

**PUBLICATIONS & PRESENTATIONS POLICIES**

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**I. Overview**

TRACE-CORE, a Cardiovascular Center for Outcomes Research located at the University of Massachusetts Medical School and funded the National Heart, Lung, and Blood Institute (NHLBI), is assembling a cohort of 2,500 patients admitted to 6 hospitals in Central Massachusetts and in Atlanta and Macon, Georgia, to be followed for up to 2 years. As a multi-center study, it involves Investigators from each of its 3 main sites (UMass, Kaiser-Permanente Georgia, and Medical Center of Central Georgia). TRACE-CORE data are collected through the sites (baseline interview and medical record abstraction), and centrally (follow-up interviews) through computer-assisted telephone interviews (CAPIs) by the UMass Office or Survey Research. In addition, medical claims data will be merged into the final TRACE-CORE dataset. TRACE-CORE data available for analyses are stored within the Department of Quantitative Health Sciences (QHS), where the TRACE-CORE PI holds her primary affiliation.

TRACE-CORE requests that individuals working on projects involving TRACE-CORE data work closely with at least one of the TRACE-CORE Investigators and follow the policies of our Center. This is to ensure that persons using TRACE-CORE data have access to all pertinent information, including the documentation notebook which is distributed by the Center with the data, once a request for data has been approved; this notebook gives detailed information on the data set including the edits which have been performed, any problems in the data set, and lists of calculated variables and their algorithms. This documentation also includes the data forms that are used in the research process by the Investigators. We also encourage you to obtain access to the manual of operations that describes the data collection process and quality control procedures used by the study.

TRACE-CORE has implemented policies involving the use of its data, (1) to ensure that investigators know of ongoing research efforts and have the opportunity to participate in the efforts if they so desire; (2) to ensure that duplication of analyses is kept to a minimum; (3) to permit the Center to maintain control of the official TRACE-CORE data base includes being informed of any problem areas in the data base; (4) to ensure that publication or presentation of TRACE-CORE data does not occur without the knowledge and approval of the Steering Committee; and (5) to maintain the integrity of study data longitudinally. The TRACE-CORE PI has final say over all TRACE-CORE publications and presentations.

**II. Publications and Presentations (P&P) Committee**

The success of TRACE-CORE will be judged largely on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of the TRACE-CORE data, timely completion of projects, and adherence to the principles of authorship.

## **Role of the Publications and Presentations (P&P) Committee**

Although the TRACE-CORE PI has final responsibility and say over all TRACE-CORE publications and presentations, the PI's decisions will be made upon recommendation of the P&P Committee and are expected to only rarely, if ever, not follow P&P recommendations.

The P&P committee approves the proposal of publications and the submission of abstracts; as well as all publications and presentations before they are submitted for publication or presented in a public forum. The P&P Committee may decide who assumes lead responsibility for a paper if there is more than one interested candidate. The P&P Committee also may re-assign lead responsibility if reasonable progress on completing an abstract or manuscript has not occurred.

In addition to the above, the P&P committee will recommend prioritization of TRACE-CORE analytic resources (faculty statistical supervision and technical staff time) if demand for these resources exceeds supply.

## **Composition of P&P Committee**

The P&P Committee is chaired by the TRACE-CORE PI (Kiefe), and includes as voting members (1) the PI and co-PIs of the 2 TRACE-CORE research projects (Allison, Goldberg, Anatchkova, D McManus, Saczynski, Waring); (2) the PIs of the 2 Georgia sites (Roblin, Parish); (3) the TRACE-CORE lead faculty statistician (Ash); and (4) additional investigators (currently Gurwitz) as requested, if approved by P&P and the TRACE-CORE PI. Should another site be added to TRACE-CORE, the center PI will be invited to join the P&P committee as well. A current list of P&P members is posted on the TRACE-CORE website.

