

SEARCH MOP - Section 19
Publications and Presentation Policy
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19. Publications and Presentation Policy

19.1. GOALS OF THE PUBLICATION AND PRESENTATION (P&P) COMMITTEE

- To organize, lead in the development of, and stimulate scientific presentations and papers from SEARCH Study investigators.
- To assure that press releases, interviews, abstracts, presentations, and publications of data from SEARCH and its approved ancillary studies are accurate and objective, and do not compromise the scientific integrity of this collaborative study.
- To assure that all investigators, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide publication and presentations of SEARCH study papers.
- To assure appropriate writing group membership and to monitor the progress of all proposed manuscripts and presentations to ensure their prompt completion and publication.
 - Additions/changes to WG membership should be submitted to P&P in the form of a memo. These will be reviewed by the co-chairs and brought to the committee as needed. WG chairs should take into consideration the number of authors permitted by the journal (usually 12 or less) when adding additional members. (9/11)
- To conduct a timely review of proposals, publications and presentations from SEARCH and its approved ancillary studies.
- To assure and expedite timely presentations of the results of the SEARCH and its approved ancillary studies to the scientific community.
- To maintain up-to-date lists of SEARCH and its approved ancillary study abstracts, presentations, and publications, that will be made available to SEARCH Study investigators via the Study website.

19.2. COMMITTEE MEMBERSHIP AND RESPONSIBILITIES

- The P&P Committee is a standing committee of the SEARCH Study and is open to all Study Group members.
- Committee does not require membership from all SEARCH sites, but will consist of members with expertise in epidemiology, health services research, biostatistics, endocrinology, and laboratory methods.
- Committee will convene calls and meetings when over 50% of voting members are present. Documents may be approved by the Committee via email as determined by the P&P Co-chairs.

- Initial appointments will include co-chairpersons appointed by Steering Committee who will be invited to serve for the five-year term of the study. Co-chairs will each have a vote on the Committee.
- Co-chairs will: (a) manage the processes of proposal review and approval; (b) monitor and encourage progress of work through to the point of publication; and (c) actively participate in Steering, Study Group and Executive Committee conference calls and Meetings.
- Committee may review/approve the ordering of authors (except for ancillary study papers) as proposed by the WG chair.
- Committee has the authority and responsibility to:
 - Rank the priority of abstracts and papers for analysis (as needed), in consultation with the Steering Committee, WG chairs of specific papers, and the CoC to take into account issues related to work load and efficiency.
 - Monitor and encourage progress with manuscripts via the P&P committee project manager and liaison for specific papers. The P&P Committee may propose to change the composition of the WGs, including the WG Chair, that has not resulted in a manuscript according to the schedule originally agreed upon by the Group and the P&P Committee. This process will be overseen by the P&P Project Manager.
 - Require limitations on the scope of the paper to reasonably reflect the original, approved proposal, should the proposal as outlined not result in a mutually agreeable scope of work in the manuscript. Should conflict arise in this regard, the procedures outlined in Section 19.11 will be followed.
 - Modifications to approved proposals. The WG chair should notify the P&P co-chairs in writing of proposed modifications and their rationale. The P&P co-chair is delegated authority to determine if the proposed changes are acceptable or not and to inform the P&P committee in a timely manner.

19.3. TYPES OF COMMUNICATION FOR SEARCH P&P APPROVAL

- Publications. Any document submitted to a professional journal listed in the Index Medicus or any popular periodical with national circulation, including categories such as “short reports” and “letters” that include new data not presented elsewhere. This includes abstracts submitted for presentation at national meetings that are published in a journal.
 - Letters include: (1) a document submitted by a SEARCH investigator to a professional journal reporting original SEARCH data in a format not considered a publication (e.g., Short Communication); (2) letters written in response to a non-

SEARCH published manuscript but relevant to SEARCH; (3) a response to a letter written by non-SEARCH investigator in response to a SEARCH publication.

