LEUKEMIA & LYMPHOMA SOCIETY®

Specialized Center of Research

Guidelines & Instructions

Letter of Intent & Full Application

Effective dates:
October 6, 2023 - July 30, 2024

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<u>Application Compliance</u>

- It is highly recommended to access the **LLS Research Portal, Fluxx**, at https://lls.fluxx.io to begin the application process well in advance of any deadlines. In addition, each stage of the application process (letter of intent/full application should be completed well before the deadlines.

- No aspects of the application, except regulatory approvals, will be accepted past the deadline.

- All components of the application must be presented in the order indicated in these guidelines.

- Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template. Font must be black Arial 11 pt. including figure legends, which should be text boxes separate from the figure itself. **If character limits and font restrictions are not adhered to, or the preset margins are altered, the application may be administratively disqualified.**

- Line spacing is preset in the Word document. **Do not change this setting**. Pasting text from another document into the template may result in a change in the line spacing. Check the line spacing in the template before pasting, and if there is a change after pasting, return the line spacing to the original setting. Any modifications in line spacing, particularly if the change allows for more text to fit into the page, **may result in administrative disqualification of your application.**

- Do not attach documents to the application that are not specifically called for. **The application may be administratively disqualified if this rule is violated.**

- The SCOR Director may apply to more than one grant program during an application cycle if the aims do not substantially overlap with the aims of any other application across all programs. You may not be on a different project within the same grant program unless you are a Collaborator.

- 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.

- Completion of several steps in the process initiates auto generated emails sent from the LLS Research Portal. LLS staff may also send emails during the application process. Spam filters should be monitored for these emails. Contact researchprograms@lls.org if expected emails are not received by the times indicated in these guidelines or if you have questions not clarified in this document.

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.

Program Description

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 emphasis in the SCOR grant program is on clinical translation of scientific results (see Mission Scores). Ideally, a SCOR application will propose a combination of basic and translational laboratory research that will lead to eventual clinical translation. There should be clear and direct "bench to bedside" translational trajectory from one or more of the Projects in the SCOR. It is important to note that the inclusion of a clinical trial in and of itself may not satisfy this requirement. Any clinical translation must be a coherent and integrated extension of other SCOR activities, and there should be substantive interactions and synergy between clinical trials and more basic or early translational Projects in the SCOR.

Each SCOR is comprised of 3-5 scientific Projects and 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 maximum total award is $5,000,000. The maximum total annual award is $1,000,000 for each year of the five-year grant. The maximum annual indirect cost is $150,000 (15% of total annual costs). You may claim less than 15% indirect costs and apply those costs to the direct costs. 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.

Professional Headshot for the SCOR Director and Project Leaders

LLS requires submission of a photo (head shot) for the SCOR Director and the Project Leaders. The photos will be used alongside the Biography and Lay Description which is collected at the full application phase for publicity and fundraising purposes and displayed on the LLS website. ***The photos 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. Prior to or at the conclusion of the site visit, the SCOR Director must provide LLS Research staff with copies of progress presentation materials (PowerPoint decks or PDF documents) which must include descriptions of proposed goals/milestones for the upcoming grant year.

Annual Post-Site Visit Assessment

After the annual Site Visit, LLS staff and the external reviewers will assess the progress made and the quality of synergistic activity of the SCOR. 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, remedial actions will be discussed with the SCOR Director; such actions might include changes in project aims or scope and/or a reduction in future funding. 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 communicated to the SCOR Director within 60 days of the Site Visit.

SCOR Project Replacement Policy

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 Project/Core.

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 and grant award.

Annual SCOR Progress Meeting

Each year, there is a mandatory, in-person 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, Conflict and Other Disclosures, 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 approval of 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 program 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
The program welcomes applications worldwide from appropriate academic institutions and investigators of any nationality.

General Eligibility
Applicants must hold a PhD, MD, DVM, or equivalent degree and must be affiliated with a non-profit 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 approved LOIs and funded SCORs must be approved by LLS. Please contact researchprograms@lls.org for any change requests.

