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 <u>></u>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 <u>https://phacsstudy.org/Our-Research/Core-Review-Form</u>
- 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 time line



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 <u>phacs@hsph.harvard.edu</u> 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 <u>https://my.phacsstudy.org/document/search?category_id=12&keyword=slc&start=&end=</u>
- 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

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

