

RESEARCH PROGRAMS POLICIES & PROCEDURES

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LLS Mission

The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health organization dedicated to funding blood cancer research, education and patient services. The mission of LLS is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families. Since 1949, The Leukemia & Lymphoma Society has invested over \$1 billion to find cures and ensure access to treatments for blood cancer patients and continues to fund innovative research to advance more breakthrough therapies.

To this end, LLS also supports patient aid, community service programs, advocacy, and public and professional education. LLS supports research in a variety of different funding mechanisms. The full list of research programs currently being offered is available here: <u>https://www.lls.org/academic-grants</u>.

Grant Application and Review

LLS funds qualified investigators (holding a PhD, MD, and/or equivalent degree) conducting research directly related to blood cancer. Program availability varies from year to year, but the following programs typically open annually for new applications:

Career Development Program (CDP)

Translational Research Program (TRP)

Specialized Center of Research (SCOR)

In addition, the following programs may be available periodically:

Screen to Lead Program (SLP)

Blood Cancer Discovery Grant (BCDG)

Influential Medicine Providing Access to Clinical Trials (IMPACT)

For a full list of available programs and for application information, including Application Guidelines & Instructions for each program, please visit <u>https://www.lls.org/academic-grants</u>.

All application processes are conducted in the LLS Research Portal at <u>http://lls.fluxx.io</u>. Applicants must have an account in this portal in order to submit an application. To request an account, contact the Research Administration Team at <u>researchprograms@lls.org</u>. Administrators or assistants may also request accounts in order to provide assistance to applicants. (<u>More information on the LLS Research Portal</u>)

Full applications are peer reviewed by members of an external panel. After each program review meeting, the Medical & Scientific Affairs Committee meets to create a final recommendation of the pay line to present to the Board of Directors. Upon final approval by the Board of Directors, results are made available via email and the LLS Research Portal to all applicants. No results are given over the telephone.

An Award Letter and Grant Agreement will be available on the LLS Research Portal after approval by LLS's Board of Directors. The Grant Agreement must be signed by the Grantee, Institutional Signing Official, Financial Officer, and Technology Transfer Official. The Grant Agreement must be fully executed before LLS will activate the project or distribute funds. The Grant Agreement is non-negotiable except where pertaining to state law and/or written institutional policy.

Requirements of Research Funding

Reporting: LLS requires Grantees to submit Progress Reports, Invention, Patent, Commercialization, Intellectual Property & Revenue Sharing Disclosure (IP Disclosure Reports), Financial Reports, Conflict Disclosures, and Publications Reports as a condition of receiving LLS funding. These reports are reviewed by LLS staff. LLS reserves the right in its sole discretion to terminate any project based on its review of an associated report. Any report that is more than thirty days late may result in suspension of funding. Failure to produce the report within ninety days of the deadline may result in premature termination of the award.

 Progress Reports: The Grantee will submit Progress Reports annually, in accordance with the schedule provided on the Grant Agreement. Progress Report submissions must include 1) a completed template, using the most current available version and 2) the web form, both of which are found on the LLS Research Portal at <u>http://lls.fluxx.io</u>. Each report must be submitted by the Grantee through the online portal.

All components of the Progress Report are confidential except for the *Lay Summary of Research Progress*. Each Progress Report must include an updated summary written for the lay public, which reflects the progress made since the original Application was submitted. *Lay Summaries of Research Progress* are critical for LLS's efforts to educate the public about ongoing research. This web form field is required and must contain highlights from the past year of research that we can share with our donors. Because LLS's ability to continue providing research funding relies in part on the continued support from voluntary donations, it is important that LLS remain informed of research results that help to maintain the level of donations received. Therefore, please take care to provide high quality research updates in the *Lay Summary of Research Progress*, omitting any confidential information.

IP Disclosure Reports: Sponsoring Institution's patent officer (Technology Transfer Official or TTO) must submit at least one Invention, Patent, Commercialization, Intellectual Property & Revenue Sharing Disclosure (IP Disclosure Report) per year of funding. All patent, commercialization, or intellectual property activity during the year must be reported, but the report must be submitted regardless of whether or not there is activity to report, in accordance with the schedule provided on the Grant Agreement. IP Disclosure Report submissions must include 1) the most current template downloadable from the LLS Research Portal at http://lls.fluxx.io and 2) completion of the online form within this portal. In order to access the reporting for a project, the Technology Transfer Official must have an LLS Research Portal account and be listed as the Technology Transfer Official on the award/grant. Please contact

researchprograms@lls.org to have this set up or updated.

Note: In addition to annual reporting, the Sponsoring Institution agrees to send LLS a copy of all patent applications filed during the funded period, no later than thirty days after the filing date. Said filings must also be disclosed on the next due annual report.

