



# POLICIES & PROCEDURES

REVISED JANUARY 2018

**OVERVIEW**

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 three (3) traditional research grant programs:

- [Career Development Program](#) (CDP)
- [Translational Research Program](#) (TRP)
- [Specialized Center of Research](#) (SCOR)
- Screen to Lead Program (SLP) (not run annually)
- New Idea Award Programs (NIA) (not run annually)

The following statements of policy are provided to assist Applicants, Grantees/Principal Investigators, Sponsors and Sponsoring Institutions in understanding the terms and conditions that apply to each awarded grant. The full terms and conditions are set forth in the grant agreement/contract which incorporates these policies. Applicants, Sponsors and Sponsoring Institutions should reference each program's specific Guidelines & Instructions document for eligibility criteria, submission instructions and deadlines.

Periodically, LLS will issue specific RFPs that are not associated with the traditional research grant programs. For policies and procedures governing those awards, please refer to the specific RFP or contact [researchprograms@lls.org](mailto:researchprograms@lls.org) for more information.

**GENERAL**

By accepting a grant from LLS, the Sponsoring Institution, Grantee/Principal Investigator (and Sponsor in the case of a CDP award) agrees to the terms and conditions of these policies. The Sponsoring Institution accepts full responsibility for the conduct of the sponsored research and the acts of the Grantee/Principal Investigator. LLS does not assume any legal responsibility or obligation for the conduct or acts of the Grantee/Principal Investigator or other project personnel. LLS grants do not constitute an employer-employee relationship between the Grantee/Principal Investigator or project personnel compensated in full or in part with funds awarded by LLS. LLS's ability to fund research is dependent upon voluntary donations, and awards will therefore be payable subject to the continued availability of funds.

**Grant Funds**

LLS shall not be responsible for any expense incurred prior to the start date of the grant or any amount in excess of the grant. Full disclosure of all other funding for a research project must be made as part of the application and at the time funding is approved. All funds are in U.S. dollars.

**Award Notification**

After each program review meeting, the Medical & Scientific Affairs Committee meets to create a final recommendation of the pay line to present to the Mission Oversight Committee (MOC). Upon final approval by the MOC, results are made available via email and hard copy letter to all applicants. No results are given over the telephone.

**Use of Funds**

The funds given pursuant to this Grant shall be solely used for the purposes specified in the Application submitted to LLS as executed by the Applicant, Sponsoring Institution, Sponsor (in the case of a CDP award) and collaborating staff and institutions (in the case of a SCOR award), and in compliance with the budget included in the said Application. Any significant deviation from either the purpose or the budget in the original Application requires prior written approval from LLS. Requests must be submitted in writing to LLS's Research Administration Department ([researchprograms@lls.org](mailto:researchprograms@lls.org)). Requests will be reviewed on a case-by-case basis. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

**Distribution of Funds**

A contract will be forwarded for signature by the Grantee/Principal Investigator, Sponsoring Institution representative

and Sponsor (in the case of a CDP Award). Funds will not be distributed until LLS receives the grant agreement executed by all appropriate individuals.

The failure of the Grantee or the Sponsoring Institution to adhere to any of the terms and conditions of the Grant Agreement may constitute sufficient grounds for LLS, at its sole discretion, to withhold any or all funds due pursuant to the Grant Agreement until such time as the default is corrected, or to terminate the Grant.

LLS reserves the right in its sole discretion to suspend or terminate any Grant based on its review of Progress, Patent/Invention Disclosure, and/or Financial Reports.

Any of LLS, the Grantee or the Sponsoring Institution may terminate this Agreement upon giving thirty (30) days' written notice to the other Parties. In such case, any unexpended balance of the Grant funds must be returned to LLS within thirty (30) days of the termination of the Grantee's employment or the expiration of the notice period, whichever is sooner.

This Grant must be activated (Agreement signed and work commenced) no later than the start date (provided below) in the year for which the Application is approved. The total annual Grant will reflect the budget outlined in the Grantee's application, up to the maximum award value.

Award Program	Start Date	End Date
Career Development Program	July 1	June 30
Translational Research Program	October 1	September 30
Specialized Center of Research	October 1	September 30
Screen to Lead	July 1	June 30
New Idea Award	July 1	June 30

#### **Grant Payments**

Grant payments will be mailed pro rata on or about the last day of each calendar quarter (that is, at the end of September, December, March, and June) to the Controller or other Financial Officer of the Sponsoring Institution indicated on the Application. For SLP, 50% of the approved budget will be paid upon agreement signing, 25% at the one year go/no-go decision point and 25% at termination after all reports are received. If a no-go decision is determined, the maximum amount payable will be the initial 50% payment or ½ of the budget whichever is lessor. The Sponsoring Institution shall be responsible for disbursing funds to the Grantee/Principal Investigator during the term of the grant and in accordance with the budget, as approved by LLS. The final Grant payment shall be made only after receipt by LLS of satisfactory Final Reports (Progress, Patent/Invention Disclosure and Financial). If for any reason, funds are expended in excess of the designated amount, it will be the responsibility of the Sponsoring Institution to make restitution to LLS in the event of transfer or premature termination of the Grant. It is expected that awarded funds shall be expended on a pro rata basis so that in the event of transfer or premature termination of the grant, the prorated unspent funds shall be returned to LLS by the Sponsoring Institution.

