Translational Research Program Guidelines & Instructions

Effective dates:
August 26, 2024 – June 30, 2025

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Application Compliance

- 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. In addition, each stage of the application process (letter of intent/full application) should be completed well before the deadline.

- Note that **early-stage, pre-translational, or discovery work is not the best fit for TRP** and will not be competitive. These types of applications are best suited for our Discovery Grant Program (formerly known as our Blood Cancer Discoveries Grant program) and potential Principal Investigators are encouraged to apply to that program.

- All components of the application must be present in the order indicated in these guidelines.

- **If you are the PI or Co-PI on a clinical trial in this application, a Patient Involvement Plan is required**.

- Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template. Font must be black Arial 11 pt. including figure legends, which should be text boxes separate from the figure itself. **If character limits and font restrictions are not adhered to, or the preset margins are altered, the application may be administratively disqualified.**

- Line spacing is preset in the Word document. **Do not change the setting**. Pasting text from another document into the template may result in a change in the line spacing. Check the line spacing in the template before pasting, and if there is a change after pasting, return the line spacing to the original setting. Any modifications in line spacing, particularly if the change allows for more text to fit into the page, **may result in administrative disqualification of your application.**

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

- **The PI and/or Co-PI** may apply to more than one grant program during an application cycle if the aims do not substantially overlap with the aims of any other application across all programs. **You may not be on a different project within the same grant program**.

- **Project/Core Leaders, Collaborators or Key Personnel** may be on different projects or programs provided the aims differ.

- 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.

- 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 or if you have any questions not clarified in this document.

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.

Program Description

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

The 2025 TRP Grant application process will be changed. The TRP Grant program is geared towards translational medicine for blood cancers. Earlier work in the translational environment has been funded in the past through the TRP mechanism, however, these types of projects would be a better fit for our Discovery Grant Program and applicants are directed to apply under that mechanism.

For the 2025 application cycle we will only consider applications that adhere to the following submission guidelines:

- For small molecule compounds the application must have in vivo proof of concept (POC) in appropriate mouse models. Alternatively, based on the mechanism of action, an in vitro POC with patient-derived samples may be considered.
- For cellular or immunotherapies, in vivo POC would make for a stronger application. We acknowledge, however, that depending on the type of therapy being developed an in vitro POC may be more appropriate or necessary.

Applications that don't meet these criteria should not submit a Letter of Intent for consideration.

Applicants must submit a proposed budget with justification. The budget submitted should reflect the actual needs of the project but cannot exceed $250,000 USD per year / $750,000 USD total for the three (3) years of the grant. This budget ceiling includes all costs associated with the grant including indirect costs (often referred to as Institutional Overhead), which will be capped at 10% of the total award. Indirect costs are optional and can be applied to direct costs instead. **Please note that LLS does not follow NIH guidelines for budgets.**

Maximum TRP Award Duration & Value		
Duration	***Maximum Per Year***	***Maximum Award Value for Grant Duration***
3 years	**$250,000**	**$750,000**

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.).

If selected for funding, the award amount 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

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

Degree

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

Leadership and Staffing

The Principal Investigator (PI):

- MUST be a person (companies or institutions are not eligible)
- MUST be an independent investigator, 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
- MUST be an established investigator, defined as a researcher with more than three years in an independent faculty appointment
- May only submit one application per application cycle per grant program provided the aims differ
- CAN serve as a Collaborator on other applications provided the aims differ
- If the applicant can demonstrate a significant track record in malignant hematology and/or blood cancer research, a Co-PI may strengthen the proposal but is not required
- If the applicant has scientific achievements and significant expertise in another scientific area and no track record in blood cancer research, the applicant MUST have a Co-Principal Investigator(s) who has the required significant track record in hematology and/or blood cancer research

Not eligible to apply for a grant in this program:

- Predoctoral scientists or postdoctoral fellow

A Co-Principal Investigator (Co-PI):

- MUST be a person (companies or institutions are not eligible)
- MUST be an independent investigator with an independent appointment
- If the PI has the necessary track record in blood cancer research, a Co-PI may strengthen the proposal but is not required
- If the PI has no expertise or proven track record in any of the blood cancers, an expert Co-PI is REQUIRED
- May only submit one application per application cycle per grant program provided the aims differ
- CAN serve as a Collaborator on other applications provided the aims differ
- MUST be designated at the LOI phase detailing the nature and extent of the scientific interaction
- At least one research aim of the proposal fully depends on their expertise, typically performed in their laboratory and/or facility

Scientific Staff/Collaborators/Other Key Personnel

- MUST be a person (companies or institutions are not eligible)
- May strengthen the work proposed but is not required
- May provide expert insight, guidance, or feedback on research progress
- May be included on different projects or programs provided the aims differ

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 and in the Funding Agreement, if funded.

