



Policy Documentation

Publications

Policy & Procedures

What is covered in this document

- Manuscript authorship, preparation and submission
- Abstract and meeting presentation authorship, preparation and submission
- Press or media releases, or interviews with the media

What is not covered in this document

- Publication of data to clinical trial results databases (Data Sharing Policy in preparation)
- Sharing of raw or other ITN-generated data in non-manuscript form (Data Sharing Policy in preparation)

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Abbreviations

BDR	Biomarker & Discovery Research Group COM (Clinical Operations Manager)
CTA	Clinical Trial Agreement
ICMJE	International Committee of Medical Journal Editors ITN (Immune Tolerance Network)
JDRF	Juvenile Diabetes Research Foundation LPLV (Last Patient, Last Visit)
NCO	Network Central Office
NEC	Network Executive Committee
NIAID	National Institute of Allergy and Infectious Diseases NIH (National Institutes of Health)
NSC	Network Steering Committee

1.0 Goals and Scope of this Policy

1.1 Policy Goals

The ITN Publications Policy aims to:

- encourage and facilitate the preparation of high quality publications from ITN- sponsored studies
- ensure that publication proceeds in a fashion consistent with academic norms, adhering to the practice of presenting complete data to the public only after it is published in a peer-reviewed journal or through abstracts presented at scientific meetings
- facilitate the rapid dissemination of research results from ITN studies
- ensure appropriate academic recognition to individuals involved in ITN activities

1.2 Scope

This policy covers the preparation, revision, review, submission and publication of all scientific communications of type and category described below in sections 1.2.1 and 1.2.2 that contain information or data that has been collected or generated, in full or in part, with funds provided by ITN subcontract, or as a result of work performed by staff compensated using ITN subcontract funds. Furthermore, this policy governs those publications within which an ITN affiliation of one or more named authors is described. The following publications types are covered by this policy:

1.2.1 Publication Types

Manuscript

Defined as writings that describe the results of ITN research activities that are submitted for publication to a professional scientific or medical journal, periodical, proceedings or book, both peer-reviewed and non-peer-reviewed.

Meeting Abstract

A summary of research results or activities being prepared or submitted for consideration for presentation at a medical or scientific meeting.

Meeting Presentation

Refers to the delivery, either oral (with or without audiovisual materials) or in poster format, of information to scientific, professional or public groups.

Case Report

A detailed report of the diagnosis, treatment, and follow-up of an individual patient. Case reports also contain some demographic information about the patient (for example, age, gender, ethnic origin).

Editorials

A manuscript consisting of the author's commentary or conjecture concerning a specific topic or manuscript.

Press Release

A document distributed on the internet or provided to radio, television, newspapers, popular periodicals, institutional public affairs personnel or scientific journals not indexed in Index Medicus.

Interview

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.

1.2.2 Publication Categories

Primary publications

Manuscripts or abstracts that disclose data, analyses, opinions or other information central to the main objectives of the trial. This includes interim analyses of clinical or mechanistic data in ongoing trials.

Secondary publications

Manuscripts or abstracts that describe data, analyses, opinions or other information that is peripheral to the main objectives of a study, but have utilized resources or data generated in that study. Examples include comparison of assay techniques on a specific clinical samples set, methodological studies, etc.

Tertiary publications

Manuscripts or abstracts that report data and/or analyses arising from the collection or additional information/data from study participants or specimens that was not collected as part of the initial protocol, or that compare data across multiple studies. Examples include mechanistic assays performed after-the-fact, etc.

Ancillary publications

Ancillary publications are those manuscripts or abstracts whose purpose is the general communication of ITN goals, methods, research activities, progress, etc.

Review Articles

A publication in which current literature is reviewed on a specific topic, in which no currently unpublished ITN data is presented or discussed.

ITN Staff publications

Manuscripts or abstracts in which the lead and/or corresponding author is an ITN staff member, and for which the content derives from research or other activities directly overseen by ITN staff.

2.0 Guiding Principles

2.1 Open Access Policy

The ITN subscribes to the principles of open access to scientific research, as documented in the Bethesda Statement on Open Access (<http://www.earlham.edu/~peters/fos/bethesda.htm>). As an NIH-funded entity, manuscripts arising from ITN-sponsored research are subject to the NIH Open Access Policy, which may be found at <http://publicaccess.nih.gov/>.

2.2 Protection of Research Integrity

All presentations and publications using ITN trial data must not compromise the main objectives or findings of the trial. The ITN will grant approval as to the timing of presentations of data and the meetings at which they may be presented.

Study results may be discussed with the news media only upon authorization of the Network Executive Committee (NEC) and never before the results are presented (unless embargoed until after the presentation). Any written statements about this study that are shared with national media should be approved by the ITN before release (as per Section 8.0).

