



Specialized Center of Research Program Guidelines & Instructions

Letter of Intent & Full Application

Effective dates:

May 1, 2019 – April 30, 2020

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2019-2020 Updates

The Leukemia & Lymphoma Society is implementing a new rule regarding overlapping aims in grant proposals submitted to LLS. This policy applies to proposals submitted within the same application cycle, which is defined as all LLS calls for proposals – across all grant programs – that open within the same calendar year. An application to any LLS grant program may not have aims that substantially overlap with the aims of any other application (either to the same program or to a different program) that includes the same investigator(s) as PI(s), Co-I(s), Project or Core Leaders, or collaborator(s). All such duplicate grant proposal submissions with substantially overlapping aims are subject to administrative disqualification, and such proposals will not be reviewed further or considered for funding. Contact researchprograms@lls.org with any questions about this policy or to discuss with LLS scientific staff any questions concerning potential overlap between applications.

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 Specialized Center of Research (SCOR) Award

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.

Each SCOR is comprised of 3-5 scientific Projects, 2-5 supportive Cores, including an administrative Core. There must be objective evidence of interdisciplinary research and the potential for synergism by linking the various Projects and Cores into a SCOR team. The quality and significance of the Projects and Cores and the enhanced productivity that is likely to be achieved by linking investigators are primary determinants of funding decisions. 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 maximal total annual award is \$1,000,000.00 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.

Lay Abstract

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 notification. After the funding decision has been made, LLS will contact the SCOR Director 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 the SCOR Director and LLS staff are due prior to the start of funding.***

Site Visits

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.

SCOR Project Replacement Policy

Continuing from 2018, LLS will enforce its policy regarding underperforming Projects/Cores. All Projects/Cores within a SCOR program are meant to contribute substantially to the overall program goals and synergize with other SCOR components. If a Project or Core becomes unviable or unproductive, the SCOR Director must notify LLS within two weeks of this determination. Alternatively, if LLS staff judge a Project/Core to be no longer viable, they will notify the SCOR Director. LLS staff will determine whether LLS Mission goals will be best

served by substituting a replacement Project/Core for the terminated one or by continuing support of the SCOR program with one fewer component Projects/Cores.

LLS staff and outside advisors will review replacement Project/Core proposals submitted by the SCOR Director to determine if replacement is a viable option. If a replacement Project/Core is determined to be a viable option, that Project/Core will be funded at an appropriate level that may be the same or less than the funding for the prior Project/Core.

If a Project/Core is terminated and there is no viable replacement, LLS will determine whether the funding previously allocated to the terminated Project/Core will be distributed to the remaining Projects/Cores, or whether funding for that project will be terminated, reducing the overall SCOR budget.

Annual SCOR Progress Meeting

Each year, there is a mandatory Progress Meeting for representatives from all currently-funded SCOR teams. Travel to and from this meeting should be factored into the yearly travel budget of the SCOR.

Annual Reports

Financial, Intellectual Property, and Progress Reports are due annually while Publication Reports are due quarterly. The Progress Report will contain a summary of the year's research and is essential for staff evaluation of progress and for donor development activities. 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 SCOR progress and planning.

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/Core is led by a Project Leader/Core Leader, who is responsible for the management of that Project or Core. **There must be at least three but no more than five Projects. There must be at least two scientific Cores and one administrative Core but no more than five Cores in total.**

Modifications to 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 2020
- 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.

LLS's budget is not set until later in the year; therefore, LLS cannot fully commit to the number of SCORs that will be funded in 2020.

Application Process

The SCOR application process consists of two parts: the Letter of Intent and Full Application.

Letter of Intent

The LOI presents a description of the overall scientific problem and the integration of the various Projects and supporting Cores. In addition, the LOI has abstracts for each Project and Core, as well as NIH biosketches for each Project and Core Leader/co-Leader.

The LOI stage is a competitive step that is reviewed by an independent and voluntary expert panel. Therefore, it is critical to have a well-thought out and well-presented LOI to enhance the chances of a favorable review. Changes to submitted LOIs are not allowed.

