



WWW.LLS.ORG

Specialized Center of Research
Program
Guidelines & Instructions

Letter of Intent
and
Full Application

Effective dates:

July 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

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.

Post-Award Management

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. The SCOR Progress Review Committee, consisting of 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 last year in relation to the aims of the SCOR and the milestones/deliverables agreed upon the year before. Any problems encountered should be discussed and any changes from the original aims should be justified.

Annual Assessment

After the annual Site Visit, the SCOR Progress Review Committee will assess the quality of the integration of the SCOR team and the progress made. The Committee will make a recommendation 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 brief summary of the year's research as presented at the Site Visit.

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.

Who Can Apply

Citizenship

LLS welcomes applications from both US citizens and non-citizens, as well as applicants who are performing research outside the U.S.

General Eligibility

Applicants must hold a PhD, MD, DVM, or equivalent degree and must be affiliated with a non-profit Sponsoring Institution at the time funding commences and for the duration of the award. Applications may involve multiple institutions.

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 and Core is led by a Project Leader or 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.

Leadership Limitations

SCOR Director

- May only submit one application as a SCOR Director
- May be the SCOR Director on only one active SCOR; current SCOR grantees may submit an application if their current SCOR funding ends in 2018
- May be the Project Leader on one other SCOR application submitted per cycle
- Must be a Project Leader on one proposed Project
- May or may not be a Core Leader

Project Leader(s)

- One Project Leader must be the SCOR Director
- May not be a Project Leader on more than one Project in a SCOR
- May be the Project Leader on a maximum of two Projects on separate SCOR applications submitted per cycle
- May have a Project co-Leader

Co-Project Leader(s)

- May be a co-Project Leader and/or Project Leader on a maximum of two Projects on separate SCOR applications submitted per cycle

Core Leader(s)

- May be a Core Leader on no more than one Core for any one SCOR application submitted per cycle
- May not be a Core Leader on more than two separate SCOR applications submitted per cycle
- May or may not be a SCOR Director

The Projects and Cores may be at the same institution or at different institutions. Either the demonstrated synergy or the potential synergy of the SCOR components will be a critical part of the review process.

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. The current contract is found on LLS's website, www.lls.org ("Academic Grants" subsection of the "Researcher's & Providers" section).

Application Process

The SCOR application process consists of two parts: the LOI and full application.

Letter of Intent

In the LOI, the applicant presents a brief description of each Project and Core together with an overview of how the SCOR will function as a unit. The LOI is competitive, and historically approximately 1/3 are invited to submit a full application.

Full Application

The full application is a more complete description of the SCOR. In some cases, the SCOR Directors of several top-ranked applications may be asked to address questions from the review panel. The review panel will then consider those answers before rendering final scores. Only top-ranked applications may be asked for clarification, but this does not guarantee funding.

Review Process

LOIs are reviewed by an independent and voluntary expert panel. The panel decides which LOIs should be invited to submit a full application using the criteria listed below (see *Review Criteria*).

If there is a researcher that you would like excluded from reviewing your LOI and/or full application, please email researchprograms@lls.org no later than the LOI deadline of September 22, 2017. LLS will make every effort to accommodate these requests, but cannot guarantee such exclusion(s).

Full applications are reviewed by an independent and voluntary expert panel. The panel assigns two scores to each full application. In some cases, the SCOR Directors of several top-ranked applications may be asked to address questions from the review panel. The review panel will then consider those answers before rendering final scores. Only top-ranked applications may be asked for clarification, but this does not guarantee funding. The Priority Score follows the NIH 1-9 scoring system and scores using the criteria listed below (see *Review Criteria*). The reviewers also assign a Mission Score, which evaluates the applications adherence to LLS's Mission (see *Mission Score*).

Review Criteria

1. The significance of the proposed research to the diagnosis, treatment, or prevention of hematologic malignancies and/or relevant premalignant conditions.
2. The experience, background, and qualifications of the SCOR Director and Project/Core Leaders.
3. The synergy that is likely to derive from joining interdisciplinary Projects and Cores into an interactive group.
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.

Mission Score

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
Call for Proposals	July 2017	
Letter of Intent deadline	September 22, 2017	3:00 PM EST
Notification of Full Application invitation	December 2017	
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	

The submission deadlines will be strictly enforced. 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 "Information" on the left navigation bar, click "Specialized Center of Research."

Click "Apply to SCOR!"

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 at that stage. Contact researchprograms@lls.org if you submit in error (must be before the deadline).

