



TRIALNET
Publications and Presentations Subcommittee
Policies and Procedures

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Table of Contents

1. Goals of the Publications and Presentations Policy	3
2. Definitions	3-4
2.1 Forms of Communication	3
2.2 Other Definitions.....	3-4
3. Roles and Responsibilities	5-6
3.1 Role of the Publications and Presentations Subcommittee (PPS)	5
3.2 Role of the TrialNet Coordinating Center (TNCC).....	5
3.3 Role of the TrialNet Network Chair & Vice Chair.....	5
3.4 Responsibilities of the Lead Author	5-6
3.5 Responsibilities of the Corresponding Author	6
4. Policy and Procedures	6-11
4.1 Manuscript Proposal	6
4.2 Analysis Procedures	6-7
4.3 Press Releases and Interviews	7
4.4 Abstracts and Presentations	7-9
4.4.1 <i>General Policies</i>	7-8
4.4.2 <i>Procedures</i>	8-9
4.5 Manuscripts	9
4.5.1 <i>General Policies</i>	9
4.5.2 <i>Procedures</i>	9-10
4.6 Cooperation with Industrial Partners	10
4.7 Preservation of the Integrity of the Study	11
5. Guide to Authorship of Manuscripts	11-13
5.1 General Authorship Policies.....	11-13
5.1.1 <i>Assignment of Authorship</i>	11
5.1.2 <i>Where the Number of Authors is Limited</i>	11
5.1.3 <i>Categories of Authorship</i>	11-12
5.1.4 <i>Authorship Criteria and Contributions</i>	12-13
6. Acknowledgments	13-14
7. Public Access	14
8. Dispute Resolution	14
9. Appendix A: Statement of Authorship	15

1. Goals of the Publications and Presentations Policy

The TrialNet Publications and Presentations Subcommittee (PPS) is responsible for ensuring the timeliness, quality, and quantity of scientific reporting from the TrialNet Network. In order to facilitate the publication process within the collaborative environment of TrialNet, all members of the TrialNet Study Group must agree to abide by TrialNet policies for the publication and public presentation of data. These policies and procedures also apply to TrialNet Ancillary Studies. The goals of the Publications and Presentations Policy are:

- To encourage and facilitate the timely preparation of high quality publications and presentations from TrialNet studies
- To assist TrialNet investigators with development of presentations/publications from the identification of a topic through presentation and/or publication.
- To provide appropriate scientific and academic recognition to all TrialNet investigators who make significant contributions to the research of TrialNet

2. Definitions

2.1 Forms of Communication

- *Press release* refers to a document provided to radio, television, newspapers, popular periodicals, or scientific journals not indexed in Index Medicus.
- *Interview* refers to a discussion with a member of the press, a science writer, or a radio or television commentator, which provides information for public dissemination.
- *Presentation* refers to the oral delivery (with or without audiovisual materials) or poster display of information to scientific, professional or public groups.
- *Manuscript* refers to the text of a presentation, or a draft text to be, or that has been, submitted for consideration for publication in a medical or scientific journal.
- *Publication* refers to any document (other than an abstract) printed in a professional journal listed in Index Medicus or any popular periodical with regional or national circulation
- *Abstract* refers to a summary of research findings from TrialNet studies and/or related data analyses, usually prepared for a presentation at a scientific meeting.

2.2 Other Terms used in this Document

- *TrialNet-Wide Activities* are those involving study participants from all or most Clinical Centers.
- *Restricted Activities* are those involving study participants from a subset of Clinical Centers.
- *Methodological Publications* are those whose focus is methodological and which do not use original unpublished data from any TrialNet study participants or uses data being published simultaneously elsewhere or previously published.

