or presented publicly at a scientific conference (and thus previously approved by the SLC), should notify [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) to get clearance to proceed. Such presentations should only include the material that has been previously presented or published. As a courtesy, it is recommended that the first author of previous presentations be notified and acknowledged. PHACS should be acknowledged in any such presentations.

Presentation of PHACS research findings that have not previously been published or presented publicly require approval by the SLC as described above.

## 5. Use of Site-Specific PHACS Data by a Site

Any data collected for PHACS protocols or PHACS-funded concepts using PHACS resources is considered PHACS data. Sites are free to access and analyze their own PHACS data for internal uses, such as quality assurance or educational purposes. PHACS should be acknowledged when appropriate.

Presentations at regional or national meetings that are descriptive of PHACS site activities or include a presentation of PHACS data require prior approval by the members of the PHACS PC and should acknowledge PHACS support. To obtain approval, a written request should be submitted to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) (with a copy of the abstract if appropriate) prior to the presentation or abstract submission.

Likewise, manuscripts that are descriptive of PHACS site activities or include a presentation of PHACS site data require prior approval by the PHACS PC and should acknowledge PHACS support. To obtain approval the manuscript should be submitted to [phacs@hsph.harvard.edu](mailto:phacs@hsph.harvard.edu) prior to submission for publication.

## VIII. REFERENCES

- <sup>1</sup> [PHACS Website](#) On the public side, go to Our Research/Resources for Researchers/Funding Acknowledgements, select which acknowledgements or funding statement apply to you.
- <sup>2</sup> [International Committee of Medical Journal Editors \(ICMJE\) Defining the Role of Authors and Contributors](#)
- <sup>3</sup> [PHACS Website](#) On the public side, go to Findings/Research Summaries, and select the research summary you want to view.
- <sup>4</sup> [National Institute of Health Manuscript Submission \(NIHMS\) System](#)
- <sup>5</sup> [PHACS Website](#) On the public side, go to Our Research/Resources for Researchers/Data Request form.
- <sup>6</sup> [PHACS Website](#) After logging in, go to Documents/Analyses/Templates and Guidelines and select “PHACS Poster Template” either in landscape or portrait, depending on your preference.

## IX. INQUIRIES

For questions, please email [phacs.pm@fstrf.org](mailto:phacs.pm@fstrf.org)

**Figure 1: Capsule and Concept Sheet Development and Recommended Timeline**

DELIVERABLES	PROCESS	TIMELINE
<b>CAPSULE</b>	Lead Investigator develops & sends capsule to WG co-chairs	No Timeline
	Working Group reviews and approves capsule Lead Investigator sends approved capsule to HECC/ESC	Within 1 wk of capsule approval
<b>CONCEPT SHEET (CS)</b>	Lead Investigator: <ul style="list-style-type: none"> <li>Develops CS with team</li> <li>Works with Stat/epi</li> <li>Incorporates HECC comments</li> </ul>	<ul style="list-style-type: none"> <li>Works with primary WG to review/approve CS</li> <li>Sends CS to SLC for review</li> <li>Presents CS on SLC</li> <li>Addresses SLC comments</li> </ul>
<b>LAB TESTING &amp; DATA REVIEW</b>	Conducts lab assays	Varies
	Analysis Team checks data quality and sends queries	1-2 months
<b>PRELIMINARY ANALYSIS REPORT</b>	Analysis Team: <ul style="list-style-type: none"> <li>Performs preliminary data analysis</li> <li>Sends preliminary report to lead investigator</li> </ul>	≤4 months from data availability
<b>FINAL DATA ANALYSIS REPORT</b>	Analysis Team: <ul style="list-style-type: none"> <li>Performs final data analysis</li> <li>Sends final report to lead investigator and team</li> </ul>	≤4 months from prelim. report
<b>FIRST DRAFT MANUSCRIPT</b>	Lead Investigator: <ul style="list-style-type: none"> <li>Works with writing team to write first draft of manuscript</li> <li>Additional analysis may be required.</li> </ul>	≤3 months
<b>FINAL MANUSCRIPT</b>	Lead Investigator: <ul style="list-style-type: none"> <li>Incorporates team comments and finalizes manuscript</li> <li>Receives approval from team of final manuscript</li> <li>Writes participant summary</li> </ul>	≤2 months
<b>PUBLICATIONS COMMITTEE (PC) REVIEW</b>	Lead investigator: <ul style="list-style-type: none"> <li>Sends final manuscript, author checklist &amp; community research summary to PC</li> </ul>	<10 Working Days
	Publications Committee Review: <ul style="list-style-type: none"> <li>Approves and gives recommendations/comments</li> </ul>	
<b>MANUSCRIPT SUBMISSION TO JOURNAL</b>	Lead investigator submits manuscript to journal	

