2020 Call for Applications for ALS research projects

Application Guidelines - Full Grants

Submission Deadline: June 11th, 2020, 1.00 pm

General Instructions

Online Registration

Application form (hereby Form) for "**2020 Call for Applications for ALS research projects**" must be completed online by the Principal Investigator (PI) at the following website and electronically submitted once completed in all its sections.

PIs should pay careful attention to the instructions, because Applications failing to meet the requirements will be rejected. An accurate Application will facilitate the review process.

A PI not already registered should create an account by clicking on "Create account", after confirming to have read the *Information Notice on personal data treatment*. She/he will then receive an email confirming Username and assigned Password to access the Form. Once logged in, the system will ask to change the Password.

It is mandatory that the name entered in the Registration form matches the PI since all communications will be sent to the registered email. This is the only account that allows to modify the Application.

Please note that only one user at a time is allowed to enter information in the Application.

PIs already registered must enter the same email address (Username) used previously. At the first log she/he must confirm to have read the *Information Notice on personal data treatment*. If the Username has been forgotten, this can be retrieved by sending an email to bandi@arisla.org. Please **avoid account duplication.**

If the Password has been forgotten, an automatic email with a new Password will be sent to the registered e-mail address after clicking on "Forgot your Password" entering the Username. Once logged in, the system will ask to change the Password.

Click on the **Full Grant button to apply for a Full Grant. Please note that once selected Full Grant option, the Application type cannot be modified.** Please contact bandi@arisla.org to change the type of grant, considering that all the information entered in the Application will be lost.

General requirements

The Application must be written in English. For abbreviations and acronyms not universally known, spell out the terms the first time they are used, with the appropriate abbreviation in parentheses; the abbreviation should then be used thereafter. The text must be single-spaced, not exceeding the character number limitations specified (which include spaces).

In order to submit the Application **all Applicants and the Legal Representatives of their Research Institute (or their delegates) must stamp and sign the completed *General Information* page and upload the scan (in PDF format) of this page in the *Signature* Section.**

In the case of Multi-centre Application, the PI is responsible also for the upload of the documents signed by Partner/s.

The Form is organized into sections, which can be completed in any order: remember to click on the "**Save changes**" **button to save data before leaving the page**.

A PDF document of the Application can be downloaded at any time by clicking on the link "**Download Proposal"** at the upper right of the page.

Submitting the Application

As reported in the "2020 AriSLA Call for Applications for ALS research projects", the Applications **must be submitted within the deadline** (June 11th, 2020, 1.00 pm).

Please check the status of each part of the Application in the *Submit* Section and verify that:

- all sections have been completed (mandatory to submit the Application);
- the stamped and signed *General Information* page has been uploaded.

To submit the Application, click on the "**Submit**" button.

An automatic alert will appear confirming the completeness of the Application. Please confirm the submission by pressing the button "**Confirm Submit**". The Application will be then formally closed by the system and cannot be further modified. An automatic message will appear acknowledging about the success of the submission.

The PDF version of the submitted Application can be downloaded at any time by logging in at this website.

Assistance

For any information about the Call or about the Application Form compilation please contact:

E-mail Help Desk: bandi@arisla.org;

Phone Help Desk: at the phone number +39 02.20.24.23.90 from 9.00 am to 5.00 pm (Mon-Fri).

Guidelines for preparing the Application

The Form contains nine Sections:

I. General Information
II. Project Information
III. Work Plan
IV. Budget
V. Applicant
VI. Lay Summary
VII. Suggestions on reviewers
VIII. Privacy Statement
IX. Signature

Please note that only Sections I, II and V will be made available to the International Scientific Committee (ISC) members for the Triage phase (see the "Evaluation steps" in the Call for Applications).

Text boxes can be filled out by a limited number of characters. The maximum number of characters (including spaces) is indicated at the bottom right of each box. **The indication of the maximum number of characters is mandatory**.

All fields marked with an asterisk must be filled in order to submit the Application.

Text boxes can be enlarged or narrowed at any time by dragging the bottom right corner of the box.

General information - Section I

- **PROJECT TITLE** and **ACRONYM**.
- **PRINCIPAL INVESTIGATOR** – name and surname of the PI of the project.
- **HOST INSTITUTION** – data of the research Institution of the PI where the project will be carried out; use the complete Italian name.
- **APPLICANT** – Choose the appropriate option from the drop-down menu (Single-centre – Multi-centre); for a Multi-centre Applications the number of participating Partners and their names and Institutions must be specified.
- **RESEARCH AREA** – indicate if the project concerns *preclinical or clinical research. Please note that Applications addressing basic research mechanisms or clinical interventional studies are not admitted.*
- **RESEARCH STEPS** – select the Research Step that most truly represents the proposed activities: therapeutic approaches in cellular models; therapeutic approaches in animal models; clinical study.
- **TYPE OF APPLICATION** – select the correct option from the drop-down menu, identifying the submitted project as:
  - "*New Application",* if it has never been submitted before;
  - *"Already funded PI - Renewal application",* if the new funding request is based on data from the previously AriSLA funded project; indicate year and acronym of the previous funded project;

- *"Already funded PI - New Application",* if the new funding request is dealing with a research topic different from that of previously funded AriSLA project; indicate year and acronym of the previous funded project;
- *"Revised Application",* if it is a revision of a previously submitted Application. Indicate year and acronym of the previous Application.

