

IIT Submission Guidelines

This document provides guidelines for investigators interested in submitting an Investigator Initiated Trial (IIT) proposal through the Lundbeck Contribution Portal. We strongly recommend that investigators review the information in its entirety before creating a login/registration and/or submitting a proposal.

Proposals can be submitted through the [Lundbeck Contribution Portal](#), which is Lundbeck's online submission portal. This portal is available to facilitate and streamline the registration and submission process.

The portal contains a series of check/drop boxes and open-text fields to guide investigators during the process of submitting their proposal. Click on the register button and complete the required information.

Note: All materials submitted through this website are done so in a non-confidential basis. By submitting your materials to Lundbeck for review, you understand that the information will not be treated as confidential or proprietary. It is necessary to refer a submission to a number of different persons within Lundbeck to ascertain whether or not a proposal is of interest. Thus we can assume no obligation to keep it confidential.

If your organization's Investigator Initiated Trial grant request is approved, Lundbeck's IIT agreement must be executed prior to initiation of the study.

Submitting a Proposal

All IIT grant proposals must be submitted online with the required support documentation.

Investigators will need access to the following information and documents before they can register and submit a proposal through the [Lundbeck Contribution Portal](#):

Log onto the Lundbeck Contribution Portal

- First time user? [Register here](#) for an account.
- Already have an account? Please use your existing account information to log in.
- Please ensure all required documentation is available prior to proceeding with your online submission.

Initial Submission – Brief Proposal

- Requestor information (name, email, phone)
- Study Title
- Resources requested, dollar amount/or product amount (compound and/or funding)
- Country(s) where study will be conducted
- Compound
- Study duration
- Organization tax identification number
- Current year, signed IRS W9
- Current IRS nonprofit determination letter (if applicable)
- Medical license number
- NPI number
- Curriculum vitae
- Initial concept with hypothesis, rationale and references
- Primary/secondary objectives and endpoints
- Plan for data dissemination
- Budget

Protocol Submissions – Full Proposal

- Background & rationale
- Study objectives
- Inclusion/exclusion criteria
- Study design and schedule of procedures
- Study endpoints
- Safety reporting plan
- Statistical analysis plan
- Data management plan
- Publication plan
- References
- Detailed Budget (NOTE: Study budgets without specific line-item details will not be accepted and will delay the review process)

Investigators will receive email notification that their completed study proposal has been received, and notifications of incomplete submissions will also be sent to encourage investigators to revise their proposals prior to committee review. Official notification of the committee's decision to approve support or decline support will be communicated via e-mail.



Submission Deadlines

Lundbeck accepts and reviews research proposals on a monthly basis.

For any Investigator Initiated Trial question/s not answered by viewing this website please contact the Lundbeck IIT Team by calling 844-634-7867 or via email at: US-IIT@lundbeck.com. Please allow at least 2-3 business days for a response to your email inquiry.
