SOP Number: ADM 03, Part A
SOP NAME: StrokeNet Publications Committee and Policy
Effective Date: 22-May-2015

DEFINITIONS AND ABBREVIATIONS

GCP	Good Clinical Practice
NCC	National Clinical Coordinating Center
NDMC	National Data Management Center
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
PMC	PubMed Central
PPI	Protocol Principal Investigator
RCC	Regional Coordinating Center
SOP	Standard Operating Procedure

1. PURPOSE

The purpose of this document is to encourage and facilitate presentation and publication while providing guidelines that ensure appropriate use of data and resources of trials done within the StrokeNet, timely completion and submission of publications, and adherence to the principles of authorship and policies for federally funded research. Submission to and approval by the publication committee of proposals are required for all manuscripts and abstracts that use data from trials and ancillary studies conducted within the StrokeNet. Investigators may not take any part of the data and publish it prior to publication of the major findings of the trial. However, they are not prohibited from publication using data from the study after release of the public use data set.

2. SCOPE

This SOP has been developed to align with all federal regulations and GCP guidelines. The policies and procedures in this SOP apply to the StrokeNet NCC and NDMC, and to all RCCs and affiliated investigators, staff, and/or other entities associated with the StrokeNet. Individuals responsible for executing this policy include PPIs, PPI designees, NCC PI or designee, NDMC PI or designee, RCC representatives and their designees, and the NINDS Scientific Program Director.

3. FEDERAL, NIH AND NETWORK REQUIREMENTS REGARDING STROKENET PUBLICATIONS AND ACKNOWLEDGMENT OF NIH SUPPORT

All publications based on work from the StrokeNet must acknowledge the support of the NIH/NINDS by including an acknowledgement such as: “Research reported in this publication was supported by the National Institute of Neurological Disorders and Stroke of the National Institutes of Health under Award Number XXXXXXX. The content is solely the responsibility of the authors

and does not necessarily represent the official views of the National Institutes of Health." Grant numbers to be listed in this statement must include the study specific grant and the infrastructure grant for the NCC, NDMC, and each RCC that participated in the study. Additional terms and conditions of publication as defined in any NINDS CRADA or third-party agreements established for the specific study.

All publications from StrokeNet studies must comply with federal regulations detailed on the National Library of Medicine's PMC website. As such, no later than 12 months after the official date of publication, an electronic version of the final peer-reviewed manuscript of such publication must be submitted to the PMC to be made available publicly.

All NIH funded trials, results and publications posting on the ClinicalTrials.gov is required.

All publications must comply with the terms and conditions defined in the NIH StrokeNet Publication ADM SOP #3, Part A.

4. PROCEDURES FOR THE STROKENET PUBLICATIONS COMMITTEE

A. Overview

The StrokeNet Publications Committee is a standing sub-committee of its Executive Committee. The members are responsible for ensuring the development and dissemination of knowledge derived from StrokeNet studies, for updating or amending the Publication Policy SOP and for providing to the PPIs protocol-specific publication policy template (in collaboration the NCC and NDMC as necessary). This Committee is also responsible for any manuscript proposals that are StrokeNet-specific and not related to any particular StrokeNet study. It also manages StrokeNet publication collaborations arising from trials performed in multiple networks (such as the NETT, NeuroNEXT and other national and international networks). This Committee does not have authority over the Protocol-Specific Publications Committees listed in ADM SOP #3, Part B, except where data from multiple StrokeNet studies are to be used.

B. Membership

Members of this Committee include the PI of the NCC (Chair), PI of the NDMC (Co-chair), the Scientific Program Director from the NINDS, Chairs of the Acute, Prevention, and Recovery Working Groups, Chair of the Imaging Core, and as applicable and *ad hoc*, the PI of the studies for which the data are used for the publication. For any publication related to educational activities within the StrokeNet, the Co-chairs of the Education Core would act as *ad hoc* members of the Committee. The StrokeNet Administrative Coordinator for the NCC at the University of Cincinnati or designee, is an *ex officio* member of the StrokeNet Publications Committee to provide administrative support to the Committee.

5. APPLICABLE REGULATIONS AND GUIDELINES (LISTS REFERENCE TO SPECIFIC POLICIES AND GUIDANCE DOCUMENTS FROM WHICH THE SOP IS WRITTEN)

PubMed Central posting: Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) NIH's Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NOT-00-08-033

ClinicalTrials.gov reporting requirements: Food and Drug Administration Amendment Act 2007

GCP as set forth in the 1996 ICH E6 Consolidated Guidance.

