

GENERAL CONDITIONS APPLICABLE TO ALL PEER-REVIEWED GRANTS

The Mission of the Alpha-1 Foundation, Inc. (the “Foundation”) is to support research that furthers scientific/medical understanding, future treatment and a potential cure for Alpha-1 Antitrypsin (AAT) Deficiency. In accordance with that mission, the Foundation awards grants to certain researchers or research institutions based on the Foundation’s criteria. In addition to the criteria contained in grant applications, and the specific limitations applicable to each grant, as set forth in the Notice of Award, there are General Terms and Conditions (the “Terms”) that apply to all of the Foundation’s grants.

Recipients of grants (“Grantees”) agree to the Terms as a condition of the acceptance and receipt of a grant award. Grantees are bound by and must comply with the Terms throughout the duration of the period of performance and at all times thereafter. The Foundation may, from time to time, revise and update the Terms. In the event there is a revision of the Terms, the Grantee and the Foundation must mutually agree to the revision in writing. The amended Terms will be submitted to the Grantee once both parties approve the revision.

AWARD OF GRANTS

Electronic Execution of Documents

The Alpha-1 Foundation’s regulatory documents associated with this award may be executed in any number of counterparts, including counterparts received electronically as signed confirmed facsimiles or via email, and by different parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement.

Award Payments

The following requirements for a final progress report pertain to the following grant categories: Bridge, Pilot and Feasibility and ELSI Pilot and Feasibility Grants:

The Foundation will issue the first award payment within ten (10) business days from the Foundation’s receipt of an executed Notice of Award, the Grant Award Release of Information Form and the Directory Form. The second and third payments will be issued at the end of each following quarterly interval. The final payment will be issued once the final progress report is received, reviewed and approved by the Foundation. Full funding is contingent upon the timely receipt of a satisfactory and complete final progress report. Continued funding is contingent upon the Foundation having sufficient working capital (as determined by the Foundation in its sole discretion) to continue to fund the applicable grant installment(s).

The Alpha-1 Foundation requires that each applicant allocate \$1,000 of the total budget to pay for travel to the Alpha-1 Foundation’s Biennial Investigators’ Meeting. This one-time mandatory \$1,000 line item is reflected on the budget form page of the application. In case the applicant cannot attend the Investigators’ Meeting, the \$1,000 budgetary line item is not refundable.

The following requirements for an annual and final progress report pertain to the following grant categories: Postdoctoral Research Fellowship, ELSI Postdoctoral Research Fellowship, Research and ELSI Research Grants:

The Foundation will issue the first award payment within ten (10) business days from the Foundation's receipt of an executed Notice of Award, the Grant Award Release of Information Form and the directory form. Subsequent payments will be issued on a quarterly basis. However, the annual and final payments will be issued after the annual and final progress reports are respectively received, reviewed and approved by the Alpha-1 Foundation. Continued funding is contingent upon the timely receipt of a satisfactory and complete annual and final progress report. Continued funding is contingent upon the Foundation having sufficient working capital (as determined by the Foundation in its sole discretion) to continue to fund the applicable grant installment(s). **The Foundation may withhold the final payment if an abstract or paper has not been submitted by the Principal Investigator as part of the final progress report.**

The Alpha-1 Foundation requires that each applicant allocate \$1,000 of the total budget to pay for travel to the Alpha-1 Foundation's Biennial Investigators' Meeting for the first year of the proposal's period of performance. This one-time mandatory \$1,000 line item is reflected on the budget form page of the application. In case the applicant cannot attend the Investigators' Meeting, the \$1,000 budgetary line item is not refundable.

Publications/Acknowledgement

Publications, abstracts, manuscripts and/or presentations at scientific conferences or meetings based on or resulting from any study or research performed during the period of performance must acknowledge the Foundation using the following language: "Funded in part by a grant from the Alpha-1 Foundation." The Alpha-1 Foundation reserves the right to modify the required acknowledgement. The Alpha-1 Foundation shall notify the Principal Investigator in writing in the event that a modification to the acknowledgement is required. The acknowledgement may be modified depending if the grant is co-sponsored by another organization.

