

# The Lundbeck Foundation's General Terms and Conditions for Grants Supporting Biomedical Research

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## 1 The Lundbeck Foundation's terms and conditions for research grants supporting biomedical research

- 1.1 The Lundbeck Foundation ("LF") has commercial as well as charitable activities with the purpose of "creating powerful ripple effects that bring discoveries to lives through investing actively in business and science at the frontiers of their fields". The aim of its grants supporting biomedical research is to make a significant difference to people's health and lives by furthering research of the highest scientific standard within the biomedical sciences and with a special focus on the study of the brain and brain disorders from basic to clinical.
- 1.2 These general terms and conditions for research grants supporting biomedical research ("the General Terms") apply to all of LF's grants supporting biomedical research, unless these terms have been dispensed with in a written agreement with LF. Therefore, all such grant holders shall accept this document, thereby confirming that they are acquainted with and accept the General Terms.

## 2 Research plan and compliance

- 2.1 Each Project is based on a specified Research Plan. To ensure that the Research Plan reflects the current and planned research in the Research Project at any time, the Research Plan shall if needed be regularly updated.
- 2.2 LF expects researchers who receive funding to conduct their research honestly, according to recognised codes of good research practice, including the Danish Ministry of Higher Education and Science's Code of Conduct for Research Integrity, the Medical Research Council's Good Research Practice, and the International Society for Pharmacoepidemiology's Guidelines for Good Pharmacoepidemiology Practices. This includes interaction with other researchers, collection, generation and analysis of data, applications for research funding, publication of research results and recognition of direct and indirect contributions by peers, partners, and others. It is a prerequisite that researchers who receive funding from LF within the field of biomedical sciences are affiliated with institutions that have their own published codes and guidelines for good research practice, and that the researchers are acquainted with and comply with such guidelines. Moreover, it is a prerequisite that these institutions have formally described procedures, which must be adhered to when handling any suspicion of scientific dishonesty.
- 2.3 To be eligible to receive a grant from LF, the Grant Holder (see paragraph 4.1) and the Host Institution (see paragraph 4.2), as well as researchers and third parties affiliated with the research project, must also comply with all legislation, rules and regulations relevant to the

research project. Thus, it is a prerequisite that the Grant Holder, the Host Institution, researchers, other persons or third parties connected with the research project has accepted and comply with the currently applicable rules:

- National and international rules on the safety and rights of patients and healthy subjects
- National and international rules on animal welfare
  - Animal experiments conducted at foreign institutions must, as a minimum, comply with Danish national rules on animal welfare
- National and international rules on the processing of personal data, including the EU General Data Protection Regulation (GDPR)
- Applicable rules on working conditions and working environment at the Host Institution and other institutions at which the research is performed
- Any specific conditions determined by LF in Project- specific Terms

2.4 The performance of certain research activities requires the permission or approval of public authorities such as the Danish National Committee on Health Research Ethics (NVK), the Danish Health Authority, the Danish Patient Safety Authority, the Danish Health Data Authority, the Danish Medicines Agency, the Danish Animal Experiments Inspectorate. It is a condition for receipt of funding from LF that all such necessary permits and approvals for commencement of the research described in the application have been issued before the project begins. If it is not possible or appropriate to acquire such permits or approvals for (parts of) the project before commencement of the project, the Grant Holder must prove – to LF's satisfaction – that it is likely that it will be possible to obtain the necessary approvals before the relevant parts of the project commence according to the project schedule.

### **3 Responsible Research and Innovation**

3.1 LF adheres to the belief that research should be conducted in accordance with Responsible Research and Innovation, cf. the EU's HORIZON programmes. Consequently, LF expects that, in their research, both the Grant Holder and other scientists affiliated with the project shall comply with the principles of Responsible Research and Innovation.

### **4 The Grant**

#### **4.1 The Grant Holder**

4.1.1 LF allocates grants based on an application from one or more applicants. The person who is appointed grant holder by the foundation ("the Grant Holder") is the foundation's contact person and is in charge of the practical administration of the grant on behalf of the entire project, including reporting and presentation of accounts.

4.1.2 If a need for substantial amendments to the Research Plan arises, the Grant Holder must notify Lundbeckfonden to that effect without undue delay and submit a revised Research

Plan (or an addendum to the existing Research Plan) to Lundbeckfonden for information and approval.

#### 4.2 The Host Institution

4.2.1 LF pay out each grant to a research account belonging to the institution at which the researcher with the overall responsibility for the project (usually the Grant Holder) is employed ('the Host Institution').

4.2.2 The Host Institution must notify Lundbeckfonden of the research account, bank account and TIN /CVR number for the purpose of paying the instalments and reporting to the Danish tax authorities (SKAT).

