

TRIGR Publication and Presentation Committee (PPC)
Publication Policy Document, version 7 (09/2014)
Publications and Presentations – Definitions and Policies

PRESS RELEASES AND INTERVIEWS

A press release is a document given to radio, television, newspapers, popular periodicals, or scientific journals not indexed in the Index Medicus.

An interview is a discussion with a member of the press, a science writer, or a radio or television commentator that provides information for public dissemination.

Except for the purposes of recruitment, press releases and interviews regarding TRIGR outcome data will not be initiated by Study Centers. Centrally prepared press releases will be reviewed by the International Executive Committee (IEC)/Central Coordinating Committee (CCC) and distributed to the Centers. These prepared releases should be given to the media when interviews are requested. This procedure will help insure uniformity and accuracy in the information disseminated through the media. In this instance, use of such press releases and interviews need not receive prior approval from the Publication and Presentation Committee (PPC).

Should a Study Center be solicited for information other than that detailed above, then the Center should refer the soliciting party to the PPC.

PRESENTATIONS

A presentation is the delivery of information to scientific, professional or public groups.

A presentation may be given without prior review and approval by the PPC provided that the content is limited to published information or that provided by the International Coordinating Center (ICC) or the Data Management Unit (DMU) for this purpose. All presentations involving any "NEW" data (not published as a peer-reviewed article) must be reviewed by the PPC as described below.

1. Forum identification: The PPC will identify scientific and professional fora where presentation about TRIGR should be made on behalf of the group. Suggestions for such fora and topics for presentations will be sought from the PPC itself and individual investigators. The PPC will identify one or more persons from a list of volunteer investigators to prepare and present the material.

2. **Invited presentations:** If a member of the TRIGR Study Group is personally invited to present TRIGR data or represent TRIGR to a professional biomedical group, the invitation must be forwarded to the PPC. The PPC reserves the right to accept or not accept the invitation and to suggest a presenter other than the member who received the original invitation.

3. **Preparation and review schedule:**

a) The PPC Chairman must receive an abstract for a proposed presentation at least 14 days prior to the scientific society's deadline for receipt of the abstract, in order to provide time for review and possible revision. The PPC Chairman and two PPC reviewers selected by the Chairman must approve abstracts. Copies of all approved abstracts will be distributed to the International Executive Committee.

b) For an invited presentation for which there is no scientific society abstract review, an abstract should still be prepared and submitted to the PPC at least 14 days prior to presentation.

c) The PPC will review and approve all slides and posters for presentation. To allow sufficient time for this review the material must be received by PPC at least 14 days prior to the beginning of the meeting where the slides or poster will be shown. Failure to submit abstracts, slides and posters at least 14 days for review may result in a situation where the presentation is not approved.

PUBLICATIONS

A publication is any document submitted to a professional journal listed in Index Medicus or any popular periodical with regional or national circulation. All publications of principal outcomes of the TRIGR will be prepared under the overall review of the PPC. Re-analysis and publication of results obtained in individual Study Centers related to principal study outcomes and for which there is a publication authored by the study group will not be allowed. Publication results of ancillary studies by individual investigators are permitted with approval by the PPC. It must be recognized that approval of publications or presentation of ancillary studies may be withheld until such time as is deemed appropriate by the PPC. The manuscripts should be circulated to the members of the regional steering committees. Response should be given in 3 weeks. The Chair of the Publications and Presentations Committee will organize this circulation.

Manuscripts can be proposed to the PPC by completing the form available on the TRIGR member website (<https://trigr.epi.usf.edu/members/>). The same form may be used for requests to DMU for data analyses. The proposal has to be approved by the PPC before the request is submitted to DMU.

1. **Journal identification:** The PPC will endorse or suggest the choice of an appropriate journal for the publication of each proposed manuscript.
2. **Preparation and review schedule:** The PPC will select a writing group of maximally ten individuals for each proposed manuscript. One individual will be designated as Chair and will be responsible for ensuring that the first draft of the publication is written.

The PPC Chairman will coordinate the efforts of the writing teams, help establish priorities for data analysis, help edit the manuscripts produced by the writing teams, and may participate in the writing chores. For manuscripts, the PPC Chairman will designate at least two internal reviewers who must submit their review to the PPC within 14 days. The PPC Chairman will distribute the manuscript and reviews to the PPC for its consideration. PPC members will either approve or reject the opinions of the two reviewers within 14 days. The PPC Chairman will then inform the writing groups of its action, as well as any suggestions for revision.

If revisions are requested, the writing group must obtain approval of the revised manuscript from the PPC Chairman who may consult with the original reviewers, depending upon the revisions suggested. Upon receipt of such approval, the final manuscript will be reviewed by the IEC. Any member of the IEC who wishes to comment on the paper must communicate his/her concerns directly to the PPC Chairman within 14 days. If issues are raised, the writing group Chairman and the PPC Chairman will delay the submission until resolution is reached. If approved by a majority of the IEC the paper may be submitted for publication. For manuscripts deemed potentially acceptable by a journal pending revisions, the writing team will make these revisions and submit the revised manuscript and responses to the reviewers' critiques to the PPC. Depending upon the complexity and extent of the revisions, the PPC Chair may approve the revised manuscript, may request revisions and approval by the initial two reviewers of the manuscript, and/or review and approval by the IEC.