Renewal of the Second Year of a Two Year Award

(This term does not apply to the following grant categories: Bridge, Pilot and Feasibility and ELSI Pilot and Feasibility Grants)

The renewal of the second year of a two-year award is contingent upon the timely receipt of an applicable, satisfactory and complete progress report. A progress report reminder letter is mailed to the administrative official and the Principal Investigator approximately thirty (30) days prior to the due date of the report. The Progress Reports section of the Terms lists the reporting requirements. The progress report will be reviewed by the Foundation to ensure that sufficient work and progress has been made on the grant in order to continue funding the project. If the Foundation determines that an insufficient amount of progress has been made on a project, the Foundation reserves the right to discontinue financial support for a grant. In addition, if a project requires IRB approval, the investigator must submit each IRB approval and renewal letter to the Foundation in order to continue funding for the project.

Carry Over of Funds

(This term does not apply to the following grant categories: Bridge, Pilot and Feasibility and ELSI Pilot and Feasibility Grants)

A carry over of funds is defined as the utilization of funds from a one period of performance to a subsequent period of performance without an extension to the grant's originally approved end date. Requests for a carry over of funds must be submitted in writing to the Foundation's Manager of Research Administration at least thirty (30) days and no more than sixty (60) days prior to the award's annual anniversary or official termination date. Prior written authorization must be obtained from the Foundation before a carry over of funds will be issued. The request must provide a clear justification for the carry over of funds. The exact amount of funds to be carried must be indicated. The budget line items affected by the carry over must be clearly indicated, including details of changes in the supplies or equipment portion of the budget. All affected items must be individually itemized. To obtain more details about the requirements for a request to carry over funds, please contact the Foundation's Manager of Research Administration.

No Cost Extension

A no-cost extension is defined as an extension of the termination date of the grant period from the end date of the original award, which is not associated with a request for additional funding. A no cost extension can be requested to allow for the completion of the project as originally described. A no cost extension cannot be requested to complete an experimental plan different from the one approved in the original grant. Nor can a no cost extension be utilized for the purpose of spending unused funds. Requests for a no-cost extension must be submitted in writing to the Foundation's Manager of Research Administration at least thirty (30) days and no more than sixty (60) days prior to the award's annual anniversary or official termination date. Prior written authorization must be obtained from the Foundation before a no cost extension will be issued. The request must provide a clear justification for the need of a no cost extension.

Grant Extension Requesting Additional Funds

Requests made by the Grantee for additional funds to continue a project funded by an approved Foundation grant beyond the period of performance of the original award must follow the regular procedures for the submittal of a new grant request. This begins with the submission of a Letter of Intent (LOI) to the Foundation. If the LOI is approved, the investigator would then be required to submit a grant application requesting the additional funds. The application will be reviewed for scientific merit and a decision is made whether or not to fund the grant. It should be noted, however, that the Foundation has a policy that discourages funding the same project in successive grant periods. At the completion of a project funded by the Foundation, investigators are expected to seek funding from other sources, such as the National Institutes of Health extramural funding sources.

Authorized Award Holders

The Foundation awards grants to a particular, designated individual and institution.

Change of Principal Investigator

A grant may not be transferred to or held by an individual to whom it was not specifically awarded without prior written authorization from the Foundation. A request to transfer a grant to another individual must be made in writing to the Foundation's Manager of Research Administration. The Foundation, in its sole discretion, may approve a transfer of a grant or may require a competitive process for renewal of the grant.

Change of Mentor

(This term applies to the following grant categories: Postdoctoral Research Fellowship and ELSI Postdoctoral Research Fellowship Grants)

Grant awards from the Foundation are awarded to the individual named as the Principal Investigator in the original application. In the case of a Postdoctoral Research Fellowship Grant or an ELSI Postdoctoral Research Fellowship, the Principal Investigator is the Fellow, not the mentor. However, the mentor plays an important role in the fellow's training, and this is reflected in the scoring of the original application. A request to change the mentor for a Postdoctoral Research Fellowship Grant named in the original application must be made in writing to the Foundation's Manager of Research Administration. The letter of request must state the reason(s) for the change in mentor. In addition, a letter of support from the new mentor must be included and must describe: 1) their role on the project; 2) commitment to the Fellow; 3) supervisory relationship with the fellow; 4) any changes to fellow's training program. A grant may not be transferred to or held by a fellow different from the individual named in the original grant application without prior written authorization from the Foundation. The Foundation, in its sole discretion, may approve a transfer of a grant or may require a competitive process for renewal of the grant.