- Financial Report: The Sponsoring Institution's financial officer must submit annual Financial Reports during the funded period and one final report after the funded period ends. These reports shall be submitted in accordance with the schedule provided on the Grant Agreement. Financial officers must use the most current template downloadable from the LLS Research Portal at http://lls.fluxx.io and must submit the reports through this portal. In order to access the reporting for a project, the financial officer must have an LLS Research Portal account and be listed as the Financial Officer on the award/grant. Please contact researchprograms@lls.org to have this set up or updated.
- Publications Report: The Grantee must submit a quarterly report listing all publication activity (i.e. works published, approved for publishing, or in print) during the preceding quarter that involves LLS-funded research. A Publications Report should be submitted on each July 1, October 1, January 1, and April 1 of the funded period, with a final report due on the July 1, October 1, January 1, or April 1 immediately following the end of the funded period. Any advertising, promotion, publications, presentation or exhibition relating to the LLS-funded research must cite The Leukemia & Lymphoma Society. Prior to distribution, the Grantee must notify LLS of any such disclosure, including a copy of the materials intended for release, as well as the time, place, and manner of disclosure.
- Conflicts Disclosure: The Sponsoring Institution's patent officer (Technology Transfer Official or TTO) must submit an annual report disclosing any conflicts of interest, financial or otherwise, related to the LLS-funded research. Patent officers must use the most current template downloadable from the LLS Research Portal at http://lls.fluxx.io and must submit the reports through this portal. In order to access the reporting for a project, the patent officer must have an LLS Research Portal account and be listed as the Technology Transfer Official on the award/grant. Please contact researchprograms@lls.org to have this set up or updated.

Organization Assurances: The Grantee and Sponsoring Institution agree to comply with any and all existing or new federal, state and/or local guidelines that affect the research that is supported by LLS's funding and to give LLS prompt notice of any deviation from such federal guidelines. Failure to do so may result in the suspension or termination of research funding.

 Human Subjects: Sponsoring Institution will ensure that Grantee obtains prior written approval from the Sponsoring Institution's Institutional Review Board (IRB), or equivalent institutional authority, for the protection of human subjects before undertaking any form of human subject research. An original executed copy of this approval must be submitted to LLS within ten days after such approval is obtained. With respect to research projects that do not deal with human subject research, Sponsoring Institution must furnish to LLS a letter executed simultaneously with the Grant Agreement stating that: "The research project does not involve the use of human subjects or human tissue." Sponsoring Institution agrees, and will ensure that Grantee agrees, that any deviation from such research projects that will involve human subject research will not be undertaken unless prior written approval from the IRB is obtained. Any such approvals must be forwarded to LLS within ten days of approval. If the IRB disapproves of any changes from the original Application, then LLS in its sole discretion reserves the right to modify or terminate the Grant Agreement.

If the Grantee's human subject research privileges are suspended, LLS must be notified within ten business days of the suspension. LLS will take whatever action it deems appropriate, including suspension or termination of the Grant. Failure to notify LLS of any suspension will result in suspension or termination of the Grant. If the Grant is terminated, any unused Grant funds and/or funds paid after the ten-day notice period must be returned to LLS immediately.

- Animal Subjects: LLS adheres to the most current guidelines applicable to the care • and treatment of animals used in laboratory work as outlined by the National Institutes of Health (NIH). Sponsoring Institution acknowledges, and will ensure that Grantee acknowledges, that the Application includes a statement indicating that Sponsoring Institution meets and adheres to these guidelines, and Sponsoring Institution must provide LLS with an accompanying letter signed by the Institutional Animal Care and Use Committee (IACUC), or equivalent institutional body, confirming the same. Those research projects that do not involve the use of laboratory animals must so state in the Application. If the animal use privileges of Sponsoring Institution and/or Grantee are suspended, then LLS must be notified within ten business days of the suspension. LLS will take whatever action it deems appropriate, including suspension or termination of the Grant Agreement. Failure to notify LLS of non-compliance with the guidelines on the use of laboratory animals will result in suspension or termination of the Grant. If the Grant is terminated, any unused Grant funds and/or funds paid after the ten-day notice period must be returned to LLS immediately.
- Biohazards: Sponsoring Institution acknowledges, and will ensure that Grantee acknowledges, that the statements in the Application concerning potential biohazards and the safeguards to be employed are accurate descriptions of the circumstances pertaining to this aspect of the research. Those research projects that do not involve the use of biohazards must so state in the Application. Failure to notify LLS of non-compliance with the stated safeguards on the use of biohazards will result in suspension or termination of the Grant Agreement.
- Recombinant DNA: Grantee and Sponsoring Institution acknowledge that the statement in the Application concerning recombinant DNA and the safeguards to be employed is an accurate description of the circumstances pertaining to this aspect of the research proposed in the Application. Projects which do not involve recombinant DNA must so state in the Application. Failure to notify LLS of non-compliance with these guidelines on the use of recombinant DNA will result in suspension or termination of the Grant Agreement.

