



CMML Special Initiative

Expanding Research in Chronic Myelomonocytic
Leukemia to Develop New Therapies and Optimize
Outcomes for Patients

Synergistic Team Award (STA) Guidelines and Instructions

**Effective dates:
March 20, 2023 – November 1, 2023**



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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 information must be typed in English using commonly accepted grammar and punctuation. All applicants must use single-spaced text and Arial size 11 font (figure legends and references must be in Arial size 11 font). If the text within the figures is not legible or is too small, it will impact the ability of reviewers to evaluate your application and may be negatively reflected in the final scoring. Margins are preset in the templates and must remain as set. LLS uses *Blood* citation format for references.
- 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.
- Do **not** attach documents to the application that are not specifically called for. ***The application could be administratively disqualified if this rule is violated.***
- Note that **there are two subprograms under the CMML Special Initiative**. Please ensure that you are applying to the subprogram that best fits the goals and structure of your proposal.
- You may apply to more than one LLS research grant program during an application cycle. Please note: The Leukemia & Lymphoma Society has a rule regarding overlapping aims in 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 research grant programs – that open within the same calendar year. An application to any LLS research 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 Program Director(s), PI(s), Co-PI(s), Project or Core Leader(s), or collaborator(s). All such duplicate submissions with substantially overlapping aims are subject to administrative disqualification, and such proposals may not be reviewed further or considered for funding. Contact researchprograms@lls.org with any questions.



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

Goal of the CMML Special Initiative

LLS plans to invest up to \$13 million over five (5) years in targeted research to build a more comprehensive foundational understanding of the molecular basis of CMML, discover new therapeutic avenues, develop better therapies, and most importantly, **optimize outcomes in clinical research for the patient population already diagnosed with CMML.**

Priority will also be given to research that aims to deliver results on a timeline that can optimize outcomes for the patient population that has already been diagnosed with CMML.

Research Focus Areas

While investigators are encouraged to submit proposals in any clinical or biological topic related to CMML, certain research areas will be prioritized. On the clinical side, these include a) studies of innovative treatments using novel agents, pre-existing agents, or novel combination therapies; b) immunotherapies with high potential for clinical activity in CMML; or c) improved quality of life such as normalization of blood counts or reduced need for blood transfusions. Equally important, we also seek a deeper understanding of the disease and will support studies focused on a) uncovering novel features of CMML biology and cellular vulnerabilities; b) investigations into mechanisms of CMML relapse and therapy resistance; and c) identifying new targets that may be therapeutically exploitable. Such fundamental studies should be focused on translational potential and driven ultimately by the goals of improved patient outcomes and reduction or elimination of disease.

This STA subprogram will provide support over a five (5) year period. Please note that LLS does not follow NIH guidelines for budgets. Please adhere to the LLS rules as outlined in this document.

CMML Special Initiative Subcategories

LLS is activating a global call for inventive proposals that have the potential for high impact in the field of CMML. Research funding during this first RFP will be allocated as stated below. The grant subprograms are as follows:

Synergistic Team Award (STA). Up to two five (5) year, \$5 million multi-investigator awards will be funded. These awards will support programs designed to increase our understanding of the molecular basis of CMML, identify methods to overcome resistance to existing therapies, and most importantly, clinical application of knowledge that may manifest as new clinical trials with novel agents or correlative studies with on-going clinical studies. The group must have demonstrated knowledge in the field as well as the ability to perform clinical trials, biomarker/PD assessment, and/or basic CMML biology research. Support for core facilities may include clinical trial services, the use of animal models, computational expertise, single-



cell analysis, or other expertise required to advance new therapies. The program is designed to create a synergistic team that will work well together to advance the overall goals of the program.

Translational Grant (TRL). Up to four three (3) year, \$750,000 awards will be funded. These grants will support clinical and/or biological research led by one to three investigators. A clearly outlined translational plan is a plus for proposals in basic research, but outstanding biological research proposals without a translational element will be considered. The award is expected to support senior investigators, although young independent investigators with a proven track record will be considered.

All awardees will be invited to give a progress update at an annual in-person group meeting to be held in the autumn timeframe. This is complemented by an annual report of activities in the Spring timeframe. Awardees must attend or appoint a colleague to give the progress update.

These guidelines are for the STA subprogram. Please review the link below regarding the TRL subprogram to ensure you are applying to the subprogram that best suits your research. If you are unsure, please contact researchprograms@lls.org.

TRL Award Guidelines and Instructions:

<https://llsorg.widen.net/s/sdz8xtblsh/cmml-trl---guidelines>

Up to two (2) Synergistic Team Awards (STAs) will be awarded. This multi-investigator award will **focus on novel clinical trial(s) in CMML**; the group may be from multiple centers. The group must have the knowledge and capacity to perform biomarker/PD assessment and/or basic CMML biology research. Additional features of this award mechanism are:

- Program activities can include pre-clinical development and correlative studies
- Multiple projects that do not contribute to the overall synergy will be unfavorably reviewed
- Approximately 3 to 4 independent investigators (Project/Core Leaders) led by a Program Director (PD)
- There must be at least three but no more than five Projects
- There must be a minimum of one scientific Cores (e.g., clinical trial services, genomics, animal models, registries, or computation) and one administrative Core. There can be no more than three Cores. Cores should not be research-oriented, as they serve supportive functions
- Five (5) years of support
- \$1,000,000/year (\$5,000,000 total)

Maximum Award Duration & Value

	<i>Duration in Years</i>	<i>Maximum Annual Total Costs</i>	<i>Maximum Annual Direct Costs</i>	<i>Maximum Annual Indirect Costs*</i>	<i>Maximum Total for Duration</i>
STA	5	\$1,000,000.00	\$900,000.00	\$100,000.00	\$5,000,000.00

*Indirect Costs are limited to 10% of the total costs requested in the application's budget.