#### **Reports**

LLS's ability to award grants is in part dependent upon continued support from voluntary donations. In order to maintain the level of such donations, donors and potential donors (the public) need to be informed of the continued progress made by LLS-funded researchers. LLS must, therefore, be kept informed of research results. LLS will not release confidential information provided in the Research Progress Report or Patent/Invention Disclosure Report but will draft communications from the General Audience Summary which is provided as part of the Annual Report. Therefore, Grantees/Principal Investigators should not include confidential information in the General Audience Summary. Please be sure that the General Audience Summary contains highlights from the past year of research that we can share with our donors. Please do not simply repeat your future research plans or copy previous general audience summaries into this section. See *Confidentiality* section below.

#### **Term & Termination**

**Term.** The term of the Grant Agreement will commence on the Effective Date and expire upon delivery of all final reports required, unless earlier terminated by either party as set forth in this section or extended or in a writing signed by authorized representatives of both parties.

**Termination for Breach.** If Sponsoring Institution fails to meet any of its material obligations under the Agreement and does not remedy such failure within sixty (60) days following receipt of written notice thereof from LLS, then LLS will have the

right to terminate the Agreement effective upon provision of written notice thereof to Sponsoring Institution.

**Termination for Convenience.** Sponsoring Institution acknowledges that LLS's continued funding of the Sponsored Research is contingent on the availability of funds and the progress of the Sponsored Research. Accordingly, LLS will have the right to unilaterally terminate the Agreement at any time in its sole discretion by giving thirty (30) days' advance written notice thereof to Sponsoring Institution.

**Termination for Unavailability of Grantee.** If the Grantee resigns or otherwise becomes unavailable and Sponsoring Institution and LLS are unable to agree upon a successor within thirty (30) days after LLS is so notified, then LLS may terminate the Agreement on fifteen (15) days' written notice to Sponsoring Institution.

**Termination by Mutual Consent.** LLS and Sponsoring Institution may terminate the Agreement at any time by mutual written consent.

**Effect of Termination.** Upon expiration of the Agreement, Sponsoring Institution must return to LLS a prorated amount of unexpended funds covering any post-termination period for which Sponsoring Institution received funding. Expiration or termination of the Agreement will not relieve the parties of any obligation accruing prior to such expiration or termination.

### **Annual Report**

LLS requires Grantee to submit Progress Reports, Patent/Invention Disclosure Reports, and Financial Reports as a condition of accepting LLS funding. These reports will be reviewed by LLS staff. **LLS reserves the right in its sole discretion to terminate any Grant based on its review of a Grantee's Reports. Any Report (Progress, Patent/Invention Disclosure, and/or Financial) that is more than thirty (30) days late may result in suspension of funding. Failure to produce the Annual Report within ninety (90) days of the deadline may result in premature termination of the award.**

Transfers will not be permitted if the Grantee's/Principal Investigator's Annual Reports are in arrears in excess of sixty (60) days and/or if the officially signed transfer application is not received by LLS within thirty (30) days prior to the transfer. See contact information located at the end of this document.

#### **Research Progress Report**

The Grantee/Principal Investigator must submit a written report according to the schedule found in the grant agreement. The additional information requested in report forms/templates is important to LLS for measurements of research outcomes, program productivity and portfolio management. The Grantee/Principal Investigator should fully complete the report forms/templates as instructed or risk suspension of funds.

The Grantee will submit Progress Reports by May 1<sup>st</sup> of each year the Grant is in effect, except for the final year, when the Final Report is due within sixty (60) days of the Expiration Date or any early termination date of the Grant. Each Progress Report must include an updated summary written for the lay public, which reflects the progress made since the original Application was submitted. General Audience Summaries are critical for our efforts to educate the public about our ongoing research. Progress Reports must use the most current template available through the online portal at <http://lls.fluxx.io>. Each report must be submitted through the online portal.

Final Reports are the only reports due for the New Idea Award Program. Each Final Report is due within sixty (60) days of the Expiration Date or any early termination date of the Grant.

In addition to the annual report described above, SLP requires quarterly scientific progress and financial reporting as outlined in the grant agreement. Patent reports are due upon filing by the institution while the grant is enforce and after termination of the grant if the intellectual property was generated using LLS funds.

