Investigator Initiated Studies Program: Study Concept Form

The purpose of this form is to collect preliminary information on the nature of the proposed study and its institution(s). Once completed, please forward to IIS_grants@chiasmapharma.com. All submissions will be reviewed by the Chiasma Investigator Initiated Studies Committee on the basis of scientific merit, regulatory requirements, site qualifications, and budget. Please allow 6-8 weeks for review.

Responsibilities of the investigator include all SAE reporting, drug accountability, posting and maintaining study on clinicaltrials.gov and responding promptly to requests for study updates.

Section I: Personnel	
Submitted by: Name **Title** **Office** **Institution**	
Primary Contact (if different from above)	
Date Submitted	
Primary Investigator: **Name** **Title** **Institution** **Address** **City** **State/Zip** **Phone** **Fax** **Email**	
Other Investigators: **Name** **Title** **Institution** **Address** **City** **State/Zip** **Phone** **Fax** **Email** **Please attach a comprehensive list.**	

Section II: Study Overview	
Study Title	
Description of Concept	
Therapeutic Area (s)	
Study Institution (if different from Primary Investigator's) Name Title Institution Address City State/Zip Phone Fax Email	
Support Type Monetary? Product?	
Total Funding Request Please attach a full breakdown of expenses	
Have you submitted a concept form to Chiasma before? If so, what was the committee decision?	
Does the study institution listed above currently have an IIS with Chiasma?	

Section III: Study Design	
Use this section to provide a more comprehensive summary of the study	
Provide justification for why this study has scientific merit and requires Chiasma's support	
Study type: registry, prospective, retrospective, other	
Randomized, controlled, other	
Cohort, case series	
Hypothesis	
Primary Objective	
Secondary Objective(s)	
Primary Endpoint	
Secondary Endpoint(s)	
Key Inclusion / Exclusion Criteria	
Anticipated Start and End Date Please attach a timeline of major events.	
Enrollment Period	
Number of sites	

Number of subjects	
Target subject demographics (age and gender)	
Anticipated output (manuscript, abstract, conference presentation, other) **Please also list your anticipated target.**	

Section IV: Institution Profile	
Research Institution if different from above Institution Address City State/Zip Phone Fax Email	
Central or Local IRB?	
IRB Name	
Additional facility approvals necessary	
Other necessary resources available to support the study	

Certification and Acknowledgement

1. I understand that all studies affiliated with and supported by Chiasma must follow all laws and regulations at the local, national, and international level.
2. I understand that all studies affiliated with and supported by Chiasma must follow all applicable scientific and ethical guidelines.
3. I understand that the responsibilities of the investigator include all SAE reporting, drug accountability, posting and maintaining the results of studies, and responding to scheduled requests for updates.
4. I hereby certify that I have read and acknowledge the above statements, and that all information as part of this application are true and complete to the best of my knowledge.
5. I hereby certify that this study and design do not in any way violate applicable law and regulation.

_____

Signature

_____

Name

_____

Date