Mantle Cell Lymphoma Research Initiative II (MCL2)

Translational Grant (TRL)

Effective dates:
October 1, 2022 – June 30, 2023

Application Deadlines	
LOI Deadline	December 5, 2022, 3:00 PM (ET)
Invitation for Full Application Submission	December 15, 2022
Full Application due:	February 24, 2023, 3:00 PM (ET)
Notification of Awards	May 2023
Grant Start date:	July 1, 2023

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Key Points

- 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.
- The deadlines stated in the Key Dates section are strictly enforced. No exceptions are made to this policy.
- 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.
- If you do not receive an expected email within two business days, contact researchprograms@lls.org.
- Do **not** attach documents to the application that are not specifically called for.

About The Leukemia & Lymphoma Society, Inc.

The Leukemia & Lymphoma Society® (LLS) is a global leader in the fight against cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world, provides free information and support services, and is the voice for all blood cancer patients seeking access to quality, affordable, coordinated care.

Description of Awards

Goals

LLS proposes a renewed and robust initiative (**MCL2**) to support targeted research to better understand disease mechanisms, develop more efficacious treatments and improve the outcome for MCL patients. **This program is primarily focused on relapsed disease. However, novel work focused on early disease intervention or improved risk stratification is of interest.** LLS calls for the submission of creative proposals with the potential for high impact in MCL. Applications should address both transformative issues in MCL biology and promising new directions in MCL therapy.

Research Focus Areas

LLS invites innovative and ambitious proposals that can lead to better treatments and cures for MCL. **In particular, the goals of MCL2 are to better understand and develop therapeutic approaches for relapsed MCL.** Among key topics for proposed studies are:

- Understanding of the MCL tumor microenvironment and the properties of lymphoma cells responsible for disease relapse
- Identifying the best treatment combinations based on solid preclinical rationale and data
- Understanding and developing novel immunotherapies for MCL that have the potential to cure cancer
- Identification and validation of novel targets in relapsed disease
- Developing treatment approaches that replace cytotoxics with targeted therapies or immunotherapies that retain efficacy while reducing toxicity
- Understanding the basis of resistance to existing and newly emerging therapies
- Developing novel therapeutics, especially to targets that are unique to MCL and have previously been difficult to drug (e.g., transcription factors)
- Developing additional, accurate animal models of the disease for critical testing of drugs
- Developing predictive biomarkers of disease that can be used for early detection, prediction of treatment response, and to identify patients most likely to respond well to different treatments

Grant Funding Mechanisms

LLS is calling for inventive proposals that have the potential for high impact in the field of MCL. Research funding will provide support for two types of grants: Synergistic Team Award (STA) and Translational Grants (TRLs).

Please review the links below regarding the other MCL2 subprogram to ensure you are applying to the program that best suits your research.

STA Guidelines and Instructions

If you are unsure, please contact researchprograms@lls.org.

Translational Grants (TRL) will fund new and innovative research that advances laboratory discoveries toward clinical application. Key features of the TRL awards include:

- Support for preclinical and/or biological research
- Project led by a single PI
- Three years of support
- Third year of funding dependent on progress assessment at end of year two
- $750,000.00 total award; $250,000.00 per year
- Indirect costs capped at 10% of total award amount
- Three grants are planned to be awarded

Maximum Award Duration & Value

	Duration in Years	***Maximum Annual Total Costs***	***Maximum Total for Duration of Award***
TRL	3	$250,000.00	$750,000.00

The budget must align with the actual costs of the research; this will be reviewed both by the grant review panel as well as LLS staff.

Please note: The 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 researchprograms@lls.org and are subject to the availability of funds.

Eligibility of Applicant and Project

- Citizenship: The program welcomes applications worldwide from appropriate academic institutions and investigators of any nationality.

- Degree: Applicants must hold an MD, PhD, DVM or equivalent degree.

- Institutional affiliation: Applicants must be independent investigators affiliated with a non-profit Institution at the time funding commences and for the duration of the award. Applications from non-academic organizations are not eligible.

- Research Environment: Investigators must demonstrate that their research environment is equipped and suitable for all aspects of the work. Applications for projects that depend on clinical samples or drugs which are not commercially available must provide documentation confirming sample or drug availability. Collaborations between multiple

investigators to strengthen the work proposed will be considered favorably but are not required. Applications may involve multiple institutions; however, the Applicant will be responsible for signing off on all terms of the Funding Agreement.

