



# **Specialized Center of Research Program Guidelines & Instructions**

## **Letter of Intent**

Revised September 2015

## **I. What's New**

- We have a new SCOR review process. We will continue with the competitive Letter of Intent phase, and invited full applications will be reviewed as usual. As an addition to the full application review process, we may ask that several of the top applicants address questions provided by the review panel for further assessment.
- Funded grantees will undergo a formal annual assessment process involving a SCOR Progress Review Committee. A part of the assessment will be an annual site visit by members of the SCOR Progress Review Committee. See “Post Award Management” for more details.
- The LLS is now accepting the current NIH biosketch, which includes the biosketch and other research support. In addition, the other research support section must contain the specific aims as written in the original grants. A summary of goals is not sufficient.
- The budget will have a limit of \$1,000,000 per year of direct and indirect costs.

## **II. Guidelines**

### **About The Leukemia & Lymphoma Society**

The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health organization 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.

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 hematological malignancies and relevant premalignant conditions. To be funded in this program, the proposed research must be multidisciplinary and the SCOR must demonstrate synergy among the research Projects. These Projects are supported by one or more Core laboratories. LLS permits an application for continued funding beyond five years for current SCORs. These applications complete with all proposals submitted in that application year.

### **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. The overall goal of this mechanism is to enhance the development of 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 translational projects.

Research areas may include, but are not limited to, the following:

1. **Mechanisms underlying the development of hematological malignancies.** Our understanding of the molecular basis of cancer is leading to the development of predictive tests and targeted therapeutics. The LLS recognizes that understanding the basic mechanisms of hematological diseases, using state of the art technologies, forms the foundation of new therapies.
2. **Biomarkers (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management).** The development of validated biomarkers and pharmacodynamic endpoints will be valuable in guiding the future of medicine for hematological diseases. Many hematological malignancies offer the opportunity to monitor the disease state at a molecular level. Application of these methods for disease management will be very useful in the future.
3. **Therapies (including small molecules, biologics, gene- and DNA/RNA-based therapies, cell therapies, and immunotherapies).** The LLS is very interested in supporting well-justified therapeutic approaches to all types of blood cancers. The aim of these efforts should be to significantly extend the lives of patients, or, for certain blood disorders, provide curative intent, with an excellent safety profile. We encourage applications that apply the principals of

precision medicine and use sophisticated animal models to predict responsiveness to molecular therapies. In addition, with the advances in our understanding of the immune system and immunotherapies, the LLS encourages the submission of applications that focus on harnessing the immune system for therapeutic intent.

4. **Stem cell transplantation (including but not limited to allogeneic, autologous, non-myeloablative).** As HSCT provides effective therapy for some patients with blood cancer, improving upon current methods is valuable.

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, synergy, and focus on one or more hematological malignancy and/or relevant premalignant condition. LLS allows up to 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 \$1,000,000 for each year of the five year grant (Table 1). The 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 and Value**

| <b>Duration</b> | <b>Maximum Annual Direct Costs</b> | <b>Maximum Annual Indirect Costs</b> | <b>Maximum Annual Total Costs</b> | <b>Maximum Total Costs 5 Years</b> |
|-----------------|------------------------------------|--------------------------------------|-----------------------------------|------------------------------------|
| 5 years         | \$833,330                          | \$166,666                            | \$1,000,000                       | \$5,000,000                        |

## **Post Award Management**

### **Milestones and deliverables**

Projected milestones and deliverables to be achieved on a quarterly basis are asked for 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 LLS Research staff, the SCOR grant review committee and the LLS Medical & Scientific Affairs Committee, will visit the SCOR Director and members of the SCOR team. The SCOR Director, Project PIs and Core PIs must be present. Though

it is expected that each PI must be present, in some circumstances, a key member of the PI's team may take his/her place at the discretion of LLS. The SCOR team will give presentations that provide an 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 quality of 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. 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 Site Visit.

### **Annual SCOR Symposium**

Each November, there is a mandatory symposium for all currently-funded SCOR teams. This is an opportunity to showcase the research from each team to the other SCOR recipients. It is also an opportunity to meet with senior LLS leadership as well as a select number of Medical & Scientific Affairs Committee members.

### **SCOR Team Meetings**

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

## **Who Can Apply**

### **General Eligibility Criteria, Citizenship, and Degree**

All Applicants must hold an MD, PhD, or equivalent degree, and work in domestic or foreign non-profit organizations. Applications may involve multiple institutions. Applicants need not be US citizens, and there are no restrictions on Applicant age, race, gender or creed. Applications from non-academic facilities will not be considered.

