D2d Ancillary Study Letter of Intent

D2d

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 <u>not</u> a member of the D2d study group, please specify:
D2d Co-Investigator _____
Institutional Affiliation _____

Significance, Brief Background, Proposed Central Hypothesis and Specific Aims

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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

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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.