#### 4.3 Conditions for the grant

4.3.1 When approval is given for a grant for a research project, LF may define project-specific terms and conditions for the grant ("Project-specific Terms") in a notice of funding and/or in a separate agreement.

4.3.2 By accepting the grant, the Grant Holder and the Host Institution declare their consent to comply with the General Terms and any Project-specific Terms during implementation of the project and practical administration of the grant.

4.3.3 The grant is further subject to the explicit condition that the Grant Holder and the Host Institution ensure that all of the project's participants and collaborators comply with the guidelines defined in the General Terms and in the Project-specific Terms.

4.3.4 The Grant Holder is responsible for implementation of the project within the scientific and financial framework and the time schedule specified in the project description. The Grant Holder is responsible for any other participants' implementation of the project or parts thereof, including procurement of the necessary contract base.

4.3.5 The Grant Holder and the Host Institution warrant (i) that the Grant Holder's and the Host Institution's information provided in the Application, the Research Plan and the Budget is correct, and (ii) that the Grant will be used only for the Research Project in accordance with these terms and the specific Grant agreement if one such is entered into.

4.3.6 LF must be notified if the Grant Holder wishes to change the budget for the grant or adjust the content of the project within the funded framework, and the foundation shall grant written approval of the revised budget, cf. section 5.2.2, and/or an adjusted project schedule.

4.3.7 LF must be notified immediately if the project is delayed or if the prerequisites for implementation of the project change significantly in relation to the project description including any agreed amendments, and the Grant Holder shall make a proposal for overcoming the changed conditions in order to obtain LF's written consent.

- 4.3.8 It is not permitted to receive grants from other sources for the budget items covered by LF's grant.
- 4.3.9 The grant may in part cover the Host Institution's project-related indirect costs. Coverage of such indirect costs can only in exceptional cases exceed 10% of the total amount of the grant and only after specific agreement with LF. LF does not cover indirect costs related to prizes, travel grants and research abroad.
- 4.3.10 The Host Institution shall provide the resources necessary for the research project as defined in the application and in the Project-specific Terms if such apply.
- 4.3.11 In case of a multi-year grant, funds will only be paid out after the first instalment if, in LF's opinion, the progress of the project is satisfactory.
- 4.3.12 LF shall be given access to inspect the progress of the funded project, both during the course of the project and after its completion, through the Grant Holder's reporting activities and presentation of accounts and any further inspections as described in paragraph 5.3 'Audit and inspection'.
- 4.4 Further funds
  - 4.4.1 The Grant is inclusive of all applicable VAT and other taxes and levies, if any.
  - 4.4.2 LF is not obliged to provide any funding for the project beyond the funds provided by the grant. Thus, an overrun of the overall budget, e.g. due to price or salary increases, changes in foreign exchange rates or additional working hours, will not be covered. The Grant Holder may submit a motivated application - on LF's ordinary application deadlines - for further funds for, or an extension to, a research project that is already being funded.
- 4.5 Payment of grants
  - 4.5.1 Grant funds will not be paid out before the Grant Holder and the Host Institution have met the conditions for the grant, cf. paragraph 4.3.
  - 4.5.2 In case of multi-year grant, instalments will be paid out as stipulated one year at a time unless otherwise agreed. Payment of the subsequent instalment is subject to LF's written approval of a status report and balance sheet submitted for the preceding project year as well as the annual reporting in Researchfish.
  - 4.5.3 Payments will be made to a separate research account. This account must be managed by the Host Institution in accordance with the Host Institution's rules.
  - 4.5.4 If, in LF's opinion, the terms and conditions for the foundation's grant have not been complied with, the foundation may suspend payments until the issue has been clarified. Furthermore, LF is entitled to require repayment of funds already paid out.

## **5 Reporting and presentation of accounts**

### **5.1 Scientific reporting**

- 5.1.1 The Grant Holder shall send a brief scientific status report to LF via the LF application and nomination system, LANAS, with an account of the progress of the project, no later than three months after the end of each project year. Upon request the Grant Holder shall give an oral report on the research project's status, the progress and development of the preceding period and report on the activities planned in the subsequent periods at a meeting with LF
- 5.1.2 It is the responsibility of the Grant Holder once annually – in the announced reporting slot - to report research results to the foundation via Researchfish such that these data may be used in LF's continued research impact assessment.
- 5.1.3 LF may call an open meeting for grant holders on an annual basis. The Grant Holder is required to participate in said meeting if asked by LF to present his/her project.
- 5.1.4 The Grant Holder shall submit a final scientific report for the entire project period to LF no later than three months after the project finishes. The Grant Holder must continue the annual reporting of research result via Researchfish. For projects with project periods of three years or less, reporting must continue for a period of three years after the completion of the project. For projects with a project period longer than three years, reporting must continue for a period of five years after the completion of the project. Failure to comply will make the Grant Holder ineligible for application for LF grants until the reporting has been submitted.
- 5.1.5 If, after the end of the reporting period defined in 5.1.4, scientific output is published where the grant from LF is acknowledged, these activities must also be reported in Researchfish.

