



Publications, Presentations and Communications Policies and Procedures

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1. Goals of the Publications and Presentations Policy

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, which are described elsewhere in the TrialNet Policy Manual. The goals of the Publications and Presentations Policy are:

- To encourage timely preparation of high quality publications and presentations from TrialNet studies
- To provide appropriate academic recognition to participants 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) 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

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- *Methodological Publications* are those whose focus is methodological and which do not use original unpublished data from any TrialNet study participants or uses data being published simultaneously elsewhere.
- *Primary Communications* address issues that are central to the main objectives of the trial.
- *Secondary Communications* address issues that are peripheral to the main objectives of the 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 a subset of TrialNet participants. Such studies typically involve a small subset of clinical sites participating in the main study.
- *Study Leader* refers to the individual 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 for a specific protocol or trial.
- *Lead Author* refers to the individual appointed by the PPCC, with the concurrence of the Study Leader, who will coordinate the development, preparation, revision, and submission 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 manuscripts for publication, or presentations at scientific meetings, as appointed jointly by the Lead Author for that publication/presentation and the PPCC.
- *CRADA* refers to a Cooperative Research and Development Agreement between a government agency, such as NIH, and another institution
- *CTA* refers to a Clinical Trials Agreement with a government agency

3. Roles and Responsibilities

3.1 Role of the Publications, Presentations & Communications Committee

The TrialNet Publications, Presentations, and Communications Committee (PPCC) acts as the primary body to oversee the publication and release of TrialNet information. The PPCC functions to set TrialNet publications policy, monitors, assesses, and facilitates the timely publication of TrialNet results, and mediates any disputes arising over the publication/presentation of TrialNet results. PPCC recommendations are reported directly to the TrialNet Executive Committee

3.2 Role of the TrialNet Coordinating Center

The TrialNet Coordinating Center (TNCC) at The George Washington University Biostatistics Center 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. All such materials must be submitted to the TNCC for inclusion in a central publications database. The TNCC will assist the PPCC and TrialNet Executive Committee with the gathering and distribution of all materials necessary for evaluating adherence to TrialNet Publications Guidelines. For tracking and historical purposes, the TNCC must receive copies of internal reviews, drafts, and revisions of manuscripts at the milestones defined in this document. The TNCC will file copies of all final manuscripts, abstracts, and reprints with the NIDDK in a timely fashion. All correspondence relating to final manuscripts must use the address of the TNCC and all communication must first be approved by the TNCC for accuracy of data and validity of analyses. The TNCC will maintain an extensive array of approved materials, including presentation materials for lay and professional audiences.

3.3 Role of the TrialNet Study Chair

The TrialNet Study Chair or his designee(s) will act as the scientific editor of all final TrialNet manuscripts. The TrialNet Study Chair will be the principal spokesperson for TrialNet. The TrialNet Study Chair, or the designated scientific editor, will review all manuscripts, slide sets and other materials for presentations and will have the final decision on wording, organization and content.

3.4 Responsibilities of the Lead Author

Upon completion of a study or other activity such as the development and validation of a new assay, the Lead Author (designated by the PPCC) will be charged with coordinating the preparation of the planned presentation or publication. In the absence of timely effort in this respect (decided in conjunction with the Study Leader), the PPCC may request an alternate Lead Author.

TrialNet is committed to ensuring fair and equitable acknowledgment of all scientists who contribute to each research project and recognizes the right of all authors to review manuscripts before submission. The Lead Author is expected to make available to all co-authors a draft of each manuscript, abstract, revision and/or review comments in sufficient time for comments to be returned to him/her and appropriate modifications to be made before submission or re-submission of the manuscript. The Lead Author must also ensure that all co-authors have had an opportunity to review and comment upon the list of authors of planned submissions before the Study Leader submits a request to publish to TrialNet.

The Lead Author will agree to file with the TNCC all necessary TrialNet forms, copies of first, final, and revised manuscripts, and supporting materials, correspondence with journal editors on materials pertaining to the manuscript in question, galley proofs and article reprints.

All Investigators, including the Study Leader, are expected to follow the guidance and instructions of the NIDDK and the TNCC in the interpretation of terms reflected in all fully executed Clinical Trials Agreements or CRADAs. These agreements may include clauses related to rights for review and comment on drafts of publications by corporate sponsors prior to submission for presentation or publication.

