



2018 Grant Instructions & Policies

A. INSTRUCTIONS

I. SCOPE of RESEARCH

Before starting to work on your application, please make sure the scope of your research project fits with the topics required by ELA International:

ELA International represents national ELA associations from different countries that contribute together to the financing of research on leukodystrophies. It is run by parents and /or patients affected by leukodystrophies. Accordingly, ELA International wishes to focus funding on programs devoted to the improvement of the health and welfare of patients. This objective can be achieved through studies aimed at understanding disease mechanisms, developing natural history studies including outcome measures and biomarkers, and conducting clinical trials.

Themes proposed in the 2018 call for proposals will focus on unmet needs in the field of leukodystrophies.

Research Topics of Interest include:

- Clinical trial / clinical trial readiness for leukodystrophies including the development of longitudinal outcome measures, biomarker characterization, imaging modalities and pharmacodynamics /pharmacokinetic studies.
- Preclinical studies specifically testing therapies (gene, cell, enzyme or pharmacologic therapies) for leukodystrophies.
- Developing animal or cell-based models (e.g. patient derived iPSC) relevant to human leukodystrophies.
- Study of mechanisms responsible for leukodystrophies, in order to identify new therapeutic approaches.

Studies should address a knowledge gap in the field of leukodystrophies and a preference will be given to clinical trials and clinical trial readiness for leukodystrophies. Translational studies using animal models should use genetic models of leukodystrophies. Novel gene discovery studies fall outside of this funding opportunity. Joint funding initiatives for clinical trials are encouraged.

Direct costs cannot exceed 100,000 per year, for a maximum funding period of two years.

II. PREPARING YOUR APPLICATION

The submission of applications shall be done online at <http://elainternational.eu/site/en/ao-prive>. Prepare the application by filling up all the sections.

Read and follow the instructions carefully.

The document must be filled out in English *ONLY* and must comply with the format specifications and page limits detailed in this document. Do not reformat the forms or exceed the space provided in the different sections of the grant application. **Failure to comply will result in administrative withdrawal.** Decisions of administrative withdrawal are final and not subject to appeal.

A. GENERAL INSTRUCTIONS

Most of the sections in the online application are self-explanatory.

Warning, PLEASE READ

- Your application must be submitted online • All mandatory fields must be completed. • If non applicable, indicate N/A in the field, not to leave it empty.
- **Attention: you must save your data before leaving a page**
- You can save a draft of your application and update it until its final validation.
- Once your application is validated, you will not be able to modify it and your login will be disabled.
- If absolutely necessary, you will have the option to address a modification request to elise.vivar@ela-asso.com. Indicate "Call for proposals – modification request" in the subject of your email.
- After validation of the online form, the pages requiring a signature and/or a stamp of your institution will need to be printed, completed and sent to ELA office (ELA - Pôle recherche - 14 rue La Fayette - 75009 Paris France). These signature fields will only be accessible on the printed version.
- Your login will be valid until the end of the call for proposals.

Choose the form to fill

A Grant Application or Research Fellowship Application can be submitted. Select the appropriate value. Attention to select carefully, this choice cannot be modified once confirmed.

Grant Application

Select the appropriate values between Individual project and collaborative project involving 2 or 3 teams. Indicate if the project is a pilot project.

RESEARCH GRANT APPLICATION

Eligibility: The Principal Investigator and co-investigators must have a faculty appointment (position equivalent to assistant professor or higher) in order to be eligible for a grant from ELA International.

Collaborative Projects

The Principal Investigator of a collaborative project will be the contact and manager of the project. Therefore, its name should be entered in the Team A section. Team A represents the principal investigator's team.

Grant Application and Research Fellowship

A research project/fellowship can be funded for a maximum of two years. Type the appropriate value: 1 year or 2 years. Pilot projects can only be funded for a year.

Select the Research topic of interest addressed by your proposal.

Attention to select carefully, this choice cannot be modified once confirmed. The format of the application cannot be modified later on.

B. SPECIFIC INSTRUCTIONS

You can now access the sections to be completed. Either all the sections, or a selection of sections related to the budget, the science or the teams. Click on "ALL", "Budget", "Science", or the "Team" of your choice to access the list of items.

Each section will open a page to be completed.