Intellectual Property (IP) Policies: Upon execution of the Grant Agreement, the Sponsoring Institution must submit a copy of its current Intellectual Property Policy (IP)

Policy) to <u>researchprograms@lls.org</u>. The Sponsoring Institution must provide LLS with a copy of this policy whenever it is updated.

Acknowledgement and Publicity: All publications, advertising, promotions, presentations, exhibitions, and/or disclosures about the Grantee's research released by the Sponsoring Institution or Grantee shall indicate that such research is being funded by The Leukemia & Lymphoma Society by including the following statement:

"Supported by a Grant from The Leukemia & Lymphoma Society."

Presentations or posters at major meetings at which funded research is included must include the current LLS logo in addition to this statement. Contact <u>researchprograms@lls.org</u> for the logo. The Sponsoring Institution and the Grantee must notify LLS at <u>researchprograms@lls.org</u> at least seven days prior to any advertising, promotion, publication, presentation or exhibition relating to the results of the Sponsored Research. Notification must include a copy of the materials intended for release, as well as the time, place and manner of disclosure. Sponsoring Institution and Grantee shall cooperate with LLS in connection with any written, photographic, filmed, broadcast or any other forms of materials LLS elects to produce to publicize the work.

When support for a Grant is, in part or whole, provided by a donor to LLS, the Grantee agrees to participate in promotional/publicity activities (including but not limited to meeting the Board of Trustees of the donor's affiliated organization, being interviewed for their newsletter, etc.) as requested. LLS's ability to award grants is dependent upon continued support from voluntary donations and LLS-sponsored events. It is expected that Grantees will make all reasonable efforts to attend and participate in events when requested by LLS.

Payment & Expenses

Payment Schedule: For all LLS research programs except the <u>Screen to Lead</u> <u>Program</u>, payments are made pro rata each June, September, December, and March of the funded period. The final payment is sent in the June, September, December, or March following LLS approval of all final reporting. To confirm the payment schedule of a particular project, refer to that project's Grant Agreement. LLS research funding payments do not run on invoices; it is not necessary to submit invoices.

Contingency: Continuation of funding for all LLS research programs is contingent on the submission and LLS approval of all reports due up to the payment date. Submission of any report after the deadline may result in delay of payment to the quarterly check run following LLS approval of the report.

Underspending & Fund Carry Forward: Carry forward of unspent funds in excess of 15% of the direct costs for that year requires prior written approval. If an underspend remains at the end of the funded period, the unexpended amount must be repaid to LLS, unless a no-cost extension of the project is approved. Refer to the following section, *Changes to the Grant Term*, for information about no-cost extensions. *Exceptions: Fund carry forward is prohibited for CDP and does not apply to NIA, which*

only lasts one year. For these programs, all unexpended funds must be refunded to LLS annually.

Overspending: The Sponsoring Institution is responsible for covering any expenses in excess of the amount awarded by LLS. LLS will not award additional funding once a project has been activated. Translational Research Program (TRP) Grantees have the option of applying for competitive renewal of their TRP. For details, refer to the <u>TRP</u> section of this document.

Changes to the Grant Term

Leave of Absence: LLS approval is required at least 30 days prior to the interruption of an award. Leaves of absence may not exceed 1 year in duration. Acceptable reasons for requesting a leave of absence include but are not limited to family leave, military leave, and personal illness. In order to submit a request for leave of absence, complete a Special Requests report in the LLS Research Portal at <u>http://lls.fluxx.io</u>. If the request is approved, funding of the award will be suspended during the leave period, and the award term will be extended for a period equal to the duration of the suspension (e.g. following an approved 1-year leave of absence, an award originally scheduled to end 6/30/2022 will end 6/30/2023).

Exceptions: SCOR Directors and Project and Core Leaders may only take leave during the 5-year Grant period in rare, unavoidable circumstances. NIA Grantees may not request a leave of absence.

No-Cost Extension: In the final year of funding, Grantees may request up to a one-year no-cost extension. At the end of the no-cost extension period, any funds remaining must be returned to LLS. To request a no-cost extension, complete a Special Requests report in the LLS Research Portal at <u>http://lls.fluxx.io</u>. If the request is approved, the Grant period will be extended for up to one year, and final reports will be due 60 days following the new end date. The final payment will be paid once all final reports are received and approved by LLS.

Exceptions: CDP awardees may not apply for no-cost extensions.

Premature Termination: In the event that the Grantee is unable to continue the funded project, becomes ineligible to receive the funding, or in the event of a breach of the Grant Agreement, the funded project may be terminated. All final reports – progress, IP disclosure, financial, publications, and conflict disclosure – are due 60 days following any such termination. LLS will request immediate return of any unexpended funds, and any remaining funds due to the Sponsoring Institution will be paid by LLS following LLS approval of all final reports.

