



**D2d Ancillary Study Letter of Intent**

Office Use

Ancillary Study Number \_\_\_\_\_

Date Submitted (MM/DD/YYYY) \_\_\_\_\_

To: D2d Ancillary Studies Subcommittee

Re: D2d Ancillary Study Preliminary Concept Proposal

Title of Proposal  
(81 character limit)

Principal Investigator \_\_\_\_\_

Institutional Affiliation \_\_\_\_\_

Street Address 1 \_\_\_\_\_

Street Address 2 \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip (9-digit) \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

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

D2d Co-Investigator \_\_\_\_\_

Institutional Affiliation \_\_\_\_\_

**Significance, Brief Background, Proposed Central Hypothesis and Specific Aims**



## *D2d Ancillary Study Letter of Intent*

### **Study Design**

---

Please address study type (e.g. intervention or observational); population and setting (inclusion/exclusion); study design (e.g. study procedures, outcomes assessment and time-points, confounders); analytical methods (e.g. preliminary sample size/power calculations and assumptions).

### **Innovation and Impact**

---



**D2d Ancillary Study Letter of Intent**

**Subject Burden and Potential Risks**

Please describe (1) additional procedures that will be required of participants; (2) risks to participants from the proposed procedures; (3) ways to minimize burden and risk

[Empty box for subject burden and potential risks]

**Use of Stored Specimens**

Please select all specimens required for the ancillary study.

DNA

Plasma Amount needed: \_\_\_\_\_ mL Time point(s): \_\_\_\_\_

Serum Amount needed: \_\_\_\_\_ mL Time point(s): \_\_\_\_\_

Urine Amount needed: \_\_\_\_\_ mL Time point(s): \_\_\_\_\_

**Funding**

Anticipated Funding Source \_\_\_\_\_

Anticipated Date of Submission to Funding Agency \_\_\_\_\_

**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)

D2d Co-Investigator Signature \_\_\_\_\_ Date \_\_\_\_\_  
(e-signature accepted)