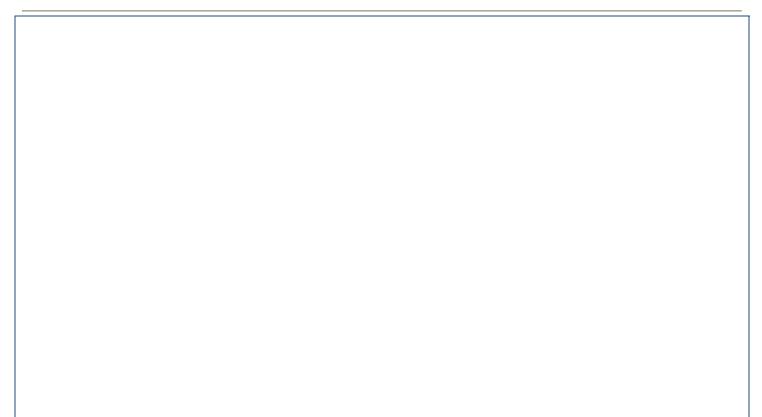
Office Use Ancillary Study Number			Date Submitted (MM/DD/YYYY)							
To: D2d Ancillary S	D2d Ancillary Studies Subcommittee									
Re: D2d Ancillary Study Preliminary Concept Proposal										
Title of Proposal (81 character limit)										
Principal Investigator										
Institutional Affiliation										
Street Address 1										
Street Address 2										
City		State	Zip Code							
Phone	Fax	Email								
D2d Co-Investigator	is <u>not</u> a member of the D									
Institutional Affiliation										

## Significance, Brief Background, Proposed Central Hypothesis and Specific Aims





### 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**

# **D2d Ancillary Study Letter of Intent**



### 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 s	specimens require	ed for the a	ancillary	r study.				
Plasma	Amount noo	dod.	ml	Time point(s):				
Serum	Amount nee			Time point(s): Time point(s):				
Urine	Amount nee	eded:	mL	Time point(s):				
Funding								
Anticipated Fundi Anticipated Date	•							
Acknowledgement of D2d Ancillary Studies Policies & Procedures								
I have read and a the document tin <i>Proposals</i> , and data sharing pol	led: D2d Ancilla specifically rega	ary Studie	s Polic	ies and Proced	dures & Instru	ctions for	Submission of	
Principal Investiga (e-signature accept						Date		
D2d Co-Investiga (e-signature accept	<u> </u>					Date		
Final steps to sub Save a copy of this Click on the "Subm manually to an ema	form to your comp t" button and follow	v the direction			v. Alternatively, y	ou may attac	h the file	