6. REFERENCES TO OTHER APPLICABLE SOPS

7. ATTACHMENTS AND REFERENCES (

8. DOCUMENT HISTORY

SOP Number: ADM 03, Part B
SOP NAME: StrokeNet Protocol-Specific Publications Committee and Policy
Effective Date: 22-May-2015

DEFINITIONS AND ABBREVIATIONS

GCP	Good Clinical Practice
NCC	National Clinical Coordinating Center
NDMC	National Data Management Center
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
PMC	PubMed Central
PPI	Protocol Principal Investigator
PS	Protocol-Specific
RCC	Regional Coordinating Center
SOP	Standard Operating Procedure

1. PURPOSE

The purpose of this document is to encourage and facilitate presentation and publication while providing guidelines that ensure appropriate use of data and resources of a specific trial conducted in the StrokeNet, timely completion and submission of publications, and adherence to the principles of authorship and policies for federally funded research. Submission to and approval by the PS Publication Committee of proposals are required for all manuscripts and abstracts that use data from the corresponding study and its ancillary studies conducted. Investigators may not take any part of the data and publish it prior to publication of the major findings of the trial. However, they are not prohibited from publication using data from the study after release of the public use data set.

2. SCOPE

This SOP has been developed to align with all federal regulations and GCP guidelines. The policies and procedures in this SOP apply to the PPI and his/her study team, PIs of the StrokeNet NCC and NDMC, and to all RCCs and affiliated investigators, staff, and/or other entities associated with the StrokeNet. Individuals responsible for executing this policy include PPIs, PPI designees, NCC PI or designee, NDMC PI or designee, RCC representatives and their designees, and the NINDS Scientific Program Director.

3. FEDERAL, NIH AND NETWORK REQUIREMENTS REGARDING STROKENET PUBLICATIONS AND ACKNOWLEDGMENT OF NIH SUPPORT

All publications based on work from the StrokeNet must acknowledge the support of the

NIH/NINDS by including an acknowledgement such as: "Research reported in this publication was supported by the National Institute of Neurological Disorders And Stroke of the National Institutes of Health under Award Number XXXXXXX. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Grant numbers to be listed in this statement must include the study-specific grant and the infrastructure grant for the NCC, NDMC, and each RCC that participated in the study. Additional terms and conditions of publication as defined in any NINDS CRADA or third party agreements established for the specific study.

All publications from StrokeNet studies must comply with federal regulations detailed on the National Library of Medicine's PMC website. As such, no later than 12 months after the official date of publication, an electronic version of the final peer-reviewed manuscript of such publication must be submitted to the PMC to be made available publicly.

All NIH funded trials, results and publications posting on the ClinicalTrials.gov is required.

4. PROCEDURES FOR THE PROTOCOL-SPECIFIC (PS) PUBLICATIONS COMMITTEE

A. Overview

The PS Publications Committee is a standing sub-committee of the Study Executive Committee. The members are responsible for ensuring the development and dissemination of knowledge derived from the study and for updating or amending this Publication Policy SOP.

B. Membership

Members of this Committee include the PPI, the Primary Study Statistician, at least one NCC scientific representative, at least one NDMC scientific representative, the Scientific Program Director from the NINDS, and others with relevant expertise. The StrokeNet Administrative Coordinator for the NCC at the University of Cincinnati or designee, is an *ex officio* member of the StrokeNet Publications Committee to provide administrative support to the Committee.

C. Publication Policy

The details of the procedures and policies are provided in the Appendix.

5. APPLICABLE REGULATIONS AND GUIDELINES (LISTS REFERENCE TO SPECIFIC POLICIES AND GUIDANCE DOCUMENTS FROM WHICH THE SOP IS WRITTEN)

PubMed Central posting: Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) NIH's Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NOT-00-08-033

ClinicalTrials.gov reporting requirements: Food and Drug Administration Amendment Act 2007

GCP as set forth in the 1996 ICH E6 Consolidated Guidance.