The LOI is reviewed for responsiveness to the goals of the SCOR, and include :

- **qualifications of the SCOR Director and Leaders**
- **significance of the research to blood cancer**
- **quality of each Project and Core**
- **the likelihood of synergy among the Projects**
- **the significance of each Core to multiple Projects**
- **the likelihood of near-term clinical translation**

The review panel determines which LOIs will be invited to submit a Full Application. Historically, approximately 1/3 are invited to submit a Full Application.

Full Application

The Full Application is a more complete description of the SCOR. There should be no changes to the original intent, aims, or leadership between the LOI and the Full Application.

Full Applications are reviewed by an independent and voluntary expert panel. Full Applications will be assigned two scores. 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 application's adherence to the SCOR award's intent (see [Mission Score](#)).

If there is a person 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 August 31, 2019. 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 any individual project in isolation.

- The significance of the proposed research to the diagnosis, treatment, or prevention of hematologic malignancies and/or relevant premalignant conditions.

- The qualifications of the SCOR Director and Project/Core Leaders.
- 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 that should result in synergy.**
- The quality of the Cores and their ability to support multiple projects; the Cores should not be research-oriented as the Projects are. Appropriate Cores may be animal modeling, sequencing/informatics, clinical trial support, etc.
- 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.
- The quality of the resources and environment.
- The alignment of the quality of and access to patient populations and/or patient specimens with the research plan (where applicable).
- The clarity of thought and presentation, including an adequate number of figures that clearly present the data. **Each Project must have a minimum of three figures.**
- 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
Call for Proposals	June 2019	
Letter of Intent Deadline	August 31, 2019	3:00 PM EST
Notifications of Full Application Invite	November/December 2019	
Full Application Phase Deadline	February 15, 2020	3:00 PM EST
Notification of Awards	August 2020	
LLS's receipt of signed Grant Agreement, Lay and Scientific Abstracts and Milestones and Deliverables	September 1, 2020	
Funding start date	October 1, 2020	

*LLS's non-negotiable Grant Agreement Terms & Conditions are available on www.lls.org.

The submission deadlines will be 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 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. The [LLS Research Portal](#) automatically shuts down new submissions after the deadline has passed.

General Application Instructions

The SCOR application will be completed in two phases: Letter of Intent and Full Application. Below are step-by-step instructions for applying:

1. Read the Guidelines & Instructions (this document) in full.
2. Log in to the [LLS Research Portal](#) and select Specialized Center of Research. Click "Apply to SCOR!" to begin the application process (well ahead of the deadline).
 - o If you need a new account or need to reset your password for an existing account, contact researchprograms@lls.org.
3. Familiarize yourself with the [LLS Research Portal](#).
4. Click "Edit" and follow the instructions for each web form field. Bold font indicates required information.
 - o 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.
 - o 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).

5. Once your LOI is submitted, you will receive an automated email from the [LLS Research Portal](#) within two business days. Consider that these emails may end up in your spam.
6. If your LOI is selected by the review panel, you will have access to the Full Application. Click on your request, found in New or Pending, to continue with your application.
7. Please carefully follow the instructions on the [LLS Research Portal](#) and this document. Full Applications require completion of both the web form and the current application template, which should be downloaded from the *Project and Supporting Documentation* section of the [LLS Research Portal](#). **Failure to follow all application instructions may result in administrative triage of your application.**
8. Submit your Full Application to LLS prior to the Full Application deadline. **We strongly recommend submitting at least 1 week in advance of the deadline, as site traffic on the day of and days leading up to the deadline will be heavy.**
 - Contact researchprograms@lls.org with any questions about the application that are not addressed in the [LLS Research Portal](#) or this document.

Carefully check every page of your application prior to submission. You are ultimately responsible for this submission, even if someone else submits your final application.

At any time during the application process, including after submitting your Full Application, you can check the status of your application by logging in to the [LLS Research Portal](#), selecting your application (under *Requests* in either “New or Pending” or “Submitted”) and referring to the Status in the yellow box at the top of the page.