Change of Key Individuals

Requests to change a key personnel on an approved grant award must be made by the Principal Investigator in writing to the Foundation's Manager of Research Administration. The request must include a copy of the new key personnel's Biosketch and Other Support page. Prior written authorization must be obtained before the requested new key personnel begins work on the project.

Change of Individuals Who Are Not Key Individuals

Any change made to individuals who are not named as Key Personnel in the grant application, may be made by the Principal Investigator at any time during the performance of the grant. The Foundation does not require prior written authorization for such changes. However, the Principal Investigator is required to notify the Foundation in writing at the time such changes are made.

Change of Institution

The Foundation awards grants to a particular, designated institution. A grant may not be transferred to or held by an institution to which it was not specifically awarded without prior written authorization from the Foundation. A request to transfer a grant to another institution must be made in writing and submitted to the Manager of Research Administration. The Foundation, in its sole discretion, may approve a transfer of a grant or may require a competitive process for renewal of the grant. If a change in institution is authorized by the Foundation, any funds that have been unexpended at the former institution must be returned to the Foundation within thirty (30) days after the transfer takes effect.

Financial Conflicts of Interest

The Institution shall adhere to the Department of Health and Human Service's Regulation on Responsibility of Applicants for Promoting Objectivity in Research for which Health Service funding is sought (42 C.F.R. Part 50, Subpart F).

Early Completion of Grants

The Foundation will only pay for work performed. Should an investigator complete his/her project ahead of the scheduled end date of the period of performance, the Foundation will only pay for the time spent completing the work.

Grant Ending Notification

A grant is considered complete once the final progress report has been received and approved by the Foundation and final payment has been issued to the applicant organization. A letter is sent to the grant's Administrative Official stating that the grant has completed and each party has successfully met its obligations and requirements.

REPORTING REQUIREMENTS

Be advised that in accordance with the provisions of the Physician Payments Sunshine Act, 42 U.S.C. 1320a-h and its implementing regulations ("PPSA") and Alpha-1 Foundation's contractual obligations related thereto, Alpha-1 Foundation may disclose to third parties, or otherwise make public, any payment or other transfer of value (as such term is defined in the PPSA) it makes to any physician or teaching hospital.

Progress Reports

This term applies to the following grant categories: Bridge, Pilot and Feasibility and ELSI Pilot and Feasibility Grants:

A final progress report will be requested and must be completed to assist the Foundation in shaping future policies with respect to its award program. A satisfactory and complete final

progress report must be submitted to the Foundation as a condition of receiving the final payment due on an award.

The reporting requirements for the final progress report are the following: Lay Summary, Activity Summary, Impact, Budget Summary, Publications, Presentations, Patents, Grants, Clinical Trials, Educational Materials, Public Policy, Other Pertinent Study Generated Findings and Continuation of Academic Career.

A progress report will be deemed unsatisfactory if any of the mutually agreed upon reporting requirements is unfulfilled. A reminder letter will be sent to the Administrative Official prior to the due date of the report. The due dates are also reflected in the Notice of Award. Any future payments due on the project will be withheld until the progress report is received reviewed and approved by the Foundation. All progress reports must be submitted to the Foundation's Manager of Research Administration electronically.

This term applies to the following grant categories: Postdoctoral Research Fellowship, ELSI Postdoctoral Research Fellowship, Research and ELSI Research Grants:

An annual and a final progress report will be requested and must be completed to assist the Foundation in shaping future policies with respect to its award program. Satisfactory and complete annual and final progress reports must be submitted to the Foundation as a condition of continued funding of the award.

The reporting requirements for the annual progress report are as the following: Activity Summary, Budget Summary, Presentation of Results and Ongoing Plans Involving Study Generated Data. In addition, Grantees are required to provide an updated Other Support Page to the Foundation with each annual progress report for the grant.

The reporting requirements for the final progress report are the following: Lay Summary, Activity Summary, Impact, Budget Summary, Publications, Presentations, Patents, Grants, Clinical Trials, Educational Materials, Public Policy, Other Pertinent Study Generated Findings and Continuation of Academic Career.