Transfer/Relocation of the Grantee

LLS approval is required at least 30 days prior to an award's transfer to a new institution or laboratory. In order to submit a request for transfer, complete a Special Requests report in the LLS Research Portal at http://lls.fluxx.io. This report includes a form, which must be signed by the awardee, sponsor (if a CDP award) and signatory of the pre-transfer institution, and sponsor (if a CDP award), signatory, and financial officer of the post-transfer institution. The request will be reviewed, and an LLS research administrator

will contact the awardee with confirmation or a request for further information. Approval is contingent upon continued research support and sponsorship, fitness of the new research environment, and eligibility of the post-transfer institution to receive LLS funding (must be a not-for-profit research or academic institution).

Once the transfer request is approved and all final reports from the pre-transfer institution are received and approved, LLS will provide an Assignment and Amendment Agreement to the pre-transfer institution. The pre-transfer institution must provide all required signatures and then pass along to the post-transfer institution and grantee for signatures before being returned to LLS.

Exceptions: NIA grantees or CDP awardees in their first year may not transfer their funding to a new institution. For the policies regarding SCOR Grant transfers/relocations, see <u>SCOR Transfer/Relocation</u>.

For all programs except for CDP, the Sponsoring Institution or Grantee may request that the Grant be transferred to another qualified investigator. These requests should be sent to <u>researchprograms@lls.org</u> and will be reviewed on a case-by-case basis.

LLS Research Portal

The LLS Research Portal at <u>http://lls.fluxx.io</u> is integral to LLS Research processes from applications and reviews to reports and payments. Every person who plans to submit a research application or report to LLS or assist a researcher with an application or report must have access to this system in order to do so.

Accessing the LLS Research Portal: In order to request a new account in the LLS Research Portal, or to request updates to an existing account, email researchprograms@lls.org. Administrative departments may share one account using a common email address but may not set up more than one account with the same email address. Administrators who require access to existing Grant applications or current Grants must indicate which awards and grants they need to access (using the Request ID or Applicant name for applications and the Grant ID or Grantee name for current Grants) when requesting or updating accounts.

Creating and Editing Applications: In order to create a new application, log in to the LLS Research Portal and select the program title from the top left corner of the page. If the program is open, there will be a button displaying "Apply Now." Click here to begin a new application. If "Apply Now" is not visible, the program is not currently accepting new applications. Application cycle schedules are published on https://www.lls.org/academic-grants.

In order to edit an existing application, log in to the LLS Research Portal and select "New or Pending" under the section labeled *Requests* on the left panel. Click "Edit" to continue working on the application form. If the application is not listed, contact <u>researchprograms@lls.org</u> to restore access to the application. All application materials must be submitted through this portal and will not be accepted via email.

Submitting Reports: Access all report requirements by logging in to the LLS Research Portal and selecting "Reports Due" on the left panel. All upcoming report requirements

for all Grants linked to the account that was used to access the portal should be listed. Contact <u>researchprograms@lls.org</u> if there are reports missing from this page. All reporting materials must be submitted through this portal and will not be accepted via email. For more detailed instructions, refer to the <u>Fluxx Report Submission Guide</u>.

Submitting Special Requests: Refer to the above instructions for submitting reports and click Special Requests Report under "Reports Due."

Program-Specific Policies & Descriptions

The sections below outline the policies and procedures specific to each current LLS research program.

Career Development Program (CDP)

About CDP: The Career Development Program (CDP) provides salary support for researchers dedicated to advancing the understanding and diagnosis of blood cancer, as well as the development of treatment and prevention options that will ultimately lead to cures for blood cancer patients. The CDP is currently divided into four subprograms: Fellow, Special Fellow, Scholar, and Scholar in Clinical Research.

CDP Fellow Subprogram: The Fellow Award provides 3 years of salary support for top performing, mentored postdoctoral fellows and instructors who are training for a career in blood cancer research and/or treatment.

CDP Special Fellow Subprogram: The Special Fellow Award provides 2 or 3 years of salary support, depending on eligibility of the awardee, for mentored postdoctoral fellows and instructors who are training for a career in blood cancer research and/or treatment. The intent of the program is to support top performing postdocs who have clearly demonstrated success as postdocs and who need 2-3 years of training to be competitive for an independent position.

CDP Scholar Subprogram: The Scholar Award provides 5 years of salary support for tenure-track, junior faculty who have established themselves as blood cancer researchers.

CDP Scholar in Clinical Research Subprogram: The Scholar in Clinical Research Award provides 5 years of salary support for tenure-track, junior faculty who have established themselves as clinical blood cancer researchers.