### **Leadership and Staffing**

The SCOR shall have 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 conduct of the research programs and adherence with all stipulations made by LLS in this document and in the grant contract. Each participating research Project and Core shall have a Leader

responsible for the management of the Project or Core under the overall direction of the SCOR Director; the SCOR Director must also be the Project Leader of **no more than one** Project. The SCOR Director can also be a Leader of a Core. Modifications to leadership and staffing must be approved in writing by LLS.

## **Application Process**

### **Overview**

The overall SCOR review process consists of three parts. The first part is the LOI phase, whereby a brief description of each SCOR is reviewed by an expert review panel. Approximately 25-50% of the LOIs will be chosen for full application submission. In this second phase, the full applications will be reviewed by the expert panel. Several top-ranked applications may be selected for further consideration in the third and final phase. In this final phase, SCOR applicants may be asked to address questions provided by the expert panel. Only the top applicants will be asked for clarification, but this does not guarantee funding.

**Table 2: Deadlines**

| <b>Application Phase</b>                    | <b>Date</b>       | <b>Time</b> |
|---|-------------------|-------------|
| Call for Proposals                          | September 2015    |             |
| Letter of Intent Deadline                   | November 2, 2015  | 3:00 PM ET  |
| Notification of Full Application Invitation | December 30, 2015 |             |
| Full Application – open                     | January 2, 2016   | 3:00 PM ET  |
| Full Application Deadline                   | March 16, 2016    | 3:00 PM ET  |
| Notification of Awards                      | June 30, 2016     |             |
| LLS's receipt of signed contracts*          | September 1, 2016 | 3:00 PM ET  |
| Funding start date                          | October 1, 2016   |             |

**\*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.**

### **Letter of Intent**

We initially ask for a Letter of Intent (LOI). The LOI contains an explanation of the overall question to be addressed as well as how all the teams will interact and how the Projects and Cores will synergize. LOIs are peer reviewed and scored. Based on this scoring and available funding, some applicants will be invited to submit a Full Application.

The LOI (and 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.
- The experience, background and qualifications of the PIs.
- The synergy that is likely to derive from joining interdisciplinary Projects and Cores into an interactive group.

- The quality of the resources and environment (e.g. facilities, special equipment), including demonstrated access to patient populations or patient samples.

LOIs and full applications will only be accepted via Fluxx (see below). 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.

### **Full Application**

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. Applicant responses to these questions will be analyzed by the review panel, who will then determine final scores. 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 scientific quality of applications (Priority Score), relevance to the LLS Mission (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.

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.

Any Applicant selected for funding will be notified within 45 days of 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 LLS staff. **Written critiques are not provided.**

## **III. Instructions**

### **General Information**

LLS is using Fluxx as our online grants management system, which is accessed here: <https://lls.fluxx.io>. Only online submissions through the Fluxx website will be accepted.

### **Registration**

Both the Applicant (SCOR Director) and Sponsoring Institution must be registered in Fluxx. If you have applied to LLS in the past, you do not need to create a new registration. Simply click the "[reset or create password](#)" and enter your email address. The system will send your username and a link to update your password. Once registered, the Applicant can begin the LOI. Email [researchprograms@lls.org](mailto:researchprograms@lls.org) for assistance creating a new account in Fluxx if you do not already have one. Only LLS staff members have administrative permission to create new accounts.

### **Institutional Designation**

During the registration process, the Applicant should create their profile from the standpoint of where the SCOR Director's research will be performed. Fluxx currently has a list of organizations registered. To register a new institution, contact [researchprograms@lls.org](mailto:researchprograms@lls.org).

### **Data Entry**

Both the LOI and the full application may be accessed and changed multiple times as needed prior to the submission deadline. However, neither the LOI nor the full application can be changed once the deadline has passed or the application has been finally submitted. Moreover, some fields may not be modified in the full application following submission of the LOI.

### **Contacting LLS**

Questions that are not clarified in this document should be addressed to:

Director, Research Programs  
The Leukemia & Lymphoma Society  
1311 Mamaroneck Avenue, Suite 310  
White Plains, New York 10605  
[researchprograms@lls.org](mailto:researchprograms@lls.org)

### **Forms and Format**

Applicants will provide information on the Fluxx website at the LOI phase; there is no other template necessary at this phase. For the full application phase, a template will be provided 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. In addition, character limitations must be adhered to.

## **IV. Letter of Intent**

Each SCOR Director must submit an LOI by **November 2 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 Applicant should carefully craft the information requested in the LOI as this information is automatically populated during the full application phase and is subject to the Changes clause listed below. The SCOR Director must input all the information into Fluxx, including the information for each Project and Core.

### **Completing the LOI**

#### **1. SCOR Information**

##### **Institution and Department**

Indicate the institution and department for the SCOR Director. If this institution is not listed, please contact [researchprograms@lls.org](mailto:researchprograms@lls.org).

