

April 20, 2007

### **DCCT/EDIC Publication and Presentations Committee Procedures**

The DCCT/EDIC Research Group has been extremely productive since its inception with more than 120 published papers including 13 in the *New England Journal of Medicine*, *JAMA*, or *Annals of Internal Medicine*, 35 in *Diabetes*, *Diabetes Care*, or *Diabetologia* and many others in high quality specialty journals. The recent increased level of writing and publishing activity has strained the capacity of study leadership, the Publications and Presentation Committee [PPC], and the Coordinating Center to review and manage the preparation of manuscripts. In order to maintain the high quality and consistency that have characterized DCCT/EDIC manuscripts, the Executive Committee, with the PPC Chair, have formulated this policy regarding preparation of DCCT/EDIC manuscripts.

Any member of the DCCT/EDIC study group can submit a proposal for a new manuscript topic to the Publications and Presentations Committee. Proposals should be submitted to Paddy Cleary at the EDIC Coordinating Center who will then coordinate review with the PPC chair, Bernie Zinman. The proposal should explicitly describe the background to the proposal and its justification, the objectives to be addressed, and the data to be used as the basis for the analyses. The PPC will provide a review of the proposal on the basis of scientific merit. The proposal and the review, whether favorable or not, will then be submitted to the Executive Committee for review. If approved by the Executive Committee, a writing committee and committee chair will then be appointed by the Executive Committee, and the manuscript will be entered into the work queue at the Coordinating Center. On the basis of the anticipated requirements of a particular proposal, and the availability staff to address those requirements, the Executive Committee will assign each approved paper a priority to help effectively manage the workload and production of manuscripts.

Investigators with whom we are collaborating may also propose a paper requiring analyses of DCCT/EDIC data stored at the Data Coordinating Center. Such proposals should follow the process outlined. The collaborating investigator may also recommend other individuals outside the study group as writing team members. The writing team for such a paper will be appointed by the PPC and it should include A DCCT/EDIC principal investigator who is the liaison person to the DCCT/EDIC study group, as well as appropriate members of the Data Coordinating Center. The Executive Committee will assign a priority to such manuscripts, in accordance with the then current and planned workload of the Data Coordinating Center.

The Coordinating Center will maintain a ledger of all approved manuscript proposals that identifies the writing committee chair, the date approved by the Executive Committee, the CoC statistician assigned to support the manuscript, the projected completion date, the target journal and whether (and when) a presentation is planned. As new papers are approved or others completed the ledger will be updated and shared with the PPC chair. Periodically, at least every 3 months, or when new proposals are approved, the Executive Committee will review all approved proposals and can re-adjust priorities

as appropriate.

The Executive Committee may also recommend new manuscripts, and the Publications and Presentations Committee may also generate proposals for manuscripts for review by the Executive Committee at any time.

The Coordinating Center will work jointly with the writing committee to develop a detailed analysis plan for each manuscript. The analysis plan will state each specific hypothesis, objective or question to be addressed and the specific analyses to be conducted. Analyses will commence after this plan has been completed and approved by John Lachin.

The writing committee chair may request that the EDIC data be shared with the investigator's local statistician who would perform the analyses specified in the analysis plan. Such a request must also be approved by the PPC and the Executive Committee.

The assigned statistician will then work with the writing committee to generate a draft of the paper (or the presentation). The paper (or presentation) will then be distributed to the PPC and Executive Committee for joint review. The Study Editor (David Nathan) will receive the individual reviews and provide final instructions on revision of the manuscript. After appropriate revisions, if needed, and approval from the Study Editor, the manuscript will be distributed to the study group for review and approval for submission for publication.