



**EPIDEMIOLOGY OF
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Publications Policy (Chapter 6 of the EDIC Protocol)

Editorial Policy

The “DCCT/EDIC Research Group” is used when referring to or citing the DCCT/EDIC Research Group in publications and presentations of the DCCT/EDIC study. The Publications and Presentations (P&P) Committee will assume responsibility for arranging the preparation of all press releases, interviews, presentations, and publications relating to the study. The P&P Committee will review and monitor content development, preparation and review of all manuscripts. Recommendations will be presented to the Executive Committee and Research Group for approval.

Publications Working Group

The Publication Working Group (PWG), composed of the study leadership, such as the Study Chair, the Principal Investigator and Director of the Data Coordinating Center, the Chair of Publications and Presentations Committee, the Principal Investigator of the Clinical Coordinating Center and one of the Co-chairs of the Study Coordinators Committee, is responsible for reviewing and coordinating proposals for publications and presentations. The PWG provides the study-wide vision of the progress of the study, knowledge of the provenance of topics and the workings of our collaborations, ancillary and sub-studies, content expertise, and knowledge regarding historic/recent/current involvement of Research Group members in publication and presentation activities.

Publications and Presentations Duties and Policies

The Publications and Presentations (P&P) Committee will: recommend policy and procedures for review and approval of all communications (written and spoken) regarding the study to outside groups; monitor the writing of each paper to ensure timely publication; establish standards of excellence for publications; review, edit and approve all publications and presentations prior to submission; review any publications arising from ancillary studies; suggest appropriate journals for publications and monitor the process of publication, and; perform other writing, reviewing, or editing tasks assigned by the DCCT/EDIC Research Group or the Executive Committee. Manuscript reviews will be conducted following editorial policy guidelines to:

- Ensure that all publications preserve the scientific integrity of the study
- Maintain the highest standards in the preparation of presentations and publications
- Correct factual and conceptual inaccuracies if necessary
- Safeguard the rights of volunteer participants
- Prepare comments to assist collaborating scientists in publishing papers of the highest quality and clarity
- Inform the Executive Committee, Research Group, NIDDK, and external EDIC advisory groups of all public dissemination of information about the study and coordinate press releases with the NIDDK
- Avoid conflict with and/or duplication of other publications
- Coordinate the releases of major study data with NIDDK

Authorship

The DCCT/EDIC study has evolved from a randomized controlled clinical trial to an observational study of individuals with T1DM. In addition, we have developed numerous broad based collaborations with



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investigators outside of the DCCT/EDIC Research Group who are making unique contributions to our understanding of T1DM and its associated complications. Responsibility for the category assignment for all manuscripts will rest with the Publications Working Group in consultation with the Executive Committee. The categories of papers are classified based on the following authorship principles:

- **Primary Outcome Manuscripts (Category 1):** These manuscripts address the major primary outcomes of the DCCT/EDIC study. The authorship is the DCCT/EDIC Research Group. The writing team for these papers is identified in the manuscript. The complete list of DCCT/EDIC investigators appears as part of the manuscript, usually in an appendix at the end of the manuscript, as negotiated with the publishing journal.
- **Other Outcomes Manuscripts (Category 2):** These manuscripts report various analyses of complication outcomes, metabolic intermediates and biomarkers, or natural history of T1DM that utilize the database from the entire cohort. This category will represent the majority of the manuscripts. These manuscripts also include sub-studies and ancillary studies conducted as additional initiatives beyond the initial DCCT/EDIC protocol. The authorship will be the writing group: Chairperson, authors A, B, C, etc. and the DCCT/EDIC Research Group.
- **Miscellaneous Manuscripts (Category 3):** These manuscripts generally focus on methodological issues and may include results of subgroup analyses that do not include data from the entire DCCT/EDIC cohort. Authorship includes named authors A, B, C, etc.; the DCCT/EDIC Research Group is acknowledged in the manuscript but not included as a named author.



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Publications Policy (Revised)

To: DCCT/EDIC Research Group

From: David Nathan on behalf of the Executive Committee

Re: Publication Policies (revised)

Date: August 18, 2014 (revised May 20, 2016)

This revision is intended to clarify the distinction between the roles of the Publications Working Group and the main Publications and Presentations Committee.

DCCT/EDIC has an extraordinarily productive record of publications and presentations. With more than 250 publications and many hundreds of abstracts, the Study Group has produced consistently high quality scientific presentations and publications describing the findings and clinical advances from DCCT/EDIC.

The Publications and Presentations (P&P) Committee's role focuses primarily on reviewing and editing the numerous manuscripts and presentations that have emerged from the DCCT/EDIC working groups and active collaborators. The P&P Committee members are fully engaged in this review and editorial process, and the committee will continue to fulfill this function on behalf of the Study Group.

All Research Group members have the opportunity to participate in writing groups and in this context it is important that the credit as well as the responsibilities are shared among as wide a group of DCCT/EDIC investigators as possible. Many of the DCCT/EDIC papers are "group authored" and Pubmed usually cites all members of the Study Group. However, study group members who are named members of the writing team of manuscripts may receive additional recognition and academic credit from their respective institutions for their participation.

The responsibility for suggesting topics for papers and presentations lies with the Study Group and thus ALL members of the Study Group and study collaborators are encouraged to propose topics.