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 2023 or 2024.
- Must be a Project Leader on one proposed Project.
- Cannot be a Project Leader on more than one proposed Project.
- May be the Project Leader on <u>one</u> other SCOR application submitted per cycle.
- 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 Project Co-Leaders (up to 2).

Project Co-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 SCOR grants that will be funded in 2024.

<u>**Project Overlap and Multiple Submissions**</u>
You may apply to more than one grant program during an application cycle if the aims do not substantially overlap with the aims of any other application across all programs.
In addition, you may have the same investigator(s) as PI(s), Co-PI(s), Project or Core Leaders, or key personnel/collaborator(s) on a different project provided the aims differ.
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.

Application Process & Applicant Notification

The application process will occur in two phases, the Letter of Intent (LOI) phase and Full Application phase. Applicants will be notified via an automated email whether they are invited to submit a full application or whether their LOI was declined. If the applicant is invited to submit a full application, immediate access to the full application phase is enabled in the LLS Research Portal. If you have not received an email regarding your LOI by **January 18, 2024**, contact researchprograms@lls.org.

Key Dates

	Date	Time
Call for Proposals	October 6, 2023	
Letter of Intent Deadline	December 7, 2023	3:00 PM EST
Notifications of Full Application Invite	January 18, 2024	
Full Application Deadline	March 28, 2024	3:00 PM EDT
Notification of Awards	June 2024	
LLS's receipt of signed Funding Agreement and agreed-upon Milestones and Deliverables	September 1, 2024	
Funding Start Date	October 1, 2024	

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

The submission deadlines will be enforced. Please note that all times are Eastern Time (ET).

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 deadlines. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible.

Review Process for the Letter of Intent and Full Application

Letters of Intent for the SCOR Grant Program are reviewed and approved by LLS after submission. Once the LOI has been reviewed, the applicant will be notified via e-mail as to whether they have been invited to submit a full application. The LOI stage is a competitive step; all LOIs will be reviewed for eligibility as well as for relevance and responsiveness to the goals of the program. If invited for full application submission, the

applicant will immediately have access to the application submission capability in the LLS Research Portal. If you have not received an email regarding your LOI by **January 18th, 2024**, contact researchprograms@lls.org.

Full applications will be reviewed by a peer review committee composed of a diverse group of external experts. An application that does not meet the program goals, scope, or guidelines will be administratively disqualified. Applications will be assigned an initial score by the primary and secondary reviewers. Only applications that fall above a scoring level determined by program staff and the committee chair will be discussed in detail for final ranking by the entire committee. Applications will be evaluated for potential significance, novelty, innovation, and feasibility. Once ranked by the peer review panel, the highest scoring proposals will be reviewed by LLS research staff. LLS will identify those proposals to be funded based on scientific merit, responsiveness to programmatic goals, and budget availability. Final approval of funding will be made by the LLS Board of Directors. Any applicant selected for funding will be notified in June 2024 of the funding decision. Please do not call or email LLS to determine whether the application has been received, when it will be reviewed, or the results of the review. Funding decisions are relayed by email only and are not available by telephone. Please also check the LLS Research Portal for the status of your application. All priority scores are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, LLS's National Board of Directors, and Research and administrative personnel only. Feedback may only be provided for applications discussed by the full review committee. Written critiques of the application are not formally provided to applicants.

Review Criteria for Full Application
An application receives a Priority Score based on a 9-point rating scale (1=most meritorious; 9=least meritorious) using the criteria outlined below. This score reflects the SCOR proposal 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 quality and relevance of the preliminary data.

- The perceived feasibility of the proposed experimental and investigative approaches.
- 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.

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.

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 **December 7, 2023**. LLS will make every effort to accommodate these requests but cannot guarantee such exclusion(s).

<u>General Application Instructions</u>

All submissions must use the LLS Research Portal, Fluxx, at https://lls.fluxx.io. It is recommended that you familiarize yourself with this portal well in advance of any deadlines.

Registration
Both the applicant and institution must be registered in the LLS Research Portal. If you have applied to LLS in the past, you do not need to create a first-time registration. Simply log in with your username and password. If you forgot your password, click the "reset or create password" link and enter your email address. The system will send your username and a link to update your password. Once updated, the applicant can begin the LOI. If you are a first-time user to the LLS Research Portal, please complete the intake form located here: Account Creation Request so an account can be created for you. Only LLS staff members have administrative permission to create new accounts.