It is ITN Policy that ITN study results are to be reported on a study-wide basis. Thus, an individual center participating in a multicenter study may not report the data collected from its center alone, except as in the form of an individual case report and/or with the approval of the ITN.

2.3 Publications Policy Oversight

The NEC acts as the primary decision-making body overseeing ITN publication policy. Changes or alterations to ITN publications policy are subject to ratification by the NEC.

2.4 Confidentiality of ITN Reviews

Manuscripts submitted to the ITN for review and the subsequent review will be held in the strictest confidence and will not be shared with any individuals except for those directly involved in the manuscript review process and/or program staff of the awarding agency, NIAID.

2.5 Clinical Trial Agreements

Clinical Trial Agreements (CTAs) with collaborating companies/institutions that agree to supply their proprietary materials (such as drugs and biologics) for ITN-led research are negotiated by NIAID on behalf of the ITN and its investigators.

Negotiated CTAs may contain a publications clause that will, at 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, such publications delays will not exceed 90 days: the industrial partner and/or the inventor's institution will have 30 days from time of submission of draft manuscript/publication by study leader to determine if a patent is going to be filed; an additional 60 days will be granted for purposes of filing patent claims if requested. Note that these timeframes are goals within the ITN - the negotiated terms of the CTA, as outlined in the Terms of Award of the Subcontract

Agreement from the Benaroya Research Institute (BRI) - shall supersede the time frames outlined in this policy and shall be the governing terms of award. A copy of the final executed subcontract agreement will be forwarded to the Investigator and BRI by the awarding agency.

It is standard practice that publications arising from ITN studies where industry participation is involved may not disclose any confidential or proprietary information unless prior authorization is granted by the owner of such information.

Note that supplemental agreements concerning ITN-led research between an investigator and an industry partner that affect publication of results from ITN research studies may be entered into only upon the authorization of the NEC and NIAID.

All investigators, including the Study Leader, are expected to look to the office of the Authorized Official of their respective institution or organization and the ITN for guidance and

instructions in the interpretation of terms reflected in all fully executed CTAs and ITN Subcontracts.

2.6 Dispute Resolution

In all disagreements and disputes relating to the publication of Network related research materials, every effort should be made to resolve the issues amongst the relevant parties.

In those cases where consensus agreement cannot be reached through this process, a written request may be forwarded to the Director of Strategic Review and Planning for immediate review by the ITN. Disputes will be mediated by the NEC, who will solicit information for all relevant parties to produce a recommendation that is binding upon all involved.

2.7 Exceptions

Under exceptional circumstances, those not specifically covered by this policy, the NEC shall have final decision-making authority and is bound to interpret these policies in the spirit of their stated goals.

Exceptions to this policy may only occur in order to allow rapid release of clinical trial results to disseminate information that is of public health importance. Such exceptions may be authorized only by the NEC and the awarding agency, NIAID.

3.0 Roles and Responsibilities

3.1 Principal Investigator

The Principal Investigator is expected to ensure that publication of study results proceeds in a timely fashion. The PI will chair the ITN Publication Team for his/her study (Section 4.0). A publication plan should be in place before the close of the study.

The Principal Investigator will assign individuals the role of Lead and Corresponding Authors of primary and secondary publications arising from their study. It is expected that the Principal Investigator/Study Leader himself/herself will most often assume this role on primary publications; the Principle Investigator should encourage junior members to take the lead role on secondary and ancillary publications.

It is the responsibility of the Principal Investigator to ensure that authorship of primary and secondary publications and presentations provides fair and equitable acknowledgement for individuals who have contributed to the study, according to authorship rules (Section 9.0).

3.2 Lead Author

It is the responsibility of the Lead Author to coordinate the writing, revision and submission of the publication in a timely fashion, under the guidance and direction of the publication team. The Lead author will ensure that all co-authors of a publication or presentation are provided the opportunity to review all publication drafts, revisions and review comments.

It is ultimately the Lead Author's responsibility to submit all requested copies of manuscripts, abstracts, presentations, reprints, etc. for ITN review and/or or tracking purposes as required according to ITN publications policy.

In cases where long, unwarranted delays in the publication of study results occur, as a last resort, the NEC reserves the right to appoint an alternate Lead Author.

3.3 Corresponding Author

“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 Principal Investigator. The corresponding author is responsible for submission of final manuscripts to the selected journal, for all future correspondence with the journal regarding the publication and for keeping the ITN Director of Strategic Review and Planning informed of all communications with the journal.