- **Presentations**. The delivery of information to scientific, professional, or public groups (e.g., an abstract to be published by the group to which the presentation is submitted, or an invited presentation using SEARCH data, including oral and poster formats).
- **Press Releases**. A document given to radio, television, newspapers, popular periodicals, or scientific journals (including publications of pharmaceutical companies or professional organizations) not indexed in Index Medicus.
- **Interviews**. Any discussion with a member of the press, a science writer, or a radio or television commentator, who in turn provides information for public dissemination.

19.4. SEARCH PUBLICATIONS CATEGORIES

- **Key papers**

Key papers describe the study methods and are the primary publications that result from the major aims of the study.

- Includes approximately 1-3 *key* papers for each of the aims of SEARCH.
- P&P Committee will query all center PIs about interest, expertise, and commitment to chair and co-chair main study papers and collate this information.
- List of topics for key papers along with persons who have been identified to chair/co-chair main study papers will be discussed by the PI group.
- Each center, including the CDC and NIH, will be invited to join the WG for these key papers.
- The author for key papers is listed as the “SEARCH for Diabetes in Youth Study Group.”
- WG members for each paper will be listed noting the chair and co-chair (if applicable) of the WG first with remaining WG members listed alphabetically. The acknowledgement section for these papers will include the full Study Group list.
- Lead authorship of key SEARCH papers will be distributed among SEARCH investigators.

- **Investigator-initiated papers**

Investigator-initiated papers include all other papers using primary data from the SEARCH study, including those that report on the remaining main hypotheses and overall results of the study and those based on data collected in the SEARCH study that do not test the main hypotheses and aims of the study.

- Each center, including the CDC and NIH, will be invited to join the WG for these papers.
 - All investigator-initiated papers will include individual authors' names and "for the SEARCH for Diabetes in Youth Study Group" in the authorship list (if permitted by the journal). Inclusion of "for the SEARCH for Diabetes in Youth Study Group" in the authorship list indicates that the manuscript is unanimously endorsed by every SEARCH site (06/12), including the Coordinating Center, the Laboratory, the CDC, and the NIH when appropriate.
 - Papers will be categorized on the SEARCH website according to the major aims of the study, and topic areas within each aim, as well as those not related to the aims and hypotheses of SEARCH ("other" papers).
 - Individuals making a substantive contribution to the development of the questionnaires, data collection, or study design for SEARCH will be given first opportunity to explore secondary hypotheses using collaborative data.
 - Persons not involved in the questionnaire development, study design, or data collection (e.g., Postdoctoral Fellows, doctoral students, other researchers) *may* be allowed to conduct analyses and write abstracts/papers using collaborative data if 1) sponsored by member of the Steering Committee, and 2) the proposed project is approved by the P&P Committee.
- **Ancillary Study papers**

Ancillary study abstracts and manuscripts are those that use data from ancillary studies which additionally are linked to data from the main SEARCH study.

- P&P will review proposals, abstracts, manuscripts and presentations with the same degree of scientific rigor as for the key papers and investigator-initiated papers.
- P&P will not have the responsibility or the authority to assign paper topics or designate chairs for the WGs or influence WG composition.
- A P&P liaison will be assigned to each Ancillary Study manuscript proposal at the time of approval by P&P. The liaison will approve abstracts prior to submission for meetings. The WG chair for an Ancillary Study abstract is not required to make any changes to the abstract based on the comments and input from their P&P liaison unless it is directly related to the methods or results from the main SEARCH study. (02/13)
- The PIs of the Ancillary Study will be copied on any correspondence about questions or concerns that arise during the review of the abstracts and manuscripts, and they may contact the P&P co-chairs directly for any clarification. (02/13)

- The WG chair for Ancillary Study manuscripts is not required to make any changes to the manuscript based on the comments and input from the P&P committee unless it is directly related to the methods or results from the main SEARCH study. (02/13)
- The P&P committee will review revisions to ancillary study manuscripts based on input and comments by P&P at the request of the WG chair or Ancillary Study PI. (02/13)
- The Ancillary Study PI should review manuscripts prior to submission to the journal. (02/13)
- P&P will not monitor the progress or productivity of approved ancillary study papers.
- **Single Study Site papers** (02/13)

Single site abstracts and manuscripts are those that use data primarily from one single SEARCH site that are not a part of the SEARCH protocol but are linked to SEARCH study data.