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

If your LOI is selected by the review panel, you will have access to the full application. Click on your request to continue with your 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.

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

Specific Instructions for Applying

Letter of Intent

Sponsor Institution

Indicate the institution for the SCOR Director.

SCOR Director

Indicate the SCOR Director who is responsible for the application and will oversee the integration of the Projects and Cores.

Institutional Signing Official (ISO)

The ISO is the institutional representative responsible for signing and agreeing to the accuracy of the application and the terms of the award, should the application be funded.

Financial Officer

The Financial Officer is the institutional representative responsible for the financial administration of externally-funded research.

Additional Access

Access may be given to one other individual to assist in the application process. The SCOR Director is ultimately responsible for the successful submission of the application.

Technology Transfer Officer

The TTO is responsible for the contractual and business-related aspects of any patentable discoveries resulting from the Grantee's research activities. Contact information for the TTO will be asked for from those applicants selected for funding.

Zip Code of Sponsor Institution

Provide the zip code of the SCOR Director's institution.

Amount Requested

The maximum total amount (direct and indirect costs) is \$1,000,000/year. The maximum total amount over the life of the grant is \$5,000,000.00. The amount requested will be the amount funded, should the SCOR be awarded.

SCOR Title

100 character limit including spaces.

Previous Submission

Indicate whether this proposal (or a similar one) was submitted to LLS by the SCOR Director or a Project Leader previously.

Proposed Start Date

SCORs start on October 1, 2018.

Proposed End Date

SCORs end on September 30, 2023.

Projects

Provide the title, Project Leader(s) and Institution of the Project Leader(s) of each Project. There must be at least three but no more than five Projects. See *Leadership* under the *Who Can Apply* section.

Cores

Provide the title, Core Leader(s) and Institution of the Core Leader(s) of each Core. There must be at least two but no more than five Cores. See *Leadership* under the *Who Can Apply* section.

SCOR Scientific Statement

The SCOR Director should provide an overview of the SCOR. Describe the overall proposed research and a brief overview of each Project and Core. Discuss the interactions between the components that will create synergy. Discuss plans for clinical translation of findings. Scientific/Greek characters or symbols must not be used. 6,000 character limit.

Scientific Abstract

Leave blank (we require this only for those selected for funding).

Lay Abstract

Please do not complete this section. Lay abstracts will be required of those selected for funding following Award notification.

Project Details

Provide a brief description, including the specific aims and anticipated results for each Project. Scientific/Greek characters or symbols must not be used. 1,500 character limit.

Core Details

Provide a brief description, including the specific aims and anticipated results for each Core. Scientific/Greek characters or symbols must not be used. 1,500 character limit.

Collaborators Information

Indicate any personnel, outside of your institution, with whom you have a significant and current interaction regarding your project. Only include those people who are at or above tenure-track level (or equivalent). List up to 5 people.

This information will assist in identifying potential conflicts of interest during the reviewer assignment process.

Biosketches

All Project Leaders and Core Leaders must provide a biosketch using the current NIH format, which includes Other Research Support. Upload the biosketches to the Project and Supporting Documentation section.

Submission and Confirmation

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

Changes

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.

Review and Notification

The independent review panel will review LOIs. LLS will notify applicants via email if the LOI is accepted for full application submission. See *Key Dates*.

Full Application

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.

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.

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.

Budget

Enter the information on the web form (and provide on the budget 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.).

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

1. Table of Contents

2. 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.

There are additional requirements for applicants who are currently on a SCOR or who have previously submitted a SCOR application that was not funded. See *Additional Requirements for Returning Applicants*.

3. 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.

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

5. 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

Additional Requirements for Returning Applicants

Applicants who have previously held, or currently hold, an LLS SCOR must include the following information.

- If there is a Project or Core Leader named on your application and they are on another LLS-funded SCOR, it should be clear how the work proposed in the new application is

different from that of the other SCOR grant. Include this information in the Other Support section of the Biosketch, still adhering to the NIH page limit.

- If you previously held, or currently hold an LLS SCOR as the SCOR Director, you must clearly outline how SCOR funding has contributed to scientific/clinical productivity. Provide specific examples of accomplishments that are attributed to LLS funding. Include this in the SCOR Justification and Major Resources section, still adhering to the 5 page limit.

6. 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.

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 of equipment*
 - 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 5% of total direct costs requested. For Sponsoring Institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Grantee's stipend or fringe benefits cost.

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

7. 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 will result in disqualification of the application.

Submission and Confirmation

After clicking the “Submit” button, you will receive an automated email stating that your information 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.