3.4 Clinical Operations Manager (COM)

The COM assigned to a given trial will be responsible for ensuring appropriate ITN representation on the team and scheduling of Publications Team meetings. The COM will act as secretary to the committee, setting and distributing agendas, as well as keeping and distributing minutes. The COM will assist the team with additional project management functions as required.

3.5 ITN Reviewers

The following individuals may be asked to act as reviewers for individual ITN abstract, manuscript, presentation or other reviews, as assigned by the ITN Director of Strategic Review and Planning.

- ITN Network Director and/or Deputy Directors
- NIAID representative
- area experts selected from the NSC membership
- ITN Chief Medical and/or Scientific Officer(s)

In some cases, the ITN may also solicit reviews from external individuals when specialized expertise is required. External reviewers will be required sign confidentiality agreements prior to receiving materials for review.

Individuals requested to review publications or presentations arising from ITN research activities will endeavor to provide timely, thoughtful and objective feedback to authors. Conflicts that could prevent a reviewer from carrying out this responsibility must be reported immediately to the ITN so that alternate reviewers may be assigned.

3.6 Office of Strategic Review, Planning, and Communications

The ITN Office of Strategic Review, Planning, and Communications is responsible for coordinating publications activities and will act as liaison between the ITN reviewers, staff and authors in publications matters. The Director of Strategic Review, Planning and Communications also provides authors with assistance in the preparation of publications and presentations, and in the interpretation of ITN publications policy. All publication policy related submissions should be sent to the Director of Strategic Review, Planning and Communications.

The Office of Strategic Review, Planning and Communications will submit all publication materials to the Office of the Director, who will file copies of all final manuscripts, abstracts, and reprints with NIAID in a timely fashion.

4.0 Publication Teams

4.1 Purpose & Responsibilities

ITN publications teams are working groups charged with analyzing and interpreting ITN study data and developing publications for individual studies.

The purpose of the team is to streamline the preparation and dissemination of ITN results and ensure investigators have ready access to data and ITN support resources, such as biostatistics, editing, etc. They are comprised of the study PI, select study investigators, representatives of industry partners, ITN executive and staff and other supporting individuals.

The Publication Team's responsibilities include:

- Developing and maintaining plans and timelines for publications
- Developing consensus on the interpretation study data/analyses
- Facilitating the timely preparation and group review of abstract and manuscripts
- Assigning appropriate authorship according to ITN authorship guidelines
- Review of relevant press releases

4.2 Team Membership

The Publications Team will consist of, at a minimum, the following individuals:

- Principal Investigator
- Study Chair(s) (if appl.) and other key investigators
- Industry partner representatives
- NIH Project Manager and/or ITN Clinical Operation Manager
- ITN Clinical Trials Physician
- ITN-contracted Biostatistician
- ITN BDR rep.
- ITN Publications rep.

Additional members may be appointed at the request of the PI or the ITN.

4.3 Formation & Meetings

The Publication Team for a given study must meet:

- Within two weeks before or after the initial internal release of primary study data and/or analyses
- Within two weeks before or after the initial internal release of new interim data and/or analyses
- Periodically, as required, to review publications plans and timelines

5.0 Manuscripts & Case Reports

This section applies to all categories of manuscripts and case reports (primary, secondary, ancillary and tertiary), as defined in Section 1.2.

It is the responsibility of the Principal Investigator to initiate the publication process and to assign Lead and Corresponding Authors (as per Section 3.1-3.3). Remaining authorship of the manuscript should be assigned based upon the Authorship Guidelines contained in Section 9.0.

5.1 Manuscript Preparation

The Lead Author will coordinate the writing process with the support of the Publications Team, maintaining communication with other authors/advisors during development of the manuscript, soliciting input and feedback wherever necessary.

It is strongly recommended that agreement on the complete author list be reached prior to completion of the initial draft. The final authorship list must follow ITN guidelines (Section 9.0) and receive unanimous agreement.

5.1.1 ITN Acknowledgement

All manuscripts (except T1D manuscripts, see below) must contain the following sentence within the acknowledgements section:

“Research reported in this publication was performed as a project of the Immune Tolerance Network and supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number UM1AI109565. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

All Type 1 Diabetes (T1D) manuscripts must contain the following sentence within the acknowledgement section:

“Research reported in this publication was performed as a project of the Immune Tolerance Network and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health under Award Number UM1AI109565. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

All other reports (posters, oral presentations at scientific meetings, seminars, and any other forums in which ITN supported research is presented) must contain a version of the appropriate acknowledgment within the confines of the space requirements.

5.1.2 HIPAA Regulations

Investigators must ensure that the text of the manuscript complies with all HIPAA regulations regarding the disclosure of patient information. In general, all patient identifiers should be removed from the manuscript. However, if this is not possible (ie. this information is essential to the conclusions of the paper/case report), investigators must provide the ITN with written proof that informed consent has been satisfied under HIPAA regulations and that the patient(s) have seen and approved the manuscript for publication.

