

Publications Policy

Procedure Overview

To define guidelines for preparing, reviewing, submitting and maximizing productivity of high quality peer-reviewed publications.

Responsible Individuals

Trial PI, Trial PI designee, designees from the NETT Clinical Coordinating Center (CCC), NETT Statistics and Data Management Center (SDMC), NETT Hub Complexes, and the Scientific Program Director from NINDS.

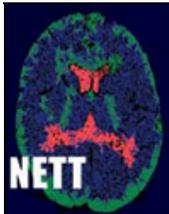
Study-Specific Publication Procedure – Publications Committee

The goal of this policy is to maximize productivity of high quality peer-reviewed publications. For each trial carried out by NETT, a Publications Committee will be formed immediately after the Notice of Award is obtained. The charge of this Committee is to encourage paper production, ensure timely publication of data, maintain a high standard for the quality of papers produced by NETT, and determine appropriate authorship. This Committee will be chaired by the Trial PI and include a person selected by the Trial PI who was instrumental in drafting the study protocol and conducting the research. The Committee will also include a member of the NETT Clinical Coordinating Center (CCC), a member of the NETT Statistics and Data Management Center (SDMC) and the Scientific Program Director from NINDS. One Hub PI will also serve on the Publications Committee and will be chosen randomly for each trial.

Papers will be submitted to the Publications Committee at two time points. First, as proposals to include the designation listed below as primary, secondary, etc., list of 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. After approval, the paper will be reviewed once more 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.

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

Version Number: FINAL 03	Release Date: 3/23/07
Original Approval Date: 3/23/07	Revision Date: 11/9/07
Policy Number: TBD	Page 1 of 4



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.

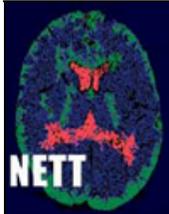
The Trial PI and his or her designees have the first rights to publish collective study data per the Publications Committee approval. It is expected that within six months of analysis availability, the manuscript presenting the primary study results will be sent to the Publications Committee by the PI. All studies carried out by NETT must submit their primary data for publication regardless of the study results.

Hub PIs and members of the CCC and SDMC are next in-line for publication rights. Only the Trial PI and their designees, Hub PIs, and members of the NETT CCC and SDMC have collective data rights until three years after the publication of the primary manuscript. Individual institution's shall retain ownership of all data that they generate. Institutions shall grant to NETT non-exclusive license to use data for educational and research purposes. The Publications Committee will retain oversight of the collective data and decision making authority with respect to the collective data three to five years after publication of the primary study results. Finally, five years following the publication of the primary manuscript, 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 whom request for data can be addressed. All reasonable requests for data will be honored by the Publications Committee in accordance with the NIH policy on data sharing.

Individual study investigators will be given one year from trial 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 Publications Committee will be evaluated on a first-come, first-served basis.

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 Trial PI, NETT Steering Committee, and the NINDS Scientific Program Director. All publications from NETT conducted trials will contain a list of

Version Number: FINAL 02	Release Date: 3/23/07
Original Approval Date: 3/23/07	Revision Date: 8/10/07
Policy Number: TBD	Page 2 of 4



Hub PIs at the end of the publication. They will be identified as NETT Clinical Centers. Additional hub/spoke investigators and coordinators should be listed as well.

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, design, obtaining funding, conduct, analysis and/or drafting of the manuscript. 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.

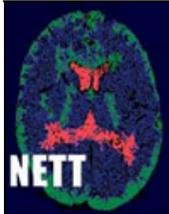
The first author for publications should be the individual who was most fully responsible for the concept, design, funding, conduct, analysis and drafting of the manuscript. The last author should be the senior member who contributed the most to the items listed above. The order of the remaining authors 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 Publications Committee by the first author and Trial PI with a recommendation for resolution. The Publications Committee has the final word with respect to authorship decisions.

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

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

Members of the NETT CCC, SDMC and Hub PIs may wish to publish methods papers that describe the network's function, or papers that are otherwise wholly independent from the trials conducted. These paper proposals and final manuscripts will be submitted to the NETT General Publications Committee. The NETT General Publications Committee includes the NETT CCC PI, the NETT CCC Publications Director, the NETT SDMC PI and co-PI and a NINDS Program Director. This committee does not have authority over individual study Publications Committees. Papers published from this group will not address topics in the studies'

Version Number: FINAL 02	Release Date: 3/23/07
Original Approval Date: 3/23/07	Revision Date: 8/10/07
Policy Number: TBD	Page 3 of 4



specific aims, and will require authorship and review by the studies' PIs whose data are used in these methods papers.

Individual Hub Investigator Publication Rights

Hub investigators who wish to publish their own institution's data will be able to proceed with such publication, provided that the Hub PI has first sought approval for multi-site publication in accordance with the procedures set out under the study-specific publication procedure. Individual hub investigator publication can be delayed for one year after the primary publication has been published or two years after the study has ended (database lock), whichever comes first.

Adherence to Policy

Participation in NETT requires adherence to the publication policy described in this SOP, even though Hub PI's 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.

Version Number: FINAL 02	Release Date: 3/23/07
Original Approval Date: 3/23/07	Revision Date: 8/10/07
Policy Number: TBD	Page 4 of 4