Investigator Sponsored Research Proposal

All fields are required. If a field is not completed, please note the reason. If it's not applicable, please indicate N/A.

Request Date:	
Principal Investigator Contact Information	
Name:	
Title:	
Address 1:	
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Phone:	
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Sub-Investigator Contact Information	
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Institution Contact Information	
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Address 1:	
Address 2:	
City, State, Zip, Country:	
Phone:	
Fax:	
Website:	

Legal/Contracts Contact Information	
Name:	
Title:	
Phone:	
Fax:	
E-mail:	
Study Information	
Proposed Study Title:	
Akebia Drug (if applicable):	
Sample Size:	

Background and Study Rationale

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

Study Objectives

- **List the objectives and endpoints to correspond directly with the listed Hypotheses**

Hypothesis

- **List the Hypotheses in order of priority**

Study Design/Research Plan

- **Provide a concise overview stating the type of experimental design**

Treatment Plan

- **Describe the dosing regimen, administration, and schedule**

Inclusion and Exclusion Criteria

- **Define the target population and include demographic and clinical characteristics for (in)eligibility**

Laboratory Procedures/Evaluations

- List all laboratory tests to be done (i.e. biochemistry, biomarkers, etc.)

Statistical Plans

- Include justification for sample size and primary hypothesis testing

Budget Summary	
Total Amount Requested:	
Additional sources of funding required (Yes/No)? If Yes, please specify.	
Regulatory	
Will an IND be required:	❑ Yes ❑ No ❑ Unknown
Timelines and Study Plans	
Number of Sites:	
Site Names:	
Study Start Date:	
Study End Date:	
Drug Supply Information	
Drug supplies required (Yes/No)?	
List drug supplies and amount required.	**Drug Name:** **Amount:**
Placebo Required (Yes/No)?	
Additional sources of drug supply (Yes/No)? If Yes, please specify.	

The requirements for the **transfer of collected adverse event data to Akebia**, including timeframes, are defined in the ISR Agreement. They include the transfer to Akebia in an ongoing manner of reports of SAEs, drug exposure during pregnancy, drug misuse or abuse and, where required, non-serious adverse drug reactions and any other information that may suggest a change in the benefit-risk profile for the Akebia drug. In addition, AE reconciliation between the Sponsor's trial database and an output from the Akebia safety database will be required to be performed periodically throughout the trial. Once the study concept is approved and the ISR agreement is executed, please refer to the ISR agreement for exact requirements for the type of trial you are proposing.

Key References	*[Please list all key references here.]*

Investigator Attestation Statement
Akebia supports medically and scientifically sound independent research initiated by external investigators and aimed at the advancement of scientific knowledge in therapeutic areas of interest for Akebia. Akebia evaluates unsolicited proposals from independent researchers or their institutions for support. By signing below, you represent that: • the research proposal you are submitting was independently conceived by you and not solicited by any Akebia employee, • you will comply with Akebia safety requirements, • you have the capability to run the ISR in an ethical and compliant manner, • you assume all of the responsibilities in your role as the Sponsor and Investigator per applicable guidelines.

Investigator's Name and Signature (MUST BE WET SIGNATURE)	
Name:	
Signature:	
Date:	