5.2 Review & Submission Process

5.2.1 ITN Review

Once a 'suitable for submission' draft of the manuscript has been completed and agreed upon by all authors, it is to be forwarded to the ITN for review, complete with all figures, tables, and supplementary content, together with the name of the journal to which it will be submitted.

For all primary manuscripts, the ITN must receive copies of the ITN "Author Agreement Form" signed by each named author of the manuscript, and, if applicable, a copy(s) of the "Manuscript Approval Form" signed by a representative of all corporate partner(s) holding a CTA for the associated study. It is the Lead Author's responsibility to ensure all such forms are received by the ITN in a timely fashion. For all other manuscripts, a copy(s) of the "Manuscript Approval Form" signed by a representative of all corporate partner(s) holding a CTA for the associated study must be submitted to the ITN and the primary author must attest that all named authors agree to authorship as per the "Author Agreement Form".

The ITN will coordinate an internal review of the primary manuscript, the results of which will be forwarded to the Lead Author within 5 business days.

ITN manuscript reviews contain three sections:

1. General Comments – contains the reviewers' broad observations on the manuscript, the results and their interpretation
2. Required Changes - those specific changes of high importance that must be included in the manuscript prior to submission to the journal in order for ITN approval to be received
3. Recommended Changes – changes that the reviewers believe will strengthen the manuscript, although they are not strictly required in order to receive ITN approval.

It is strongly recommended that lead authors share the results of ITN reviews with all authors of the manuscript.

For secondary, tertiary, ancillary, editorial and review articles, and ITN staff manuscripts, any named ITN author (in coordination with the Director of Strategic Review and Planning) will be responsible for reviewing the publication and involving appropriate members of the ITN leadership. Upon the discretion of the Director of Strategic Review and Planning, these publications may undergo formal review as described for primary publications.

If there were Required Changes listed in the ITN review, the author must submit a revised version to the Director of Strategic Review and Planning for final approval. If the author was provided with no Required Changes, submission to the journal may proceed, as ITN approval of the final draft is implicit.

A copy of the final submission, including the manuscript text and associated tables, figures, and cover letters is to be sent to the ITN for record keeping purposes.

5.2.1.1 Disagreement with ITN Review

Should there be a consensus among all named authors of disagreement with the Required Changes requested by ITN reviewers, an exception may be requested by submitting the objection(s) to the ITN in writing. The ITN will consider the request, contacting the author(s) and principal investigators for clarification and discussion where necessary, in order to resolve the disagreement in a mutually satisfactory manner.

Note that if agreement between the ITN and manuscript authors cannot be reached, and the authors intend to publish without ITN approval, both parties remains bound by the confidentiality requirements of a fully executed Clinical Trial Agreement (CTA) and/or ITN subcontract. The ITN reserves the right to attach the following statement within the acknowledgement section of any manuscript submitted for publication without ITN approval:

"Research reported in this publication was performed as a project of the Immune Tolerance Network and supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number UM1AI109565. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

This manuscript was not prepared in collaboration with members and investigators of the Immune Tolerance Network. The content and/or conclusions of this manuscript do not necessarily reflect the opinions or views of the Immune Tolerance Network or its sponsors."

5.2.2 Journal Reviews

The results of the journal editors' review are to be communicated to the ITN by the corresponding author, together with copies of the editors' comments.

In cases where only minor revisions are requested by the journal, no additional ITN review is required. The Lead Author must submit the final revised version to the ITN for filing purposes.

In cases where substantial changes (changes in the data presented, modification of the conclusions of the manuscript) are requested/required by the journal or are made by the authors to attempt submission in an alternate journal, additional ITN review (as per Section 5.2.1) is required for the revised manuscript.

5.2.3 Notification of Acceptance

Lead authors must immediately notify the ITN of the acceptance of the manuscript.

As per NIH Open Access Policy, the Corresponding Author must submit the approved manuscript to the PubMed Central digital archive upon acceptance for publication. More information can be found at <http://publicaccess.nih.gov/>.

5.2.4 Proofs, Reprints

Proofs of manuscripts sent to the corresponding author by the publisher are not required to be forwarded to the ITN. However, it is requested that authors notify the ITN of the impending publication date of the manuscript.

Within 5 business days of publication of the manuscript, the Lead Author will email an original reprint of the article, in electronic format to the ITN. If an electronic version of the article is not available, the ITN will accept a hardcopy version via fax.