A progress report will be deemed unsatisfactory if any of the aforementioned reporting requirements are unfulfilled. A reminder letter will be sent within thirty (30) days of the due date of the progress report. The due dates are also reflected in the Notice of Award. Any future payments due on the project will be withheld until the progress report is received reviewed and approved by the Foundation. **The Foundation may withhold the final payment if an abstract or paper has not been submitted by the Principal Investigator as part of the final progress report.** All progress reports must be submitted to the Foundation's Manager of Research Administration electronically.

Budget Summary Portion of the Progress Report

At the conclusion of the first year of the award period and/or at the end of the award period, the Foundation requires a complete budget summary encompassing the entire award period. The Foundation issues the request for a budget summary to the Administrative Official and the

Principal Investigator as part of the progress report reminder letter. The Budget Summary must provide a detailed listing of actual expenditures so as to allow comparison with the projected expenditures that were submitted with the grant application and which were approved by the Foundation. A sample budget summary will be included with the reminder letter and must be used as the basis for the submission of the budget summary portion of the progress report. If an investigator wishes to reallocate funds, please see the Change in Budget section of these Terms. Any funds used for unauthorized expenditures or unexpended funds must be returned to the Foundation thirty (30) days after the award has terminated.

Change of Budget

The original budget refers to the description of funds awarded to the Grantee in the original application.

A change to the original budget representing an amount less than 25% of the total amount of the annual budget may be made at the discretion of the Principal Investigator and does not require approval by the Foundation. Any cumulative change to the grant's budget representing an amount greater than 25% of the total amount of the annual budget requires prior written approval for the Foundation. Budget change requests greater than 25% of the entire annual budget must be in writing and submitted to the Foundation's Manager of Research Administration. When requesting a change to the budget, the Grantee must indicate the US dollar value of the requested change (using the current bank exchange rate, where applicable). The budget line from which the funds are to be removed and the budget line to which the funds are to be transferred must also be indicated. In addition, a narrative justifying the request to change the budget must also be submitted to the Foundation. In the case of a change to the supply or equipment portion of the budget, all items that will be affected by the budget change must be individually itemized. Any funds used for any unauthorized expenditures, in excess of 25% of the entire budget and for which the Foundation's authorization was not obtained, must be returned to the Foundation within thirty (30) days of the termination of the period of performance. Any change to the budget must be reflected in the budget summary that is submitted with the Grant's annual and/or final progress report.

Reporting Requirements for Institutional Review Board (IRB) Documentation

Initial IRB Approval

In projects involving human subjects that require IRB approval, the Principal Investigator must provide a copy of an IRB approval letter to the Foundation upon notification of approval of funding of the grant award and prior to the commencement of the proposed project. This policy applies to Institutional Animal Care and Use Committee Approvals as well.

IRB Renewal

The Principal Investigator must submit each IRB approval letter and, if applicable, each IRB renewal letter, to the Foundation immediately upon receipt from his/her IRB. It is the investigator's obligation to ensure that IRB renewal submissions are made in a timely fashion. Grant payments may be withheld if a Principal Investigator is delinquent in submitting an IRB

renewal letter to the Foundation.

IRB Approved Amendments

If the investigator's IRB has approved an amendment to the protocol, the amendment and the IRB amendment approval letter must be submitted to the Foundation. This policy applies to Institutional Animal Care and Use Committee Approvals as well.

Serious Adverse Events

If a clinical trial funded by a Foundation grant is placed on clinical hold by the U.S. Food and Drug Administration (FDA) or another institution due to a serious adverse event (SAE), the Principal Investigator must notify the Foundation in writing within one (1) week of the decision to halt the trial.

Reporting Requirements for Institutional Animal Care and Use Committee (IACUC) Documentation

Animal Welfare

Whenever animal use is a part of a Foundation research funded project, the following documentation must be received by the Foundation:

A.

A copy of the Public Health Services (PHS) "assurance" statement that certifies a facility's adherence to PHS guidelines. This assurance can be obtained from the Office of Laboratory Animal Welfare at the National Institutes of Health.

B.

A copy of the Institutional Animal Care and Use Committee (IACUC) report that confirms that the facility where the project will be performed has been inspected and approved by the local animal use review committee. The Principal Investigator must submit each IACUC renewal letter, if applicable, to the Foundation immediately upon receipt from his/her IACUC. It is the investigator's obligation to ensure that IACUC renewal submissions are made in a timely fashion. Grant payments may be withheld if a Principal Investigator is delinquent in submitting an IACUC renewal letter to the Foundation.

