

# THE LEO FOUNDATION

## General Terms and Conditions Governing the Use of Research Grants Awarded by the LEO Foundation (hereinafter “these Terms”)

### 1 PURPOSE

- 1.1 Purpose. The purpose of these Terms is to outline the terms and conditions under which the LEO Foundation shall offer, award, make, promise, pay out or otherwise commit to any financial support towards research within the fields of medicine, chemistry and pharmacy (hereinafter “the Grant(s)”). Consequently, the Grantee (as defined below) and the Host (as defined below) shall be bound by these Terms, unless otherwise specifically deviated from in the Grant letter and/or in a supplemental written agreement (hereinafter jointly “the Project Specific Terms”). In case of any conflict between these Terms and the Project Specific Terms, the latter shall prevail.

### 2 AWARD, PAYMENT AND USE OF THE GRANT

- 2.1 Grant Application and Grantee. Any Grant to be considered by the LEO Foundation shall be applied for in writing using the application form available on the public website of the LEO Foundation, and otherwise in accordance with the application process outlined on such website. The Grant shall be awarded to the person appointed by the LEO Foundation as the grant recipient (hereinafter “the Grantee”) who shall also act as the primary contact person vis-à-vis the LEO Foundation and be responsible for proper usage of the Grant from a scientific, financial and legal perspective.
- 2.2 Host. The Grant will be paid out to the university, hospital, institute or other legal entity at which the Grantee is employed (hereinafter “the Host”). The Host shall be responsible, jointly with the Grantee, for proper administration of the Grant. The Host shall make staff, equipment, facilities and other resources available for the benefit of the Grantee and the relevant research project (hereinafter “the Project”) in accordance with the descriptions in the Grant application and as otherwise set out in the Project Specific Terms.
- 2.3 Cessation of Grantee’s Employment with Host. In case the Grantee should cease to be employed with the Host during the term of the Project, neither the Grantee nor the Host shall be entitled to receive any remaining part of the Grant, unless agreed to by the LEO Foundation.
- 2.4 Use of Grant. The Grant shall be used strictly and solely towards the running and completion of the Project in accordance with the Project description and Project budget outlined in the Grant application and the Project Specific Terms. The Grant must not be applied towards payment of any administration fees, overheads or similar charges imposed by the Host or any third party.
- 2.5 Adjustment of Project Scope or Budget. In case the Grantee should desire to propose any material adjustment of the Project scope and activities and/or any increase of the Project budget, the Grantee shall apply for and obtain the LEO Foundation’s prior written approval hereof, cf. also Clause 3.4 below.
- 2.6 Delay of Project. The Grantee shall immediately notify the LEO Foundation in case a material delay of the Project is likely to occur, or in case any of the assumptions behind the Project have changed, or are about to change, significantly. Along with such notification, the Grantee shall make a proposal as to how to overcome the delay or changed assumptions, as applicable, in the best possible manner. Such proposal shall be subject the LEO Foundation’s approval, such approval not to be unreasonably withheld.
- 2.7 Progress of Project. The Grantee shall use best efforts to ensure progress of the Project. In case a Grant has been awarded in support of a Project which is based one or more scientific milestones to be achieved, the LEO Foundation shall not be obligated to make the next milestone payment, unless and until the related milestone, in the reasonable opinion of the LEO Foundation, has been reached
- 2.8 Payment of Grant. The Grant, or each agreed portion hereof, shall be paid out to the Host once all agreed conditions have been met, including accomplishment of related milestone(s). All such Grant payments shall be placed in a separate research account to be administered by the Host in accordance with its inter-

nal rules. The Grant is awarded and shall be paid out in Danish Kroner which implies that the LEO Foundation shall not carry the risk of any currency fluctuations. Likewise, any taxes and charges that may become due as a result of payment and receipt of the Grant shall be the responsibility of the Host and/or the Grantee, as applicable, and shall be of no concern to the LEO Foundation.

