



HCHS/SOL PUBLICATIONS POLICY AND PROCEDURES

1. ADMINISTRATIVE NOTES

- 1.1. **Study website.** * The HCHS/SOL investigator website <https://sites.csc.unc.edu/hchs/> has abundant information to assist researchers within and outside the HCHS/SOL network to become involved with the study. Questions related to manuscript proposals and ancillary studies can be made through contact with HCHSAdministration@unc.edu if you do not find your answer on the website.

***Please note that website links as listed in this document are subject to change as the website continues to be updated.**

- 1.2. **Website portal.** All Publications Committee work is done through the website portal. Please reference the following link to learn how to use the Web portal. <https://sites.csc.unc.edu/hchs/WebsiteHelpPage>. No email submissions (of proposals, abstracts, etc.) are accepted. Contact HCHSAdministration@unc.edu if you have a question regarding the process or website.

- 1.3. **Investigator accounts.** All investigators must have a study website account and a complete directory listing. A new account may be obtained through the HCHS/SOL website with the assistance of any HCHS/SOL Principal Investigator (PI) or Co-Principal Investigator (Co-PI). Contact HCHSAdministration@unc.edu for questions. Please be sure to keep your contact information up to date.

2. PUBLICATIONS POLICY OBJECTIVES. The objectives of the publications policy of the HCHS/SOL Study are as follows:

- 2.1. To ensure expeditious and timely dissemination of major HCHS/SOL findings to the scientific community.
- 2.2. To ensure accurate and scientifically sound publications from HCHS/SOL.
- 2.3. To ensure there is no overlap in manuscript study aims.
- 2.4. To encourage high-quality publications and presentations.
- 2.5. To create a system for a fair determination of collaborative authorship on HCHS/SOL publications.
- 2.6. To ensure opportunities for investigators from participating HCHS/SOL centers, Coordinating Center, NIH, and other outside investigators with appropriate expertise to participate and be recognized in study-wide publications and presentations.

3. PROPOSAL FOR A MANUSCRIPT: SUBMISSION AND REVIEW. An investigator seeking to write a HCHS/SOL paper must first submit a manuscript proposal to the Publications Committee. Prior to submission on the Web Portal, this proposal must first be reviewed and approved by the senior author and/or PI sponsor. After the proposal has been approved, the paper will receive a manuscript number, and the author may proceed with data use agreements and analyses. Any further product (abstract, presentation, manuscript) related to the approved aims must be linked with this specific approved manuscript number. Abstracts, presentations, or manuscripts linked with the approved manuscript number must concur with the approved aims of the proposal, or a modification and/or new manuscript proposal may be needed. Please consult with your PI sponsor and/or the Publications Committee leadership if additional guidance is needed.

- 3.1. **Proposal sponsorship.** All paper proposals must be sponsored (i.e., reviewed and approved) by a PI/Co-PI of the four HCHS/SOL field centers, coordinating center, central lab. We encourage all authors proposing a manuscript that will include HCHS/SOL ancillary study data to collaborate with the Ancillary Study PI/s to benefit from their knowledge and expertise. However, this is not **required** if the Ancillary Study data have already been deposited into the HCHS/SOL master dataset and/or publicly accessible platforms

(BioLINCC, dbGaP). Lead authors often wish to use data from an Ancillary Study (or Studies) that are not yet part of the master HCHS/SOL dataset and that are therefore not publicly accessible. In this case, at least one PI/Co-PI of each such Ancillary Study must also serve as a sponsor of the proposal.

3.2. **Scientific Interest Groups.** Investigators wishing to write a HCHS/SOL paper may also benefit from first discussing it with one or more of the HCHS/SOL Scientific Interest Groups (SIGs). SOL SIGs are comprised of investigators and researchers with shared interests in a topic area who work collaboratively to advance the field and strengthen the work of early-stage investigators. A list of current active SIGs can be found on the study website: <https://sites.csc.unc.edu/hchs/sigmemb>. The SIGs provide an excellent opportunity to engage with experts in the field who are familiar with our data. This discussion will also aid in avoiding overlap with existing manuscripts and proposals. It is the responsibility of the sponsor/s of the manuscript proposal to help identify manuscript proposals that would benefit from discussion with an HCHS/SOL SIG, and to introduce the lead author to the relevant SIG chairperson.