- *Mechanistic Publications* report investigations of underlying pathophysiology to expand knowledge of both the natural history and the response to interventions in subjects with prediabetes or type 1 diabetes. Methodological and mechanistic studies may use data that are not included in primary and secondary TrialNet publications.
- *Primary Communications* address issues that are central to the main objectives of a trial.
- *Secondary Communications* address issues that are peripheral to the main objectives of a trial but utilize the database from all, or at least many, participating Centers. A major feature of these papers is that they include study-wide data generated by TrialNet. Examples are: recruitment, assessment of compliance, informed consent procedures, and methodological analyses.
- *Ancillary Studies* involve the collection of additional information on all or a subset of TrialNet participants. Such studies may involve more complex or expensive tests conducted on a subset of participants at a limited number of clinical sites participating in the main study. Such studies can obtain data from volunteers/patients selected for additional testing to help with understanding mechanisms underlying the clinical observations and course of the disease. Ancillary Studies usually require an external funding source.
- *Substudies* are similar to Ancillary Studies but of sufficient interest to receive support from the Network.
- *Study Leader* refers to the investigator appointed by the Executive Committee who is responsible for the overall conduct and/or coordination of a TrialNet protocol. This will often be the same person who chaired the protocol development committee for that study.
- *TrialNet Study Group* refers to members of the TrialNet Steering Committee, as well as associate members not employed by a funded site but who are members of a TrialNet Committee, or a TrialNet affiliate.
- *Protocol Study Group* refers to members of a protocol committee or key investigators responsible for developing and conducting a specific protocol or trial.
- *Lead Author* refers to the investigator appointed by the PPS, with the concurrence of and in collaboration with the Study Leader, who will coordinate the development, preparation, submission, and, if needed, revision of a specific publication arising from a TrialNet study (often this will be the Study Leader). Multiple publications may emanate from a specific study, each with a designated Lead Author.
- *Writing Committee* refers to the composition of a committee of co-authors to assist in the preparation of a manuscript for publication, or presentation at scientific meetings. Members are appointed jointly by the Lead Author for that publication/presentation and the PPS.
- *CRADA* refers to a Cooperative Research and Development Agreement between a government agency, such as NIH, and another institution. This document defines the rights and obligations of the involved parties.
- *CTA* refers to a Clinical Trials Agreement with a government agency. This is a more formal agreement. More details are provided in the appendix.

3. Roles and Responsibilities

3.1 Role of the Publications and Presentations Subcommittee

The TrialNet Publications and Presentations Subcommittee (PPS) acts as the primary body to oversee the presentations and publication and other public release of TrialNet information. The PPS establishes TrialNet publications policy, monitors, assesses, reviews and makes recommendations regarding release of information. It facilitates the timely publication of TrialNet results, and mediates any disputes arising over the publication/presentation of TrialNet results. The PPS will review all manuscripts, slide sets and other materials for presentations and will have the final decision on wording, organization and content. All communications including, but not limited to, manuscripts, abstracts, oral and poster presentations at major meetings and interviews must first be approved by the PPS. PPS recommendations are reported directly to the TrialNet Executive Committee and to the Steering Committee.

3.2 Role of the TrialNet Coordinating Center

The TrialNet Coordinating Center (TNCC) is responsible for network development, oversight and management including overall protocol development, assurance of high quality data in all network studies, data analyses and verification of presentations and publications. It has overall responsibility for version control of all network documents. The TNCC will work with the Executive Committee and the NIDDK to provide administrative oversight of all network activities. The TNCC will act as the clearinghouse for all TrialNet related information that is released to the public domain, including press releases, scientific publications, abstracts and presentations. Statistical analyses of all primary and secondary communications will be conducted by the TNCC unless otherwise agreed upon by the PPS and the Executive Committee.

The TNCC will retain copies of all final manuscripts, official correspondence, abstracts, and reprints and provide requested copies to the NIDDK in a timely fashion.

3.3 Role of the TrialNet Network Chair and Vice Chair

The TrialNet Network Chair has overall responsibility for coordinating and overseeing Network activities. The Chair and/or his/her designee(s) will act as the scientific editor and co-author of all primary TrialNet manuscripts. The TrialNet Network Chair will be the principal spokesperson for TrialNet. To facilitate study development, the Network Vice Chair will oversee protocol development and implementation.

3.4 Responsibilities of the Lead Author

All TrialNet studies will have a protocol development committee and protocol chair. Upon completion of a study or other activity such as the development and validation of a new assay, plans for presentations and/or manuscripts will be developed and the Lead Author will be charged with coordinating the preparation of the planned presentation and/or publication. This will include developing a manuscript completion timeline and obtaining PPS approval of the plan. In the absence of timely effort in this respect, the PPS (decided in collaboration with the Study Leader), may request or select an alternate Lead Author.

