

Southern HIV & Alcohol Research Consortium (SHARC)

SHARC Concept System

Policies and Procedures

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I. CONCEPT SUBMISSION

The submission of a Concept is required for all investigations proposing analyses using existing data sets hosted by the Southern HIV and Alcohol Research Consortium (SHARC). The [Concept Submission Form](#) and Concept Research Plan (**Appendix A**) are used to propose a Concept and identify collaborating Investigators. The [Concept Submission Form](#) is an online form. Following transmittal of the Concept Submission Form, Concept Lead Investigators will receive feedback on their proposal through a peer review process conducted by study-related researchers and faculty. All decisions regarding SHARC Concept submissions are ultimately under the purview of the Concept Executive Committee.

A. Concept Roles

Concept Lead Investigator and Concept Co-Investigators

Each Concept will have a Lead Investigator, who will be the primary point of contact for the Concept, provide updates on the status of the Concept, and initially lead the Concept Writing Group. Students and non-faculty Lead Investigators will identify at least one SHARC faculty member as a Faculty Sponsor. External or unaffiliated students or faculty must also identify a SHARC faculty member to sponsor and collaborate on the Concept. That is, for all Concepts, at least one affiliated SHARC faculty member should be identified. All other collaborators on a Concept project should also be listed as Concept Co-Investigators.

Concept Review Committee

A new Concept is reviewed first by the Concept Review Committee. This committee is made up of faculty and researchers, including the Principal Investigator, who are responsible for the requested dataset. The Concept Review Committee provides feedback on the Concept within **10 business days**, and each Reviewer indicates his or her interest in joining the Concept Lead Investigator's Writing Group.

Concept Executive Committee.

Members of the Concept Executive Committee consider the feedback of the Concept Review Committee in determining whether to recommend Approval, Revision and Resubmission, or Rejection of a Concept. Letters must be signed by the Executive Committee Lead, Dr. Natalie Chichetto.

Concept Administrator.

The Concept Administrator manages the Concept process from initial submission of a Concept through both levels of peer review followed by recommendation of a decision in response to the proposed Concept. Concept Lead Investigators are required to maintain communication with the Concept Administrator to report research progress and to initiate requests for approval of presentations, abstracts, and manuscripts for publication. Questions at any stage in the Concepts process can be addressed to the Concept Administrator (sharcconcepts@php.ufl.edu). The Concept Administrator will bring to the Concept Executive Committee any question that addresses a topic beyond guidance around administrative policy and procedures.

B. Types of Concepts

Concepts can be submitted to request approval for analysis of existing data, or to conduct an ancillary project to ongoing data collection (add new data collection or modify an existing project).

Concepts related to existing data or specimens.

The SHARC data repository includes data from several ongoing as well as previously completed projects. Each dataset has a Principal Investigator; most datasets will also have a Project Review Committee and/or a list of additional investigators who should be invited to be part of a Writing Group. Information about each available dataset is listed on the SHARC website. Concept investigators should indicate a specific dataset and provide a summary of the key variables of interest. Requests for access to study specimens (e.g., blood in our repository) may require additional review.

Ancillary Projects.

Proposed investigations involving the collection of new data (questionnaires, clinical and physical measures), modification of consent forms, or modification of study procedures will be considered ancillary Projects. Ancillary Projects will undergo additional review related to the types of resources needed to modify an existing project, and to consider the potential burden on study participants or research staff. Ancillary Projects will require review by the SHARC Concept Executive Committee.

C. Concept Submission, Review, and Approval

Concept submissions are submitted through the [Concept Submission Form](#). Questions about the process can be answered by the Concept Administrator (sharcconcepts@php.ufl.edu).

Once the Concept is received, the Concept Administrator will ensure that all required information is present and confirm with the Data Manager that the requested data variables are available. Once complete, the Concept Administrator will circulate the Concept Submission Form and Concept Research Plan to the appropriate Concept Review Committee. Each dataset will have its own Concept Review Committee, including the Principal Investigator who is responsible for the dataset. To facilitate the concept review process, the concept investigator may be invited to the concept meeting to present the concept study plan and get feedback from the Concept Review Committee during the meeting.

