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Specialized Center of Research
Program
Guidelines & Instructions

Full Application

Effective dates:

November 1, 2017 - June 30, 2018

General Information

About the Leukemia & Lymphoma Society, Inc.

The Leukemia & Lymphoma Society, Inc. (LLS) is a national voluntary health agency dedicated to the conquest of hematologic malignancies and relevant premalignant conditions. LLS supports research, patient aid, community service programs, advocacy, and public and professional education.

Description of Awards

Overview

LLS's Specialized Center of Research (SCOR) grant program is intended to bring together established investigators from one or several institutions to develop a focused research program, foster new interactions and cooperation, and enhance interdisciplinary research among the participants. The overall goal of this mechanism is to enhance the development of innovative strategies for the treatment, diagnosis or prevention of hematological malignancies. Strategies that move discoveries from the bench to the clinic are of high importance as are integrated translational projects. A major focus is translatability to the clinic within the time frame of the SCOR, or shortly after the grant term ends.

A SCOR team will be judged as a unit and funding will not be available for otherwise meritorious but non-synergistic parts of an application. The quality and significance of the Projects and Cores, and the enhanced productivity that is likely to be achieved by linking the investigators, are the primary determinants of funding decisions.

Each SCOR is comprised of a minimum of three scientific Projects and a minimum of two scientific Cores that will cooperate under the leadership of a SCOR Director. There must be objective evidence of interdisciplinary research among the Projects and Cores.

The maximal annual total cost is \$1,000,000 for each year of the five year grant. The maximum annual direct cost is \$833,333.33 while the maximum annual indirect cost is \$166,666.66. The SCOR Director has the authority to budget these funds among the various Projects and Cores.

Milestones and Deliverables

Projected milestones and deliverables to be achieved on a quarterly basis are required of awarded SCORs. As soon as the funding decision is made, LLS will contact the SCOR Director to initiate a discussion on milestones and deliverables. These milestones and deliverables will serve as the foundation for the annual assessment and should be brief statements related to the specific aims in your proposal. Both parties will need to agree to the final wording of the milestones and deliverables. These are due by the contract due date.

Site Visit

Annual Site Visits will occur around the anniversary of the grant start date. LLS Research staff and external reviewers will visit the SCOR Director and members of the SCOR team. The SCOR Director, Project Leaders and Core Leaders must be present. The SCOR team will present an overview of the progress made in the prior year in relation to the aims of the SCOR and the milestones/deliverables agreed upon. Any problems encountered should be discussed and any changes from the original aims should be justified.

Annual Assessment

After the annual Site Visit, LLS staff and the external reviewers will assess the quality of the integration of the SCOR team and the progress made. From this evaluation, a recommendation will be made as to the level of continued funding. In the case of well-integrated and productive teams, the funding will remain the same. In the unlikely event that progress is not sufficient, a warning will be provided, which may result in future funding being reduced if progress does not improve. After this assessment, the Committee will work with the SCOR Director to establish milestones for the coming year. The outcome from the Annual Assessment will be sent to the SCOR Director within 60 days of the Site Visit.

Annual SCOR Progress Meeting

Each October, there is a mandatory Progress Meeting for representatives from all currently-funded SCOR teams.

Annual Reports

Financial, Intellectual Property, and Progress Reports are due annually. The Progress Report will contain a summary of the year's research. These Progress Reports are essential for donor development activities. These reports will be evaluated by LLS staff. Release of the next SCOR funding payment is contingent on submitting satisfactory Reports.

SCOR Team Meetings

A key element of a SCOR is the integration of the various Projects and Cores. Therefore, an essential component to the success of a SCOR is regular interaction of the SCOR team. SCOR teams should meet via teleconference or in person at least quarterly to discuss results.