3.3. **Local papers.** Generally, proposals should include the entire HCHS/SOL cohort, rather than data from only one or a subset of centers, to preserve and maximize use of the full, unique cohort. A proposal for using only local data may be considered if appropriate to the research question.

3.4. **Proposal review process.** The Publications Committee Chairs will assign manuscript proposals and manuscripts to two reviewers for consideration of scientific merit, analytic issues, interpretation and discussion issues, and policy issues, as described below. Paper proposals are not as extensive as full manuscripts but should briefly address the major points below.

3.4.1. The rationale for the paper should be clear.

3.4.2. Objectives or specific aims should follow from the rationale and should be feasible to address in the HCHS/SOL cohort.

3.4.3. Variables needed for analysis and definitions of variables, if appropriate, should be provided; for example, outcome variables should be defined. It is recognized that the derivation of new variables may occur as the analyses progress.

3.4.4. Analysis plans should be clear and sufficiently detailed to determine the appropriateness to the research questions and data.

3.4.5. **Table shells are required**, as these show the nature of the analyses and help analysts and authors to focus their efforts once the proposal is approved. It is recognized that analyses often evolve as the paper progresses, but the basic analytic strategy and planned tables must be presented.

3.4.6. Sample size availability should be considered for specific objectives. If appropriate, authors should consider and describe statistical power.

3.4.7. Authors are responsible for checking published papers and other proposals on the website for potential overlap. **Proposals should include a specific section labeled “overlap” within the proposal (as part of the rationale section) that discusses potentially related proposals and papers and how the proposed aims are distinct.**

3.4.8. If the paper is not data-driven, but rather is a descriptive, methods, or opinion paper, some items may not apply, however, an outline should be provided.

3.4.9. Part of the approval process includes the nomination of additional co-authors with appropriate expertise from throughout the HCHS/SOL network (see Section 7.4).

3.4.10. NOTE: Proposals for papers that involve a consortium may be subject to a streamlined review process where the HCHS/SOL Consortium Liaison acts as the primary reviewer. Please see “Policy and Procedures for the Involvement of HCHS/SOL in Research Consortia” for additional information.

4. MANUSCRIPTS.

4.1. **Manuscript Preparation.** Once the manuscript proposal is approved, the lead author may begin preparing the manuscript in collaboration with the co-author group. In preparing the draft manuscript, please be sure to review additional guidance on the publications section of the website such as:

“Important Special Notes for Primary Authors / Presenters - Funding Acknowledgement Text”.

- 4.2. **Writing group approval of original and revised manuscripts.** Prior to submission to the Publications Committee, all members of the writing group should review and approve the manuscript draft. Once the manuscript is submitted to a journal for review, if asked to revise and resubmit, the lead author does not need to submit the revision to the Publications Committee prior to journal resubmission. However, the co-authors group should be provided an opportunity to review and approve any major revisions made in response to the revision request. The lead author should update their manuscript status through the web portal to indicate when the paper is in press.
- 4.3. **Privacy Act adherence.** Publications and presentations shall comply with the rules and procedures of disclosure set forth in the Privacy Act (<https://www.justice.gov/opcl/privacy-act-1974>). Confidential or proprietary information shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the paper or presentation.
- 4.4. **Submission Process.** Manuscripts are submitted through the Web Portal and linked with a specific approved manuscript number. Conversely, only one manuscript can be submitted for an approved proposal.
- 4.5. **Requests to Amend Approved Manuscript Proposals.** Requests to amend approved manuscript proposals may be submitted by email, provided the requested revision does not substantially expand the original aims and scope of the paper. Examples of acceptable amendments include:

- A request to split a single approved manuscript proposal into more than one manuscript.
- A request to add later-visit data that have become newly available since the proposal was approved (e.g., extending a previously approved analysis of changes in blood pressure and hypertension from baseline to Visit 2, to additionally examine changes from baseline to Visit 3).
- A request to expand the set of biomarkers examined.

4.5.1. Procedures for Requesting an Amendment. To request an amendment, please send an email with the subject line “**Request to amend HCHS/SOL approved MS #XXXX**” to the HCHS/SOL PC Committee Chairs (currently Drs. Sylvia Smoller, Sylvia.Smoller@einsteinmed.edu and Linda C. Gallo, lgallo@sdsu.edu; cc: HCHSAdministration@unc.edu). Please include the following in the email text:

- Original manuscript # and title.
- Specific amendment(s) requested.
- Brief rationale for the request (e.g., “We have determined that the content is too extensive for a single paper;” “New biomarkers of the condition have become available”).
- A statement confirming that the investigator team has reviewed existing and proposed HCHS/SOL manuscripts to ensure that the requested revision does not introduce overlap with other work
- If the request is to split an approved proposal into two or more manuscripts, please also include the proposed title(s) for the new manuscript(s).

If the amendment is approved, the contents of this email will be uploaded as a PDF attachment to the original manuscript proposal.

4.5.2. Limitations on Amendments. Requests to amend existing proposals will only be accepted prior to SOL PC approval of the associated manuscript for journal submission. The Publications Committee may deny amendment requests and request a new proposal if the proposed changes substantially expand or alter the originally approved aims, hypotheses, analytic plan, or scope of work.

4.6. **Manuscript review process.** As with proposals, draft manuscripts are assigned to two reviewers who consider scientific merit, analytic issues, interpretation and discussion issues, and policy issues. In addition:

4.6.1. Manuscripts should follow the plan approved in the proposal phase, recognizing that additional analyses may be performed. Major deviations from the proposal plan or expansion of the scope of the paper will need approval of the modification by the Publications Committee, and/or a new manuscript proposal.

4.6.2. The manuscript should be accurate, and the data appropriately analyzed.

4.6.3. All co-authors must approve the final draft of the manuscript prior to submission through the Web Portal.

4.6.4. Any changes to the approved authors list must follow the guidelines and procedures noted below. **(See Section 7.5).**

4.6.5. NOTE: Papers that involve a consortium may be subject to a streamlined review process where the HCHS/SOL Consortium Liaison provides the primary review. Please see “Policy and Procedures for the Involvement of HCHS/SOL in Research Consortia” for additional information.

5. **DATA ANALYSIS VERIFICATION.** The Coordinating Center may periodically randomly select manuscripts to be submitted to peer-reviewed journals for independent verification of the data management and statistical analysis. The following elements may be reviewed: Datasets used in the analysis; Inclusion and exclusion criteria employed; Employment of the multi-stage sample design in survey analysis techniques; Comparison of statistical approach to Publications Committee approved analysis plan; Numerical accuracy in tables, figures, and text citations.

6. **CONFERENCE PRESENTATIONS AND INVITED TALKS.**

6.1. **Abstract submission.**

6.1.1. Abstracts to be submitted for possible presentation at a National or International Conference of a poster, presentation, symposium, etc., must be linked to an approved paper proposal and submitted via the Web Portal for review by the Publications Committee. The process for submission is available on the HCHS/SOL investigator’s website. <https://sites.csc.unc.edu/hchs/WebsiteHelpPage>

6.1.2. Abstracts and presentations should generally include all authors from the approved writing group and all co-authors must be provided an opportunity to review and approve the abstract prior to submission for Publications Committee review.

6.1.3. Abstracts must be submitted to the Publications Committee for review at least two weeks before the due date unless special circumstances prevail.

6.1.4. Final abstracts accepted for presentation or publication should be submitted through the Web Portal for archival purposes.

6.1.5. Previously cleared abstracts may be submitted to other meetings; copies should be submitted through the web portal for inclusion in the listings of HCHS/SOL Publications and Presentations.

