



Platelet-Oriented Inhibition in TIA and minor Ischemic stroke (POINT) Trial

Publications Policy

Policy Overview

The goal of the POINT Trial Publications Policy is to provide guidelines for preparing, reviewing, submitting and maximizing productivity of high quality peer-reviewed publications.

Responsible Individuals

Members of the POINT Executive Committee.

Study-Specific Publication Procedure – POINT Executive Committee

The goal of this policy is to maximize the yield of high quality peer-reviewed publications. In addition to overseeing the performance of the trial, the Executive Committee is responsible for encouraging paper production, ensuring timely publication of data, maintaining a high standard for the quality of papers produced for POINT, and determining appropriate authorship. When the Committee is discussing manuscripts associated with ancillary studies, the PI of the ancillary study and his/her designee will also join the Executive Committee for that discussion.

Manuscript proposals will be submitted to the Executive Committee by completing the POINT Trial Manuscript Proposal Form (**Appendix A**) and following the proposal review process described in this policy. These proposals will include the type (primary, secondary and tertiary), list of authors and their qualifications for authorship, a statement that no others deserving authorship have been omitted, the scientific rationale for the paper, the data needed and a description of the proposed analyses and any deadlines for submission of abstracts or presentation dates if applicable.

Such proposals will be reviewed by the Executive Committee within 90 calendar days of submission. The Committee may suggest changes to the proposed analyses or to included authors, and may decline a proposal if it considers it scientifically unsound or if resources for the analyses are unavailable. A proposer may request reconsideration if a proposal is initially declined.

All trial-related manuscripts will be reviewed prior to journal submission to ensure that statements made at the time of the paper proposal were carried forward in manuscript formation, and that the final manuscript meets the highest standards regarding scientific rigor, thoroughness, clarity and full disclosure of conflicts of interest.

Paper proposals will be divided into three distinct types based on their relation to the underlying study hypotheses. These designations are important to the Executive Committee since primary and secondary papers should be published early and authored by the POINT PI and colleagues.

Proposal Types

- **Primary:** Primary papers are pre-specified as including the primary outcome data of the trial as described in the Statistical Analysis Plan (SAP).
- **Secondary:** Secondary papers are defined as containing the secondary, pre-specified data as described in the SAP.
- **Tertiary:** Tertiary papers are *post hoc* analyses that relate to the central hypotheses being tested, but not pre-specified in the grant application.

The POINT PI and his designees have the first rights to publish collective study data per the Executive Committee approval. It is expected that within six months of analysis availability, the manuscript presenting the primary study results will be sent to the Executive Committee by the PI. The primary analysis of POINT will be submitted for publication within 3 months of study database lock.

Members of the POINT Executive Committee, the POINT CRC (Emmes), the NETT-CCC and SDMC are next in line for publication rights. Only the POINT PI and designees, POINT Executive Committee members, and members of the CRC, NETT CCC and SDMC have collective data rights until 2 years after the publication of the primary manuscript or 4 years after completion of the study, whichever comes first. Individual institutions shall retain ownership of all data that they generate. Institutions shall grant to the POINT PI and designees non-exclusive license to use data for educational and research purposes. Sites agree to delay any presentation or publication of their own site's data until the primary results of the trial have been published or 2 years after study completion, whichever comes first. The Executive Committee will retain oversight of the collective data and decision making authority with respect to the collective data for 18 months after publication of the primary study results or 4 years after study completion, whichever comes first.

Finally, within 5 years of study completion, the public use data sets will be created by the SDMC and forwarded to the National Technical Information Service (NTIS) (website: www.ntis.gov), to which requests for data can be addressed. All reasonable requests for data will be honored by the Executive Committee in accordance with the NIH policy on data sharing (https://grants.nih.gov/grants/policy/data_sharing/).

The POINT PI will be given 1 year from database lock to specify publications that he/she or his/her designee wishes to author using the collective data. After this time, ideas submitted to the Executive Committee will be evaluated on a first-come, first-served basis.

Group authorship is encouraged. This is especially true for secondary and tertiary publications. The appendix at the end of both group and named authored papers should contain the names of the POINT PI, the POINT Executive Committee, the CRC Director, the NETT-CCC, the NETT SDMC, NETT and CRC investigators, and the NINDS Scientific Program Director. All publications from POINT will contain a list of PIs and other independent trial PIs at the end of the publication. Additional investigators and coordinators should be listed as well, acknowledging whether they arise from the NETT or the CRC.

Named authored papers should follow logical criteria for authorship. All investigators who make a creative, substantive contribution to the research should be listed as authors. This includes those who creatively participated in the study concept, design, funding, conduct and/or analysis, or who drafted the manuscript. Individuals whose involvement is limited to following the protocol within the context of their job do not qualify for named authorship, but may be recognized in the acknowledgment section.

The first author for publications should be the individual who was most fully responsible for the concept, design, funding, conduct, analysis and drafting of the manuscript. The last author should be the senior member who contributed the most to the items listed above. The order of the remaining authors should follow from their relative contribution to the manuscript. The NINDS Scientific Program Director should be a co-author on the primary publication. All relevant individuals should receive a copy of the manuscript in a timely fashion and be offered the option to request that their name be listed, moved in order, or remove themselves from authorship. All grievances should be conveyed to the Executive Committee by the first author and POINT PI with a recommendation for resolution. The Executive Committee has the final word with respect to authorship decisions.

POINT Executive Committee members will be given 10 business days to review publications and offer any suggestions for change. If changes are suggested but not made by the POINT PI, the POINT Executive Committee members may elect to have their name removed from the publication, but they may not remove their data from the analysis.