## **P&P Committee Meetings**

The P&P Committee meets periodically by conference call on a flexible schedule to be determined according to the needs of TRACE-CORE with additional meetings as needed. All P&P Committee members are expected to review all proposals in preparation for P&P Committee Meetings. During these calls only P&P Committee members will vote on decisions requiring a vote. However, all investigators associated with TRACE-CORE are invited to attend and are welcome to contribute to deliberations of the committee. Lead authors of manuscripts, proposals, abstracts, or presentations that are to be discussed during a P&P Committee call are invited to either attend themselves or send a representative TRACE-CORE staff will arrange the calls and take minutes, to be forwarded to the TRACE-CORE Steering Committee.

## **III. Proposing Manuscripts and Abstracts**

Proposals for manuscripts and abstracts may be initiated by any person interested in TRACE-CORE analyses but must include as a co-author at least one member of the TRACE-CORE P&P committee. This P&P Committee member is responsible for representing the proposed writing group (all named authors) and ensuring that TRACE-CORE policies are adhered to. TRACE-CORE values collegiality and across-center collaborations very highly. In this spirit, we encourage that co-authors from more than one site be included in each Abstract or paper proposal. We also encourage that the number of authors be kept at or below 4 at time of submission of a paper proposal to the P&P committee. The purpose of this is to allow additional TRACE-CORE authors to join the writing group at the time of

paper proposal approval by the P&P committee. We recognize it is not always possible to adhere to these recommendations.

After review by all initially named authors, paper proposals and abstracts should be submitted to the **P&P Committee**, preferably one week prior to the regularly-scheduled **P&P Committee** conference call. Each abstract must include a TRACE-CORE investigator, as designated above.

### **Abstract Format**

The TRACE-CORE P&P Committee strongly encourages the use of a structured abstract format, even when this is not required by the meeting at which the Abstract is to be presented. We suggest that, at a minimum, each Abstract be written in four sections, with the headings of **Background/Objectives, Methods, Results, and Conclusions.**

We further suggest that, even if a journal does not require it, Abstracts for completed manuscripts also be presented in a structured format. In addition, we strongly recommend that Abstracts for completed manuscripts not exceed 250 words, because MedLine will cut off Abstracts for published papers at 250 words.

### **Data Analysis and Distribution**

TRACE-CORE has some resources to perform analyses for abstracts, presentations, and manuscripts. We hope that demand for these resources will soon exceed supply. Therefore, in addition to analyses to be performed within QHS under the supervision of a faculty statistician and by TRACE-CORE staff, we have a mechanism to provide investigators with analytic datasets for approved manuscript proposals, Abstracts, or Presentations. To obtain such an analytic dataset, upon approval of a manuscript proposal, the lead author must complete and sign the TRACE-CORE Data Distribution Agreement. Upon receipt of the Data Distribution Agreement, TRACE-CORE analysts will prepare an analytic dataset that will be sent to requesting investigator(s).

## **IV. Authorship**

The initiator generally assumes first authorship of the proposed manuscript. The initiator is encouraged to contact other potentially interested individuals before the paper or abstract is proposed. At the time of proposal, individuals at each of the sites are given the opportunity to be co-authors. The first author is encouraged to involve individuals with specific expertise or experience as necessary. Each manuscript must include a TRACE-CORE P&P committee member.

## **V. Co-Authorship**

The criteria for authorship will be those of the International Committee of Medical Journal Editors (ICMJE, the "Vancouver Group"). [1] These criteria are similar to those of other major organizations concerned with authorship, especially those written recently. Excerpts of these criteria follow.

“All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.

Authorship credit should be based only on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.”

Co-authors should become involved in manuscript development as early as possible. The lead author should seek involvement by soliciting help early on, e.g., by circulating to co-authors a paper outline with some table shells and/or a request for suggestions of additional table and figure shells. Early drafts should be circulated to all co-authors, with a deadline for responses. Though the time allowed for co-author response will vary, it is suggested that two weeks is a reasonable interval. The lead author is expected to play a pro-active role in seeking co-author involvement and in taking action if this involvement is not forthcoming. If during the completion of the manuscript or presentation it becomes apparent that the contributions of one or more co-authors do not merit authorship, the lead author should discuss the possibility of removing the names of individuals from the paper. Failure to respond in a timely manner to a request for comments, especially if unexplained or repeated, should be grounds for considering the removal of a co-author. In addition, each co-author should critically examine his/her role in the process and volunteer to remove his/her name if warranted. The first author should attempt to reconcile divergent views of the co-authors with his/her own. However, sometimes a co-author may elect to remove his/her name because of disagreements in the interpretation of the data or in the style of writing, even though substantial contributions were made. [1] <http://www.icmje.org>