- **KEYWORDS** – identify and select the keywords that better represent the Application; these will be used for reviewers' matching.
- **PROJECT DURATION** – indicate project duration (min 12 - max 36 months).
- **AMOUNT REQUESTED (€)** – indicate the amount requested to AriSLA (max 80000 euro/year). Please use whole numbers only and enter values without dots or commas. Please note that this value must correspond to the amount indicated in the *Budget* Section in the **OVERALL BUDGET** table.

Project Information - Section II

- **SUMMARY** (2,500 CHARACTERS MAXIMUM) – please organize the summary in different parts specifying:
  - **RATIONALE**
  - **PRELIMINARY DATA**
  - **BROAD OBJECTIVES**
  - **PROJECT DESIGN AND METHODS**
  - **EXPECTED RESULTS**
- For Revised Application, please fill out the **CHANGES FROM PREVIOUS REVISION** box (5,000 CHARACTERS MAXIMUM). In this Section the relevant modifications made from previous Application must be highlighted, including a detailed reply to the critiques. If the PI is different from the previous Application, the reasons must be provided.
- For Renewal Application, please fill out the **RESULTS OBTAINED FROM PREVIOUS GRANT** box (2,500 CHARACTERS MAXIMUM), describing data obtained from the previously funded AriSLA Grant on which the new funding request is based.
- **PRELIMINARY DATA** (5,000 CHARACTERS MAXIMUM) – describe in details preliminary data that support the project. Results are considered 'preliminary' only if unpublished. You can insert a limited number of images and/or tables about your preliminary data in the box "**FIGURES**".
- **FIGURES (MAX 5 MB)** – insert figures that are considered relevant for the project (i.e. preliminary data, work plan flow chart, etc.) in pdf format.
- **INNOVATION AND ORIGINALITY** (2,500 CHARACTERS MAXIMUM) – indicate innovation and originality of the proposed project and novelty of objectives/methodologies/expected results. Specify if the expected results may be eligible for intellectual property protection.
- **RELEVANCE AND SIGNIFICANCE FOR ALS** (2,500 CHARACTERS MAXIMUM) – clearly indicate how the proposed study will improve knowledge on the disease.
- **BACKGROUND AND RATIONALE** (3,000 CHARACTERS MAXIMUM) – give information about the background and rationale of the project, briefly assessing what is already known or being researched regarding the specific proposed topic.
- **GENERAL OBJECTIVES AND SPECIFIC AIMS** (4,000 CHARACTERS MAXIMUM) – indicate the general objectives and the specific aims that the project intends to achieve

- **PROJECT DESIGN AND METHODS** (2,500 CHARACTERS MAXIMUM) – describe the project design and list the methods that will be employed.
- **EXPECTED RESULTS, POTENTIAL CRITICAL ISSUES AND POSSIBLE ALTERNATIVE APPROACHES** (2,500 CHARACTERS MAXIMUM) – clearly describe which results are expected from the project, which potential critical issues may arise and possible alternative approaches to overcome them.
- **COLLABORATION DETAILS** (2,500 CHARACTERS MAXIMUM) – fill out the details about collaborators' role and contribution to the proposed project and upload the signed collaboration letter.
- **REFERENCES** – report references relevant for the project.

Work Plan - Section III

In this Section the Applicant has to detail project activities, intermediate and final expected results, timing, and techniques and methodologies that will be used to carry out the research activities.

In **WORK PACKAGES (III.1)** detail the work plan by dividing it into work packages (WPs) according to the logical phases of the project implementation. The WPs can be considered as interconnected units of the project activities.

Indicate the WPs number necessary for the project and the corresponding box will automatically appear.

If the project is Multi-centre the first WP is dedicated to the coordination and management process of project activities carried out by the PI and the project Partners. Please describe how the Multi-centric project will be managed, indicating strategies aimed at:

- monitoring activities of all centres
- facilitating communication
- promoting exchange of ideas and methodological approach
- stimulating the analysis and the integration of results.

