CCASAnet Principles of Collaboration

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1. Introduction

The Caribbean, Central and South America network for HIV epidemiology (CCASAnet) brings together the expertise and resources of Vanderbilt University and clinical and research sites in Argentina, Brazil, Chile, Haiti, Honduras, Mexico, and Peru. CCASAnet is a member of the International Epidemiologic Databases to Evaluate AIDS (IeDEA) consortium, a global network of researchers sponsored by the U.S. National Institute of Allergy and Infectious Diseases and other institutes of the U.S. National Institutes of Health.

The goal of all IeDEA regions, including CCASAnet, is to create regional consortia with repositories of observational HIV data that can be used to answer questions about the characteristics of the global HIV epidemic.

The CCASAnet project has the following specific aims:

1. To create and support a network of participating sites in the Caribbean and Central and South America for sharing of research and clinical data related to the epidemiology of HIV and related conditions;
2. To create a shared data repository and associated technologies for data merging that forms the union of the data sets submitted by sites;
3. To conduct and facilitate research using the shared data repository that enables answers to questions that cannot be answered by any single source;
4. To develop and evaluate new biostatistical methods relevant to HIV epidemiology;
5. To provide education and training to assist sites to improve the quality and consistency of their clinical research activities;
6. To collaborate with other regional IeDEA networks on global HIV analyses and the development of international standards for sharing and standardization of HIV-related data.

This document describes the principles of the CCASAnet collaboration. It is understood that these principles will be reviewed regularly and that this document can be modified by the CCASAnet Executive Committee (CCASA-EC, see item #10) as experience accrues.

2. CCASAnet Collaborations

CCASAnet collaborations are research projects that use all or part of the CCASAnet data set, which is defined as any combination of the individual data sets submitted by CCASAnet sites (currently in Argentina, Brazil, Chile, Haiti, Honduras, Mexico, and Peru) or metadata maintained by the Vanderbilt Data Coordinating Center (VDCC).

Any CCASAnet member or outside researcher who wants to use CCASAnet data should submit the "Concept Sheet for Research Proposal" form, also known as the Concept Sheet, which is available on the CCASAnet website http://www.ccasanet.org/collaborate/ and distributed regularly to CCASAnet investigators via the CCASAnet email list. All project proposals will be reviewed in a timely fashion by the CCASA-EC.

3. Commitment of Participants

In order to maintain an updated and harmonized IeDEA database and simplify data preparation, sites agree to submit a full data update at least once per year. Data should be prepared according to the CCASAnet Data Transfer Protocol, or as agreed upon with the VDCC. Submitted data should be up-to-date through one year prior to the submission date.

Participation in CCASAnet collaborations is on a project-by-project basis. Member sites are not required to allow their data to be used for a particular project or participate actively in every study or analysis. Site Principal Investigators (Site PIs) may opt out of participation on a project by informing the VDCC via email during circulation of a specific project concept sheet.

By agreeing to collaborate, participants commit to supplying the requested and relevant data from their site, along with any metadata necessary for interpreting the information. These data shall be used only for the purposes defined in the concept sheet. CCASAnet members are encouraged to contribute their expertise to a project even if the proposal does not request their site data. Sites should review all circulated abstracts and manuscripts in which their data are used.

4. Confidentiality of Data

All electronically stored data are to be kept confidential by the collaborators, members of their immediate scientific teams, and those directly involved in coordinating the project. All data collected and merged by the VDCC will be anonymized first by local centers. Local centers will maintain the anonymization key and ensure this key is not shared with anyone conducting CCASAnet related analyses. To protect the privacy and security of these data, all data sets transferred to the VDCC or from the VDCC to the sites or investigators shall be sent via secure mechanisms (e.g., CCASAnet file upload server, REDCap Send-It). Unencrypted data sets should never be sent via email. In the case of a data breach, sites and the VDCC should report the event to their local IRBs and provide a written plan to avoid future occurrences.

When CCASAnet data are transferred to investigators outside of IeDEA for research collaborations, the VDCC will perform full de-identification of all HIPAA identifiers, including date shifting, to ensure appropriate protocols have been applied to all components of the data set. External investigators shall provide written documentation that data will be used only for the approved purpose as defined in the concept sheet, and that data shall be destroyed, deleted, or returned upon completion of the project. If analysis-ready data sets developed by external investigators require archiving, in case of audit or scientific challenges to the work, then the VDCC will archive such data sets on behalf of the external investigator.

