



Eisai Inc.

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

Dear Applicant:

Thank you for your interest in Eisai's Investigator Initiated Studies (IIS) program. To assist you with preparing your IIS application, we have prepared a list of information that you should have ready when you complete the application forms. The following is a checklist of the items which we request as part of your submission:

- Cover letter on institutional letterhead with principal investigator signature and title of IIS request**
 - **The request letter must include the following information:**
 - 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
 - A short description of the IIS request
 - A statement declaring to whom the funds should be paid to (provide contact and address details)
 - Tax ID number of the institution
 - Signature of the principal investigator
 - Include full contact, phone, fax, address and email information
- IIS Request Form**
- Budget spreadsheet(s)**
- Hard copy of principal investigator CV and CV for all sub-investigators, to the extent applicable**
- Copies of current professional license for principal investigator and all sub-investigators, to the extent applicable**



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Cover Letter

Please attach a signed cover letter on institutional letterhead which includes 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 appropriate representative
- Include full contact information, phone, fax, address and email information

Budget Spreadsheet

A template is provided on the website for your reference. Please provide a detailed outlines of all costs for which you are requesting support. Costs should be provided on a per-patient basis and include (where applicable). **Please note that the IIS Committee does NOT fund capital equipment or personnel/salary costs.**

Patient-Related Expenses
Non-Standard of Care Study Costs
Indirect/Overhead Costs
Start-up Costs

IIS Request Form (Application)

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



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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).

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.

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.



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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**.

Special Equipment/Measures - List any special equipment and/or materials that must be procured in order to complete this study. In addition, list any laboratory tests (indicating safety/efficacy) required during the study. Note: Eisai funds cannot be utilized to purchase capital equipment.

Drug and Funding Request

Total Drug Supply - Provide drug supply requirements by unit (tablets, capsules, vials, syringes, etc.).

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.**

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



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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)

Insurance

Insert the amount of professional liability, general liability and all other insurance coverage that will be obtained to cover this study.

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

TO ACCESS THE IIS HOME PAGE, GO TO
<http://www.eisagrants.com/IIS.html>

If you have any questions, please contact:

IIS Coordinator
Eisai Inc.
Medical Services Department
100 Tice Boulevard
Woodcliff Lake, New Jersey 07677

Phone: 201.746.2499
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