### **5.2 Budget and presentation of accounts**

- 5.2.1 The budget must reflect the expenses the Grant Holder expects to incur conducting the activities proposed in the application whereas the presentation of accounts must reflect the actual costs. The accounts must document those transactions made comply with the conditions for the grant, including the most recently approved budget for the grant.
- 5.2.2 The budget must be revised if special circumstances arise. If there are scientific grounds for doing so, within the scope of the grant's conditions, the Grant Holder may make changes to the distribution between individual budget items and between individual budget years. LF must be notified of and shall approve any amendments to the original budget. This may be done in connection with annual reporting and presentation of accounts, unless funds redistributed between budget items exceed 10% of the individual budget item. In such cases, LF's consent must be obtained up front. Furthermore, the foundation must be notified of any significant delays in activities and expenses incurred and, in such cases, LF's consent must be requested.

- 5.2.3 The Grant Holder shall submit accounts for the grant to LF no later than three months after the end of each project year. Furthermore, the Grant Holder shall submit final accounts covering the entire grant period to LF no later than three months after the project finishes. The accounts must be prepared according to the principles specified below and must be submitted via the LF application and nomination system, LANAS. Failure to comply will make the Grant holder ineligible for application for LF grants until the reporting has been submitted.
- 5.2.4 The presented accounts must adhere to the budget received by LF in the original application, and which forms the basis for the grant, or to the most recent version of the budget approved by the foundation. In addition, the accounts must be presented with at least the same degree of detail as the by LF latest approved budget.
- 5.2.5 The accounts must show expenses during the project period compared with the most recently approved budget as well as any deviation between the two. The received grant and any co-financing must be presented separately in the accounts. The accounts for grants covering several project years must include the current project year and the accumulated project period.
- 5.2.6 If the grant relates to projects covering activities performed by participants from institutions other than the Host Institution, the Grant Holder shall obtain partial accounts/financial reports from such other participants in the project to enable the Grant Holder to prepare and submit complete accounts for the entire grant to LF. The Grant Holder is responsible for establishing instructions and principles for financial reporting such that uniform accounting formats and principles are applied by all participants in the grant included in the reporting.
- 5.2.7 Furthermore, the Grant Holder and other participants in the project must comply with the expenditure rules currently applicable to the Danish state and the Host Institution or with standard terms and conditions for accounting, vouching, payments, etc. applicable at any other relevant partner. Income and expenses must be documented by the Grant Holder or other persons authorised to do so by the Grant Holder.
- 5.3 Audit and inspection
- 5.3.1 LF or a state-authorized public accountant appointed by LF shall have access (up to one year after the project finishes), with fair notice and within normal office hours, to inspect the facilities at which the project is being carried out and to review accounting and other documentation which may be considered of significance for evaluation of the project's accounts and for assessment of the project's status and compliance with the conditions of the grant. The Grant Holder and the Host Institution shall provide assistance, to the extent required, during such visits and shall present all relevant documentation. LF will cover the costs for an external auditor.
- 5.3.2 The auditor shall verify expenses incurred and any co-financing received against underlying documentation, including laws, other regulations and concluded agreements, and shall recount and check internal consistence. Furthermore, the auditor shall verify whether expenses incurred were approved according to guidelines for approval, whether expenses were incurred in compliance with the conditions of the grant and that transactions included

in the presentation of the accounts were made in compliance with both the grant conditions and customary practice.

- 5.3.3 The auditor shall conclude on whether the accounts give a true and fair view of the activities performed compared with the budget. In the case of grants that cover activities performed by participants from institutions other than the Host Institution and/or co-financing partners, the auditor shall check that the costs and co-financing disclosed by the participants for each category are sufficiently documented and correctly recorded in the total accounts and check that costs are placed under the same categories.
- 5.3.4 The auditor shall submit a statement describing the work performed and a conclusion in accordance with rules applicable to the assurance activities of auditors. The independent auditor's opinion must be sent to LF together with the relevant accounts for LF to consider if General Terms and Project- specific Terms has been adhered to.
- 5.3.5 Should LF, based on an audit performed by LF or external auditors, conclude that General Terms and Project-specific Terms have not been adhered to, LF is entitled to call for a repayment of the grant in part or in full.