For each WP report the following information:

- **WP TITLE** – insert a title; for Multi-centre Applications the WP1 title (management and project coordination) is pre-compiled and uneditable.
- **START DATE** and **END DATE** – report the month of start and end of activities.
- **DESCRIBE SPECIFIC AIMS AND STRUCTURE** (2,500 CHARACTERS MAXIMUM) – describe specific aims, structure and operative management of the activities.
- **TASKS AND METHODS** (4,000 CHARACTERS MAXIMUM) – describe the work to be performed to achieving the goals and the corresponding methods. Explain how data will be analysed and interpreted and describe in detail the statistical methods to be employed.

For clinical observational studies the following items should be clearly defined:

- *Study design*.
- *Study population*. Indicate the inclusion and exclusion criteria, the number of patients based on power calculation (if applicable), etc.
- *Procedures*. Report the clinical procedures and medical examinations planned and the time interval between them. If new methodologies are developed or employed state their advantages over existing methods.
- *Safety*. Define the potential adverse events and how they will be monitored; describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness.
- *Data management and statistical plan*. Discuss how data will be collected, analysed and interpreted and describe in detail the statistical methods that will be applied.
- *Ethics Committee's Approval*. Indicate if the study has already obtained the pertinent Ethics Committee's approval. This is not mandatory to submit the Application. However, please note that in case the Application is approved for funding, the project will not be activated until the protocol and any related documents, including the informed consent and declaration of approval by the Ethics Committee, will be made available to AriSLA.

If the project implies the use of **animal models,** it must be explained why the scientific objectives cannot be achieved without using animals. Where experiments using animals are necessary, it is required to strictly adhere to the relevant Italian laws, rules and regulations (D.to L.vo 116/92); moreover, approval by the PI's Institution Ethics Review Body is mandatory. Measures should be put in place to avoid unnecessary duplication of research/testing and fully implement the Three Rs (Reduction, Replacement and Refinement, from "The Principles of Humane Experimental Technique", Russell and Burch, 1959). Provide a detailed description of the proposed use of the animals in the work outlined and identify the species, strains, ages, and sex of animals to be used in the proposed work. Provide information on the veterinary care of the animals involved. Make sure that the fewest animals compatible with obtaining a valid scientific result are used and carefully justify the number of animals needed. Documentation must be made available upon request.

- For Multi-centre Applications describe in the **PARTNER CONTRIBUTION** box, the contribution and added value of each Partner to the research activities and progression in reaching each WP aim.

Clicking on the **"Save Changes"** button the **GANTT CHART (III.2)** will be automatically compiled with the information entered in the *Work Packages* Section.

Fill out the **LIST OF DELIVERABLES AND MONTHS (III.3)** chart summarizing and listing deliverables (the expected results for each task previously listed) of all WPs in chronological order, as well as the delivery date as in the Gantt chart.

Budget - Section IV

The **OVERALL BUDGET TABLE (IV.1)** will be automatically compiled with the project total expenses for each cost item and each Partner reported in the following tables.

OTHER FUNDS – It is mandatory that all Applicants lists in this box all financial resources available in direct support of their research endeavours, including, but not limited to, research grants, cooperative agreements, contracts, and/or institutional awards. Specify title and duration of the project, the relative period, the gross amount, the granting agency, and a brief description of the project. If applicable, indicate possible overlaps with the proposed Application.

In the following Section **COST JUSTIFICATION (IV.2),** the Applicant has to provide a detailed and reliable projection of the project budget for each cost item allocated by the year of incurred costs. For Multi-centre Applications, the budget should be allocated for each Partner centre and financial commitment should be proportional to the role in the project. Costs will be considered by AriSLA ISC during the evaluation process, in order to judge their consistency with the project.

In the first **PERSONNEL TABLE (PERSONNEL REQUESTED TO ARISLA)**, indicate the job title (e.g. clinician, engineer, technician, post-doc, PhD student, graduate) of eligible personnel's salary requested to AriSLA, detailing his/her contribution to the project in terms of employment time (months/man dedicated to the project) and the WPs on which he/she is involved.

Please note that the total amount request to AriSLA for Personnel must correspond with the amount indicated in the first budget table of the Section IV.2.

In the second **PERSONNEL TABLE (OTHER PERSONNEL WORKING ON THE PROJECT, NOT REQUESTED TO ARISLA)**, indicate the other personnel working on the project, comprehensive of scientific responsible (PI or Partner), whose salary is NOT requested to AriSLA, specifying job title, months of employment and by whom their salary is granted.

In the following text boxes, the PI and Partners have to provide details for each cost item.

- **PERSONNEL** (1,500 CHARACTERS MAXIMUM) – fill out with the name, if known, role and competences of eligible personnel's salary requested to AriSLA, detailing profile and contribution to the project in terms of employment time.
- **MATERIALS, SUPPLIES, EQUIPMENT** (1,500 CHARACTERS MAXIMUM) – justify reagents, consumables and equipment costs detailing each subcategory (i.e. plasticware, kits/arrays, etc.) and quantity and use for each year.
- **SUB-CONTRACTING** (1.500 CHARACTERS MAXIMUM) – justify sub-contracting costs in the framework of project specific objectives and specify subcontractors.
- **OTHER EXPENSES** (1.500 CHARACTERS MAXIMUM) – justify costs in the framework of project specific objectives.