- P&P will review proposals, abstracts, manuscripts and presentations with the same degree of scientific rigor as for the key papers and investigator-initiated papers.
- Because the scope of single site manuscripts may vary widely, ranging from local studies for quality improvement to those that may address the aim(s) of the main SEARCH study, the P&P committee will discuss whether involvement of other SEARCH site investigators may be appropriate.
- Liaisons will be assigned to all manuscript proposals to approve abstracts prior to submission for meetings.
- P&P will not monitor the progress or productivity of single site study manuscripts.
- The WG chair for Single Site manuscripts is not required to make any changes to the manuscript based on the comments and input from the P&P committee unless it is directly related to the methods or results from the main SEARCH study.
- The P&P committee will review revisions to single site manuscripts based on input and comments by P&P at the request of the WG chair.
- The Site PI should review manuscripts prior to submission to the journal.

19.5. PUBLICATION AND AUTHORSHIP ISSUES

- Topic areas will be established based on SEARCH aims. Each paper will be assigned to a topic area.
- Non-SEARCH investigators (e.g., doctoral students, outside researcher) may propose investigator-initiated papers under the guidance and direction of a SEARCH investigator.

- All members of the WG who are named as authors must have the opportunity to review any manuscripts on which they are listed prior to their submission to P&P for review, before being presented at a meeting (posters and presentations), and before submission for publication.
- All members of the WG who are named as authors, either in the authorship position below the title or in a footnote, will meet the criteria for authorship as specified by the ICBE criteria and any additional requirements imposed by the specific journal. WG members who do not meet these criteria will be listed, with their permission, in the acknowledgments or in an appendix. SEARCH will adhere to the 1997 Uniform requirements for manuscripts submitted to biomedical journals.
 - Being included as a WG member on the proposal does not guarantee the person will be listed as an author. Authorship requirements differ by journals. WG chairs should provide opportunity for input from their WG members. Additionally, WG members should be responsive to requests for their input and review of manuscript drafts. (09/11)
- A SEARCH investigator cannot be a WG chair for more than two active SEARCH manuscripts at a time. A proposal submitted by a SEARCH investigator who is a WG chair on more than two active proposals will be tabled until at least one of the proposed manuscripts is submitted to P&P for review.
- If the WG for an approved paper proposal determines that more than one paper will result from the original proposal, then new proposals need to be submitted for approval, with a note of explanation that indicates that the new proposals replace the original approved proposal. This is based on the “one proposal - one manuscript” policy.
- All manuscripts should specify:
 - contributions that need acknowledging but do not justify authorship
 - acknowledgments of technical help
 - acknowledgments of financial and material support, which should specify the nature of the support, and
 - relationships that may pose a conflict of interest.
- Individual sites may use site specific data without P&P approval for the purpose of:
 - evaluating quality of care within their site and/or for providing feedback of clinical data to clinicians
 - developing research proposals.

- Manuscripts using site-specific data based on a study question particularly pertinent to that site and/or including data only available at that site require review and approval by P&P.
- All SEARCH posters, presentations and manuscripts should include the following statements (this does not apply to ancillary studies):
 - “The contents of this [paper, poster, presentation] are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases.”
 - “The SEARCH for Diabetes in Youth Study is indebted to the many youth and their families, and their health care providers, whose participation made this study possible.”
 - All posters and presentations based on submitted abstracts (new SEARCH data) or that focus solely on the SEARCH study findings should include the SEARCH study logo. They should not include other logos such as the investigators affiliation, CDC, NIH, etc. The affiliations of all of the authors can be listed, along with the lead author’s contact information.
- SEARCH investigators may ask to leave a writing group or have their name(s) removed from a manuscript prior to submission or resubmission, although it is preferred that this is done prior to submission. In addition, the Principal Investigator of any SEARCH site (including the laboratory and the Coordinating Center) or a funding agency (CDC or NIH when appropriate) may explicitly request removal of the phrase “for the SEARCH for Diabetes in Youth Study Group” from the authorship list. All such manuscripts would be processed through the established study governance and would still require approval by both the P&P and Steering Committees. (06/12)

