

## 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.*

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Please complete and sign the Letter of Agreement and upload directly into the grant proposal 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.

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### 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 Letter of Agreement 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](mailto: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.

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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](mailto:mededgrants@lundbeck.com). Please allow at least 2-3 business days for a response to your email inquiry.

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**LETTER OF AGREEMENT**

**Regarding Terms, Conditions and Purposes of an Independent Educational Grant**

Between Lundbeck LLC., Six Parkway North, Deerfield, Illinois 60015 and Grant Provider/Accredited Provider (“Provider”): \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Telephone \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

Contact Person: \_\_\_\_\_

Tax I.D. No.: \_\_\_\_\_

Activity Title: \_\_\_\_\_

Location: \_\_\_\_\_ Date(s): \_\_\_\_\_

Lundbeck LLC. (“Lundbeck”) agrees to provide support for, the named activity by means of: An educational grant in the amount of \$ \_\_\_\_\_.

1. **Statement of Purpose:** This activity is for educational purposes only and is designed to further the education of physicians and health care providers and the public to enhance their ability to care for patients. The educational activity is based on valid content, is independent of commercial interest, is for scientific and/or educational purposes only, and will not promote any Lundbeck product, directly or indirectly, either in the content or selection of topics. 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. The amount of the grant has not been determined in a manner that takes into account the volume or value of referrals or business, if any, generated between Lundbeck and the Provider or any of their respective officers, directors, employees, agents, affiliates, parents or subsidiaries.
2. **Control of Content, Invitation & Selection of Presenters & Moderators:** Lundbeck policy affirms the ACCME Standards for Commercial Support. The parties agree as follows:
  - (a) Provider will ensure that the following decisions are controlled by the Provider and are completely free of the commercial control of the Commercial Interest and/or their co-promoters:
    - (1) Identification of educational needs and selection of target audiences;
    - (2) Determination of educational methods and objectives;
    - (3) Selection and presentation of content;
    - (4) Selection of all persons and organizations that will be in a position to control the content of the educational activity, including teachers, authors, or participants; and
    - (6) Evaluation of the educational activity.
  - (b) Lundbeck shall not offer nor respond to requests from Providers or their Educational Partners for suggestions on topics, attendees, and/or speakers.

There will be no editorial or dissemination control, “scripting,” targeting points for emphasis, or other actions designed to influence content or any educational material associated with the program by Lundbeck LLC or its agents.

- (c) Invitations and mailing lists pertaining to the activity will not be generated by Lundbeck and will not be generated by the Provider in a manner to reflect the sales or marketing goals of Lundbeck.
- (d) Provider certifies they are not also providing promotional services for Lundbeck.
- (e) The following language should be used when acknowledging commercial support: *Supported by an educational grant from Lundbeck*. Provider will not otherwise use Lundbeck’s name or logo without prior approval from the company.

3. Objectivity & Balance: Provider represents and warrants that:

- (a) The content and format of the educational activity and its related materials will promote improvements or quality in healthcare and not the specific proprietary business interest of a commercial interest.
- (b) The activity will give an objective and “balanced view,” which means that recommendation or emphasis must fairly represent, and be based on, a reasonable view and valid interpretation of the information available in the subject.
- (c) The activity must present discussion of multiple treatment options, and shall not focus on a single product, except when options are so limited as to preclude meaningful discussion.
- (d) If, in the Provider’s sole discretion, Lundbeck products are mentioned in the course of this activity, the Provider will make every effort to ensure that data regarding Lundbeck’s products (and competing products) are objectively selected and presented, with the favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
- (e) Generic names of products, rather than Brand names, shall be utilized for all products mentioned in the program.
- (f) The title of the activity should fairly and accurately represented the scope of the presentation.
- (g) Provider will ensure, to the extent possible, disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion(s)).

4. Use of Commercial Support: The parties agree that:

- (a) Funds will be in the form of an educational grant made payable to the Provider. 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 Provider.
- (b) The Provider will make all decisions regarding the disposition and disbursement of commercial support.

