**Amicus Investigator-Initiated Studies**

By applying for support of an Investigator-Initiated Study (IIS), you agree that the personal data submitted by you and collected by Amicus may be processed for conducting and facilitating any interactions between you and Amicus in connection with your enquiry about research related funding and any related interactions, in each case in accordance with the GDPR and all other applicable laws (the “**Purposes**”).

In order to carry out the aforementioned Purposes your personal information may be disclosed to Amicus’ authorized personnel within Amicus’ affiliates, who may be located outside of your home country, including to the U.S. or to other non-EEA countries. Your data will be processed in accordance with Amicus’ Global Privacy Policy, but you will have the right to access, rectify, or erase your personal data that is being processed by Amicus at any time. You may also withdraw your consent, following which Amicus will no longer be able to communicate or otherwise interact with you, whether for the Purpose or otherwise.

To exercise these rights, or if you have concerns about Amicus’ processing of your personal data, please address these to: dataprivacyofficer@amicusrx.com.

Amicus’ receipt of the IIS Concept form does not and will not constitute a legally binding agreement or commitment to enter into an agreement.

|  |
| --- |
| **Amicus Investigator-Initiated Study Concept**All fields are required, incomplete forms will not be reviewed. If a field is not applicable, please indicate ‘N/A’. |
| **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 (do not exceed one page).** |
|  |
| **Study Design****Provide a concise study design overview stating the type of experimental design, the hypotheses, and objectives. List the objectives to correspond directly with the listed hypotheses.** |
|  |
| **Treatment****List the clinical dosage/dosage form, route, and dose regimen, if applicable. If treatment is not part of the study,** **please indicate ‘N/A’.** |
|  |
| **Statistical Plans****Include a simple description of how you plan to analyze the study data. Provide a justification for clinical sample size and primary hypothesis testing.** |
|  |
| **Budget Summary****A detailed budget will be required if your study is moved to full protocol.****Indirect costs (overhead) should not exceed 30%** |
| **Total Amount Requested:****(Include overhead)****Please also add additional detail- Lab costs, Personnel costs, etc.** |  |
| **Additional sources of support required? (Yes/No)****Please be specific. Drugs supply, Assay support, etc.** |  |
| **Timelines and Study Plans** |
| **Study Start Date:** |  |
| **Study End Date:** |  |
| **Number of Subjects:** |  |
| **Enrollment Period in Months:** |  |
| **Publication Plan** |
| **Where are you planning to submit for publication? (journals, etc.)** |  |
| **Are you planning to present your data at a scientific meeting? If yes, list the name and the location of the meeting.**  |  |
| **Please list your target date for submission of publication.** |  |
| **Drug Supply Information** |
| **Drug Supplies Required (Yes/No)?**  |  |
| **Additional Sources of Drug Supply (Yes/No). If Yes, please specify** |  |

|  |
| --- |
| **Please respond.** A) Are you requesting funding from any source other than Amicus? B) Has any portion of the protocol been initiated? Please do not begin the IIS until the protocol is fully approved and the research agreement has been executed. C) Have you ever been debarred, excluded, or otherwise restricted from research funding from any regulatory agency? |
| **A)****B)****C)** |