- 2.9 Unused Grant. Any part of the Grant which has not been duly spent on the Project shall be returned to the LEO Foundation by the Host upon completion of the Project.

### **3 SCIENTIFIC AND FINANCIAL REPORTING**

- 3.1 Scientific Reporting on Project. No later than 3 (three) months after the end of each agreed Project year, the Grantee shall provide the LEO Foundation with a scientific status report. In addition, no later than 3 (three) months after finalisation of the entire Project supported by the Grant, the Grantee shall provide the LEO Foundation with a scientific report covering the entire Project period and outlining the main results obtained and conclusions to be drawn.
- 3.2 Maintenance of Information, etc. The Grantee and the Host shall ensure that any and all data, results and other information generated during the Project shall be registered and maintained for a period of at least 5 (five) years after finalisation of the Project. During the same period of time, the LEO Foundation shall be entitled, upon request, to receive information about any scientific publications and reports made and/or any patent applications submitted containing elements of or otherwise being based on such data, results, etc.
- 3.3 Financial Reporting. No later than 3 (three) months after the end of each Project year, the Grantee shall provide the LEO Foundation with a report on how the funds received under the Grant have been applied during such Project year, based on realised use of such funds. For Projects lasting more than two years, these reports shall include an overview covering the most recent Project year, as well as the accumulated Project period up until then. Moreover, no later than 3 (three) months after completion of the entire Project, a final report on the use of all Grant funds shall be provided by the Grantee to the LEO Foundation. All of the aforementioned reports shall (i) be presented in a structure and at a level of details so as to make them easily comparable to the Project budget most recently approved by the LEO Foundation, and (ii) include an overview of the use of any co-funding of the Project. The reports shall, furthermore, be signed and approved by the Grantee, as well as by a legal representative of the Host.
- 3.4 Adjustment of Project Budget. The Project budget must be assessed by the Grantee on a running basis and adjusted in case the preliminary outcome of the Project or any special circumstances should make such revisions required or desirable in the view of the Grantee. The Grantee shall be entitled to re-allocate Grant funds as between the various Project budget items within a margin of 10% of each budget item. In case the Grantee should desire to make a re-allocation of Grant funds which would affect any Project budget item by more than 10%, the LEO Foundation shall be notified in advance and approve hereof, such approval not to be unreasonably withheld.

### **4 DOCUMENTATION, AUDIT RIGHTS AND CONTROL**

- 4.1 Duty to Provide Documentation. Upon written request by the LEO Foundation, or its authorized representative, the Grantee and the Host shall, as soon as practicably possible and no more than once every Project Year, provide copies of files, records, journals and other documentation relating to the Project status, the use of the Grant funds and the adherence by the Grantee and the Host to these Terms and the Project Specific Terms.
- 4.2 Inspection Rights. The LEO Foundation, or its authorized representative, shall have access, during regular working hours and subject to giving reasonable prior written notice to the Grantee and the Host, to conduct on-site inspection of the facilities at which the Project is being carried out and, furthermore, to review and control any physical and electronic files, records, journals and documentation relating the Project status,

the use of the Grant funds and the adherence by the Grantee and the Host to these Terms and the Project Specific Terms. The Grantee and the Host shall reasonably collaborate with the LEO Foundation, or its authorized representative, during any such inspection to make relevant material available.