- (c) All commercial support from the Commercial Interest associated with the educational activity will be given with the full knowledge and approval of the Provider.
- (d) This Letter of Agreement will be signed by the official representative of each party before funds are disbursed.
- (e) To the extent that actual fees and/or costs associated with the educational activity are less than the commercial support, such excess commercial support will be returned to the Commercial interest within ninety (90) days of the conclusion of the educational activity. Parties failing to complete reconciliation will be prohibited from receiving additional grant funding.
- (f) Provider must have written policies and procedures in place governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
- (g) Payment of honoraria and reimbursement of out-of-pocket expenses for any faculty and/or author will be reviewed for fair market value and provided directly by the Provider and will be in compliance with the Provider's written policies and procedures.
- (h) 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 or participating in the program, 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).
- (i) The Commercial Interest will not make any payments directly to the program director, faculty, joint sponsors or any others involved with the educational activity.
- (j) Faculty or authors facilitating or conducting a presentation or session and participating in the remainder of the event as a learner will be reimbursed for their expenses and honoraria for their teacher or author role only.
- (k) No funds from Lundbeck will be used to compensate for the time spent by healthcare professionals attending the conference or meeting.
- (l) Due to the reporting requirements of the Sunshine Act, no funds provided in connection with this educational grant may be used by Provider for food and beverage to attendees of the educational Activity. Provider represents and warrants that no such portion, in whole or in part, of the funds provided pursuant to this Agreement shall be used for food and beverage and that Provider will either: (1) charge attendees a reasonable registration fee; or (2) use its own funds to provide food and beverage for attendees.
- (m) 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.
- (n) No funds from Lundbeck will be used to subsidize recreational events, entertainment, extravagant meals or receptions.

(o) Commercial support may not be used to purchase capital equipment or to provide general operational support for the Provider.

5. Discussion of Unapproved Uses: Provider represents and warrants that if an unlabeled (unapproved) use of a commercial product, or an investigational use not yet approved for any purpose by the FDA, is discussed during the educational activity, Provider will require disclosure that the product is not labeled for the use under discussion or that the product is still investigational.
6. Opportunities for Debate: To the extent the educational format allows, the Provider will ensure meaningful opportunities for questioning or scientific debate.
7. Ancillary Promotional Activities: The Commercial Interest represents and warrants that arrangements for commercial exhibits or advertisements will not influence or interfere with the educational activity, nor will they be a condition for the provision of commercial support for the educational activity. The Provider represents and warrants that:
  - (a) Product promotion material or product-specific advertisement of any type will be prohibited in or during print, computer-based, audio and video recorded and live educational activities. Live (staffed exhibits or presentations) or enduring (printed or electronic advertisements) promotional activities will be kept separate from the educational activity, including presentations by sales representatives and/or commercial promotional exhibit booths; and
  - (b) it shall comply with ACCME Standard for Commercial Support 4.
8. Government Employees: If any person participating in the development or delivery of the program is a government employee (Federal, State, or Local), Provider will obtain a signed copy of explicit written approval by an authorized representative of the applicable government agency to participate in the program in a form substantially similar to the Government Affiliation and Participation form attached to this Agreement. This written approval must be attached to the agreement with the government employee and must be received and on file with the Provider prior to any work being performed on the program.
9. Resolution of Personal Conflicts of Interest: Provider is responsible for identifying Conflicts of Interest of potential faculty and either resolving them or disqualifying those faculty member(s) for whom a resolution cannot be reached. Provider represents and warrants that:
  - (a) “Meaningful disclosure” of Relevant Financial Relationships<sup>1</sup> with the Commercial interest from faculty, joint sponsors and others able to control the content of the educational activity will be required.

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<sup>1</sup> Relevant Financial Relationships: Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g. stocks, stock options or other ownership interest) or other financial benefit. Financial benefits are usually associated with such roles as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory boards or review panels, board membership and other activities from which remuneration is received or expected. Financial relationships shall include the financial relationships of a spouse or partner.