Attention: Remember to save your data before leaving a page. Unsaved data will be lost. Once a section is complete, a check mark will be visible in front of the corresponding line in the general menu.

Executive Summary

Amount Requested (€)

Warning: The amount in Euros listed as "Amount Requested (€)" representing the contribution requested to ELA for the entire project will be automatically calculated once the detailed budget tables are completed.

Abstract (less than 500 words)

State the general interest of the project, the application's objectives and specific aims. Describe concisely the research design and methods for achieving the stated goals. Describe the rationale and techniques you will use to pursue these goals. Clearly describe the expected results and the relevance to health and therapy for leukodystrophies. Do not exceed the space provided.

Rationale

Describe in less than 500 words the novelty of your project, its relevance with regards to the topics of the 2017 call for proposals of ELA International and

the potential impact of your project to advance research on leukodystrophies towards the development of therapies.

Personnel involved in the project

List all personnel, including names, degrees, birthdate, institution, % effort and detailed roles on the project.

Recommended format: John Doe, M.D., 23.04.1967, Principal Investigator, UCLA (Effort: 30%), will be responsible for the construction of PLP-GFP mutants and...

Publications

List the 3 main articles published by the principal investigator related to this proposal.

FELLOWSHIP

References

Name three references that are or have been associated with the applicant and that know him/her well. Choose referents primarily outside the applicant's current institution.

Research Plan

Enter the text online or upload a 10 pages pdf (respecting the format). If you want to paste text from a Word document, please use the icon "Paste from Word" to keep the layout.

Page limitations

Do not exceed 10 pages. All tables, charts, graphs, figures, diagrams, images, photographs, and references must be included within the 10-pages limit.

Font

For the research plan, use Arial font size 11 point. Greeks letter are allowed. Same font size applies.

Figures

Figures, graphs, charts, tables and figure legends may be small in size but must be clear and legible. Photographs and images must be a part of the electronic application file and cannot be sent separately.

No applicant should have an advantage over other applicants by providing more content in his/her application by using smaller, denser type.

If terms are not universally known spell out the term for the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Structure of the research plan

A. Specific Aims

List the broad, long-term objectives and the goal of the specific research proposed and the rationale.

B. Background and Significance

Briefly sketch the background leading to the present application, critically evaluate existing knowledge,

and specifically identify the gaps that the project is intended to fill.

C. Preliminary studies

Provide the preliminary studies pertinent to this application.

D. Research Design & Methods

Describe the research design, procedures, and analyses to be used to accomplish the specific aims of the project. Indicate how the data will be collected, analyzed, and interpreted. Describe any new methodology, novel concepts, approaches, tools, or technologies and their advantages over existing ones.

Describe the expected results for each aim and discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced in the field of leukodystrophies. In case of a human/clinical study, describe the ethical aspects of the project.

E. Timeline

Provide the planned milestones by year (and by team in case of collaborative projects) for the entire project.

For Collaborative Projects

F. Leadership plan

A rationale for choosing a multiple PI approach should be described. The roles and administrative, technical, and scientific responsibilities for the project should be delineated for the PI and co-investigators.

G. Literature Cited

List all references. It is important to be concise and to select only the references pertinent to the proposed research.

Follow the following format: Authors' names, Title, *Journal*, **Year**, Volume, Pages. If a publication contains more than 10 authors, just list the first 3 authors.

PI/Co-Investigator/Fellow/Supervisor Bio Sketch Form (2 pages max)

Education, Training, Positions and Honors

List in chronological order your education, training, current and previous positions, starting with your present position. Include start/end dates, position title, name of organization and department. In case of non-permanent/non tenure or fixed term position, state the term of the current contract.

Select and list professional memberships and academic/professional honors received.

Peer-reviewed publications

List your most significant peer-reviewed publications in the last five years in chronological order starting from the most recent ones. Include accepted manuscripts in press but omit manuscripts submitted or in preparation. Follow the following format: Authors' names, Title, *Journal*, **Year**, Volume, Pages and mark the publications obtained with ELA funds with an asterisk.

For Fellows only

List active, approved, completed and pending fellowships for the last three years using the following sample:

Project number:

Start date – End date:

% Effort:

Funding Organization:

Award amount:

Title of the project:

Goals of the project:

Overlap (justify):

For pending applications, precise when answers are expected.