CDP Budget:

 Permissible Direct Costs include the Grantee's/Principal Investigator's salary, wage, or stipend and fringe benefits. The final value of a CDP award may be limited by the Sponsoring Institution's allowable salary range. Benefits may be paid from a Grantee's/Principal Investigator's award as mutually determined with the Sponsoring Institution. Benefits are generally accepted to be medical and dental insurance, life insurance and retirement benefits. Benefit charges applied against the Grantee's/Principal Investigator's award require that he/she is eligible to be a participant in such programs. Expenditures for laboratory costs/equipment, travel funds, etc. are explicitly excluded as fringe benefits. K99 awardees may use the CDP award funds for other purposes related to the funded research. For details, see <u>CDP and K99 Awards</u>.

- 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 Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Indirect costs are limited to five percent (5%) of total direct costs. For Sponsoring Institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Grantee's/Principal Investigator's stipend or fringe benefits cost.
- *Impermissible Costs* include membership dues, tuition, books, journals, publication costs, research-associated costs, travel, and equipment.

CDP and K99 Awards: Current K99 awardees may apply for a Fellow or Special Fellow award, and current Fellow or Special Fellow awardees may accept a K99 award and keep the CDP Award, pending LLS approval. Certain information, including the aims of the K99 award must be provided to LLS to ensure that the K99-funded research is relevant to LLS's Mission. If approved, funding from the Fellow or Special Fellow Award may be used for any purpose related to the CDP application/award, whether it be awardee salary, technician salary, or research supplies, pending LLS approval. It is recommended that Fellow or Special Fellow application process. Contact researchprograms@lls.org for questions about LLS's approval process for holding both awards.

CDP Achievement Awards: Each year, beginning in 2019, LLS awards a CDP Achievement Award to one CDP awardee in the subprograms: Fellow, Special Fellow, and Scholar or Scholar in Clinical Research. Awardees are invited to apply for the award in the final year of their award funding, and winners are chosen based on the career milestones, publications, and other markers of success reached during the award term. Achievement Award funds must be used for LLS mission-relevant purposes. Instructions for applying for this award are sent out annually via email to eligible CDP awardees.

Translational Research Program (TRP)

About TRP: The Translational Research Program (TRP) aims to enhance the transfer of basic research findings to clinical usefulness. Projects selected for funding utilize novel approaches to investigate prevention, diagnosis, or treatment of hematological malignancies and related pre-malignant conditions. The TRP Grant period is three years with the option to apply for competitive renewal (See <u>TRP Renewal</u>).

TRP Budget:

- Permissible Direct Costs include the following with the specified limitations:
 - Personnel Expenses including salary, wage, or stipend benefits. In total, no more than forty percent (40%) of the direct costs may be requested for

the salary and fringe benefit expenses of professional staff with a postgraduate degree (i.e. M.D., Ph.D., D.V.M.) regardless of function or role. This restriction does not apply to technical staff (lab assistants, nurses, etc.).

- Supplies & Materials should be itemized by category.
- Equipment must identify each item of equipment with an acquisition cost of more than \$500.
- \circ Travel expense cannot exceed \$1000 per year of the award.
- Other Direct Cost should be itemized and can include patient care costs.
- Permissible Indirect Costs (often referred to as Institutional Overhead, IDC, M&A, G&A or pooled costs) means 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 Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Indirect costs are limited to (11.1%) of total direct costs. For Sponsoring Institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Grantee's/Principal Investigator's stipend or fringe benefits cost.
- *Impermissible Costs* include membership dues, tuition, books, journals, and publication costs

TRP Renewal: TRP Grantees may apply for competitive renewal for two additional years of funding. To be considered for a TRP renewal award, a clinical protocol for a Phase I or Phase II clinical trial based on the initial TRP Grant must be submitted to the institution's IRB for approval and the work must be a direct result of the funded TRP project. TRP Renewal applications should be submitted in the final year of the original TRP Grant or up to two years after the Grant end date (for example, a TRP Grant scheduled to end June 30, 2021 is eligible for renewal in the 2020, 2021, or 2022 application cycles).

TRP Progress Meeting: During the third year of funding, TRP Grantees will be invited to present their research progress to LLS Research staff as well as to TRP Grantees in the same funding year. This meeting is typically held in the fall in New York City. Grantees working outside of the continental United States will be invited to attend via video conference. Each participant (either the project's PI or a representative) will present the research progress using PowerPoint. Each presentation should last no more than 15 minutes with 5 minutes for questions and answers (maximum slide deck of 10 slides). LLS will cover travel expenses for those who choose to attend. Further information regarding this meeting will be sent via email from <u>researchprograms@lls.org</u> to the PI approximately 6 months prior to the meeting.

Progress Meeting Confidentiality: LLS Research Progress Meetings are closed discussion meetings at which participants talk freely about their own work, including unpublished data, and comment on presentations in a critical but positive manner. To engage in this style of meeting, participants must be confident that their data and remarks remain confidential.

