Epidemiology of Diabetes Interventions and Complications Study (EDIC)
Ancillary Studies Policy and Procedures

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 study are to be encouraged. Such studies should augment and promote the continued interest of both subjects and investigators. To protect the integrity of the major study, a proposal to conduct an ancillary study must be reviewed and approved by the Research Review Committee before its initiation. Ancillary studies must also be approved by the Study Group. All approved ancillary studies will be reviewed yearly by the Research Review Committee for progress and impact on the study as a whole.

I. Definition of an Ancillary Study

An ancillary study is defined as research or data collection involving study subjects or specimens, using any technique, medication, procedure, questionnaire or observation other than those set forth in the Protocol.

The investigator responsible for the conduct of an ancillary study must be a member of the Study Group. If an external research request is made by an individual who is not a member of EDIC, a member of the Study Group must be a co-investigator.

II. Funding of Ancillary Studies

The study will not provide funds for ancillary studies. In particular, no funds are provided for Central Laboratory or other units or for the Data Coordinating Center activities or services in support of ancillary studies. If funds are needed, the investigator must explore other avenues such as: (1) submission of a research grant application; or (2) use of other sources of funds (i.e., a foundation, drug company, etc.) The anticipated source of funds must always be identified.

III. Reason for Requirement of Approval

Investigators and subjects are entitled to prior assurance that all ancillary studies are of high scientific merit and that no ancillary study will:

1. Cause a deviation from the Protocol;
2. Confound interpretation of the study results;
3. Adversely affect subject cooperation;
4. Jeopardize the public image of the study;
5. Create a significant diversion of the study resources locally or at the Coordinating Center or any other unit;
6. In any way negatively influence the cooperative spirit of the collaborating investigators;
7. Otherwise compromise the scientific integrity of the study.

Levels of Approval Required for Ancillary Studies

There are two levels of approval for ancillary studies:

Level I: Approval by the Research Review Committee
Level II: Further approval by the Study Group.

In general, Level I approval will suffice if the ancillary study involves analyzing available data from the study for questions not addressed in the major study, and no additional tests or observations will be made on the subjects. Other types of ancillary research will customarily require both Level I and Level II approval. The decision regarding the necessary level of approval will be made on a case by case basis by the Chair of the Research Review Committee in consultation with the Executive and/or Study Groups.

After approval by the Research Review Committee and the Study Group, final approval is contingent upon the Research Review Committee receiving a letter signed by the principal and all collaborating investigators in which they agree to abide by the policies for ancillary studies herein described including that regarding publication or presentation of results.

IV. Implementation

The request for approval of an ancillary study should be in narrative form. It should contain a brief description of the objectives, methods, significance of the study, plans for analysis and publications, and information regarding funding level and source. If a proposal is being submitted elsewhere for funding (e.g., a grant application), the source of funding should be identified and the application may be used as the basis for the request. Full details should be given concerning any procedures or tests to be carried out on a study patient including: any ophthalmologic, renal, cardiovascular, neurologic, psychological or other evaluation to be performed; any substances to be injected or otherwise administered to the patients; any observations to be made or procedures to be conducted on patients outside of the clinic; any extra clinic visits required of the patient or any prolongation of the patient's usual clinic visits; any additional specimens (blood, urine, etc.) to be obtained or additional procedures to be done on specimens collected according to the EDIC Protocol. The proposal should discuss the measures to be taken to ensure patient safety and confidentiality and an assessment by the investigator(s) of the potential impact of the ancillary study on EDIC. Prior approval by the appropriate Human Subjects Review Committee should be demonstrated. The proposal should also specify whether Level I or both Levels I and II approval is requested.

The investigator should send his/her ancillary study proposal to the Data Coordinating Center, which will distribute it to all members of the Research Review Committee. The proposal should be written in sufficient detail so that the Research Review Committee can assess the study's scientific merit and potential impact on the EDIC. To ensure thorough scientific review, the Chair of the Research Review Committee may elect to seek outside expert opinion in advance of the Committee meeting. Within 30 days of receiving the proposal, the Chairman of the Research

Review Committee will summarize the questions and objections (if any) raised by members of the Committee and refer this summary to the applicant so that he/she may amplify, clarify, and/or withdraw the request. The members of the Research Review Committee will have another opportunity to review the request and the Chair will then prepare a statement of the Committee consensus, including any remaining reservations or objections. This statement will be sent to the investigator requesting approval for the ancillary study. If only Level I approval is required and the study has been approved by this Committee, the investigator may proceed with the study when it has been approved and authorized by NIDDK. Approval or disapproval is based on majority opinion.

If Level II approval is also needed, the approval statement of the Research Review Committee will be forwarded to the Study Group. Each member should respond to the Chair of the Research Review Committee within one month. No response will be considered approval. Recommendations of the Research Review Committee and Study Group will be forwarded to the EAC for assessment of impact on the EDIC. Approved Research Review will then be forwarded to NIDDK for final authorization. The investigator may proceed with the ancillary study once it has been authorized by the NIDDK.

In the event that the Research Review Committee disapproves of a proposed ancillary project, the investigator can appeal to the Study Group, whose decision may override that of the Research Review Committee. If the Study Group also disapproves of the ancillary study, the proposed study will not be undertaken.

V. Publication of Ancillary Study Results

All manuscripts, abstracts or presentations for scientific meetings based on ancillary study data must be reviewed and approved by the Editorial Committee before publication or presentation.