For Research Grant Applications

Personnel's Biographical Sketch

A one-page personnel's biographical sketch is required for all individuals listed in the Personnel Form(s) to be funded by ELA but the principal investigator and co-investigator(s) (if applicable). Describe education, positions and list publications of the last 3 years.

Collaborative Projects: Each team has to provide personnel's biographical sketches for the personnel to be funded by ELA.

Budget Forms

Use ONLY the Euro currency in these tables.

Notes:

The maximum budget requested to ELA cannot be higher than 100.000 € per year.

ELA International neither covers overhead/indirect costs, nor salaries for principal investigators, co-investigators and scientists with permanent or tenure-track positions.

Personnel

ELA-funded personnel

Salaries for Ph.D. students and postdoctoral fellows or other personnel must match the salary grid of the applicant's country. The corresponding grid needs to be submitted by the applicant. The annual base salary represents the salary for a period of 12 months.

Enter the name, annual salary base and fringe benefits of the personnel to be funded by ELA. Enter the % of time dedicated to the project effort and the total annual salary requested to ELA. Fringe benefits are supported by ELA International and are required for all personnel including Ph.D. students and postdoctoral fellows.

FELLOWSHIP

Only Personnel funding can be requested for ONE fellow to ELA. No funding can be asked for Supplies, Equipment and Travel.

Non-ELA funded personnel

List the salaries of all personnel participating to the project whose salaries will be covered by other means.

Equipment

ELA will participate to the cost of old/new equipment required for the conduct of the project, in the limit of expenses related to the project.

Global Budget Justification Form

Personnel

List all personnel and their detailed roles on the project. No individual salary information should be provided here.

Supplies

Itemize supplies by year in separate categories such as glassware, chemicals, radioisotopes, etc... and justify their use. If animals are to be purchased, state the species and the number to be used. Each category must be accompanied with the corresponding amount of money requested. Each yearly amount for supplies must match the amount listed in Budget Forms.

Equipment

List each item of equipment by year, justify their use and fill out the provided table documenting the amount corresponding to the expenses related to the project.

The total annual amount must match the amount listed in Budget Forms.

Provide the company's estimate for new equipment costing more than 4 000 € (not applicable for fellowship applications).

Travel

Travel can only be requested to cover meetings between partners of a collaborative project. No travel can be asked for individual projects or fellowships. Travel to scientific congresses is not eligible for funding. Specify for each year the trip destination and names of individuals. The travel amounts must match the amounts listed in Budget Forms.

Lay Summary

Describe in a plain, lay language the aims of your research project, the means to be used to test your hypotheses and the relevance to health & therapy for leukodystrophies. Do not exceed the space provided.

If the application is awarded, the lay summary will become public information. Therefore, do not include proprietary/confidential information.

Research Support

List active, approved, completed and pending grant supports for the last three years using the following sample:

Project number:

Start date – End date:

% Effort:

Funding Organization:

Award amount:

Title of the project:

Goals of the project:

Overlap (justify):

For pending applications, precise when answers are expected

APPENDIX MATERIAL

Manuscripts accepted for publication but not yet published must be submitted (along with the acceptance letter) as PDF files. Do not include manuscripts submitted for publication or in preparation.

For applications developing clinical trials, the full protocol, budget of the trial and IRB approval are required.

Internet addresses may not be used to provide additional information.

Do not attach any documents other than those specifically requested.

FELLOWSHIP

Include a letter of recommendation from the supervisor. This letter should describe the ability of the supervisor as a mentor, the funds available to the applicant from the supervisor for the project's supplies, equipment and travel (if applicable). It should also provide an assessment of the applicant, describe the relationship of the proposed project to ongoing research in the supervisor's lab, describe the supervisor's plan to develop the applicant's research capabilities, describe the relationship of the research training with the applicant career goals and clarify the role the fellow played in the development of the research proposal.

Include a cover letter documenting the fellowship application title. The letter must describe the fellow's career goals.

SUBMITTING YOUR APPLICATION

Electronic submission

The electronic research grant application must be submitted by midnight CET on May, 28th, 2018 (Paris time).

Signed paper pages

Original application pages requiring a signature (and only these) must contain the required **SIGNATURES AND SEALS** and must arrive by June 1st, 2018 to: ELA – Research Department - 14, rue La Fayette - 75009 Paris, France.

