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Potential Collaborators

The DCCT/EDIC Research Group welcomes scientific collaboration with investigators in the field of diabetic complications. Our part in such collaborations is often to provide blood and/or urine specimens, as well as clinical and biochemical data for joint analyses.

We wish to make clear our policy in providing specimens for joint projects. All the specific measurements which will be made on DCCT/EDIC samples must be designated and agreed on in advance. No additional measurements of any analyte in DCCT/EDIC specimens can subsequently be performed on left-over sample volume without the prior knowledge and concurrence of the DCCT/EDIC Research Group.

The reason for this policy is not to inhibit scientific advancement or entrepreneurship. Quite the contrary, we would expect in most instances to agree to additional measurements. Our reasons for requiring that a formal request be made before undertaking any new, not previously agreed on measurements, are 3 fold.

1.) First, the DCCT/EDIC research wishes to be an active intellectual partner in any collaboration, rather than simply a passive useful source of samples and phenotypic data.

2.) Sample volumes that remain after completing the original planned analyses might be better returned to the DCCT/EDIC repository and stored for other potential future use, than for what a current collaborator wishes to measure ad hoc.

3.) Most important, we need to avoid the situation in which 2 different laboratories, unbeknownst to us, are measuring the same analyte on identical specimens. This opens up a Pandora's box of possible conflicting results and interpretations, conflicts of priority and authorship, possible IRB issues with uses for which participants had not given consent or might not if asked after the fact, and a loss of control over the study and its directions.

We intend to express this policy clearly and unequivocally to all future collaborators. We trust that all of our present collaborators will also strictly hew to this policy from now on.

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Ancillary Study Application Process

Ancillary studies will be evaluated with careful consideration of their potential impact on the objectives and performance of the EDIC. Ancillary studies that complement the objectives and thereby enhance the value of the EDIC study are encouraged. Such studies should augment and promote the continued interest of both participants and investigators. To protect the integrity of the EDIC study, a proposal to conduct an ancillary study must be reviewed and approved by the Executive and Research Review Committees followed by the Research Group before its initiation. All approved ancillary studies will be self-funded and reviewed regularly for progress and impact on the EDIC study as a whole.

A preliminary description of the project should be submitted to the EDIC Data Coordinating Center (DCC). The **3 page** summary should include the following information:

1. Investigators and collaborators name, role, and institutional affiliation. Attach NIH biosketches for investigators and key personnel.
2. Planned start and end dates.
3. Estimated costs and plans for funding, including the anticipated source of funding.
4. Design and methods:
    - Hypotheses to be tested with statement of primary and secondary goals and objectives.
    - Brief background, significance, and rationale.
    - Justification for performing study within DCCT/EDIC.
    - Description of additional methods, procedures, or tests to be carried out on study participants, including:
        - Any ophthalmologic, renal, cardiovascular, neurologic, psychological, or other evaluation to be performed, as well as tests on biological samples.
        - Any substances to be injected or otherwise administered to the participants.
        - Any observations to be made or procedures to be conducted on participants outside of the clinic.
        - Any extra clinic visits required of the participant or any prolongation of the participant's usual annual, one-day clinic visit.
        - Any additional specimens (blood, urine, etc.) to be obtained or additional procedures to be done on specimens collected according to the EDIC Protocol.
        - Any additional questionnaires or surveys to be administered to the participants.
    - Data needed (a) from the EDIC study central database and (b) from additional tests, surveys, etc. Note that data and/or samples should be requested from the NIDDK data and/or bio-repository if available to meet the needs of the proposed study.
    - Analysis plan.
    - Sample size and justification, including power calculation.
    - Burden on participants and impact on the EDIC study clinical centers and central units.
    - Measures to be taken to ensure participant safety and confidentiality.

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The applicant should explicitly state that they understand and commit to adhere to the DCCT/EDIC Publications and Presentations Policies.

In addition to the 3 page proposal, each collaborating investigator should provide a statement that they have reviewed and approved the application, are committed to participate and that they approve the funding arrangements and level of funding proposed.

All proposals should be submitted to the DCC at least 3 months prior to any grant application deadline (i.e. R01). Each proposal will be forwarded by the DCC for review by the Research Review Committee and Executive Committee, and if approved, also by the DCCT/EDIC Research Group.

After each stage of the review, the DCC will provide the applicant with an update on the status of the application and give the applicant the opportunity to reply to questions or criticisms. The PI of each application will be promptly notified of the results of the evaluation by the DCC if it is approved for implementation (conditional on funding). If the application is not approved at any step of the process, the PI will be promptly notified by the DCC and the RRC chair.

If approved, and if support is required from 1) the DCC or its subcontractors including the Central Biochemistry Laboratory and the central reading units or 2) the Clinical Coordinating Center (CCC) for study coordinator effort and clinical center protocol-based needs, the requirements (staffing and work scope) should be discussed with the DCC and CCC at least 5 weeks prior to the application due date. Final budget components and documentation should be completed by the applicant at least 15 days before the submission due date.

Contact for the DCC:
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Contact for the CCC:
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