Translational Research Program
Guidelines & Instructions

Effective dates:
June 3, 2019 – April 30, 2020

Contents

Key Points:

- It is highly recommended to access the LLS Research Portal at https://lls.fluxx.io to begin the application process well in advance of any deadlines.
- It is recommended that final submissions at each stage (letter of intent/full application) be completed well before the deadline.
- All components of the application must be present in the order indicated in these guidelines.
- All formatting must adhere to the policy stated in these guidelines.
- Completion of several steps in the process initiates emails sent from the LLS Research Portal. LLS staff may also send emails during the application process. Spam filters should be monitored for these emails.
- Contact researchprograms@lls.org if expected emails are not received by the times indicated in these guidelines.
- The deadlines stated in the *TRP Key Dates* section are strictly enforced. No exceptions are made to this policy.
- Please do not attach documents to the application that are not specifically called for such as papers in press or published papers. The application could be administratively triaged if this rule is violated.
- The Leukemia & Lymphoma Society is implementing a new rule regarding overlapping aims in grant proposals submitted to LLS. This policy applies to proposals submitted within the same application cycle, which is defined as all LLS calls for proposals – across all grant programs – that open within the same calendar year. An application to any LLS grant program may not have aims that substantially overlap with the aims of any other application (either to the same program or to a different program) that includes the same investigator(s) as PI(s), Co-I(s), Project or Core Leaders, or collaborator(s). All such duplicate grant proposal submissions with substantially overlapping aims are subject to administrative disqualification, and such proposals will not be reviewed further or considered for funding. Contact researchprograms@lls.org with any questions about this policy or to discuss with LLS scientific staff any questions concerning potential overlap between applications.

General Information

About The Leukemia & Lymphoma Society

The Leukemia & Lymphoma Society, Inc. (LLS) is a national voluntary health agency dedicated to the conquest of hematologic malignancies and relevant premalignant conditions. LLS supports research, patient aid, community service programs, advocacy, and public and professional education.

Description of Awards

The formation of the Translational Research Program (TRP) was to enhance the transfer of basic research findings to clinical usefulness.

Applications are sought proposing novel approaches to the prevention, diagnosis or treatment of hematological malignancies and related pre-malignant conditions. Proposals should be based on molecular, cellular or integrated systems findings and be conceptually innovative. The application should have a clear plan for the eventual clinical translation of the studies proposed and the results expected. This feature will be an important consideration of the review process.

This program is intended to provide support over an initial three-year period. Two additional years may be available through the competitive, peer-reviewed TRP Renewal process to solidify progress made in the initial award and further support a clinical trial. To be considered for a TRP renewal award, a clinical protocol for a Phase I or Phase II clinical trial based on the initial TRP grant must be submitted to the institution's IRB for approval and the work must be a direct result of the funded TRP award (see Renewal Guidelines and Instructions for detailed information).

Maximum TRP Award Duration & Value

***Please note: The TRP award amount you are given will reflect the amount you request in the budget section of your application. Any requests to increase funding must be in writing to LLS and are subject to the availability of funds.**

Duration	**Maximum Annual Direct Costs**	**Maximum Annual Indirect Costs**	**Maximum Annual Total Costs**	**Maximum Total for 3 Years**
3 years	$195,019.50	$21,647.16	$216,666.66	$650,000.00

Who Can Apply

Citizenship

LLS welcomes applications from both US citizens and non-citizens, as well as applicants who are performing research outside the US. Applicants must be appointed to a not-for-profit institution at the time the funding commences.

Degree
Applicants must hold a PhD, MD, DVM or equivalent degree.

Sponsoring Institution's Acceptance of the Terms and Conditions
Applicants who are offered a TRP Award will be sent a Grant Agreement. The current Agreement is found on LLS's website, (www.lls.org/research/translational-research-program). Currently, the NIH does not accept LLS's Terms and Conditions.

Leadership and Staffing
A Principal Investigator may only submit ONE application per application cycle and cannot serve as a Principal Investigator OR Co-Principal Investigator on more than ONE application per cycle. A Co-Investigator (also known as Collaborator) CAN serve as Co-Investigator on more than one application with no limit. A Principal Investigator or Co-Principal Investigator can serve as a Collaborator on other applications. Members of the peer review committee cannot apply for a TRP award. They may apply for a renewal award if they are not serving on the renewal committee since these are awarded independently of the regular TRP awards.

The Application will require one Principal Investigator who is responsible for the preparation and submission of the proposal including budget, the conduct of the research programs and adherence with all stipulations made by LLS in this document, the Policies & Procedures document, and in the Grant Agreement, if funded. Co-investigators are allowed on multiple applications; however, one individual is to be designated as the Principal Investigator and this individual is limited to one application only.

An Applicant may only submit one new application and/or one Renewal application per award cycle.

Relevance
The proposed research should be clinically directed or clinically translatable in hematologic malignancies that is intended to develop innovative approaches to treatment, diagnosis, or prevention. Projects currently funded by LLS can be viewed under the Grant Finder section of the LLS website at http://www.lls.org/grant-finder.

Review Process & Applicant Notification

Review Process of LOI
Letters of Intent for the traditional TRP RFP topics are reviewed and approved by LLS at the time of submission. Once the LOI has been reviewed, the Applicant will be notified via an automated email as to whether or not they have been invited to submit a Full Application. The LOI is non-competitive and is for eligibility purposes only. If invited for Full Application submission, the Applicant will immediately have access to this web form in Fluxx. If you have not received an email regarding your LOI approval within five business days, contact researchprograms@lls.org.

The deadline to submit all Full Applications is October 31, 2019 at 3 PM ET. Full Applications will only be accepted via the LLS Research Portal (https://lls.fluxx.io). The submission deadlines will be strictly enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

TRP Key Dates

	Date	Time
Call For Proposals	June 2019	
Letter of Intent due	August 31, 2019	3:00 PM ET
Full Application due	October 31, 2019	3:00 PM ET
Panel Review Meetings	March 2020	
Award Notification*	April/May 2020	
LLS's receipt of signed contract	June 1, 2020	
Award Start Date	July 1, 2020	

**Current contract Terms & Conditions can be found on the TRP webpage.*

It is highly recommended that submissions are done well before the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. The LLS Research Portal automatically shuts down submissions after the deadline has passed.

Review Criteria

An application will be judged on these criteria:

- The probability of an advance in prevention, diagnosis or treatment in the near-term
- The conceptual basis upon which the proposal rests
- The novelty of the concept and strategy
- Thoughtful and clear presentation
- The overall plan for bringing the research findings to clinical application
- Experience, background and qualifications of investigators
- Adequacy of resources and environment (facilities, access to patient samples if needed, data management and data analysis, etc.)
- Adequacy of provisions for protection of human subjects

Review Process of Full Applications

Full Applications will be reviewed after the October 31st submission deadline by the TRP Subcommittee of the Medical & Scientific Affairs Committee. If an application does not meet the program goals, scope or guidelines, it will be administratively triaged. Applications are assigned an initial score by the primary and secondary reviewers. Only applications that fall above a scoring level determined by the committee chair will be discussed in detail for final ranking by the entire committee.

Once ranked, priority scores and funding recommendations of the TRP Subcommittee will be presented to the Medical & Scientific Affairs Committee and LLS's National Board of Directors for final determination of awardees. The Board of Directors will determine the number of awards funded, based on scientific merit and the budget approved.

TRP applications will be rank-ordered based on their Overall Priority Score (10-90; which reflects the average of all the reviewers' priority scores multiplied by ten).

Any Applicant selected for funding will be notified by the date indicated in the Key Dates section**.** Please do not call or email LLS to determine whether the application has been received, when it will be reviewed or the results of the review. Please check Fluxx for the status of your application. All priority scores are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, its Research Subcommittee, LLS's National Board of Directors, and administrative personnel only. Feedback may only be provided for applications discussed by the full review committee.

LLS will continue to pursue proposals in several specific research areas that it considers "high unmet need."

General Instructions for Applying

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

Registration

Both the Applicant and Sponsoring Institution must be registered in Fluxx. If you have applied to LLS in the past, you do not need to create a new registration. Simply log in, or contact researchprograms@lls.org to reset your password. Once updated, the Applicant can begin the LOI. Email researchprograms@lls.org for assistance creating a new account in Fluxx if you do not already have one. Only LLS staff members have administrative permission to create new accounts.

Institutional Designation

Applicants should create their profile from the standpoint of where they will perform their research described in the application. The Applicant must indicate the name of the Sponsoring Institution as well as the name of the signing officials for that institution. To register a new institution, contact researchprograms@lls.org.

Data Entry

Both the LOI and the full application may be accessed and changed multiple times as needed prior to the submission deadline. However, neither the LOI nor the full application can be changed once the deadline has passed or the application has been finally submitted. Moreover, some fields may not be modified in the full application following submission of the LOI.

Forms and Format

Applicants will provide information on the Fluxx website at the LOI phase; there is no other template necessary at this phase. For the full application phase, a template will be provided in Fluxx. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on Fluxx. Fields in bold are required. All Applicants must use single-spaced text and Times New Roman, size 12 font. Figures may use size 10 font (figures which are not legible or too small will impact the ability of reviewers to evaluate your application and may reflect in the final scoring). Margins are preset in the template and must remain as set. The Applicant's name should be typed in the upper right corner of each page of the template. Failure to use the provided template or to adhere to font size, spacing, margins and/or page limitations will result in the disqualification of the application. In addition, character limitations must be adhered to.

Contacting LLS

Questions that are not clarified in this document, the FAQ on the TRP webpage, or Fluxx should be addressed to researchprograms@lls.org.

Beginning an Application

Under "Information" in the left navigation bar, click "Translational Research Program."

Click "Apply to TRP!" and you will be directed to the Letter of Intent form.

Follow the instructions for each web form field. Bold font indicates required information.

Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be triaged.

You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your application and prevent further modification at that stage. Contact researchprograms@lls.org if you submit in error (must be before the deadline).

After your letter of intent is approved, you will receive an automated email from Fluxx. Consider that these emails may end up in your spam filter. If selected to submit a Full Application, log back in and click "New or Pending" under "Requests" to continue with your application.

Download and complete the project description template, including all required signatures, and upload to the gray "Project or Supporting Documentation" section of the web form. Margins are preset and must not be changed. Text must be written single spaced in Times New Roman size

12 font. Figures can be size 10 font. **Only one PDF file is accepted in this section (Project Description Template combined with biosketch(es))**, so delete any other documents uploaded during the process.

Click "Submit" to formally submit your application to LLS.

Specific Instructions for Applying

Letter of Intent

Each Applicant must submit the LOI by **August 31st at 3:00pm ET** via the LLS Research Portal (https://lls.fluxx.io) or the following business day if this date falls on a weekend or a U.S. holiday. The Applicant should carefully craft the information requested in the LOI as this information is automatically populated into the full application and is subject to the Changes clause listed below.

The LOI for the traditional TRP RFP topics will be evaluated by staff on a rolling basis. If the LOI is approved, the Applicant will be notified by an automated email from Fluxx stating that he/she may proceed to the Full Application phase. Applicants may also check the status of their LOI on Fluxx.

Completing the LOI

Organization Information

Sponsor Institution: Indicate the name of the institution where the research will be performed. If this institution is not listed, please contact researchprograms@lls.org.

Principal Investigator: The Principal Investigator is the Applicant.

Institutional Signing Official (ISO): The ISO is the institutional representative responsible for the signing and agreeing to the accuracy of the application and the Terms and Conditions of the award, should the application be selected for funding.

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

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

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

Zip Code of Sponsor Institution: Enter the zip code of the Sponsoring Institution if located within the United States. If not located within the U.S., this can be left blank.

Project or Program Information

If you are applying to the Renewal program, check the corresponding box in the drop-down menu, provide the previous TRP grant number, then refer to the Renewal Guidelines & Instructions to complete your application.

Request Proposal Information

If your proposed research falls within a topic listed, please choose "Yes" from the selections. Otherwise, choose "No." Choosing "No" for all topics does not disqualify your application from review. The LLS seeks proposals responsive to the requests for proposals, but will also consider other exceptional proposals with the near-term potential of clinical translation. LLS has a particular interest in Special Topic 2: **Prevention of disease by detection and/or treatment of pre-blood cancerous states, smoldering low grade disease, or relapse using state-of-the-art methodologies and new therapies.** *Applicants with research proposals that are responsive to the RFP should indicate this on the title page of their Full Application.*

Special Topics of Interest

1. **LLS-Snowdome Foundation-Leukaemia Foundation: Translational Research Program.** The Snowdome Foundation (SF) and the Leukaemia Foundation (LF) are Australian-based not-for-profit organizations funding lifesaving Australian blood cancer clinical research. To enhance our common goal, LLS, SF, and LF will jointly fund up to two meritorious TRP applications focused on blood cancer research from investigators working in Australia, Australian investigators working in other countries, or to Australian and non-Australian researchers jointly applying as co-PIs. While any area of blood cancer research will be considered, the organizations especially seek work focused on the role of epigenetics in blood cancer. Applications must be submitted to the LLS TRP program and will be evaluated within the general pool of TRP applications. In addition, applications will be jointly reviewed by the Australian foundations to ensure they meet their respective funding objectives, and scientific progress of each awarded TRP will be evaluated by both organizations on an annual basis. LLS will administer the grant program.

2. **Prevention of disease by detection and/or treatment of pre-blood cancerous states, smoldering low grade disease, or relapse using state-of-the-art methodologies and new therapies.** Advances have been made in recent years to understand the molecular basis of smoldering disease and mutations found in the blood of otherwise healthy individuals as a prelude to clinical disease. Additionally, new therapeutics including immunotherapy have been recently developed that may have a sufficient safety window that would allow their use to prevent disease emergence or re-emergence after disease clearance. This special topic of interest aspires to advance translational research that aims to prevent blood cancers from either occurring initially in healthy individuals (no neoplasm detected), advancing to full-blown blood cancers in patients with benign conditions, or blocking reoccurrence of blood cancer after therapy.

   Areas of interest could include but are not limited to **clinical trials** to examine novel agents, pharmaceuticals, biologics, immunotherapies or life style changes as prevention of blood cancer onset, progression to full blown disease, or relapse. Applications could

be for any premalignant conditions before the onset of blood cancer or the prevention of relapse after therapy. Develop **novel therapeutics** specifically to eliminate drivers of disease that initiate or predispose to disease onset. Develop or employ **experimental systems** to identify safe and effective therapies to eliminate mutant clones in early disease or prevent recurrence of disease. Develop and apply sensitive minimally invasive methods to use as **biomarkers** to detect precursor conditions before disease onset or sustained after successful therapy.

3. **Novel Technologies and Artificial Intelligence to enhance the diagnosis or treatment of blood diseases.** Recent advances in new technologies to diagnose disease, examine mechanisms of disease and monitor effectiveness of therapies have the potential to significantly advance our understanding and treatment of blood cancers. LLS is calling for proposals to use existing technology to advance the diagnosis, monitoring and treatment of blood cancers. Examples of such technology would include single cell monitoring, high throughput sequencing, multicolor flow, circulating DNA, new or improved disease models etc. This proposal is also encouraging the development of improvements to nascent technology and the creation of new technology to diagnose, monitor and determine the effectiveness of blood cancer therapies.

   Recognizing the impact of artificial intelligence (AI) and computing power on science, medicine and technology, LLS is seeking proposals that employ the use of AI in the diagnosis, management, treatment and detection of disease. LLS recognizes that this proposal is outside of the typical blood cancer RFP and we hope this would encourage collaboration between blood cancer researchers/clinicians and bioinformatics, AI and computing engineers to envision and design AI protocols that would have significant impact on treatment paradigms for blood cancer cures. LLS is not seeking unfocused big data approaches, rather LLS is seeking ways to incorporate AI into specifically improving blood cancer outcomes.

<u>General Topics of Particular Interest:</u>

1. **Personalized medicine approach for cancer treatment.** Advances in cancer care have significantly improved lives of patients with hematologic diseases such as CLL, CML, Hodgkin Lymphomas, MM, and ALL. LLS believes that, with time, cures can be achieved for certain diseases or subtypes of diseases. Therefore, LLS will continue to support research that may revolutionize cancer care for any hematologic disease including the use of state of the art technologies for molecular profiling, novel target identification, prognostic/predictive biomarkers that can be associated with patient selection and development of liquid biopsy technology.

2. **Development of novel therapies and/or novel therapeutic strategies including those that target mutational and epigenetic events both in the tumor cells and within the microenvironment. Such therapies can be applicable to any hematologic malignancies but emphasis is warranted in the following areas:**
   a. Aggressive subtypes of Non-Hodgkin Lymphoma including but not limited to DLBCL, tFL, MCL, PTCL, and ALCL

b. Indolent lymphoma including but not limited to CLL, FL, WM (therapies with the potential to provide significant extension of lives of patients or total disease control in defined subtypes)
c. Myeloid disorders including MPN/MDS/AML as well as lymphoid disorders such as ALL
d. Multiple Myeloma and pre-emergent conditions
e. **LLS is especially interested in novel immunotherapy approaches and understanding novel immune synapses relevant to blood cancers.**

3. **Improvements in the safety and efficacy of stem cell transplantation.**

4. **Long-term outcome assessment following therapies.**

5. **Pediatric research.** LLS recognizes that new precision medicine and immunotherapies are needed to improve outcomes for pediatric blood cancers. The goal is to develop curative therapies that have reduced long-term complications compared to current cytotoxic therapies. Research may focus on pediatric leukemias, lymphomas, as well as other pediatric blood cancers such as Langerhan's Cell Histiocytosis. We encourage research applications attempting to justify and explore novel therapies for pediatric blood cancers, especially those that uniquely target mutations found in pediatric cancers.

6. **Progress in understanding neoplastic stem cell growth and differentiation as well as cancer cell/microenivronment interactions especially with translation to novel therapies.**

Grant Information

Project Title: Provide a title adhering to the 100 character limitation (which includes spaces).

Project Summary: Provide a summary adhering to the 500 character limitation (which includes spaces). Charts and graphs cannot be included in the project summary section of Fluxx.

Scientific Abstract: Briefly describe the proposed research in 3,000 characters (including spaces) or less using technical language. Once the LOI has been submitted, the scientific abstract may not change. Greek characters or symbols must not be used.

Lay Abstract: Using lay language, clearly state the proposed research in 3,000 characters (including spaces) or less. Once the LOI has been submitted, the lay abstract may not change. Greek characters or symbols must not be used.

Amount Requested: The total amount, including both direct and indirect costs, cannot exceed $216,666.66/year. Enter the total amount of funding requested over the life of the grant (Maximum $650,000.00). The amount requested on Fluxx should match the budget section of the full application template.

Proposed Start Date: The start date for all TRP grants is July 1 in the year the award is made (i.e. if an award is made to your application in May 2020, the start date will be July 1, 2020).

Proposed End Date: The end date for all TRP grants is June 30 three years after the year the award is made (i.e. if an award is made to your application in May 2020, the end date will be June 30, 2023).

Previous Submission: Indicate whether you have previously submitted this proposal (or one similar) to LLS and indicate the date of any prior submission.

Key Personnel or Collaborators Information
New collaborator or key personnel contacts may be added to the collaborator section by typing the name(s) into the box. These include Co-Principal Investigators and Co-Investigators. *This section helps LLS identify conflicts with reviewer assignments.*

If you plan to submit an application or serve as Co-Principal Investigator on an application, you will not be eligible to serve on the program's review panel this cycle.

Save and Review
Validation will automatically occur after clicking the "Save" button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system notifies the Applicant of fields that require information.

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

Submission of the LOI
Each Applicant must submit the LOI by **August 31st at 3:00 pm Eastern Time** via Fluxx or the following business day if this date falls on a weekend or a U.S. holiday. After clicking the "Submit" button, the Applicant will receive an email from Fluxx stating that the LOI was successfully submitted. **If you did not receive the confirmatory email from Fluxx within five business days of LOI submission, please e-mail researchprograms@lls.org.**

Signatures of the Applicant and Sponsor Institution Officials are not required for submission of the LOI.

Changes
Information collected in the LOI will automatically populate fields in the full application. Once submitted, changes may only be made after receiving prior approval from LLS. The Applicant must email LLS (researchprograms@lls.org) requesting any change and identifying the elements to be changed. Any changes made without the prior approval of LLS may result in the disqualification of the application.

Full Application
Each Applicant must submit a full application by **October 31st at 3:00 pm Eastern Time** via Fluxx or the following business day if this date falls on a weekend or a U.S. holiday. Some sections of the full application will be automatically captured electronically on Fluxx from the LOI. Other pieces of information will be captured in the application template that must be downloaded, completed and then uploaded by the Applicant. The Applicant may not modify any

information provided in the submitted LOI as this is subject to the Changes clause listed above and may result in disqualification of the application.

Completing the Full Application

Project or Supporting Documentation

Log onto the LLS Research Portal (https://lls.fluxx.io), click "New or Pending" under "Requests" on the left, click on your application, and then click "Edit."
Download and complete the Project Description/Budget Template. The Project Description is limited to 7 pages.
The completed Project Description/Budget Template and all appendices, including biosketch(es), must be uploaded as one single PDF file. Failure to submit as a single PDF may result in disqualification of your application.

Project Description/Budget Template

The Project Description/Budget template includes 4 fields, as follows: a) Project Description b) Other Research Support c) Budget d) Budget Justification.
Each Project Description is limited to 7 pages and should be presented in the following sequence:

- Title and Specific Aims (approximately 0.25 pages)
- Scientific and Clinical Significance of the Work (approximately 1.0 page)
- Previous Studies/Preliminary Data (approximately 2.5 pages)
- Research Methods (approximately 0.75 pages)
- Interaction with Other Investigators (approximately 0.5 page)
- Resources and Environment (Major lab items or facilities) (approximately 1.0 page)
- References Cited (approximately 1.0 page)

Budget

The Budget and Budget Justification should provide itemized detail for each major category for all years of the project. The budget can be summarized in Year One and extrapolated for the remaining three years. All totals and subtotals should be completed on the form.
The maximum annual total cost (direct and indirect) cannot exceed $216,666.66 per year. The aggregate costs over three (3) years cannot exceed $650,000.00.

Permissible Direct Costs include the following with the specified limitations:

- 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.).
- Supplies & Materials requests should be itemized by category.
- Equipment Purchase requests must identify each item of equipment with an acquisition cost of more than $1,000.
- Travel Expense requests cannot exceed $2,000 per year of the award.
- 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 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.

Biosketch(es) and Other Support

Use the NIH Biosketch format and include Other Support. ERA Commons user name is not required. The Other Support section must contain all current and pending support from any source. The section of the Biosketch containing the Research Support section may be used, but all current and pending support must be included; completed support should not be included. As per the NIH format, the goals of each grant must be stated. **In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap with the LLS application.** This includes any grants or portions of grants submitted to any organization, including LLS.

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

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

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

Signature Page

All applications must be signed by the Principal Investigator (and Co-Principal Investigator, if applicable) and Institutional Signing Official.

Upload the Project Template to "Project or Supporting Documentation"

Upload the completed template and biosketch(es) as one single PDF to the gray "Project or

Supporting Documentation" section by clicking the green plus sign. Choose "TRP Project Description/Application" from the drop down menu before uploading.

Organization Assurances

The Applicant must complete the organization assurances section. The following provides an overview:

Human Subjects: The Applicant must indicate if human materials or subjects will be involved in the proposed research. The status (approved, pending or exempt) of Institutional Review Board (IRB, or equivalent oversight entity) approval must be provided. The Human Subject Assurance Number (OHRP) must be included. If the research project has received IRB approval, the date must be provided and documentation must be included in the single PDF of the application. The application may be submitted with IRB approval pending. However, an award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the March review date if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be included in the single PDF of the application.

Laboratory Animals: The Applicant must indicate if laboratory animals will be involved in the proposed research. The status and date of Institutional Animal Care and Use Committee (IACUC, or equivalent oversight entity) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of Sponsoring Institutional approval must be included in the single PDF of the application. The application may be submitted with IACUC approval pending. However, an award will not be made without documented IACUC approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the March review if the IACUC status has changed.

Recombinant DNA: The Applicant must indicate if the proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be included in the single PDF of the application.

Biohazard Statement: The Applicant must indicate if the proposed research involves the use of biohazards. If the Applicant indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be included in the single PDF of the application.

Clinical Protocol Appendix (if applicable)

Provide a one-page summary and a link to the clinicaltrials.gov website for any clinical protocol essential to the proposed research. Include IRB approval date, IRB compliance number and effective dates of approval. Projects for which IRB approval is pending must include a statement to that effect. The Applicant should notify LLS of IRB approval prior to the March grant review. The applicant must provide information **if a trial is receiving funding from a sponsor** specifically how much money is to be received and what the funds will be used for.

Budgeting Information
Enter the budgeting information as required on the web form fields.

Applicant Assurance
Check the box to accept the terms as stated on the web form field.

Save and Review
Validation will automatically occur after clicking the "Save" button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system notifies the Applicant of fields that require information.

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

Once an application is submitted, only LLS staff can delete files. If you need a file deleted, contact researchprograms@lls.org for assistance.

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

- Regulatory approvals
- Significant updates to clinical trials:
    - IRB updates
    - Opening of the trial
    - Patient enrollment
    - Opening of new clinical sites
    - Efficacy and/or safety updates
- Manuscripts that have been accepted for publication; the following must be provided:
    - List of authors
    - Title
    - Journal
    - A copy of the acceptance letter from the journal
- Updates regarding any transfers to a new institution

If you plan to withdraw your application at any time during the application cycle, please inform LLS staff of your decision by writing to researchprograms@lls.org.