- Application Limitations: An Applicant may submit only one application per cycle as a Program Director or Principal Investigator in either of the MCL2 grant mechanisms. A Program Director or Principal Investigator can only serve as a Co-Principal Investigator on one other application or as a Project/Core Leader on one other application. A Co-Principal Investigator or STA Project Leader may serve as a Co-Principal Investigator or STA Project Leader on a maximum of two applications. A Principal Investigator or Co-Principal Investigator can serve as a Collaborator on an unlimited number of applications.

- Institution's Acceptance of the Terms and Conditions: Applicants who are offered an MCL2 grant will be sent a Funding Agreement. This must be accepted and signed by the Applicant and by a responsible institutional official.

- Leadership and Staffing: The Application will require one Principal Investigator who is responsible for the preparation and submission of the proposal including the budget, the conduct of the research project and adherence with all stipulations made by LLS in this document, the LLS Policies & Procedures document, and the Funding Agreement, if funded.

- The PI must be an independent investigator (generally at least assistant professor-level or equivalent), which is defined as a scientist who has dedicated laboratory space, directly hires and supervises laboratory personnel (technicians, graduate students, postdocs and staff scientists) and makes all decisions concerning research activities and use of the grant funds. Postdoctoral fellows and instructors (or equivalent) are not eligible to apply for a grant through this program.

  The PI must demonstrate a significant track record in the area of hematology and/or blood cancer research. If the scientific achievements and expertise of the PI are in another scientific area, they must have a Co-PI who has the required significant track record in the area of hematology and/or blood cancer research.

- Relevance: The proposed research must be directly aimed toward advancing our understanding of and/or treatments for MCL. Projects must be concerned with understanding properties and vulnerabilities of MCL and/or focused on developing and testing novel MCL therapies. **A top priority for this funding cycle is on projects addressing relapsed disease or strategies to guide disease interception.** Applications that do not meet the relevance requirement will be disqualified.

Application Process

The application process will occur in two phases. The first phase is submission and consideration of a Letter of Intent (LOI). The LOI will be evaluated for eligibility, and all eligible applicants will be invited to submit a Full Application. The Applicant and Institution must register independently with

the LLS Research Portal in order for the Applicant to apply. Both LOI and Full Application submissions must be made electronically through the LLS Research Portal.

Full Applications will be reviewed by a committee composed of experts in MCL, blood cancer biology, and cancer therapeutics. Applications will be evaluated based on significance, scientific rationale, innovation, feasibility, experience and track-record of the investigators, and potential impact and benefit to MCL patients. LLS will make final funding decisions based on the committee evaluation, program priorities, and the availability of funds.

Key Dates

Phase	Date
Call For Proposals	October 10, 2022
Letter of Intent Due	December 5, 2022 at 3 PM ET
Notification of Full Application Invite	December 15, 2022
Full Application Deadline	February 24, 2023 at 3 PM ET
Review Panel Meeting	April 2023
Notification of Awards	May 2023
Grant Term Begins	July 1, 2023

It is highly recommended that submissions are done the day *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.** The best way to reduce problems with submission is to submit both phases well ahead of the deadline.

Review Process & Applicant Notification

The deadline to submit a Letter of Intent (LOI) is December 5, 2022 at 3 PM ET. ***LOIs are reviewed by LLS scientists for eligibility and relevance so it is imperative that LOIs are clearly presented with all the required information provided (See "*Eligibility of Applicant and Project*" and "Detailed Letter of Intent Phase Instructions").***

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. If invited for Full Application submission, the Applicant will immediately have access to the full application web form in the LLS Research Portal (https://lls.fluxx.io). If you have not received an email regarding your LOI approval within two business days, contact researchprograms@lls.org.

The deadline to submit all Full Applications is February 24, 2023 at 3 PM ET. Full Applications will only be accepted via the LLS Research Portal. 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.

Review Criteria for Full Application

An application will be judged on these criteria:

- The likelihood that investigations will lead to advancements in our understanding of MCL that can be exploited for therapeutic development, and/or lead to direct advancements in therapeutic development
- Overall scientific quality of the proposal
- Presence and quality of substantial preliminary data
- Scientific accomplishments of the PI and Co-PI, where applicable; these accomplishments must include either the PI or the Co-PI having experience with MCL research and/or treatment
- Access to applicable key materials and models, including patient materials, animal models, drugs, etc., to demonstrate feasibility of proposed experiments
- Clarity of presentation

Full Applications received by the February 24, 2023 submission deadline will be reviewed by LLS scientists for adherence to the MCL2 program goals and application guidelines; lack of adherence may result in administrative triage. Compliant applications will be reviewed by an independent committee composed of experts in MCL, blood cancer biology and cancer therapeutics.