TrialNet is committed to ensuring fair and equitable acknowledgment of all scientists who contribute to each research project. It recognizes the responsibility of all authors to review and approve initial plans and draft manuscripts before submission to the PPS and prior to submission of the final version to a journal. The Lead Author is expected to make available to

all co-authors a draft of each manuscript, abstract, revision and/or review comments with sufficient time for comments to be returned to him/her and appropriate modifications to be made before submission or re-submission of the manuscript. Failure of a coauthor to participate by review/comment on a manuscript under development is reason for his/her removal from the writing committee.

The Lead Author will provide the PPS with all necessary TrialNet forms, copies of first, final, and revised manuscripts, and supporting materials including correspondence with journal editors pertaining to the manuscript in question until manuscripts are accepted. After acceptance the Lead Author will provide to the PPS an Adobe.pdf of the accepted manuscript. The accepted manuscript will be distributed to the PPS and Steering Committee confidentially and under embargo one week before it appears on-line if the author has this information. A copy of the accepted manuscript will be sent to NIDDK.

It is expected that the Study Leader and/or Lead Author will work with the PPS to reach consensus on matters affecting publications, such as assignment of lead authorship and co-authorship, selection of appropriate journals/conferences for presentation, etc. If agreement can't be reached, the PPS Chair will resolve the issue in consultation with the TrialNet Executive Committee.

3.5 Responsibilities of the Corresponding Author

The Corresponding Author refers to the individual designated to correspond with the publishing journal concerning a particular publication. The corresponding author will generally be the Lead Author of a manuscript or the TrialNet Network Chair. The corresponding author is responsible for submission of final manuscripts to the selected journal and for all future correspondence with the journal regarding the publication. The corresponding author is also responsible for ensuring that all substantial communications including important manuscript revisions are approved by the PPS.

4. Policies and Procedures

4.1 Manuscript Proposal

All plans for manuscripts or data analyses require advanced review and approval from the PPS. All analysis requests to the TNCC require submission of a completed Manuscript Template and approval by the PPS. This form is required prior to any requests for abstract data analyses. Minimal information required includes: 1) identification of the main question(s) to be addressed, 2) brief plans for data analysis, 3) a statement why the author believes the topic is important and 4) a review of approved, in progress, and completed TrialNet publications with a statement regarding any duplication that is identified. (This could lead to discussions that would modify the new proposal or a decision to consolidate two manuscripts.)

4.2 Analysis Procedures

- Submission of Requests for Analysis

After completion of a given TrialNet study and data lock, the data will be analyzed to address the primary and secondary objectives as pre-specified in the protocol. Any subsequent changes must be justified, approved by the PPS and recorded in permanent protocol documents. Changes may require approval by the Executive Committee and DSMB. Additional objectives

and analyses can be proposed and they will be prioritized by the PPS and TNCC. The study leader will submit proposals to the PPS and the TNCC for one or two primary analyses and a list of secondary analyses.

In the event that more than one investigator has requested similar analyses, collaboration will be suggested. However, if collaboration is not possible, one proposal will be selected by the PPS.

For primary papers/analyses, efforts should be made to develop the framework of the paper before study data and results are available. Expedited publication of such studies is highly desirable, and preparation of a draft manuscript prior to the study results becoming known will expedite completion of the manuscript and rapid publication regardless of outcome. A draft of the study's primary analyses manuscript will be submitted by the Lead Author to the writing committee as soon as possible but within six months after data lock. After agreement by the writing committee, the TNCC and the TrialNet Network Chair, a draft of the primary analyses manuscript will be submitted to the PPS.

The overall goal is for final primary and secondary manuscripts to be submitted for publication as soon as possible and generally within six months of study completion. If Lead Authors have difficulty preparing manuscripts in a timely fashion, the PPS may need to add a co-author to expedite completion and possibly reassign authorship.

4.3 Press Releases and Interviews

All press releases and communications with the mass media should be submitted to and cleared by the PPS. Except for the purpose of local recruitment, participating TrialNet Clinical Centers, Affiliates, Laboratories and other units will not initiate press releases and interviews. Centrally prepared press releases will be reviewed by the Public Relations and Recruitment Committee and distributed to the Clinical Centers and Affiliates. These prepared releases should be provided to the media when interviews are requested. This procedure will help to ensure uniformity and accuracy of the information disseminated through the media. In this instance, use of such press releases for interviews need not receive prior approval from the PPS.