While the following provides an overview of reporting expectations within each grant program, the Grantee/Principal Investigator must follow all LLS-provided instructions:

#### **CDP Awards**

- Research progress accomplished since last Annual Report
- Outline of specific research plans for next year
- Clinical Trials update since last Annual Report (if applicable)
- List of publications since last Annual Report

- Sponsor's Evaluation of year's research progress
- General Audience Summary of year's research progress
- Patent/ Invention Disclosure Report

#### TRP Awards

- Research progress accomplished since last Annual Report
- Outline of specific research plans for next year
- Clinical Trials update since last Annual Report (if applicable)
- List of publications since last Annual Report
- General Audience Summary of year's research progress
- Patent/Invention Disclosure Report

#### SCOR Awards

- Project Information and Signatures
- SCOR project scientific abstract
- Summary of research progress accomplished since last Annual Report, for all Projects and Cores
- Overview of Research Plans for next year
- Research progress accomplished since last Annual Report, for individual Projects
- Clinical Trials update since last Annual Report (if applicable)
- List of publications since last Annual Report (in SCOR summary and with individual Project/Core reports)
- General Audience Summary of year's research progress, for all Project and Cores
- Attendance and Presentation at the LLS Annual Progress Review Meeting
- Patent/Invention Disclosure Report

#### NIA Awards

- Project Information and Signatures
- Description of tested hypothesis and overall result
- List of publications and presentations related to the research
- List of grants pending or received from results of the research
- Summary of Scientific Progress
- Patent/Invention Disclosure Report

#### SLP Awards

- List of original aims
- Research progress accomplished since last report
- Outline of specific research plans for the next period
- List of publications since last report
- General Audience Summary of research progress
- Patent/Invention Disclosure Report, if applicable

The Grantee/Principal Investigator is responsible for submitting the Research Progress Report.

- **Annual Patent/Invention Disclosure Report**

The Sponsoring Institution agrees to have its patent officer or other appropriate designated official submit at least one annual Patent/Invention Disclosure Report detailing any patent or intellectual property activity during the year. This report shall be submitted by May 1<sup>st</sup> of each year the Grant is in effect except for the final year, when it is due within sixty (60) days of the Expiration Date or any early termination date of the Grant. Patent/Invention Disclosure Reports must use the most current template available through the online portal at <http://lls.fluxx.io>. SLP Patent Disclosure is upon filing but will require at least one report at termination of grant. Each report must be submitted through the online portal. **In the event that a patent application is filed at any time during the year, the Sponsoring Institution agrees to send LLS a copy of the patent application no later than thirty (30) days after the filing date. The Disclosure Report will also refer to any applicable filings.**

- **Annual Financial Accounting Report**

The Sponsoring Institution agrees to have its financial officer submit annual Financial Reports detailing how the Grant funds were expended during the year as well as cumulative totals. This Report shall be submitted within sixty (60) days after each Grant anniversary date. Said Sponsoring Institution also agrees to submit a cumulative Final Financial Report within sixty (60) days of the Expiration Date or any early termination date of the Grant. Financial Reports must use the most current template available through the online portal at <http://lls.fluxx.io>. In addition to the annual accounting, SLP requires quarterly financial accounting. Each report must be submitted through the online portal. The Sponsoring Institution agrees to repay any portion of the Grant from LLS that is not used for the specified purposes of the Grant and to return to LLS any unexpended Grant funds at the end of each grant year (unexpended funds must be returned with the exception of carry forwards and no-cost extensions).

**Annual Renewal**

All LLS grants are subject to an annual renewal; continued funding of this Grant is contingent upon the availability of funds, the Grantee's research progress, and audit requirements. Where funding is not available for a renewal and LLS does not elect to renew the Grant Agreement, the Grantee will be given sixty (60) days written notice prior to the annual start date in the year for which renewal is sought that the Grant will not continue (i.e. July 1<sup>st</sup> in the case of CDP and SLP, and October 1<sup>st</sup> in the case of TRP and SCOR). LLS does not send out continuation notices if the Grant has been renewed.

**Designated Donor Grant Funds/ 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 LLS logo in addition to this statement. The LLS logo is available upon request from [LLSResearchCommunications@lls.org](mailto:LLSResearchCommunications@lls.org).

Sponsoring Institution will, and will ensure that Grantee will, acknowledge the support of LLS in any releases to the media regarding accomplishments made through support by LLS grant funds. The Sponsoring Institution and the Grantee will notify LLS at [LLSResearchCommunications@lls.org](mailto:LLSResearchCommunications@lls.org) at least seven (7) days prior to any advertising, promotion, publication, presentation or exhibition relating to the results of the Sponsored Research. Notification will 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 Grantee is, in part or whole, provided by a donor to LLS, the Grantee agrees, as a condition of receiving funds under this Agreement, 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.

**Costs**

*Policies differ regarding costs (permissible, impermissible, carryover and reallocation) for the different programs. Each program's specific information is provided in separate sections below.*

**Career Development Program (CDP) Awards**

The maximum annual total cost (direct and indirect), the aggregate costs (total award) and duration (years) cannot exceed the following:

Category	Years	Maximum Award Per Year	Total Award
Scholar	5	\$110,000	\$550,000
Scholar in Clinical Research	5	\$125,000	\$625,000
Fellow	3	\$60,000	\$180,000
Special Fellow	2 or 3	\$67,000	\$134,000-\$201,000

Special Fellow in Clinical Research (not available in 2015, 2016, or 2017)	2 or 3	\$67,000	\$134,000-\$201,000
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CDP funding for Scholars, Fellows, Special Fellows and Special Fellows in Clinical Research is limited to salary support only for the Grantee/Principal Investigator which may be supplemented by funds from other appropriate sources as determined by the Grantee's/Principal Investigator's Sponsoring Institution. CDP funding for Scholars in Clinical Research allows for salary support for the Grantee/Principal Investigator and/or other approved personnel, based on the budget outlined in the application. In the case that a Fellow or Special Fellow awardee is also awarded an NIH K99, upon LLS approval, the awardee may use LLS funding for purposes other than salary, wage or stipend benefits. Support for research-associated costs must be provided from another appropriate source.