It is expected that the Study Leader will work with the Chair of the PPCC, the Study Chair and senior Coordinating Center staff to reach consensus on matters affecting

publications, such as assignment of lead authorship and general authorship, selection of appropriate journals/conferences for presentation, etc.

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 will be designated by the TrialNet Study 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. To provide uniformity and continuity, to ensure quality and to maintain a study archive, all manuscripts will be submitted with the address of the TNCC, accompanied by a letter from the Lead Author, c/o TNCC. The corresponding author is responsible for ensuring that all communications are first approved by the TNCC.

4. Policies and Procedures

4.1 Analysis Procedures

- Submission Of Requests For Analysis

Approximately two months after completion of follow-up for a given TrialNet study, the database will be "locked" (i.e., considered final and not subject to further change). After data lock, the data will be analyzed to address primary objectives. Within three months of the Protocol Subcommittee receiving the primary result, the Protocol Subcommittee Chair will submit proposals to the TNCC for one or two primary analyses and up to eight secondary analyses, which may include biological specimens. These proposals will be distributed to the Steering Committee members at the next scheduled meeting and posted on the TrialNet website.

At the time of the Steering Committee meeting, the Chair of the protocol subcommittee will announce that additional proposals for secondary analyses will be accepted from each participating center. Two names from one center may be included if a proposal is submitted by a fellow (e.g. a fellow and the P.I. or Alternate). These will be submitted to the protocol subcommittee Chair.

The subcommittee will prioritize the analysis requests and submit them to the TNCC and the PPCC Chair. In the event that centers have requested similar analyses, collaboration will be suggested. However, if collaboration is not possible, one proposal will be selected by the PPCC.

A draft of the Final Report will be submitted by the TNCC to the protocol subcommittee within six months after data lock. Comments from the subcommittee will be sent to TNCC and revisions made within one month, after which the Final Report will be distributed to the Steering Committee.

A draft of the primary analysis manuscript should be available for the subcommittee to review within three months of the date that the requested data is received. Revisions will be made to the manuscript within one month, after which the final manuscript will be submitted to the PPCC.

The authors of secondary analysis manuscripts will have six months after requested data are received to submit a draft to the protocol subcommittee. The final manuscript must be submitted for publication within one year of the receipt of requested data. If this deadline is not met, the PPCC may reassign authorship. The PPCC Chair will assure compliance with these timelines. A need for extension of the timelines may be presented to the PPCC for approval.

- Prioritization Of Analysis Requests

The PPCC, working with the TNCC, will assign priorities and timelines to all analyses for abstracts, presentations or publications. Primary analyses will be given the highest priority. The PPCC will consult with the appropriate study subcommittee to prioritize secondary and ancillary analyses. The Coordinating Center will periodically update all authors and the TrialNet group on the status and priorities of all ongoing analyses.

4.2 Press Releases and Interviews

Except for the purpose of local recruitment, participating Clinical Centers and Affiliates 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 PPCC.

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 Chair.

4.3 Abstracts and Presentations

4.3.1 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 proceedings
- general TrialNet overviews via presentation and/or publication

An overriding principle of TrialNet is that the Lead Author of the study should present the results of TrialNet-sponsored studies at scientific meetings unless he/she designates another individual to do so. Likewise, the principal author of meeting abstracts should be the presenting investigator or a designee.

For material to be presented at major meetings, a slide set will be made available by the Office of the TrialNet Chair and the TNCC. Presentations may only be given without prior review and approval by the PPCC if the content is limited to the information that has been provided by the PPCC or the TNCC specifically for this purpose.

All other presentations given prior to public release of the data must be reviewed by the PPCC as described below. This includes presentations and materials, including

slides or handouts for Grand Rounds and other such presentations at local institutions.