(b) An individual who refuses to disclose his or her relationships will be disqualified from any involvement in the planning, development, teaching/presenting, managing or evaluation of the educational activity.

(c) Based on the disclosures provided, the Provider will be responsible for identifying and resolving all Conflicts of Interest<sup>2</sup> prior to the educational activity being delivered to learners.

10. Disclosures Relevant to Potential Commercial Bias: Provider represents and warrants that:

(a) Prior to the beginning of the educational activity, a disclosure will be made to the learners of any Relevant Financial Relationship(s) for all individuals who have control over educational content. The disclosure will include the following information:

- 1) The name of the individual;
- 2) The name of the commercial interest(s); and
- 3) The nature of the relationship the person has with each commercial interest.

(b) For an individual with no Relevant Financial Relationship(s), the learners will be informed that no Relevant Financial Relationship(s) exist.

(c) Prior to the beginning of the educational activity, the source of all support from commercial interest must be disclosed to learners. Disclosure must never include the use of a trade name or product-group message.

11. Disclosure Pursuant to Applicable Laws: The Parties acknowledge that certain state or federal laws now or in the future may require Lundbeck and other companies to disclose information on compensation or other remuneration provided to healthcare professionals or healthcare institutions. Lundbeck may report information about remuneration provided under this Agreement, as required by law, which may be made publicly available. To the extent that such laws apply to Provider's activity under this Agreement, Provider agrees to assist Lundbeck in complying with any such disclosure and reporting obligations.

12. Right to Audit: Commercial Interest reserves the right, upon reasonable notice to the Provider, to audit the records of the Provider that relate to the educational activity at a mutually acceptable time and location during the two-year period following the activity date. In the event that the Commercial Interest designates an agent to perform such audit, Commercial Interest shall designate an agent to which Provider has no reasonable objection.

13. Monitoring: Lundbeck reserves the right to send [IME/Medical Affairs] representative to attend the educational activities in which this grant supports, for the purpose of monitoring the activity for alignment with the grant application, as well as Provider's adherence to all applicable standards governing commercial support of independent educational activities. The [IME/Medical affairs] representative may be subject to registration fees, if any, and may accept registration discounts, as long as they are offered to all other attendees.

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<sup>2</sup> Conflict of Interest: A conflict of interest is created when an individual has an opportunity to affect the educational content about the products or services of a commercial interest with which he/she has a financial relationship.

14. Cancellation of Agreement: Termination of Activity and Change of Scope: The parties agree as follows:

(a) Cancellation by the Commercial Interest. Commercial Interest reserves the right to terminate this agreement for convenience upon written notification to the Provider. Payment will be made to the Provider for all expenses reasonably incurred pursuant to this Agreement prior to the date of termination (provided such expenses cannot be canceled, recovered or otherwise reasonably mitigated by Provider);

(b) No such payment will be made if the Commercial Interest determines that the Provider and or/Agent breached any of the terms and conditions set forth herein. In no event will any such payment exceed the total grant amount, and payment under this paragraph will be contingent upon receipt of proof satisfactory to the Commercial Interest that such expenses have been incurred and are not cancelable or recoverable. Provider will return any unused or recovered funds to the Commercial Interest within ninety (90) days of cancellation of the agreement.

(c) In the event that the Provider is unable to conduct the educational activity within the Start and End dates noted above, the Provider will return the commercial support to the Commercial interest within ninety (90) days of notification that the educational activity was not conducted or within ninety (90) days of the End date, whichever is sooner.

(d) Change in Scope of Grant. The Provider will notify the Commercial Interest in writing of any changes in scope to the educational activity; including, for example, modifications in budget requirements, a change to the educational activity Start and End dates or the number and/or types of activities. Upon review, the Commercial Interest reserves the right to cancel the agreement if the changes in scope are not aligned with the Commercial Interest's review criteria. If changes are acceptable, this agreement will be amended to reflect the newly agreed upon terms. If the agreement is cancelled, Provider will return any unused funds to the Commercial Interest within ninety (90) days of cancellation of the agreement.

