

The Specialized Center of Research Program Guidelines & Instructions

Full Application

Revised November 2015

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GENERAL INFORMATION

1. ABOUT THE LEUKEMIA & LYMPHOMA SOCIETY
The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health organization dedicated to funding blood cancer research, education and patient services. LLS's mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

LLS's Specialized Center of Research (SCOR) grant program was developed to encourage the interaction of complementary sciences, including basic, translational and clinical sciences focused on the prevention, diagnosis, or treatment of hematologic malignancies and relevant premalignant conditions. To be funded in this program, the proposed research must be multidisciplinary and the SCOR must demonstrate synergy among at least three research Projects; these are supported by scientific Core laboratories. LLS permits an application for continued funding beyond five years for current SCORs. These applications compete with all proposals submitted in that application year.

Details on SCORs funded by LLS may be found on LLS's website: http://www.lls.org/grant-finder

2. DESCRIPTION OF AWARDS

The SCOR Award mechanism 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 that is intended to develop innovative approaches 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 projects that are translational or clinical in nature.

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 relevant scientific Projects that will cooperate under the leadership of a SCOR Director. There must be objective evidence of interdisciplinary research, synergy, and focus on one or more hematologic malignancy and/or relevant premalignant condition. LLS allows for five Projects in a SCOR, but may permit additional Projects to be included, if strong rationale is provided. Quality, not quantity, is the principal objective. Each scientific Core must be essential to the work of at least one Project, but it is preferable that each Core has a role in multiple Projects in the SCOR.

The maximal annual total cost, direct and indirect, cannot exceed \$1 million. The aggregate costs over five years cannot exceed \$5 million. The direct costs, if justified by the aggregate budget, may be up to \$833,330 per year. The indirect or institutional costs cannot exceed 20% of the direct costs per year (and are capped at \$166,666). The Applicant (SCOR Director) has the authority to budget these funds among participating Projects and Cores as he/she deems most appropriate.

Table 1: Maximum SCOR Award Duration & Value

*Please note: The award amount you are given will reflect the amount you request in the budget section of your application. Any requests to increase funding must be in writing to LLS, and are subject to the availability of funds.

Duration	Maximum Annual Direct Costs	Maximum Annual Indirect Costs	Maximum Annual Total Costs	Maximum Total Costs 5 Years
5 years	\$833,330	\$166,666	\$1,000,000	\$5,000,000

Budget and 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.

The Center's maximum annual total cost, direct and indirect, cannot exceed \$1 million. The aggregate costs over five (5) years cannot exceed \$5 million.

Permissible Direct Costs, if justified by the aggregate budget, may be up to \$833,330 per year. A description of permissible direct costs includes the following with the specified limitations:

- Scientific Cores budget cannot exceed \$75,000 per year in direct expenses.
- Personnel Expenses include salary, wage, or stipend with fringe benefits. Expenses for administrative staff (including secretarial) costs cannot exceed one full-time equivalent for the Center per year.
- Supplies &Materials requests should be itemized by category.*
- Equipment Purchase requests for any and all equipment cannot exceed a total of \$100,000 per year. Equipment over \$5,000 is permitted if at least fifty percent (50%) of the cost is covered from another source such as grants from other agencies or institutional support.*
- Travel Expense requests cannot exceed \$10,000 per year for all investigators and should include the costs for the lead PI to attend the SCOR Progress Review Meeting held each year in New York City, and annual Site-Visit (airfare, one night's lodging and incidental expenses).
- Patient Care costs can be included in other direct costs.
- Other Direct Costs requests such as office supplies and telephone costs cannot exceed \$6,000 per year for the Center.

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. The indirect costs cannot exceed twenty percent (20%) of the direct costs per year.

Impermissible Costs include membership dues, tuition, books, journals, and publication 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.

3. APPLICATION PROCESS AND DEADLINES

The deadline for submission of the Full Application is March 16th. Submissions must be made electronically to the LLS grants management portal powered by Fluxx (https://lls.fluxx.io).Full Applications will only be accepted via Fluxx. The submission deadlines will be strictly enforced. **Please note that all times are Eastern Time.** If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

Application Phase	Date	Time
Full Application – open	January 9	3:00 PM ET
Full Application – close	March 16	3:00 PM ET
Review	May/June	
Notification of Awards	Mid-summer	
LLS's receipt of signed contracts*	September 1	3:00 PM ET
Award start date	October 1	

Table 2: SCOR Grant Application Deadlines

Data Entry

The full application may be accessed and changed multiple times as needed prior to the submission deadlines. However, the full application **cannot be changed once the deadline has passed or the application has finally been submitted**. Moreover, some fields may not be modified in the full application following submission of the LOI.