Foreign organizations proposing research that will involve vertebrate animals are required to comply with the terms described above or provide evidence that acceptable standards for the humane care and use of animals will be met.

TERMS AND CONDITIONS ON THE USE OF FOUNDATION RESEARCH FUNDS

Permitted Uses of Funds

Salary Support

Salary support will be provided for the Principal Investigator or other individuals working on a project funded by a Foundation grant only in an amount equivalent to the effort of the individuals on the project. Salary support in excess of the effort provided by an individual may not be requested. Salary support is calculated by multiplying the individual's institutional base salary by the percent of effort on the project. The maximum effort that can be listed on the budget page for an individual is 100% effort. If the salary support requested by a key individual is less than the percent effort to be provided, the source of the additional salary support for this individual must be indicated, e.g., endowed position or other institutional sources. Any deviation from these policies may result in a request for clarification or modification of the original budget by the Foundation prior to initiation of funding. Such adjustments related the salary support will be made at the time of award.

Direct Expenses

The Alpha-1 Foundation will only pay for those direct costs, including fringe benefits, associated with execution of a grant award. An applicant may not request funds to include any items that are treated by the applicant organization as indirect costs.

Prohibited Uses of Funds

Indirect Costs

The use of grant funds to pay for overhead and/or indirect costs is not permitted.

Equipment Repair & Service Contracts

The use of grant funds to pay for the repair or maintenance of, or for service contracts on, Grantee's equipment is not permitted.

Project Support Expenditures

The use of grant funds for the purchase of furniture, construction or renovation of facilities, payment of honoraria or membership dues, travel to non-grant related meetings, purchase of textbooks or periodicals or payment for secretarial support is not permitted.

Restricted Uses

Equipment and Supply Purchases

Upon conclusion of the award, equipment and supplies purchased with funds from the award, and in accordance with the original grant application, become the property of the institution at which the work was performed. Any departure from this Term requires prior written authorization from the Foundation.

PATENTS AND INTELLECTUAL PROPERTY RIGHTS AND OWNERSHIP

Inventions and discoveries resulting from or in connection with research performed during the term of a Foundation grant will be governed by the Foundation's patent and intellectual property policy, as described below.

A. All inventions or intellectual property made with support in whole or in part by awards from the Foundation must be reported, in writing, at the earliest practical time to the Foundation's Manager of Research Administration. The Grantee agrees to notify the Foundation immediately of the decision to apply for letters of patent or other legal protection for intellectual property, and to consider seriously and in good faith, any comments or objections the Foundation may have concerning such applications. The Foundation agrees to keep all information confidential in accordance with its established practices and charitable mission. All patenting expenses shall be borne by the Grantee.

B. All rights to patentable discoveries conceived and reduced to practice by Grantee in the performance of the project supported by this Grant (Invention) shall belong to Grantee and shall be disposed of in accordance with Grantee's written policies, a copy of which will be provided to the Foundation prior to the disbursement of any Grant funds. In the event of a conflict between the Grantee's policies and the terms hereof the parties agree to negotiate in good faith a resolution to such conflict. In the event Grantee does not have a written policy covering such issues, the Foundation's policies shall govern such situation. Grantee shall appraise Foundation of subsequent patent protection and commercialization activities for the Invention. Grantee shall include diligence provisions in all license agreements for the Invention for the timely commercial development and early marketing of Invention in accordance with paragraph D hereof.

C. Distribution of income derived from an invention or intellectual property, which might include equity disposition, shall provide that the Foundation will participate in income derived from the invention or intellectual property to the extent and at a rate of remuneration determined by mutual agreement, based on a good faith negotiation, between the Grantee and the Foundation no later than one month after the first receipt of income. Such agreement shall be guided by the principle that the Foundation's proportion of sharing in the income shall be reasonably related to the Foundation's proportion of support for the invention or intellectual property.

D. No patent, patent application, or other type of protection shall be abandoned without first notifying the Foundation's Manager of Research Administration in writing. At such time, the Grantee shall give the Foundation the opportunity to proceed with the application in the Foundation's name and to take title to the invention or other intellectual property.