Applications will be ranked by final scores and funding recommendations will be approved by the LLS National Board of Directors.

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. Final scores are confidential and are available only to LLS administrative staff, LLS's Medical & Scientific Affairs Committee, its Research Subcommittee and LLS's National Board of Directors.

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 Institution must be registered in the LLS Research Portal. Request an account here, as only LLS staff members have administrative permission to create new accounts. If you have applied to LLS in the past, you do not need to create a new registration. Simply log in using your current username (the e-mail address provided when your account was established) and password. If you do not remember your password, please use the password reset functionality in the LLS Research Portal to reset your password. Once registered with an updated password, the Applicant can begin the LOI.

Institutional Designation
Principal Investigators (Applicants) should create their profile from the standpoint of their institution. The Applicant must indicate the names of the Institution and 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. If you have submitted your LOI or full application and you would like to make changes, ***and the deadline has not passed,*** contact researchprograms@lls.org. However, changes made near the deadline run the risk of missing that deadline. ***The deadline will still be strictly enforced, even if you are in the process of making changes.***

Forms and Format
Applicants will provide information on the LLS Research Portal as well as an NIH biosketch and Other Support form at the LOI phase. For the full application phase, a template will be available in the LLS Research Portal, and updated biosketches and Other Support must be provided. 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. Figure legends must also use Arial, size 11 font. 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. No other attachments may be provided outside of those asked for.

Contacting LLS
Questions that are not clarified in this document or the LLS Research Portal should be addressed to researchprograms@lls.org.

Beginning an Application

Under "Information" in the left navigation bar, click "Mantle Cell Lymphoma Research Initiative II"

Click "Apply to MCL2!" and you will be able to select the TRL LOI 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 these limits are not adhered to, the application may be administratively triaged without full review.

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 LOI is approved, you will receive an automated email from the LLS Research Portal. Consider that these emails may be affected by spam filters. 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 and figure legends must be written single spaced in Arial size 11 font. **Only one PDF file is accepted in this section (Project Description Template combined with biosketch(es) and Other Support form(s))**, so delete any other documents uploaded during the process.

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

Detailed Letter of Intent Phase Instructions

The LOI must be submitted by December 5, 2022 **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 will be evaluated by LLS scientists. If the LOI is approved, the Applicant will be notified by an automated email from the LLS Research Portal stating that they may proceed to the Full Application phase. Applicants may also check the status of their LOI on the LLS Research Portal.

Organization Information

Institution: Indicate the name of the PI's institution. If this institution is not listed, please contact researchprograms@lls.org.

Principal Investigator: See "Leadership and Staffing" in the "Eligibility" section.

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.

Co-Principal Investigator (optional): You may have one co-Principal Investigator.

Co-Principal Investigator's Institution (optional): Provide the co-Principal Investigator's Institution.

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

Grant Information

Brief Biography: A brief biography written for a lay audience. Approximately 1,000 characters including spaces.

Project Title: 100-character limit including spaces.

Project Summary: Up to 500 characters. Provide an overall summary of the TRL project using lay language. The purpose of this section is to give a brief overview of your project, which should serve as a summary of the lay abstract.

Scientific Abstract: 2,500-character limit including spaces. Describe the overall proposed research. Discuss how the research may be exploited for therapeutic development, and/or contribute to direct advancements in therapeutic development. Proposed research must be directly aimed toward advancing our understanding of and/or treatments for MCL. The *direct* relationship to MCL of the research must be clearly stated and will form an essential component of the review of the LOI.

Lay Abstract: 2,000 character minimum and 2,500 characters maximum including spaces. The lay abstract should clearly state the relevance to MCL and describe your proposed research, including problem/question to be addressed, approach, and anticipated results using non-technical language that can be easily understood by an educated non-scientist. Avoid using too many scientific terms and define those that are used, except common terms such as “DNA.” The lay abstract is essential for LLS to continue successful fundraising to support our current and future principal investigators. Thus, a well-written lay abstract, with sufficient detail and suitable language for the general public is required. If selected to submit a full application, the lay abstract will be viewable by the review committee. If selected for funding, LLS will review the lay abstract with our non-scientific writers and we may require modifications to the lay abstract.

