

Research and Development Policy Summary

Aim of capsule and concept sheet (CS):

To produce a single manuscript, or at the most two manuscripts, if based on a single set of analyses

*Investigators should follow the recommended timeline
from capsule development to CS approval by SLC*

Capsule

Role and Responsibilities of Lead Investigator

Proposing investigator

- Identify appropriate working group (WGs), contact Co-Chairs
 - Consider topical and scientific alignment for WG review
 - May have joint WG review but only one primary WG approval required before moving to next stage
- Investigator(s) outside PHACS should identify a PHACS co-investigator
- Investigators are welcome to submit new capsule
 - However, prior to submitting a new capsule, if proposing investigator is leading ≥ 2 active CSs (not counting grants) timing of submission must be discussed with WG Co-Chairs
 - Submit timeline for completion of ongoing CS to WG Co-Chairs
- Invite/include co-investigators as initial development of writing group
- Send to WG Co-Chairs for approval to move forward
 - Active discussion with Co-Chairs that capsule aim is one manuscript (max 2 manuscripts from single set of analyses, but must be approved by WG Co-Chairs)

Capsule Elements

No more than 4 pages (excluding cover page and references)

- **Cover page** - Title, lead and co-investigators, PHACS primary WG (secondary if needed)
- **Background and Significance** - including summary of background literature
- **Major study objectives**
- **Study population (inclusion and exclusion criteria)** - Estimated sample size, feasibility
- **Brief study design each aim – e.g. cross-sectional, longitudinal, exposures and outcomes**
- **Scientific impact** - Impact of sub-study/analysis on science, guidelines, and/or patient care
- **Resources required** - Funding source, if not PHACS. Estimate of resources and time (FTE) needed by DRC statisticians or epidemiologists
- **Collaborating networks** (if relevant)
- **Key references** (not included in page count)
- **List of ongoing concept sheets and timeline for completion**

Capsule Review

Capsule review by WG, ESC, and HECC

- Two reviewers assigned by WG co-chairs (one clinical, one methodologic)
- Investigators and reviewers give brief presentation on WG call
 - In rare instances when there is a time constraint or scheduling difficulties, the WG members can review a capsule by email at the discretion of the WG Co-Chairs
- A capsule is approved by a majority of votes cast in the WG (even if not on call)
 - WG Co-Chairs and members may ask for revisions
- If approved, investigator fills out HECC/ESC Design Review Form directly on the PHACS website <https://phacsstudy.org/Our-Research/Core-Review-Form>
- This will lead to further reviews of capsule by HECC and ESC
- WG Co-Chairs must send the finalized approved capsule to phacs@hsph.harvard.edu
- **See Figure 1 for Capsule and concept sheet development and recommended timeline**

Concept Sheet – Development

Lead investigator

- Primarily responsible for development and finalization of CS with input from writing team
- CS must include an epidemiologist or statistician from the PHACS Data Resources Core, and when appropriate a site coordinator and community group member
- Investigator sends CS to WG Co-Chairs for review (or a late draft of a grant proposal)
 - Active discussion with Co-Chairs that CS will result in one manuscript (max 2 from single set of analyses, must be approved by WG Co-Chairs)

Concept Sheet (CS) Elements - I

(typically 7-10 pages)

- **Cover page** - Title, lead and co-investigators, authorship order (first, second and last authors), PHACS Primary WG (secondary WG/TF if applicable)
- **Background and significance** - including summary of the background literature
- **Major study objectives** - Aims and hypotheses

- **FOR EACH AIM:**
- **Study population** - PHACS cohort (e.g. SMARTT, AMP Up/Lite, HOPE, etc.) and substudy if appropriate (e.g. HPV), inclusion and exclusion criteria, site selection
- **Study design** - Describe design (e.g. cross-sectional, longitudinal, case-cohort), define exposure(s), outcome(s), potential confounders, effect modifier(s)
- If new data will be collected indicate proposed assessments and how and where will be obtained
- **Analysis plan** - Descriptive statistics, model details (univariable and multivariable analyses), justification if plan for two manuscripts
- **Sample size/power calculations** - Sample size, power calculations, or detectable differences for each main exposure on each outcome

Concept Sheet (CS) Elements - II

(typically 7-10 pages)

- **Accrual timeframe** - If appropriate, and estimated timeframe for completion of analysis
- **Timeline, milestones and deliverables**
- **Scientific impact** - Brief statement of impact this sub-study or data analysis on science, guidelines, and/or patient care
- **Resources required** - Funding source, if not PHACS, Estimate of FTE for statisticians and/or epidemiologists in DRC, Training needs if applicable
- **Budget** - Justification when requesting PHACS discretionary funding or ECI/ERP funds, indicate if outside funding will be sought (e.g. R01)
- **Collaborating networks** - if appropriate
- **Key references**
- **See Figure 1 for Capsule and concept sheet development and recommended timeline**

Concept Sheet –WG Review

Concept sheet review by WG

- Two reviewers assigned (one clinical, one methodologic)
- Investigators and reviewers give brief presentation on WG call
 - In rare instances when there is a time constraint or scheduling difficulties, the WG members can review a capsule by email at the discretion of the WG Co-Chairs
- A CS is approved by a majority of votes cast in the WG (even if not on call)
 - WG Co-Chairs and members may ask for revisions

Concept Sheet – SLC Review

Lead investigator

- Sends approved CS and CS Checklist to phacs@hsph.harvard.edu for Scientific Leadership Committee (SLC) review
 - Must be sent at least 15 business days before a SLC conference call
- If this CS is for a grant refer to Section IV.7 in the Research and Development Policy for more details about SLC review

SLC Conference call

- Lead investigator does a brief (~10 minute) presentation of CS using PHACS template https://my.phacsstudy.org/document/search?category_id=12&keyword=slc&start=&end=
- Clinical and methods reviews presented
- Lead investigator responds to reviews and SLC member comments
- A ballot is sent out to SLC members.
- When at least two-thirds of the SLC voting members (a quorum) have voted, the CS is approved if 2/3 of those ballots received approve the CS after excluding abstentions
 - SLC members may ask for revisions

FIGURE 1: Capsule and concept sheet development and recommended timeline

