



CCASAnet Concept Workflow, SOP

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Purpose

This Standard Operating Procedure (SOP) defines a process to standardize the development, approval, and research activities of CCASAnet research proposals.

Scope

This Project Workflow SOP applies to all CCASAnet concept proposals with activity in the CCASAnet 3.0 funding cycle (July 2016-June 2021). Concept Sheets may be submitted by individuals and groups affiliated or unaffiliated with CCASAnet. The process for proposal of regional concepts, detailed below, must be followed. The use of CCASAnet data is restricted to the scope of the approved project.

Roles and Responsibilities

The following individuals have responsibilities according to this SOP. Roles and sample tasks are below:

- **Concept Sheet Lead:** develop concept sheet, present concept to appropriate CCASAnet Working Group (WG) and Executive Committee (CCASA-EC), forms the writing group (WrG), manage research (e.g., draft introduction, participate in analysis), report back to the CCASA-EC and VDCC on progress, circulate draft and submitted abstracts and manuscripts according to timelines
- **Working Groups (WG):** advise on project revisions, monitor concept sheet
- **Writing Groups (WrG):** Comprises at minimum concept sheet lead, one investigator from each participating site, and senior investigators from the VDCC. The WrG may also include additional site investigators, VDCC staff or other collaborators with relevant experience. The WrG must review all concept publications (abstracts, posters and manuscripts), and participate in the majority of concept conference calls.
- **CCASA-EC Members:** review and vote on concepts, review and approve abstract and publication submissions
- **VDCC:** track concept sheet status, circulate documents for review and voting, prepare data set, support analysis and drafting of abstract/manuscript (as needed), review authorship and grant citations

Procedure for CCASAnet Projects

1. A project idea is developed by an investigator and documented using the CCASAnet Concept Sheet template available on the ccasanet.org website <http://www.ccasanet.org/collaborate/>.
2. The concept sheet is assigned to a CCASAnet Working Group for review, via call or WG email list.
3. Once circulated and refined in the WG, the concept sheet is submitted to CCASAnet Program Coordinator (hilary.vansell@vanderbilt.edu).
4. The concept sheet is sent to the CCASAnet-ALL mailing list for review; each CCASAnet site will assess whether their cohort
 - a. has the data requested for the proposed project,
 - b. wishes to contribute data to the project,
 - c. is able to provide the data in the necessary timeframe (for projects outside the annual data submission)
5. Members of the CCASA-EC will discuss whether CCASAnet should allocate resources for the proposed project and whether the project is in line with CCASAnet's strategic vision.
6. The concept sheet is then voted on by voting members of the CCASA-EC (via email or call).
7. A concept sheet receives a status of additional revision required, approved, not approved based on voting.
8. Concept sheets requiring additional revision will return to the WG for discussion and editing.

Once a concept sheet is approved:

1. Concept sheet lead identifies and manages the Writing Group (WrG), with VDCC help, and coordinates project-specific calls (via Skype, or VDCC can support with GoToMeeting).
2. If required, an SOP for additional data collection is developed by VDCC and investigator, and circulated to sites.
3. If required, participating sites deliver additional data.

4. External collaborators will be asked to provide written documentation that cohort data will be used only for the approved project and that data will be destroyed or returned to Vanderbilt once the project is complete.
5. A data analysis plan is created by the project's statistical lead or in collaboration with VDCC.
6. Data analysis occurs.
7. While data analysis is underway, the lead investigator conducts a literature review and drafts the introduction to the manuscript.
8. The lead investigator circulates any draft abstract or manuscript to the CCASAnet-ALL mailing list for review before submission, allowing least 1 week for abstracts and 2 weeks for manuscripts. For investigators external to CCASAnet, the VDCC Program Coordinator can assist with the group mailings.
9. The concept sheet lead will be the first and corresponding author and will present abstracts at conferences unless otherwise agreed upon by the WrG. Members of the WrG will be co-authors provided that they meet the criteria for authorship according to the Uniform Requirements issued by the International Committee of Medical Journal Editors (see <http://www.icmje.org/>) The order of authorship will be determined by the concept sheet lead and senior authors. The by-line should include 'of the Caribbean, Central and South America network for HIV epidemiology (CCASAnet)'. An acknowledgement list of collaborators from each site should also be included, found on the CCASAnet website (insert link). An exception to this general rule will be any publications with a methodological focus.
10. The VDCC will review each draft to ensure up-to-date use of the CCASAnet Acknowledgments text and grant funding numbers.
11. After submission of the abstract or manuscript, the final submitted version should be circulated to CCASAnet-ALL for bookkeeping and sent to the CCASAnet Program Coordinator for tracking.
12. Accepted abstracts and manuscripts should be announced to the CCASAnet-ALL list for tracking and congratulations!

Pre-Publication Check List

This check list should be used for all abstracts, posters, and manuscripts.

- Confirm submission matches conference or journal guidelines
- Confirm authorship, proper name spelling, and correct affiliations with all participating sites
- Confirm grant numbers, English grammar review (if applicable), and author list with VDCC PI
- Circulate abstract or manuscript to CCASAnet-ALL mailing list before submission, allowing at least 1 week for abstracts and 2 weeks for manuscripts
- Submit publication and send final version to VDCC for tracking
- Update VDCC with submission status
- Announce acceptances to CCASAnet-ALL mailing list

NOTE: Given current funding constraints, CCASAnet investigators should discuss journal selection and publication costs with the VDCC prior to submission. External investigators are responsible for covering their own publication costs. All investigators submitting conference abstracts, posters, or presentations are responsible for their own expenses to attend these events, as CCASAnet 3.0 includes no budget for meetings or travel.