Contacting LLS Regarding Filing of Application

Questions that are not clarified in this document or on the Fluxx site should be addressed to researchprograms@lls.org .

Forms and Format

An application template for the full application is on the Fluxx website. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the Fluxx website. Fields in bold are required. All Applicants must use single-spaced text and Times New Roman 12 pt. Margins are preset in the template and must remain as is. The Applicant's name should be typed in the upper right corner of each page of the template. Failure to use the provided template or to adhere to font size, spacing, margins, and/or page limitations may result in the disqualification of the application.

Applicants must submit a full application by March 16th at 3:00 PM ET via the Fluxx website (https://lls.fluxx.io), or the following business day if this date falls on a weekend or a U.S. holiday. The SCOR Director is responsible for submitting the full application. Applications that are not submitted through the Fluxx site will be disqualified from review.

Full Applications will only be accepted via Fluxx. The submission deadlines will be strictly enforced. **Please note that all times are Eastern Time.** If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

^{*}There is a strict deadline for returning the signed contract. In the event that a contract is not returned by the deadline, LLS reserves the right to rescind the Award offer.

Relevance

A SCOR is a focused, cohesive, interdisciplinary, and synergistic research team focused on a significant problem and likely to make important advances in treatment, diagnosis or prevention of hematologic malignancies and related premalignant disorders. A Center involves at least three, but no more than five research Projects and must involve at least one scientific Core that enhances the synergies in the Projects.

4. REVIEW PROCESS

Review of Full Applications

Full Applications will be reviewed in May/June by the SCOR Subcommittee of the Medical & Scientific Affairs Committee. Top ranked applicants may be asked to address questions provided by the review panel before a final decision is made. Only the top applicants will be asked for clarification, but this does not guarantee funding. Applicant responses to these questions will be analyzed by a subcommittee of the review panel, who will then determine final scores. Once ranked, priority scores will be presented to the Medical & Scientific Affairs Committee. Two scores will be given for each application; the Overall Priority Score reflects the overall scientific quality of applications, and the Mission Score, which reflects the relevance to the LLS mission.

Review Criteria

The Full Application will be reviewed using these criteria:

- The significance of the proposed research to advances in diagnosis, treatment or prevention of hematologic malignancies and/or related premalignant conditions.
- The likelihood that the research findings will find clinical application, ideally within the period of SCOR funding or at least the foreseeable future.
- The experience, background, and qualifications of the SCOR Director, Project PIs and Core Leaders.
- The synergy that is likely to derive from joining interdisciplinary Projects and Cores into an interactive group.
- The quality of the available resources and environment (e.g. facilities, special equipment, patient population).

The Mission Score is given based on:

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.

Once ranked, priority scores will be presented to the Medical & Scientific Affairs Committee. The Medical & Scientific Affairs Committee creates a funding recommendation based on the Overall Priority Score), Mission Score, programmatic review, and funds available (LLS Board of Directors determines the budget available for research grants each year). The recommendation is presented to the Mission Oversight Committee (MOC) for final approval.

Any Applicant selected for funding will be notified within 45 days of the review. Funding decisions are relayed by email only and are not available by telephone. All priority scores are confidential and are only available to LLS's Medical & Scientific Affairs Committee, its Review Subcommittee and administrative personnel only. Written critiques of the application are not formally provided to an Applicant.

5. Post Award Management

Milestones and deliverables

Projected milestones and deliverables to be achieved on a quarterly basis are required in the grant application and will be evaluated by the Review Panel. LLS staff will work with the SCOR Director of those grants that are funded to make any final changes.

Site visit

An annual Site Visit will occur around the anniversary of the grant start date (October 1). The SCOR Progress Review Committee consisting of members of the LLS Research staff, the Grant Review Committee and the LLS Medical and Scientific Affairs Oversight Committee will visit the SCOR team. The SCOR Director, Project PIs and Core Leaders must be present. though in some circumstances, a key member of the team may take the place of a Project PI/Core Leader at the discretion of LLS. The SCOR team will give presentations that give a detailed overview of the progress made in the last year as they relate to the original aims as well as the milestones/deliverables agreed upon the year before. Any problems encountered should be discussed and any deviations from the original aims must be justified. The SCOR Director should give a presentation on the integration of the Projects and Cores and the resulting synergies.