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

4.3.2 Procedures

◆ Forum identification

- The PPCC 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 recruitment. Suggestions for such forums and topics for presentations will be sought from individual investigators and from the PPCC itself. The PPCC will identify one or more persons from a list of volunteer investigators to prepare and present the material.
- 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 PPCC. The PPCC 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 consideration at a scientific meeting or those invited to present TrialNet data and/or overviews should notify the PPCC in writing, with the signatures of both the Study Leader and the Lead Author (if different).
- *If the abstract represents the first public disclosure of the data of a primary TrialNet study:*

The PPCC Chairman must be notified no less than 14 business days prior to the submission deadline. The PPCC will review this submission and reply to the Lead Author within 5 business days. The PPCC Chairman and two PPCC reviewers selected by the Chairman must approve abstracts. Copies of all approved abstracts will be distributed to the TrialNet Steering Committee.

At least 10 business days prior to the meeting date, 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, or other) materials to the TNCC to ensure the veracity of the data. These must be accompanied by a completed and signed (by all authors) copy of the TrialNet Publications Agreement Form. Electronic signature is acceptable. The PPCC will review these materials for content and respond within 5 business days.

- *For all other abstracts :*

The PPCC may be notified at the time of submission to the conference/journal. No TrialNet review will take place at this time.

- ◆ 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 TNCC for filing purposes. The Author must make note of the bibliographic citation to ensure that the TNCC maintains a current list of all TrialNet publications at all times.

4.4 Manuscripts

4.4.1 General Policies

All publications of principal outcomes of TrialNet will be prepared under the overall direction of the PPCC. 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 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 TNCC to accompany the submission of the manuscript. All manuscripts will be submitted by the TNCC. The TNCC is responsible for proofing all final copies of manuscripts and will submit the manuscript and supporting materials to the intended journal. The Corresponding Author will agree to provide copies of all correspondence between him/herself and the journal to the TNCC for filing.

4.4.2 Procedures

- ◆ Journal identification
 - The PPCC will endorse or suggest the choice of an appropriate journal for the publication of each proposed manuscript.
- ◆ Preparation and Review
 - Upon completion of a study, it is the responsibility of the Study Leader to initiate the publication process with the PPCC. The task of organizing the process of writing and editing the manuscript will be assigned to a Lead Author by the PPCC 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 PPCC. The Lead Author may recommend that the final composition of the committee be revised based on individual contributions to the preparation of the manuscript.
 - Before any analyses will be performed, an Analysis Plan will be generated by the writing committee and study statistician that specifies the major questions to be addressed and all sub-questions, as well as the sets of patients,

observations and variables to be used to address those questions, the statistical methods to be employed, and graphical displays to be generated. Analyses of primary outcomes should be specified before the investigators examine the data. The analysis plan must be submitted to the PPCC for review and approval prior to the conduct of any analyses. Analyses will be performed by the TNCC unless otherwise agreed upon by the Executive Committee.

- Following initial analysis of the study data, the Study Leader will notify the TNCC, TrialNet Chairman and the PPCC of the impending publication to allow each group to anticipate publications, provide writing and editing assistance and facilitate timely internal review. 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.
 - During manuscript preparation, biostatisticians at the TNCC will be available to assist authors with data analysis. 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 first draft, the Lead Author must forward a complete copy (with figures and references) to the Chairman of the PPCC and to all listed authors. The Chairman of PPCC will forward copies to the following individuals, who will provide their comments to the Lead Author within 7-10 business days:
 - two or more members of the PPCC
 - the director of the TNCC
 - the Chairman of TrialNet
 - During the writing of the final manuscript, the official copy shall be maintained on the TrialNet website. The writing committee will have access to the manuscript and, together with the TNCC, will proof the final copy. .
- ◆ Upon Completion of the Final Manuscript
- The Lead Author should forward a copy of the final manuscript along with a completed and signed (by all authors) copy of the TrialNet Publications Agreement Form to the Chairman of the PPCC and await TrialNet authorization for submission. Final TrialNet authorization for submission will generally be granted within 5-7 days business days, barring any objections from listed authors or the TrialNet Executive Committee.
 - Upon receipt of manuscript reviews, the Corresponding Author will distribute copies of the reviews to all listed authors and to the Chairman of the PPCC. The Lead Author will coordinate the revision of the manuscript in an acceptable time frame.
 - Upon completion of the revised manuscript, the Lead Author should forward a copy of the manuscript and supporting materials to the Chairman of the PPCC. Final TrialNet authorization for submission will generally be granted within 2-3 business days, barring any objections from listed authors or the TrialNet Executive Committee.

