**INVESTIGATOR INITIATED STUDIES (IIS) APPLICATION FORM**

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| **Protocol Title:**  | [Insert the full title as it appears in the protocol.] |
| **Principal Investigator Name:** | [Insert name.] |
| **Principal Investigator Contact Information:** | [Insert address, phone and e-mail address.] |
| **Institution Name(s):** | [Insert Institution where study will be conducted.] |
| **Sub-Investigator Name and contact details if applicable:** |  [Insert] |
| **Do you plan on using other Institutions or centers to conduct study?**  | [ ]  YES [ ]  NO\*\*Please note that Institution will be responsible for contracting with any sub-sites\*\* |
| **Rationale:** | [List the major reasons why the study should be conducted including, but not limited to, the novel scientific question which will be evaluated during the study. Provide a scientific rationale and brief summary of information gathered from past studies.] |
| **Study Design:**  | [Insert key details including treatment duration, blinding, control agent, randomization, and treatment sequence .] |
| **Objectives:** **Study Schema:**  | Primary: [Insert the primary objective(s)]Secondary: [Insert the secondary objective(s)][Insert study schema.] |
| **Subjects and Centers:** | [Insert a summary of the study population, total number of subjects, subjects per each arm, etc.] |
| **Inclusion Criteria:**  | [Insert the key inclusion criteria.] |
| **Exclusion Criteria:** | [Insert the key exclusion criteria.] |

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| **Other Therapy:**  | [Clarify the expected sourcing for other therapies]  |
| **Efficacy Measures:**  | [Provide information about the main efficacy assessments with a descriptive statement and frequency for each: include clinical, laboratory, radiographic, and subject self-assessment.]  |
| **Safety Measures:** | [Provide information about the main safety assessments with a descriptive statement and frequency for each: include clinical, laboratory, radiographic, and subject self-assessment.] |
| **Translational Science:** | [Planned assays and methods, planned time points for each assay, and justification for the correlative science.] |
| **Statistical Analysis:** | [High level sample size calculations and rationale, statistical plan, and whether there will be interim analyses] |
| **Data Collection:** | [Describe methods of collecting study data (e.g. Case Report Forms (CRFs), Electronic Data Capture (EDC), etc.). |
| **Study Drug Regimens:** | [Insert dose, frequency, route, and duration for both investigational drug and any comparative drug.] |
| **Study Drug Requested per Patient:** | [Provide an estimate of the amount of drug and placebo required for the trial.] |

**Type of Support Requested (check one):**

**Drug** [ ]

**Financial** [ ]

**Drug and Financial** [ ]

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| **Estimated Study Start**  | [Insert the estimated start of the study using the format : DD/MM/YYYY.] |
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| **Estimated Study Stop:** | [Insert the estimated end of the study using the format : DD/MM/YYYY.] |
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| **Funding:** | [Insert the estimated budget requested.]**\*\*Please note that the IIS Grants does NOT fund capital equipment or personnel/salary costs\*\*** |
| **Other sources of funding:** | **Other sources of funding for this study are**:[Insert other current sources of funding including NIH grants and other company-sponsored grants] |
| **Other sources of study drug:** | [Insert any current or pending sources of study drug supply and other company-sponsored grants.] |
| **Intellectual Property Disclosure:** | [Please disclose if you or your institution have any intentions to file intellectual property positions or if there are existing intellectual property positions related to the study drug] |
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