6. REFERENCES TO OTHER APPLICABLE SOPS

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of Modification	Justification for Modification	Completion Date	Issue Date	Effective Date
1.0	Final		22-May-2015	22-May-2015	22-May-2015
2.0	Pg. 1 Section 1. Purpose-Expanded conditions/ exceptions for publication committee approval.	Meet criteria for public institution publication policies	1-Mar-2016	1-Mar-2016	1-Mar-2016
3.0	Appendix 7 and 9	Process for determining authorship listing, Third Party Partnership with NINDS	19-Jul-2016	19-Jul-2016	19-Jul-2016
3.1	Biannual review with minor administrative changes		15-Sep-2016		
4.0	Final		16-Sep-2016	16-Sep-2016	16-Sep-2016
5.0	Review with minor administrative changes	Clarifying language with MPIs	11-Apr-2022	18-Jul-2022	18-Jul-2022

APPENDIX: Manuscript Development and Submission Process

1. MANUSCRIPT PROPOSAL SUBMISSION

Any investigator wishing to write a manuscript using data from a study conducted in the StrokeNet must submit a formal proposal to the PS Publications Committee. The proposal should be no more than 4 pages and should be emailed to the PPI and the Administrative Coordinator working with the PS Publications Committee. The proposal must include the following summary information:

- Manuscript title
- Potential author(s)
- Brief rationale and background
- Research Hypothesis (clearly state scientific questions to be addressed)
- Data (list variables to be used, sample inclusions/exclusions)
- Mock tables for results, if known
- Brief data analysis plan
- Major references
- Journal to which the manuscript is planned to be submitted.

2. MANUSCRIPT PROPOSAL REVIEW

Study-specific manuscript proposals will be submitted to the PS Publications Committee at two time points. The PS Publications Committee first reviews and prioritizes the proposal within 2 weeks of its submission.

At the initial review presentation, the proposals needs to include the designation of the type of publication listed below as primary, secondary, etc., a list of potential authors and their qualifications for authorship, a statement that no others deserving authorship have been omitted, the scientific rationale for the paper, and the data needed.

The final manuscript will be reviewed once more by the PS Publications Committee 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.

The PS Publications Committee also reviews the manuscript proposals to determine if there is potential overlap with any other papers or abstracts, proposed or in progress. In cases of potential overlap, the investigator(s) are encouraged to collaborate with the existing project. Upon initial review by the PS Publications Committee, the proposal is assigned a manuscript number and entered in the Manuscript Proposal Index on the study-specific website.

3. PROTOCOL/TRIAL EXECUTIVE COMMITTEE REVIEW

The Study Executive Committee for a given trial, in consultation with the NDMC/Protocol Statistician, determines the priority for data analyses of manuscripts to be performed.

4. FORMATION OF WRITING GROUP

If the initial proposal is approved, it is posted on the Study Website for 2 weeks. All investigators participating in the study are notified by email of the new posting. Any investigators with sincere interest in participating in the writing of the proposed manuscript may sign up during the posting period as a potential author. The Writing Group on the topic is then formed, chaired by the investigator who developed and submitted the proposal. For each approved initial proposal, a statistician from the NDMC or the PPI's group is assigned to the Writing Group by the Primary Study Statistician.

To ensure that all investigators have the opportunity to participate and be recognized in the papers, any StrokeNet Investigators (clinicians as well as study coordinators) wishing to contribute in a substantive manner to any Writing Group may do so by contacting the Writing Group Chair via the Study Website publication-presentation section or by email. The Writing Group members also may be nominated by the Chair of the Writing Group and by the PS Publications Committee, although nomination is no guarantee of co-authorship. Final review of the Writing Group members is made by the PS Publications Committee. The PS Publications Committee reviews the nominees to ascertain if any investigator who is able to significantly enhance the Writing Group should be added; or, when it is in the best interest of publication, a smaller Writing Group may also be recommended.

The Writing Group is generally limited to 10 investigators, including the statistician. Usually, the investigator who submits a manuscript proposal is the first author or senior author of the paper. S/he receives written notification of all Writing Group members.

Once authors have been vetted/finalized, the proposal and any "common manuscript draft" is then posted on the Study Website accessible to the writing group for editing and composing by permitted password only.

5. WRITING GROUP RESPONSIBILITIES

The Writing Group Chair is responsible for all phases of manuscript preparation, from conception through publication and initiation of public access policy procedures. The Writing Group Chair responsibilities include:

- Preparation of manuscript outline;
- Identification of data analyses needed (creation of analysis plan);
- Submission of interim status reports to the PS Publications Committee;
- Assignment of tasks/responsibilities to Writing Group members with clear deadlines for completion

of these tasks and determination that the tasks are completed on schedule;
    - Preparation and posting or circulation of drafts for review by each member of the Writing Group before submission of a penultimate draft to the PS Publications Committee and before submission to a journal;
- Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the Writing Group in the preparation of the manuscript. Substantial contribution to the intellectual content of the paper will be evaluated by the following criteria based on the AHA Publication Authorship statement. To qualify for authorship, an author must have made substantial contributions to the intellectual content of the paper. Authors must indicate their contribution(s) (per below) to this manuscript and the Writing Group Chair must agree.
    - conceived and designed the research
    - acquired the data including enrollment of subjects
    - analyzed and interpreted the data
    - performed statistical analysis
    - handled funding and supervision
    - drafted the manuscript
    - made critical revision of the manuscript for important intellectual content
    - other (specify)
- Choice of a journal to which the manuscript will be submitted, determination of the journal's compliance with the NIH Public Access Policy and correspondence with the journal regarding compliance with the NIH Public Access Policy.
- Correspondence with co-authors regarding paper outline, data analysis plan, writing assignments for each member as well as communication with the StrokeNet Protocol-Specific Publications Committee, and responses to journal editors.
- Determination of dates and times for the Writing Group teleconferences, if needed, although most communication among the Writing Group is expected to occur through email. If necessary, the Study Administrative Coordinator may arrange teleconferences among the Writing Group members once the date and time is determined by the Writing Group.
- Guide the PPI in assuring the funding source for the publication related costs.

Writing Group members are responsible for performance of tasks assigned by the Chair within the allotted time period. Each member is expected to actively participate in the preparation of the manuscript. If a Writing Group member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she may be removed from the Writing Group by the Writing Group Chair. The Chair will then email a letter to the PS Publications Committee requesting the removal of non-contributing members. Approval for additional members of a given writing group requires approval of the PPI and Chair of the PS Publications Committee

If the initial results lead to a split of the original paper into more than one manuscript, a new proposal and description should be submitted to the PS Publications Committee. The same Writing Group members are usually retained on the second paper.

6. PROCESS FOR DESIGNATION OF MANUSCRIPT CATEGORY

Papers will be divided into primary, secondary, tertiary and quaternary manuscripts defined as follows. These designations are important to the PS Publications Committee since primary and secondary papers should be published early and authored by the PPI and colleagues.

- **Primary**: Primary papers are pre-specified as including the primary outcome data of the trial as described in the grant application.
- **Secondary**: Secondary papers are defined as containing the secondary, pre-specified data as described in the grant application.
- **Tertiary**: Tertiary papers are post-hoc analyses that relate to the central hypotheses being tested, but not pre-specified in the grant application.
- **Quaternary**: Quaternary papers utilize the dataset for data that do not relate to the hypotheses of the study.

7. PROCESS FOR DETERMINING AUTHORSHIP LISTING

Group authorship is encouraged. This is especially true for primary publications. The Appendix at the end of both group and named authored papers should contain the name of the PPI(s), the Executive Committee of the specific study, StrokeNet NCC and NDMC PIs and personnel who contributed to the study, and the NINDS Scientific Program Director. In addition, PIs and contributing personnel at the StrokeNet satellite or performance sites that enrolled subjects will be listed and identified as StrokeNet sites. Finally, PIs and contributing personnel from sites who enrolled subjects but who are not part of a participating site within an NIH StrokeNet RCC also will be listed.

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 concept and design of the trial, obtained funding, conducted analysis or drafting/revision of the manuscript, unless it is more explicitly defined by the journal authorship policy. 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.

Individuals whose involvement is limited to following the study 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.

All grievances should be conveyed to the PS Publications Committee by the first author with a recommendation for resolution. The PS Publications Committee has the final word with respect to authorship decisions.

8. PROCEDURES FOR NETWORK MANUSCRIPT REVIEW AND TIMELINES

RCC PIs will be given seven days to review publications and offer any suggestions for change. If changes are suggested but not made by the Writing Group Chair, PPI, the RCC PI may elect to have their name removed from the publication, but they may not remove their data from the analysis.

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.

9. PROCEDURES FOR FINAL MANUSCRIPT PREPARATION AND EXPECTED PUBLICATION SCHEDULE

The expected schedule for the development of a manuscript is described below. Generally, the manuscript is expected to be submitted to a journal within 1 year of receiving acceptance for the manuscript concept from the StrokeNet Protocol-Specific Publications Committee. Deviation from this schedule must be approved by the StrokeNet PS Publications Committee. Failure to adhere to this schedule will prompt a review of circumstances by the Subcommittee. If it is determined that a manuscript is delinquent, this could be the basis for replacing member(s) of the Writing Group responsible for the delay, or for disbanding the Writing Group.