Study-Independent Publication Procedures (POINT operations and methods papers)

Members of the NETT-CCC, SDMC, CRC and UCSF CCC, and site investigators may wish to publish methods papers that describe their function, or papers that are otherwise wholly independent from the trials conducted. These paper proposals and final manuscripts will be submitted to the POINT Executive Committee.

Additional paper proposals and final manuscripts will be submitted to the NETT General Publications Committee if they are relevant to the operations or organization of the NETT. The POINT Executive committee does not have authority over individual study Publications Committees or policies. Papers published on such topics will not address topics in the study's specific aims, but will require an option for authorship and review by the POINT Executive Committee if POINT is referenced in the manuscript.

Individual POINT Site Investigator Publication Rights

A POINT Site Investigator who wishes to publish his or her own institution's data will be able to proceed with such publication, provided that publication is delayed for 1 year after the primary publication has been published or 2 years after the study has ended (database lock), whichever comes first.

Adherence to Policy

Participation in POINT requires adherence to the publication policy described in this document, even though Site PIs retain ownership of the data collected at their sites. Authors who publish articles that are not compliant with this policy must contact the journal and retract the publication.



POINT Executive Committee

S. Claiborne Johnston, MD, PhD, J. Donald Easton, MD, Anthony S. Kim, MD, MAS, Mary Farrant, MBA, Yuko Palesch, PhD, Jordan Elm, PhD, William Barsan, MD, Anne Lindblad, PhD, Robin Conwit, MD, Scott Janis, PhD.

POINT TRIAL PROPOSAL REVIEW PROCESS

1. Complete POINT Trial Manuscript Proposal Form (**Appendix A**)
2. Submit completed form via email to POINT Executive Committee for review at POINTOperations@ucsf.edu.
3. The Executive Committee reviews request and within 90 calendar days approves, modifies or disapproves the request using the POINT Manuscript Proposal Review Form (**Appendix B**). More detailed information may be requested from the authors.
4. The final version of the completed abstract, poster, slides and/or manuscript must be sent to the POINT Executive Committee for review at least 6 weeks prior to the submission deadline or presentation date; for manuscripts, the submission cover letter must be included with the copy of the manuscript.
5. The Executive Committee approves, approves with modification or disapproves the abstract, poster, slides or manuscript. (**Appendix C**)
6. If the manuscript is denied, feedback is given within 2 weeks of the denial, detailing the rationale for disapproval.
7. If changes are recommended, the revised version is submitted to the Executive Committee prior to submitting the manuscript or abstract for publication.
8. The Executive Committee is kept informed about acceptances, rejections or resubmissions of materials; if a manuscript is changed for resubmission, it should be submitted to Executive Committee for re-approval prior to being submitted for publication.
9. The Executive Committee reserves the right to make final determinations in conflicts or disputes about authorship ranking.

Appendix A

POINT Trial Publications Proposal Form

Please read the POINT Publications Policy before completing this form.

Date Submitted:

Is this the first review of this proposal by the POINT Executive Committee? Yes No

POINT Executive Committee member agreed to this submission:

Note: Authors are encouraged, but not required, to collaborate with a member of the POINT Executive Committee, as they are familiar with the study and can provide insight throughout the manuscript development process.

1. Proposal Type:

Secondary

Tertiary

2. Proposal Title:

3. Lead Author Information

First Author's Name:

Institutional Affiliation:

Address:

Email Address:

Telephone:

Please provide Co-Author Information at the end of Appendix A.

4. Rationale:

5. Data to be Used:

6. Description of Planned Analyses:

7. Deadlines for Submission of Abstract(s) or for Presentation:

8. Journals Anticipated for Submission (list up to 3 in priority order):

9. Will this manuscript be submitted to an upcoming conference or meeting? Yes No
If yes, which one(s)? Include conference or meeting date(s).

10. Is this manuscript proposal based on an ancillary study? Yes No

I have read and agree to the POINT publications policy as outlined in the POINT Publications Policy.

Name:

Date:

Email the completed form and manuscript to Mary.Farrant2@ucsf.edu

Co-Author Information	
1. Author's Name:	Email Address:
Institutional Affiliation:	
2. Author's Name:	Email Address:
Institutional Affiliation:	
3. Author's Name:	Email Address:
Institutional Affiliation:	
4. Author's Name:	Email Address:
Institutional Affiliation:	
5. Author's Name:	Email Address:
Institutional Affiliation:	
6. Author's Name:	Email Address:
Institutional Affiliation:	
7. Author's Name:	Email Address:
Institutional Affiliation:	
8. Author's Name:	Email Address:
Institutional Affiliation:	
9. Author's Name:	Email Address:
Institutional Affiliation:	
10. Author's Name:	Email Address:
Institutional Affiliation:	

Appendix B

POINT Trial Manuscript Proposal Review Form

Date of Review:

Reviewer:

Proposal Title:

Ratings:

	Excellent	Very Good	Good	Fair	Not Acceptable
Importance of Question					
Originality/Innovation					
Quality of Methods					
Overall Scientific Merit					
Relevance to POINT Key Scientific Questions					
Statistical Considerations					

Recommendation:

- Accept as is
- Accept pending revisions
- Reconsider after revisions
- Disapprove for reasons noted:

Appendix C

POINT Trial Manuscript Review Form

Date of Review:

Reviewer:

Proposal Title:

Ratings:

	Excellent	Very Good	Good	Fair	Not Acceptable
Importance of Question					
Originality/Innovation					
Quality of Methods					
Overall Scientific Merit					
Relevance to POINT Key Scientific Questions					
Statistical Considerations					

Recommendation:

- Accept as is
- Accept pending revisions
- Reconsider after revisions
- Disapprove for reasons noted: