



LEUKEMIA &
LYMPHOMA
SOCIETY®

fighting blood cancers

POLICIES & PROCEDURES

REVISED JULY 2012

POLICIES & PROCEDURES

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 its founding in 1949, LLS has invested more than \$875 million for research specifically targeting blood cancers.

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)

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. Applicant, Sponsors and Sponsoring Institutions should reference each program 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 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 payline to present to our Mission Oversight Committee (MOC). Upon final approval by the MOC, results are made available via email and hard copy letter to all applicants within 45 days after the subcommittee meeting. No results are given over the telephone.

- **Use of Funds**

The funds awarded shall be used solely for the purposes specified in and in strict compliance with 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), or any subsequent budget approved by LLS. LLS shall have the right to audit the use of grant funds.

- **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. Grant start dates for CDP awards is July 1 and for TRP and SCOR awards the start date is October 1.

Award Program	Start Date	End Date
Career Development Program	July 1	June 30

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Translational Research Program	October 1	September 30
Specialized Center of Research	October 1	September 30

All grants shall be activated no earlier than the start date provided above. All grants not activated by the start date may need to be resubmitted and compete on an equal basis with new grant applications during the following year's grant cycle.

All grant payments shall be made pro rata at the end of each quarter (that is, at the end of September, December, March, and June). Payments shall be mailed on or about the last day of each quarter to the controller or financial officer of the Sponsoring Institution as indicated in the grant application. 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. If for any reason funds are expended at an amount in excess of the monthly-designated amount, it shall be the responsibility of the Sponsoring Institution to make restitution to LLS in the event of transfer or premature termination of the grant.

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 to the Sponsoring Institution only after the timely receipt by LLS of a satisfactory and complete Final Annual Report (see *Final Annual Report* below for requirement details).

- **Contingent upon Annual Report**

Although contracts are issued for the full term of the award, continuation of funding is contingent upon timely submission of satisfactory and complete Annual Reports (see *Annual Report* section below). Upon review of the Annual Report, LLS reserves the right to terminate any grant if, at its sole discretion, it determines that there has been inadequate research progress or a failure to adhere to the originally submitted application. Continuation of funding is a function of 1) audit requirements and 2) LLS's ability to continually raise funds.

- **Failure to Produce Annual Report**

Any Annual Report more than thirty (30) days late shall result in suspension of funds. Failure to produce the Annual Report within ninety (90) days of the deadline shall result in premature termination of the award.

Designated Donor Grant Funds

When support for a Grantee's/Principal Investigator's research is, in part or whole, provided by a donor to LLS and is restricted to said project, the Grantee/Principal Investigator agrees, as a condition of receiving funds under the contract, to participate in promotional/publicity activities (including but not limited to meeting the Board of Directors of the donor's affiliated organization, being interviewed for their newsletter) as requested.

Costs

Policies differ regarding costs (permissible, impermissible, carryover and reallocation) for the different programs and thus 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 table.

Category	Years	Maximum Award Per Year	Total Award
Scholar	5	\$110,000	\$550,000
Scholar in Clinical Research	5	\$110,000	\$550,000
Special Fellow	2 or 3	\$65,000	\$130,000-\$195,000
Special Fellow in Clinical Research	2 or 3	\$65,000	\$130,000-\$195,000
Fellow	3	\$55,000	\$165,000

CDP funding 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. 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 requires 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.

Carryover of Funds (to move unexpended funds from the first award year to the second award year) is **not** permitted for Grantees/Principal Investigators of CDP awards.

Reallocation of Funds (to move funds from one expense category to another expense category) is not permitted for Grantees/Principal Investigators of CDP awards unless it is to reallocate overhead to salary.

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 \$1,000,000.

Permissible Direct Costs include the following with the specified limitations:

1. Personnel Expenses including salary, wage, or stipend with fringe 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.).
2. Supplies & Materials requests should be itemized by category.
3. Equipment Purchase requests must identify each item of equipment with an acquisition cost of more than \$500.
4. Travel Expense requests cannot exceed \$1000 per year of the award.
5. Other Direct Cost requests can include patient care costs.

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 eleven point one percent (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.

Carryover of Funds is permitted for Grantees/Principal Investigators of TRP awards. Up to fifteen percent (15%) of awarded funds can carryover from the first award year to the second or the third without prior written approval of LLS. For carryover amounts that are greater than fifteen percent (15%), prior written approval of LLS must be obtained. To obtain permission, the request should be made in writing, specifying the dollar amount to be carried-over 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). Completed requests should be forwarded to LLS's Research Administration Department.

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 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

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- 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 should be made in writing, specifying the dollar amount, which category is impacted, a justification to exceed the funding limits and cosigned by appropriate institutional officials (Fiscal Officer and/or Grants & Contracts officials). Completed requests should be forwarded to LLS's Research Administration Department.

Specialized Center of Research Awards

The Center's maximum annual total cost, direct and indirect, cannot exceed \$1.25 million. The aggregate costs over five (5) years cannot exceed \$6.25 million.

Permissible Direct Costs, if justified by the aggregate budget, may be up to \$1.042 million per year. A description of permissible direct costs includes the following with the specified limitations:

1. Scientific Cores budget cannot exceed \$75,000 per year in direct expenses.
2. 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.
3. Supplies & Materials requests should be itemized by category.
4. 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.
5. 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 Review Meeting held each year in New York City (airfare, one night's lodging and incidental expenses).
6. Patient Care costs can be included in other direct costs.
7. 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.

Carryover of Funds is permitted for Grantees/Principal Investigators of SCOR awards. Requests to carryover 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 over 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 over, and provide a revised budget for the years affected. Completed requests should be forwarded to LLS's Research Administration Department.

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, specifying the amount to be reallocated, which categories are involved and the reason for the request.

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.

- **Annual Report**

The Grantee/Principal Investigator must submit Annual Reports as a condition of LLS funding. In general, the Annual Report includes three components 1) a research progress report, 2) an intellectual property and invention disclosure report and 2) a financial accounting report. The following provides more specific details on each of these reports. LLS shall review all reports to evaluate the research progress of each Grantee/Principal Investigator and review expenditure of grant funds. LLS reserves the right to terminate any grant if, at its sole discretion, it determines that there has been inadequate research progress or a failure to adhere to the original proposal submitted with the application.

- **Research Progress Report**

The Grantee/Principal Investigator must submit a written report according to the schedule outlined in the section below titled *Submission of Annual Reports* and found in award contracts. 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. While the following provides an overview of reporting expectations within each grant program, the Grantee/Principal Investigator must following all LLS-provided instructions (see [Grant Reporting & Requests](#) page). See the section below titled *Submission of Annual Reports* for instructions on submission of this report.

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
- Biosketch
- 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
- Biosketch
- 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
- Biosketch
- Patent/Invention Disclosure Report

The Grantee/Principal Investigator is responsible for submitting the Research Progress Report (see *Submission of Reports* below).

- **Annual Patent/Invention Disclosure Report**

As a condition of each LLS-funded grant, the Grantee/Principal Investigator must disclose to LLS any discoveries,

inventions or improvements that have been conceived or reduced to practice in the performance of the research funded in whole or in part by LLS. In addition, the Grantee/Principal Investigator must disclose protection (i.e. patent or invention applications, copyright, etc.) sought/received and any commercialization (i.e. third party agreements, licenses). For more information see the *Patent and Intellectual Property Policy* below. This information is captured on a LLS-provided form (see [Grant Reporting & Requests](#) page) that contains instructions for submission of protection and commercialization document copies.

It is the responsibility of the Grantee/Principal Investigator to obtain and complete the Patent/Invention Disclosure Report. This must then be routed through the Sponsoring Institution's Office of Technology Transfer (or equivalent) for signature. See the section below titled *Submission of Annual Reports* for submission instructions. While it is anticipated that the Technology Transfer official will submit the Invention/Patent Disclosure Reports it is ultimately the responsibility of the Grantee/Principal Investigator to ensure timely submission of complete and satisfactory reports or risk suspension of funds.

LLS must also be notified of any patents applications filed based on work funded by LLS after submission of the Final Annual Report. The Grantee/Principal Investigator and Sponsoring Institution should use the same LLS-provided form as during the grant funding period.

- **Annual Financial Accounting Report**

The Financial Officer of the Sponsoring Institution must submit Annual Financial Accounting Reports detailing how the grant funds were expended during the year. These reports shall be submitted within sixty (60) days after each grant anniversary date. While it is anticipated that the Fiscal Officer will submit the Financial Reports, it is ultimately the responsibility of the Grantee/Principal Investigator to ensure timely submission of complete and satisfactory reports or risk suspension of funds.

Any unexpended funds must be returned to LLS within sixty (60) days of the expiration or termination of the grant. The final grant payment shall be made only after the receipt by LLS of a timely, complete and satisfactory final research progress report, patent/inventions disclosure report and final accounting report. The Sponsoring Institution also agrees to submit a **cumulative** Final Financial Accounting Report immediately upon completion or termination of the grant.

- **Final Report**

Within sixty (60) days of the expiration of the grant period, the Grantee/Principal Investigator shall submit a Final Annual Report, including a summation of all research activities, together with copies of all publications stipulated in the final progress report. ***Again, a one page summary of the research project's progress must be included for the general audience public or your progress report will be rejected.***

The final grant payment shall be made only after the receipt by LLS of timely, satisfactory and complete final research progress report, accounting report and patent/invention report.

Submission of Reports

Due dates for each Annual Report can be found in the Grantee/Principal Investigator's contract agreement. Reports for CDP and TRP must be submitted on LLS-provided forms/templates (available via <http://www.lls.org/#researchershealthcareprofessionals/academicgrants/requestreportingforms/>) or be judged by LLS as unsatisfactory. The financial, progress and patent reports must be uploaded to LLS site and submitted in hard copy or will be considered incomplete. When accessing the www.lls.org/forms site for progress report submission, a LLS user name and password are required. Selecting the checkbox for your grant under Grant History will allow you to submit the report. This screen will also show other report due dates in the current and future years. (Please contact researchprograms@lls.org for password information).

SCOR grant reports must use the templates found on www.lls.org/#researchershealthcareprofessionals/academicgrants/requestreportingforms/. Currently, an electronic copy of these reports must be submitted to LLS by PDF. If the file is too large and cannot be compressed to allow for electronic submission the investigator must submit the report on a CD/USB or other storage device by mail. (LLS is working to establish online submission for Grantees/Principal Investigators of the SCOR Awards directly within the grant management system and will announce its availability when completed). Meanwhile, each component must be submitted electronically or on CD in PDF format for narrative reporting to LLS's Research Administration Department.

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Impact of Delinquency

All reports more than thirty (30) days late, incomplete or unsatisfactory (as determined by LLS) shall result in suspension of funds. Failure to produce any component of the Annual Report within ninety (90) days of the deadline shall result in premature termination of the award at the sole discretion of LLS. 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.

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 initiated an IRB-approved clinical trial 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 1) 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) 2) 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 or she is doing is different in this application from that of the other SCOR grant.

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 time on leave.

TRP Award Grantees/Principal Investigators are permitted to request one (1) no-cost extension for a maximum of one year in length. The request for a no-cost extension must utilize the appropriate form (via www.lls.org/forms) and submitted online and in hardcopy to LLS's Research Administration Department thirty (30) days prior to the end of the grant term.

SCOR Award Grantees/Principal Investigators are permitted to request one (1) no-cost extension for a maximum of one year in length. The request for a no-cost extension must be in writing and submitted in hardcopy to LLS's Research Administration Department thirty (30) days prior to the end of the grant term.

Co-mingling / 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.

Organizational Assurances

The Grantee/Principal Investigator agrees to comply with any existing or new federal 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.

Human Subject Investigation - The Grantee/Principal Investigator (and Sponsor in the case of a CDP award) must obtain approval from the Sponsoring Institution's Council on Human Investigation if the project pertains to human research or the use of human materials. Projects that do not deal with such human investigations must furnish a letter signed by the Grantee/Principal Investigator (and Sponsor in the case of a CDP award) stating, "This research project funded by LLS does not involve the use of human subjects or human tissue". Grantee/Principal Investigator (and Sponsor in the case of a CDP award) agrees that any deviation from proposed research involving human subjects will not be undertaken unless prior written approval from the Sponsoring Institution's Council on Human Investigation is obtained. LLS reserves the right to

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terminate this grant, at its sole discretion, if the Committee does not approve any change to the original research application. Failure to notify LLS of the use of human material or subjects by a Grantee/Principal Investigator shall result in suspension or termination of the grant.

Laboratory Animals - LLS adheres to the most current guidelines applicable to the care and treatment of animals used in laboratory work, as outlined by the United States National Institutes of Health. The Grantee/Principal Investigator (and Sponsor in the case of a CDP award) must obtain approval from the Sponsoring Institution's Institutional Animal Care and Use Committee (IACUC). The Grantee/Principal Investigator must include in the application a statement that the Sponsoring Institution meets and adheres to these policies. Failure to notify LLS of compliance with these guidelines or the use of laboratory animals shall result in suspension or termination of the grant.

Biohazard - The Grantee/Principal Investigator, Sponsoring Institution (and Sponsor in the case of a CDP award) acknowledge that the statement in the application is an accurate description concerning potential biohazards and the safeguards to be employed. Projects that do or do not involve biohazards must be so written by an institutional official. LLS assumes no responsibility or liability for any such biohazard and shall be held harmless from the results of the use of any such biohazard. Failure to notify LLS of compliance with these guidelines shall result in suspension or termination of the grant.

Recombinant DNA - The Grantee/Principal Investigator, Sponsoring Institution (and Sponsor in the case of a CDP award) acknowledge that the statement in the application is an accurate description concerning the use of recombinant DNA and the safeguards to be employed. Projects that do or do not involve recombinant DNA must be so written by an institutional official. Failure to notify LLS of compliance with these guidelines shall result in suspension or termination of the grant.

Deviations

Any deviation from the originally proposed research requires prior approval by LLS. Written requests must be submitted in hardcopy to LLS's Research Administration Department. Requests will be reviewed on a case-by-case basis. See contact information located at the end of this document.

Relocations or Transfers

For Grantees/Principal Investigators of CDP and TRP 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 online at <http://www.lls.org/#researchershealthcareprofessionals/academicgrants/requestreportingforms/>) and return the completed form thirty (30) days before the date of relocation. Transfers can only be executed on the first or last day of a month. Only one transfer to another institution per award period shall be allowed. 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. **Special Fellows and Special Fellows in Clinical Research cannot request a transfer during the first year of their grant term.** If the 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.

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 the Annual Report. 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. In some instances, the funds can be sent directly to the new Sponsoring Institution. Please contact LLS to determine the best course.

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.

For 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

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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. 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.

Interruption, Abandonment or Leave of Absence For Grantees/Principal Investigators of CDP and TRP 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.

Requests for a leave of absence from LLS must be made by the Grantee/Principal Investigator utilizing the appropriate forms available online (<http://www.lls.org/#/researchershealthcareprofessionals/academicgrants/requestreportingforms/>). 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.

For 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.

Breach and Termination

The failure of the Grantee/Principal Investigator, Sponsoring Institution (and the Sponsor in the case of a CDP award) to adhere to any of the terms and conditions in the grant shall constitute sufficient grounds for LLS, in its sole discretion, to withhold any or all funds due, until the deficiency is corrected. Either LLS or the Sponsoring Institution may then terminate the contract upon giving ninety (90) days written notice, if the deficiency cannot be corrected. In such case, any unexpended funds must be returned to LLS.

Governing Law

This Agreement shall be governed by and construed in accordance with the law of the State of New York, without giving effect to its principles or rules of conflict of laws to the extent such principles or rules are not mandatorily applicable by statute or would require or permit the application of the laws of another jurisdiction.

Publications & Publicity

Prior Notification

The Sponsoring Institution and Grantee/Principal Investigator shall give LLS's Vice President of Research Communications (see *Inquiries* section below) written notice at least seven (7) days prior to any advertising, promotion, publication, presentation or exhibition relating to the results of work supported by grant funds from LLS (which notification shall include a copy of the materials intended for release, as well as the details of the information to be disclosed and the time, place and manner of disclosure). The Sponsoring Institution and Grantee/Principal Investigator 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.

Recognition, Credit, and Identification

POLICIES & PROCEDURES

Any LLS-funded research related advertising, promotion, publication, presentation and or exhibition produced by the Grantee/Principal Investigator or the Sponsoring Institution shall contain the following credit:

“Supported by a [insert Grantee’s / Principal Investigator’s award program name] Award from The Leukemia & Lymphoma Society”. Poster presentations and other visual illustrations displayed at national meetings featuring working supported in whole or in part by LLS should also bear the LLS logo which is available by contact us at researchprograms@lls.org.

