

The **G**lycemia **R**eduction **A**pproaches in **D**iabetes: A Comparative **E**ffectiveness Study
(GRADE Study)

GRADE Publications and Presentations

Policies and Procedures

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GRADE Study Coordinating Center
Biostatistics Center
George Washington University
6110 Executive Boulevard
Rockville, Maryland 20852

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GRADE PUBLICATIONS AND PRESENTATIONS POLICY AND PROCEDURES

GRADE is a randomized clinical trial to evaluate the relative effectiveness, and associated costs, of the therapies commonly used to treat type 2 diabetes mellitus (T2DM). In addition to the members of the research group, GRADE plans to develop collaborations with investigators outside of the GRADE Research Group who will conduct additional research to augment the core research program. In addition, GRADE data and biological specimens will be made available to investigators for future use. All of these activities will result in publications and presentations that will be generated under the auspices of the GRADE Publications and Presentations Committee (PPC).

The goals of the PPC are to:

1. ensure that all publications and presentations from GRADE are of the highest scientific quality;
2. preserve the scientific integrity of GRADE in publications and presentations;
3. protect the rights and privacy of the subject participants in publications and presentations;
4. promote the selective generation of as many high quality publications and presentations as possible with the resources available and establish priorities for the allocation of resources to do so;
5. ensure that authorship of all publications and presentations is equitable and that proper attribution to GRADE is provided.

This policy and its application will further these objectives.

1. Definitions

- **Research Group:** The set of professional investigators (physicians, nurses, etc.) who are employed at a GRADE clinical site or central unit (including the Coordinating Center) and who contribute a portion of their effort to the core GRADE project with funding from the U01 grant from the NIDDK
- **Collaborator:** Any professional investigator who is not a member of the research group but who participates in research conducted under the auspices of GRADE with independent funding or through donation of effort.
- **Consultant:** Any professional who provides service to GRADE of a limited nature on either a fee for service or *pro bono* agreement.
- **Ancillary Study:** Research using GRADE study participants (including their laboratory specimens or tests) to collect or derive *supplemental data for purposes above and beyond those set forth in the GRADE protocol*. This includes use of specimens, a questionnaire, or observation that results in the acquisition of additional data. An ancillary study can involve all or a subset of study participants. Funding support is provided by sources outside the primary study. The study is designed and conducted under the auspices of the ancillary study research group. Such studies will require approval by the Ancillary Studies Committee, the Steering Committee and the DSMB. The ancillary study investigators would be considered collaborators per above. The publication or presentation of the research would comply with the policies stated herein.
- **Sub-Study:** Research using GRADE study participants (including their data, laboratory specimens or tests) to collect or generate data *for purposes set forth as or consistent with the hypotheses/study aims in the GRADE protocol*. The substudy can involve all or a subset of study participants. Funding support is provided by the primary study and/or

supplemented by sources outside of the core funding of the study. The study is designed and conducted under the auspices of the GRADE research group. Such sub-studies would also require approval of the Ancillary Studies Committee, the Steering Committee and the DSMB. A sub-study may involve other investigators who are not members of the Research Group who would then be considered collaborators. The publication or presentation of the research would comply with the policies stated herein.

- **Ancillary Analysis:** An analysis of pre-existing GRADE study data that addresses questions not addressed by the planned analyses of the GRADE research group and that is funded independently of the core GRADE funding. Proposals for such analyses would require approval of the Ancillary Studies Committee, the Publications and Presentation Committee and Steering Committee. The plans for such analyses should also be approved by the GRADE statisticians at the Coordinating Center. The dissemination of the research would comply with the policies stated herein.
- **Publicly Independent Research:** GRADE data and biological specimens will be made available to investigators in the scientific community through the NIDDK Data, Biological Specimen and Genetic Specimen Repositories. GRADE will play no role in such research or in the publication or presentation of such research, and the policies herein would not apply. However, GRADE requests that all publications and presentations using materials that originated with GRADE provide an appropriate acknowledgement.
- **Press Release:** A statement released to print, non-print or electronic media that is not scientifically indexed.
- **Interview:** Any communication with a print, non-print or electronic media reporter, who in turn provides information for public dissemination.
- **Presentation:** The formal delivery of information to scientific, professional, or public groups.
- **Publication:** Any document submitted to a professional journal indexed scientifically, or any lay publication, or a document that would appear as part of a book in whole or in part. A book is any material that has been assigned an International Standard Book Number (ISBN) or an electronic document that has been assigned a Digital Object Identifier (DOI).