6.2. **Posters and Presentations.**

6.2.1. After an abstract is accepted and before the conference presentation, all posters and presentations must be submitted via the Web Portal for review by the Publications Committee. The process for submission is available on the HCHS/SOL investigator’s website. <https://sites.csc.unc.edu/hchs/WebsiteHelpPage>

6.2.2. If possible, please use the HCHS/SOL poster and presentation templates shown on the website <https://sites.csc.unc.edu/hchs/study-templates>.

6.2.3. Posters and presentations should generally include all authors from the approved writing group and all co-authors must be provided an opportunity to review and approve the content before submission to the Publications Committee for review.

6.3. Invited talks.

- 6.3.1. The HCHS/SOL investigators welcome opportunities to participate and present reports of HCHS/SOL findings at local, national and international scientific meetings.
- 6.3.2. When an invitation is directed to the Chair of the Steering Committee or the Chair of the Publications Committee, the respective chairs will decide who is to represent HCHS/SOL. Invitations directed to the NHLBI will be reviewed and approved by the NHLBI Project Office.
- 6.3.3. When a HCHS/SOL investigator or Project Office scientist receives a personal invitation to make a presentation, they should notify the Publications Committee to ensure listing of the presentation on behalf of the HCHS/SOL.
- 6.3.4. All presentations in response to such invitations should be based on published HCHS/SOL reports unless prior approval is granted by the Publications Committee and the Project Office.
- 6.3.5. Requests received by HCHS/SOL investigators or their team to present or discuss at the investigator's institution any previously published HCHS/SOL data need no prior clearance by the PC and acceptance of such invitations is encouraged.
- 6.3.6. We encourage investigators to share copies of high-profile invited talks with the Coordinating Center.

7. AUTHORSHIP AND WRITING GROUPS

- 7.1. The HCHS/SOL Publications Committee does not limit the number of co-authors per manuscript or presentation and defers to specific journal or conference guidelines. However, in the interest of recognizing author contributors while not diluting their importance, the Publications Committee suggests a reasonable number of co-authors, generally not exceeding 14 total authors, except for consortia and other special papers that may have more authors.
- 7.2. A multi-center study requires the contribution of many people to conceive, obtain funding for, and implement the study, often for many years before data are available. Recognition must be given to the contribution of HCHS/SOL investigators to obtaining and providing HCHS/SOL data. This applies even to papers that use ancillary study data but also use HCHS/SOL parent study data. This recognition is reflected by including HCHS/SOL parent study investigators as co-authors.
- 7.3. The PC adheres to the International Committee of Medical Journal Editors (ICMJE; <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) Guidelines, adopted by most journals, which list 4 criteria for authorship:
 - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; AND
 - Drafting the work or reviewing it critically for important intellectual content; AND
 - Approval of the version to be published; AND
 - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- 7.4. **Co-Authorships.** There are two routes to becoming a co-author, 1) being named by the lead author in the manuscript proposal, and 2) being nominated by a HCHS/SOL PI or Co-PI, as described below.
 - 7.4.1. **Co-authors named in the proposal.** Lead authors may name up to seven additional persons (from their center or elsewhere) for automatic co-authorship at the time of the proposal submission. Including the lead author, the total number of named authors will not be more than eight. The co-authors named on the proposal submission are expected to have reviewed the manuscript proposal prior to submission to the Publications Committee. It should be noted that listing a PI/Co-PI sponsor does not automatically confer authorship. If you wish to name the PI/Co-PI sponsors as co-authors, please also list them in the co-author section.
 - 7.4.2. **Additional co-author nominations.** After the proposal is approved by the Publications

Committee and assigned a manuscript number, HCHS/SOL parent study PIs/Co-PIs and HCHS/SOL associated NIH program officials/scientists may add names of persons who could contribute to the paper. The nominations for individuals not named by the lead author must be accompanied by a justification for the nomination. The nominations close at the end of each month for the recently approved proposals and lead authors are notified by email that the website listing for the specific manuscript has the updated list of co-authors. The lead authors are encouraged to communicate promptly with the co-authors. Co-authors must provide comments or indicate approval prior to submission of the manuscript for Publications Committee review. The study website's Manuscripts in Progress report has an email tool for communications.