Should a Clinical Center or Affiliate be solicited for information other than that detailed above, the site should refer the soliciting party to the Office of the TrialNet Network Chair.

4.4 Abstracts and Presentations

4.4.1 General Policies

The procedures below pertain to the presentation and publication of the following:

- scientific abstracts
- invited or keynote presentations at scientific meetings
- symposium presentations
- publications in scientific conference proceedings
- general TrialNet overviews via presentation and/or publication

A general principle of TrialNet is that the Study Leader of each study should present the results of TrialNet-sponsored studies at scientific meetings unless he/she designates another individual to do so. Likewise, the first author of meeting abstracts should be the presenting investigator or a designee.

For general TrialNet information to be presented at major meetings, a slide set will be made available by the Office of the TrialNet Chair. This slide set will have been approved by the TNCC and the PPS. No presentations may be given without prior review and approval by the PPS unless the content is limited to the information provided in this slide set.

Approved materials may be used for presentations but must remain within the confines of the approved forum, should not be distributed, and are not to be presented at venues where presentations may be simulcast on the internet or otherwise broadcasted.

All other presentations given prior to public release of the data must be reviewed by the PPS as described below. This includes slides, handouts for Grand Rounds, interviews and posters and other such presentations at local institutions and to wider audiences.

4.4.2 Procedures

◆ Forum identification

- The PPS will identify scientific and professional forums where presentations about TrialNet studies should be made on behalf of the group. This excludes Grand Rounds in which TrialNet studies may be described for purposes of subject recruitment. Suggestions for such forums and topics for presentations will be sought from the study leader, individual investigators and from the PPS.

- If a member of the TrialNet Study Group is personally invited to present TrialNet data or represent TrialNet to a professional biomedical group, the invitation must be forwarded to the PPS. The PPS reserves the right to accept or decline the invitation and to suggest a presenter other than the member who received the original invitation.

◆ Preparation and Review

- Authors who plan to submit an abstract for possible presentation at a scientific meeting or those invited to present TrialNet data and/or overviews must notify the PPS at least 10 business days prior to the event. This will provide time for PPS review and possible modifications.

- Abstracts and requests to present TrialNet data must be submitted to the PPS no less than 10 business days prior to the submission deadline. The PPS will review this submission and reply to the Lead Author within 5 business days. Only PPS approved abstracts can be presented. All investigators need to note these required deadlines; we do not want to have to refuse abstracts because they are submitted late.

- At least 10 business days prior to the start of the meeting, the Lead Author must submit copies of all materials to be presented (including slides, overheads, electronic presentations, handouts, and/or the content of poster presentations) and/or published (including abstracts, papers to be included in the scientific proceedings, and other) materials to the PPS for approval. The PPS will review these materials for content and respond within 5 business days of the receipt deadline. Since, TNCC biostatisticians are members of the PPS, if data analyses were not performed by the TNCC, they will review to insure the analyses are appropriate.

◆ Upon Publication/Presentation

- The Lead Author will submit an original reprint (if available) or a copy of the final materials (presentations, poster, etc.) to the PPS and TNCC for filing purposes. The Lead Author must include the bibliographic citation to ensure that the PPS and TNCC maintain a current list of all TrialNet publications and presentations at all times.

4.5 Manuscripts

4.5.1 General Policies

All publications of primary and secondary outcomes of TrialNet will be prepared under the overall direction of the PPS. Publication of results of individual Centers or affiliates related to principal study outcomes and for which there is or will be a publication authored by the TrialNet Study Group will not be allowed. Reanalysis of results will not be allowed until such time as TrialNet ceases to exist and/or the data have been placed in the public domain, unless approved by the Executive Committee.

It is the responsibility of the Lead Author (or designated Corresponding Author) to provide materials to the PPS to accompany the submission of the manuscript. The office of the TrialNet Network Chair will be the Corresponding Author for manuscripts presenting primary study outcomes. The Corresponding Author for secondary manuscripts can be either the Lead Author or the office of the TrialNet Network Chair. The Corresponding Author will provide copies of all correspondence between him/herself and the journal to the PPS. A permanent archive of TrialNet publications/presentation and related materials will be maintained by the TNCC.