## **5 CONDITIONS APPLICABLE TO EMPLOYEES**

- 5.1 Working Conditions. The Grantee and the Host must ensure that any and all persons working on or otherwise allocated towards the Project are employed on conditions which are compliant with applicable legislation and no less favorable than the standards and terms generally applicable for employees of the Host.
- 5.2 No Coverage for Non-contributing Activities. The Grant funds may only be used to cover direct salary costs related to persons actively contributing towards the Project. Thus, the Grant funds may not be used to cover salaries, fringe benefits, severance payments or any other types of costs or charges in relation to persons who are on parental leave, longer-lasting sick leave, major training programmes or any other absence out of the ordinary.
- 5.3 Acceptance of Terms. The Grantee and the Host must ensure that any persons working on the Project, whether employed by the Host or a third party, have been made familiar with and have accepted, in writing, to comply with relevant parts of these Terms, as well as the Project Specific Terms.
- 5.4 Replacement of Leading Host Researchers. In case any of the researchers who are having a leading role in relation to the Project should, for whatever reason, cease working on the Project and/or are going to be substituted by other researchers, the Grantee and the Host shall inform the LEO Foundation of such change, as soon as possible. The LEO Foundation shall be entitled to reject or approve the contemplated change, provided, however, that any such approval shall not be unreasonably withheld.

## **6 EQUIPMENT, MATERIALS, PUBLICATION AND INTELLECTUAL PROPERTY RIGHTS**

- 6.1 Equipment and Materials. To the extent any part of the Grant funds shall be used for the purpose of acquiring any equipment or materials for use in the Project, the Grantee and the Host shall ensure that such equipment and materials are, in fact, available for use in the Project whenever needed. Strictly subject to the foregoing, any equipment acquired may also be used by the Grantee and/or the Host for other projects and purposes. Any equipment and materials acquired through Grant funds shall belong to the Host during and after the Project and the Host therefore undertakes to maintain, store and insure such equipment and materials at its own cost and risk.
- 6.2 Ownership of Results. The LEO Foundation acknowledges that the Host, the Grantee and/or any other relevant employees of the Host shall have the right to apply for patent protection and/or to claim copyrights over the Project results, as applicable and in accordance with the Host's internal rules on ownership and protection of intellectual property rights.
- 6.3 IPR Protection and Publication. The Grantee and the Host shall use their best efforts to pursue publication of the Project results in recognized international scientific journals. In case of any such scientific publications, the Grantee and the Host shall ensure proper recognition of the LEO Foundation by mentioning under "acknowledgements" that the relevant Project has been funded through the Grant.
- 6.4 Publicity re Grants. The Grantee and the Host are aware that the LEO Foundation will, on a regular basis, make public an overview of any and all Grants awarded over a given period of time, and they both accept and agree to the fact that their names will appear as part of such overview which will also include a description of the Project and its status.

## **7 COMPLIANCE AND APPLICABLE LAW**

- 7.1 Legal Compliance. The Grantee and the Host shall ensure that the Project is managed and carried out in accordance with any applicable national and international legislation and research standards, including without limitation:
  - Generally recognized standards for good research practice, including "Good Research Practice" from the Medical Research Council" and Guidelines for Good Pharmacoepidemiology Practices" from International Society for Pharmacoepidemiology.

- National and international rules on protection of safety and rights of patients and healthy volunteers, including “Good Clinical Practice” (GCP) as laid down in the EU Directive on good clinical practice, the ICH guidelines on good clinical practice, the Helsinki declaration and any additional ethical rules or guidelines.
- National and international rules on animal welfare
- National and international rules on protection of personal data
- National rules and Host guidelines on work environment, cf. also Clause 5.1 above

7.2 Required Approvals. The Grantee and the Host shall be responsible for obtaining any and all approvals and consents from public authorities and third parties which are necessary for carrying out the Project. In case any such approvals and consents cannot be obtained within the time frame stated by the Grantee in the Grant application and/or agreed in the Project Specific Terms, the LEO Foundation shall not be obligated to pay out any part of the Grant and may, furthermore, demand the return of any funds already paid by the LEO Foundation to the Host.

7.3 Governing Law and Jurisdiction. These Terms and the Project Specific Terms shall be interpreted and governed in accordance with Danish law. Any dispute hereunder which cannot be settled amicably shall be referred to the Danish court system, with the Court of Copenhagen acting as the court of first instance for such dispute.