Institutional Designation
Applicants should create their profile from the standpoint of where they will perform their research described in the application. The applicant must indicate the name of the institution as well as the name of the signing officials for that institution. If your institution is not displayed as an option under this field of the application, you may contact researchprograms@lls.org to have it registered in the system.

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 respective deadlines have passed or the final application has been submitted. Moreover, some fields may not be modified in the full application following submission of the LOI.

Forms and Format
Applicants will provide information on the LLS Research Portal 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 LLS Research Portal. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when applicants populate fields on the LLS Research Portal. Fields in bold are required. Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template. The applicant's name should be typed in the upper right corner of each page of the template.

Font must be black Arial 11 pt. including figure legends, which should be text boxes separate from the figure itself. If character limits, font restrictions, margins and/or page limitations are not adhered to, the application may be administratively disqualified.

In case there is a discrepancy between the application template and the guidelines document, the downloadable template supersedes the guidelines.

Contacting LLS
Questions that are not clarified in this document, on the SCOR Grant Program webpage, or the LLS Research Portal should be addressed to researchprograms@lls.org.

Beginning an application

The 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 in full and familiarize yourself with the LLS Research Portal.

2) Log into the LLS Research Portal, and under "Information" in the left navigation bar, select SCOR Grant Program. Click "Apply to SCOR!" to begin the application process (well ahead of the deadline).

3) Click "Edit" and follow the instructions for each web form field. Bold font indicates required information.
   - Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be administratively disqualified.
   - 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).

4) Once your LOI is submitted, you will receive an automated confirmation email within two business days from the LLS Research Portal. Consider that these emails may end up in your spam filter.

5) If your LOI is selected, you will have access to the full application. Click on your request, found in *New or Pending*, to continue with your application.

6) Please carefully follow the instructions on the LLS Research Portal and this document. Full applications require completion of both the web form and the 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 disqualification of your application.**

7) Submit your Full Application to the LLS Research Portal prior to the full application deadline. **We strongly recommend submitting well before 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 phases that are not addressed in the LLS Research Portal, the FAQ, or this document.

8) To create a fair process to all applicants, these Guidelines & Instructions and information on the LLS Research Portal must be followed. *Do not ask for exceptions to these policies, including but not limited to exceptions to deadlines or making corrections to your document past the deadline.*

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

At any time during the application process, including after submitting your full application, you can check the status of your application by logging into 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.

Detailed Letter of Intent Phase Instructions

Each applicant must submit the LOI using the webform available on the LLS Research Portal. There is no LOI template available for download and the LOI abstract must be typed or copied/pasted directly into the respective text fields. Only characters available in the standard Latin alphabet may be used, and no images nor references are allowed.

The applicant should carefully compose the information requested in the LOI as this information is automatically populated into the full application and is subject to the Changes clause listed below.

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 scientific abstracts for each Project and Core, as well as NIH biosketches for each Project and Core Leader.
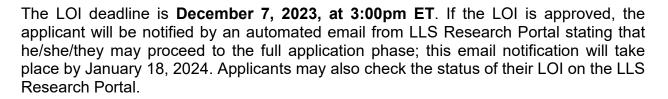
The LOI stage is a competitive step with a scientific review process. Therefore, it is critical to have a well-thought out and well-presented LOI to enhance the chances of a favorable review.

The LOI is reviewed for responsiveness to the goals of the SCOR, and include:
- **qualifications of the SCOR Director and Project 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 one-third are invited to submit a full application.

The LOI deadline is **December 7, 2023, at 3:00pm ET**. If the LOI is approved, the applicant will be notified by an automated email from LLS Research Portal stating that he/she/they may proceed to the full application phase; this email notification will take place by January 18, 2024. Applicants may also check the status of their LOI on the LLS Research Portal.

Completing the Letter of Intent (LOI)

Organization Information

Institution: Indicate the name of the institution where the research will be performed. If this institution is not listed in the LLS Research Portal, please contact researchprograms@lls.org with the institution name, address, and tax ID number (if applicable) so an account can be created.