## **VI. Three Paper Limit for First Authors of Papers in Progress**

Investigators are limited to first authorship on no more than three papers in progress (prior to submission to a journal). The P&P Committee may grant exceptions to this policy, such as in the case of demonstrated productivity of the investigator, invited papers, or other special circumstances.

## **VII. Six-Author Rule**

Some medical journals, such as the Journal of the American Medical Association (JAMA), limit the number of authors on a manuscript to six. Moreover, it is difficult to work on a writing project with more than six people. Thus, TRACE-CORE will attempt to limit the number of authors on a paper or presentation to no more than six. Exceptions to this rule are allowed in the case of papers that legitimately require additional expertise or mainstream results papers that require the input and acknowledgment of many investigators. The New England Journal of Medicine allows 12 authors in a multi-center study, while Annals of Internal Medicine allows a maximum of 10 authors. Also note that in Item III we encourage paper proposals to have no more than 4 authors at the time of submission of the proposal to the P&P committee. Again, the purpose is to leave "room" for additional authors to join at the time of proposal approval, and thus promote across-site collaborations.

## **VIII. Manuscript Completion Process**

In general, manuscripts are initiated and completed as described below:

1. Investigator submits a proposal (one to two pages recommended) for review by the P&P Committee.

**The proposal must include:**

- A. Title and list of proposed collaborators.
- B. Scientific background and rationale.
- C. Research questions and hypotheses, when appropriate.
- D. Brief description of methods of analysis.

A template for a manuscript proposal is attached to these policies as Appendix A.

2. Once the proposal is approved by the P&P Committee, the initiating author, in conjunction with the selected co-authors, should agree upon assignments for research, analysis and writing, as appropriate. If not included in sufficient detail in the proposal, the first author should circulate a detailed plan for data analysis among the co-authors and solicit their input.
3. Early in the process, there should be at least one communication (phone, E-mail or regular mail) between the lead author(s) and each co-author about research strategy; additional communications will be needed. Response to communications from any author should be as quick as possible, typically less than two weeks. Response the same day is desirable, given the critical nature of collaborative feedback in the paper writing process. Failure to participate collaboratively may be taken by the lead author(s) as a signal that the co-author no longer wishes to participate in the paper.
4. The P&P Committee monitors each stage of the paper writing process. The first author is encouraged to keep P&P informed of the manuscript's progress. Chronic failure to advance in the writing of a manuscript may result in the reassignment of the topic to another investigator.
5. In the cover memo accompanying a manuscript draft, first authors should provide a time line to co-authors for returning the draft. The first authors may clearly state that the coauthor will be removed from the manuscript if a response is not received by the specified date. Removal of a co-author will be at the discretion of the first author and not a requirement of the publication policies. However, we strongly encourages adherence to reasonable timelines.
6. The lead author must submit the final version of the manuscript for review and approval by the P&P Committee before journal submission. All co-authors must be willing to take public responsibility for the manuscript as submitted to the P&P Committee. See next section on P&P Committee Review for Manuscripts.
7. Authors should keep P&P informed of journal submission(s) (dates and journal name), results of reviews (acceptance, rejection or request for revision) and final acceptance by journal.
8. If there are any substantial changes to an approved manuscript prior to publication, whether required by the journal or not, these changes must be discussed with the coauthors. Co-authors should receive proposed re-submissions at least one week prior to journal re-submission.

**NOTE:** Approval of a paper proposal is not required prior to approval of an abstract/presentation. However, it is expected that approved abstracts will be followed by a formal paper proposal. Authors are encouraged to, whenever possible, leave sufficient time before abstract submission deadline to submit and have approved a paper proposal.