5.2.5 Page Charges

All page charges, color charges, processing fees, submission fees and other charges levied by journals for the publication of the manuscript are the responsibility of the lead and/or corresponding authors.

5.3 ITN Staff Manuscripts

ITN Staff manuscripts (as defined in Section 1.2) are subject to the same review process as described in Section 5.2, with one exception. Prior to manuscript preparation, a short “storyboard” outline of the manuscript must be submitted to the Director of Strategic Review and Planning for review and comment by ITN Directors. The storyboard will contain the following information:

- Title
- proposed authorship
- a short (2-3 sentence) summary
- all tables/figures and pertinent data that will be included, presented as intended for submission, with a short statement of significance attached to each
- A short list of possible discussion points
- Conclusions

6.0 Meeting Abstracts and Presentations

This section applies to all categories of Meeting Abstracts (primary, secondary, ancillary and tertiary), as defined in Section 1.2, including late breaking abstracts and invited presentations.

It is the responsibility of the Principal Investigator to initiate the process of preparing a scientific abstract. Thereafter, the task of coordinating, writing and editing the abstract falls upon the Lead Author (usually the PI, but otherwise appointed by consensus of the co-PIs and/or collaborators). Authorship of the abstract should be assigned based upon the Authorship Guidelines contained in Section 9.0.

6.1 Abstract Preparation

The Lead Author will coordinate the writing process with the support of the Publications Team, maintaining communication with other authors/advisors during development of the abstract, soliciting input and feedback wherever necessary.

It is strongly recommended that agreement on the complete author list be reached prior to completion of the initial draft. The final authorship list must follow ITN guidelines (Section 9.0) and receive unanimous agreement.

6.1.1 ITN Acknowledgement in Abstract

In cases where group authorship is used (as per Section 9.1.2), no additional acknowledgement of the ITN is required.

Where group authorship is not used, primary and secondary abstracts are to include the following acknowledgement in the body of the abstract:

“This research was performed as a study of the Immune Tolerance Network (UM1AI109565).”

Tertiary and ancillary abstracts are to include the following acknowledgement in the body of the abstract:

“This research was performed with the support of the Immune Tolerance Network (UM1AI109565).”

6.2 Abstract Review & Submission

6.2.1 ITN Review

Once a complete, 'suitable for submission' draft of the abstract has been completed and agreed upon by all authors, the lead author is to forward to the ITN:

- A copy of the abstract title, body and author list
- Name and date of the meeting to which the abstract will be submitted
- Meeting organizer's deadline for abstract submission

Note that if the abstract and/or associated presentation will represent the first disclosure of primary or secondary data from a study that has an associated Clinical Trial Agreement with a corporate partner(s), a signed "Publication Approval Form" must be completed, signed and returned to the ITN by each corporate partner prior in order to receive ITN approval.

The lead author must affirm that all authors have agreed to authorship as per the "Author Agreement Form".

The ITN will coordinate an internal review of the abstract for reports of primary clinical and/or mechanistic data, the results of which will be forwarded to the Lead Author within 3 business days.

ITN abstract reviews contain two sections:

1. Required Changes - those specific changes of high importance that must be included in the abstract prior to submission to the journal in order for ITN approval to be received
2. Recommended Changes – changes that the reviewers believe will strengthen the abstract, although they are not strictly required in order to receive ITN approval.

It is strongly recommended that lead authors share the results of ITN reviews with all authors of the abstract.

If there were Required Changes listed in the ITN review, the author must submit a revised version to the ITN for final approval. If the author was provided with no Required Changes, submission to the meeting organizers may proceed, as ITN approval of the final draft is implicit.

For abstracts reporting the results of secondary, tertiary, or ancillary studies, in coordination with the Director of Strategic Review and Planning, named ITN authors will be responsible for ITN review involving members of ITN leadership as required.

A copy of the final submission is to be sent to the ITN for record keeping purposes.

6.2.1.1 Disagreement with ITN Review

Should there be a consensus among all named authors of disagreement with the Required Changes requested by ITN reviewers, an exception may be requested by submitting the objection(s) to the ITN in writing. The ITN will consider the request, contacting the author(s) and principal investigators for clarification and discussion where necessary, in order to resolve the disagreement in a mutually satisfactory manner.

Note that if agreement between the ITN and manuscript authors cannot be reached, and the authors intend to publish without ITN approval, both parties remain bound by the confidentiality requirements of a fully executed Clinical Trial Agreement (CTA) and/or ITN subcontract. The ITN

reserves the right to attach the following statement within the body of an abstract submitted for publication without ITN approval:

"This abstract was not prepared in collaboration with members and investigators of the Immune Tolerance Network. The content and/or conclusions of this abstract do not necessarily reflect the opinions or views of the Immune Tolerance Network or its sponsors."