2. Duties and Responsibilities

Specifically, for all publications and presentations that emanate from the core GRADE study or a GRADE ancillary study, the Committee shall:

1. Recommend policy and procedures for generation, review and approval of all communications (written and spoken) regarding GRADE.
2. Identify publications/presentations to be prepared on behalf of GRADE.
3. Review proposals for publications/presentations on special topics submitted by a member of the Research Group or a Collaborator.
4. Assign the publication/presentation category to each paper that will then govern the designation of authorship.
5. Approve the naming of first and senior authors of each publication, and make such assignments as appropriate. Recommend co-authors as appropriate.

6. The Research Group will be notified of new manuscripts that have been approved by the Publications and Presentations Committee to solicit volunteers to participate as co-authors.
7. Establish a target for completion of each manuscript and monitor the writing of each paper to ensure publication in a timely fashion.
8. Review, edit and approve all manuscripts and abstracts emanating from GRADE, or an ancillary study, initiative or supplemental analysis prior to submission, enlisting the special assistance of the appropriate expertise. The review will be conducted pursuant to the following editorial policy:
 - a) To ensure that all publications/presentations preserve the scientific integrity of the study.
 - b) To correct factual and conceptual inaccuracies.
 - c) To safeguard the rights of volunteer participants.
 - d) To prepare comments to assist collaborating scientists in publishing papers of the highest quality and clarity.
 - e) To avoid conflict with and/or duplication of other publications/presentations.
9. In addition to the issues cited in the editorial policy above, proposed publications/presentations of ancillary studies will be scrutinized to ensure that their presentation will not threaten the integrity or conduct of GRADE.
10. Approve or recommend an appropriate journal for each publication.
11. Monitor the process of manuscript development and publication, and take action as appropriate.

3. Policies and Procedures

3.1 Press Releases

Press releases related to the overall conduct or major results of GRADE will be issued centrally by the NIDDK. All such press releases will then be distributed to all study units for simultaneous release by their local press offices timed in conjunction to the release centrally. These prepared releases should be provided to the media when interviews are requested. This procedure will help ensure uniformity and accuracy in the information disseminated through the media.

Individual sites can issue press releases related to the site activities in GRADE, such as to promote recruitment provided that the release is limited to information available in the final Protocol, the Manual of Operations, or in papers already published as peer reviewed articles, with no added interpretations or inferences. Such releases do not require prior review and approval by the Publications and Presentations Committee.

There should be no press release related to study results that have not been published or presented at a scientific meeting.

3.2 Interviews

A Research Group member can provide a statement or interview without prior review and approval by the Publications and Presentations Committee provided that the substantive content is limited to information available in the final Protocol, the Manual of Operations, or in peer reviewed articles or presentations, with no added interpretations or inferences.

Should a Research Group member be asked to speak on behalf of GRADE about the overall conduct or major results of the study, then the soliciting party should be referred to the GRADE Office of the Study Chair and to the chair of the Publications and Presentations Committee.

3.3 Publication Categories

The following categories apply to Publications generated on behalf of the GRADE Research Group, including ancillary studies, initiatives and supplemental analyses.