The NDMC maintains a list of papers waiting to be started and assigns available analysts to papers with the highest priority.

a. Manuscript Versions

Draft: After notification by the StrokeNet Protocol-Specific Publications Committee of manuscript approval and the availability of statistical analysis personnel effort, the Writing Group has 4 months to prepare a first draft. A first draft will consist, at a minimum, of an Introduction, Methods and Results Sections. This draft should be sent to the members of the Writing Group. It is recommended that a response deadline of 3 weeks be given to the Writing Group members to prevent unnecessary delays.

Penultimate Draft: The penultimate draft becomes due 4 months after the first draft is distributed to the Writing Group. A penultimate draft should be sufficiently developed for subsequent submission to a peer-reviewed journal.

b. Final Reviews and Sign Offs

Final Writing Group Review and sign off: The Writing Group members have no more than **3 weeks** to review the final manuscript.

Corporate Partner Review and sign off: For those protocols/trials that involve a corporate partner, the industry partner will have the right to review as an ad hoc member of the PS Publications Committee any publication in which the performance of their product is discussed or described as described by the contractual relationship of the industry partner with a given trial within StrokeNet.

Third Party Partnership with NINDS: All manuscripts, whether individual or cumulative, should be provided to NINDS prior to submission for immediate delivery to the involved Third Party for its advisory review and comment. A Third Party will have a pre-determined period of time from the date of receipt for review. The Third Party may request a delay in the submission in order to ensure that its confidential and proprietary data, in addition to any intellectual rights, are protected. All abstracts and posters will be provided to NINDS two weeks prior to submission to facilitate a short review period by the Third Party.

Specific data sharing policies will be developed in accordance with NINDS policy and NIH Guidelines. It is expected that investigators submit to NINDS Office of Clinical Research a complete, cleaned, and de-identified dataset and any supporting documentation (including but not limited to the study protocol, statistical analysis plan, and data dictionary) required for the analysis of the data within one year of the primary publication or within 18 months of the last study visit of the last subject, whichever occurs first (NIH NGA R | Version: 1 - 06/15/2015).

Final PS Publications Committees Review: The PS Publications Committees has up to forty-five (45) days to review the manuscript. The StrokeNet Publications Committees will review each manuscript followed by a discussion during a conference call. Afterward, the Writing Group chairperson will be sent a summary of reviewers' comments. If a manuscript is not approved, the draft will be returned to the Writing Group Chair with comments regarding the necessary revisions before resubmission.

The Writing Group Chair is responsible for corresponding with the target journal to verify:

- Whether the journal is on the NIH list of journals that automatically submit to PubMed Central http://publicaccess.nih.gov/submit_process_journals.htm
- What is the publications' position on compliance with the NIH Public Access Policy ***(i.e. the author retains the right to submit the peer-reviewed manuscript to PubMed Central upon acceptance of publication to be made available for public viewing within 12 months of publication)??*** If the Journal position is opposed then a StrokeNet staff member will assist the Working Group Chairman in negotiating permission to retain the right to comply with the policy. If the chosen journal is unwilling to negotiate or comply with the NIH Policy another journal must be selected for publication of the manuscript.
- Does the journal submit to PubMed Central on behalf of the authors within 12 months of publication?
- Does the journal have specific Public Access stipulation language it wants included in the manuscript to indicate the "publisher position"?
- Any journal-specified language regarding Public Access should be added to the penultimate draft PRIOR to review by the StrokeNet Publications Committee and Corporate Partners.
- After review and approval of the penultimate draft by the Writing Group members, the penultimate draft should be sent to the PS Publications Committee with a cover letter stating that this penultimate draft is ready for review. A copy should also be sent to the overall StrokeNet

Publications Committee.

10. PROCEDURES FOR JOURNAL SUBMISSION

The manuscript will immediately be submitted to a journal. A copy of the journal cover letter and final draft of the manuscript must be sent to the PS Publications Committee in addition to all co-authors. The Writing Group Chair must keep the PS Publications Committees and the co-authors informed as to the manuscript's progress through the journal review process.

a. Substantive changes to manuscript

If there are substantive changes made in the manuscript during journal review (major findings or conclusions, alterations of the sample, exclusion/inclusion of major covariates), the revised manuscript should be submitted to the PS Publications Committees for re-review prior to resubmission to the journal. The revised manuscript should be resubmitted within 3 months of receiving reviews of the original submission from the journal.

b. When accepted to publication /published

Upon publication of the manuscript, the Writing Group Chair must provide either a reprint or copies of the final publication to the PS Publications Committees.