4.5.2 Procedures

◆ Journal identification

- The Lead Author, in conjunction with the co-authors, should propose a journal appropriate for submission of the manuscript. The PPS will endorse or suggest an alternative choice of an appropriate journal for the publication of each proposed manuscript.

◆ Preparation and Review

- Within 3 months of the last subject's final visit of a study, it is the responsibility of the Study Leader to initiate the primary outcome publication with the TNCC. The task of organizing the process of writing and editing the manuscript will be assigned to a Lead Author by the PPS with the concurrence of the Study Leader and the Executive Committee. The Lead Author will then appoint members of the Writing Committee, with the concurrence of the PPS. Authorship selection should consider ongoing contributions to the study and willingness to work on preparation of the manuscript. The Lead Author may recommend that the final composition of the committee be revised based on individual contributions to the manuscript.

- The outcomes for primary manuscripts are specified in each TrialNet study protocol. Secondary manuscripts may also be pre-specified or may be proposed based upon the study's results. Proposals for manuscripts will usually be accomplished by completing the TrialNet manuscript proposal template. The Study Leader should specify the working title, list of authors, a synopsis of the results and the conclusions to be contained in the manuscript, a timeline for submission and other relevant information.

- Analyses will be performed by the TNCC unless otherwise agreed upon by the Executive Committee.
- During manuscript preparation, biostatisticians at the TNCC will be available to assist authors with data analysis and in selecting ways to best present the results.
- It is expected that the Lead Author will maintain communication with other authors during development and preparation of the manuscript and solicit input wherever necessary.
- Upon completion of the draft manuscript, the Lead Author must forward a complete copy (with figures and references) to the PPS. This draft manuscript must have been approved by all members of the writing committee and the TNCC. The Chairman of PPS will forward copies to two or more members of the PPS, who will provide their comments to the PPS chair within 14 days. If needed, the manuscript will be returned to the Lead Author to be revised, taking into consideration the suggestions of this review by the PPS. When the revised manuscript is approved by the writing committee and the PPS, the PPS Chair will notify the Lead Author that it can be submitted to a journal for consideration. If extensive or major revisions are required by a journal, the PPS must approve the revised manuscript prior to the re-submission.
- Upon publication of the manuscript, the office of the TrialNet Study Chair will respond to requests for reprints.

4.6 Cooperation with Industrial Partners

TrialNet is aware of the need to protect proprietary interests of academic and industrial partners. The NIDDK will execute a Clinical Trials Agreement (CTA) or Cooperative Research and Development Agreement (CRADA), as appropriate, with collaborating companies/institutions that agree to supply their proprietary materials for use by TrialNet and its investigators, or to co-sponsor a TrialNet study.

It is the expectation of TrialNet that a negotiated CTA or CRADA will contain a publications clause that will, upon the request of the industrial partner, allow a brief delay in submission of manuscripts/abstracts to ensure that associated intellectual property rights can be protected. Consistent with current industrial operating standards and NIH policy, it is expected that such publications delays would not exceed 90 days, and ideally will be confined to 30 days.

When these agreements are utilized, a copy of the current wording of the publications clause within the executed agreement will be forwarded to the Study Leader and the TNCC by the awarding agency.

It is standard practice that publications arising from TrialNet studies where industry participation is involved may not disclose any confidential or proprietary information unless the owner of such information grants prior authorization. Note that supplemental agreements between a Study Leader and an industry partner that affect publication of results from TrialNet research studies may be entered into only upon the authorization of the TrialNet Executive Committee and the NIDDK.

4.7 Preservation of the Integrity of the Study

The scientific integrity of trials dictates that results be reported on a study-wide basis. Thus, an individual center may not report the data collected from its center alone. All presentations and publications using TrialNet trial data must protect the main objectives of the trial. Data that could be perceived as threatening the conduct or scientific validity of a study cannot be presented prior to release of the primary study outcomes. The PPS, in consultation with the Executive Committee, will decide if there are disputes regarding this issue.