Leadership

The SCOR is led by an overall Principal Investigator, called the SCOR Director, who is responsible for writing and submitting the application. The SCOR Director of a funded SCOR is also responsible for the disbursement of funds to the various Projects/Cores, the conduct of the Projects and Cores, and adherence with LLS policy. Each Project/ Core is led by a Project Leader/Core Leader, who is responsible for the management of that Project or Core.

Modifications of leadership of funded SCORs (and approved LOIs) must be approved by LLS.

Sponsoring Institution's Acceptance of Contract Terms

Applicants who are offered a SCOR Award will be sent a contract after Award notification. The Sponsoring Institutional representatives from each participating institution will need to agree to the terms of this contract.

Lay Abstracts

Lay abstracts are not asked for during the application process. Lay abstracts will be required of those selected for funding following Award notification. ***The lay abstract is essential for LLS to continue successful fundraising to support our current and future grantees.*** Thus, a well-written lay abstract suitable for the general public is required post-award. After the review meeting, LLS will contact top-ranked applicants regarding lay abstract submission. Wording modifications may be asked for in cases where LLS determines that improvements are warranted.

Final lay abstracts acceptable to both awardees and LLS staff are due prior to the start of funding.

Review Process

Full applications are reviewed by an independent and voluntary expert panel. The panel assigns two scores to each full application. The Priority Score follows the NIH 1-9 scoring system using the criteria listed in the *Review Criteria* section. The reviewers also assign a Mission Score, which evaluates the applications adherence to SCOR award's intent (see *Mission Score*).

If there is a person that you would like excluded from reviewing your full application, please email researchprograms@lls.org no later than the full application deadline of March 3, 2018, 3:00 PM EST. LLS will make every effort to accommodate these requests, but cannot guarantee such exclusion(s).

Review Criteria

Priority Score

The Priority Score of 1-9 follows the NIH formula using the criteria below to evaluate the quality of the proposal. This score reflects the SCOR as a unit and is not based on individual projects.

1. The significance of the proposed research to the diagnosis, treatment, or prevention of hematologic malignancies and/or relevant premalignant conditions.
2. The qualifications of the SCOR Director and Project/Core Leaders.
3. The synergy that will likely result from the interactions of the Projects and Cores; it is critical that the SCOR be more than a collection of high-quality Projects/Cores-these must be weaved together with a common theme with clear interactions between them.

4. The likelihood that the research findings will lead to eventual clinical application, ideally within the period of SCOR funding or soon after the funding period.
5. The quality of the resources and environment.
6. The alignment of the quality of and access to patient populations and/or patient specimens with the research plan (where applicable).
7. The clarity of thought and presentation, including an adequate number of figures that clearly present the data.
8. If the SCOR Director has previously held, or currently holds a SCOR as the SCOR Director, the applicant must describe how SCOR funding has contributed to their scientific/clinical productivity.

Mission Score

The Mission Score evaluates the alignment of the proposal with the intention of the award mechanism; it does not evaluate the scientific/clinical quality of the research. Though the Priority Score is the most prominent for funding decisions, the Mission Score may be used to distinguish between two applications with similar Priority Scores. For example, an application with a Mission Score of 1 may be funded over an application with the same/similar Priority Score, but with a Mission Score of 3.

Mission Score of 1: There is a very high degree of integration between basic and translational research with strong potential to lead to a clinical trial during the duration of the award.

Mission Score of 2: There is a very high degree of integration between basic and translational research with a moderate potential to lead to a clinical trial during the duration of the award.

Mission Score of 3: There is a moderate degree of integration between basic and translational research with a limited potential to lead to a clinical trial during the duration of the award.

Key Dates

	Date	Time
Full Application Phase deadline	March 3, 2018	3:00 PM EST
Notification of Awards	July 2018	
LLS's receipt of signed contracts	September 1, 2018	
LLS's receipt of Lay and Scientific Abstracts	September 1, 2018	
Funding start date	October 1, 2018	

Please note that all times are Eastern Time (ET). If any date falls on a weekend or US holiday, the deadline becomes the next business day.