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 16, 2024, at 3 PM ET. Letters of Intent for the TRP RFP topics will be reviewed after the LOI deadline. Applicants will be notified via an automated email whether they are invited to submit a full application or whether their LOI was declined. We will only be inviting full applications that will be competitive. If the applicant is invited to submit a full application, immediate access to the full application phase is enabled in the LLS Research Portal. If you have not received an email regarding your LOI approval by November 15, 2024, contact researchprograms@lls.org.

The deadline to submit all full applications is January 21, 2025, at 3 PM ET. Full applications will only be accepted via the LLS Research Portal.

Key Dates

Phase	Date
Call For Proposals	August 26, 2024
Letter of Intent Due	October 16, 2024
Full Application Due	January 21, 2025, 3:00 PM ET
Panel Review Meeting	March 2025
Award Notification	May 2025
Award Start Date	July 1, 2025

**LLS's non-negotiable funding 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.

It is highly recommended that submissions are done *prior* to the deadlines.
Internet traffic may be slow near the deadlines, which may result in difficulties in submissions. In addition, LLS's response time to questions may be delayed by the high volume received near the deadlines. Therefore, it is imperative that any submissions or questions be posed to LLS well ahead of any deadlines.

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.
- A well-planned strategy to accomplish the aims presented.
- 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 investigator(s).
- 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.
- **DEI (if applicable)**: The applicant demonstrates understanding of any health disparities associated with the indication; and the applicant presents an appropriate rationale and plan for the proposed trial study population based on current knowledge of the groups at risk for the target indication, including underserved populations. The rationale and plan for the study population align with the objectives of the trial.
- **Patient Involvement Plan (if applicable)**: If the PI or Co-PI(s) is involved with a clinical trial, a Patient Involvement Plan is required. Patient engagement activities are appropriately planned and resourced to achieve meaningful engagement. The patients' need (both unmet medical needs and first-hand experiences) are reflected in the design of the clinical trial.

Full Applications will be reviewed after the January 21, 2025, 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 may be administratively disqualified. 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.

TRP applications will be rank-ordered based on their Overall Priority Score (1-9; which reflects the average of all the reviewers' priority scores).

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.

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 will 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 for 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 Grants through the LLS Translational Research Program (TRP):

1) **LLS – Snowdome Translational Research Program**. The Snowdome Foundation is an Australian-based not-for-profit organization with whom LLS is partnering to enhance our common goal to accelerate cures and better treatments for blood cancer patients. Snowdome Foundation will contribute funding for one meritorious TRP application focused on blood cancer research from an investigator working in Australia, an Australian investigator working in another country, 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 LLS and Snowdome Foundation to ensure they meet the funding objectives of both organizations, and scientific progress of each awarded TRP will be evaluated by both organizations on an annual basis. LLS will administer the grant program.

   If you have selected eligibility for Snowdome Foundation, please ensure you select at least one topic of interest as outlined below.

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 AML, CLL, Hodgkin and Non-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.

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**

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. If you have applied to LLS in the past, you do not need to create a new registration. Simply log in with your username and password. If you forgot your password, 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, you can begin the LOI. If you are a first-time user to the LLS Research Portal, please complete the intake form located here: Account Creation Request so an account can be created for you. 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 the research described in the application. The applicant must indicate the name of the institution as well as the name of the signing officials for that institution. If your institution is not displayed as an option under this field of the application, you may contact researchprograms@lls.org to have it registered in the system.

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 respective deadlines have 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. Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template.

Font must be black Arial 11 pt. including figure legends, which should be text boxes separate from the figure itself. *If character limits, font restrictions, margins, and/or page limitations are not adhered to, the application may be administratively disqualified.*

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

The application will be completed in two phases: Letter of Intent and Full Application.
Below are step-by-step instructions for applying:

1) Read the Guidelines & Instructions in full and familiarize yourself with the LLS Research Portal.

2) Log into the LLS Research Portal, and under "Information" in the left navigation bar, select Translational Research Program. Click "Apply to TRP!" to begin the application process (well ahead of the deadline).

3) Click "Edit" and follow the instructions for each web form field. Bold font indicates required information.
   - Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be disqualified.
   - 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).

4) Once your LOI is submitted, you will receive an automated confirmation email within two business days from the LLS Research Portal. Consider that these emails may end up in your spam filter.

5) If your LOI is selected, you will have access to the full application. Click on your request, found in *New or Pending*, to continue with your application.