Participation in LLS Events

LLS’s ability to award grants is dependent upon continued support from voluntary donations and LLS-sponsored events. It is expected that Grantees/Principal Investigators will make all reasonable efforts to attend and participate in events when requested by LLS.

Participation in Other Projects

While LLS-funded grant is in effect, the Grantee/Principal Investigator agrees not to participate in any agreement or activity which would prohibit the disclosure of Grantee’s/Principal Investigator’s research or obligate the Grantee/Principal Investigator to undertake his/her research for the exclusive benefit of the Sponsoring Institution. Participation in such an agreement or activity shall result in termination of the award.

No LLS grantee shall hold more than two LLS awards simultaneously.

Participation in Multiple LLS-Funded Projects

Grantees/Principal Investigators that serve as Project/Core leaders on SCOR grants shall not participate in more than two SCOR grants. This participation limitation does not apply retroactively to SCOR grants awarded prior to July 1, 2007.

Outcome Reporting

LLS may contact the Grantee/Principal Investigator within two (2) years of 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.

Patent and Intellectual Property Policy

LLS’s Patent and Intellectual Property policy is provided after the “Inquiries” contact information section herein.

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 the reports shall be treated as confidential with the noted exception of General Audience Summaries which should not be submitted to LLS containing confidential information (see *Annual and Final Reports* sections above).

Inquiries

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

For contract matters:

Director of Research Administration
The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue, Suite 310
White Plains, New York 10605
Telephone: (914) 821-8301/8859
Fax: (914) 821-3301
Email: researchprograms@lls.org

For news and publications matters:

Vice President of Research Communications
Deborah Banker, Ph.D.
The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue, Suite 310
White Plains, New York 10605
Telephone: (914) 821-8920
Email: deborah.banker@lls.org

The Leukemia & Lymphoma Society’s Patent and Intellectual Property Agreement

The Leukemia & Lymphoma Society’s (“LLS”) primary purpose in funding scientifically meritorious research is to advance its mission to cure leukemia, lymphoma, Hodgkin’s disease and myeloma, and to improve the quality of life of patients and their families around the world. In this regard, LLS recognizes that certain Inventions (defined below), potentially having public health, scientific, business, or commercial application or value, may be discovered or made in the course of research or development supported with funds furnished by LLS. LLS desires that such Inventions be effectuated and brought into public use at the earliest possible time, and it recognizes that often this may be best accomplished through patenting and/or licensing of such Inventions.

Each sponsor and individual grant recipient (collectively “Grantee”) and each institution (“Sponsoring Institution”) receiving grant funds from LLS agree to the following provisions regarding patent and intellectual property rights and licenses resulting or stemming from research conducted by Grantee and funded in whole or in part by LLS.

This Patent and Intellectual Property Agreement (“IP Agreement”) forms part of the accompanying Grant Agreement between LLS on the one hand, and the Grantee and Sponsoring Institution on the other hand, executed concurrently herewith. Although intended to be consistent with the Grant Agreement, the terms of this IP Agreement supersede any conflicting terms of the Grant Agreement, to the extent any conflicting terms exist.

