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Study Protocol, General Description and Study Management

January 8, 2008 - Version 1.0

Study website - <http://www.csc.unc.edu/hchs/>

4.0 Publication Policy

4.1 Policy Objectives

The objectives of the publications policy of the HCHS/SOL Study are to assure:

- A. Expeditious and timely dissemination of major HCHS/SOL findings to the scientific community;
- B. Accurate and scientifically sound publications from HCHS/SOL;
- C. Encouragement of high-quality manuscripts among the HCHS/SOL investigators;
- D. A system for fair determination of collaborative authorship on HCHS/SOL collaborative publications;
- E. Opportunities for investigators from participating HCHS/SOL centers, NIH, and other outside investigators with appropriate expertise to participate and be recognized in study-wide publications and presentations.

4.2 Definitions of HCHS/SOL and non-HCHS/SOL Investigators

A HCHS/SOL study investigator is defined as a research investigator named on a current and active contract or consulting agreement with NHLBI or its contractors to work on the HCHS/SOL study. Project Office staff are also considered investigators for the purpose of this document. All other investigators would be considered non-HCHS/SOL Investigator

4.3 Priority / Primary Papers

4.3.1 Priority Papers The Publications Committee (PC) and Steering Committee (SC) will develop a list of **priority papers**. Process for authorship of these papers will be established by PC for approval by SC. One method may be to rotate first authorship among the centers, PO (Project Office), and Reading Centers.

4.3.2 Group-Authored and “Unauthored” Publications and Presentations

The HCHS/SOL PC may recommend to the SC, and the SC may decide that one or more publications be written on behalf of the HCHS/SOL group. For example, a design paper might be unauthored or group authored. An appropriate list of participating investigators will be identified in an appendix to such publications, and members of the actual writing group will either remain anonymous or, as appropriate per journal policy, be acknowledged in the publication.

4.3.3 Manuscript Progress Tracking

The PC will produce an updated progress report, with assistance from the CC, of all approved HCHS/SOL publications (e.g., approved, in preparation, submitted, in press, published) which the CC will post on the website, along with approved manuscript proposals.

4.4 Proposals for Other Papers

4.4.1 First Author

The first author of a paper will generally be the proposer unless that proposer indicates in writing that he or she nominates another member of the writing committee to be lead author. Approval of the PC is required.

4.4.2 Proposal Submissions

Paper proposals may be submitted by:

Any HCHS/SOL investigator, HCHS/SOL connected investigator in a Field Center, Reading Center or Coordinating Center, with the local PI approval, for local tracking and priority setting.

- A. PO staff, upon invitation by the PC. PO staff may not be first, last, or corresponding authors on primary papers.
- B. Non- HCHS/SOL investigators: These require approval by any one of the HCHS/SOL PIs, in a Field Center, Reading Center, Coordinating Center or Project Office.
- C. Ancillary Study Investigators (See Section 11 for manuscripts from ancillary studies.)

4.4.3 In general, first authors should lead no more than 3 study-wide papers at any one time, unless there are special considerations. This is to ensure timely progress on the papers and to afford the opportunity for others to propose papers.

4.5 Authorship and Writing Groups

4.5.1 Each study-wide paper should give each of the field centers, PO, and CC and the relevant reading center, depending on topic of paper, opportunity for representation on the writing group. PO staff may be co-authors on primary and secondary papers if requested by the PC. Others may be nominated for special expertise.

4.5.2 The lead author (writing group chair) determines the order of authorship. A major criterion for the order of authorship is the level of effort and contribution made by the members of the writing group.

4.5.3 When the writing group chair is identified, it is his/her responsibility to communicate with other writing group members to identify data needed from the CC, and to establish a plan for writing the manuscript.

4.5.4 All members of the writing group should review the final manuscript proposal and the final manuscript draft before its submission to the PC.

4.5.5 By the determination of the writing group chair, if some members of a writing group have shown little or no interest in participating in the work of the group or have failed to contribute to the task of preparing the manuscript, their names may be left off the list of authors, pending review by the PC. If a problem emerges, the PC will resolve it.

4.5.6 The Chair of each writing group is to update the PC on manuscript progress every six months after the writing group is formed. If the PC has not received a report from a lead author within 12 months, or if satisfactory progress has not been made:

- A. The PC may replace the lead author with another member of the writing group.
- B. If no writing group members are interested in assuming the lead position, other HCHS/SOL investigators outside of the writing group may be solicited to be lead author.

4.5.7 The writing group should see the manuscript after revisions suggested by the journal are made.

4.5.8 The writing group must prepare a lay summary that will be used by the PO for publicity and also be available to participants on the HCHS/SOL website.

4.6 Data to be obtained from HCHS/SOL

4.6.1 Some papers will have data analyses done by the CC. Other papers will have analyses done locally under the supervision of the lead author.