- Upon receipt of TrialNet authorization, it is the responsibility of the Corresponding Author to provide materials to the TNCC to accompany the submission of the manuscript.
- Upon receipt of Journal Proofs, the Corresponding Author will share the proofs with the TNCC for joint review.
- Upon publication of the manuscript, the Corresponding Author will forward to the TNCC the complete reference of the article and the bulk of the reprints. The TNCC will respond to requests for reprints.

4.5 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, delay 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.

A copy of the final 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 NIDDK.

4.6 Preservation of the Integrity of the Study

The scientific integrity of the trial 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 the study will not be presented prior to release of the primary study outcomes. The TrialNet Steering Committee will grant approval as to the timing of presentations of data and the meetings at which they may be presented. Study results should be discussed with the news media only upon authorization of the Steering Committee and never before the results are presented. Any written statements about this study that are shared with national media should be approved by the Steering Committee before release.

At the conclusion of a TrialNet study, analyses of the principal study results will be conducted leading to publication of the study results. Six months after the completion of those analyses and acceptance of the final paper for publication, the data

(HIPAA de-identified) will be shared with the study investigators. At that time the investigators will be free to conduct additional analyses of the study data that are not addressed in the primary results paper, or in other papers under development.

5. Guide To Authorship of Manuscripts

5.1 General Authorship Policies

5.1.1 Assignment of Authorship

The Study Leader 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).

Authorship must be granted to the Study Leader and to individuals who have participated in accrual and/or treatment of patients, design of the study, analysis of results, or assay studies, or patient monitoring procedures that directly affected clinical procedures in the study, or have specific relevance to the publication's hypothesis and/or conclusions.

Order of authorship shall be based on the relative contributions of each individual who participates in the conduct of the trial, as judged by the Study Leader, with input from the study participants where necessary.

The Study Leader must submit a list of study participants prior to the beginning of the study, detailing the anticipated order of authorship. The content of this form should be acceptable to other investigators involved in the trial and should be updated when significant changes occur during the course of the study.

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 (i.e. "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; ii) a truncated listing of primary authors, with remaining contributors named in the acknowledgments

5.1.3 Categories of Authorship

A) TrialNet Wide Primary Study Reports

The PPCC 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, "TrialNet Study Group" will be listed as the corporate author. In the first publication, all members should be listed with an

asterisk. In subsequent publications, “TrialNet Study Group” with reference to the publication that lists the study group will suffice.

B) TrialNet Wide Secondary Reports

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. Authorship on the publication must be granted for:

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 xyz protocol Subgroup.” 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 TN structure will have named authors. The authors shall be listed as “names of writing committee members,...and the xyz protocol Subgroup of the Type 1 Diabetes TrialNet.” Again, all members of the subgroup should be listed with an asterisk in the initial publication.

D) Methodological Publications

Individuals or groups of individuals supported by TrialNet may also author papers that report methodological or other activities. Whenever TrialNet resources are used, a proposal should be made to the PPCC, 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.

6. Acknowledgments

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

“This research was performed under the auspices of the Type 1 Diabetes TrialNet, a collaborative clinical research project Sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Allergy and Infectious

Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD), the National Center for Research Resources (NCRR), the Juvenile Diabetes Research Foundation International (JDRF), and the American Diabetes Association (ADA) and various corporate sponsors. (Where appropriate add: “*Corporate Name* co-sponsored the study through a (*specify CTA or CRADA*) with the NIDDK.”)

7. Dispute Resolution

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

Any Investigator who wishes to make public a dissenting publication, will be able to proceed with such a dissenting publication provided that (i) the Investigator has first sought approval for publication in accordance with the procedures set out in this policy; (ii) upon rejection, the Investigator has attempted to resolve the dispute in accordance with this section 7; and (iii) the Investigator includes the following disclaimer in the acknowledgements section: “ this publication does not express the views of the Type 1 Diabetes TrialNet although the research was conducted under its auspices, nor does it express the views of the collaborative research sponsors including the NIDDK, NIAID, NICHD, NCRR, JDRF, ADA or Corporate Name through a CRADA with NIDDK.”