Annual Report

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.

Annual Assessment

After the annual Site Visit, the SCOR Progress Review Committee will meet to assess the progress made and the quality of integration of the SCOR team. 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. These milestones will form the foundation of the following year's review. The outcome from the annual assessment will be sent to the PI by email within sixty days of the review.

Annual SCOR Symposium

Each November, there is a mandatory symposium for all SCOR teams. This is an opportunity to showcase the research from each team to the rest of the SCOR recipients.

SCOR Team Meetings

A key element of a SCOR is the integration of multiple 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. All PIs on the SCOR must make every effort to attend, and this is a good opportunity for the interaction of postdocs and other staff from each team.

Grant Payments

The funds awarded shall be used solely for the purposes specified and in strict compliance with the budget submitted in the application to LLS and executed by the Applicant and the Applicant's Institutional representatives. All grant payments will be made pro rata at the end of each quarter to the SCOR Director's institution. It is the responsibility of the SCOR Director's Institution to disburse funds to the SCOR team during the term of the award. The final grant payment shall be made only after the receipt by LLS of satisfactory and complete final Annual Progress, Patent, and Financial Reports (see the following paragraph for an overview).

Annual Renewal of Funding

Although contracts are issued for the full term of the Award, continued funding is contingent upon timely submission of satisfactory and complete Annual Progress, Patent, and Financial Reports and LLS's ability to continually raise funds. The annual Progress Report is due 60 days before the grant anniversary date. A Financial Report is due 60 days after the grant anniversary date. Report templates are on the Fluxx website (https://lls.fluxx.io), and are to be re-uploaded on this site. Reports will be reviewed by LLS staff to evaluate the research progress of each Grantee. LLS reserves the right to terminate any grant if, in its sole discretion, it determines that there has been inadequate research progress or a failure to adhere to the original proposal. Annual Reports that are more than 30 days late or are incomplete or unsatisfactory will result in suspension of funds until the delinquency is resolved. If delinquency persists beyond 90 days, LLS reserves the right to terminate the award with prior written notice provided to the Grantee and their research administrator.

Withholding of Funds

The failure of the Grantee, the Sponsor, and/or the Sponsoring Institution to adhere to any of the terms and conditions in the contract shall constitute sufficient grounds for LLS, in its sole discretion, to withhold any or all funds due until the deficiency is corrected to LLS's satisfaction. Either LLS or the Sponsoring Institution may then terminate the contract upon giving 90 days written notice, if the deficiency cannot be corrected. In such a case, any unexpended funds must be returned to LLS.

GUIDELINES - FULL APPLICATION

Log on to the Fluxx site (https://lls.fluxx.io), click "New Request" on the left, click on your application then click "Edit".

LOI COMPONENTS

The information provided in the LOI phase will carry through into the full application phase. This LOI information will be provided to the review panel along with the rest of the full application. Since the LOI was accepted through a competitive, peer review process, the LOI components generally may not be changed. Any changes must have prior approval by LLS, and may not involve changes to the scientific content. Acceptable changes (which must be approved) may include stylistic changes, and changes to the budget.

ORGANIZATION ASSURANCES

The Applicant must complete the organization assurances section. The following provides an overview.

Human Subjects

The Applicant must indicate if human materials or subjects will be involved in the proposed research. The status (approved, pending or exempt) of Institutional Review Board (IRB, or equivalent oversight entity) approval must be provided. The Human Subject Assurance Number (OHRP) must be included. If the research project has received IRB approval, the date must be provided and documentation must be uploaded as the Human Investigation Statement. The application may be submitted with IRB approval pending. However, an award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the May review date if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be uploaded as the Human Investigation Statement.

Laboratory Animals

The Applicant must indicate if laboratory animals will be involved in the proposed research. The status and date of Institutional Animal Care and Use Committee (IACUC, or equivalent oversight entity) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of Sponsoring Institutional approval must be uploaded as the Laboratory Animal Statement. The application may be submitted with IACUC approval pending. However, an award will not be made without documented IACUC approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the May review if the IACUC status has changed.

Recombinant DNA

The Applicant must indicate if the proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be uploaded with the application.