Along with the signed paper pages, include a cover letter documenting the application title, type of research project (individual, collaborative, fellowship) and disciplines involved if multidisciplinary project. For fellowship, the letter must describe the fellow's career goals. In this letter, list referees (with their contact information) who should not review your application because of conflict of interest. Mandatory: give three names of referee with their contact information (excluding your project's collaborators) that you judge qualified to evaluate your project (Yet other experts might be considered to evaluate your proposal).

III. GENERAL CONSIDERATIONS

No signed paper pages will be returned.

The application must be complete and accurate at the time of submission. An application is considered complete only when accurate electronic and signed paper pages have both been received by their respective deadlines.

Incomplete applications will be administratively withdrawn and not returned to the applicant.

Late applications will not be accepted.

Modifications

The electronic and signed paper pages must match entirely. No modifications are allowed. If changes are being made, the application will be withdrawn. If minor administrative changes are needed after submission (such as budget miscalculations, incorrect address...), the principal investigator needs to contact the ELA Scientific Coordinator.

Supplementary material

No supplementary material or updates will be accepted after the deadline. The only exceptions are missing documentation requested by ELA Research Department.

Scientific Overlap

Grant/Fellowship applications showing identical or significantly similar content will be rejected. **Only applications with strictly different aims may be funded.**

Acknowledgment of receipt

After reception of the complete grant/fellowship application by the ELA Research Department, the PI, co-investigators (if applicable), fellow, supervisor and legal grant officer(s) will receive an acknowledgment of receipt to the e-mail addresses entered in the grant application.

Maximum submissions

A maximum of 2 grant applications can be submitted by the same investigator to ELA International.

Only one fellowship (either Ph.D. or postdoctoral) application is allowed per laboratory.

Resubmission

The same application cannot be resubmitted more than 3 times.

IV. SUPPORT

For assistance, contact the Scientific Coordinator of ELA at ELA – Research Department - 14, rue La Fayette - 75009 Paris, France.

E-mail: elise.vivar@ela-asso.com

B. ELA GRANT POLICIES

I. GENERAL GUIDELINES

WARNING

The application must be complete and accurate at the time of submission. An application is considered complete only when accurate electronic and signed paper pages have both been received by their respective deadlines.

Incomplete applications will be administratively withdrawn and not returned to the applicant.

I.1. In signing the application, the principal investigator, co-investigators, fellowship applicant and his/her supervisor and legal grant officer(s) (hereinafter referred to as the "Applicants") agree to comply with the ELA International policies.

I.2. On no account does a grant by ELA International constitute an established right.

I.3. Assurances & Ethical Issues

If ethical approval is required for the Research Project, the Applicants and their respective institutions are responsible for ensuring that appropriate authorization and assurance for the protection of human subjects and animals is being contracted. Animal experimentation and use of material of human origin related to the proposed project must be carried out in agreement with the Applicants' institutions rules and regulations.

I.4. Privileged Communication

Material and information provided by the Applicants in the grant/fellowship application are considered privileged communication with the exception of the lay summary that will become public information if the proposal is funded.

I.5. Equipment purchase

Equipment bought with ELA funds are considered a donation made to the Applicant and his/her institution.

I.6. Equipment repair & maintenance

ELA International does not cover expenses related to equipment repair and/or maintenance.

I.7. Missing reports

Teams awarded grants from ELA International in the past are reminded that receipt of missing reports/documents related to past awards, as indicated in the signed grant agreements, is awaited.

I.8. Research support

If the application is approved by ELA International, a new Research Support form (one per application) will have to be submitted to ELA International along

with the grant agreements. Grant agreements will ONLY be processed when the Research Support form will be received by ELA International.

II. OBLIGATIONS of the APPLICANT & INSTITUTION

II.1. The grant/fellowship is allocated for the execution of the Research Project submitted by the Applicants to ELA International (referred to as the "Research Project").

II.2. In return for the grant allocated, the Applicants are committed to:

A. Inform ELA International of a possible interruption of the Research Project,

B. Ask ELA International for approval before any changes need to be made to the Research Project,

C. Submit a detailed progress report to ELA International within a year, and, in all cases, prior to any renewal of the Research Project and at the end of the Research Project,

D. Submit within a year a lay summary describing the progress of the Research Project to ELA International in view of transparency for the public whose generosity has enabled the funding of the Research Project, under the restriction of confidentiality when some information in the lay summary is likely to be protected by intellectual property.

