



Investigator Initiated Studies Program: Full Application

This application is to be completed after the Chiasma IIS Review Committee has examined a concept proposal and has approved the submission of a formal application. Once completed, please forward to iis_grants@chiasmapharma.com. All submissions will be reviewed by the Chiasma Investigator Initiated Studies Committee. Please allow two 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.

All applications must be accompanied by the following materials:

1. Letter of Formal Request, including:
 - a. On department letterhead and signed by the grant requestor
 - b. Research team overview
 - c. All other funding sources
 - d. Relevant FDA requirements and plans to comply with these regulations
2. Proposed Protocol, including
 - a. Design
 - b. Endpoints
 - c. Number of subjects
 - d. Inclusion and exclusion criteria
 - e. Dosing (planned and total)
 - f. Adverse event reporting
 - g. Data collection methods
 - h. Statistical analysis plans and methods of endpoint analysis
3. Details Study Timeline of Execution, including post-IIS activities and publications
4. Detailed Study Budget, including itemization of costs and services
5. Medical License and Updated CV of all Investigators
6. IRB and Ethics Board Approval
7. Training Documentation
8. Informed Consent Form
9. FDA Form 1571 / 1572 is applicable
10. Evidence of good medical standing, including no debarments.



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 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.
4. I hereby certify that this study and design do not in any way violate applicable law and regulation.
5. I understand that grant support is contingent about the execution of a formal Agreement between Chiasma and my institution.

Signature of Grant Requestor

Name of Grant Requestor

Date