## APPENDIX I

### COMMUNITY RESEARCH SUMMARY GUIDELINES FOR PHACS AUTHORS

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

#### **When to submit a Community Research Summary:**

The lead investigator should submit a Community Research Summary based on the final manuscript. It should be submitted along with the final version of the manuscript to the PHACS Publications Committee for review. Manuscripts will not be approved for submission unless they are accompanied by a Community Research Summary.

#### **Contact:**

The Director of Health Education and Communication will be listed as the contact on the Community Research Summary and will respond to basic questions from participants about the summary. However, when necessary, some questions will be forwarded to the authors.

Please feel free to reach out to the Health Education and Communication Core ([hecc@hsph.harvard.edu](mailto:hecc@hsph.harvard.edu)) if you would like assistance as you are drafting the summary.

#### **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. Please confirm the reading level of your Community Research Summary before submitting to the Publications Committee. Reading level depends on many factors, including the length of sentences and complexity of terms and syntax. Microsoft Word has a proofing feature under the "Spelling and Grammar" option (it may be under the "Review" or "Tools" tab), where you can run readability statistics on your summary (check with your IT department if you are unsure of how to turn this feature on). 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.

**We aim for a 6<sup>th</sup> – 8<sup>th</sup> grade reading level, which is** the average reading level of U.S. adults and the OHRP-recommended reading level for informed consent materials. However, an exception can be made if your summary includes a lot of medical terminology. If this is the case, please aim for a Microsoft Word reading level of 10<sup>th</sup> grade or below.

#### **Community Research Summary Outline**

Please fill out each section for your manuscript.

**Manuscript Title and authors:** Include the title and all authors listed on the manuscript, and the primary working group.

*For instance:* Rough K, Tassiopoulos K, Kacanek D, Griner R, Yogev R, Rich KC, and Seage GR III for the Pediatric HIV/AIDS Cohort Study. 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:* Drug and Alcohol Use in Pregnant Women Living with HIV Went Down Over Time

**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 some women with HIV used drugs and alcohol while pregnant. Using drugs and alcohol while pregnant can hurt mothers and their infants. We wanted to see if drug and alcohol use during pregnancy has changed over time for women with HIV. This can help 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-affiliated studies and substudies (SMARTT, AMP, AMP Up, TERBO, HOPE) or other study affiliation, HIV status, pregnancy status, etc.

*For instance:* 4,408 pregnant women with HIV participated. Some women were in the SMARTT study. Others were from a 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 pregnant women with HIV used drugs and alcohol over time. We compared women in our study with 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:* We found that fewer pregnant women used drugs and alcohol over time. In 1990, 82% used these substances but by 2012, only 23% did. Women who used drugs or alcohol in a past 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:* Having HIV does not make pregnant women more likely to use drugs or alcohol. However, we should give extra support to women who 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 Community Research Summary?

## APPENDIX II

### PHACS MANUSCRIPT AUTHOR CHECKLIST

Manuscript Title:

Lead Author:

Working group(s):

Target journal:

Link to Target journal authorship guidelines:

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 manuscript cites the appropriate PHACS and/or HOPE grant numbers.
- 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, AMP-Up, SMARTT, or both AMP and SMARTT, TERBO Brain and/or HOPE).
- If required by the target journal, funding sources have been included on the title page or where the journal specifies.
- Include PDF or a link to the journal’s guidelines for manuscript submission
- The manuscript is in the format required by the target journal and is in a single MS Word. (If necessary, figures may be submitted separately.)
- Does the journal require that data from the published manuscript be available to interested investigators?     Yes     No
  - ***If yes***, did you confirm with the Data Resources Committee (DRC) that the data from your specific manuscript can be made publically available?  
 Yes     No

- **If yes**, did you include in your manuscript the link to access the form on the PHACS website for investigators interested in accessing the data?

