Eisai Inc.

Investigator Initiated Studies (IIS) Program
Information Needed for Your Neurology Application

Thank you for your interest in Eisai's Investigator Initiated Studies (IIS) program. To assist you with submitting your IIS application, we have prepared a list of the required information. The following is a checklist of the items needed, as well as details on each specific item:

- Cover letter on institutional letterhead with principal investigator signature and title of IIS request – see below for more details
- Eisai IIS Request Form (Application) – see below for more details
- Eisai Budget spreadsheet – see below for more details
- Principal investigator CV and CV for all sub-investigators, to the extent applicable
- Current professional license for principal investigator and all sub-investigators, to the extent applicable

Cover Letter

Please attach a **signed** cover letter on institutional letterhead which **must** include the following:

- The subject line of the letter should read as follows: Subject: IIS Request; (Product Name); (Study Title)
- A statement requesting funds and/or drug supplies and a short description of the request
- A statement declaring to whom funds should be paid (provide contact and address details)
- List the Tax ID number of the institution
- Provide an original signature by the principal investigator or appropriate representative
- Include full contact information, phone, fax, address and email information

Budget Spreadsheet

A template is provided on the EisaiGrants website which we require you to use for the budget review. Please provide a detailed outline of all costs for which you are requesting support. Costs should be provided on a per-patient basis.

Important Information

1. Please note that the IIS Grant Committee does NOT fund capital equipment.

2. Please note that the IIS Grant Committee does NOT fund personnel/salary costs. However, we will cover tasks/time it will take personnel involved in the study to complete these tasks. Along with this, please provide detail on the tasks (costs for each/percentage of time) each person is going to complete (ie, medical history, informed consent, vital signs, etc.).

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3. Please note that if you are requesting funding for a study which includes indirect costs for institutional overhead, the IIS department requests a copy of your site's policy for these costs.

4. Please note - if your OH is over 25% please send in a copy of your institutional OH Policy

Eisai IIS Application Form

Study Sites

Provide the names of the personnel involved with the study. The Primary Investigator (PI) for each site and his/her CV must be provided along with the following:

- Site Name
- Primary Investigator
- Primary Contact
- Address
- Phone
- Fax
- Email

Study Details

Rationale - List the major reasons why the study should be conducted. 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.

Primary Objectives - List the primary objective(s).

Secondary Objectives - List the secondary objective(s).

Study Schema – Please insert your study schema into the application or include it separately.

Subjects and Centers - Insert a one-line summary of the study population, total number of subjects, subjects per each arm, etc.

Inclusion Criteria - List all the inclusion criteria.

Exclusion Criteria - List all the exclusion criteria.

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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. Insert length of washout period, if applicable.

Efficacy Measures - List all 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, statistical plan, and whether there will be interim analyses. List 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 Drug Supply - Provide drug supply requirements by unit (tablets, capsules, vials, syringes, etc.).

Study Timelines:
Estimated study start date
Estimated first patient in (if applicable)
Estimated 50% enrolled date (or 50% completed date if you are not enrolling patients)
Estimated final study report completion date
Estimated study end date
Publication Plan (expected journal name and estimated date of publication submission)

Manuscript Assistance Program – Please confirm whether or not you would like to receive a nominal fee of $5,000 for assistance in your publication.

Budget - Insert total Budget requested and per patient amount on the application form AND complete the Eisai IIS budget template. **Please note that the IIS Committee does NOT fund capital equipment or personnel/salary costs.**

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Other Funding/Study Drug Sources – Will you be receiving support from any other organizations (Ex. – NIH or company-sponsored grants)?

Intellectual Property Disclosures - 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 – Please list all members of your team

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 – Please list any past history of IIS Studies you have conducted or have been a part of

IND – Please confirm if you will be submitting for an IND Exemption or Number from the FDA

Additional documentation that supports your application may also be provided in your email.

TO ACCESS THE IIS HOME PAGE, GO TO
http://www.eisaigrants.com/