

# 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 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)

### Final steps to submission:

Save a copy of this form to your computer.

Click on the "Submit" button and follow the directions to submit electronically. Alternatively, you may attach the file manually to an email and send to: [D2d@TuftsMedicalCenter.org](mailto:D2d@TuftsMedicalCenter.org).