Investigator Qualifications: 1,000 characters or less. Describe how the Principal Investigator and optional Co-Principal Investigator and collaborators are uniquely qualified to address the research proposed.

Previous Submission: If you’ve previously submitted this proposal, please indicate the date of submission. If you’ve been previously awarded an MCL-RI grant, in 5000 characters or less, please indicate the following:
1) The overall themes of the previous award
2) How funding has contributed to the current/prior scientific and clinical productivity, providing specific examples.

Justification that Project Addresses TRL goals: 1,000 characters or less.
Describe how the substantial preliminary data leads to the proposed investigations that will lead to advancements in our understanding of MCL that can be exploited for therapeutic development, and/or lead to direct advancements in therapeutic development.

Amount Requested: Enter the total amount of funding requested over the life of the grant (maximum $750,000). The amount requested on the LLS Research Portal should match the budget section of the full application template.

Proposed Start Date: The start date for all TRL is July 1, 2023.

Proposed End Date: The end date for TRL is June 30, 2026.

Major Collaborators Information: Provide information for all investigators with whom you have significant interactions (including those not associated with the proposed Projects) and who are substantially involved with the Projects. Individuals listed here may be contacted by LLS to verify their connection to your work.

- Include only researchers who are at or above tenure-track level (or equivalent)
- Include only names, institutions, and a brief description. **Do not include any other information**
- Indicate if they are collaborators on the proposed STA Projects or unrelated work

Biosketches and Other Support

The PI and optional Co-PI must each provide a biosketch and an Other Support form using the current NIH format. eRA Commons username is not required. The Other Support form must contain all current and pending support from any source. 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***. This includes any grants or portions of grants submitted to any organization.

If funding decisions about potentially overlapping, pending grants become available following submission of this 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 these rules on disclosure of current or pending support may jeopardize the funding of the current grant application.

Combine all biosketches and Other Support forms into a single PDF file and upload to the Project and Supporting Documentation section of the LLS Research Portal.

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 **December 5, 2022 at 3:00 pm Eastern Time** via the LLS Research Portal 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 the LLS Research Portal stating that the LOI was successfully submitted. **If you did not receive the confirmatory email from the LLS Research Portal within two business days of LOI submission, please e-mail** researchprograms@lls.org**.**

Signatures of the Applicant and 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.

Detailed Full Application Phase Instructions

The full application is due by **February 24, 2023 at 3:00 PM ET** via the LLS Research Portal, 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 the LLS 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** file. 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.

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

The following two sections are required in the uploaded PDF.

Section 1: Project Description Template (downloaded from the LLS Research Portal)

The template consists of the following required elements:

a. Applicant and Project Information

Provide the PI name, Co-PI name (where applicable) and institution(s) and copy/paste the project title and abstract from the LOI Phase. Note that the Co-PI must be declared at the LOI stage.

Co-Principal Investigator (optional): You may have one co-Principal Investigator.

Co-Principal Investigator Institution (optional): Provide the co-Principal Investigator's Institution.

b. Graphical Abstracts (1 page maximum)

Provide one graphical abstract (which may include text) of essential components of your Project Description. This may be a signaling pathway, technological approach, and/or overall visual of

your scientific approach. This must fit on the next page (instructions cannot be removed). ***This cannot be professionally made but*** must be simple graphics from a standard program such as PowerPoint or Adobe Photoshop. ***Artistic ability will not be judged***. Rather, you will be judged on your ability to represent your research in a simplified manner so that the reader can quickly and easily understand your project. (1 page maximum).

c. **Major Collaborators Information:** Provide information for all investigators with whom you have significant interactions (including those not associated with the proposed Projects) and who are substantially involved with the Projects. Individuals listed here may be contacted by LLS to verify their connection to your work.
   - Include only researchers who are at or above tenure-track level (or equivalent)
   - Include only names, institutions, and a brief description. **Do not include any other information**
   - Indicate if they are collaborators on the proposed STA Projects or unrelated work

d. Drugs essential to the research described

Complete this section for any drugs used in your research that cannot or will not be commercially obtained available from a pharma/biotech company or that are provided by an academic collaborator. For each drug needed, you must provide a letter stating that you have access to these drugs.

e. Description of Model Systems and Patient Samples

This section will provide the reviewers with an easily accessed source to understand the models described in the project (cell lines, mouse models, patient samples, etc.), including names, species, tissue origin, and any genetic or other relevant descriptive information. If there is direct patient contact, provide an overview of the patient populations. ***All materials mentioned in the text and figures must be described here.***

f. Access to Non-Commercially Available Reagents and Models*

Indicate that you have access to the reagents and models essential to your research. This is a critical part of demonstrating feasibility of your proposal. If your proposal is to build a model, then you should have demonstrated access to the materials and processes for that effort.

