# EDIC Ancillary Study Application Process

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.

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 EDIC Study 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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