Biohazard Statement

The Applicant must indicate if the proposed research involves the use of biohazards. If the Applicant indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be uploaded as the Biohazard Statement.

Clinical Protocol Appendix (if applicable)

Provide a one page summary and a link to the clinicaltrials.gov website for any clinical protocol essential to the proposed research. Include IRB approval date, IRB compliance number, and effective dates of approval. Projects for which IRB approval is pending must include a statement to that effect. The Applicant should notify LLS of IRB approval prior to the May grant review.

BUDGETING INFORMATION

Enter the budgeting information as required on the web form fields.

SUPPORTING DOCUMENTATION

Download and complete the Project Description/Budget template.

Please follow character limits and page lengths carefully. In addition, make sure that margins are no smaller than 0.5 inches on each side. Only Times New Roman 12 may be used. <u>Failure to adhere to this</u> rule will result in administrative disqualification of your application.

The full application must contain the following components:

1. Table of Contents

2. SCOR Justification and Major Resources (5 page maximum)

This section should include:

- Title
- Aims/goals
- Background with scientific and clinical significance
- Innovation
- Overall approach
- Shared Core and other resources
- Collaborations among SCOR personnel
- Citations

There are additional requirements for applicants who are currently on a SCOR or who have previously submitted a SCOR application that was not funded. Please refer to the "Additional requirements for returning applicants" below.

3. Project

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

Project (5 page maximum for each Project)

- Project number
- Project title
- Project PI(s)
- Project description
 - Specific aims

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

4. Core

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

Core (3 page maximum for each Core)

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

5. Appendices

This section should include:

- Table of contents
- Human, animal, and biohazard assurances/approvals
- Letters of support or collaboration
- Clinical protocols

Additional requirements for returning applicants

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

- 1. If there is a Project or Core leader named on your application and they are currently working on another LLS-funded SCOR grant, it should be clear how the work he or she is doing is different in your application from that of the other SCOR grant. **Please include this in the Other Support section.**
- 2. If you previously hold, or currently held an LLS SCOR grant as the SCOR Director, you must clearly outline how LLS funds have contributed to your productivity including specific examples

of accomplishments that can be attributed to LLS funding. Please include this in the SCOR Justification and Major Resources section, still adhering to the 5 page limit.

For applicants that have previously submitted a SCOR application that was not approved, please include a description indicating how your present application has changed in relation to your last full SCOR application. Please append this 1 page description before the SCOR Justification and Major Resources section.

Budget

The Detailed Budget and Budget Justification sections should provide itemized detail for each major category for the year of the program. All Totals and Subtotals should be completed on the form.

Signature Page

All applications must be signed by the Principal Investigator (and Co-Principal Investigator if applicable), Institutional Signing Official, Research Administrator, Financial Officer, and Technology/ Transfer Official. The signature page is provided in the downloadable application template. The Grants and Contracts Office of the Sponsoring Institution can help ensure appropriate signatures are obtained.

• Principal Investigator

The Principal Investigator is the Applicant.

• Financial Officer

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

• Research Administrator

The Research Administrator is the institutional representative responsible for the day-to-day administration of externally-funded research.

• Institutional Signing Official (ISO)

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

Technology/Transfer Official

The Technology Transfer Official is the institutional representative responsible for overseeing Intellectual Property.

• Co-Principal Investigator

The Co-Principal Investigator is the Co-Applicant.

UPLOAD THE PROJECT TEMPLATE - SUPPORTING DOCUMENTATION

Upload the completed template as one single PDF to the Supporting Documentation section by clicking the green plus sign. Choose "Project Description" from the drop down menu before uploading.

The completed Project Description/Budget template and all appendices must be uploaded as one PDF file.

APPLICANT ASSURANCE

Check the box to accept the terms as stated on the web form.

SAVE AND REVIEW

Validation will automatically occur after clicking the "Save" button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system notifies the Applicant of fields that require information. The system will notify the Applicant when character limits are exceeded. Exceeding the character limit on any field of the application will automatically disqualify the application.

SUBMIT

After clicking "Save" you will be directed to review your application. Please ensure all information is accurate, and then click the "Submit" button to submit your application.

Once submitted, only LLS staff can delete the file. If you need a file deleted from the upload section, contact researchprograms@lls.org for assistance.

If you plan to withdraw your application at anytime during the application cycle, please inform LLS staff of your decision by writing to researchprograms@lls.org.