AUTHORSHIP

Responsibility for the category assignment for all manuscripts rests with the PPC.

Four categories of manuscripts are anticipated:

- I. **Primary TRIGR Manuscripts:** These are papers that address the principal goals and objectives of the trial.
- II. **Secondary TRIGR Manuscripts:** These are papers that utilize the data base from all, or at least many, participating Study Centers, but address issues that are peripheral to the major objectives of the trial. Thus, the major features of these papers are that they include studywide data generated by TRIGR. Examples are: recruitment, assessment of compliance, informed consent procedures, methodological analyses. In addition, this category includes ancillary studies that use significant amounts of TRIGR data or where the data have been collected in Centers throughout the TRIGR.
- III. **Tertiary TRIGR Manuscripts:** These papers would either utilize data from certain sub-groups of Study Centers or from one Center and/or would utilize significant amounts of non-TRIGR data.
- IV. **Miscellaneous Manuscripts:** Some papers, mostly concerned with methodological issues, may arise which do not deal with the TRIGR cohort or the TRIGR study directly but which are prompted by discussions during development and/or performance of TRIGR. A manuscript such as this, prepared by a member of the TRIGR Study Group, should include an acknowledgment of their TRIGR grant support. Authorship in each of these categories will be as follows:

Authorship in each of these categories will be as follows:

- I. **Primary TRIGR Manuscripts.** "The TRIGR Study Group" shall be the sole author of these papers. The list of study group members appears as part of the manuscript, usually at the end of the manuscript, if at all possible, or in an electronic supplement.
- II. **Secondary TRIGR Manuscripts.** "Drs. Chairperson, Jones, Smith, and the TRIGR Investigators" shall be the authorship form for these papers. Footnote at bottom of the title page: A complete list of TRIGR investigators appears either as a part of the manuscript or in an electronic supplement. The lead author has to ensure that each investigator is listed as an author in PubMed.
- III. **Tertiary Manuscripts.** If significant amounts of TRIGR data or effort are involved, the form should be the same as for secondary

manuscripts. If this is not the case, those individuals performing the study will be the authors but the study group should be acknowledged. For example, under acknowledgements a statement should be included such as “the authors thank the TRIGR Study Group for (complete list of the TRIGR Study Group is published on the TRIGR website (<http://trigr.epi.usf.edu/centres.html>)).

IV. Miscellaneous Manuscripts. TRIGR support should be acknowledged (see below).

ACKNOWLEDGEMENTS

Under acknowledgements, support by the TRIGR Study Group and/or TRIGR grants should be mentioned as appropriate with use of the following statement to acknowledge funding agencies and sponsors:

“This work was supported by Grant Numbers HD040364, HD042444 and HD051997 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Special Statutory Funding Program for Type 1 Diabetes Research administered by the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health), Canadian Institutes of Health Research, the Juvenile Diabetes Research Foundation International, the Commission of the European Communities (specific RTD programme “Quality of Life and management of Living Resources”, contract number QLK1-2002-00372 "Diabetes Prevention". It does not reflect its views and in no way anticipates the Commission’s future policy in this area.) and the EFSD/JDRF/Novo Nordisk Focused Research Grant. The study formulas were provided free of charge by Mead Johnson Nutrition”

DISPUTE RESOLUTION

In all disagreements and disputes relating to the publication of TRIGR related research materials, 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 PPC for immediate review. The PPC will thoroughly investigate the matter and in a timely manner produce a recommendation to the IEC. The IEC will make the final decision that is binding upon all involved parties.

RECOMMENDATION FOR LISTING OF THE TRIGR STUDY GROUP AND TRIGR INVESTIGATORS IN PUBLICATIONS

1. The list of the TRIGR Study Group should include all study centers and laboratories in addition to the TRIGR PI, his Deputy, the Co-PIs in North America and the DMU PI. Each center and laboratory including the International Coordinating Center, the Data Management Unit and the Nutritional Epidemiology Unit should be asked to compile a list of the persons to be included. Study nurses and dieticians are appropriate members of the Study Group. Both former and present members may be listed. The listing should also include the names of the chairs of the official TRIGR committees.

The listing should include the official names of all study centers and institutions involved in the study.

2. The list of TRIGR Investigators should include the names of TRIGR PI, his Deputy, the Co-PIs in North America, the DMU PI and the heads of the TRIGR laboratories and Nutritional Epidemiology Unit. In addition national investigators, local investigator of each study center and one or two other members of each study center with long standing and important contribution to the study (study nurses or dieticians), and personnel of the International Coordinating Center and DMU should be listed.
3. Each primary manuscript should include a list of the Study Group in an appendix.
4. Secondary manuscripts should include a complete list of TRIGR investigators which appears either as a part of the manuscript or in the electronic supplement.
5. Tertiary and miscellaneous manuscripts can refer to the list published on the TRIGR website (<http://trigr.epi.usf.edu/centres.html>) which will be updated regularly.