**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.

**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 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.

**Carry forward** of unexpended funds from one year to another is not allowed for any reason. At the end of each year, based on the Final or Interim Financial Report submitted to LLS, any unexpended funds must be returned to LLS promptly.

**Reallocation of funds** is not permitted unless it is to reallocate overhead to salary. This Grant is intended to be used solely to support the Grantee's salary with only five percent (5%) of the total direct costs allowed for institutional overhead expenses. Further, the funds awarded shall be used for the purposes specified in the Application submitted to LLS as executed by the Grantee, Sponsor and Sponsoring Institution and in strict compliance with the budget submitted with the Application and approved by LLS.

**Other Career Development Support** held in addition to a CDP award is not permitted. No other comparable or better career development award (as measured by the total award amount) may be held prior to, or at the time of the Award start date. If a comparable (or better) career development award is activated after receiving a Fellow Award, the LLS Award must be relinquished. The exception to this rule is regarding the K99 Award; in this case, the applicant is still eligible for the Fellow Award. K99 awardees may apply for the CDP award. Awardees who receive a K99 may keep both awards, pending LLS approval. Applicants expecting a K99 award should contact [researchprograms@lls.org](mailto:researchprograms@lls.org) as soon as possible for instructions on how to request approval to retain both awards. If approved, funding from the Fellow Award may be used for any purpose, whether it be awardee salary, technician salary, or research supplies. Any changes to the approach in the original Fellow application must be approved by LLS in order to continue LLS Fellow funding.

#### **Translational Research Program (TRP) Awards**

The maximum annual total cost (direct and indirect) cannot exceed \$200,000. The aggregate costs over three (3) years cannot exceed \$600,000. For TRP renewal awards, the aggregate costs over two (2) years cannot exceed \$600,000.

**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 post-

graduate 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.
- 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 Circular A-21. 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.

**Carry forward of funds** is permitted for Grantees/Principal Investigators of TRP awards. The Grantee will be permitted to carry forward up to fifteen percent (15%) of the funds from one grant year to the next without prior written approval of LLS. For carry forward amounts greater than fifteen percent (15%), prior written approval by LLS must be obtained. Approval by LLS to carry forward funds does not extend for more than one year. To obtain permission, this request must be made in writing to [Researchprograms@lls.org](mailto:Researchprograms@lls.org).

**Reallocation of Funds** is permitted for Grantees/Principal Investigators of TRP awards. Reallocation of funds from one expense category to another without prior written approval of LLS is permitted. However, the following requirements apply:

- No more than forty percent (40%) of the direct costs may be used for professional salaries. Professional salaries are defined as salaries for personnel with post-graduate degrees (i.e. M.D., Ph.D., D.V.M.), regardless of their role.
- No more than \$1000 per year may be used for travel costs.
- Indirect costs are limited to 11.1% of the total direct costs.

For reallocation of funds which exceed the above categories, written approval of LLS must be obtained. To obtain permission, this request must be made in an email to [Researchprograms@lls.org](mailto:Researchprograms@lls.org).

#### **Specialized Center of Research Awards**

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

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

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

**Permissible Indirect Costs** (often referred to as Institutional overhead, IDC, M&A, G&A or pooled costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.) as defined in Office of Management and Budget Circular A-21. The indirect costs cannot exceed twenty percent (20%) of the direct costs per year.



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

**Carry forward of funds** is permitted for Grantees/Principal Investigators of SCOR awards. Requests to carry forward funds from one award year to the next require prior written approval of LLS. To obtain permission, this request should be made in writing, specifying the dollar amount to be carried forward and to which category it is to be applied. This request must be cosigned by appropriate institutional officials (Fiscal Officer and/or Grants and Contracts officials). The letter should specify the Research Project(s) or Scientific Core(s) involved and the dollar amount to be carried forward, and provide a revised budget for the years affected. Completed requests should be forwarded to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org).

**Reallocation of Funds** is permitted from one expense category of a project or core to another within that project or core without prior written approval of LLS as long as it does not relate to the percent effort of an investigator or deviate from LLS policy. If required, permission for the reallocation of funds should be made in writing to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org), specifying the amount to be reallocated, which categories are involved and the reason for the request.

**New Idea Award Program Awards**

The maximum total cost, direct and indirect, cannot exceed \$75,000.