It is highly recommended that submissions are done the day *prior* to the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. Our electronic grants management system automatically shuts down new submissions after the deadline has passed.

General Instructions for Applying

All submissions must use LLS's online grants management portal at <https://lls.fluxx.io/>. It is highly recommended that you familiarize yourself with this portal well in advance of any deadlines.

If you do not have an account with LLS, contact researchprograms@lls.org with your full name and organization contact information. A new account will be created for you and your log in credentials will be emailed to you by an LLS staff member.

Under "Requests" on the left navigation bar, click "New or Pending" to access your full application.

Download and complete the project description template, including all required signatures, and upload to the "Project Document" section towards the bottom of the web form. Margins are preset and must not be changed. Text must be written single spaced in Times New Roman 12pt. Only one PDF file is accepted in this section, so delete any other documents uploaded during the process.

Follow the instructions for each web form field. Bold font indicates required information.

Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be triaged.

You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your application and prevent further modification. Contact researchprograms@lls.org if you submit in error (must be before the deadline).

Click the "Submit" button to formally submit your application to LLS.

Once your full application is submitted, you will receive an automated email from the system. Consider that these emails may end up in your spam filter.

Specific Instructions for Applying

Full Application

Information provided in the LOI phase will carry through to the full application and must not be changed. The following information is required on the grants management portal and the project template.

Project Description

Download the project template (including budget and signature page). Complete the information, including required signatures, and upload to the Project and Supporting Documentation section of the grants management portal.

Follow the character limits (which include spaces) and page lengths. Margins are preset at 0.5 inches on each side and should not be changed. Only Times New Roman 12 pt. font is acceptable.

Figure legends should be formatted with a font size equivalent of 10 pt or above. The figure legends and the corresponding sections in the project template must clearly identify the model system(s) used (e.g. cell line name, etc.).

1. Table of Contents

2. Previous SCOR productivity (3 page maximum, not including citations)

For SCOR Director/Applicants who currently hold, or have held, a SCOR as a SCOR Director, the following points must be addressed.

- Indicate how many prior SCORs have been held.
- Indicate the overall themes of each SCOR.
- Describe how funding has contributed to the current/prior SCOR scientific and clinical productivity, providing specific examples.
- Citations; list publications directly related to SCOR funding and in which The Leukemia & Lymphoma Society was cited in the acknowledgements/funding section of the manuscript (4 page maximum; Blood citation format). For lists longer than 4 pages, indicate the total number of relevant, LLS-cited publications and list the most impactful.

3. SCOR Justification and Major Resources (5 page maximum, not including citations)

This section should include in this order:

- Title
- Overall aims/goals

- Background with scientific and clinical significance
- Innovation
- Overall approach
- Shared Cores
- Resources (other than Cores)
- Collaborations with other SCOR personnel
- Plans for clinical translation of findings

Citations for this section are limited to 4 pages (Times New Roman 12 pt. font) and should use the Blood citation format.

4. Projects (6 page maximum for *each* Project, not including citations)

Each Project should be listed as a separate section and include in this order:

- Project title
- Project Leader(s)
- Project description
 - Specific aims
 - Background with scientific and clinical significance
 - Previous studies/preliminary data
 - Methods for each aim including potential problems and alternative solutions
 - Interactions with other Projects and Cores
 - Statistical approaches (where applicable)
 - Description of patient populations and samples and how they will be accessed (where applicable); when applicable, robust access to patients and/or samples will form an important part of the review process
 - Resources and environment, particularly those aspects critical to the Project

Citations for each Project section are limited to 2 pages (Times New Roman 12 pt. font) and should use the Blood citation format.

Each Project must have a minimum of 3 figures.

5. Cores (3 page maximum for *each* Core, not including citations)

Each Core should be listed as a separate section and include in this order:

- Core title
- Core Leader(s)
- Core description
 - Aims/goals
 - Function/operation
 - Benefits to, and relation with other SCOR components

Citations for each Core section are limited to 2 pages (Times New Roman 12 pt. font) and should use the Blood citation format.