During a maximum **10 business day** review period, all Concept Review Committee members will have the opportunity to evaluate the science, assess the feasibility of the study, and consider whether the proposal overlaps with existing research. Concept Review Committee members will be asked to decide to (1) approve as is; (2) recommend revision and re-review; (3) or reject. If there is overlap with existing projects, reviewers may recommend that the project be combined with other related projects or revised. Concept Review Committee members also indicate whether they would like to participate in the Writing Group for the submitted Concept.

Following the review period, the Concept Executive Committee will convene for a final review of the Concept Review Committee decision. If revisions are requested, the Concept Administrator will inform the Concept Lead Investigator of Concept Executive Committee recommendations for Concept modification. The Concept Lead Investigator will submit a revised Concept, together with a cover letter specifically stating how each suggestion from the reviewers was addressed, via the original online [Concept Submission Form](#). The revised Concept then will be sent back to the Concept Review Committee for re-review followed by a second review by the Concept Executive Committee. All decisions regarding SHARC Concept submissions are ultimately under the purview of the Concept Executive Committee.

Once the Concept is approved, the Concept Lead Investigator will receive an approval letter from the Concept Administrator, and the Concept will be listed as “In Progress” on the SHARC website. The Writing Group, consisting of the original Co-Investigators and interested Concept Review Committee members, is established in the Concept Approval Letter.

II. REQUEST FOR DATA

The SHARC Data Manager will coordinate with the Concept Lead Investigator to determine the best strategy to provide access to the data, and also identify any data management or data analytic needs. The Concept Lead Investigator, Concept Co-investigators, and Concept Executive Committee Lead, Dr. Chichetto, will sign a Data Use Agreement (DUA) that outlines specific rules and responsibilities related to storage of the data, the appropriate uses of the data, and requirements related to abstracts and manuscript submission and authorship. Once the appropriate Data Use Agreement (DUA) is signed and returned by **all** parties, the Data Manager will confirm that appropriate IRB approvals (UF and/or FDOH) are present for all persons who will have access to the data and will provide access to the dataset.

Datasets will be kept on secure servers (e.g., University of Florida shared drive) and should not be placed on jump drives or laptops. Data will be de-identified or will only include limited identifiers such as ID numbers and dates (with appropriate IRB approval). Datasets will only include the variables requested on the approved Concept Submission Form; any additional data will require a revision of the Concept and is subject to re-review for approval. If the data request is complex, additional effort may be necessary, and funding support may be required.

III. CONCEPT TRACKING, REVISIONS, AND RETIREMENT

A. Tracking of In Progress Concepts

The Concept Lead Investigator is required submit an online form for approval of all [Manuscripts](#), [Abstracts](#) or [Presentations](#) created from the Concept dataset. In addition, semesterly (January, May, and August) progress reports are required to maintain a Concept's "In Progress" status. A unique link to the Progress Report Form for the concept will be emailed to the lead investigator each semester or as needed.

B. Revisions for In Progress Concepts

Revisions to Concepts can be made at any time and are used to request modifications to the Concept Research Plan, access additional data, or alternate members of the Writing Group. Revisions will include a brief summary of requested modifications, a revised [Concept Submission Form](#), and a revised Concept Research Plan with "track changes". All revisions are subject to an

additional review and approval by the Concept Review Committee and the Concept Executive Committee.

C. Retirement of In Progress Concepts

If the semesterly progress report submitted to the Concept Administrator indicates that no activity is occurring on the project, the project will be considered in probation or retired, and the Concept investigator will be asked to justify the lack of activity. If no progress is made on an approved Concept within two years, it will be automatically retired.

IV. WRITING GROUP AND AUTHORSHIP

The Concept Approval Letter provides Lead Investigators with contact information for all Writing Group members. The Writing Group includes the Concept Lead Investigator, original Co-investigators, and interested Concept Review Committee members who were assigned to the Writing Group during the Concept review process.

The Protocol Writing Group varies for each dataset and is defined by the Principal Investigator of the specific dataset. For previously collected data, the Principal Investigator should indicate up front if any other persons need to be considered for co-authorship (e.g., persons involved in the original collection of the data). For multi-site studies such as the Florida Cohort, each site that contributed data has the opportunity to identify a potential co-author from that site. More than one co-author from a specific site not involved in the submission of a given Concept will require justification (e.g., a second Writing Group member from a site who has special expertise or interest in a given topic).