- I. Category 1, Primary GRADE Manuscripts: These papers address the major, i.e. primary, objectives of the GRADE study, e.g. effects of the differences among the randomized treatment groups on durability of glycemic control, or any other major finding from GRADE or a GRADE sub-study that in the opinion of the committee merits a category 1 designation. The authorship in the journal masthead will be the GRADE Research Group. The writing committee (authors) on behalf of GRADE will be named elsewhere, as in a footnote, per *Journal* policy. The complete list of Research Group members will appear either as part of the published manuscript, such as at the end of the manuscript, or as supplemental material (an online appendix). If the paper reports the results of a sub-study involving a subset of the research group, then the list of members may differentiate members of The GRADE (sub-study title) Research Group and other members of The GRADE Research Group (or members of the full research group).
- II. Category 2, Other GRADE Outcome Manuscripts: These papers report analyses of secondary outcomes, and of metabolic intermediates and biomarkers, or epidemiologic analyses emanating from the core GRADE funding or a GRADE sub-study that do not merit a category 1 classification by the committee. The writing authors will be named followed by “and the GRADE Research Group.” The complete list of Research Group members should either be included as part of the manuscript, or in supplemental material, as above for a Category 1 paper. If the paper reports the results of a sub-study involving a subset of the research group, then the list of members may differentiate members of The GRADE (sub-study title) Research Group and other members of The GRADE Research Group (or members of the full research group).
- III. Category 3, Ancillary Study and Ancillary Analysis Manuscripts: These papers report analyses of results of ancillary studies or ancillary analyses as defined above. The writing authors will be named followed by “and the GRADE Research Group.” The paper should refer to a recent publication that presents the members of the Research Group. If all ancillary study participants are not named authors, then the list of members may differentiate members of The GRADE (ancillary study title) Research Group and other members of The GRADE Research Group (or members of the full research group).
- IV. Category 4, Methodological Manuscripts: These papers focus on methodological issues, and do not include any new or original study outcome results. Such papers may include data generated from GRADE to address a methodological objective that is not a GRADE objective or outcome. Authors are named with appropriate acknowledgment of GRADE.

Responsibility for the category assignment for each manuscript will rest with the Publications and Presentations Committee, usually at the time that the manuscript is approved. The Executive Committee will be apprised of all category 1 designations.

3.4 Presentation Categories

Presentations will only be considered for topics (papers) that have already been approved by the Publications and Presentations Committee. The category assigned to the paper will also apply to all presentations based on the results for that paper.

3.5 Proposals

The PPC will identify and initiate individual papers and presentations to be generated based on the results of the core study to address the study objectives. It will also work with the Principal Investigator and co-investigators of sub-studies and ancillary studies or ancillary analyses to identify and initiate papers and presentations to be generated from those studies. The PPC will maintain a list of all papers and presentations planned or in progress that will be available to the research group on the study website.

Members of the Research Group may also propose additional topics for papers or presentations to the PPC. The proposal should define the research objectives, the data to be employed and a statistical analysis plan with an assessment of the study operating characteristics (precision, power). Approved proposals will be added to the list of papers and presentations along with the category designated by the PPC.

3.6 Authorship

The PPC will appoint the lead (first and/or senior) author(s) for category 1 and 2 study papers that emanate from the core study. For category 1 and 2 papers that emanate from a sub-study, the PPC will appoint or approve the appointment of the lead author(s) in conjunction with the sub-study Principal Investigator (who may request to be a lead author). Likewise, for Category 3 ancillary study or ancillary analysis papers, the PPC will approve the appointment of the lead author(s) in conjunction with the study/analysis PI. The PPC may also appoint co-authors for papers or presentations.

When a new topic is approved and added to the list of pending papers or presentations, the Research Group will be notified and individual members may then volunteer to participate as a co-author for a given paper or presentation. Co-authors will be selected by the lead author(s) in conjunction with the PPC and must be approved by the PPC.

In the event of a controversy over authorship, a member of the Research Group may petition the Executive Committee. If the matter is not satisfactorily resolved, the matter may be brought before the full Steering Committee for final resolution.

3.7 Publications

The first draft of each manuscript should be produced within 3 months following completion of analyses.

After a category 1 or 2 paper has been reviewed and approved by the Publications and Presentations Committee, the paper will be distributed to the GRADE Steering Committee for review. The Steering Committee will be provided 14 days to comment and to vote on approval to submit and on the selected journal. All comments will be provided to the Coordinating Center and the Chair of the Publications and Presentations Committee. The authors, with approval of the Chair of the Publications and Presentations Committee, should then complete a final revision that addresses comments received from the Steering Committee. After appropriate revisions, if any, the paper may be submitted for publication.