5. **Guide to Authorship of Manuscripts**

5.1 General Authorship Policies

5.1.1 Assignment of Authorship

The Lead Author will assign authorship to individuals based on their contribution to the project (except when the decision is made to use a corporate author, as described below). Order of authorship shall be based on the relative contributions of each individual who participates in the conduct of the trial or other study, as judged by the Lead Author, with input from other members of the protocol committee or writing team where necessary.

5.1.2 Where the Number of Authors is Limited

In those cases where a limit on the number of authors is mandated by a journal, the authors must agree upon a suitable method to acknowledge all contributors, which is acceptable to the specified journal. Options may include: i) The appropriate Protocol Study Group (e.g. "TrialNet XYZ Subgroup") listed as the primary author, with a complete list of contributing authors (as determined by the Study Leader, following the criteria listed above) placed in the acknowledgments section of the publication or an on-line appendix; ii) a truncated listing of authors, with remaining contributors acknowledged as the "Type 1 Diabetes TrialNet Study Group" or "TrialNet XYZ Subgroup" and try to list the participants in the printed or on-line appendix or refer to a prior publication where they are listed. The listing of contributing authors is evolving for most journals and TrialNet's policy is to provide maximal recognition for the contributions of specified individual authors especially when databases are electronically searched by PubMed or other similar vehicles.

5.1.3 Categories of Authorship

A) TrialNet Wide Primary Study Communications

The PPS or Executive Committee may recommend corporate authorship for publications of major TrialNet study results. The Steering Committee must approve the recommendation of corporate authorship.

For papers designated as corporate authored based on a recommendation and Steering Committee vote, the "Type 1 Diabetes TrialNet Study Group" will be listed as the corporate author. In the first publication from a study, all members should be listed with an asterisk. In subsequent publications of the same study, mechanisms that provide maximal credit for the members of the TrialNet Study Group, as discussed above, should be employed.

B) TrialNet Wide Secondary Communications

Unless otherwise agreed upon, the Lead Author of secondary publications will be the Principal Investigator of the secondary study. The Lead Author will name additional authors based on their contribution to the project (unless publication is designated as corporate authored as described above). The list of authors must be acceptable to the appropriate Subgroups.

Group authors shall be used in the publication (see Section 5.1.2), unless designated as corporate authored (Section 5.1). The authors shall be listed as "...name, name, and the whole TrialNet Study Group. All agreed upon authors should be listed with an asterisk in the initial publication.

C) Restricted Primary or Secondary Results (from TrialNet Subgroups)

Papers presenting results from TrialNet studies or sub-studies that are not implemented by the full TrialNet structure will have named authors. The authors shall be listed as names of writing committee members and/or the TrialNet XYZ Subgroup." Again, all members of the subgroup should be listed in the way that provides maximal recognition for the contributions of individual authors, especially when databases are electronically searched for authorship.

D) Methodological Publications

Individuals or groups of individuals supported by TrialNet may also author papers that report mechanistic, methodological, or other activities. When data from multiple studies are used in a report, authorship will depend upon the importance of each investigator's contributions to the manuscript. Whenever TrialNet resources are used, a proposal should be made to the PPS, which will consider the work involved and decide whether TrialNet should be listed as an author or acknowledged, or if the author may be a single individual (without mention of TrialNet).

If the work involves several TrialNet investigators, the publication may be group authored (as in 5.2). For Papers reporting the work of individuals that involve TrialNet only minimally, the authors may be listed as "Names of Writing Group Members" with an Acknowledgment of TrialNet (see section 6). In unusual circumstances, if the work was exclusively performed by a single individual who is not supported by TrialNet, that individual may be listed as the sole author, without acknowledgment of TrialNet.

5.1.4. Authorship Criteria and Contributions

The authorship criteria for TrialNet are adapted from criteria for authorship currently in use at *JAMA*. In the *JAMA* guidelines, each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Authorship credit should be based only on (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and (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. To qualify for authorship, each author must check at least one box for each of the three categories of contributions listed below.