- All presentations must be regarded as personal communications and not referred to except with the written permission of the individual being quoted, and with due acknowledgement in any paper.
- Blogging and tweeting of the contents of the meeting is not permitted.
- The proceedings of meetings must not be recorded using tape recorders, still or video cameras, phones, or any other mechanical or electronic devices.
- There must be no public communication of the proceedings of the meeting or results presented without the expressed consent of the individual presenting the results.
- Participation in the meeting implies acceptance of these conditions, which are intended to encourage free communication and discussion of unpublished work.

Specialized Center of Research (SCOR)

About SCOR: 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 five-year Grant term of the SCOR or shortly after the Grant term ends.

Each SCOR is comprised of 3-5 scientific Projects and 2-5 supportive Cores, including an administrative Core. The individual Projects, each led by a Project Leader, and Cores, each led by a Core Leader, cooperate to form one SCOR team, led by the SCOR Director. LLS sends Grant payments to the SCOR Director's institution, and this institution is responsible for dispensing funds as needed to other participating institutions.

SCOR Budget:

- *Permissible Direct Costs,* if justified by the aggregate budget, may be up to \$833,333.33 per year. A description of permissible direct costs includes the following with the specified limitations:
 - Scientific Cores budget cannot exceed \$75,000 per year in direct expenses.
 - Personnel Expenses include salary, wage, or stipend with fringe benefits. Expenses for administrative staff (including secretarial) costs cannot exceed one full-time equivalent for the Center per year.
 - Supplies & Materials requests should be itemized by category.
 - Equipment Purchase requests for any and all equipment cannot exceed a total of \$100,000 per year. Equipment over \$5,000 is permitted if at least fifty percent (50%) of the cost is covered from another source such as Grants from other agencies or institutional support.

- \circ $\;$ Patient Care costs can be included in other direct costs.
- Other Direct Costs requests such as office supplies and telephone costs cannot exceed \$6,000 per year for the Center.
- *Permissible Indirect Costs* (often referred to as Institutional overhead, IDC, M&A, G&A or pooled costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.) as defined in Office of Management and Budget Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. The indirect costs cannot exceed twenty percent (20%) of the direct costs per year.
- *Impermissible Costs* include membership dues, tuition, books, journals, and publication costs

SCOR Transfer/Relocation: If the SCOR Director moves to a new institution or is unable to conduct the leadership expected, LLS must be notified immediately and LLS may, at its sole discretion, terminate funding of the SCOR Grant within thirty days of the incapacity or departure of the Grantee. If a research Project or scientific Core leader leaves the institution or is incapacitated, LLS must be notified immediately. The Sponsoring Institution and/or SCOR Director must inform LLS of actions to be taken to replace the Project/Core leader so as to maintain the Project/Core. LLS shall have the prerogative to suspend funding for the SCOR within thirty days after notification should a resolution satisfactory to LLS not be proposed.

If a leader of a Project or a Core intends to move to a new institution during the course of the SCOR Grant term and the SCOR Director feels that continued collaboration is desirable and possible, the SCOR Director or Sponsoring Institution must submit to <u>researchprograms@lls.org</u> a detailed explanation and justification for continued participation by the Project/Core leader. This request must have the approval of the institution at which the Center resides and the new institution to which the leader of the Project/Core is moving. LLS will retain the right to discontinue funding for the SCOR within thirty days after departure of a Project or Core leader if arrangements acceptable to LLS are not established.

SCOR Milestones and Deliverables: LLS staff will work with the SCOR Director on projected milestones and deliverables to be achieved on an annualbasis. The first year, this will happen prior to the Grant start date, whereas in subsequent years, this will happen after the Site Visit.

SCOR Site Visit: An annual Site Visit will occur around the anniversary of the Grant start date (October 1). The SCOR Progress Review Committee, composed of LLS Research staff and an independent expert or experts, will visit the SCOR Director and his/her team. The SCOR Director, Project Leaders and Core Leaders must be present. Though it is expected that each Project/Core Leader be present, in some circumstances, a key member of the Project/Core Leader's team may take his/her place at the discretion of LLS. Members of each Project and Core will give presentations that give a detailed

overview of the progress made in the prior year as they relate to the original aims as well as the agreed upon milestones/deliverables. Any problems encountered should be discussed, and any deviations from the original aims must be justified and must abide by LLS's policy on Project replacement (see below).

