

Keryx Investigator Sponsored Research

All fields are required. If a field is not completed, please note the reason. If not applicable, please indicate NA

Proposed Study Title

Study Title:

Request Date:

Principal Investigator Contact Information

Name:

Title:

Address 1

Address 2

City, ST, Zip

Phone/Fax:

E-mail:

Institution Contact Information

Name:

Address 1

Address 2

City, ST, Zip

Phone/Fax:

website

Contracting Information (if applicable)

Name:

Phone/Fax:

E-mail:

Study Information

Indication

Phase:

Number of Subjects:

Background and Rationale

- Provide background on unanswered question(s) the study is attempting to answer

Study Objectives

- List the objectives to correspond directly with the listed hypotheses

Hypothesis

- List the clinical Hypotheses in order of priority

Study Design/Research Plan

- Provide a concise overview stating the type of experimental design

Tests

- Include biomarkers

Statistical Plans

- Include justification for clinical sample size and primary hypothesis testing

Budget Summary	
Direct Study Costs Please enumerate	Subject related cost: Study related personnel cost: Diagnostic Fees: Data management: Other:
Indirect Study Costs Please enumerate	IRB Fee: Equipment/Supply Fee: Animal-related costs: Other:
Total Amount Requested:	
Additional sources of funding required? (Yes/No) If Yes, please specify.	
Timelines and Study Plans	
Number of Sites:	
Site Names:	
Study Start Date:	
Study End Date:	
Sample Size:	
Publication Plan	
Where are you planning to submit for publication? (journals, etc):	
Are you planning to present your data at a scientific meeting?	
Please list your target date for submission of publication.	

Drug Supply Information

Drug Supplies Required (Yes/No)?	
List Drug Supplies and Amount Required:	Drug Name: Amount:
List Drug Supplies and Amount Required:	Drug Name: Amount:
Placebo Required (Yes/No)?	
Additional Sources of Drug Supply (Yes/No). If Yes, please specify	