For large Writing Groups, the Concept Administrator may help to facilitate a conference call for all persons on the Proposal Writing Group to discuss the proposal before getting too far into the analyses. It is ultimately the responsibility of the Concept Lead Investigator to ensure that each member of the Writing Group has the opportunity to provide input and to participate on abstracts and papers. If a Writing Group member does not respond to abstracts and papers that are circulating, the Concept Lead Investigator should let the Concept Administrator know. The Concept Administrator will consult the Concept Executive Committee for a decision as to whether or not to remove the Writing Group member from the Writing Group.

Membership in the original Writing Group does not guarantee authorship on papers or abstracts but provides the opportunity to participate and to be a co-author if criteria for authorship are met. Final authorship decisions should be consistent with criteria as outlined by the International Committee of Medical Journal Editors (<http://www.icmje.org/>). Specifically, all persons who are listed as co-authors should have been involved in **all three** of the following aspects of the abstract or paper.

1. Participation in one (or more) of the following areas:
 - a. Planning, design, or interpretation of study data
 - b. Data collection
 - c. Writing the primary draft of the paper
 - d. Data analysis
2. Reading/editing/commenting on a draft of the abstract or paper.
3. Approval of the final abstract/paper for submission.

Order of authorship is at the discretion of the Concept Lead Investigator, and generally should be based on the amount of input provided by peer Writing Group members on a specific project. Typically, the Concept Lead Investigator would be the first author, and the Principal Investigator of the dataset would have the option to be listed in the last (senior) author position if desired. If multiple co-authors provide similar amounts of input, the order can be listed either alphabetically or chosen at random. The Principal Investigator of the dataset can also assist with authorship issues, if needed. Persons who contribute to the work but do not meet all three criteria for authorship can be listed in acknowledgements.

V. ABSTRACTS, PRESENTATIONS, AND MANUSCRIPTS

A. Abstracts and Presentations

Abstracts and presentations that include SHARC data and are submitted to conferences must be associated with an approved Concept. Abstracts must be circulated for reviews by all co-authors in the original Writing Group, with sufficient time for the authors to respond. Typically, it is common courtesy to give co-authors and the Concept Review Committee members at least one week to review an abstract or presentation and provide edits. If any members of the Writing

Group are not responsive to requests for comments on abstracts or papers, the Concept Lead Investigator should inform the Concept Administrator. The Concept Administrator will consult the Concept Executive Committee for a decision as to whether or not to remove the Writing Group member from the Writing Group.

A [Manuscript, Abstract, & Publication Submission Form](#) must be submitted, together with the final abstract, prior to submission of the abstract to a conference. The [Manuscript, Abstract, & Publication Submission Form](#) must list the name and dates of the conference, conference abstract submission deadline, abstract title, list of co-authors, and a copy of the abstract. The Concept Administrator will evaluate the submission for 1) Authorship requirements, 2) FDOH approval if applicable, 3) Senior SHARC co-author verification of validity of methods, and 4) Acknowledgement of funding support (**Appendix B**).

Once an abstract has been submitted, the Concept Lead Investigator must inform the Concept Administrator about the result of the abstract or presentation submission acceptance. We request that the Concept Lead Investigator provide the Concept Administrator with a PDF copy of the final poster or final slide presentation, and a photo of the Lead Investigator at the event. Accepted abstracts, poster presentations, and oral presentations will be acknowledged on the SHARC website.

B. Manuscripts for Publication

A first draft of a manuscript must be circulated to all members of the Writing Group, with sufficient time to consider incorporation of any suggestions from Writing Group members. All persons who will be co-authors of a paper should comment on the first draft or a subsequent draft that is not the final paper draft. If a Writing Group member does not respond in a timely manner, the Concept Administrator will consult the Concept Executive Committee for a decision as to whether or not to remove the Writing Group member from the Writing Group.