SCOR Project Replacement: All of the projects within a SCOR grant program are meant to contribute substantially to the overall program goals and synergize with the other projects. If a project is terminated, LLS may continue supporting only the other projects within a SCOR program or may invite the SCOR Director and Project Leader to propose a new project to replace the unsuccessful one. Such a replacement project must meet the original review criteria and be approved by LLS via the following procedure:

- 1. In the event that one of the projects within a SCOR grant program becomes unviable or unproductive, the SCOR Director must notify LLS staff within two weeks of this determination. Alternatively, LLS scientific staff may determine that a project is no longer viable. If such determination is made, LLS will notify the SCOR Director.
- 2. LLS scientific staff will determine whether LLS Mission Goals will be served best by substituting a replacement project for the terminated one or by continuing support of the SCOR grant program with fewer component projects. In the latter case, the program award, going forward, may be reduced by the amount previously committed to the terminated project. LLS will continue to fund a terminated project for up to three months following the decision to terminate to enable the orderly wind down of the project.
- 3. LLS may invite the SCOR Director to submit a proposal for a replacement project. The SCOR Director and Project Leader should discuss with LLS staff, prior to submission, the appropriateness and feasibility of potential projects. The new proposal must be submitted to LLS within four weeks of the invitation.
- 4. The proposal for the replacement project should:
 - Include the following sections:
 - Rationale and Specific Aims
 - Background with scientific and clinical significance
 - Previous studies/preliminary data
 - Methods
 - Interaction with other Projects and Cores
 - Statistical approaches
 - Description of patient populations/samples (if relevant)
 - References
 - Include biographical sketches and information about resources and environments for any new Investigators or new environments which were not included in the original application
 - Not exceed 6 pages
 - Be submitted as a single PDF document
- 5. The proposal will be reviewed by LLS scientific staff and by two outside scientists who have expertise in the subject area of the proposed research.
- 6. The proposal will be evaluated for significance, feasibility, translatability, and synergy with the other projects.
- 7. LLS will determine whether the proposal is acceptable, requires modification or is unacceptable. LLS will communicate this decision to the Program Director within 6 weeks of receiving the proposal.

8. LLS shall have the final decision with respect to all project terminations and substitutions.

SCOR 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 coming year's review. The outcome from the annual assessment will be sent to the SCOR Director by email within sixty days of the review.

SCOR Annual Progress Meeting: Each year, there is a mandatory Progress Meeting for representatives from all currently-funded SCOR teams. The meeting is typically held in the fall in New York City. Travel to and from this meeting should be factored into the yearly travel budget of the SCOR. During the meeting, each SCOR Director (or another representative) will present progress on his or her current Grant by PowerPoint. Each presentation should last no more than 25 minutes with 5 minutes for questions and answers (maximum slide deck of 20 slides). Further information regarding this meeting will be sent via email from researchprograms@lls.org to the SCOR Director each year.

Progress Meeting Confidentiality: LLS Research Progress Meetings are closed discussion meetings at which participants talk freely about their own work, including unpublished data, and comment on presentations in a critical but positive manner. To engage in this style of meeting, participants must be confident that their data and remarks remain confidential.

- All presentations must be regarded as personal communications and not referred to except with the written permission of the individual being quoted, and with due acknowledgement in any paper.
- Blogging and tweeting of the contents of the meeting is not permitted.
- The proceedings of meetings must not be recorded using tape recorders, still or video cameras, phones, or any other mechanical or electronic devices.
- There must be no public communication of the proceedings of the meeting or results presented without the expressed consent of the individual presenting the results.
- Participation in the meeting implies acceptance of these conditions, which are intended to encourage free communication and discussion of unpublished work.

Screen to Lead Program (SLP)

About SLP: The Screen to Lead Program (SLP) supports drug discovery specifically directed towards medicinal chemistry and/or drug target screening in hematological malignancies. LLS recognizes a significant need for investigators to receive resources for high-throughput screening and/or optimization of small molecules into drug-like compounds suitable for in vivo testing in a disease-relevant model. LLS, the Grantee and sponsoring institution, and appropriate contract service organizations (CROs) or

core facilities at academic institutions work together to develop compounds with the potential to change the standard of care for patients with blood cancer.

SLP is not a Grant in the traditional sense. Rather SLP is an interactive development process requiring active management of the applicants and their teams as well as appropriate contracted facilities/services by LLS staff. The SLP mechanism is expected to span a two-year period with a go/no-go decision point at the end of year one (See *SLP Midpoint Assessment*).

SLP Budget: The funds awarded shall be used solely for the purposes specified in the Application submitted to LLS as executed by the Grantee and Sponsoring Institution and in strict compliance with the budget annexed to said application, or any subsequent budget approved by LLS. The indirect costs are limited to 11.1% of the total direct costs per year.

SLP Reporting Schedule: Progress and Financial Reporting for SLP Grants are due quarterly, every October 1, January 1, April 1, and July 1 of the Grant term. IP Disclosure Reports are due upon filing of any invention, patent, commercialization, intellectual property, or revenue sharing. At least one IP Disclosure Report must be filed with the Final Reports upon termination of the Grant. Additionally, Publications reports are due quarterly and Conflicts Disclosures annually.

SLP Payment Schedule: An initial upfront payment of 50% of the award amount will be made by LLS upon execution of the Grant Agreement. A further payment of 25% will be released at the end of the first year contingent upon compliance with the Grant Agreement and results of the Midpoint Assessment. The final payment of 25% will be released upon termination of the Grant following LLS approval of all required reporting. Each of these payments will be made during the closest quarterly check run (end of the month of March, June, September or December).