E. The Grantee agrees that if it licenses any invention or intellectual property, it will obligate the licensee as follows: The licensee agrees to exert its best efforts to commercialize or cause to be commercialized the invention or intellectual property as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event that the licensee has failed to commercialize the invention or intellectual property within the number of years determined to be reasonable for the invention or intellectual property, the Grantee, upon conferring with the Foundation, shall have the right to convert an exclusive license to a non-exclusive license or to terminate a non-exclusive license. If the licensee or Grantee has an ongoing and active research, development, manufacturing, marketing or licensing program

appropriately directed toward the production and sale of the invention or intellectual property, the same may be deemed to be sufficient evidence that the licensee or Grantee institution has commercialized the invention or intellectual property.

F. The Foundation reserves the right to public acknowledgement for inventions or intellectual property resulting from research conducted with support from the Foundation; however, the Foundation's name and logo may not be used in association with an invention or intellectual property without prior written approval of the Foundation.

G. The Foundation shall have access to and use of inventions or services/products protected as intellectual property without payment of royalties or fees for use by the Foundation in accordance with its established practices and charitable mission.

TERMINATION

Both Parties reserve the right to terminate this Agreement for any reason upon thirty (30) days prior written notice to the other Party. In the event of such termination, the Foundation shall immediately cease incurring any additional costs in connection with this Award. The Foundation's sole obligation to the Grantee shall be limited to payment for grant related activities performed prior to the effective date of such termination. Any funding provided by the Foundation prior to termination and not utilized by the Grantee prior to receiving notice of such termination shall be returned to the Foundation. The Grantee is obligated to provide a progress report on the work performed prior to the effective date of termination.

MISCELLANEOUS

Correspondence

The Foundation office directs all correspondence to the Administrative Official named on the face page of the grant application submitted to the Foundation. As such, it is the responsibility of the Administrative Official to ensure that grant personnel, and all other appropriate personnel, are copied on all Foundation and Administrative Official correspondence.

Release of Information

The Grant Award Release of Information Form authorizes the Foundation to disseminate information about the award. Information regarding the award will be posted on our website (www.alpha1.org). The names of the Principal Investigator, institution, as well as the grant's title, and a description of the project will be included on our website as a part of the award announcement. The Administrative Official or the Principal Investigator may be contacted by the Foundation's Development and/or Communications Departments for additional information or authorizations.

LIABILITY AND INDEMNIFICATION

The Grantee agrees to indemnify and hold the Foundation harmless from any and all liabilities, losses, claims, costs, damages, causes of action, judgments or settlements arising therefrom, including reasonable attorney's fees, arising out of its breach of any of its representations or obligations set forth herein, its utilization of an informed consent or other disclosure document that fails to adequately address all risks or disclosures that should be set forth in such document and from any research or investigations performed by the Grantee, whether or not such research or investigation was supported by grant funds. The Foundation agrees to indemnify and hold the Grantee harmless from any and all liabilities, losses, claims, costs, damages, causes of action, judgments or settlements arising therefrom, including reasonable attorney's fees, arising from its failure to provide the grant funds as required after written notice and expiration of a ten (10) day period to cure. The Foundation will not be obligated to indemnify or hold harmless the Grantee or any party through any provision or section of any agreement that the Foundation does not execute. In the event of a conflict between any such document or agreement and this Agreement, the terms of this Agreement shall govern.

MISCELLANEOUS

Health Insurance Portability and Accountability Act Compliancy

Where applicable, the Grantee will comply with the Health Insurance Portability and Accountability Act (HIPAA) as well as all regulations promulgated thereunder. If requested by the Foundation, the Grantee must provide executed copies of all agreements demonstrating complicity with all applicable HIPAA regulations, if any.

Equal Employment Opportunity

The Foundation's grants are awarded to individuals working in institutions identified as Equal Opportunity Employers.

Employment Status

At the time of the application's submission and throughout the award, the Principal Investigator must be employed by the applicant organization named on the grant application's face.

Governing Law

The Notice of Award and the Terms shall be governed by and construed in accordance with the laws of the state of Florida without regard to its conflict of laws doctrines. Any legal action arising out of or in connection with the Foundation's grant shall be adjudicated in a state or federal court located in Miami-Dade County, Florida.