Please note that the "**TOTAL REQUESTED TO ARISLA**" in the **OVERALL BUDGET TABLE** must correspond to the "**AMOUNT REQUESTED**" box in the *General Information* Section.

Eligible Costs

A correct use of funds can be defined when expenses are consistent with the proposed activities, hereby criteria for costs are reported.

Please consider that VAT is a cost for AriSLA. Therefore, the gross amount should be indicated for all item costs.

DIRECT COSTS

Personnel

Costs for unstructured staff are allowed, following rules of the Host Institution. The PI is obliged to report every staff change that will occur during the project implementation.

Please note that the total annual labour cost should be indicated in the Application budget.

Material, supplies and equipment

Reagents, consumables and lab materials are considered eligible costs considering necessities and consistency to the project.

Scientific equipment: purchase is allowed up to a maximum of € 20,000 for minor essential equipment. For each item please justify the specific need for the project.

Hardware/software purchase is allowed if strictly specific for the project up to a maximum of € 2,500.

Sub-contracting (services)

Applications may be assisted by sub-contractors.

The sub-contractor provides external services or supplies which are necessary for the execution of the project. **Total budget request for subcontracting must not exceed 20% of the funding requested to AriSLA.**

Other expenses

Travels: project-related travel costs to visit Collaborators or Partners need to be justified. Expenses related to participation in Congresses are eligible up to a maximum of € 3,000/year/Applicant.

Other costs include expenses for scientific publications, reprints, software (only if in line with the needs for the project), etc..

The AriSLA Grant has to be acknowledged in any material or scientific publication related to the financed project. Moreover, Investigators of a funded project should adhere to the Open access Policy (as indicated in AriSLA Dissemination Policy). For this reason, it is recommended **to include in this category the fee costs for Open Access publications (please consider at least € 3,000/project).**

INDIRECT COSTS

Overheads

Overheads can be required and include general expenses incurred by the Host Institution, administrative and maintenance costs, expenses for any machinery and equipment as part of the project activities.

These costs are calculated as a lump sum. A maximum of 10% of incurred direct costs is allowed.

Non eligible costs:

- Salary of PI and Partner/s;
- Salary of structured staff;
- Salaries, travel and other expenses related to sabbatical leave;
- Membership in Scientific Societies;
- Organization of meetings and workshops, if not functional for the activity of WP1 in case of Multi-centre Application;
- Construction and/or renovation of space, furniture, rental of space or rooms, call charges and/or fax;
- Setting up and maintaining animal facilities;

- Major basic equipment such as incubators, hoods, -80°C freezers.

Applicant - Section V

Detail name and surname, date of birth, and Applicants' contacts. Complete the Section with the data required. PI's Host Institution name box is automatically pre-compiled with the information entered in the *General information* Section.

Applicants have to declare that their Host Institution is an eligible subject according to the "2020 Call for Applications for ALS research projects".

Research experience relevant for the project must be reported in brief **to demonstrate scientific independence of the Applicants** as well as a **short description of the Host Institutions** (3,000 CHARACTERS MAXIMUM).

Selected Publications

Fill out the Section with:
- the 5 more recent publications
- the 5 more important publications
- the 5 more relevant for the proposed theme.

These three categories are not mutually exclusive.

Lay Summaries - Section VI

LAY SUMMARY (2,500 CHARACTERS**)** – summarize the project (in English and Italian) using terms of ordinary language, avoiding acronyms and technical terms.
If the project will be funded, this description will become public. Therefore, do not include confidential information (not already published or disclosed) that you do not want to disclose or that may influence a potential patent application.

Organize the lay summary in different parts specifying:

- **TITLE** – it may slightly differ from the project title if this helps to make the topic of the project clearer to the lay public.
- **STRUCTURE** – it should contain the following elements:
  - Background containing the research focus and how it is linked to ALS
  - Project aims
  - Impact on ALS.

AriSLA reserves the right to amend the lay summary before publishing it.

Suggestions on reviewers - Section VII

The Applicant may suggest up to two reviewers of proved experience that could be included in the AriSLA ISC and indicate up to two undesirable reviewers specifying the reasons of the request.

Privacy Statement - Section VIII

In this Section, the PI should confirm to have read the *Information Notice on personal data treatment* document.

Signature - Section IX

In this Section, PI/Partners and the Legal Representatives of their Research Institute (or delegates) must stamp and sign the completed Ge*neral Information* page. It is a duty of the PI to collect all signed documents from Partners and upload the scan (in PDF format) of this page.