Once a manuscript is ready for submission, it should be submitted using the [Manuscript, Abstract, & Publication Submission Form](#). The Concept Administrator will evaluate the submission for 1) Authorship requirements, 2) FDOH approval if applicable, 3) Senior SHARC co-author verification of validity of methods, 4) Acknowledgement of funding support (**Appendix**

B), and 5) Approval of manuscript submission by Principal Investigator of the dataset. The Concept Administrator will inform the Concept Lead Investigator that the manuscript is approved for submission, or if any changes are suggested prior to submission.

The Concept Lead Investigator is responsible for informing the Concept Administrator about the status of the manuscript. Once a manuscript is accepted for publication, SHARC can assist with press release or other publicity related to the article.

C. Submission of Manuscripts to NIH

The National Institute of Health (NIH) requires all investigators who are participating in studies which are funded by NIH to make their peer-reviewed final manuscripts available to other researchers and to the public at the National Library of Medicine's (NLM) PubMed Central (PMC) (<http://www.pubmedcentral.nih.gov>) within 12 months of the publication date. If your approved Concept uses NIH data, please make sure to follow the NIH's PubMed submission request for your manuscript(s). If you are unsure if your Concept uses NIH data, contact your senior SHARC co-author or Principal Investigator for clarification. Once you have submitted your manuscript to PubMed, please notify the Concept Administrator of your submission with confirmation.

Acknowledgement

We would like to acknowledge our use of the *MACS/WIHS CCS Concept Sheet and Publication Policies and Procedures* document to guide development of this *SHARC Concept Submission Policies and Procedures* resource for investigators proposing analyses utilizing existing data sets hosted by the Southern HIV and Alcohol Research Consortium (SHARC).

Appendix A: SHARC Concept Research Plan Form

SHARC Concept *Research Plan Form*

Please collaborate with your Concept Co-investigators, Faculty Mentor and SHARC Faculty collaborator in the construction of your Research Plan using the following template. You may insert relevant figures, tables or images into this template. Once completed, upload this document as a single file to your online Concept Submission Form.

1. Concept Title

2. Abstract (Maximum 400 words)

3. Background

4. Specific Aims & Hypotheses (Maximum 200 words, not including references)

5. Approach

Please include a summarized study design(s), inclusion/exclusion criteria, analytical methods, & sample size calculations. *Identify the data analyst who will oversee the analyses necessary to support this project.*

For projects that will use participant specimens, describe the criteria for selecting specimens, the lab testing methods, and the procedures for QA/QC.

6. Will the Concept have any need for receiving identifiers in the data set? If yes, please explain.

7. What are the goals of this work (e.g., abstract, paper, grant, etc.)?

8. Indicate any special support you will need (e.g., data analysis, IRB submission, subject area expertise for one or more variables specified in the study, staff training, etc.)

9. References

Appendix B: SHARC Research Projects and Funding Support

"The research reported in this [publication/abstract/poster] was supported by The Southern HIV and Alcohol Research Consortium and *[name of the Institute(s), Center, or other NIH offices]* of the National Institutes of Health under award number *[NIH grant number(s) in this format: R01GM987654]*."

Research Project	Funding Project Support with Grant #
30 Day Challenge/ACME	30 Day Challenge: NIH/NIAAA U01 AA020797
ACME	NIH/NIAAA U01AA026225
Florida Cohort Wave 2	The Southern HIV and Alcohol Research Consortium NIH/NIAAA U24 AA022002
Florida Cohort Wave 3 Florida Cohort Transgender Supplement	The Southern HIV and Alcohol Research Consortium NIH/NIAAA U24 AA022002
Florida Cohort Wave 4	The Southern HIV and Alcohol Research Consortium NIH/NIAAA R01AA030481
MAPLE MAPLE Microbiome Supplement MAPLE Alzheimer Supplement	The Southern HIV and Alcohol Research Consortium NIDA R01DA042069
WHAT-IF	NIH/NIAAA U01 AA020797
PATH	The Southern HIV and Alcohol Research Consortium NIH/NIAAA P01AA029543
Less is More	The Southern HIV and Alcohol Research Consortium NIH/NIAAA P01AA029543
T32 Funding	T32AA025877
**If the SHARC data team provided statistical support, acknowledge the data core funding support.	NIH/NIAAA U24 AA022002