

# D2d Ancillary Study Letter of Intent



Office Use

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

Date Submitted \_\_\_\_\_

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 Code \_\_\_\_\_

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

## Study Design

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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

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## 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

## 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)*