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

|  |  |
| --- | --- |
| **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 fax number, and e-mail address] |
| **Institution Name(s):** | [Insert Institution where study will be conducted] |
| **Sub-Investigator Name, if applicable:** |  |
| **Do you plan on using other Institutions or centers to conduct study?** **If yes, please list name(s) and address(es):** | [ ]  YES [ ]  NO[Insert name(s) of other Institution(s) or center(s) and their respective Principal Investigators and Sub-Investigators, if applicable]\*\*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 brief summary of information gathered from past studies, and conclude with the reason this study is taking place. Include justification for any placebo control.] |
| **Study Design:**  | [Insert one sentence including treatment duration, blinding, control agent, randomization, and treatment sequence (e.g., parallel groups, etc).] |
| **Objectives:** **Study Schema:**  | Primary: [Insert the primary objective(s)]Secondary: [Insert the secondary objective(s)][Insert study schema] |
| **Subjects and Centers:** | [Insert a one-line summary of the study population, total number of subjects, subjects per each arm, etc.] |
| **Inclusion Criteria:**  | [Insert all the inclusion criteria.] |
| **Exclusion Criteria:** | [Insert all the exclusion criteria.] |

|  |  |
| --- | --- |
| **Other Therapy:**  | [If required, split the therapies into prior and concomitant therapy. Mention any therapy that will be specifically allowed or disallowed by the protocol.] Length of washout period will be [Insert length of washout period]. *(Delete this statement if study has no washout period.)* |
| **Efficacy Measures:**  | [List all efficacy assessments with a descriptive statement and frequency for each: include clinical, laboratory, radiographic, and subject self-assessment.] *(If a Quality of Life, patient-related outcome, or other self-assessment is used, note if translation will be required.)* |
| **Safety Measures:** | [List all safety assessments with a descriptive statement and frequency for each: include clinical, laboratory, radiographic, and subject self-assessment.] |
| **Correlative Science:** | [Planned assays and methods, which planned laboratories will be used, planned time points for each assay, and justification for the correlative science.] |
| **Statistical Analysis:** | [Specify power, sample size calculations and rationale, statistical plan, and whether there will be interim analyses][Insert criteria for evaluability including intent to treat, per protocol, and safety population] |
| **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 exact amount of drug and/or placebo **per patient**]  |

|  |  |  |
| --- | --- | --- |
|  | **Total study drug amount in units (tablets, capsules, vials, etc.):** |  |
|  | **Total Active Drug** |  |  |
|  | **Amount of Pure Substance (if applicable)** |  |  |

**Are Clinical/Drug Supplies Requested? (**check only 1 box**): [ ]  ‘YES’ [ ]  ‘NO’**

|  |  |
| --- | --- |
|  |  |
| **Estimated Length of Enrollment:** | [Insert duration of time in weeks, months or years. First patient in to last patient out] |
| **Description of Site Enrollment Capabilities:** | [Insert information supporting your/your site’s capabilities for enrolling the patient population included in this study] |
| **Estimated Study Duration:** | [Insert approximate number of months from fully executed contract to completion of all study-related activities] |
| **Potential written outcomes of this study (check all that apply):** | [ ]  Final Study Report [ ]  Submit for Presentation at scientific conference [ ]  Submit for Publication [ ]  Submit Abstract/Poster at scientific conference |
| **Publication Plan (if applicable):** | [Include expected journal name and estimated date of publication submission.] |
| **Manuscript Publication Assistance:** | Do you require Manuscript Publication Assistance, as outlined below?: **[ ]** Yes  **[ ]** No ⁪Eisai supports the exercise of academic freedom and transparency regarding the results of clinical studies of its products, and therefore encourages Investigators to publish study results, whether or not the results are favorable to the Study Drug. In furtherance of the development of robust scientific literature regarding its marketed products, Eisai offers manuscript publication assistance to Investigators/Institutions in the form of a nominal payment of up to a maximum amount of $5,000.00 to help defray editorial costs or other outlays or publication expenses which are directly related to preparing and submitting manuscripts for research funded under Eisai’s IIS Program. The amount of this manuscript publication payment is not negotiable and no payment is available for the preparation or submission of abstracts, posters, or any related travel costs or presentation costs for any abstracts or posters. This payment is not conditioned in any way on the achievement of any specific scientific outcomes or the inclusion of any specific conclusions in any such manuscript. In order to be eligible for such payment, the Investigator/Institution must comply with recognized ethical standards concerning publication and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, www.icmje.org, established by the International Committee of Medical Journal Editors, and must, in the form of manuscript disclosure statements, appropriately disclose funding and other support received in connection with the Study and the preparation of any manuscript. Prior to publication of such manuscript, Institution agrees to provide Eisai with a copy of such manuscript disclosure statements so that Eisai may have a reasonable opportunity to review and confirm that such statements fully and accurately describe Eisai’s relationship with the author(s), including the funding and other support received in connection with the Study and the preparation of any manuscript. This additional payment will be paid upon Eisai’s receipt of a copy of the final draft manuscript with a signed Publication Certification, a copy of which is attached as Appendix 1, [along with a reasonably detailed invoice for the payment]. |