4.6.2 For those analyses done by the writing group, the following rules apply:

- A. HCHS/SOL data required for analyses for the paper will be provided by the HCHS/SOL CC, after approval of manuscript proposals that specify the dataset required. The data may also be available from complete files distributed to HCHS/SOL PIs.
- B. NHLBI rules for data distribution will apply, implemented through signed data distribution agreements.

4.7 Local Papers

Most papers will be study-wide, i.e. will use data from all the field centers, to preserve and make maximum use of the full, unique cohort. A proposal for using only local data may be considered if appropriate. Authorship for local papers will be considered on a case-by-case basis.

4.8 Abstracts

4.8.1 Abstracts should be derived from approved paper proposals.

4.8.2 Abstracts must be submitted to the committee for review at least two weeks before the due date unless special circumstances prevail. The process for submission is available on the HCHS/SOL investigator's website.

4.8.3 Abstracts will be expeditiously reviewed by two PC members with simultaneous review by the Project Office (PO). PC reviewers will be asked to respond expeditiously and to recommend approval, modifications, or disapproval of the abstract.

4.8.4 All abstracts accepted for presentation or publication should be submitted to the CC for archival purposes.

4.8.5 It is permissible to submit previously cleared abstracts to other meetings; copies should be sent to the CC for inclusion in the listings of HCHS/SOL Publications and Presentations.

4.9 Invited talks

4.9.1 An investigator receiving an invitation for a national talk on behalf of HCHS/SOL should send an abstract of the talk to PC and must obtain PC and PO approval. No approval is necessary for local talks or grand rounds.

4.9.2 When an invitation is directed to the Chair of the Steering Committee or the Chair of the PC, 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.

4.9.3 When a HCHS/SOL investigator or PO scientist receives a personal invitation to make a presentation, they should notify the Chair of the PC to ensure listing of the presentation on behalf of the HCHS/SOL Research Group.

4.9.4 All presentations in response to such invitations should be based on published HCHS/SOL reports unless prior approval is granted by the PC and the Project Office.

4.9.5 Requests received by PIs or their staff to present or discuss at investigator's institution meetings any previously published HCHS/SOL data need no prior clearance by the PC and acceptance of such invitations is encouraged.

4.10 Ancillary Studies

Ancillary studies follow the same publications process as main HCHS/SOL papers. The AS must submit proposal to PC, but ancillary study may select its own author group. In most instances, this should include representation from Field Centers (if data from the larger study are included in analyses), the Coordinating Center, Project Office and relevant Reading Centers. Ancillary studies will get only partial datasets relevant to their analyses (see AS policy statement).

4.11 Ancillary Study Proposal Process

4.11.1 Requests for proposed publications should include a 4-6 page document, to be submitted to the PC Chair that includes:

- A. tentative title;
- B. name of proposer;
- C. name of up to 3 suggested co-authors;
- D. rationale;
- E. keywords;
- F. main hypothesis or study questions/objectives;
- G. analysis plan (pertinent variables, analysis definitions, characteristics of population to be analyzed, table shells limited to a reasonable number);
- H. pertinent references;
- I. dummy tables.

4.11.2 The request should be in the format provided in the current Manuscript Proposal Form found on the HCHS/SOL website.

4.11.3 Proposals will be expeditiously reviewed by the PC. Reviewers will be asked to respond expeditiously and to recommend approval, modifications, or disapproval of the proposal.

4.11.4 The PC will consider the issue of overlap with other proposals and publications, and if a problem of emerges, the PC will confer with the involved writing group chairs to resolve the situation. The CC will provide a search engine to all investigators to enable an easy search of the set of approved proposals of related proposals. Proposals will be reviewed by the PC and PO,

with a decision to request modifications of the proposal or with recommendation to approve or reject, and if approved a priority will be recommended.

4.11.5 After PC conference calls, requests for modifications to the proposals will be sent directly to the proposer, whereas the PC recommendations for approvals or rejections for manuscript proposals will be first circulated electronically to the Steering Committee. Steering Committee members are invited to comment by email within one week on the recommendations. After consideration of SC recommendations the PC will notify submitters of proposals of the decision.

4.12 Review of HCHS/SOL Publications and Presentations

4.12.1 The Chair will assign the final manuscripts to 2-3 reviewers for review for, scientific merit, analytic issues, interpretation and discussion issues, and policy issues, and reviewers will be asked to agree to a specific deadline date for submission of reviews to the PC.

4.12.2 The materials will simultaneously be submitted to the Steering Committee for optional review due by the same date asked for required reviews.

4.12.3 Reviews will be discussed by the full PC at monthly calls, and proposals, papers and presentations will be approved by full committee.

4.12.4 When the final manuscript has been approved by the PC it will be sent for review by the NHLBI Project Office.

4.12.5 Review and approval by the PC and review by the NHLBI Project Office are required for all HCHS/SOL publications prior to their submission for publication. When the final manuscript has been approved by the PC and reviewed by the NHLBI Project Office, it may be submitted for publication.

