

D2d Ancillary Study Application



Office Use

Ancillary Study Number _____

Date Submitted (MM/DD/YYYY) _____

Title of Proposal
(81 character limit)

Principal Investigator _____

Institutional Affiliation _____

Street Address 1 _____

Street Address 2 _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____ Email _____

Co-Investigator 1 _____

Institutional Affiliation _____

Phone _____ Fax _____ Email _____

Co-Investigator 2 _____

Institutional Affiliation _____

Phone _____ Fax _____ Email _____

If Principal Investigator is not a member of the D2d study group, please specify:

D2d Co-Investigator _____

Institutional Affiliation _____

Other Key Persons (biosketch is not required)

Name _____ Ancillary Study Role _____

Name _____ Ancillary Study Role _____

Name _____ Ancillary Study Role _____

Name _____ Ancillary Study Role _____

D2d Ancillary Study Subcommittee Use Only

Ancillary Studies Subcommittee Action

Date

Steering Committee Action

Date

DSMB Action

Date

Approved Applications

Consent form required?

Part 1: Research Plan

1a. Anticipated Timeline and Enrollment

Planned Start Date _____

Planned End Date _____

Anticipated Enrollment 250

1b. Hypothesis and Specific Aims

Please describe the question(s) you are asking and what you expect to happen (3/4 page limit).

1c. Significance and Brief Background

Please describe the scientific relevance (1 page limit).

1d. Innovation & Impact

Please describe the research innovation and potential impact (1/2 page limit).

1e. Research Approach

Please address the following: (1 and 1/2 page limit)

- *Study type (e.g. interventional or observational)*
- *Population and setting (inclusion/exclusion criteria)*
- *Study design (e.g. details of study procedures, outcome assessments, confounders, bias)*
- *Schedule of assessments*
- *Sample size (power) calculations*
- *Data analysis plan*

Please continue Research Approach on next page.

1f. References Cited

Please attach a list of references (PDF format document) with the application.

Part 2: Description of Data

2a. Required Sources of Data

Please select all that apply:

Existing data collected as part of D2d study

If yes, please complete **D2d Ancillary Study Data Request Form**

New data derived through use of stored biological specimens collected as part of D2d study

If yes, please complete **D2d Ancillary Study Specimen Request Form**

New data derived through direct contact with D2d participants (e.g. procedure, survey, observation)

If yes, please complete question 2b

If available, please include a copy of the proposed protocol with your application.

2b. New Data Acquisition, if applicable

Please describe the additional procedures, interventions or surveys required for new data acquisition and address the need for additional visits and/or the prolongation of existing visits. (1/2 page limit).

Part 3: Facilities & Resources

3a. D2d Collaborating Clinical Sites

Please note: By marking the box next to a site(s), the ancillary study PI has secured the commitment of the site(s) to the proposed ancillary study to allow generation of new data by direct contact with D2d participants at the site.

Please select all D2d collaborating clinical sites that have agreed to participate in the proposed Ancillary Study.

- | | |
|---|---|
| Atlanta VA Medical Center | NIDDK Phoenix |
| Baylor College of Medicine | Northwestern University |
| Beth Israel Medical Center | Pennington Biomedical Research Center |
| Duke University Medical Center | Stanford University Medical Center |
| Florida Hospital Translational Research Institute | Tufts Medical Center |
| HealthPartners Research Foundation | Tulane University Health Sciences |
| Los Angeles Roybal | University of Kansas Medical Center |
| Maine Medical Center Research Institute | University of Nebraska Medical Center |
| Medical University of South Carolina | University of Tennessee Health Science Center |
| MedStar Health Research Institute | University of Texas Southwestern Medical Center |

3b. Description of Clinical Laboratory Facilities, *if applicable*

Please describe clinical laboratory facilities and where and how bio-specimens will be handled (e.g. storage, shipping of biological material; laboratory staff experience).

Part 4: Potential Burden on the D2d study

*Please describe the potential burden of the ancillary study **on the D2d study** in relation to the following and provide ways to minimize the burden:*

4a. Participant Burden and Potential for Compromising Participant Retention

4b. Participant Safety and Confidentiality

Please describe measures taken to ensure participant safety and confidentiality and address plan for data management (secure storage, monitoring etc.).

4c. Burden on Collaborating Clinical Sites

4d. Regulatory Requirements

Please describe how informed consent will be obtained and describe plan for local IRB approval. If available, please attach a copy of the informed consent form.

Part 5: D2d Support

Please note: The costs associated with the use of resources (D2d or other) must be included in the plans for funding the ancillary study. All negotiated services must be documented in a letter of commitment from the provider of such services.

Please select resources at the D2d Coordinating Center or D2d Central Laboratory that will be required. There will be a fee associated with these services:

- Data extraction and transfer
- Specimen selection and transfer
- Data analyses (depending upon staff availability, proposed analyses may be conducted by the analytical team at the D2d Coordinating Center)
- Other study-specific services for studies that will collect new data in real time

Part 6: Funding

6a. Funding Source(s)

Please describe ancillary study funding source(s) or plans to apply for funding.

6b. Planned Date of Submission to Funding Agency _____

Part 7: NIH Biosketch

Please attach NIH Biosketches **for PI only** with your application upon submission.

Part 8: Acknowledgement of D2d Ancillary Studies Policies & Procedures

I have read and agree to abide by the policies and procedures for D2d Ancillary Studies as described in the document titled: *D2d Ancillary Studies Policies and Procedures & Instructions for Submission of Proposals*, and specifically regarding the presentation and publication of ancillary study results and data sharing policies.

Principal Investigator Signature _____ Date _____
(e-signature accepted)

Part 9: Attachments

Please indicate all documents that are included with your application:

- NIH Biosketches for PI only (**required for all applications**)
- References Cited (**required for all applications**)
- D2d Ancillary Study Data Request Form
- D2d Ancillary Study Specimen Request Form

Please note: The following forms are not required with application, but are required *prior to study initiation*:

- Ancillary Study Proposal (DRAFT Research Strategy as of 01 06 14)
- Ancillary Study Manual of Procedures (Brief Summary of Scope of Work is attached as Appendix A)
- Informed Consent Form (*required for studies involving generation of new data via direct contact with D2d participants*)
- IRB Approval Letter

Final steps to submission:

Save a copy of this form to your computer.

Click on the "Submit" button, which will open an email and automatically attach application. In that email, attach additional documents checked above to complete application then send.

Thank you for your interest in the D2d Study