##### **SCOR Director**

Indicate the SCOR Director who is responsible for overseeing the integration of all Projects.

##### **Institutional Signing Official (ISO)**

The ISO is the institutional representative from the SCOR Director's institution responsible for signing and agreeing to the accuracy of the application and the terms of the award, should the application be selected for funding.

##### **Financial Officer**

The financial officer is the institutional representative responsible for the financial administration of externally-funded research at the SCOR Director's institution.

##### **Additional Access**

Access may be given to personnel to assist in the application process.

##### **Technology Transfer Official**

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

##### **Zip Code of SCOR Institution**

Please provide the zip code of the SCOR institution.

#### **2. SCOR Components**

##### **Amount Requested**

The total amount, including both direct and indirect costs, cannot exceed \$1,000,000/year.

##### **SCOR Title**

Provide a title adhering to the 100 character limitation.

**Previous Submission**

Indicate whether you have previously submitted this proposal (or one similar) to LLS, and indicate the date of any prior submission.

**Proposed Start Date**

The start date for all SCOR grants is October 1<sup>st</sup> in the year the award is made (i.e. if an award is made to your application in July 2016, the grant start date will be October 1<sup>st</sup>, 2016).

**Proposed End Date**

The end date for all SCOR grants is September 30<sup>th</sup> five years after the year the award is made (i.e. if an award is made to your application in July 2016, the grant end date will be September 30<sup>th</sup>, 2021).

**Projects**

For each SCOR Project, provide the Project Title, the Project Leader, and the Institution. There must be at least three, but no more than five Projects.

**Cores**

For each Core, provide the title, Core Leader, and the institution.

**3. SCOR Statement and Abstracts**

**SCOR Scientific Statement**

The SCOR Director should provide an overview of the SCOR and describe the interactions between the Projects and Cores that will result in synergy. Clearly state the relevance to one or more hematologic malignancies and/or related premalignant conditions. Briefly describe the overall proposed research including the problem/question to be addressed, an overview of the Projects and Cores and how they will synergize with each other, and the anticipated results. Scientific/Greek characters or symbols must not be used. Maximum 6,000 character limit.

**Scientific Abstract**

Describe the overall objective of the SCOR in 1,500 characters or less. Scientific/Greek characters or symbols must not be used.

**Lay Abstract**

Describe the overall objective of the SCOR in 1,500 characters or less for a lay audience. Scientific/Greek characters or symbols must not be used.

**Project Details**

Provide a brief description of each Project. Describe the problem/question to be addressed, the specific aims, and anticipated results. Scientific/Greek characters or symbols must not be used. It is not required in this section to describe in detail the interaction with the other Projects (which is addressed in the SCOR Scientific Statement). Maximum 1,500 characters or less for each Project.

**Core Details**

Provide a brief description of each Core. Provide information on the scientific/technical nature of the Core. It is not required in this section to describe in detail the interaction with the other Projects (which is addressed in the SCOR Scientific Statement). Scientific/Greek characters or symbols must not be used. Maximum 1,500 characters or less for each Core.

### **Biosketches**

The SCOR Director, Project Leader, and Core Leader must provide a biosketch using the current NIH format, which includes Other Research Support. Provide the Specific Aims for each grant listed.

### **Save and Review**

Validation will automatically occur after clicking the “Save and Review” 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.

After clicking “Save and Review,” you will be directed to review your LOI. Please ensure all information is accurate, and then click the green “Submit” button (top right corner) to submit your LOI.

### **Changes**

Information collected in the LOI will automatically populate fields in the full application. Once submitted, changes may only be made after receiving prior approval from LLS. The Applicant should email LLS ([researchprograms@lls.org](mailto:researchprograms@lls.org)) requesting any change and identifying the elements to be changed. Any changes made without the prior approval of LLS may result in the disqualification of the LOI.

### **Submission of the LOI**

It is the responsibility of the SCOR Director to input the information into Fluxx. The SCOR Director must submit the LOI by **November 2 at 3:00 pm Eastern Time** via the Fluxx website, or the following business day if this date falls on a weekend or a U.S. holiday. After clicking the green “Submit” button, the Applicant will receive an email from Fluxx stating that the LOI was successfully submitted. **If you did not receive the confirmatory email from Fluxx within 2 business days of LOI submission, please e-mail us at [researchprograms@lls.org](mailto:researchprograms@lls.org).**

### **Review of the LOI**

LLS staff will process submitted LOIs, which will then be reviewed by an independent committee. After the LOI is reviewed, the Applicant will be notified via email whether or not they have been invited to submit a Full Application. If invited for Full Application submission, the Applicant will have access to this section in the Fluxx grant management system. If you have not received an email regarding your LOI review by January 5 at 3 PM ET, contact us at [researchprograms@lls.org](mailto:researchprograms@lls.org).