

Lundbeck Letter of Agreement (Standard)

This document provides the Lundbeck Letter of Agreement for anyone interested in applying for funding through the Lundbeck medical education grant portal and it is recommended that it is reviewed in its entirety before creating a login/registration and/or submitting a new application.

Please complete and sign the LOA and upload directly into the grant management portal at the time of submission.

Please note this is for informational purposes only. Adherence to these guidelines does not automatically guarantee support of a grant application.

All Lundbeck sponsored grants require a Lundbeck Letter of Agreement signed by the Institution. Lundbeck does not accept LOAs other than its' own. Any funds approved for an activity are contingent upon receiving the signed LOA.

Completed grant requests must be submitted at least 60 days before the program start date.

Decisions are made on a case-by-case basis. Lundbeck will notify the requestor about the decision prior to the program start date.

Standard Letter of Agreement

Please note: Due to the reporting requirements of the Sunshine Act, Lundbeck will not provide funding for food and beverage.

1. What if I have my own Letter of Agreement?

If the recipient requires a separate Letter of Intent that needs to be signed in order to proceed with this program, the terms of the Lundbeck LOA will govern if the two documents are inconsistent with one another.

2. What if I have questions about the Lundbeck LOA?

If you have any questions regarding the Lundbeck LOA, please contact the Lundbeck Grants Office at 844-634-7867 or mededgrants@lundbeck.com.

Please note: Any organization with a written policy to discriminate based on race, religion, gender, sexual orientation, national origin, disability, military status or any other protected status is ineligible for funding.

For any medical education questions not answered by viewing this website please contact the Lundbeck Grants Office by calling (844) 634-7867 or via email at: mededgrants@lundbeck.com. Please allow at least 2-3 business days for a response to your email inquiry.

**LUNDBECK LLC. LETTER OF AGREEMENT FOR
SUPPORT OF CONTINUING MEDICAL EDUCATION**

Between Lundbeck LLC. and the Grant Recipient/Accredited Provider (as applicable and as described below) (“Recipient”) and _____

Activity Title: _____

Educational Objectives: _____

Location: _____ Date(s): _____

Sponsor: Lundbeck LLC., Four Parkway North, Deerfield, Illinois 60015.

Grant Recipient/Accredited Provider: _____

Address: _____

City, State, Zip: _____

Telephone _____ Fax: _____ Email: _____

Contact Person: _____

Tax I.D. No.: _____

Lundbeck LLC. (“Lundbeck”) agrees to provide support for, the named activity by means of:

An unrestricted educational grant in the amount of \$ _____ (see attached proposal).

Please note: Due to the reporting requirements of the Sunshine Act, Lundbeck will not provide funding for food and beverage.

1. Statement of Purpose: The activity is for scientific and educational purposes only and will not promote Lundbeck or any other Commercial Interest’s products, directly or indirectly. This grant is not being given in exchange for any explicit or implicit agreement to purchase, prescribe, recommend, influence or provide favorable formulary status for any of Lundbeck or any other Commercial Interest’s products.
2. Control of Content & Selection of Presenters & Moderators: The Recipient will ensure that the Program will be independent, objective, fair, balanced and scientifically rigorous, so that it will not be viewed as nor in fact be promotional. Accordingly, Recipient is responsible for control of content and selection of presenters and moderators (if any). Lundbeck will not control in any way the planning, content, speaker selection or execution of any activity that is funded pursuant to this Letter of Agreement.
3. Disclosure of Financial Relationships: Recipient will ensure disclosure to the audience of (a) Lundbeck funding and (b) any significant relationship between the Recipient and Lundbeck or between individual speaker(s) and/or moderator(s) and Lundbeck. The Recipient will acknowledge support from Lundbeck in any material which describes the program.
4. Involvement in Content: There will be no “scripting,” targeting points for emphasis, or other actions designed to influence content by Lundbeck LLC or its agents.
5. Ancillary Promotional Activities: In the event that the activity to be funded includes commercial exhibits as part of the overall activity, such exhibits will neither influence planning nor interfere with the presentation of the activity. No promotional activities will be permitted in the same room as an educational activity. The element of promotional activities is in no way a condition of the making of this grant.
6. Objectivity & Balance: The activity will be independent, non-promotional, and free from commercial influence or bias. If Lundbeck products are mentioned in the course of this activity, the Recipient will ensure that data regarding Lundbeck products (and competing products) are presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternate treatments. The title of the activity will fairly and accurately represent the scope of the presentation. The activity will present discussion of multiple treatment options, and will not focus on a single product or therapy.

