

Review Process

This document provides all necessary information 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.

IIT proposals are reviewed by a committee comprised of Lundbeck medical, regulatory and scientific personnel. Decisions are based upon scientific merit as well as alignment with research areas of interest and availability of resources. Support for an IIT is awarded strictly based on research merit criteria. Support of a study does not imply any obligation toward nor is connected to the recommendation, referring or prescribing of Lundbeck products.

The role of the Committee is to scientifically review each submitted proposal according to the following evaluation criteria:

- The proposed research is legitimate and scientifically rigorous:
- The hypothesis is justified by an appropriate review of literature and/or supported by pilot data
- The proposed research is novel or supports a specific local/geographic need
- The study is appropriately designed to answer the question being posed (including objectives and end points, statistical powering, and analysis plan)
- Likelihood the results will be published in peer-reviewed scientific journal
- The potential benefit to patients outweighs the risks (for clinical studies)
- The proposed research is aligned with Lundbeck's research objectives and established Areas of Interest.
- Welfare of research study subjects
- Adherence to Good Clinical Practice
- Principal and sub-investigators experience in conducting research
- Compliance with company policy and requirements.

In addition to the scientific evaluation described above, the Lundbeck Committee will also ensure that:

- Requested funds are justified and reasonable, and are commensurate with fair market value
- Submitting investigators are eligible to conduct the proposed research.

It is highly recommended that prior to submitting a study proposal, investigators contact their local Lundbeck Medical Science Liaison (MSL), local Medical Director, or other appropriate Lundbeck personnel to address any questions, and to ensure the proposal and associated budget are complete and compliant.

Investigators who do not know who their local Lundbeck contact is should email: US-IIT@Lundbeck.com for assistance.

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.

Contracting

Once a proposal has been granted final approval, Lundbeck's legal department will draft an IIT agreement. The draft is based on the final budget and protocol that has been approved by the Committee. When both parties agree on a final version of the contract, it can be fully executed and upon Lundbeck's receipt of IRB approval, the investigator can begin his/her research.

For any Investigator Initiated Trial 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.
