Translational Research Program Guidelines & Instructions

Effective dates:
August 1, 2021 – June 30, 2022

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Key Points

- It is highly recommended to access the LLS Research Portal at https://lls.fluxx.io and 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 *Key Dates* section are strictly enforced. No exceptions are made to this policy.

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

- Note that **early-stage, pre-translational or discovery work is not the best fit for the TRP program** and will likely be uncompetitive. These types of applications are best suited for our Blood Cancer Discoveries Grant program and potential grantees are encouraged to apply to that program.

- The Leukemia & Lymphoma Society has a 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.

About The Leukemia & Lymphoma Society, Inc.

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

Description of Awards

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

Applications are sought that propose 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 TRP Renewal Guidelines & Instructions for detailed information).

Maximum TRP Award Duration & Value

Duration	***Maximum Annual Total Costs***	***Maximum Annual Indirect Costs***	***Maximum Total for 3 Years***
3 years	Year 1: $200,000 Year 2: $200,000 Year 3: $200,000	$19,982.00*	$600,000.00

*Indirect Costs are limited to 11.1% of the total direct costs requested in the application's budget.

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. MD, PhD, DVM) regardless of function or role.

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.

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 of application submission.

Degree

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

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. Applicants may also 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. The TRP program is intended for independent, established researchers. Therefore, applicants holding positions such as post-doctoral fellows, instructors, etc. are discouraged from applying.

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.

Review Process & Applicant Notification

The deadline to submit all Letters of Intent (LOI) is October 29, 2021, at 3 PM ET. LOIs for the traditional TRP RFP topics will be reviewed after the deadline. Once the LOI has been reviewed, the Applicant will be notified via an automated email as to whether they have been invited to submit a Full Application. We will only be inviting full applications that will be competitive. Therefore, in addition to what was required in past cycles, we have expanded the TRP LOI to include one page of previous studies and preliminary data. If invited for Full Application submission, the Applicant will immediately have access to this web form in the LLS Research Portal. If you have not received an email regarding your LOI approval by November 23rd, contact researchprograms@lls.org.

The deadline to submit all Full Applications is January 21, 2022, at 3 PM ET. Full Applications will only be accepted via the LLS Research Portal.

Key Dates

Phase	Date
Call For Proposals	August 30, 2021
Letter of Intent Due	October 29, 2021, 3:00 PM ET
Full Application Due	January 21, 2022, 3:00 PM ET
Panel Review Meetings	March 2022
Award Notification*	May 2022
Award Start Date	July 1, 2022

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

All submission deadlines will be enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or US holiday, the deadline becomes the next business day. **There are no exceptions permitted.**

It is highly recommended that submissions are done *prior* to the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the 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. **Late submissions due to technical difficulties will not be accepted.** Every year, a few applicants get caught with difficulty near the deadline; some are unable to submit because of these issues. The best way to avoid this problem is to submit every phase well ahead of the deadline.

Review Criteria

An application will be judged on these criteria, again noting the preference for later stage asset development:

- 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

Full Applications will be reviewed after the January 21st 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 the LLS Research Portal for the status of your application. All priority scores are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, 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."

Request For Proposal Information

If your proposed research falls within a topic listed, please choose "Yes" in the LLS Research Portal. If it does not, 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. *Applicants with research proposals that are responsive to the RFP should indicate this on the title page of their Full Application.*

Special Opportunity for Australian and Canadian Grants through The LLS Translational Research Program (TRP):

1. **LLS – Snowdome Foundation – Leukaemia Foundation Translational Research Program**. The Snowdome Foundation and Leukaemia Foundation are Australian-based not-for-profit organizations with whom LLS is partnering to enhance our common goal to accelerate cures and better treatments for blood cancer patients. LLS, Snowdome Foundation and Leukaemia Foundation 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. 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 all three foundations to ensure they meet the funding objectives of the organizations, and scientific progress of each awarded TRP will be evaluated by the organizations on an annual basis. LLS will administer the grant program.

