

# **Family Investigation of Nephropathy of Diabetes (FIND)**

## **Subprojects and Ancillary Studies**

### **I. Objectives of the Subprojects and Ancillary Studies Subcommittee**

Subprojects and ancillary studies will be evaluated with regard to scientific merit and the potential impact on the objectives of the Family Investigation of Nephropathy of Diabetes (FIND) Study. Projects that complement the objectives of FIND will enhance the value of the study and, therefore, are encouraged. The Subproject Evaluation Subcommittee will evaluate each proposal and make a recommendation to the Steering Committee. The Steering Committee's final approval is necessary before the substudy can begin. In addition, the customary approval of the relevant Institutional Review Board(s) must be obtained.

### **II. Definition**

Subprojects and ancillary studies are defined as investigations not set forth in the primary FIND protocol that require resources (including analytic resources and genotypic data) shared by all of the FIND Participating Investigator Centers (PICs) or that relate to the molecular genetics of nephropathy. These investigations include the following types of proposals:

1. Proposals that the Genetic Analysis and Data Coordinating Center (GADCC) conduct analyses of data that are collected by one or more individual PICs and that are not part of the analyses proposed by the overall FIND protocol.
2. Proposals that the GADCC type candidate genes, which are not proposed in the FIND protocol, in samples that are collected by one or more individual PICs.
3. Proposals that individual PICs, or other collaborators, type candidate genes in samples obtained from more than one PIC, which are collected for the primary FIND protocol.
4. Analyses conducted by individual PICs or other collaborators, which employ genotypic data generated by the main FIND.
5. Proposals that all PICs collect data that is not specified in the primary protocol.
6. Proposals that an individual PIC investigate the molecular genetics of nephropathy (e.g., by association or linkage studies utilizing candidate genes or genomic segments) in data collected by the individual PIC under the FIND protocol.

Analyses, conducted by an individual PIC, of clinical phenotypic data collected by that PIC or of molecular genetic data that are unrelated to nephropathy, do not require evaluation by the Subproject Evaluation Subcommittee. (Note that any such studies using data in FIND subjects are limited by the participants' consent.)

Subprojects are defined as proposals, meeting the above definition, that are to be conducted using FIND resources. Ancillary studies are studies that require supplemental funding or resources in addition to FIND resources. For example, ancillary studies may be conducted with funding obtained from an RO1 grant from NIH. Since approval from FIND will be necessary before proceeding with such studies, it will generally be to the investigators' advantage to obtain approval for such studies from FIND before applying for supplemental funding.

### **III. Criteria**

The Subproject Evaluation Committee will evaluate proposals with regard to the following:

1. ***Impact on the objectives of FIND.*** No subproject should compromise the scientific integrity of FIND, adversely affect its public image, or cause a significant diversion of FINDS's resources. In addition, subprojects should not compete with or duplicate the main results of FIND.
2. ***Scientific merit.*** Proposals should test an important hypothesis and the design and power of the proposal should be adequate to ensure a reasonable test of this hypothesis).
3. ***Feasibility.*** Both from a practical and ethical standpoint, the input of the Consent and Ethics Subcommittee will be sought when necessary to ensure that the proposed project is within the scope of participants' consent.

### **IV. Procedures**

The Subproject Evaluation Subcommittee will meet at each FIND Investigators' meeting. Proposals for subprojects or ancillary studies should be submitted at least one month before each meeting to ensure that sufficient time is available for review.

A written request for approval of a proposed subproject or ancillary study should be submitted to the chair of the Subproject Evaluation Subcommittee. The request should be brief (no more than 5 pages), but should contain sufficient detail so that scientific merit can be assessed. It should contain the following elements in order:

1. Description of the hypothesis(es) to be evaluated
2. Background and significance of the study
3. Proposed methods
4. Analysis strategy
5. Plans for publication
6. Source of funding

If funds are being sought from outside FIND, the proposed source of such funds should be clearly identified. If additional data from subjects are to be collected (e.g., by collection of additional samples or by clinical examination), full details need to be provided. It should also be specified whether molecular or statistical analyses are to be conducted by the GADCC.

Proposals may be assigned to have a detailed or abbreviated review. Any proposals that utilize genotypic data, clinical data, or analytic resources common to more than one PIC (study types 1-5 in section II above) will receive a detailed review. Proposals that relate to the molecular genetics of diabetic nephropathy, in which all of the work, including genotyping and data analysis, will be done by a single PIC (study type 6 in section II above), will receive an abbreviated review. If a detailed review is necessary, the chair of the Subproject Evaluation Subcommittee will assign a primary and secondary reviewer from among the committee members for each proposal. The opinions of outside experts will be sought at the discretion of the committee. A statistical review by the GADCC will also be conducted.

The Subproject Evaluation Subcommittee will vote on approval or disapproval; approval is based on a simple majority of committee members. The Subcommittee chair will then prepare a written summary of the decision and forward this to the investigator(s). Copies of proposals designated for an abbreviated review will be forwarded by the chair to the Subcommittee, which will vote on whether the proposal is consistent with the objectives of FIND. Since such proposals will not use the shared molecular or analytical resources of FIND, they will not require a detailed review by primary, secondary, and statistical reviewers.

If the Subproject Evaluation Subcommittee approves the proposal, it will be forwarded to the Steering Committee, along with the summary and recommendation of the Subproject Evaluation Subcommittee. Final approval of the proposal will be based on a majority vote of the Steering Committee. If the Steering Committee approves a subproject, it will proceed. If the proposal is an ancillary study, it may proceed with Steering Committee approval once funding is obtained.

The Subproject Evaluation Subcommittee may not initially approve the proposal, but may request further information from the investigators before rendering a final decision. In such cases, the investigators will be invited to submit a revised proposal.

If the Subproject Evaluation Subcommittee disapproves the proposal, the investigators may appeal to the Steering Committee, which may override the decision of the Subcommittee. If the Steering Committee also disapproves the subproject, it will not be conducted.

#### **IV. Publication**

Publication of data from all subprojects and ancillary studies must comply with the policies of the FIND Publications Subcommittee.