|  |  |
| --- | --- |
| **FUNDING requested:** | Insert total Budget requested and complete/submit the Eisai IIS budget template. **\*\*Please note that the IIS Grants Committee 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]The following are other pending sources of funding:[Insert other pending sources of funding] |
| **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] |
| **Research Team Members/Co-Investigators and all others’ Responsibilities:** | [List members with full contact information] |
| **Insurance:** | [Insert the amount of professional liability, general liability and all other insurance coverage that will be obtained to cover this study.] |
| **Past History and Experience:** | [Insert any previous IIS experience and information regarding debarment, exclusion and/or any prior disciplinary action] |
| **References:****IND:** | [Insert references applicable to this proposal – or – provide a separate attachment as a word document][Please confirm if you will be submitting for an IND Exemption or Number from the FDA.][ ]  IND Exemption [ ]  IND Number |

**Appendix 1**

**Publication Certification**

This Publication Certification is issued pursuant to the Investigator Initiated Study Grant Agreement, dated as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 201\_ (the “**Agreement**”) by (**“Institution”**), having an address at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and (**“Principal Investigator”**), having an address at\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Any capitalized terms not otherwise defined herein shall have the same meaning ascribed to them in the Agreement.

The attached manuscript was submitted to: [INSERT NAME OF JOURNAL]

The attached manuscript was submitted on: [INSERT DATE OF SUBMISSION]

Institution and Principal Investigator each hereby certifies that, to the best of their respective knowledge and belief, they have complied with the publication terms set forth in [INSERT SECTION(S) OF AGREEMENT]. In particular, that the Institution/Principal Investigator has prepared and has submitted the attached manuscript to an objective, scientific journal having a robust peer review process and that the Institution/Principal Investigator has: (1) complied with recognized ethical standards concerning publication and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, www.icmje.org, established by the International Committee of Medical Journal Editors; (2) disclosed in connection with the submission and publication of such manuscript all financial or in-kind support received from any other third parties for the conduct of the Study; (3) disclosed Eisai’s relationship with the authors fully and clearly in the conflict of interest disclosure, including the funding and other support provided by Eisai in connection with the Study and the preparation of any manuscript; and (4) in accordance with the terms of [INSERT SECTION(S) OF AGREEMENT], provided Eisai with a copy of any manuscript generated in connection with the Study at least thirty (30) days prior to its submission to a scientific journal, in order to allow Eisai to review said publication or presentation for Confidential Information.

If the publisher of the manuscript requires additional edits to the disclosure statements which have been included in the attached manuscript, Institution and Principal Investigator agree to provide Eisai with a reasonable opportunity to review and confirm that such edited statements fully and accurately describe Eisai’s relationship with the author(s), including the funding and other support received in connection with the Study and the preparation of any manuscript.

**INSTITUTION**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PRINCIPAL INVESTIGATOR**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_