## **6 Employee relations and agreements with third parties**

### **6.1 Employment relationship**

- 6.1.1 The Grant Holder and the Host Institution shall ensure that persons allocated to the project are employed according to terms that comply with the legislation in force at any given time as well as guidelines for the Host Institution or another institution at which said persons are employed.
- 6.1.2 It is a basic assumption for the award of the grant that the Grant Holder is employed with the Host Institution for the duration of the Research Project. If the Grant Holder's employment with the Host Institution is terminated, Lundbeckfonden will be prepared to discuss whether the grant may be transferred for the purpose of continuing the research at another research institution, always provided that Lundbeckfonden will revoke the remainder of the Grant if agreement to that effect cannot be reached
- 6.1.3 The grant may only cover the direct cost of salaries for persons who contribute actively to the project.
- 6.1.4 Generally, the grant may only cover salaries corresponding to those set by the relevant collective agreement, including general pay supplements. Personal pay supplements can be covered by the grant only if approved by LF.
- 6.1.5 Thus, the grant does not cover the salary of a person allocated to the project if the person in question is not contributing to the project due to a leave of absence, or due to termination of the person's employment relationship. If a person allocated to the project is permanently or temporarily unable to contribute to the project, the Grant Holder may, after notifying LF,

allocate a substitute to replace the person in question. The Grant Holder may also request LF's consent to extend the project period if it is not possible/appropriate to find a substitute.

## 6.2 Acceptance of terms

6.2.1 The Grant Holder and the Host Institution are responsible for ensuring and documenting that the researchers, and other persons or third parties connected with the research project have accepted the General Terms and the Project-specific Terms.

## 6.3 Changes to the research team

6.3.1 If changes to the composition of the research team affect persons salaried by LF's grant LF shall be notified via the LF application and nomination system, LANAS, and if such persons are researchers with a leading or key role in the project, LF shall provide written consent of the change.

## 7 Equipment

7.1 To the extent that the grant is used for the purchase of equipment, the Host Institution's purchasing rules shall be complied with, and the Host Institution shall ensure that the equipment is clearly and unambiguously marked as belonging to the project for which the grant has been awarded.

7.2 Unless otherwise separately agreed, the Host Institution will become the owner of the equipment purchased under the grant and, as such, is responsible for, and shall defray the cost of, regular maintenance and insurance of the equipment during the project's lifetime. Equipment that is purchased for the project with funds provided by the grant shall be made available to the Grant Holder by the Host Institution and may not without LF's prior written consent be used for purposes other than the project for which the funds have been granted. However, equipment may be used by others in accordance with customary 'sharing procedures' at the Host Institution.

7.3 If, on the consent of LF and the affected institutions, the Grant Holder changes host institution during the course of the project, the purchased equipment must – in principle and if possible – be relocated together with the Grant Holder. Thus, the new host institution assumes the obligations specified in paragraph 7.2. If it is not practically possible for the equipment to be relocated with the Grant Holder, the Grant Holder must be ensured, by written agreement with the institution at which the equipment is located, the same right to use and same access to the equipment as if the Grant Holder was still attached to the institution.

## 8 Intellectual property rights

8.1 LF recognises that the protection of intellectual property rights is a valuable tool for creating incentive to apply research results to products or methods that will benefit society as a whole, and that scientists and research institutions should, to the extent possible, seek



commercialisation of inventions. Therefore, the foundation expects that attempts will be made to maximise the protection of inventions created during projects funded by its grants.

- 8.2 It is a basic assumption for the awarding of the grant that there be no pre-existing special agreements between the Grant Holder and any Third Party on the rights to commercial exploitation of any results, including inventions or other intellectual property rights or data, generated as part of the research conducted under the project and that all persons working on the project will be subject to the Host Institution's general guidelines for notification of inventions and allocation of rights etc. The Grant Holder and the Host Institution must during the term provide notice to LF before any agreements are made between the Grant Holder and any Third Party on the rights to commercial exploitation of any result, including inventions or other intellectual property rights or data, generated as part of the research conducted during the project.
- 8.3 If as part of the research conducted during the project an invention or other intellectual property right is realised, developed, conceived or reduced to practice fully or partly by employees of the Host Institution or other persons working on the project, the Grant Holder and the Host Institution must ensure that the Host Institution's guidelines for notification of inventions and allocations of rights etc. be followed and that LF receives written notification of such invention before any negotiation with a Third Party is initiated or at least within 30 days of the relevant technology transfer office or similar at the Host Institution receiving the invention disclosure. The notification shall at least contain the same information and material required by the Host Institution's internal guidelines and procedures when researchers notify the Host Institution of inventions or other intellectual property rights realised, developed, conceived, or reduced to practice as part of their work.