5. Analyses of Data

Only CCASAnet projects that have been agreed upon by the CCASA-EC will be presented outside the CCASAnet team. However, collaborators or groups of collaborators are encouraged to propose and/or perform additional projects and analyses that have different aims and address new hypotheses. If these external collaborations will use data sets or resources that have been supported by CCASAnet, then the proposals should be discussed and approved by the CCASA-EC (electronically or at meetings) and the CCASAnet grant should be cited as a funding source.

Analyses can be performed at any of the collaborating centers, contingent on the approval of the VDCC Biostatistics Core Lead. However, once the CCASA-EC approves a list of sites participating in an analysis, the work related to that research project should be restricted to the approved sites. Site PIs can opt to have their local data not included in a given analysis prior to results being published.

The Vanderbilt Data Coordinating Center will maintain a log of all datasets transmitted by participating sites and ensure the confidentiality of datasets transmitted to Vanderbilt from CCASAnet sites. The VDCC aims to include all sites in all studies, as this benefits CCASAnet's global presence. However, the VDCC retains the right to exclude site data from analyses if the data are submitted too late to be processed, queried, and incorporated in the analysis data set; if the submitted data are incomplete or improperly formatted; if unresolved data quality issues are detected in site data sets; or if sites have outstanding unresolved data queries. The VDCC is accountable to the CCASA-EC and NIH and will maintain copies of data only as required by principles of scientific integrity for CCASAnet activities, to support data harmonization, data sharing mandates, abstracts and publications, and any challenges to the validity of the data or its analysis that may arise as a result of publication.

6. Updates and Progress Reports

There will be at least four annual calls of the CCASA-EC. Site PIs or their designees shall attend at least 75% of the calls. An official in-person meeting will be held only in years when funding is available. The location of this meeting will rotate among the member countries and the CCASAnet Coordinating Center at Vanderbilt University. CCASAnet investigators may hold an informal in-person meeting at CROI if over half of sites will have representatives attending the conference.

The VDCC is responsible for submitting Annual Progress Reports on the CCASAnet collaboration to the NIH. VDCC will also circulate a list of projects and their status (monthly), and report on the status of the network-wide data (annually). Concept Sheet leads are responsible for providing project updates to the VDCC, via email or the REDCap monthly survey.

7. Circulation of Scientific Reports for Comments Prior to Submission for Publication

The results of CCASAnet projects can be presented in paper or poster format at scientific meetings or submitted to scientific journals for publication, given approval by the CCASA-EC. Abstract and manuscript drafts will be circulated to the writing group and relevant Working Group for feedback and the writing committee will revise as necessary. The revised manuscripts will then be circulated to the CCASAnet-ALL mailing list with a time limit for final comments and CCASA-EC approval prior to submission for publication. **Investigators must allow 1 week for review of abstracts and 2 weeks for review of manuscripts by the** CCASA-EC**.** The CCASA-EC retains the right to veto or delay a submission if the timeframe for review is not met.

8. Authorship of Publications, Reports, Conference presentations

All of a paper's authors should meet the authorship criteria outlined by International Committee of Medical Journal Editors, available at http://www.icmje.org. (These are also the criteria used by JAMA.) Additionally, all individuals who qualify for authorship should be listed as authors. These may include members of the paper's writing committee, CCASA-EC members, site collaborators, and external investigators using CCASAnet data. Individuals who have participated in the research project but do not meet authorship criteria shall be acknowledged in the paper for their specific contributions. Additionally, individuals who are acknowledged in a paper should know and approve of their being acknowledged. The VDCC will maintain official "CCASAnet Acknowledgment Text" that has been reviewed and approved by each site.

All manuscripts, abstracts, presentations, and scientific reports developed via the CCASAnet or IeDEA concept sheet process should reference the International Epidemiologic Databases to Evaluate AIDS (IeDEA) collaboration and the Caribbean, Central, and South America Network for HIV epidemiology (CCASAnet). These publications and presentations should reference support by NIH Cooperative agreement U01AI069923. The NIH declares the following in our CCASAnet grant award: "All publications, posters, oral presentations at scientific meetings, seminars, and other forum in which results of this co-funded research are presented must include a formal acknowledgment of the NIDA/NIMH/NICHD/NCI/NIAID support, citing the NIAID grant number."

We recommend the following wording **for CCASAnet papers**, based on the NIH text:

> **This work was supported by the NIH-funded Caribbean, Central and South America network for HIV epidemiology (CCASAnet) (U01AI069923), a member cohort of the International Epidemiologic Databases to Evaluate AIDS (IeDEA).** This award is co-funded by the U.S. National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), the National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), and the National Institute of Allergy and Infectious Diseases (NIAID).