If your lab does not have demonstrated access to materials, access should be confirmed through letters of collaboration/support from the supplier. Lack of clear access to materials will negatively affect the review of your application.

g. Project Description:

10 pages maximum.

The following information should be provided in this order:

- Background with scientific and clinical significance
- Specific aims
- Previous studies/preliminary data
- Experimental Design and Expected Outcomes, including figures
- Statistical approaches (where applicable)

- Description of patient populations and samples and how they will be accessed (when applicable); robust access to patients and/or samples will form an important part of the review process (when applicable)
- Resources and environment

Use Arial 11pt font for text and figure legends.

h. References:

Use the *Blood* citation format. 5 page maximum.

i. Other Grant Applications

Indicate other grants that the applicant is currently applying for or is awaiting a funding decision using the format provided.

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

The aggregate costs over the award period cannot exceed the amount listed in the "*Maximum Award Duration & Value*" chart.

Permissible Direct Costs include the following with the specified limitations:

- Personnel Expenses including salary, wage, or stipend with fringe benefits
- 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
- The budget must align with the actual costs of the research; this will be reviewed both by the scientific review committee as well as LLS scientists

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. Our goal is to maximize funds directed to actual research. Indirect costs are limited to a maximum of **10%** of the total award amount.

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

k. Budget Justification

2 page maximum.

l. Signature Page

This form must be completed, including the indicated signatures.

Section 2: 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 and Other Support forms
Follow the instructions in the "*Biosketches and Other Support"* section for the LOI.

b. Co-Principal Investigator's NIH Biosketch and Other Support forms (if applicable)
Follow the instructions in the "*Biosketches and Other Support"* section for the LOI.

c. Collaboration/Support Letters
These are required if reagents and/or drugs critical for the research are to be obtained that are not commercially available to researchers.

d. Clinical Protocol (Required where applicable)
For all clinical trials essential to the proposed research, provide a one-page summary of these clinical protocols. Include approval date, compliance number, effective dates of approval, and funding source for the trial. Indicate if IRB approval is pending and provide a letter from the institutional official regarding IRB status. Full approval must be obtained by the award start date. In addition, provide a link to the full clinical protocols.

e. Assurances (Required)
Human Subjects
Indicate if human subjects will be involved in the proposed research. The status (approved, pending or exempt) of IRB (or equivalent institutional designation) approval must be provided. Documentation of any current or pending approvals must be contained in the full application. There is also a section on the web form that must be completed. An application may be submitted with IRB approval pending, but IRB approval must be obtained and provided to LLS prior to the Award start date.

Laboratory Animals
Indicate if animals will be involved in the proposed research. The status and date of the Institutional Animal Care and Use Committee (IACUC) (or equivalent institutional designation) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of any current or pending approvals must be provided in the full application template. There is also a section on the web form that must be completed. An application may be submitted with approval pending, but approval must be obtained and provided to LLS prior to the Award start date.

Recombinant DNA
Indicate if the proposed research involves recombinant DNA. Documentation of any current or pending approvals must be contained in the full application template; there is also a section on the web form that must be completed.

Biohazard Statement

Indicate if the proposed research involves the use of biohazards. Documentation of any current or pending approvals must be contained in the full application template. There is also a section on the web form that must be completed.

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 Document" section on the web form.

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 the "Submit" button, you will receive an automated email within 2 business days stating that your information was successfully submitted. **If you do not receive the email confirmation of submission, contact** researchprograms@lls.org.

Only one application document and one LOI document should be present. If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document. ***This email must be received, with the correct document, prior to the deadline.***

Check the application prior to final submission. The applicant is ultimately responsible for the submission, regardless of who actually is uploading information on the LLS Research Portal.

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

- Significant updates to clinical trials:
  - IRB updates
  - Opening of a trial
  - Patient enrollment updates
  - 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