6.2.2 Notification of Acceptance

Lead authors must immediately notify the ITN of the acceptance of the abstract, noting the type of presentation for which it was selected (i.e., Poster, plenary session, etc.) and the date and session information for the meeting.

6.2.3 Meeting Materials

The Lead Author will coordinate the process of developing presentations, posters, handouts, etc. associated with the abstract with the support of the Publications Team, maintaining communication with other authors/advisors during development of the manuscript, soliciting input and feedback wherever necessary.

All meeting materials should include suitable acknowledgement of the ITN and its sponsors, the National Institute of Allergy and Infectious Diseases and the Juvenile Diabetes Research Foundation.

6.2.4 Review of Meeting Materials

An ITN review of meeting materials that will 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) is required only when materials include previously undisclosed results from ITN studies (i.e., data that has not been previously published, presented or discussed publicly). Meeting materials that do not contain such data will not require ITN review prior to presentation or publication, however, a copy of all meeting materials is to be forwarded to the ITN for filing.

No later than 7 business days prior to the commencement of the associated meeting, the Lead Author will submit copies of all materials to be presented and/or published to the ITN for review.

The ITN will coordinate an internal review of the materials, the results of which will be forwarded to the Author within 3-4 business days.

ITN presentation reviews contain three sections:

1. General Comments – contains the reviewers' broad observations on the manuscript, the results and their interpretation
2. Required Changes – those specific changes of high importance that must be included in the manuscript prior to submission to the journal in order for ITN approval to be received
3. Recommended Changes – changes that the reviewers believe will strengthen the manuscript, although they are not strictly required in order to receive ITN approval. The author must demonstrate to the ITN that "Required changes" have been instituted in the presentation prior to presentation at the meeting.

Note that if authors do not agree to incorporate the Required Changes requested by the ITN and intend to present without ITN approval, the author remains bound by the confidentiality

requirements of a fully executed Clinical Trial Agreement or ITN subcontract. The ITN reserves the right to require the following statement be placed in a conspicuous location within all materials that do not receive ITN approval:

"This work was not prepared in collaboration with members and investigators of the Immune Tolerance Network. The content and/or conclusions of this abstract do not necessarily reflect the opinions or views of the Immune Tolerance Network or its sponsors."

The results of ITN reviews should be made available to all authors at their request.

6.3 HIPAA Regulations

Investigators must ensure that the text of the abstract, presentation, handouts and other materials associated with the abstract comply with all HIPAA regulations regarding the disclosure of patient information. In general, all patient identifiers should be removed from the manuscript. However, if this is not possible (i.e., this information is essential to the conclusions of the paper/case report), investigators must provide the ITN with written proof that informed consent has been satisfied under HIPAA regulations and that the patient(s) have seen and approved the manuscript for publication.

7.0 Other Publication Types

7.1 Invited/Review Articles

Invited manuscripts or review articles prepared by ITN members or investigators are covered under Section 5 of this policy under the following circumstances:

- The manuscript describes previously unpublished data from one or more ITN studies
- One or more of the manuscript authors are listed as or identified as affiliated or employed by the ITN

7.2 Editorials, Opinions and 'Letters to the Editor'

In submitting editorial pieces, such as 'letters to the editor,' commentaries or other opinion-oriented publications, authors may not represent the opinions of the ITN as a whole without express written permission of the NEC.

Where one or more named authors list or identify their ITN affiliation within the publication, the editorial will be subject to ITN manuscript review as described in Section 5 of this document. Furthermore, the ITN reserves the right to request a disclaimer be added to the effect that the opinions contained do not necessarily reflect those of the ITN or its sponsors.

When submitting such pieces with no ITN-affiliations identified within the piece, as a courtesy, the ITN requests a copy of the publication for comment prior to submission.

8.0 Press Releases & Interviews

8.1 General Guidelines

In general, press releases concerning ITN-funded research activities may not be issued except with the prior consent and approval of the ITN. All authorized press releases concerning ITN-funded research activities will be subject to ITN review prior to release and must be received by the ITN at least 7 business days prior to the intended release date. Prior

to issuing a press release concerning the outcome of ITN-funded research, ITN must notify the NIH in advance to allow for coordination.

8.2 Research Results

The ITN and NIAID retain first right of refusal to issue press releases concerning the results of ITN-funded research.

The ITN preference is to issue joint releases to the National Press and the National Science Media together with the host institution(s)/company(s) of the Principal Investigator and/or Study Leader of the related study, with media contacts from each party listed on the release. By consensus, the host institution/company and the ITN will reach an advance understanding regarding the party responsible for dissemination of the release.