CCASAnet contributes to our research environment in many ways that extend far beyond direct funding for individual projects. Examples include intellectual exchange, mentoring, consultation, data, development of databases and electronic medical record (EMR) systems, and support for data collectors, data entry technicians, and investigators. CCASAnet sites should also cite CCASAnet in any site publication that touches on CCASAnet resources. We suggest the following wording, which adds "in part" to the first sentence, for **site papers that have benefitted from the CCASAnet collaboration**:

> **This work was supported in part by the NIH-funded Caribbean, Central and South America network for HIV epidemiology (CCASAnet), a member cohort of the International Epidemiologic Databases to Evaluate AIDS (IeDEA) (U01AI069923).** This award is co-funded by the U.S. National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), the National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), and the National Institute of Allergy and Infectious Diseases (NIAID).

9. Role of CCASAnet Sites
The in-region HIV care, treatment, and research sites participating in CCASAnet form the foundation of the network. They are responsible for collecting and de-identifying routine patient care data, ensuring the data are complete and accurate, and securely sending the data to the VDCC using the format defined in the CCASAnet Data Transfer Protocol. Sites will also participate in 2-3 annual surveys as required in the IeDEA Funding Opportunity Announcement, including the IeDEA-wide Site Assessment Survey.

Site investigators should participate actively in the CCASAnet and IeDEA-wide research agendas, including working groups and contributions to abstracts and publications. Site PIs are responsible for directing activities at their site. They should provide mentorship for junior investigators and should attend, or appoint a designee to attend, the CCASA-EC meetings. Sites are responsible for managing their local budgets and should submit financial invoices to Vanderbilt quarterly *at minimum*.

10. Role of the Coordinating Center (Vanderbilt University Medical Center)
The Vanderbilt Data Coordinating Center (VDCC) will coordinate all aspects of CCASAnet activities and management, which includes collecting and merging CCASAnet data, maintaining project logs, and hosting the CCASAnet website. The VDCC will also coordinate CCASAnet activities to the global IeDEA network, including coordinating approval of and participation in IeDEA-wide concept sheets, preparation and submission of harmonized data sets conforming to the IeDEA Data Exchange Standard, and coordination of regional distribution of IeDEA-wide surveys. The VDCC is responsible for preparing and submitting required documentation to the funding agency, including the Annual Progress Report, annual Federal Financial Report, and Just-in-Time grant information.

11. Composition and Role of the CCASAnet Executive Committee
The CCASA-EC will be composed of the Principal Investigators at each of the participating sites, the VDCC Cores leaders, and the NIH Project Scientist. Every collaborating center will be represented in the CCASA-EC; each center, the VDCC PI, and the NIH Project Scientist will have one vote. The CCASA-EC will be responsible for providing input regarding the overall direction of CCASAnet projects and the use of CCASAnet data. It has the following responsibilities:

1. Hold at least 4 CCASA-EC calls per calendar year
2. Communicate periodically to assess network progress and identify barriers to productivity
3. Monitor the activity of CCASAnet Working Groups and writing groups
4. Review and approve internal and external CCASAnet and IeDEA concept sheets
5. Oversee the writing and publication of CCASAnet analyses
6. Represent CCASAnet to regional and global organizations, including PAHO
7. Identify and address long-term technical and strategic issues regarding the collaboration, which includes defining the strategic vision of the network, ensuring active involvement of CCASAnet members in the IeDEA global network, and revising the principles of collaboration.

CCASAnet Site PIs are responsible for attending the four annual CCASA-EC calls, or appointing a site representative to attend. At minimum, sites should be represented on 75% of the calls. The VDCC shall produce minutes of the call for circulation with the broader CCASAnet network.

12. Ownership of Data
All collaborating sites retain ownership of their original data.

13. IRB Approval
All CCASAnet sites and the VDCC are responsible for maintaining active Institutional Review Board (IRB) or Ethics Board approval for CCASAnet research activities. Sites should submit annual IRB Continuing Review applications as required by their institutions. CCASAnet investigators should participate in Responsible Conduct of Research Training (the CITI course or equivalent) as required by their institutions. Documentation of investigator training and site IRB approval should be

sent to the VDCC. Participation in any CCASAnet collaboration will be consistent with the terms of written approval by a local Institutional Review Board (IRB).