E. Submit a financial report to ELA International within a year and, in all cases, prior to any renewal of the Research Project or to the submission of new grant applications. The financial report will be signed by the manager of the Institution's Accounting Services, and will detail the utilization of the funds awarded under the Grant Agreement.

F. Acknowledge the support of ELA International in all documents to be published and presented about the Research Project using the grant number provided by ELA International.

G. Participate to the ELA Families-Scientists Meeting and the ELA Scientific Congress upon ELA's request.

II.3. All necessary approvals for the conduct of the Research Project must be obtained by the Applicants from their institutions prior to the start of the Research Project.

II.4. The Applicants commits to inform ELA International of any other grant applications submitted to other funding agencies overlapping partially or entirely with the Research Project when

these applications are submitted. In the event the Applicants are awarded a grant overlapping with the Research Project, they must notify ELA International within one month of receiving the award notification in order to review the financial participation of ELA International to the Research Project and establish the co-financing arrangements.

II.5. All resumes of personnel to be hired to work on the Research Project must be sent to ELA International shortly after their recruitment.

III. MONITORING

ELA International is entitled, at any time, to ask the Applicants to provide additional information and/or results about the Research Project underway. These additional information and/or results will be kept confidentially by ELA International.

IV. PUBLICATIONS

ELA International must be informed of any type of publication or communication regarding the execution, development and results of the present Research Project, or its follow-up.

These publications and communications must, in every case, mention the contribution provided by ELA International to the execution or follow-up of the Research Project.

V. SANCTIONS

ELA International reserves the right to apply adequate sanctions as stipulated in the grant agreement (document available upon request).

VI. AWARD ACTIVATION

The date of award activation will be decided by the Applicants and the Institution but cannot be set prior to January 1st, 2019.

VII. FINANCIAL GUIDELINES

WARNING

The legal grant officer(s) must certify the budget figures by signing the budget form and stamping it with the seal of the institution.

VII.1. Salaries & Overheads

Salaries for Ph.D. students and postdoctoral fellows or other personnel must match the salary grid of the applicant's country. The corresponding grid needs to be submitted by the applicant.

Fringe benefits are supported by ELA International and are required for all personnel including Ph.D. students and postdoctoral fellows.

ELA International neither covers overhead/indirect costs nor salaries for principal investigators, co-

investigators and scientists with permanent or tenure-track positions.

VII.2. Grant Agreements & Money transfer

The grant agreements will be issued by ELA International.

The money transfer related to the Applicants' grant will be set up upon reception of two original signed grant agreements issued by ELA International, after validation of these documents by ELA International.

As the funds are allocated to the Institution, the money will be transferred directly to the Institution's bank account. Transfer of funds to intermediaries (like associations or others) will not be accepted.

VII.3. Budget considerations

The Applicants and the Institution are REQUIRED to use the funds of the grant/fellowship according to the budget lines indicated in the signed grant agreement.

ELA International authorizes transfers between categories (personnel costs, supplies, equipment and travel) without being previously informed only when the transfer represents less than 20 % of the category to be reduced. When the transfer exceeds 20%, a written authorization from ELA International in the form of an amendment modifying the original grant agreement is required beforehand. This written authorization must be granted before the end of the period covered by the active agreement.

VII.4. Financial report

The Institution is required to submit to ELA International by the end of budget period or upon ELA's request a financial report signed by the manager of the institution's accounting services and detailing the utilization of the funds awarded respecting the budget lines indicated in the signed grant agreement. For all expenses exceeding 4 000 €, the corresponding invoices must be sent to ELA International at the time of submission of the financial report.

VII.5. Credit balance

Any funds not used according to the grant agreement or any unspent funds will have to be reimbursed to ELA International.

VII.6. Credit rollover

No credit rollovers will be allowed if at the end of the Research Project the funding has not been fully spent.

VIII. LEGAL DISPUTES

Any and all disputes between ELA International and the Institution arising concerning the validity, interpretation or execution of the Grant Agreement, that could not be settled amicably, shall be submitted to the relevant courts.



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