Investigator Initiated Study(IIS) Concept Form

Submitted by (Name):				
Date Submitted:	MM/DD/YYYY			
1. Protocol Title:				
2. Request Type: **(Check all that apply)**		Drug Name:		
		Financial Support (please provide details in section 10)		

Study Objectives

3. Study Background/ Rationale: Provide brief study synopsis and justification why this study has scientific merit.	
4. Study Objective(s) and Hypothesis: State the primary and secondary objectives and hypotheses.	

Study Design

5. Study Type		Pre- Clinical/Animal		Non-Clinical, Epidemiology
		Clinical(Phase ___)		Non-Clinical, HEOR
		Non-Clinical, Registry		Non-Clinical, In vitro
6. Target Subject Demographics (Do not include any patient specific information):	Please include general description of target population for study, including: Age range, Target Disease/Population and any other relevant factors.			
7. Research Setting:	Indicate: Single-site or Multi-site			
	Country of Primary Site: Additional Countries:			
8. Study Timelines	Estimated Duration of Study: Estimated Study Start: Estimated Study Completion:			
9. Statistical Plans Include a simple description of how you plan to analyze the study data. Provide a justification for clinical sample size and primary hypothesis testing.				
10. Study Budget	Total Amount requested: $			
	insert high-level breakdown of study costs/detail of the budget			

Investigators

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11. Principal Investigator Information **ATTACH CURRICULUM VITAE**	**Name:**			
	Title:			
	Institution:			
	Address:			
	City:			
	State/Province:		**Post/Zip Code**:	
	Country:			
	Phone:			
	Fax:			
	E-mail:			
12. Co-Investigators / Sub-Investigators	list names and institutions of potential Co-, Sub-investigators			