



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



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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)