**Permissible Direct Costs** means Personnel Expenses including salary, wage or stipend with fringe benefits are limited to that defined in the original grant proposal's budget; Supplies & Materials requests should be itemized by category; Equipment Purchase requests must identify each item of equipment with an acquisition cost of more than \$500; Other Direct Cost requests can include patient care costs.

**Permissible Indirect 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 Circular A-21. For Sponsoring Institutions that do not choose to use funds for indirect costs, LLS allows the funds to be applied to the Grantee's/Principal Investigator's stipend or fringe benefit cost. The indirect costs are limited to 5% of the total Direct Costs per year.

**Carry forward of funds** is prohibited.

**Reallocation of funds** from one expense category to another is permitted without prior written approval from LLS.

**Screen to Lead Program Awards**

The maximum annual total cost, direct and indirect, cannot exceed \$500,000. The aggregate costs over two (2) years cannot exceed \$1 million.

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.

**Carry forward of funds** is permitted for Grantee/Principal Investigators of SLP awards.

**Reallocation of funds** requires written permission of LLS and should be made in writing to the LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org), specifying the amount to be reallocated, which categories are involved and the reason for the request.

**Competitive Renewal**

CDP awards are not eligible for competitive renewal, but Grantees/Principal Investigators can apply to other CDP program categories as they become eligible (e.g. Fellow, Special Fellow, or Scholar).

TRP Awards that have at least a clinical protocol submitted for IRB approval and of continued high promise are eligible to apply during the third year of the award for an additional two (2) years of funding. Grantees/Principal Investigators should reference the Guidelines & Instructions for more information on competitive TRP Renewal Support. Submission of a renewal application shall not assure the Grantee/Principal Investigator of a renewal.

SCOR Awards are eligible to apply for a continuation of funding however we no longer have a distinct renewal process. All SCOR proposals compete against each other for the same pool of funding. Investigators applying for continued funding have the added responsibility of providing information regarding the following:

- If the applicant previously or currently held an LLS SCOR grant as the Principal Investigator, they should clearly outline how LLS funds have contributed to their productivity and give specific examples of accomplishments that can be attributed to the LLS funds (a direct demonstration of clinical application/relevance of the ongoing and proposed work is encouraged).
- If there is a Project or Core leader named on the application that is currently working on another LLS-funded SCOR grant, it should be clear how the work he/she is doing is different in this application from that of the other SCOR grant.

NIA awards are not eligible for competitive renewal.

SLP awards are not eligible for competitive renewal.

### **No-Cost Extension of Grant Terms**

No-cost extensions extend the end of the grant term without supplemental funds. The duration of a no-cost extension cannot exceed one (1) year beyond the original end date of the grant term. At the expiration of the no-cost period, any remaining unspent funds must be returned to LLS. No-cost extension requests are subject to approval by LLS.

- CDP Award Grantees/Principal Investigators are not permitted to request a no-cost extension. If a CDP Award Grantee/Principal Investigator takes a leave of absence, the grant is reinstated once the Grantee/Principal Investigator returns and the grant is extended with funding for the amount of time the leave was taken.
- TRP Award Grantees/Principal Investigators are permitted to request one (1) no-cost extension for a maximum of one year in duration. The request for a no-cost extension must use the appropriate form (requested from [researchprograms@lls.org](mailto:researchprograms@lls.org)) and be submitted by email to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org). At the end of the no-cost extension period, any funds remaining must be returned to LLS.
- SCOR Award Grantees/Principal Investigators are permitted to request one (1) no-cost extension for a maximum of one year in duration. The request for a no-cost extension must use the appropriate form (requested from [researchprograms@lls.org](mailto:researchprograms@lls.org)) and be submitted by email to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org). At the end of the no-cost extension period, any funds remaining must be returned to LLS.
- SLP Award Grantees/Principal Investigators are permitted to request one (1) no-cost extension for a maximum of one year in duration. The request for a no-cost extension must use the appropriate form (requested from [researchprograms@lls.org](mailto:researchprograms@lls.org)) and be submitted by email to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org). At the end of the no-cost extension period, any funds remaining must be returned to LLS.

### **Commingling / Offset**

The use of grant funds cannot be duplicated by funds received by the Sponsoring Institution or the Grantee/Principal Investigator from any other sources, but, the grant funds may be used to supplement support from other sources.

### **Special Grants**

Special Grants vary by submitted and approved proposals. For more information on the submission and approval of Special Grants, please contact SVP and Chief Scientific Officer, Lee Greenberger, at [lee.greenberger@lls.org](mailto:lee.greenberger@lls.org).

### **Partnership Grant – Myeloproliferative Neoplasms Research Foundation (MPNRF)**

#### **Participation in In-Person events**

The Institution will cooperate with respect to Lead Researchers' attendance at an annual in-person meeting with participating researchers and representatives from other institutions and representatives of MPNRF to present results of Research Projects, assess progress in research on MPN and participate in a discussion about strategies and directions for future research on MPN. Travel costs

related to such meetings will be reimbursed by MPNRF separately from funds awarded for the Research Project.