SLP Midpoint Assessment: At the end of year one of the SLP Grant term, LLS will determine, at the sole discretion of LLS, whether to continue funding the project. Decisions will be made based on the submitted progress and financial reporting. If a no-go decision is determined, the maximum amount payable will be the initial 50% payment or half of the budget, whichever is lessor.

Blood Cancer Discoveries Grant (BCDG)

About BCDG: The Blood Cancer Discoveries Grant is funded by LLS, the Mark Foundation for Cancer Research (MFCR), and The Paul G. Allen Frontiers Group (PAFG). The program encourages basic research, technological innovation, and informatics pipeline development that can lead to an understanding of blood cancer disease mechanisms, the development of improved methods for detecting and monitoring cancer progression, and the identification of novel therapeutic targets. Grants are awarded to independent academic investigators for support of foundational, early stage research that can lead to advances in the treatment and cure of blood cancers. To this aim, the BCDG program supports research exploring the biology of blood cancer and proof-of-concept studies that could initiate completely novel approaches to treatment.

BCDG Budget:

Permissible Direct Costs include the following with the specified limitations:

- Personnel Expenses: the PI's salary and fringe benefits must be capped at 40% of the total grant amount, except in exceptional circumstances where a higher cap is justified by the applicant
- Supplies & Materials requests should be itemized by category
- Other Research Costs (e.g. animal care, pathology services, etc.)
- Equipment Purchase requests must identify each item of equipment with an acquisition cost of not more than a total of \$25,000 annually
- Travel Expense requests cannot exceed \$1,500 per year of the award
- Other Direct Cost requests can include subcontract costs (e.g. external sequencing service)

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 Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Indirect costs are limited to 11.1% of the total direct costs. For Sponsoring Institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Direct Costs.

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

Impactful Medicine Providing Access to Clinical Trials (IMPACT)

About IMPACT: The Impactful Medicine Providing Access to Clinical Trials (IMPACT) program is intended to expand access to high-quality clinical trials to patients served by community health settings, particularly patients who are rural, minority, and/or economically disadvantaged blood cancer patients. The overall goal of this award is to establish partnerships between community-based oncologists and major cancer research and treatment centers to facilitate the recruitment of blood cancer patients for participation in impactful clinical trials. This will also accelerate development, initiation, and completion of these clinical trials. As many more clinical trials now use precision medicine, based in part on mutational profiles of patients, this is an outstanding opportunity to educate community-based hematologists/oncologists about careful and appropriate use of this new information.

Each IMPACT project is comprised of a "trials hub" that will establish a network of partnerships with community-based oncologists. The hub, based at a major cancer research and treatment center (the host institution), sponsors the clinical trials and coordinates recruitment of patients into the clinical trials. A major goal by the end of the five-year Grant period is to increase the number of patients currently served by the hub that are from community centers as well as the number of rural participants, minorities, and economically disadvantaged patients. The host institution/trial leaders participate in educational outreach to community physicians and patients and serve as anchors for educating other physicians in the community about precision medicine and genomic initiatives using this community platform. This grant program does not cover clinical trial

expenses; Grantees must have funding secured from another source for these expenses.

IMPACT Budget:

The funds must be used for costs related to infrastructure for the clinical trials 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:

- Personnel expenses including salary, wage or stipend and fringe benefits
- Other Direct Costs that are clearly related to the IMPACT infrastructure needs *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 Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Indirect costs are limited to 5%

of total direct costs requested.

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

IMPACT Milestones & Annual Assessment: LLS Research staff will assess the IMPACT Program team and the progress made against the Milestones. LLS Research staff will make a recommendation as to the level of continued funding. In the case where sufficient progress is being made, the funding will remain the same. In the unlikely event that progress is not sufficient, a written warning will be provided, which may result in future funding being reduced if progress does not improve. After the second semi-annual assessment of the year, LLS Research staff will work with the Grantee to establish Milestones for the coming year. These Milestones will form the foundation of the next year's assessment. The results of the Annual Assessment will be sent to the Grantee by email within sixty days following completion of same.

Other Research Programs

LLS sometimes funds other research initiatives, often in partnership with other foundations, the details of which are not specified in this document. For information about the policies particular to these programs, please consult the Grant Agreement. Further questions should be sent to <u>researchprograms@lls.org</u>.

Inquiries & Reference Links

Research Administration Contact Information

Mailing Address: Senior Director of Research Administration The Leukemia & Lymphoma Society 3 International Drive, Suite 200 Rye Brook, NY 10573

Email: researchprograms@lls.org

Online Resources

LLS Research Portal: <u>https://lls.fluxx.io/</u> Grant Application Information: <u>https://www.lls.org/academic-grants</u> Information for Active Awardees: <u>https://www.lls.org/research/active</u>

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