## **IX. P&P Committee Review of Manuscripts**

The purpose of manuscript review is to evaluate the scientific merit, the clarity of the writing, and the consistency with other findings.

1. The first author sends the final version of a manuscript to each member of the P&P committee after approval by all co-authors.
2. Each member of the P&P Committee has an opportunity to review and communicate approval or disapproval to the first author within two weeks of receipt (at least two working days prior to the conference call when the paper will be reviewed). After discussion, the P&P Committee may make one of three recommendations to the TRACE-CORE PI: (1) unconditional approval; (2) approval with minor changes not requiring P&P re-review, or (3) major revision and re-review by P&P. P&P will seek to make recommendations by consensus but if, after an attempt to reach consensus, not all P&P members agree, a vote will be taken.
3. Disposition of a manuscript is documented in the minutes of the P&P Committee conference call. The first author ensures that any small but required changes not requiring another full cycle of review are made before the paper is submitted to a journal.

## **X. Review Process for Abstracts and Presentations**

1. Abstracts must be reviewed and approved by P&P before submission
2. If a poster or oral slide presentation is not submitted to the P&P Committee at least one week prior to the presentation date, the poster or presentation may be required to be withdrawn.
3. Review by the P&P Committee is required for all presentations of TRACE-CORE findings at meetings and conferences except:
  - a. Teaching conferences and classes for students and colleagues in a university setting, and that have no publicity involved, or
  - b. TRACE-CORE findings, ALL of which have been previously published or approved for presentation.

## **XI. Summary of responsibilities of entities involved in the publications and presentations process**

**Lead author.** The lead author leads paper proposal/analysis/writing efforts. During the entire process, the lead author keeps co-authors informed and active, including circulating final versions of the written product to co-authors to review before submission to P&P, peer-reviewed journal, or conference. The lead author is responsible for assuring that required approvals are obtained, and is responsible for timely communication with the P&P Committee. The lead author also informs co-authors of any changes after P&P Committee decision. The lead author must submit their poster or presentation (i.e., PowerPoint slides) to the P&P Committee for review.

**Co-authors.** Co-authors participate significantly in all scientific efforts, including writing. Co-authors are expected to meet ICMJE guidelines for authorship (URL provided above), including reviewing and approving the final written product before submission to the P&P Committee, journal, or conference. Co-authors will be informed of changes after P&P Committee decision and must approve major changes.

**P&P Committee.** The P&P Committee is responsible for the timely review and approval of paper proposals, manuscripts, abstracts, and presentations. The P&P Committee will approve manuscripts prior to journal submission; the Committee may delegate this review to a designated member of the P&P Committee. The P&P Committee reviews and approves abstracts prior to submission and presentations prior to meeting; the Committee may delegate this responsibility to an ad hoc committee.

## **XII. Acknowledgement of NHLBI funding**

All manuscripts using TRACE-CORE data must acknowledge NHLBI support. This acknowledgment should read, “Work on this manuscript was supported (or partially supported) by National Heart, Lung, and Blood Institute grant U01HL 105268.”

In addition, some journals are requiring that the lead author describe the role of the sponsor. If there is an NHLBI co-author on a manuscript, then this co-author will provide further guidance in describing NHLBI’s role in more detail.

## **XIII. NIH Public Access Policy**

Because TRACE-CORE publications are funded by NIH, the NIH Public Access Policy apply to these manuscripts (please see <http://publicaccess.nih.gov/>). Authors should note that some journals charge the first author for abiding by the NIH policy.

## **XIV. Other Publication Policies and Considerations**

**Causality Statements.** TRACE-CORE is an observational study, with inherent limitations on causal inferences. Authors should generally frame TRACE-CORE findings and conclusions in terms of association rather than causation. However, hypotheses involving etiological pathways can and should be generated and tested by TRACE-CORE analyses, and causal inferences are appropriate in a discussion section.