1. The following terms have the following meanings set forth below:
 - a. **“Invention”** shall mean any discovery, idea, formula, material, composition, machine, product, apparatus, program, software, work of authorship, use, method, process, or improvement thereof, which is potentially protectable by intellectual property rights, and all intellectual property covering and/or embodied therein including but not limited to associated patents, copyrights, trade secrets, and know-how.
 - b. **“Funded Invention”** shall mean any Invention conceived, made and/or obtained, in whole or in part, by Grantee in the course of, and resulting or stemming from, research or development funded in whole or in part by this LLS grant.
 - c. **“Net Royalty Income”** shall mean gross income or any other consideration resulting from the licensing, assignment, or other commercialization by Grantee or Sponsoring Institution of a Funded Invention less (1) out of pocket patent or copyright expenses, (2) distributions to the inventors, and (3) the research-related allocation to the inventor’s campus laboratory.
2. Title to, and responsibilities for, any Funded Invention shall reside in the Sponsoring Institution. All patent and other expenses for obtaining and maintaining rights to intellectual property covering and/or embodied in any Funded Invention shall be borne by Sponsoring Institution. In the event Sponsoring Institution lacks a policy or procedure that requires assignment of ownership by Grantee to Sponsoring Institution of any Funded Invention, then title to any Funded Invention shall reside in LLS. In the event this is the case, Sponsoring Institution shall confirm this to LLS in writing within ten (10) days of this agreement.
3. Sponsoring Institution agrees to notify LLS in writing of the filing of all patent applications and all issuances to it of any and all patent(s) directed to a Funded Invention. This obligation shall begin with the filing of such application(s) and such written notice shall be included in the first Progress Report due, in accordance with the accompanying Grant Agreement, following such filing(s). This obligation shall continue throughout the term of this IP Agreement. Sponsoring Institution also agrees to notify LLS in writing within 30 days of granting any license, lease, sale, or assignment of a Funded Invention, and to provide LLS with the name of any licensee or assignee, the subject matter of the license or assignment, the term of the license, and whether such license is exclusive or non-exclusive.
4. No pending patent application, issued patent, or other intellectual property covering and/or embodied in the Funded Invention shall be abandoned without first notifying LLS at least 60 days in advance of such decision. At such time, Sponsoring Institution shall provide LLS with the reasonable opportunity to (1) take title to the pending patent application or issued patent; and/or (2) prosecute the pending patent application, or pay the maintenance fee due on the issued patent, at LLS’s own expense. This opportunity shall be subject to the Sponsoring Institution’s obligations to all other sponsors of research, including the Federal Government.
5. Sponsoring Institution agrees to share with and pay LLS all income derived from Sponsoring Institution’s commercialization of any Funded Invention, including any equity disposition, as follows:

- a. LLS's share of the Net Royalty Income shall be ten percent (10%).
 - b. LLS shall have the right to audit the books and records of the Sponsoring Institution annually in order to verify the Net Royalty Income derived annually from the Funded Invention. Sponsoring Institution shall make the books and records available within 30 days of such request from LLS.
6. Sponsoring Institution agrees to exert its best efforts to commercialize or license or cause to be commercialized the Funded Invention(s), consistent with sound and reasonable business practices and judgment.
7. In the event the Sponsoring Institution licenses, leases, sells, or assigns the Funded Invention to a third party for commercialization, Sponsoring Institution shall include provisions in the license obligating the licensee to commercialize the technology in a diligent manner and include appropriate diligence requirements and milestones. The agreement shall also provide that in the event that the licensee has failed to commercialize the technology in accordance with such diligence provisions, the Sponsoring Institution shall have the right to 1) require assignment back (if previously assigned) of any Funded Invention to the Sponsoring Institution, 2) terminate any outstanding exclusive licenses, 3) convert an exclusive license to a non-exclusive license so that it may seek other licensees, 4) grant non-exclusive licenses on terms that are reasonable under the circumstances, or 5) make other reasonable disposition of rights.
8. Sponsoring Institution agrees to complete all required disclosure and progress forms supplied by LLS as set forth in the underlying Grant Agreement.
9. If a dispute arises regarding the amount of Net Royalty Income payable to LLS pursuant to paragraph 5 above, the dispute shall be resolved as follows:
- a. One of the parties shall request ("the Resolution Request") that each of the parties appoint a designated executive management representative to meet for the purpose of attempting to resolve such dispute. The parties' designated executive management representatives shall meet and negotiate in good faith in an effort to resolve the dispute.
 - b. If the parties' designated executive management representatives are unable to resolve the dispute within 30 days after the Resolution Request is made, the parties shall mediate with a mutually acceptable mediator.
 - c. If the mediation does not resolve the dispute within 60 days (unless this time is extended by written agreement of the parties) after the Resolution Request is made, the dispute shall be settled by arbitration by the American Arbitration Association ("AAA") in accordance with its procedures under its Commercial Arbitration Rules. Each party shall bear its own costs, expenses, and attorney's fees and an equal share of the arbitration fees. The award of the arbitrator(s) shall be binding, and judgment upon the award may be entered in any court having jurisdiction thereof.
10. The Term of this IP Agreement begins on the Grant Start Date as indicated on page one (1) of the Grant Agreement, and continues until the last of the patents directed to a Funded Invention expires, or for so long as the Sponsoring Institution receives royalties stemming from the licensing, lease, sale or assignment of any Funded Invention, whichever is later.
11. This policy shall be governed by and construed in accordance with the law of the State of New York.