## **9 Confidentiality**

- 9.1 Lundbeckfonden will not disclose unpublished information on the Research Project to any Third Party without prior consent. Lundbeckfonden is, however, entitled to disclose information to the extent necessary to internationally reputable researchers who, on behalf of Lundbeckfonden, evaluate research supported by Lundbeckfonden on the condition that such persons undertake to keep confidential such information to the same extent as Lundbeckfonden. The duty of confidentiality under this clause 9 will cease 5 years after the termination of the Agreement.

## **10 Transparency of research - publication and sharing of data and teaching**

- 10.1 It is a basic condition that the research results originating from the project must be disseminated by publication according to internationally recognised good publication practice. LF expects that, to the greatest extent possible, the Grant Holder will coordinate publication and communication of research results and other external communication concerning the Research Project with Lundbeckfonden, subject only to restrictions in agreements with third parties or applicable laws. It is expected that it is mentioned under "acknowledgements" that the project was carried out with funding provided by LF including the grant number. LF also assumes that, without any separate payment and with reasonable

notice, the Grant Holder will participate in relevant and reasonable initiatives arranged by the Foundation for the purpose of spreading the knowledge of the Research Project.

- 10.2 It is a basic assumption for the awarding of the grant that if research resources, such as databases or collection of biological samples, are generated as a product of the research project, these must be made available to the entire research community with the fewest possible restrictions. It is the responsibility of the Host Institution to ensure sufficient sustainability of the resources with a transparent and fair access for the appropriate users also after termination of the research project.
- 10.3 LF may stipulate that a long-term plan for storage, protection and sharing of data, which must be approved by LF, should be prepared by the Grant Holder and the Host Institution as part of the research project.
- 10.4 Research-based teaching on higher education degree programmes is essential to the quality of such programmes. Therefore, it is expected that researchers who have received funding from LF will involve themselves in the Host Institution's educational activities and comply with their teaching obligations at Bachelor, Master and/or PhD level.

## **11 Processing of Personal Data**

- 11.1 LF will process personal data received in connection with the grant and the research project as set out in the Privacy Notice— Grants and Prizes available at LF's website, [www.lundbeckfonden.com](http://www.lundbeckfonden.com). More specific terms with respect to the parties' processing of personal data may be set out in the Project-specific Terms.

## **12 Termination of the grant and repayment**

- 12.1 If LF has not received a request for payment of the grant within two years of the date of award of said grant, the grant will be revoked. If LF has not received a request for payment of the next instalment of an ongoing grant within two years of payment of the last instalment, the grant will be revoked.
- 12.2 Remaining funds not accounted for in the approved research plan must be repaid to LF when the project finishes.
- 12.3 If the terms and conditions for LF's grant are not complied with, the grant will be terminated and LF is entitled to require repayment of funds already paid out.
- 12.4 The Lundbeck Foundation reserves the right to revoke the remainder of the Grant (i) if a need for substantial amendments to the Research Plan arises during the Research Project and, based on fair reasons, the Lundbeck Foundation cannot approve a revised Research Plan; or (ii) in the event of any other failure of the basic assumptions under these terms.
- 12.5 If the Lundbeck Foundation revokes the remainder of the Grant due to failure of the basic assumptions and such failure is not the result of circumstances for which the Host Institution is responsible, the Lundbeck Foundation will, however, pay the Host Institutions'

Unavoidable Costs within the scope of the Grant. Should LF and the Host Institution disagree on what constitutes “Unavoidable Costs” it is LFs discretionary right to determine this.

- 12.6 The terms of the Agreement concerning obligations arising or that expressly or must be assumed to apply beyond the term of the Agreement, including obligations concerning confidentiality as well as any provisions required for the interpretation of the Parties' rights and obligations under the Agreement, will also apply after the termination or expiry of the Agreement

### **13 Amendment of terms and conditions**

- 13.1 LF reserves the right to amend the General Terms effective from the time at which the Grant Holder and the Host Institution were notified of said amendments.

### **14 Precedence**

- 14.1 In the event of a discrepancy between regulation of a term in the General Terms and any Project-specific Terms, the latter shall take precedence over the General Terms unless otherwise explicitly stated.

### **15 Applicable law and disputes**

- 15.1 Disputes relating to the research grant are governed by, and must be interpreted according to, Danish law, without regard to Danish conflict-of-laws rules. Disputes relating to the research grant must be settled by the ordinary Danish courts in LF's jurisdiction.