**Consistency of labeling of TRACE-CORE in papers, abstracts, and presentations.** If possible, include the word “TRACE-CORE” in the title of presentation or publication. This helps in indexing and retrieval and in gaining recognition for TRACE-CORE. Not all journals will allow the name of the study to be included in the manuscript title; instead, include “TRACE-CORE” in the article abstract. Whenever possible, abstracts and presentations should also include “TRACE-CORE” in the title.

Abstracts presented in poster format and oral presentations with slides should include the TRACE-CORE logo. Poster and PowerPoint presentation templates will be made available.

**Breadth and importance of TRACE-CORE publications.** The P&P Committee will regularly review paper assignments to determine if they are sufficient:

- A. Are enough topics being covered?
- B. Are selected topics of sufficient importance to justify continued support?

**Graduate Student Dissertations.** The use of TRACE-CORE data for doctoral or masters’ levels theses is encouraged although some aspects of graduate student work with TRACE-CORE data need special consideration. In particular, students are generally new investigators who are usually not familiar with TRACE-CORE data. This section of the publication policies attempts to balance the

opportunity to involve promising new investigators with preserving the opportunity for established TRACE-CORE investigators to publish study findings.

Publications and presentations resulting from theses are subject to all TRACE-CORE publication policies, including the requirement that the TRACE-CORE P&P Committee approve all paper proposals, all completed papers before journal submission, and all presentations before they take place. This includes seminars open to the public that are part of a thesis defense.

The distinction between approval of a dissertation proposal and approval of specific manuscript proposals resulting from a thesis is important. A specific request for thesis approval should include not more than one paper proposal and the elements specified below, with additional proposals to be entertained by the TRACE-CORE P&P Committee later, as the thesis matures. Although prompt submission of subsequent paper proposals is strongly encouraged, the student should note that approval of the thesis does not constitute approval of any manuscript proposal other than the one included in the thesis proposal.

**The request to use TRACE-CORE data in a graduate dissertation should include:**

- A. The name of at least one TRACE-CORE investigator who has agreed to serve on the student's dissertation committee and as a co-author of the first publication.
- B. Brief description of rationale, background, main hypotheses, analytic approach for the thesis.
- C. Proposal of one TRACE-CORE manuscript to result from the thesis work, in the usual TRACE-CORE paper proposal format. Like all other TRACE-CORE paper proposals, this must include at least one P&P member as co-author.
- D. Acknowledgment of having read TRACE-CORE publications policies and commitment to abide by them.
- E. Timeline for completion of analysis and proposed manuscript
- F. Formal involvement of the thesis advisor, in the form of an e-mail or letter that (1) endorses the thesis and paper proposal; (2) states willingness and availability to discuss the work with TRACE-CORE investigators; (3) states commitment to abide by TRACE-CORE publications policies.

**XV. APPENDIX A**

**Instructions for Completing TRACE-CORE Paper Proposals**

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1. Provide complete contact information for the first author. If a TRACE-CORE investigator will serve as the representative (contact person), state this on the proposal and include complete contact information for that person. Provide co-authors and e-mail addresses on separate lines. Co-authors and e-mail address to be typed from left to right, separate by a comma.
  2. It is recommended that a paper proposal be limited to two (2) pages, if at all possible.
  3. Submit the proposal to the **TRACE-CORE P&P Committee** with a request for approval via e-mail.
  4. E-mail proposal to Daniel.amante@umassmed.edu for distribution to the P&P Committee
  5. Delete these instructions prior to submitting the manuscript proposal.
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**TRACE-CORE Paper Proposal  
(Date of request)**

**I. Title:** \_\_\_\_\_

**II. Abbreviated Title:** \_\_\_\_\_

**III. Key Words:**

**IV. Writing Group (list individual with lead responsibility first)**

Lead author: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Address: \_\_\_\_\_

Co-authors (with e-mail addresses):

**V. Background**

**VI. Main Study Questions and Hypotheses**

**VII. TRACE-CORE data to be used:**  
**Recommended: variable types, names TRACE-CORE source form**

**VIII. Analytic Plan**

**IX. Timeline**

**X. References**