**Compliance with Research Project Proposal**

The Grantee Institution must notify MPNRF of material changes to the approved Research Project in writing 30 days in advance. Any such approved changes shall be attached to the approved Research Project proposal.

**Change in Personnel / Removal of Lead Researcher or Research Team Member**

The Grantee Institution must notify MPNRF immediately if it is anticipated that any individuals identified in the approved Research Project proposal will be leaving the Institution and/or if any other changes of personnel working on the Research Project are indicated or anticipated. In such event, the Institutions shall propose replacement personnel, who are subject to approval by MPNRF. In the event of a significant change in personnel without suitable replacement, MPNRF may determine in their sole discretion to terminate the grant upon 30 days written notice.

**Multiple Funding Sources**

If the Grantee Institution obtains a commitment to fund the Research Project, or a portion of the Research Project, from an alternative funding source following MPNRF's approval of the Research Project, the Institution must immediately notify MPNRF. Depending on the amount of and the conditions associated with the alternate funding, MPNRF may either modify or discontinue their funding of the Research Project.

**Reporting Requirements**

The Grantee Institution shall ensure that the Lead Researchers submit progress reports each 6 months the Research Project is running. All reports shall describe the Research Project progress and budget status.

**Confidential Information**

The Grantee Institution and MPNRF shall treat all information that is provided by either of them to the other(s) under the Research Project Agreement that consists of confidential and/or proprietary materials or information not generally available to the public as being "Confidential information".

**Return of Unused Funds**

In the event of termination of a Research Agreement for any reason, the Grantee Institution shall return all unused funds to MPNRF within 30 days of the date of termination of this Agreement.

**Indirect and Direct Costs**

Permissible Direct Costs include the Grantee's/Principal Investigator's salary, wage, or stipend and fringe benefits. 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.

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 eight percent (8%) of total direct costs. For Sponsoring Institutions that do not choose to use these funds for indirect costs, MPNRF allows the funds to be applied to the Grantee's/Principal Investigator's stipend or fringe benefits cost.

**No-Cost Extension of Grant Terms**

No-cost extensions extend the end of the grant term without supplemental funds. The duration of a no-cost extension cannot exceed one (1) year beyond the original end date of the grant term. At the expiration of the no-cost period, any remaining unspent funds must be returned to MPNRF. No-cost extension requests must be submitted in writing and are subject to approval by MPNRF.

**Relocations or Transfers**

If the Grantee/Principal Investigator plans to transfer to another Sponsoring Institution while the grant is in effect, continuation of funding at the new Sponsoring Institution requires prior written approval of MPNRF. A final accounting report of all disbursements of the grant funds by the original institution through the proposed day of transfer shall also be required.

**Partnership Grants- International Waldenstrom's Macroglobulinemia Foundation (IWMF)**

The IWMF Research Grant Program is pledged to promote and support basic research leading to improved understanding of the cause, diagnosis, treatment, and cure for the disease Waldenstrom's Macroglobulinemia (WM). Based on this strategy, the IWMF-LLS Research Roadmap Initiative was recently developed to further our knowledge in four specific areas of WM research. The Initiative includes a Request for Proposals that can be obtained by contacting the IWMF Operations Manager at the email address

appearing on the preceding page and at the end of this document, or at [www.iwmf.com/research/research-strategy](http://www.iwmf.com/research/research-strategy).

For more information on the submission and approval of IWMF, please contact IWMF Office, at [office@iwmf.com](mailto:office@iwmf.com) or 941-927-4963.

### **Organizational Assurances**

The Grantee/Principal Investigator 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 (or equivalent institutional authority) ("**IRB**") 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 (10) 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 this 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 (10) 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 this Agreement.
- If the Grantee's human subject research privileges are suspended, LLS must be notified within ten (10) business days of the suspension. LLS will take whatever action it deems appropriate, including suspension or termination of this Grant. Failure to notify LLS of any suspension will result in suspension or termination of this Grant. If the Grant is terminated, any unused Grant funds and/or funds paid after the ten (10) 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, 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 (10) business days of the suspension. LLS will take whatever action it deems appropriate, including suspension or termination of this Agreement. Failure to notify LLS of non-compliance with the guidelines on the use of laboratory animals will result in suspension or termination of this Agreement.
- If the Grantee's animal use privileges are suspended, LLS must be notified within ten (10) business days of the suspension. LLS will take whatever action it deems appropriate, including suspension or termination of this Grant. Failure to notify LLS of non-compliance with these guidelines on the use of laboratory animals will result in suspension or termination of this Grant. If the Grant is terminated, any unused Grant funds and/or funds paid after the ten (10) 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 Plan. 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 this 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 this Agreement.

### **Research Integrity**

Sponsoring Institution acknowledges that research misconduct by Grantee is contrary to the interests of LLS and the patients and their families, as well as to the integrity of research, and to the conservation of donor funds. Sponsoring Institution will cause Grantee to follow the Sponsoring Institution's policies as they relate to Research Misconduct. Sponsoring Institution represents and warrants that such policies are at least as rigorous as those followed by the NIH (Public Health Service Policies on Research Misconduct 42 CFR 93).