6) Please carefully follow the instructions on the LLS Research Portal and this document. Letters of Intent and Full applications require completion of both the web form and templates, which should be downloaded from the *Program Document Links* section of the LLS Research Portal. **Failure to follow all application instructions may result in administrative disqualification**.

7) Submit your letter of intent and full application to the LLS Research Portal prior to the deadlines. **We strongly recommend submitting well before the deadlines, as site traffic on the day of and days leading up to the deadlines will be heavy**. Contact researchprograms@lls.org with any questions about the application phases that are not addressed in the LLS Research Portal, the FAQ, or this document.

8) To create a fair process to all applicants, these Guidelines & Instructions and information on the LLS Research Portal must be followed. ***Do not ask for exceptions to these policies, including but not limited to exceptions to deadlines or making corrections to your document past the deadline.***

Carefully check every page of your application prior to submission. You are ultimately responsible for this submission, even if someone else submits your final application.

Should you have any technical difficulties with the LLS Research Portal, please contact researchprogram@lls.org.

Detailed Letter of Intent Phase Instructions

Each applicant must submit the LOI by **October 16, 2024, 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. There are two main aspects to the Letter of Intent Phase: all Fluxx webform fields and the "Previous Studies/Preliminary Data" (1 page maximum) downloadable template for completion.

The LOI for TRP 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 they may proceed to the full application phase. Applicants may also check the status of their LOI on the LLS Research Portal.

Organization Information

(If the institution or officials are not listed, please contact researchprograms@lls.org with the name and email address for the official you need added.)

Institution: Indicate the name of the institution where the research will be performed.

Location/Department: This field auto populates. Please do not change it.

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 the Institution: Enter the zip code of the institution if located within the United States. You will need to click on 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.

Co-PI: Each designated Co-PI has a specific role and associated responsibilities in the proposed project. Up to two (2) Co-PIs are allowed for an application. The designated Co-PI(s) cannot be changed after the Letter of Intent phase.

Project Information

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

Project Summary: Provide a short summary (approximately 2-4 sentences) in lay language. 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.

Brief Biography (for the PI): Provide a brief, professional biography introducing the applicant to a lay audience. Maximum 1,000 characters including spaces.

Brief Biography (for the Co-PI or Co-PIs): Provide a brief, professional biography in the allotted space introducing the Co-PI or Co-PIs to a lay audience. Maximum 1, 000 characters including spaces. If you do not have a Co-PI, please enter N/A in this field.

Lay Description: The Lay Description should clearly state the relevance of your research to blood cancer and describe your current/proposed research, including the problem/question to be addressed, specific aims, and anticipated results using non-technical language that is easily understood by the lay community. Scientific/Greek characters or symbols must not be used. The Lay Description is essential for LLS to continue successful fundraising to support our current and future grantees, including the later years of ***your*** award, should it be funded. Thus, we require a well-written Lay Description, with sufficient detail and suitable language for non-scientists. Be aware of your confidential information, as the Lay Description (and Project Summary) will be shared with others. **The Lay Description has a maximum of 3,000 characters, including spaces.**

Public Project Tags: Please check the appropriate or relevant option(s) in the following categories. You may check multiple options, but please be thoughtful when selecting your answers:

- Major Diseases
- Specific Disease Types
- Other Key Search Terms

Patient Involvement Plan (Provide this information if the PI or Co-PI is on a clinical trial. If not, please enter N/A for this section on the webform). Please describe an overview of your patient participation plans. Include patient engagement activities during design and execution of the trial, and in disseminating the results. Please describe what steps you will take to assure the patients' needs (both unmet medical needs and first-hand experiences) are reflected in the design of the clinical trial. Provide an overview of the institutional resources dedicated to this effort. (**2,500 maximum including spaces**)

Amount Requested: The total amount, including both direct and indirect costs, cannot exceed $250,000/year. Enter the total amount of funding requested over the life of the grant (Maximum $750,000 for the life of the grant). The amount requested on the LLS Research Portal should match the budget section of the full application template. Please note that LLS does not follow NIH guidelines for budgets. Please adhere to the LLS rules as outlined in this document.

Proposed Start Date: The start date for TRP grants is July 1, 2025.

Proposed End Date: The end date for TRP grants is June 30, 2028.

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: Include collaborators or key personnel (internal or external to your institution) that will help strengthen your application. Please include their name(s) and institution(s). *This section helps LLS identify conflicts with reviewer assignments.*

Previous Studies/Preliminary Data: Upload the Previous Studies/Preliminary Data template **(1 page maximum)** to the "Project and Supporting Documentation" section of the web form in PDF format. Text, figures, and references must be written single spaced in Arial size 11 font.