<https://phacsstudy.org/Our-Research/Data-Request-Form> for data requests

Yes       No

- A one-page Community Research Summary has been submitted along with the manuscript, following the guidelines in APPENDIX I of the Publications Policy (Community Research Summary Guidelines for PHACS Authors)

## APPENDIX III

### PHACS MANUSCRIPT REVIEWER CHECKLIST

Title:

First Author:

Reviewer and Date of Review:

This template has been developed to facilitate the review of manuscripts on behalf of the PHACS Publications Committee. If your comments do not fit on this form, please attach another document with your additional comments. Send this review to the PHACS Publications committee via [PHACS@hsph.harvard.edu](mailto:PHACS@hsph.harvard.edu) within 5 working days of receipt of the manuscript. Please note that a detailed review is not required. Please confirm that the manuscript is clear, does not contain major omissions or areas of concern, and complements the PHACS project.

#### **Administrative Review (Completed by PHACS Program Coordinator):**

- The manuscript cites the appropriate PHACS and/or HOPE grant numbers.
- The document includes the appropriate PHACS acknowledgements and includes "...for the Pediatric HIV/AIDS Cohort study" in the author masthead.
- The document is formatted and ready for submission.
- A one-page Community Research Summary was included with the manuscript at the appropriate reading level.

#### **Publications Committee Review:**

- The participant summary accurately reflects the results discussed in the manuscript and is appropriate for distribution to the PHACS sites and CAB.

#### **Comments on Participant Summary (optional):**

- The manuscript text is clear and does not contain major omissions or areas of concern and complements the PHACS project.

#### **Comments on manuscript:**

#### **Publications Committee Decision:**

- I hereby endorse the submission of this manuscript for publication.
- I disapprove submission of this manuscript for publication.

I conditionally approve this manuscript subject to consideration of the comments below.

***If conditionally approved for submission:***

I would like to see the manuscript again prior to submission.

I do not need to see the manuscript again prior to submission.

**Comments:**

General:

Journal formatting:

Clinical:

Methodologic (Epidemiologic/Statistical):

**APPENDIX IV**

**SUMMARY OF EMAIL ADDRESSES/WEBSITE LINKS FOR PUBLICATION POLICY REQUIREMENTS OR ASSISTANCE**

<b>Task/Assistance</b>	<b>Email/website</b>
Submit manuscript to PC for review: final manuscripts, revised final manuscripts, request expedited review Notify PC that manuscript was accepted by journal Request approval to share PHACS data for journal requirements Request approval to present previous published or presented PHACS findings Request approval to present or publish PHACS site-specific activities or data Assistance setting up Zoom calls Help with graphics or layout of presentations	<a href="mailto:PHACS@hsph.harvard.edu">PHACS@hsph.harvard.edu</a>
PHACS/ HOPE acknowledgements and funding statements General PHACS acknowledgments without aims to address Journal specific requirements	<a href="#">website</a> <a href="#">acknowledgments section</a>
Process to submit manuscript to NIHMS	<a href="https://www.nihms.nih.gov/about/overview/">https://www.nihms.nih.gov/about/overview/</a>
Location of Community Research Summaries	<a href="https://phacsstudy.org/Findings/Research-Summaries-English">https://phacsstudy.org/Findings/Research-Summaries-English</a>
Location for outside investigators to request access to PHACS data	<a href="https://phacsstudy.org/Our-Research/Data-Request-Form">https://phacsstudy.org/Our-Research/Data-Request-Form</a>
Request study design and/or methodologic assistance	<a href="mailto:phacs.esc@fstrf.org">phacs.esc@fstrf.org</a>
Templates Power Point Poster	<a href="#">PHACS Website</a> After logging in, go to Documents/Analyses/Templates and Guidelines. Select “PHACS Poster Template” or “PHACS PowerPoint Template”.