The Executive Committee has developed a more concise formal guideline for the development and management of publications than has previously been defined, designed to provide a fair, equitable and practical process for the formation of writing groups. The following process is proposed:

1. The Publication Working Group (PWG), composed of the Study Chair or Co-chair, the PI of the Data Coordinating Center, the Chair of P&P, the PI of the Clinical Coordinating Center and one of the Coordinator chairs, will be responsible for reviewing and coordinating proposals for publications and presentations. The PWG provides the study-wide vision of the progress of the study, knowledge of the provenance of topics and the workings of our collaborations and ancillary and sub-studies, content expertise, and knowledge regarding historic/recent/current involvement of study group members in publication/presentation activities. An important goal of the PWG review is to try to ensure as wide and equitable a distribution of authorship as possible, taking advantage of our highly talented Study Group.



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2. Members of the Research Group and collaborators may suggest new manuscript topics to the PWG. Some collaborators may previously have received DCCT/EDIC data to be used in conjunction with their ancillary study to address defined study objectives. Other collaborators may have a collaborative arrangement with the Data Coordinating Center to conduct analyses jointly with EDIC data. Regardless, all collaborators are expected to follow these procedures and are asked to submit a new manuscript proposal to the PWG for review prior to manuscript preparation and submission to the P&P Committee.
3. We strongly recommend that Research Group members and collaborators propose and submit paper topics to the PWG as early as possible to give the PWG adequate time to consider the topic, coordinate topics that may have overlap, determine the resources required and potentially prioritize topics.
4. At the time that a topic is proposed to the PWG, the originator(s) of the topic is asked to complete the DCCT/EDIC Manuscript Proposal Form and suggest a writing group, including a chairperson. The form can be found at: <https://edic.bsc.gwu.edu/publications>.
5. After the PWG approves the proposal for a paper/presentation, it will assist in the identification and selection of writing group members.
6. The PWG will circulate an invitation to the Study Group to invite members of the study group with an interest in the topic to request inclusion in the writing group.
7. On occasion, an author who is not a member of the DCCT/EDIC Study Group may be suggested by the writing group chair. Although the general principle is that the privilege of writing papers is reserved for members of the Study Group and our collaborators, the PWG will consider the inclusion of other individuals based on unique expertise to the content area.
8. After receiving responses from the Study Group, the PWG will compile and approve the final writing group. The writing groups will be kept to a reasonable size (usually ≤ 10). We anticipate that the designation of the final writing group will take no more than one month.
9. The writing group chair, with support from the Data Coordinating Center, will be charged with the management of the writing process including making specific assignments, setting deadlines and communicating with PWG regarding any challenges encountered that may impede the preparation process to the PWG. In the rare circumstance when the progress of a paper does not proceed at a reasonable rate, the membership of the writing group, including the chair, may be changed.
10. The PI of the Data Coordinating Center will continue to assign statisticians and other DCC staff to support individual papers based on expertise and project involvement.
11. For ancillary studies, the composition of writing groups will largely be members of the individual ancillary study working groups. Thus, representation from the Study Group in ancillary study writing groups will largely take place at the time that ancillary study working groups are formed.



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determining the authorship within a writing group, we will follow the ICMJE guidelines on authorship (attached hereto) which identify 4 criteria, ALL of which must be satisfied by an author. Prior to review of the draft manuscript by the P&P Committee, the chair of each writing committee will be asked to verify the contributions of each author or writing committee member (items 1 and 2 of the ICMJE criteria), and each author will be asked to affirm authorship (items 3 and 4). Each article will contain a statement that “All authors affirm that authorship is merited based on the ICMJE authorship criteria.”

13. The P&P Committee will continue to carry out its role as the internal review group of publications and presentations, following the established policies.

Our goal is to ensure an equitable and inclusive process in the selection of authors for future papers. DCCT/EDIC has always been a highly collaborative study and we want to make sure that everyone is offered the opportunity to participate in writing and presenting the results of the study.

Proposals for new publications should be submitted to the PWG via Barbara Braffett at braffett@bsc.gwu.edu.



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Publications Policy (ADDENDUM)

Date: July 20, 2020
To: DCCT/EDIC Research Group
From: David Nathan on behalf of the Executive Committee
Re: ADDENDUM to Publication Policies (May 2016)

The Publications Policy (dated May 2016) remains in effect. This ADDENDUM clarifies that external investigators who participate in the DCCT/EDIC manuscript development process should have demonstrated experience/expertise specific to the content of the manuscript and encourages use of the NIDDK Repository.

The Publications Working Group (PWG) aims to ensure as wide and equitable a distribution of authorship within the Study Group as possible. ALL members of the DCCT/EDIC Study Group and active study collaborators are encouraged to propose topics and all Study Group members have the opportunity to participate in writing groups.

This Addendum provides further clarification:

1. The Publications Working Group (PWG) will review each manuscript proposal. If approved, the PWG may make recommendations for writing group chair(s) as well as writing group members with specific expertise on the topic and will circulate an invitation to the Study Group to solicit further interest in joining in the writing group. The PWG will approve the final writing committee.
2. The PWG will evaluate the impact of each manuscript proposal on the finite resources at the Data Coordinating Center (DCC) to determine the feasibility of completing the proposed data analyses or data request(s) without compromising currently approved projects and prioritized manuscripts. If timely completion is not feasible, the author(s) will be encouraged to utilize other data analysis resources, such as within their own institution, and data resources that may be available through the NIDDK Repository.
3. Although the general principle is that the privilege of writing papers is reserved for members of the Study Group and our collaborators, the PWG will consider the inclusion of other individuals based on their unique experience/expertise to the content area and their relationships with other DCCT/EDIC investigators. However, the nomination of a non-study group member for the sole purpose of mentoring and training is not appropriate.
4. A Manuscript Proposal should be submitted to the PWG for review prior to manuscript preparation and submission to the P&P Committee. The form can be found at: <https://edic.bsc.gwu.edu/publications>. Proposals for new publications should be submitted to the PWG via Barbara Braffett at braffett@bsc.gwu.edu.