After a category 3 or 4 paper has been reviewed and approved by the Publications and Presentations Committee, the paper may be submitted for publication.

3.8 Presentations

A Research Group member may give a presentation without prior review and approval by the Publications and Presentations Committee to any venue, such as grand rounds, where the content is limited to substantive information available in the final Protocol, the Manual of Operations, or other published data, with no added interpretations or inferences.

All GRADE presentations involving any "new" data (not yet published as a peer reviewed article) must be reviewed by the Publications and Presentations Committee as described below:

1. GRADE Initiated Scientific Presentations: The Publications and Presentations Committee will approve the venue of any presentation (oral or poster) made on behalf of the GRADE Research Group, including ancillary studies, initiatives or supplemental analyses. For category 1 – 3 papers, the Committee will also appoint, or approve the appointment of, the first author and senior author.
2. Invited Presentations: If individual members of the GRADE Research Group are personally invited to present GRADE data or represent the GRADE Research Group, then the invitation must be forwarded to the Office of the Study Chair and to the Publications and Presentations Committee that will manage all such invitations on behalf of the Research Group.
3. Preparation and Review Schedule:
 - a) Requests for additional data from the Coordinating Center must be made sufficiently early to allow for delivery of the data requested (at least 60 days prior to abstract submission).
 - b) An abstract for a proposed presentation must be received by the Publications and Presentations Committee far enough in advance to provide time for cycles of review, revision and resubmission leading to approval by the PPC and the Steering Committee, or rejection. Abstracts received less than 15 days prior to the deadline for abstract submission will not be reviewed.
 - d) The presentation slides or poster must be reviewed and approved by the writing committee prior to presentation.

Following the presentation of a category 1 – 3 abstract, the final set of slides for an oral presentation or the final poster (in an electronic format) will be provided to the Coordinating Center for archival and access by the Research Group.

3.9 Acknowledgment

All publications and presentations should acknowledge the sponsors of GRADE, and other sponsors where relevant (see below).

All derivative papers, e.g. genetics discovery papers that use GRADE data for confirmation, must also cite "and the GRADE Research Group" among the authors.

4. PPC Operations

4.1 Research Group

The GRADE Coordinating Center will periodically update a listing of the names of members of the Research Group and its Collaborators. The listing will include professional staff, who in the opinion of the site principal investigator, merit recognition as a member of the group. Past members will be included parenthetically such as "(previously xxx)".

4.2 Sponsors

The GRADE Coordinating Center will also provide a statement acknowledging the sponsors of GRADE that has been approved by the Executive Committee and the NIDDK. If the paper or presentation emanates from an ancillary study, initiative or supplemental analysis supported by independent funding, the sponsors of the research should also be cited, but should not replace the standard GRADE sponsor acknowledgment.

4.3 Presentation Style

The GRADE Coordinating Center will develop a standard style (template) to be employed for all GRADE and GRADE sub-study slide presentations and posters that will be reviewed and approved by the Publications and Presentations Committee. A slide or poster template will be provided to the first and senior authors of each presentation and poster.

4.4 Submission

The first and senior author will designate one of the authors to serve as the corresponding author for each publication and presentation. The Coordinating Center will submit all category 1 and 2 manuscripts to the designated Journal for publication on behalf of the named corresponding author. The corresponding author of category 3 or 4 papers will conduct the submission to the Journal. The Coordinating Center will likewise submit abstracts for category 1 and 2 presentations, whereas the authors will do so for category 3 and 4 presentations.

4.5 Bibliography

The Grade Coordinating Center will maintain an official bibliography with all publications in a standard citation format (authors, title, journal or book, year, volume, pages), and will also maintain a listing of all presentations.

4.6 Website

The Grade Coordinating Center will maintain a secure study website for use by the Research Group and its collaborators. It will provide a downloadable pdf copy of all publications. The website will also provide a copy of all category 1 – 3 slide and poster presentations.