6. Appendix

This section should include in this order:

- Table of contents
- Assurances (signed copies from appropriate institutional representatives, to be uploaded in addition to information provide in the “Assurances” section of the web form)
- Letters of support or collaboration
- Clinical protocols
- Up to 2 manuscripts that are not yet available on PubMed may be provided for each Project

a. Assurances (Required)

Human Subjects

Indicate if human subjects will be involved in the proposed research. The status (approved, pending or exempt) of IRB approval must be provided. Documentation of any current or pending approvals must be contained in the full application template. There is also a section on the web form that must be completed. An application may be submitted with IRB approval pending, but IRB approval must be obtained and provided to LLS prior to the Award start date.

Laboratory Animals

Indicate if animals will be involved in the proposed research. The status and date of the Institutional Animal Care and Use Committee (IACUC) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of any current or pending approvals must be provided in the full application template. There is also a section on the web form that must be completed. An application may be submitted with approval pending, but approval must be obtained and provided to LLS prior to the Award start date.

Recombinant DNA

Indicate if the proposed research involves recombinant DNA. Documentation of any current or pending approvals must be contained in the full application template. There is also a section on the web form that must be completed.

Biohazard Statement

Indicate if the proposed research involves the use of biohazards. Documentation of any current or pending approvals must be contained in the full application template. There is also a section on the web form that must be completed.

b. Clinical Protocol (Required where applicable)

Provide a one page summary of clinical protocols essential to the proposed research. Include approval date and compliance number. Indicate if IRB approval is pending.

7. Budget

The Detailed Budget and Budget Justification sections should provide itemized detail for each major category for each year of the program. Complete all totals and subtotals. Enter the information on the web form (and on the budget template).

Use of Funds

The funds must be used for research-related costs while overhead/indirect costs strictly should be kept at a minimum as further described below.

Permissible Direct Costs include the following with the specified limitations:

- 1) Personnel expenses including salary, wage or stipend and fringe benefits.
- 2) Other Direct Costs
 - a. Supplies & Materials requests should be itemized by category*
 - b. Equipment Purchase requests must identify each item and how it relates to the SCOR*
 - c. Patient-associated costs

*Supplies, materials and equipment should be directly related to the proposed research and should be described in the budget justification section. The budget will be reviewed by both the review committee and LLS staff to be sure that purchases are well-justified. If they are not well-justified, funded grantees may be asked to modify the budget. In some cases, the budget may be reduced before funding commences.

Permissible Indirect Costs (often referred to as Institutional overhead, IDC, M&A, G&A or pooled costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.) as defined in Office of Management and Budget Circular A-21. Indirect costs are limited to 20% of total direct costs requested.

Impermissible Costs include (but are not limited to) membership dues, tuition, books, journals and publication costs.

8. Signature Page

Provide all requested signatures.

Upload the full application components, as a single PDF, in the “Project and Supporting Documentation” section on the grants management portal.

All uploaded documents must be combined into a single PDF in the order listed above. Failure to submit as a single PDF in the order above may result in disqualification of the application.

Submission and Confirmation

After clicking the “Submit” button, you will receive an automated email stating that your application was successfully submitted. **If you do not receive the email confirmation within 2 business days of submission, contact LLS at researchprograms@lls.org.**

If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted, but prior to the deadline, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document.

The following changes are allowed post-submission:

- Significant updates to clinical trials:
 - IRB updates
 - opening of the trial
 - patient enrollment
 - opening of new clinical sites
 - efficacy and/or safety updates
- Manuscripts that have been accepted for publication; the following must be provided:
 - list of authors
 - title
 - journal
 - a copy of the letter from the journal
- Change of institution of key personnel, and/or changes of key personnel resulting from a new hiring

Please email these updates to researchprograms@lls.org. Any other questions regarding the submission process should be emailed to this address as well.