7.4.3. Authorship Order. In general, the lead author determines the order of authorship.

7.4.4. Authors must match the approved writing group on website. Prior to submitting the paper for Publications Committee review via the Web Portal, the lead author must confirm that the authors list matches the list on the website. All nominated/approved co-authors must be provided an opportunity to review and participate in the paper. Any changes to approved authorships (including additions or exclusions) should be reported and explained on the manuscript submission form on the PC website portal, and follow the procedures noted below.

7.5. Authorship changes following closure of nominations.

7.5.1. Co-author Additions. If during the course of developing the paper, lead authors want to name additional co-authors, they must provide justification in an email request to the Publications Co-Chairs (currently Drs. Sylvia Smoller, Sylvia.Smoller@einsteinmed.edu and Linda Gallo, lgallo@sdsu.edu; cc to HCHSAdministration@unc.edu) and/or they may report changes with explanation at the time of manuscript submission.

7.5.2. Co-Author Exclusions The lead author may ask the Publications Committee for permission to remove a co-author from the paper if the co-author agrees to the removal. If the lead author does not have the co-author's agreement but wishes to remove a co-author, the lead author must send at least 3 emails to the co-author, at least one of which cc's the manuscript sponsoring PI/Co-PI, before asking the Publications Committee for permission to remove the co-author.

8. SPECIAL TYPES OF PAPERS AND GRANTS

8.1. Ancillary Study Papers. All policies and procedures listed above apply to Ancillary Studies papers. As noted above, Ancillary Study related papers must be co-sponsored by the Ancillary Study PI/MPIs unless the ancillary study data have already been deposited as part of the HCHS/SOL master dataset and/or into publicly accessible platforms. In addition to a statement of authorship, an Ancillary Study paper should include a clear statement that this work was an ancillary study of HCHS/SOL and the Ancillary Study's grant support must be included in the publication's funding acknowledgment.

8.2. Consortia papers. Genetics and other consortia papers often have many authors, and they may only allow a limited number of co-authorships for HCHS/SOL investigators. However, HCHS/SOL must be represented, and it is the responsibility of the HCHS/SOL Consortium Liaison to ensure representation. The PC must be notified that these papers have a limited number of slots for HCHS/SOL before the nomination process begins. In other words, these papers must adhere to the HCHS/SOL PC procedures. Please see "Policy and Procedures for the Involvement of HCHS/SOL in Research Consortia" for additional information.

8.2.1. Important: When submitting a manuscript proposal based on a consortium, the proposer is asked to include /CONSORTIUM NAME OR ACRONYM, following the study title. For example: "Identifying metabolites that are causally associated with prostate cancer among multi-ancestry populations/PAGE". (NOTE: The manuscript title used at the proposal stage may be revised before

journal submission and must ensure adherence to the title guidelines provided in the document “Important Special Notes for Primary Authors / Presenters - Funding Acknowledgement Text.”)

8.3. **Technical/Methodological/Statistical Papers.** Manuscripts describing or demonstrating statistical or technical methods that do not report any new findings from HCHS/SOL do not need to be circulated for additional authorship. However, manuscripts that apply a method to an outcome where new or reanalyzed data are presented must be open for nominations. If authors prefer their methodology paper to have restricted authorship, they may send a request and justification for this via email to the Publications Co-Chairs (currently Drs. Sylvia Smoller, Sylvia.Smoller@einsteinmed.edu and Linda Gallo, lgallo@sdsu.edu) with cc to HCHSAdministration@unc.edu).

8.4. **Dissertation and thesis papers.** All requests for use of HCHS/SOL data by graduate students, medical students, residents and other trainees for theses, dissertations, or similar academic projects are to be reviewed by the Publications Committee and follow all guidelines listed above.