2. **The Leukemia & Lymphoma Society-The Leukemia & Lymphoma Society of Canada Translational Research Program**. LLS is partnering with The Leukemia & Lymphoma Society of Canada (LLSC) to advance our common mission to find cures for blood cancers and improve the quality of life of patients and their families. LLS and LLSC will jointly fund up to three meritorious TRP applications focused on blood cancer research from investigators working in Canada. Applications must be submitted to the LLS TRP program and will be evaluated within the general pool of TRP applications. Applications will be jointly reviewed by LLS and LLSC and scientific progress of each awarded TRP will be evaluated by both organizations on an annual basis. LLS will administer the grant program.

Special Topics of Interest:

1**. 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
- Lifestyle 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.

2. **T-ALL/T-cell Lymphoma Translational Proposals**

T-ALL and T-cell lymphomas are aggressive diseases with a significant unmet need. While some progress has been made in de novo treatment outcomes, relapsed or refractory disease still has a poor prognosis. LLS is requesting proposals to investigate T-ALL and T-cell lymphomas, especially proposals for novel treatment regimens.

General Topics of Particular Interest:

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/microenvironment interactions especially with translation to novel therapies.**

General Application Instructions

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 the LLS Research Portal. If you have applied to LLS in the past, you do not need to create a new registration. Simply click the "reset or create password" link and enter your email address. The system will send your username and a link to update your password. Once updated, the Applicant can begin the LOI.

Email researchprograms@lls.org for assistance creating a new account in the LLS Research Portal 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 final application has been submitted. Moreover, some fields may not be modified in the full application following submission of the LOI.

Forms and Format

Applicants will provide information on the LLS Research Portal and a downloadable template at the LOI and full application phases. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the LLS Research Portal. Fields in bold are required. All Applicants must use single-spaced text and Arial size 11 font. Figures may use Arial 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 the LLS Research Portal should be addressed to researchprograms@lls.org.

Beginning an Application

- On the LLS Research Portal, under "Information" in the left navigation bar, click "Translational Research Program."
- Click "Apply Now," 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 template. If these limits are not adhered to, the application may be triaged.

Upload the Previous Studies/Preliminary Data to the "Project and Supporting Documentation" section of the web form. Text must be written single spaced in Arial size 11 font. Figures can be Arial size 10 font. Only one PDF is accepted in this section, so delete any other documents uploaded during the process.

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 the LLS Research Portal. 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 "Project or Supporting Documentation" section of the web form. Margins are preset and must not be changed. Text must be written single spaced in Arial size 11 font. Figures can be Arial size 10 font. **Only one PDF is accepted in this section (Project Description Template combined with biosketch(es))**.

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

Detailed Letter of Intent Phase Instructions

Each Applicant must submit the LOI by **October 29th at 3:00pm ET** via the LLS Research Portal (https://lls.fluxx.io). 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 reviewed after the deadline. If the LOI is approved, the Applicant will be notified by an automated email from the LLS Research Portal stating that he/she may proceed to the Full Application phase. Applicants may also check the status of their LOI on the Research Portal. As noted above, we have expanded the LOI to include one page of previous studies and preliminary data to allow for sufficient information to judge competitiveness of the proposal.

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 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. You will need to select the zip code from the drop-down menu to ensure it is captured in the Zip code field. If not located within the US, this can be left blank.

Project or Program Information: If you are applying to the Renewal program, select "Yes" from the drop-down menu, provide the previous TRP grant number, then refer to the TRP Renewal Guidelines & Instructions to complete your application.

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 the LLS Research Portal.

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: Enter the total amount of funding requested over the life of the grant (Maximum $600,000). The amount requested on the LLS Research Portal should match the budget section of the full application template. See Description of Awards section for annual maximums.

Proposed Start Date: The start date for all TRP grants is July 1, 2022.

Proposed End Date: The end date for all TRP grants is June 30, 2025.