19.6. PROCESS FOR MANUSCRIPT PREPARATION

Manuscript Proposals

- Topic defined by P&P committee (when applicable)
- WG Chair and co-chair named by P&P committee (when applicable, Key Papers only)
- Initial draft of manuscript proposal written by WG Chair and Vice-Chair and 1 - 2 other study group members, including CoC statistician, using the SEARCH Manuscript Proposal Submission Form (MPSF)
- Initial draft of the manuscript proposal distributed to all SEARCH PIs and collaborators from the NIH and CDC by the WG chair (or their mentor/site PI) for solicitation of writing group members (WG members). WG chairs should allow approximately 7 business days for these individuals to receive the draft proposal, identify a potential

WG member, and for the proposed WG member to give feedback on the proposal to the WG chair. (02/13)

- Revisions made to the draft proposal by the WG chair based on input from additional WG members (when applicable). (02/13)
- Final version of manuscript proposal is reviewed and approved by the Senior Statistician at the SEARCH CoC for SEARCH main study proposals or the Senior Statistician on an ancillary study and then the SEARCH Principal Investigator (PI) at the WG Chair's Center or the PI on the Ancillary Study. (02/13) (See **Section III. Required Approvals before P&P Review** of the SEARCH MPSF)
 - PIs and collaborators from the NIH/CDC only need to have the Senior Statistician's approval for the final version of the proposal. (02/13)
 - Other writing Group Chairs need the approval of their Center PI and the Senior Statistician. These approval statements should be emailed to the P&P Project Manager (PM), Maureen Goldstein (mgoldste@wakehealth.edu). (02/13)
- Manuscript proposal submitted by the WG Chair to P&P PM, Maureen Goldstein (mgoldste@wakehealth.edu) at the CoC at least 5 calendar days before the meeting (e.g., if meeting is on Wednesday, the proposal should be submitted no later than the Friday before).
- Review by the P&P committee
- Approval by the P&P committee or request made for modifications which are then resubmitted for the next call after the revisions are made or reviewed by a sub-committee for final approval.
- Assignment of a P&P liaison by the P&P PM
- Notification of WG Chair of P&P decision - automatic timeline is initiated (see below).

Manuscript Development and Submission

- SEARCH manuscripts (in progress or under review) should not be sent to anyone outside the study group who was not included in the WG list for the original proposal *or* added based on an official memo to P&P, without prior permission from P&P.
- Preliminary analyses to be completed **4 months from approval date**
- Draft circulated to WG - **4 months after receipt of preliminary analyses**
- Paper submitted to P&P/CDC for review - **3 months after completion of first draft**
- If guidelines are not adhered to, then P&P will require a plan of action to correct the lapse in productivity. If there is no productivity within an additional 2 months (total of

4 months behind timeline) then the P&P may intervene by suggesting possible changes in WG chair or WG composition, including:

