

IIT Submission Guidelines

This document provides guidelines for anyone interested in submitting an IIT proposal through the Lundbeck Contribution Portal and it is recommended that it is reviewed in its entirety before creating a login/registration and/or submitting a new application.

The Lundbeck Contribution Portal is available to facilitate and streamline the registration and submission process

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 Research 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.

A Concept or brief proposal includes a short, high-level summary of the study's Main Scientific Question including therapeutic area, application of product or protocol, an estimated budget and research design setting details.

A full Proposal submission details the study including a line item budget, a curriculum vitae of the principal investigator, and a fully developed protocol with objective, design, procedures, analysis plan, adverse event reporting, and safety plan as needed.

With this information, the IIT Committee will determine whether or not Lundbeck would like to explore the proposed study idea.

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

Logon to the Lundbeck Contribution Portal

- First time user? [Register Here](#) for an account.
- Already have an account? Please use your existing account information to login.

- Please ensure all required documentation is available prior to proceeding with your online submission.

The benefit of the portal is that it:

- Allows investigators to submit research proposals
- Provides a web-enabled database
- Tracks project progress
- Enables open communication between investigators and Lundbeck IIT Committee at each step, including:
 - study submission, review, and approval/rejection
 - study progress (milestone based)
 - study completion
 - publication

Initial Submission – Brief Proposal

- Requestor information (name, email, phone)
- Study Title
- Resources requested \$ 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 Non-Profit 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

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 through the Lundbeck Contribution Portal.

Submission Deadlines

Review meetings are held on a monthly basis

For any IIT questions not answered by viewing this website please contact the Lundbeck IIT Office by calling 844-634-7268 or via email at: US-IIT@lundbeck.com. Please allow at least 2-3 business days for a response to your email inquiry.