1. Category 1
conception and design

acquisition of data
analysis and interpretation of data

2. Category 2

drafting of the manuscript
critical revision of the manuscript for important intellectual content

3. Category 3

statistical analysis
obtaining funding
administrative, technical, or material support
supervision
no additional contributions
other (specify)

All authors (i.e., the Lead Author and each coauthor) must complete and submit a signed statement on authorship responsibility, criteria, and contributions, at the time the final draft is delivered to the PPS prior to journal submission. The statement must identify each author's specific contributions to the work described in the manuscript. A template for each author's contribution statement is attached as Appendix A. TrialNet authors should keep in mind that some journals may require identification of each author's contribution, to be submitted along with the manuscript.

6. Acknowledgments

All written Primary and Secondary TrialNet communications must contain the following sentence within the acknowledgments section:

"The sponsor of the trial was the Type 1 Diabetes TrialNet Study Group. Type 1 Diabetes TrialNet Study Group is a clinical trials network funded by the National Institutes of Health (NIH) through the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Allergy and Infectious Diseases, and The Eunice Kennedy Shriver National Institute of Child Health and Human Development, through the cooperative agreements U01 DK061010, U01 DK061016, U01 DK061034, U01 DK061036, U01 DK061040, U01 DK061041, U01 DK061042, U01 DK061055, U01 DK061058, U01 DK084565, U01 DK085453, U01 DK085461, U01 DK085463, U01 DK085466, U01 DK085499, U01 DK085505, U01 DK085509, and a contract HHSN267200800019C; the National Center for Research Resources, through Clinical Translational Science Awards UL1 RR024131, UL1 RR024139, UL1 RR024153, UL1 RR024975, UL1 RR024982, UL1 RR025744, UL1 RR025761, UL1 RR025780, UL1 RR029890, UL1 RR031986, and General Clinical Research Center Award M01 RR00400; the Juvenile Diabetes Research Foundation International (JDRF); and the American Diabetes Association (ADA). The contents of this Article are solely the responsibility of the authors and do not necessarily represent the official views of the NIH, JDRF, or ADA." (Over time some grant numbers may change and for manuscripts that do not involve all of TrialNet, some specific grant numbers may be deleted). *(Where appropriate add: the corporate sponsor(s) and what they provided. It may be necessary to explain whether the corporate sponsor(s) were/were not involved in study design, study conduct or management, data collection, data analysis, data interpretation or writing of the report; whether there are any agreements between the corporate sponsor(s) concerning confidentiality of the data and the authors of the institutions named in the credit lines; whether the corporate sponsor(s) were provided a copy of the original report before journal submission).*

Individuals who have contributed to the work reported in a manuscript but who do not fulfill the criteria for authorship can be acknowledged.

7. Public Access

All TrialNet publications must comply with the NIH Public Access Policy. The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *upon acceptance for publication* (<http://www.ncbi.nlm.nih.gov/pubmed/>). To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. The TNCC should monitor that this requirement is met and report results annually to the NIDDK. Similar procedures to verify compliance should be followed for any TrialNet study that meets criteria for registration in the Clinical Trials database (clinicaltrials.gov).

The Law

The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 Consolidated Appropriations Act, 2008) which states:

SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

8. Dispute Resolution

In all disagreements and disputes relating to the publication of TrialNet related research, every effort should be made to resolve the issues by discussions among the relevant parties. In those cases where consensus agreement cannot be reached through this process, a written request may be forwarded to the PPS for immediate review. The PPS will thoroughly investigate the matter and in a timely manner produce a recommendation. If the recommendation of the PPS is not acceptable to the aggrieved party or parties, the TrialNet Network Chair will establish an independent external review process to investigate the disputed issue and make a recommendation to the TrialNet Network Chair and to the Executive Committee.

Appendix A: Statement of Authorship

The manuscript/abstract being submitted under the auspices of TrialNet is entitled,

“ _____
_____”

List all author(s):

In this article, I participated in the following contribution categories (check all that apply):

1. Category 1
 - Conception and design
 - Acquisition of data
 - Analysis and interpretation of data
2. Category 2
 - Drafting of the manuscript
 - Critical revision of the manuscript for important intellectual content
3. Category 3
 - Statistical analysis
 - Obtaining funding
 - Administrative, technical, or material support
 - Supervision
 - No additional contributions
 - Other (specify) _____

Specifically, my role in the article was

Signature: _____

Date: _____