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 (internal or external to your institution) 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.*

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 **October 29th at 3:00 pm ET** via the LLS Research Portal. After clicking the "Submit" button, the Applicant will receive an email from the LLS Research Portal stating that the LOI was successfully submitted. **If you did not receive the confirmatory email within two 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 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.

Detailed Full Application Phase Instructions

Each Applicant must submit a full application by **January 21st at 3:00 pm ET** via the LLS Research Portal or the following business day if this date falls on a weekend or US holiday. Some sections of the full application will be automatically captured on the Research Portal 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 as a **single PDF**. The Applicant may not modify any information from the submitted LOI as this is subject to the "Changes" section listed above and may result in disqualification of the application.

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

Three sections are required in the uploaded PDF:

Section 1: Graphical Abstracts (1 page maximum)

You will provide two graphical abstracts (which may also include text) to describe some aspects of your research, such as signaling pathways, overall approach, etc. These provide reviewers with quick overviews of your research. These are similar to what is seen at the beginning of a Cancer Cell paper, though they must not be professionally developed (you will be judged on your ability to convey information in a simple manner, but you will not be judged on artistic ability).

Section 2: Project Description

The template consists of the following required elements:

a. Project Description (7 page maximum, including figures)

The following information should be provided in this order. The approximate length listed for each section in the sequence is not a strict limit for each section. It is up to the applicant to utilize more or less space for individual parts based off the specifics of their application.

- Title and Specific Aim (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 pages)
- Resources and Environment (major lab items or facilities) (approximately 1.0 page)
- References Cited (approximately 1.0 page)

Use Arial 11pt font, except for figures which may use Arial 10 pt font.

b. Description of Model Systems and Reagents

Provide information on the models, drugs and reagents described in your project description. This will be an easily assessable resource for reviewers to understand what is described in more detail in the text and figures.

c. 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 two years. All totals and subtotals should be completed on the form.

The aggregate costs over three (3) years cannot exceed $600,000. The maximum annual total cost (direct and indirect) cannot exceed $200,000.

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. MD, PhD, DVM) 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 the Office of Management and Budget, Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. ***Indirect costs are limited to 11.1% of total direct costs requested.*** 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.

d. Budget Justification
2 page maximum.

e. Signature Page
This form must be completed, including the indicated signatures.

Section 3: Appendix

The following sections must be attached in this order to the end of the template (from Section 1) to create a single PDF. ***No other information may be provided in this section.***

a. Principal Investigator's NIH Biosketch (This document is not required for the Co-Collaborators but is required for the Co-Investigator)

Use the most recent NIH biosketch format found on the NIH website. Publications submitted and under review should be indicated on the biosketch. An eRA Commons Username is not required.

b. Principal Investigator's NIH Other Support Document (This document is not required for the Co-Collaborators but is required for the Co-Investigator)
Use the most recent NIH Other Support Document format found on the NIH website. Must contain all current and pending support from any source. **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.

c. Co-Principal Investigator's NIH Biosketch (if applicable)
Use the most recent NIH biosketch format found on the NIH website. Publications submitted and under review should be indicated on the biosketch. An eRA Commons Username is not required.

d. Co-Principal Investigator's NIH Other Support Document (if applicable)
Use the most recent NIH Other Support Document format found on the NIH website. This form must contain all current and pending support from any source. **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.

e. Collaboration/Support Letters
Required if reagents critical for the research are to be obtained from non-commercial and/or commercial sources and are not currently available in your lab.

f. Clinical Protocol (Required where 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 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.

g. Assurances (Required)
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 the 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 but 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 grant review 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 but 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 grant 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.

No attachments besides those listed above can be included in the Appendix.

Applications that include additional documents besides those requested may be administratively triaged.

Uploading the project document and final submission
Upload the full application components, as a single PDF, in the "Project and Supporting Documentation" section on the web form.

All documents must be combined into a single PDF in the order listed above before uploading. Failure to submit as a single PDF in the order above may result in disqualification of the application.

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
- 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.