7. Limitations of Data: Recipient will ensure, to the extent possible, disclosure of limitations of data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. Discussion of Unapproved Uses: Meaningful disclosure is required when a product is not approved in the United States for the use under discussion.
9. Opportunities for Debate: Recipient will ensure opportunities for meaningful questioning or scientific debate.
10. Independence of Recipient in the Use of Contributed Funds and the Conduct of the Activity:
 - a. Funds will be in the form of an unrestricted educational grant made payable to the Recipient. Lundbeck's financial responsibility is limited to the amount of the grant set forth in the Letter of Agreement. Any other claims for payment are the sole responsibility of the Recipient.
 - b. All other support associated with this activity (e.g., distributing brochures, preparing slides) must be given with the full knowledge and approval of the Recipient. Lundbeck will not have editorial or dissemination control of any, educational material associated with the program.
 - c. No additional funds from Lundbeck will be paid to the program director, faculty, or others involved with the activity (additional honoraria).
 - d. No funds from Lundbeck will be used to reimburse or defray the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending the continuing education, whether directly to the individuals attending the conference or indirectly to the conference sponsor (except in the case of financial assistance for medical students, residents, fellows and other healthcare professionals in training provided that the selection of individuals who will receive the funds is made by the academic or training institution and is otherwise in conformity with the ACCME Standards and the PhRMA Code on the Interactions with Healthcare Professionals. In addition, no funds from Lundbeck will be used to compensate for the time spent by healthcare professionals attending the conference or meeting. No funds from Lundbeck will be used to subsidize recreational events, entertainment, extravagant meals or receptions.
 - e. The scheduling of meals and/or receptions, if any, in connection with a CME/IEP activity to be funded is at the sole discretion of the Recipient. Meals and/or receptions, if any, will be modest and be conducive to discussions among faculty and attendees, and the amount of time at the meals or receptions will be clearly subordinate to the amount of time spent at the educational portion of the activity. *Please note:* Due to the reporting requirements of the Sunshine Act, Lundbeck will not provide funding for food and beverage.
 - f. Invitations and/or mailing lists pertaining to the activity will not be generated in a manner to reflect sales or marketing goals of Lundbeck. Final control of mailing lists rests exclusively with Recipient. Recipient shall be independently responsible for the content of any enduring materials.
11. Multiple Letters of Agreement: If the Recipient requires a separate Letter of Intent that it needs signed in order to proceed with this activity, the Lundbeck Grant Letter of Agreement will predominate if the two documents are inconsistent with one another.
12. Reconciliation of Expenses: Recipient will furnish Lundbeck within sixty (60) days of completing this program: (i) a certified report concerning the expenditure of funds associated with this program, (ii) a copy of all outcomes measurement documentation created for the event by Recipient, if any, and (iii) the number of healthcare providers who received CME credits for the program, if applicable. In the event that the program is cancelled through no fault of Lundbeck or the specific funds granted by Lundbeck are not used for the program, Recipient will notify Lundbeck in writing of such cancellation or non-use of

funds and then Recipient will return to Lundbeck all funds not used for the program described above, within sixty (60) days of the date of the program.

13. Compliance with all Applicable Laws and Industry Standards: The Recipient agrees to abide by all applicable and relevant laws and standards including (a) ACCME's Standards for Commercial Support of Continuing Medical Education) or other governing accrediting body standards; (b) U.S. Food and Drug Administration's Guidance for Industry; Industry-Supported Scientific and Educational Activities; (c) PhRMA Code on Interaction with Healthcare Professionals; (d) AMA guidelines; and (e) the Health Insurance Portability and Accountability Act, as amended (HIPAA). Lundbeck will not be responsible for any deviation or departure from relevant standards. If the grant is for a CME/IEP program, the Accredited Provider and Partner, if any, certifies that it is fully accredited and in good standing with applicable accrediting body. Further, Recipient certifies that they have not been the subject of any regulatory enforcement actions.
14. Choice of Law: the parties agree that this Lundbeck Grant Letter of Agreement will be governed by and interpreted under the laws of the State of Illinois without regard to its conflict of laws rules.
15. Integrated Agreement: The parties agree that this Lundbeck Grant Letter of Agreement sets forth the entire understanding regarding the subject matter hereof, supersedes all prior agreements or understandings, whether written or oral, between the Recipient and Lundbeck and may only be modified upon the mutual written agreement of the Recipient and Lundbeck
16. List of Excluded Individuals/Entities: The Recipient certifies that none of its invited speakers, employees or subcontractors is on the OIG's List of Excluded Individuals/Entities, which would bar them from participation in Federal Healthcare programs; or is debarred by the FDA pursuant to sections 306(a) and (b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 335(a) and (b)).

AGREED

Authorized Representative of Recipient/Grant Provider of Continuing Education:

Signature: _____

Title: _____

Print Name: _____

Date: _____

Lundbeck LLC.:

Signature: _____
(LMGRC REPRESENTATIVE)

Title: _____

Print Name: _____

Date: _____

