

D2d Ancillary Study Letter of Intent



Office Use

Ancillary Study Number _____

Date Submitted (MM/DD/YYYY) 10/31/2014

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 _____

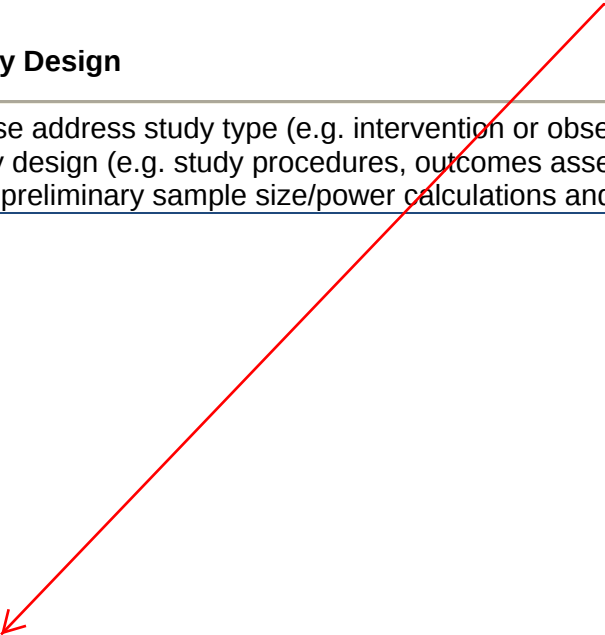
Institutional Affiliation _____

Significance, Brief Background, Proposed Central Hypothesis and Specific Aims

Study Design

Is that ethical if a person has worsening symptoms?

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
Submission

The Committee has raised concerns about using any inventor that may detect suicidal thoughts and the responsibility of the investigative site to respond and act on the reports.

How many participating sites are needed and will they all be required to have this model of device?

Please address parts 2 and 3 and detail participant time commitment.

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): _____	

Please clarify amount. We are looking for what volume per participant per timepoint is required. 100 mL does not make sense.

Funding

Anticipated Funding Source _____
Anticipated Date of Submission to Funding Agency _____

Please complete questions on funding.

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.