SCOR Director: The SCOR Director is the applicant who serves as Principal Investigator (PI) of the SCOR Grant program and typically has the academic title assistant/associate or (full) professor. If the academic title does not follow this convention, please upload a letter from the institution verifying eligibility to serve as a PI. The following criteria must be satisfied: a PI is an independent investigator who has dedicated laboratory space, directly hires and supervises laboratory personnel (technicians, graduate students, postdocs, and staff scientists), and makes all decisions concerning research activities and use of the grant funds.

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 selected for funding.

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

Additional Access (Admin/Assistant): Access may be given to personnel to assist in the application process. This is the institutional representative responsible for the day-to-day administration of externally funded research (or the Research Administrator).

Technology/Transfer Official (TTO): The TTO is the institutional representative responsible for overseeing Intellectual Property.

Additional Contact (Assistant): This is optional and may be a personal representative of the SCOR Director, such as an administrator, an assistant, or a laboratory manager to be used as an additional point of contact, typically in the post-award phase. The Additional Contact will not have access to the application in Fluxx.

Zip Code of the Institution: Enter the zip code of the institution if located within the United States. You will need to select the zip code from the drop-down menu to ensure it is captured in the zip code field. If not located within the US, this can be left blank.

SCOR Program Information

SCOR Director Name and Scientific Degree

SCOR Director Job Title

Proposal is a Continuation - Indicate whether the proposed program is a continuation of a previously funded SCOR grant.

Previous SCOR – Indicate whether the Program Director has previously received an LLS SCOR grant.

SCOR Title – Provide a title adhering to the 150-character limitation (which includes spaces).

SCOR Scientific Abstract – The applicant should provide an overview of the proposed SCOR program. Describe the overall proposed research and a brief overview of each Project and Core. Discuss the interaction between components that will create synergy. Discuss plans for clinical translation of findings. Scientific/Greek symbols or characters must not be used. (Maximum 6,000 characters including spaces.)

Amount Requested – Enter the total amount of funding requested over the life of the grant (maximum of $5,000,000.00). The amount requested on the LLS Research Portal should match the budget sections of the full application template. The total amount, including both direct and indirect costs, cannot exceed $1,000,000.00 per year. Please note that LLS does not follow the NIH guidelines for budgets.

Individual Information for SCOR Projects 1-5
- **Project Title** – Provide a title adhering to the 150-character limitation (which includes spaces).
- **Project Scientific Abstract** – Using technical language, briefly describe the proposed research (maximum 3,000-character limit including spaces for each Project). Scientific or Greek symbols may not be used. Once the LOI has been submitted, the Scientific Abstract cannot be changed.
- **SCOR Project Leaders** – The SCOR Program must be comprised of at least 3 but not more than 5 Projects. The following information must be provided for each Project Leader:
    - Name – The Project must have a single, designated Project Leader.
    - Degree
    - Institution
    - Job Title
- **Project Co-Leaders** – Project Co-Leaders are optional. Projects may have up to 2 Co-Leaders. Supply the following information for each Project Co-Leader:
    - Name
    - Degree

- o Institution

Individual Information for the SCOR Program Cores

The Program must have one Administrative Core and 2-4 Scientific Cores. Cores serve supportive functions and cannot be research oriented.

Administrative Core Information

- **Description** – Provide a brief description of the Core's activities (i.e.; Goals, Function/Operation, Benefit and relation to other SCOR components)
- **Administrative Core Leader**
  - o Name
  - o Degree
  - o Institution

Information for Scientific Core Projects A-D

- **Designation** (i.e.; animal facility…) – 150-character limit including spaces.
- **Description** – Provide a brief description of the Core's activities (i.e.; Goals, Function/Operation, Benefit and relation to other SCOR components)
- **Scientific Core Leader** – Provide this information for each Scientific Core.
  - o Scientific Core Leader Name
  - o Degree
  - o Institution
- **Core Co-Leaders** – Projects may have up to 2 Core Co-Leaders, they are optional. Supply the following for each Core Co-Leader.
  - o Core Co-Leader Name
  - o Degree
  - o Institution

SCOR Program Collaborators/Key Personnel

Indicate any personnel, outside of your institution, with whom you have 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) five people including name and institution.