### **Deviations**

Any deviation from the originally proposed research requires prior approval by LLS. Written requests must be submitted by email to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org). Requests will be reviewed on a case-by-case basis.

### **Relocations or Transfers**

**Only one (1) transfer for any award will be allowed per award period, for any reason.**

#### **Grantees/Principal Investigators of CDP, TRP and NIA Awards:**

If the Grantee/Principal Investigator plans to transfer to another Sponsoring Institution while the grant is in effect, continuation of funding at the new Sponsoring Institution requires prior written approval of LLS. To obtain permission for relocation, the Grantee/Principal Investigator must complete a transfer form (available by contacting [researchprograms@lls.org](mailto:researchprograms@lls.org)) and return the completed form thirty (30) days before the date of relocation. A final accounting report of all disbursements of the grant funds by the original institution through the proposed day of transfer shall also be required. Requests for transfer should be sent to LLS's Research Administration Department ([researchprograms@lls.org](mailto:researchprograms@lls.org)).

**Special Fellows and Special Fellows in Clinical Research cannot request a transfer during the first year of their grant term.** If a Special Fellow or Special Fellow in Clinical Research leaves the Sponsor's lab before one (1) year, the grant must be relinquished and funding returned to LLS. Special Fellow in Clinical Research will not run in 2015 or 2016.

If a Grantee/Principal Investigator receives permission to transfer in the middle of a quarter, the appropriate partial quarterly payment shall be made to the new institution at the end of the quarter. The former institution shall be paid upon receipt of all final reports. Subsequent payments shall be the usual quarterly payment. If a transfer occurs after a payment(s) has been made to the former institution, the return of funds to LLS must be pro rata, that is the proportion of the total payment that corresponds precisely to the date of transfer.

Transfers will not be permitted if the Grantee/Principal Investigator is in arrears in excess of sixty (60) days for submitting annual reports and/or if the officially signed transfer application is not received by LLS within thirty (30) days prior to the transfer. See contact information located at the end of this document (also see *Annual Report*).

In the case of a CDP award, the Grantee is not permitted to transfer labs before the grant start date of the year in which the grant is awarded (July 1<sup>st</sup>). Doing so will result in termination of the award.

If a Grantee/Principal Investigator transfers without prior notification and/or approval, the Grant may be subject to termination.

#### **Grantees/Principal Investigators of SCOR Awards:**

If the Grantee/Principal Investigator leaves the institution to which the award is made is incapacitated or is otherwise unable to conduct the leadership expected, LLS must be notified immediately and LLS may, at its sole discretion in that circumstance, terminate funding of the Center grant within thirty (30) days of the incapacity or departure of the Grantee/Principal Investigator. If a research Project or scientific Core leader leaves the institution or is incapacitated, LLS must be notified immediately. The Institution and Principal Investigator 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 Center within thirty (30) 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 Center grant's term of award and the Principal Investigator feels that continued participation, integration and function as a Center is desirable and possible, the Principal Investigator must submit a detailed explanation and justification for continued participation by the Project/Core leader at the new site to LLS's Research Administration Department at [researchprograms@lls.org](mailto:researchprograms@lls.org). 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 Center within thirty (30) days after departure of a research Project or scientific Core leader if arrangements, acceptable to LLS, are not established.

#### Grantees/Principal Investigators of SLP Awards:

Transfers outside of the original signing Institution are only allowed by written approval from LLS. Transfer approval is at the sole discretion of LLS and may possibly lead to early termination if resources or personnel are deemed unsuitable.

#### Interruption, Abandonment or Leave of Absence

##### Grantees/Principal Investigators of CDP, TRP, NIA and SLP Awards

If a grant is interrupted, written permission must be obtained from LLS in order to continue a grant at a later date. In the event a grant is not completed due to incapacitating illness or death of the Grantee/Principal Investigator, the prorated, unexpended funds must be returned to LLS. The Sponsoring Institution may name a substitute Grantee within thirty (30) days of the then-current Grantee's withdrawal from the Sponsored Research subject to the approval of LLS, which approval may be withheld in LLS's sole discretion.

Requests for a leave of absence from LLS must be made by the Grantee/Principal Investigator by contacting [researchprograms@lls.org](mailto:researchprograms@lls.org). Leaves of absence cannot exceed one (1) year in duration. The completed form must be submitted to LLS thirty (30) days before the date of your actual leave or risk early termination of the grant. If the Grantee is taking a leave of absence greater than thirty (30) days, the Sponsoring Institution may request suspension of the Sponsored Research or appointment of another investigator to serve as interim grantee pending Grantee's return. LLS may accept or deny such suspension or appointment request in its sole discretion. If LLS consents to a suspension request, then LLS will suspend funding of the Sponsored Research until the return of the Grantee, and the Term will be extended for a period equal to the duration of the suspension.