- additional statistical support from the CoC to finish analyses
- changing WG Chairs, or
- other actions deemed to assist in the process.
- Submission of penultimate manuscript - emailed to P&P PM, Maureen Goldstein (mgoldste@wakehealth.edu) at the CoC in the format of the targeted journal with names of all authors and those to be acknowledged included on the manuscript (at least one week before P&P call).
 - For main study manuscripts, an Authorship Statement as below will be emailed to each WG member by the above P&P PM upon receipt of the penultimate manuscript. For those main study manuscripts meeting the criteria for CDC clearance, the signed Authorship Statements will be emailed to the CDC according to the following: (1) when the First Author is a CDC employee/contractor, then approvals are needed from ALL co-author(s) and the First Author or (2) when the First Author is NOT a CDC employee/contractor, then approvals will be needed ONLY from the First Author and all CDC co-author(s).
 - Authorship Statement: I, INSERT YOUR NAME, approve the manuscript entitled, INSERT MANUSCRIPT TITLE HERE, to be submitted for review to P&P, CDC, NIDDK (if applicable) and INSERT JOURNAL NAME.
 - P&P reserves the right not to review any manuscript if it is not in the correct format for the journal, does not specify the primary target journal, does not include the final data for the paper, if the attestation from all authors has not been received, or if it is submitted after the deadline for the call.
- The following disclaimer should go on all papers from the main SEARCH study regardless of whether there is a CDC or NIDDK author: *“The contents of this paper are solely the responsibility of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases”*.
- Submission of the P&P approved version of the paper after any revisions (when applicable) to the CDC (and NIDDK, if necessary).
 - For both papers and abstracts, CDC clearance is needed only if a CDC investigator is a named author. All papers should have “For the SEARCH For Diabetes in Youth Study Group” in the **authorship list** unless it is not permitted by the journal or one of the SEARCH study sites as previously described.

- If the paper is submitted to a journal that does not allow “For the SEARCH For Diabetes in Youth Study Group” in the authorship line, then the "The SEARCH for Diabetes in Youth Study" should be included in the Title whenever possible. If such a paper does not have a CDC author, it does not need CDC clearance.
- *CDC clearance is NOT needed for either papers or abstracts if there is not a CDC author.*
- *CDC clearance is not required for Ancillary study papers unless a CDC or NIDDK author is listed among the authors.*
- Receipt of CDC/NIH clearance by WG Chair and CoC
- WG chair sends modified version of the manuscript to the WG (if revisions are necessary)
- Submission of completed manuscript by CoC to Steering committee for final approval (one calendar week for approval vote) (*Not required for ancillary study papers*)
- The manuscript should be reviewed to ensure that it includes the most recent funding and acknowledgement statements. If required by the journal, the study group list should be submitted as an appendix. This has been requested by several journals as a requirement when “the SEARCH for Diabetes in Youth Study Group” is part of the authorship list.
- Submission of completed manuscript by CoC or the lead author to designated journal (after P&P and CDC approval)
- If journal requests revisions, WG chair should distribute reviews to WG members and work with WG members to revise paper.
 - If minor revisions are required, paper should be resubmitted to the journal within one month after approval by WG members
 - If major revisions are required, paper should be resubmitted within two months after approval by WG members and liaison.
- If paper is rejected, WG chair should distribute reviews to WG members and work with WG members to select another journal and consider revising paper based on reviews. The P&P Committee will monitor the status of manuscripts that are approved for submission but are not currently under review if there are delays in submitting manuscripts to another journal. (02/13)
- The WG chair should notify the P&P Project Manager (and their WG members) when each of the following occur:
 - Submission of manuscript to journal (if not submitted by the CoC)
 - Receipt of reviews and decision from journal

- When manuscript is resubmitted or submitted to alternate journals
- When manuscript is accepted
- When paper is available on-line as “epub” (when applicable)
- When paper is published.
- If someone would like to reinitiate work on a manuscript for which the approved proposal has been closed, they will need to submit a new proposal to the Presentations & Publications Committee (P&P) committee project manager and follow the steps for a proposal outlined above.