Press releases announcing data or findings from ITN research will only be issued in conjunction with the publication of reported data.

In cases where the research is the result of multi-institutional collaboration, the ITN will be responsible for coordinating the preparation of all materials for public consumption together with the designated Public Information Officers (PIOs) from all participating institutions, companies and other involved parties such as journals or conferences. This will ensure equitable recognition of each institution's contributions.

If ITN partner institutions or companies wish to piggy-back releases to local media detailing their participation in a study, they are encouraged to do so and must receive ITN approval and agree to coordinate their efforts with the ITN.

Participating institutions and investigators are expected to work with the ITN in the coordination of these activities and in preparing background materials and research related to the release. In return, the ITN will provide any additional background materials and research relating to the release.

Both the ITN and institutional officials will agree to forward copies of the final release to each other in a timely manner.

Press releases must include an acknowledgement of NIH award support and a disclaimer such as:

“Research described in this publication was performed as a project of the Immune Tolerance Network and supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number UM1AI109565. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

8.3 Funding and/or Partnership Announcements

Press releases announcing the award of a research subcontract by the ITN may be issued by the recipient institution only after final subcontract language has been agreed upon and both parties have signed and are subject to ITN review and approval prior to release.

Press releases announcing the establishment of a cooperative or collaborative agreement with the ITN must not be issued without prior ITN consent and review.

8.4 Patient Recruitment

ITN subcontracted clinical sites are encouraged to issue press releases designed to stimulate patient recruitment into ITN studies. These too are subject to ITN review. In many cases, centrally prepared releases may be available from the ITN, investigators should consult their assigned COM for details.

8.5 Interviews

Should information concerning ITN research be requested from an ITN-funded institution or investigator by a member of the media, the site should first refer the soliciting party to the ITN Director of Strategic Review and Planning.

9.0 Authorship

The Principal Investigator and/or Study Leader of a study have first right of refusal as Lead Author or to present the results of ITN-sponsored studies. If declined, the PI/Study Leader may designate another individual to do so.

9.1 Authorship of Primary & Secondary Publications

9.1.1 Lead Author

In general, the Principal Investigator (or Study Chair) of the study will be assigned as the lead (and corresponding) author. Should the PI (or Study Chair) choose, he/she may designate another individual meeting authorship requirements (as in 9.1.2) to assume the role of lead and/or corresponding author.

All individuals meeting the requirements for authorship as set forth in the authorship guidelines of the International Committee of Medical Journal Editors (ICMJE) 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals' (<http://www.icmje.org>) must be listed as authors. As per ICMJE recommendations, authorship is granted to those individuals who meet ALL the following criteria:

1. Substantial contribution to one or more of the following:
 - Study concept and design
 - Acquisition of data
 - Analysis and interpretation of data
2. Drafting the article or revising it critically for important intellectual content
3. Final approval of the version to be published

9.1.3 Additional Contributors

In general, there will be additional (sometimes many) important contributors to the study whose work the investigators feel should be acknowledged, but whom do not meet the criteria set out in 9.1.2. Collective authorship is the ITN's default means of recognizing these contributions to the study, as described below. When this is not possible, additional contributors should be listed in the acknowledgements section of the manuscript. Note that lead authors are advised to consult the intended journal's authorship policies, as these can vary between journals.

- Collective authorship: When possible, modified collective (or ‘group’) authorship will be used to acknowledge these individuals’ contributions. In this model, “Immune Tolerance Network [Study Code] Study Group” is listed as the final author of the manuscript (in addition to those meeting ICMJE criteria), as in the example below:

J. Doe, J. Smith, T. Jones, A. Lee, W. Singh, for the Immune Tolerance Network ITN099ST Study Group

The remaining individuals should then be clearly listed in the manuscript as members of the study group (consult specific journal policies for where to list, generally in the acknowledgements or on the cover page).

Note that the National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

- Acknowledgements: In some cases, journals apply a strict interpretation of ICMJE guidelines such that group authorship is not possible (i.e for NEJM, all authors, including those included as part of a group author must meet JCMJE guidelines). In such cases, additional individuals should be listed in the acknowledgements section of the manuscript.

9.1.4 Author Contributions Statement

It is recommended that all primary manuscripts incorporate an Author Contributions statement. These statements specify the efforts of each author towards publication and provide editors and the community with a direct means of appreciating the achievements of individuals involved in the study. Sample statements may be viewed here:

http://blogs.nature.com/nautilus/2007/11/post_12.html.

9.1.5 Where the number of authors is limited

If the number of authors meeting the above criteria exceeds that allowed by the intended journal, modified collective authorship, as described in section 9.1.3a will be used. Several senior authors as determined by the principal investigator, will be listed as named authors, in addition to the “Immune Tolerance Network [Study Code] Study Group”. It is strongly recommended that a statement of individual contributions be drafted (as per 9.1.4) to accompany manuscripts in these circumstances.