15. Ownership, Editorial and Distribution Rights

(a) All materials prepared for the educational activity will be and remain the exclusive property of the Provider. The Provider retains copyright, editorial control and distribution rights to the educational activity.

(b) The Provider will obtain all necessary releases or assignments from participants in the educational activity to utilize the materials produced in connection with the educational activity.

16. Multiple Letters of Agreement: This Letter of Agreement needs to be signed by the Provider to proceed with this activity. Lundbeck will not sign a spate Letter of Agreement or other document from the Provider.

17. Reconciliation of Expenses: Provider will furnish Lundbeck within ninety (90) days of completing this program:

(a) a certified report concerning the expenditure of funds associated with this program,  
(b) a report, consistent with the submitted grant proposal, outlining the measurement of the program in meeting the stated educational objectives of the program,

- (c) the final agenda,
- (d) the number of healthcare providers who received CME credits for the program, if applicable, and
- (e) a reconciliation of actual expenses versus estimated expenses

If requested by Lundbeck, the grant recipient will issue a refund to Lundbeck in a timely manner for money not spent in the implementation of the program.

18. Compliance with all Applicable Laws and Industry Standards: The Provider 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) The Office of the Inspector General for the U.S. Department of Health and Human Services Compliance Program Guidance for Pharmaceutical Manufacturers
  - (e) AMA guidelines
  - (f) the Health Insurance Portability and Accountability Act, as amended (HIPAA) and
  - (g) all state, local and federal laws and regulations regarding interactions with or payments to healthcare professionals

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, Provider certifies that they have not been the subject of any regulatory enforcement actions and are not subject to any ongoing investigations or enforcement action that could affect its accreditation status. Provider certifies that it will notify Lundbeck immediately and no later than 2 business days if Provider becomes the subject of an investigation or enforcement action that could affect its accreditation status.

19. List of Excluded Individuals/Entities: The Provider 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)).
20. Assignment: This Letter of Agreement may not be assigned, nor any right or obligation delegated, by Provider without the Commercial interest' prior written consent.
21. Controlling Law. The validity, interpretation and performance of this Letter of Agreement and any dispute connected herewith shall be governed by and construed in accordance with the laws of the State of Illinois, without regard to its conflict of laws principles.
22. Dispute Resolution. Any controversy or claim arising out of or relating to this Agreement or the validity, inducement, or breach thereof, shall be settled by arbitration in Illinois before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining, except where those rules conflict with this



provision, in which case this provision controls. The Parties hereby consent to the jurisdiction of the federal district court for the district in which the arbitration is held for the enforcement of this provision and the entry of judgment on any award rendered hereunder. The Parties further agree that this agreement sets forth their entire understanding regarding the subject matter hereof, supersedes all prior agreements or understandings, whether written or oral, between the Parties, and can only be modified upon the prior mutual written agreement of the Parties.

- 23. Amendment: No agent, employee or other representative of any party is empowered to alter any term of this Letter of Agreement, unless done in writing and signed by authorized representatives of each party.
- 24. Severability. If for any reason any provision of this Agreement shall be deemed unenforceable, that provision shall be severed from this Agreement and the remaining provisions of this Agreement shall remain in full force and effect.
- 25. Survival. Notwithstanding expiration or termination of this Agreement for any reason, rights and obligations that by their nature should survive, will remain in full force.
- 26. Entire Agreement: This Letter of Agreement, together with any attachments hereto, contains the entire agreement of the parties with respect to the subject matter hereof. No representations were made or relied upon by any party other than those that are expressly set forth in this Letter of Agreement.

**AGREED BY AUTHORIZED REPRESENTATIVES**

**Authorized Representative of Provider/Grant Provider of Continuing Education:**

**Provider:**

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

**Lundbeck LLC.:**

Signature: \_\_\_\_\_

(LMGRC REPRESENTATIVE)

Title: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_