19.7. ABSTRACTS AND PRESENTATIONS

- All abstracts should emerge from approved manuscripts proposals, which should adhere to the policies and procedures as previously described.
- A P&P Liaison who is not a member of the WG will be assigned to each manuscript proposal. The Liaison will be responsible for reviewing and approving abstracts based on approved manuscript proposals for scientific meetings. The WG chair and liaison should agree upon a timeline for review and approval. Once the Liaison has approved the abstract, the WG Chair should forward the final approved abstract to the CoC, and the CoC will submit it, along with the appropriate signed Authorship Statements, for review and approval by the CDC when necessary, and then to the scientific meeting.
- The P&P strongly discourages submission of the same abstract to more than one major meeting, unless special circumstances permit.
- WG chair is encouraged to move the timeline for the manuscript forward during the period from the submission of the abstract and presentation to ensure that the analyses presented at the meeting are final (or close to final) and have been thoughtfully reviewed by the WG and will facilitate more rapid publication of study results after presentation.
- Local presentations for the purpose of recruitment, provider information and for general scientific discussion that will not be submitted for publication do not require P&P Committee approval.
- Invited presentations that will not include unpublished SEARCH data do not require P&P committee approval. If unpublished data is to be included in the presentation or the abstract, it must be based on an approved manuscript proposal. All invited presentations which focus exclusively or substantially on SEARCH data should be reported to the P&P committee co-chairs.

19.8. PRESS RELEASES

- In general, press releases about study findings will be prepared by the lead author of the paper or their designee and reviewed by the P&P committee on a conference call or via email if time does not permit prior to submission to the Steering Committee for final review prior to release.
- Press releases should be submitted for approval to the CoC for distribution to the P&P committee at least five calendar days before the stated P&P conference call.
- Press releases should be given to the media when interviews are requested to help ensure uniformity and accuracy in the information disseminated through the media.
- Press releases issued by or approved by the Steering Committee require CDC clearance. Additionally, any press release issued by the CDC or NIDDK should be reviewed by the P&P Committee and the Steering Committee prior to its release.
- Press releases based on papers pending publication must contain accurate information about the time when the embargo will be lifted as stipulated by the journal publishing the paper.
- In the case where more than one center is issuing a press release about a specific paper, the WG chair should be made aware of these press releases.

19.9. LETTERS

- Letters responding to a journal letter based on a SEARCH manuscript should be submitted to the P&P co-chairs for approval. Letters written in response to a non-SEARCH published manuscript but relevant to SEARCH should also be approved by the P&P co-chairs.
- If any letter, regardless of purpose, includes previously unpublished SEARCH data it must be approved by the P&P committee and by the Steering Committee as if it were a regular publication.
- If there is a quick turnaround time for the submission of this Letter, approval may be obtained by email.

19.10. MEDIA INTERVIEWS FOR THE MAIN SEARCH STUDY

- Members of the Steering Committee (Principal Investigators, CDC, NIH, CoC, and Central Laboratory) are authorized to discuss SEARCH purpose and objectives, methods, and published or presented data, with reporters. An exception, however, is media coverage related to any product or vendor; CDC and NIH do not allow for endorsement of any product or vendor.

- If available, media interview questions should be submitted for approval to the CoC for distribution to the P&P committee at least five calendar days before the stated P&P conference call.
- When media deadlines allow, submission of written questions and the investigator's responses should be submitted to the P&P Co-Chairs for review and approval. When this is not possible, Steering Committee members are allowed to answer media inquiries.
- The Steering Committee member or their designee is responsible for notifying the P&P Co-Chairs that an interview took place and with whom. When possible, a copy of any printed article should be sent to the CoC for posting and archiving.

19.11. CONFLICT RESOLUTION

- Should conflict arise that cannot be resolved by the interested parties themselves, this will be brought to the attention of the Co-Chairs of the P&P Committee, who will determine the first step towards conflict resolution. In many cases, resolution will occur via facilitated discussions among the parties concerned.
- As needed, the issue will be brought before the P&P committee for discussion and recommendations for resolution, relative to the stated P&P goals and policies.
- If resolution is not achieved to the satisfaction of the parties, then the issue will be brought before the Steering Committee.
- In all cases, values of fairness and respect will be upheld.