If you have any technical difficulties with the [LLS Research Portal](#), please contact researchprograms@lls.org.

Letter of Intent Phase Instructions

Information for the Letter of Intent will be entered on the web form in the [LLS Research Portal](#). Since the LOI is competitive, and no changes may be made to submitted LOIs, the LOI should be well-thought out and well-presented.

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.

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 a minimum of two scientific Cores and one Administrative Core. There can be no more than five Cores. Cores should not be research-oriented, as they serve supportive functions.** 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 including spaces.

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 including spaces.

Core Details

Provide a brief description for each Core and the role each plays in the various Projects and the overall SCOR. Scientific/Greek characters or symbols must not be used. 1,500 character limit including spaces.

Biosketches

All Project Leaders and Core Leaders must provide a biosketch using the current NIH format, and include the NIH Other Support form. ERA Commons user name is not required. The Other Support section must contain all current and pending support from any source. As per the NIH format, the goals of each grant must be stated. In addition, specific aims must be listed for current and pending grants. This includes any grants or portions of grants submitted to any organization, including LLS.

If funding decisions about potentially overlapping, pending grants become available following submission of an LLS application, LLS must be notified within five business days of the applicant's receipt of that information.

LLS recognizes that some investigations, particularly those involving clinical trials, may require multiple funding sources, so overlap of specific aims with another grant may be appropriate and acceptable. The need for and details about such overlap should be clearly explained in the application. However, LLS will consider an applicant's other current grant support in its funding decisions. This may result in LLS funding only part of the grant or none of the grant, depending on the level of overlap. In addition, LLS reserves the right to adjust the level of funding of an awarded grant should another overlapping or potentially overlapping grant that was pending at the time of grant submission be awarded to the applicant.

Failure to abide by LLS's rules on disclosure of current or pending support may jeopardize the funding of the current grant application and may affect future LLS funding decisions.

Upload all biosketches to the Project and Supporting Documentation section of the [LLS Research Portal](#) as one single PDF file.

Submission and Confirmation

Carefully check your work and PDF prior to submission. 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 researchprograms@lls.org.**

Changes

If you notice problems with your PDF or if extra documents remain after you have submitted but prior to the deadline, email researchprograms@lls.org and we will help you in addressing the issue.

Only 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 and voluntary expert panel will review LOIs. LLS will notify applicants via email if the LOI is accepted for Full Application submission. See [Key Dates](#).

Full Application Phase Instructions

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 LLS Research Portal and the project template.

Application Template

Download the application template (including budget and signature page). Complete the information, including required signatures, and upload to the Project and Supporting Documentation section of the [LLS Research Portal](#).

Follow the character limits in the [LLS Research Portal](#) (which include spaces) and page lengths. Margins are preset at 0.5 inches on each side and should not be changed. The margin size does not include the headers and footers on the project template, which also should not be changed. Only single-spaced, 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, patient tumor type, etc.).

The application template consists of the following sections:

- 1. Table of Contents**
- 2. Previous SCOR productivity (see template for detailed instructions)**
- 3. SCOR Justification and Major Resources (see template for detailed instructions)**
- 4. Projects (see template for detailed instructions)**
- 5. Cores (see template for detailed instructions)**

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 [LLS Research Portal](#) web form)
- Letters of support or collaboration
- Clinical protocols (include up to a 2 page summary for each protocol and include a link to the full protocol)
- 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 up to a two page summary of clinical protocols essential to the proposed research with a link to the full protocol. Include approval date and compliance number. Indicate if IRB approval is pending. Provide information as a figure or a narrative regarding timelines for any clinical trials (ongoing or future).

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. Payments are made to the SCOR Director's Institution and it is the responsibility of the SCOR Director to divide funds among participating institutions.

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 and 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 LLS Research 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 researchprograms@lls.org.**

If extra documents remain after submission and before the deadline, email researchprograms@lls.org and we will help you in addressing the issue.

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 in addressing the issue.

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- 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.