**Diabetes Prevention Program Outcomes Study**

# A01Ancillary Study Application Form

Title of Proposed Ancillary Study : _____

Abbreviated Title : _____

P.I: _____

Institutional Affiliation of P.I. : _____

Mailing Address: _____

P.I. Telephone: _____Fax _____ P.I. e-mail: _____

Study Coordinator: _____Tel.:_____ Fax:_____

Date Application submitted: _____/_____/_____

DPPOS Co-P.I. (if different from P.I.):_____

**PLEASE REFER TO CHAPTER 8 SECTION 8.1 OF THE DPPOS MANUAL OF OPERATIONS FOR DETAILED INSTRUCTION ON SUBMISSIONS**

Ancillary studies will be evaluated with careful consideration of their potential impact on the objectives and performance of the DPPOS. Ancillary studies that complement the objectives and thereby enhance the value of these studies are to be encouraged. Such studies should augment and promote the continued interest of both participants and investigators. To protect the integrity of the major DPPOS study, a proposal to conduct an ancillary study must be reviewed and approved by the Ancillary Study Committee and the Steering Committee before its initiation. The investigator responsible for the conduct of an ancillary study may or may not be a member of the DPPOS Study Group. If a proposal for an ancillary study is made by an individual who is not a member of the DPPOS Study Group, a member of the Study Group must be a co-investigator. A member of the DPPOS Study Group who serves as a co-investigator must be scientifically involved in the design, execution, and interpretation of the ancillary study. In addition, he/she shall be responsible for ensuring that DPPOS policies and procedures are observed during the conduct of the ancillary study.

Any investigators applying for use of biosamples will be required to first go to the NIDDK repository and determine whether the samples available at the repository will be adequate and are available for the proposed study. The repository samples should be used if at all possible, and the use of remaining DPP samples only requested if this is not possible. If investigators proceed with a request for remaining DPP samples they must explain in their application why the Repository samples will not satisfy the proposed study's needs.

**FOR ASC USE ONLY** **Ancillary Study No.** ___ ___ ___ ___

Ancillary Study Committee Action-Approval: Yes / No Date ____ / ____ / ____

DPP Steering Committee Action- Approval: Yes / No Date ____ / ____ / ____

DSMB Action-Approval (if DPPOS data is requested) Yes / No Date ____ / ____ / ____

For Approved Applications: Consent form required? Yes / No Date ____ / ____ / ____

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## General Instructions

To facilitate review of your application, please check if you have answered the following questions:

1. **Does the study have genetic components?** **Yes** ☐ **No** ☐
2. Objective and Specific Aims (1 page max) ☐
   - What questions are you asking?
   - What do you expect to happen?
3. Background and Significance (2 pages max) ☐
   - What is the scientific relevance?
4. Study Design (2 pages max) ☐
   - What is the type of study?
   - Is the study randomized?
   - Is the study blinded? (Single blind, double blind etc.)
   - What are the inclusion/exclusion criteria?
5. Methods (2 pages max) ☐
   - a) Details of Interventions
   - b) Details of Study Procedure(s)
   - c) Details of Outcome Measurements
   - d) Power calculations for Sample Size
   - e) Analysis
6. Publications (2 pages max) ☐
7. Funding Level and Source (1/2 page max) ☐
   - Is the study funded?
   - Anticipated source of funds?
8. Participant Safety, confidentiality, Informed Consent, IRB Approval (1/2 page max) ☐
   - How will informed consent be obtained? (Attach consent)
   - Plan for participant safety, data monitoring and data management
   - IRB Approval (Required before initiation of study)

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9. Potential Impact of Ancillary Study on DPPOS (1/2 page max) ..... ☐
   - o An assessment of the potential impact by the PI(s)
   - o Does study involve additional procedures/interventions?
   - o Does study require additional clinical visits?

10. CoC Support (1/2 page max and use the enclosed Data and/or Sample Request Forms) ..... ☐
   - o What data is requested from central study records?
   - o What specimens are requested?

11. Time-Table of Ancillary Study (1/4 page max) ..... ☐
   - o Anticipated start date
   - o Anticipated enrollment
   - o Anticipated end date