c. PubMed Central (PMC) Filing

If the paper is not automatically deposited in PMC, following the conclusion of all peer review, final revisions and final acceptance to the journal, the Writing Group Chair is responsible for providing NCC staff with the PI name, grant number, manuscript, and all graphics and supplemental materials associated with the manuscript. The NCC staff will facilitate final PI approval via the NIHMS system, and copyright affirmation allowing deposit to PubMed Central.

d. Rights and Responsibilities Regarding Publishable Data

The PPI and designees have the first rights to publish collective study data per the Publications Committee approval. The manuscript for the primary results of a trial should be submitted for publication to an appropriate peer-reviewed journal within approximately 6 months of the database-freeze (i.e., complete and cleaned data) of follow-up data of all study participants.

RCC PIs and members of the NCC and NDMC are next in-line for publication rights. Only the PPI and designees, RCC PIs, and members of the StrokeNet NCC and NDMC have collective data rights until 24 months after the publication of the primary manuscript. Individual institutions shall retain ownership of all data that they generate. Institutions shall grant to StrokeNet non-exclusive license to use data for educational and research purposes. The PS Publications Committee will retain oversight of the collective

data and decision making authority with respect to the collective data three years after publication of the primary study results. Individual study investigators will be given one year from trial completion initiation to specify publications that he/she or his/her designee wishes to author using the collective data. After this time, ideas submitted to the PS Publications Committee will be evaluated by order of the request.

Since all StrokeNet trials/studies are multicenter, it is mandatory that the data be pooled and analyzed as stipulated in a given protocol. No presentation or publication on subsets of data authored individually or by subgroups participating in the trial is permitted prior to and up to 12 months after the publication of the primary study results. Subsequent to 12 months after publication of the primary outcome paper, any Protocol Trial Investigator or a group of investigators may publish, with the review and sign off from the PS Publications Committee, the results of the trial conducted at their respective institutions. Data used for these publications must be obtained from the DMC who maintains the official trial data and all analyses must be conducted by the DMC or Primary Study Statistician.

11. PROCEDURES FOR ABSTRACTS AND PRESENTATIONS

Abstracts and presentations must be based on active manuscript proposals or submitted or published papers. No abstract is to be submitted to any national or international organization for consideration prior to review by the StrokeNet Protocol-Specific Publications Committee and sign-off from all co-authors. Any abstract submitted without review and sign off by co-authors will be required to be withdrawn.

a. Submission of abstract to Protocol-Specific Publications Committee

The penultimate draft of the abstract must be submitted to the PS Publications Committee at least 2 weeks prior to the abstract submission deadline for the conference. If it is submitted too late for review, there is a risk of withdrawal if the abstract is not approved.

b. Previously Approved Abstracts

Previously approved abstracts may be re-submitted or “recycled” to a second meeting without undergoing a second PS Publications Committee review process. The Writing Group Chair needs only provide the PS Publications Committee with the same details (i.e., meeting name, acceptance status, etc.) as these are required for follow-up reporting.

c. Accepted Abstracts

If the abstract is accepted for oral presentation, a PDF file of the final presentation slides must be submitted to the Protocol Trial Administrative Coordinator within one month after the presentation for archiving on the StrokeNet Website. If the presentation is in a poster format, an electronic copy of the poster must be submitted within one month after the presentation to the Administrative Coordinator for archiving on the website as well.

12. PROCEDURES FOR LAY SUMMARIES AND PRESS RELEASES AND OTHER WRITTEN COMMUNICATIONS

All written materials, including materials for the media should be submitted via email to the PPI and Chair of the PS Publications Committee within 2 weeks of intended release. The PPI or his designee responds within 3 working days of the receipt of the submitted material with comments/modification, if any, to the materials that should be released to the media.

13. ADHERENCE TO POLICY

Participation in StrokeNet requires adherence to the publication policy described in this SOP, even though RCC 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.

NIH StrokeNet Network

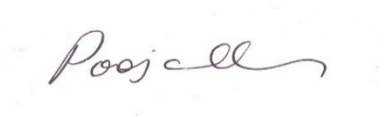
Standard Operating Procedure (SOP)

StrokeNet Publications Committee and Policy

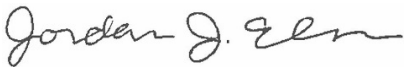
Version 5.0

ADM #3

Reviewed and Approved by:



Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)



Jordan Elm, PhD, (StrokeNet NDMC Principal Investigator)

Scott Janis, PhD, (NIH/NINDS Program Director)