##### Grantees/Principal Investigators of SCOR Awards

Grantees/Principal Investigators of SCOR Awards may not be absent during the five (5) year term of the grant from the institution that is the Center's original principal focus. Research Project or Scientific Core leaders, likewise, may not be absent during the five (5) year term of the grant from the institution originally instituted. If unavoidable, an absence greater than thirty (30) days requires prior written permission from LLS. If a grant is interrupted, LLS must be notified promptly. Written permission must be obtained from LLS for the grant to be continued at a later date. In the event a grant is not completed due to incapacitating illness or death of the Grantee/Principal Investigator, the prorated, unexpended funds must be returned to LLS.

#### Reinstatement of Grants

Funds shall not be reinstated after LLS has received notification in writing from the Grantee /Principal Investigator of the intent to terminate a grant. Those wishing to resume funding are welcome to submit a new application that will compete on an equal basis with all others applications in the next grant program cycle.

#### Participation in Multiple LLS-Funded Projects

There is no limit to the total number of awards an LLS grantee shall hold, but no more than one application can be submitted in the same application cycle and within the same program.

#### Definitions

Co-Principal Investigators, Co-Investigators, Collaborators, and Key Personnel:

- The Co-Principal Investigator is responsible for developing the Aims of the project.
- The Co-Investigator (who can also be referred to as Collaborator) is responsible for carrying out the Aims of the project.
- A Principal Investigator CANNOT be named as a Principal Investigator or a Co-Principal Investigator on another application during the same application cycle.
- A Principal Investigator can be listed as a Co-Investigator or a Collaborator on another application in the same cycle, without limit to the number of applications.
- A Collaborator or Co-Investigator can be named on more than one application or funded grant, without limit.
- Grantees/Principal Investigators that serve as Project/Core leaders on SCOR grants shall not participate in more than two SCOR grants.

Key Personnel:

- Lab assistants

- Nurses
- Other Technical Staff

**Outcome Reporting**

LLS may contact the Grantee/Principal Investigator after the conclusion of the award to determine how LLS funding influenced his/her career and how it may have contributed to new treatments, prevention or diagnosis for leukemia, lymphomas and myeloma patients.

**Confidentiality**

All applications and evaluations are considered confidential and are available to the Medical & Scientific Affairs Committee, its relevant Grant Review Subcommittees and administrative personnel only. All information provided in reports shall be treated as confidential with the noted exception of General Audience Summaries which should not be submitted to LLS containing confidential information.

It is anticipated that in the performance of the Sponsored Research each party is likely to disclose to the other party certain Confidential Information. “Confidential Information” means any information, including data, techniques, protocols or results, or business, financial, commercial or technical information that is reasonably necessary for performance under the Agreement and is identified as confidential at the time of disclosure. If such information is disclosed in non-tangible form (including orally or visually), then it must be identified as confidential at the time of disclosure and summarized with specificity in a writing marked “Confidential” and given to Recipient within thirty (30) days after such disclosure.

Exceptions. Notwithstanding the foregoing, “Confidential Information” under the Agreement will not include any information that (as shown by contemporaneously existing or created written records) (i) is or becomes publicly available through no wrongful act; (ii) was known by Recipient prior to disclosure; (iii) becomes known after disclosure from a third party having an apparent bona fide right to disclose it; (iv) is independently developed or discovered without use of Confidential Information; or (v) is disclosed to another party without restriction on further disclosure.

Restrictions on Confidential Information. For a period of three (3) years after receipt of Confidential Information, Recipient agrees that: (i) it will not use such Confidential Information for any purpose other than as specified in the Agreement, including for its own benefit or the benefit of any other person or entity; and (ii) it will use reasonable efforts (but not less than the efforts used to protect its own confidential and/or proprietary information of a similar nature) to protect Confidential Information. Further, Recipient will not disclose Confidential Information to any other person or entity except only on a need-to-know basis to its and its Affiliates’ employees, staff members and agents who are directly involved in the performance of the Sponsored Research and who are informed of the confidential nature of such information, provided Recipient will be responsible for compliance by Receiving Individuals with the terms of the Agreement and any breach thereof.

Inter-Institutional Agreements: If the Grantee has participating persons, facilities or elements at any Contract Research Organization (CRO) or has participating persons, facilities or elements at any research institution such as a university outside the Sponsoring Institution, it is the responsibility of the Sponsoring Institution to subcontract with (those) CRO(s) on the same terms agreed to in the Agreement with LLS.

To review current grant agreement templates and IP policies, please visit <http://www.lls.org> .

**Inquiries**

Contact information is provided below for individuals referenced within this document.

**For contract and other administrative matters:**

Director of Research Administration  
The Leukemia & Lymphoma Society  
3 International Drive, Suite 200  
Rye Brook, NY 10573  
Email: [Researchprograms@lls.org](mailto:Researchprograms@lls.org)

**For news and publications matters only:**

LLS Research Communications  
The Leukemia & Lymphoma Society  
3 International Drive, Suite 200  
Rye Brook, NY 10573  
Email: [LLSResearchCommunications@lls.org](mailto:LLSResearchCommunications@lls.org)