Biosketches and Other Support Forms

The documents described below must be uploaded for the SCOR Director, Project, and Core Leaders at the LOI phase as one consolidated PDF file. **Do not submit these documents for the Project or Core Co-Leaders**. These documents must also be included during the full application phase.

a. **Biographical Sketch**: use the most recent NIH biosketch format found on the NIH website. Publications submitted and under review should be indicated on the Biosketch. An eRA Commons Username is not required.

b. **NIH Other Support Form**: use the most recent NIH Other Support Document format found on the NIH website. Must contain all current and pending support

from any source and completed support should not be included. In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap with the LLS application. 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 LOI/application, LLS must be notified within (5) five business days of the applicant's receipt of that information. Please e-mail researchprograms@lls.org.

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 and Other Support forms to the *Project and Supporting Documentation* section of the LLS Research Portal **as one single PDF file.**

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

Submission of the LOI: Each applicant must submit the LOI by **December 7, 2023**, **at 3:00 pm ET** via the LLS Research Portal. After clicking the "Submit" button, the applicant will receive an automated email from the LLS Research Portal stating that the LOI was successfully submitted. If you did not receive the confirmation email from the LLS Research Portal within two business days of LOI submission, please e-mail researchprograms@lls.org. Signatures of the applicant and institution officials are not required for submission of the LOI.

The applicant is ultimately responsible for the submission, regardless of who is uploading information on the LLS Research Portal. Every year, LLS has a small number of people that notice problems with their letter of intent after the deadline. The solution to this problem is very simple and in the hands of the applicant:

- Check your letter of intent prior to final submission.
- Submit well ahead of the deadline.
- We are not responsible if any applicants are unable to submit by the deadline if our system indicates that:
    a. the letter of intent procedure was started less than 24 hours before the deadline, or
    b. a previously started letter of intent file was then only picked up again less than 3 hours before the deadline.

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 must email LLS (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 application.

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

Each Invited applicant must submit a Full Application by **March 28, 2024, at 3:00 pm ET** via the **LLS Research Portal** at https://lls.fluxx.io. Most sections of the full application will carry through from the LOI Phase. Information that carries through must not be modified; changes cannot be made to the LOI components after the LOI Phase deadline. The remainder of the full application consists of web form components and elements to be uploaded as a *single PDF*.

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*).

All sections in the Full Application template must use black **Arial 11-point font**. Margins are pre-set and must not be changed.

Failure to submit as a single PDF in the order below may result in disqualification of the application.

The application template consists of the following sections:

1. **Program Information Cover Page (see template for detailed instructions)**

2. **Public SCOR Program Information**: If awarded, your information will be featured on LLS.org for the duration of the award. Please do not use any graphical elements, such as figures or charts. The use of Greek characters or symbols is also not permitted in this section. The Public Grant Information is essential for LLS to continue successful fundraising to support our current and future grantees, including the later years of your award, should it be funded. Thus, we require a well-written lay section, with sufficient detail and suitable language for non-scientists. This section should clearly state the relevance of your research to blood cancer and describe your current/proposed research, including the problem/question to be addressed, specific aims, and anticipated results using non-technical language that is easily understood by the lay community. Be aware of your confidential information, as the Lay Description, and Project Summary and short bios will be shared with others.

   a. **Overall SCOR Program Summary:** Provide a short summary in lay language (approximately 1,500 characters including spaces).

   b. **Overall SCOR Program Lay Description**: Longer lay summary (maximum of 3,000 characters, including spaces).

   c. **Brief Biography of the SCOR Director:** Provide a brief, professional biography introducing the SCOR Director and Project Leaders to a lay audience (maximum 1,000 characters including spaces).

   d. **Individual Project Summaries:** Provide a short summary (2-5 sentences) in lay language for each SCOR project.

   e. **Individual Project Lay Description:** Longer lay summary for each SCOR project (maximum of 3,000 characters including spaces for each project).

   f. **Brief individual biographies of the Project Leaders:** Brief professional biography introducing the Project Leaders to a lay audience (maximum of 1,000 characters with spaces for each Project Leader).

