

DBDC Ancillary Study Proposal/Concept Application Form (Form A)

Notes to the Applicant on application process and flow:

Following the completion of this form, the applicant must submit an electronically signed version of this application, along with all required attachments, to the Data Coordinating Center (DCC) via email at will.simmons@duke.edu.

The DCC will circulate the submitted ancillary studies proposal/concept application to the members of the Publications, Presentations, and Ancillary Studies Committee (PPAC) with instructions that they are to send their comments to the DCC by a specified date, typically one week before the PPAC meeting at which it will be discussed.

The DCC will assist the PPAC Chair and Co-Chair to collate the comments and prepare a written memo to the Steering Committee specifying the recommendation for “approval, disapproval, or resubmit with additional information or revision.” The Steering Committee will review that recommendation and make a decision. The principal investigator of the ancillary study and the DBDC sponsor will each receive notice of the date of the Steering Committee review of the study application, in a letter indicating the Steering Committee decision, and contextual information related to the decision (see below).

PPAC members (and, as needed, other reviewers) will be asked to assess the following:

- Scientific merit
- Investigator expertise and resources needed to deliver on the project
- Participant burden
- Statistical power and adequacy of statistical analysis plan
- Overlap redundancy, or conflict with ongoing DBDC studies
- Justification of biospecimen request (volume of request, appropriateness of proposed assays) and impact on the biorepository
- Justification of dataset request
- Funding plan for the use of DBDC or non-DBDC resources for the study aims
- For studies involving biospecimens, the proposed plan and timeline for destruction or other disposition of biospecimens remaining at the completion of the ancillary study

Date:

Proposed Study Title:

Principal Investigator:

Principal Investigator Contact Information:

Site/Institution:

Email:

Phone:

Collaborating Investigators or Key Personnel (Names/Institutions):

Attestation (required): The submitting investigator attests that all study investigators have reviewed the proposal and agreed to participate **prior** to submission of the proposal to the PPAC.

<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p>
<p>DBDC sponsor (if applicable) where proposing investigators are outside of the DBDC: Site/Institution: Email: Phone:</p>
<p>Study Objectives:</p>
<p>Estimated Start Date:</p>
<p>Estimated End Date:</p>
<p>Statistical Analysis Plan (Goals/Objectives/ Research Question, Hypothesis(es), Background/Rationale, Primary and Secondary Outcomes/Endpoints, Statistical Analysis Methods, and include sample figures and table shells if available) Attached (Form D): <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Specify the DBDC resources which the ancillary study wishes to use and rationale for use of DBDC resources*:</p> <p>*DBDC data sets use the DBDC participant ID number to link records. Ancillary study investigators should request data on the DBDC participants in their study by providing the relevant DBDC ID numbers. The DCC will accept SAS, Excel, Access, ASCII, and other data files of records of DBDC ID numbers (word processing files are not acceptable, other identifiers are not acceptable).</p>
<p>Financial Considerations</p> <ol style="list-style-type: none"> 1. Specify the proposed funding source: 2. Funding amount: 3. Status of funding (i.e., awarded, submitted, etc.): 4. If not submitted, include the proposed submission date: 5. Specify if any funding is to be requested for DCC or DBDC investigator-personnel time or other costs. DCC and other DBDC central resources including the NIH-NIDDK central repository may be contacted by the ancillary study PI to provide services for the proposed ancillary study: 6. If the funding is being provided through a collaboration with industry or a federal funding agency (designated as the ancillary study's Collaboration Partner), then the DBDC sponsor must have a Collaborative Partner Agreement in place with relevant institutions.

Status of IRB Approval and Approval Date (unless the IRB application is still pending, attach IRB Approval Letter to this application):

Required Attachments:

1. Statistical Analysis Plan (Form D)
2. IRB Approval Documentation (unless the IRB application is still pending)

Attestations (required)

1. The submitting investigator attests that all study investigators have reviewed the proposal and agreed to participate **prior** to submission of the proposal to the PPAC.
Yes
No
2. The DBDC Ancillary Studies Policy and the policy on presentations and publications arising from ancillary studies have been read and will be abided by the study principal investigator and personnel.
Yes
No
3. The submitting investigator understands that they are responsible for ensuring that all uses of any DBDC biospecimens or clinical data provided to the ancillary study are in accordance with the informed consent statements signed by the DBDC study participants.
Yes
No
4. The proposed study has no conflict or overlap with existing DBDC studies.
Yes
No
5. The submitting investigator understands that the ancillary study activities may not proceed until the DBDC Steering Committee has approved the ancillary study and proof of funding has been received by the Steering Committee*.
Yes
No
6. The submitting investigator attests that this form has been completed to the best of their ability using the information and knowledge available to them at the time of this submission. Any changes to the content of the form should be submitted as a revised application making note of the amendments.
Yes
No

* Ancillary studies must be supported with independent funding from non-DBDC resources. The DBDC Steering Committee will provide a letter of support for an approved ancillary study, to use in the funding application to be submitted by the ancillary study investigator(s). If funding is not approved, the letter of support and ancillary study approval may not be used for other applications without permission. For example, a revised ancillary study proposal or amendment should be submitted to the DCC and the PPAC will review and make recommendations to the Steering Committee.