Investigator Initiated Study Protocol

Submitted by (Name):		
Date Submitted:	MM/DD/YYYY	
1. Protocol Title:		
2. Request Type: **(Check all that apply)**	☐	Drug Name:
	☐	Financial Support

Study Objectives

3. Study Background/ Rationale	Reasons for conducting the clinical study based on current knowledge of the product and /or disease state so that the study is presented in the proper perspective. Include the rationale for conducting the study and selecting the dose(s). Selected literature references critical to the study design, dosage selection, or rationale for the study should be cited, as appropriate.
4. Study Objective(s) and Hypothesis: State the primary and secondary objectives and hypotheses.	The objectives must clearly define and specifically state what the study is intended to accomplish. The primary efficacy and safety hypotheses should correspond directly with the primary objectives of the study. All hypotheses should be in the order of priority.

Study Design

5. Study Type	☐	Pre- Clinical/Animal	☐	Non-Clinical, Epidemiology
	☐	Clinical(Phase ____)	☐	Non-Clinical, HEOR
	☐	Non-Clinical, Registry	☐	Non-Clinical, In vitro
6. Target Subject Demographics (Do not include any patient specific information):	Include general description of target population for study, including: Age range, Target Disease/Population and any other relevant factors.			
7. Research Setting:	Indicate: Single-site or Multi-site			
	Country of Primary Site: Additional Countries:			
8. Study Timelines	Estimated Duration of Study: Estimated Study Start: Estimated Study Completion:			
9. Statistical Analysis Plans	<u>Power/Sample Size:</u> In studies with hypotheses, minimally, for the primary endpoint of the study, a power statement needs to be included to show the detectable difference relative to the primary hypothesis. For example: Based upon a sample size of n=40 patients per group, this study has 80% power to detect a 5.4 mmHg difference between groups in systolic blood pressure; this calculation is based on a between subject standard deviation of change of 9 mmHg			

	for systolic BP (reference for where this variability statement originated). In estimation studies, the precision of the primary/secondary estimations needs to be given with the sample size of the trial. State who will be responsible for analyzing the study data (Investigator, contract CRO, etc.). When appropriate state how the blind will be maintained during the study, as appropriate, and when the data will be un-blinded. <u>Variables/Time Points of Interest</u> All variables (primary and secondary) that are listed in the study hypotheses, and the time points at which they will be analyzed, need to be described. Efficacy variables discussed in this section should have been included as part of an objective or hypothesis section. <u>Multiplicity</u> If appropriate, describe the multiplicity approach to support the statistical conclusions of the trial. <u>Statistical Methods</u> All planned primary analyses and key secondary analyses should be discussed in this section. If other secondary and tertiary analyses are planned, include a statement describing these additional analyses. Describe the statistical methods that will be used for the primary hypotheses or estimation. State the statistical tests which will be used (e.g., ANOVA, Kaplan-Meier) along with other important considerations (e.g., factors in ANOVA, pre-specification of covariates, strata for Mantel-Haenszel, use of historical controls).
10. Specific Drug Supply Requirements	The following should be indicated in the study protocol or provided by the investigator: Indicate whether your institution's pharmacy will require bulk supplies from Kiniksa (one large container with tablets, capsules, etc.). If bulk supplies are provided, indicate if your institution's pharmacy will responsible for filling individual patient containers, labeling the containers and performing the blinding of the supplies. A description as to how the clinical supplies are to be packaged and labeled for each patient should be added to the protocol. If Kiniksa is packing and labeling the containers, provide a translation of the label text and patient instructions in your native language. If a study is to be conducted in a country within the European Union and follows the EU Clinical Trial Directive, the EUDRACT number must be obtained by the investigator and provided. Note: At conclusion of the study or upon drug expiration, Kiniksa will be responsible for

	issuing a Drug Disposition Letter to the investigator for US based studies. For US and non-US studies, the investigator will be responsible for the destruction of the supplies at the study center pursuant to the ICH/GCP Guidelines, local regulations and the investigator's institutional policies. Clinical supplies must be received by a designated person at the study site, handled and stored safely and properly, and kept in a secured location to which only the investigator and designated assistants have access. Clinical supplies are dispensed in accordance with the protocol. The investigator is responsible for keeping accurate records of the clinical supplies, the amount dispensed to and returned by the patients, and the disposition at the end of the study.
11. Publication Plan	Details of the publication and the obligations to Kiniksa will be outlined in the study agreement. The following should be considered for the publication plan if applicable: • Journals that you plan to submit a manuscript to (including projected target date for submission). • Scientific meetings that you plan to submit an abstract to (including projected target date for submission).
12. Adverse Experience Reporting	The study agreement outlines the requirement for adverse experience reporting. For clinical protocols, if the Kiniksa AER form is not used (in general, this would apply to non-US. studies whose local requirements may prohibit the use of the agreement), specific adverse experience reporting requirements must be identified.
13. Itemized Study Budget	A detailed, itemized, study budget detailing the costs associated with the study should be provided. A budget template is provided as a reference document on the Kiniksa IIS website. In general, Kiniksa limits indirect costs (overhead) to 30%. In some circumstances Kiniksa may agree to a higher rate. If your institution has a rate of greater than 30%, please provide a letter from your institution specifying the higher rate.

Investigators

14. Principal Investigator Information **ATTACH CURRICULUM VITAE**	**Name:**			
	Title:			
	Institution:			
	Address:			
	City:			
	State/Province:		**Post/Zip Code**:	
	Country:			
	Phone:			
	Fax:			
	E-mail:			
15. Co-Investigators / Sub-Investigators	list names and institutions of potential Co-, Sub-investigators			