Note: When uploading this template to Fluxx, please ensure you choose the correct file name from the drop-down menu which should read "Previous Studies/Preliminary Data." If the wrong file name is chosen, you will not be able to submit your LOI.

References are not required at the LOI phase; you may list them if you would like provided you adhere to the one-page limit.

LOI Save, Review, and Submit Instructions

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.

Each applicant must submit the LOI by **October 16, 2024, at 3:00 pm ET** via the LLS Research Portal. After clicking the "Submit" button, the applicant will receive an automated email within two business days stating that your information was successfully submitted. If you do not receive the email confirmation within two business days, contact researchprograms@lls.org.

Signatures of the applicant and institution officials are not required for submission of the LOI.

Changes

Information collected in the Letter of Intent Phase 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 21, 2025, at 3:00 pm ET** via the LLS Research Portal. Some sections of the full application will be automatically captured on the LLS Research Portal from the Letter of Intent Phase. 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 Letter of Intent Phase 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 one or 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. They must be developed primarily by the applicant using tools readily available (e.g., PowerPoint, Photoshop, Adobe Illustrator, BioRender, etc.). 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 (11 page maximum, including figures, OR 9 page maximum, including figures, if no Patient Involvement Plan is required)
Download and complete the project description template, including all required signatures, and upload to the "Project and Supporting Documentation" section of the web form. Margins are preset and must not be changed. Text, figures, and references must be written single spaced in Arial size 11 font. Only one application PDF is accepted at the full application phase (Project Description Template combined with appendix.

Do not delete the LOI "Previous Studies/Preliminary Data" PDF file.

The template consists of the following required elements:

a. **Project Description (11 page maximum, including figures, OR 9 page maximum, including figures, if no Patient Involvement Plan is required)**

   The following information should be provided in this order. The approximate length listed for each section in the sequence is a recommendation and 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 2.0 page)
   - Previous Studies/Preliminary Data (approximately 3.0 pages)
   - Research Methods (approximately 1.25 pages)
   - Patient Involvement Plan Questions (approximately 2.0 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 for text, figures, and references.

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 $750,000. The maximum annual total cost cannot exceed $250,000.

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 $4,000.
- Travel Expense requests cannot exceed $2,000 per year of the award.
- Patient Care Costs (Inpatient/Outpatient)
- Subcontract Costs
- Other Direct Cost requests

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 10% of the total award value of $750,000, or $250,000 per year.*** For institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the direct costs.

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 project description template (from Section 2) 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 Senior Staff/Collaborators but is required for the Co-Principal Investigator(s))

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 Senior Staff/Collaborators but is required for the Co-Principal Investigator(s))

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 (5) 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 (ifapplicable)
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. Assurances (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 be accompanied by a signed letter from the ***appropriate institutional official***. The applicant should notify LLS of IRB approval prior to the grant review. ***Any application without these letters attached may not be reviewed.***

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.

Full approval for all assurances that are necessary for the research must be obtained by the award start date.

Description of Assurances

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 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 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.

Note: Your institution is required to have assurance procedures in place, so please check with them if you are unsure how to obtain your assurance approval documentation.

No attachments besides those listed above can be included in the Appendix. Applications that include additional documents besides those requested may be administratively disqualified.

Uploading the project document and final submission

All final application documents must be combined into a single PDF in the order listed above.

Failure to submit as a single PDF in the order above may result in disqualification of the application. Upload the full application components, as a single PDF, in the "Project and Supporting Documentation" section on the web form. The file upload should be labeled, "TRP Project Description/Application" which you can choose from the document upload drop-down menu. **Do not delete the LOI "Previous Studies/Preliminary Data" PDF file.**

Fluxx Webform Updates

- **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 two business days** stating that your information was successfully submitted. **If you do not receive the email confirmation of submission, contact LLS at** researchprograms@lls.org.

Only one full application document and one Letter of Intent 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; there are no exceptions to this rule.***

The applicant is ultimately responsible for the submission, regardless of who actually is uploading information on the LLS Research Portal. Every year, LLS has a small number of people that notice problems with their application after the deadline. The solution to this problem is very simple and in the hands of the applicant:

- **Check your application prior to final submission.**
- **Submit well ahead of the deadline.**
- **We are not responsible if any applicants are unable to submit by the deadline if our system indicates that:**

  a. **the application procedure was started less than 24 hours before the deadline,** or
  b. **a previously started application file was then only picked up again less than 3 hours before the deadline**

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**.**