4.12.6 All review and approval functions of the PC and review by the NHLBI are to be done judiciously and expeditiously.

4.12.7 The writing group chair will provide a copy of the published paper to the CC and to the NHLBI Project Office for archiving.

4.12.8 Once published, the PC will send notification of publication to the HCHS/SOL Investigators.

4.12.9 Publications and presentations shall be in compliance with the rules and procedures of disclosure set forth in the Privacy Act. 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/presentation.

4.12.10 An acknowledgment of all HCHS/SOL Centers with their PIs and a reasonable number of key personnel are to appear in each publication, printed in an appendix per journal guidelines. There may be a short list and a long list developed.

4.12.11 The NHLBI support statement is to be on the front page of the manuscript. The acknowledgement should include all Institutes and Centers directly relevant to the specific paper.

The text would read: *“This study was initiated and funded by the National Heart, Lung, and Blood Institute, in conjunction with the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Neurological Disorders and Stroke, the National Institute on Deafness and Other Communication Disorders, the National Institute of Dental and Craniofacial Research, the Office of Dietary Supplements, and the National Center on Minority Health and Health Disparities; National Institutes of Health, Department of Health and Human Services. The study is supported by contracts (number/institutions to be inserted).*

4.12.12 All requests for reprints are to be directed to lead authors.

4.13 Authorship for Ancillary Studies

4.13.1 Proposals for publications and presentations based on special data sets collected on HCHS/SOL participants in ancillary studies are also to be submitted to the PC. The writing group preparing such a report will consist of individuals designated by the participating Ancillary Study investigators. This should include representation from Field Centers (if data from the larger study are included in analyses), the Coordinating Center, Project Office and relevant Reading Centers.

4.13.2 All HCHS/SOL PIs and investigators will be informed of such ancillary proposals through periodic circulation

4.13.3 In addition to a statement of authorship, an ancillary study paper is to have a clear statement that this work was a substudy or ancillary study of HCHS/SOL and the support from NHLBI is to be acknowledged.

4.14 Invitations to HCHS/SOL for Presentation of Papers

4.14.1 The HCHS/SOL investigators welcome opportunities to participate and present reports of HCHS/SOL findings at national and international scientific meetings.

4.14.2 When an invitation is directed to the Chair of the Steering Committee or the Chair of the PC, 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.

4.14.3 When a HCHS/SOL investigator or PO scientist receives a personal invitation to make a presentation, they should notify the Chair of the PC to ensure listing of the presentation on behalf of the HCHS/SOL Research Group.

4.14.4 All presentations in response to such invitations should be based on published HCHS/SOL reports unless prior approval is granted by the PC and the Project Office.

4.14.5 Requests received by PIs or their staff to present or discuss at investigator’s institution meetings any previously published HCHS/SOL data need no prior clearance by the PC and acceptance of such invitations is encouraged.

4.15 Use of Data for Theses or Similar Academic Projects by Graduate Students

4.15.1 All requests for use of HCHS/SOL data by graduate students, medical students, residents and other trainees for theses or similar academic projects are to be reviewed by the PC and the Project Office.

4.15.2 It is required that the student requesting use for HCHS/SOL data is associated with the study through one of the HCHS/SOL investigators who is acting as the student's "sponsor" with regard to the data.

4.15.3 HCHS/SOL data may not be used by students if the data relate to major HCHS/SOL papers in progress or if the PC deems that data to be necessary for a future major paper.

4.15.4 If the PC recommends approval for the use of the requested data, a writing group is to be established and is to include the student as convener of the group.

4.15.5 The writing group is to take no action regarding the paper until the student has completed and defended the thesis provided this occurs in a reasonable length of time, to be determined on a case-by-case basis. The student's sponsor is to report the student's progress to the PC at least annually.

4.15.6 The student must include in the completed thesis:

- A. a statement acknowledging HCHS/SOL for use of the data, and
- B. 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.

4.15.7 When the thesis has been completed, as determined by the sponsor, the entire writing group is to proceed to prepare the paper(s) for publication. It is the responsibility of the HCHS/SOL PI "sponsor" to ensure that the thesis accurately reflects the conduct and data from the HCHS/SOL, as dissertations are technically available to the public without going through the PC review process.

4.15.8 The standard HCHS/SOL publication policy applies to any material published from the thesis.

4.15.9 HCHS/SOL reserves the right to proceed with preparing a paper for publication on the thesis topic through the activation of a writing group if, in the view of the PC and the student's sponsor, the student has not made reasonable progress in completing the thesis.

4.16 Use of Data for Grant Application or Contract Proposal

HCHS/SOL data which have not been previously published but which are needed for grant applications or contract proposals must have prior approval for use by the HCHS/SOL Steering Committee and Project Office.