8.4.1. It is required that the student requesting use for HCHS/SOL data is associated with the study through one of the HCHS/SOL PIs/Co-PIs who is acting as the student's "sponsor".

8.4.2. If a dissertation involves more than one manuscript using HCHS/SOL data (e.g., 3-paper “stapled” dissertation), each paper will require a separate manuscript proposal.

8.4.3. The thesis/dissertation must include a statement acknowledging HCHS/SOL for use of the data, and a statement indicating that opinions, ideas, and interpretations included in the thesis are those of the student alone and not those of the HCHS/SOL investigators.

8.4.4. It is the responsibility of the HCHS/SOL PI/Co-PI sponsor to ensure that the thesis/dissertation accurately reflects the conduct and data from the HCHS/SOL, as dissertations are technically available to the public without going through the Publications Committee review process.

8.4.5. If the thesis/dissertation is to be submitted for publication, all co-authors approved by the HCHS/SOL Publications Committee, must be engaged in preparing and/or reviewing and revising the paper.

8.4.6. The standard HCHS/SOL publications policy applies to any material published from the thesis or dissertation.

8.5. **Papers Associated with Grant Proposals Supporting Secondary Analyses of HCHS/SOL data.**

Investigators submitting an Ancillary Study (AS) proposal for a K Award, a similar career development grant, or another type of proposal (e.g., NIH R03) that exclusively or primarily involves secondary data analysis are encouraged to also submit one or more publication proposals that reflect the HCHS/SOL-related primary aims. Doing so helps ensure that investigators preparing PC proposals are aware of the ongoing or planned work and do not propose manuscripts that overlap with the AS content. Investigators may complete this step at any time (e.g., before or after grant submission, after funding is obtained).

Investigators proposing AS projects involving secondary data analyses should work closely with their PI sponsors (and mentors, if applicable) to determine the appropriate timing for submitting manuscript proposals describing the planned or funded aims. For additional guidance, refer to the Ancillary Studies tab for related policies.

9. ACCESS TO HCHS/SOL DATA FOR PAPERS AND GRANTS

9.1. HCHS/SOL data may be obtained after a **paper proposal** has been approved by the Publications Committee. Please work with the sponsoring PI/Co-PI to determine the actual process for obtaining the data use agreement and dataset.

9.2. Please work with the sponsoring PI/Co-PI to discuss appropriate use of, and access to, unpublished HCHS/SOL data for a **grant proposal**. HCHS/SOL data that have not been previously published but are needed for grant applications or contract proposals must indicate that data are unpublished and should not be cited or circulated.

10. **ACKNOWLEDGMENTS AND FUNDING.** All HCHS/SOL papers must appropriately acknowledge the study staff and participants, and NIH funding, by including the following information:

The authors thank the staff and participants of HCHS/SOL for their important contributions. Investigators website - <http://www.cscce.unc.edu/hchs/>.

The HCHS/SOL Publications Committee has reviewed and approved the content of this manuscript.

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NOTE: Papers that also incorporate Ancillary Study data use the above text and also include the funding information for the ancillary study or studies.

11. **DATA SHARING STATEMENT.** The NIH and HCHS/SOL data-sharing policy continues to evolve, and we will update this document with additional details as possible. If asked to provide a data-sharing statement for a publication, you may use the following:

The data and computer code used for this analysis reside at [NAME OF INSTITUTION WHERE ANALYSES WERE CONDUCTED]. The HCHS/SOL fully supports data sharing for HCHS/SOL–approved manuscript proposals with outside investigators. All data sharing is conducted in accordance with HCHS/SOL study and NIH policies and governed by a Data and Materials Distribution Agreement (DMDA) between UNC and the external institution, ensuring the confidentiality and privacy of HCHS/SOL participants and their families. Alternatively, de-identified HCHS/SOL data are publicly available at BioLINCC and dbGaP for the subset of the study cohort who authorized general use of their data at the time of informed consent.