3. **Graphical Abstract**: Provide one or two graphical abstract(s) to succinctly describe the organization and key focus/themes of your proposed SCOR program. This graphical abstract provides reviewers with a quick overview of your research plan. This is similar to the graphical abstract in a Cancer Cell paper. Limited to one (1) page.

4. **Previous SCOR productivity** (see template for detailed instructions)

5. **SCOR Justification and Major Resources** (see template for detailed instructions)

6. **Projects** (see template for detailed instructions)

7. **Cores** (see template for detailed instructions)

8. **Budget**
   The Detailed Budget and Budget Justification sections should provide itemized detail for each major category for all years 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. The maximum total annual award is $1,000,000.00 for each year of the five-year grant. The maximum annual indirect cost is $150,000.00 (15% of total annual costs). You may claim less than 15% indirect costs and apply those costs to the direct costs.
   - **Use of Funds:** The funds must be used for research-related costs while overhead/indirect costs must 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
        o Supplies and materials requests should be itemized by category*
        o Equipment purchase requests must identify each item and how it relates to the SCOR*
        o 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 ensure 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 15% of total costs requested.
   - **Impermissible Costs** include (but are not limited to) membership dues, tuition, books, journals, and publication costs.

9. **Signature Page:** Provide all requested signatures.

10. **Appendix** that includes the following (in this order):

- ***Organizational Assurances (Required)*** Projects for which IRB approval is pending must be accompanied by a signed letter from the ***appropriate institutional official***. The applicant should notify LLS of IRB approval prior to the grant review. ***Any application without these letters attached may not be reviewed***.

Full approval for all assurances that are necessary for the research must be obtained by the award start date.

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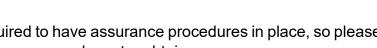
Recombinant DNA
Indicate if the proposed research involves recombinant DNA. Documentation of any current or pending approvals must be contained in the Full Application template. There is also a section on the web form that must be completed.

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.

Note: Your institution is required to have assurance procedures in place, so please check with them if you are unsure how to obtain your assurance approval documentation.

- **Letters of support or collaboration**

- **Clinical protocols (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).

- **Up to 2 manuscripts that are not yet available on PubMed** may be provided for each Project.

- ***Biosketches and Other Support (Required for the SCOR Director, Project and Core Leaders only):* Although these were provided at the LOI phase, we are asking that you include them again as part of the full application phase.** Use the NIH Biosketch format and include the NIH Other Support form. ERA Commons username is not required. The Other Support section <u>must contain all current and pending support from any source</u>. The section of the Biosketch containing the Research Support section may be used, but all current and pending support must be included; completed support should not be included. 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 that may overlap or appear to overlap with your SCOR Application.** 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; please e-mail researchprograms@lls.org.

LLS recognizes that some investigations 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 application 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 application and may affect future LLS funding decisions.

Uploading the Project Documentation and Final Submission

Upload the full application components, as a single PDF, in the *Applicant and Collaborators Documentation* section on the web form. The file upload should be labeled, "SCOR Project Description/Application" which you can select from the document upload drop-down menu. **Do not delete the PDF file which included the NIH biosketches and NIH other support forms that were uploaded during the LOI phase**.

All full application documents must be combined into a single PDF in the order listed above before uploading. 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 **within 2 business days** stating that your information was successfully submitted. **If you do not receive the email confirmation of submission, contact** researchprograms@lls.org.

There should be two PDF files once the full application is submitted in Fluxx. The LOI phase PDF which included the biosketches and other support forms and the Full Application phase (steps 1-10 as outlined in the detailed full application phase) PDF. 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, email researchprograms@lls.org, and we will help you upload the correct document if you are unable to delete the incorrect document. **This email must be received, with the correct document, prior to the deadline; there are no exceptions to this rule**.

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  a. the letter of intent procedure was started less than 24 hours before the deadline, or
  b. a previously started letter of intent file was then only picked up again less than 3 hours before the deadline.

Once the deadline has passed, only the following updates may be made:

- **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.