Investigator Initiated Trial Concept Submission Form

Date:	
Study Title:	
Principal Investigator:	
Principal Investigator Contact Information:	
Affiliation/Institution:	
Type of Study	◯ Clinical ◯ Non-Clinical

Background and Rationale: (Brief discussion of study rationale and the unmet need this study addresses)
Study Summary: (Hypothesis, Rationale Primary Objective, Secondary Objectives, Exploratory Endpoint)

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Study Concept Design: (Briefly describe study design, study scheme, drug dose, key inclusion/exclusion and safety stopping rules)
Sample Size and Estimated Trial Duration: (Briefly describe sample size, statistical analysis, and estimated duration for the study)
Timeline for Enrollment:
Duration of Study:
Estimated number of patients with this disease seen at your center:
Publication Plan: (Estimated 1st publication – Identified journal or congress)
IRB Meeting Schedule: (Estimated timeline for regulatory review and contracting)
Research Staff/Coordinator:

Grant Request: (Attach draft simple budget per patient including overhead costs)

◯ Drug Only ◯ Funding (Attach Draft Budget) ◯ Drug and Funding (Attach Draft Budget)