9.2 Authorship of Tertiary Publications

9.2.1 Lead Author

In general, the Lead author shall be the Principal Investigator of the tertiary study will be assigned as the lead (and corresponding) author. Should this individual choose, he/she may designate another individual meeting authorship requirements (as in 9.2.2) to assume the role of lead and/or corresponding author.

9.2.2 Other Authors

All individuals meeting the requirements for authorship as set forth in the authorship guidelines of the International Committee of Medical Journal Editors (ICMJE) ‘Uniform Requirements for Manuscripts Submitted to Biomedical Journals’ (<http://www.icmje.org>) will be listed as authors. As per ICMJE recommendations, authorship is granted to those individuals who meet ALL the following criteria:

1. Substantial contribution to one or more of the following:
 - Study concept and design
 - Acquisition of data
 - Analysis and interpretation of data
2. Drafting the article or revising it critically for important intellectual content
3. Final approval of the version to be published

All contributors who do not meet the criteria for authorship should be listed in the acknowledgments section.

9.3 Authorship of Ancillary Publications & Review Articles

Authorship of ancillary publications should be limited to those individuals directly contributing to the writing and preparation of the publication or those providing information pertinent to the conclusions or objectives of the publication. The ITN may request ITN staff members to be added to the authorship list in publications where descriptions of the results of ITN staff efforts/innovations are central to the objectives of the publication.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section.

9.4 Authorship of Case Reports

The Principal Investigator at the associated clinical site shall have first right of refusal for the authorship of case reports. Other authorship for case reports is limited to:

- Contributing individuals at the primary clinical site presenting the case
- The principal investigator and co-principal investigators of the study
- Individuals providing assay services relevant to the report

In addition, the ITN may require certain ITN or NIAID staff to be included in the authorship of case reports where there was significant participation in regards to the subject of the case report.

9.5 Authorship Disputes & Dispute Resolution

All disputes regarding publication authorship will be mediated by the NEC. Individuals wishing NEC mediation in authorship disputes should submit a written request containing relevant background information to the Executive Director of Strategic Review, Planning, and Communications prior to submission for ITN manuscript/abstract review.

10. TrialShare

ITN TrialShare is a clinical trials research web portal developed to share information about ITN's clinical studies and specimen bio-repository with the scientific community. Data and analysis code underlying ITN-published manuscripts are publicly available with the goal of promoting transparency, reproducibility, and scientific collaboration.

10.1 Data Availability

All published data, including published figures and their underlying data sets, are made available via ITN TrialShare at the time of publication. Unpublished data from closed ITN studies (18 months after final sign off of the Clinical Study Report) may be made available to the public via ITN TrialShare.

10.2 Sample Sharing

Biological specimens from closed studies (18 months after last patient last visit) are made available for external investigators to request for their own research. An inventory of the available samples and information about submitting a request for specimens are available on ITN TrialShare.

11. Revision History

Date	Ver	Changes	Auth
2009-10-26	3.00	Established version 3.0	JM
2010-03-22	3.01	Added ITN contract number to required acknowledgement Added revision history	JM
2010-12-07	3.02	Changed publications point person to Director of Strategic Review and Planning	LS
2010-12-09	3.20	Added role of Office of Strategic Review and Planning to Section 3.6	LS
2011-03-11	3.21	Changed “see data sharing policy” to “data sharing policy in preparation” (p.2)	PB
2011-09-13	4.00	Changed review policy so that only primary clinical or mechanistic publications undergo formal internal ITN review. For all other publications (secondary, tertiary, ancillary, etc.), any named ITN author will be responsible for involving appropriate ITN leadership in the review (in coordination with Director of Strategic Review and Planning).	PB
2012-04-03	4.01	Changed “Tolerance Assay and Data Analysis (TADA)” references to “Biomarker & Discovery Research (BDR)”	LS
2013-11-13	4.02	Changed attribution statement to say ITN is headquartered at the Benaroya Research Institute, and funded only by NIAID (not JDRF); added specification that press releases will only be issued in conjunction with published data; changed Office of Strategic Review and Planning to Office of Strategic Review, Planning, and Communications	LS
2014-12-23	4.12	Modified the publication acknowledgement language to reflect NIH requirements under the new UM1 award, UM1AI109565; Added Section 10 (TrialShare)	LS
2017-12-15	5.00	Established version 5.0 – Addition of NIDDK acknowledgement to section 5.1.1., Formatting improvement and minor changes to sub-list styles (for consistency)	