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 scientific staff.



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.).

Please note: If funded, the amount awarded 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 CMML program welcomes applications worldwide from appropriate not-for-profit academic institutions and investigators of any nationality.

Degree

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

Leadership and Staffing

The CMML Special Initiative welcomes applications from independent investigators (generally at least assistant professor-level or equivalent). An investigator may only be a Program Director, and/or Project/Core leader on a maximum of one application. There is no limitation on the number of collaborations an investigator may have, and collaborators may be listed on more than one application so long as they are not in the leadership roles highlighted above.

The Program Director and Project and Core Leaders must have significant track records in hematology and/or blood cancer research.

The STA subprogram is intended for independent, established researchers. Therefore, applicants holding positions such as post-doctoral fellows, instructors, etc. are not allowed to apply.

Relevance

The proposed research must be directly aimed toward advancing our understanding of and/or treatments for CMML. Programs must be concerned with understanding properties and vulnerabilities of CMML and/or focused on developing and testing novel CMML therapies. Applications that do not meet the relevance requirement will be disqualified without full review.

Review Process & Applicant Notification

The deadline to submit all Letters of Intent (LOI) is May 1, 2023, at 3 PM ET. LOIs for the STA subprogram award will be reviewed after the deadline. 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. We will only invite full applications that are relevant and eligible. The STA LOI includes 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 May 5, 2023, contact researchprograms@lls.org.

The deadline to submit all full applications is June 30, 2023, at 3 PM ET. Full applications will only be accepted via the [LLS Research Portal](#).

Key Dates

Phase	Date
Call For Proposals	March 20, 2023
Letter of Intent Due	May 1, 2023, 3:00 PM ET
Notice of Full Application Invite	No Later than May 5, 2023
Full Application Deadline	June 30, 2023, 3:00 PM ET
Review Panel Meeting	August 2023
Notification of Awards	September 15, 2023
Award Start Date	November 1, 2023

Submission deadlines.

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 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. 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:

- 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
- The synergy resulting from contributions from each Project to the overall goals of the STA and the role of the Cores in enhancing this synergy
- Experience, background, and qualifications of the 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

In addition to the general characteristics noted above. **The CMML STA subprogram include these specific objectives:**

- Develop a deep understanding of the molecular basis of CMML using new state-of-the-art techniques
- Identify new molecular targets (disease drivers or cell surface markers) that could be stimuli for new therapeutics for CMML
- Support the discovery of innovative new therapeutics for CMML
- Understand the basis for resistance of approved or experimental therapies
- Explore existing novel experimental therapies (used for other diseases) for CMML in the laboratory, including in vitro and in vivo models
- Enable early-stage clinical trials demonstrating safety and preliminary efficacy based on 1) reduction in monocytosis; 2) reduction in blast count; and/or 3) relief of symptoms (e.g., spleen size reduction or transfusion dependence)
- This is a large, multi-investigator award that should focus on the acceleration of therapies for CMML, primarily with a focus on clinical advancements or late-stage pre-clinical research that has rapid translational potential

Full Applications will be reviewed by the CMML Subcommittee of the LLS Medical & Scientific Affairs Committee. Applications that do not meet the subprogram goals, scope, or follow these guidelines will be administratively disqualified. Applications will be 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. STA 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 CMML Subcommittee will be shared with the donor for review before being presented to the LLS 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, the donor, and administrative personnel only. **Feedback will only be provided for applications discussed by the full review committee.**



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 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 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 downloadable templates 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 and references must be Arial size 11 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 or the [LLS Research Portal](#) should be addressed to researchprograms@lls.org.

Beginning an Application

- Read these (Guidelines & Instructions) in full.
- Log into the [LLS Research Portal](#), under “Information” in the left navigation bar, click



“**CMML Special Initiative.**” Click “**Apply to CMML**” to begin the application process (well ahead of the deadline).

- 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 templates. Font must be Arial size 11 pt. If character limits and font restrictions are not adhered to, or the preset margins are altered, the application may be disqualified.
- Carefully check every page of your application prior to submission. You are ultimately responsible for this submission, even if someone else submits on your behalf.
- 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 at least one hour prior to the deadline).
- At any time during the application process, including after submitting your full application, you can check the status of your application by logging in to the [LLS Research Portal](#), selecting your application (under Requests in either “New or Pending” or “Submitted”), and referring to the status in the yellow box at the top of the page.
- If you have any technical difficulties with the LLS Research Portal, please contact researchprograms@lls.org.

Detailed Letter of Intent Phase Instructions

Each applicant must submit the LOI by **May 1, 2023, at 3:00pm ET** via the LLS Research Portal at <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 LLS Research Portal webform fields and the “Previous Studies/Preliminary Data” (1 page maximum) downloadable template for completion.

The LOI for the STA subaward will be reviewed on a rolling basis. 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 LLS Research Portal.

Organization Information

(If the institution or officials are not listed, please contact researchprograms@lls.org)

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

Program Director: The Program Director 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.

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 select the zip code from the drop-down menu to ensure it is captured in the zip code field. Leave this blank if the institution is not located within the US.

Award 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.

Brief Biography (for the Program Director only): Provide a brief biography written for a lay audience (approximately 1,000 characters including spaces).

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 Description: Using lay language, clearly state the proposed research in 3,000 characters (including spaces) or less. Once the LOI has been submitted, the lay description 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 award (maximum \$5,000,000). 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. 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 STAs is November 1, 2023.

Proposed End Date: The end date for STAs is October 31, 2028.

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

STA Components:

Enter the Project Title, Project Leader(s), and Project Leader(s)' Institution(s) for all proposed Projects. There must be at least three but no more than five Projects.

Enter the Core Title, Core Leader(s), and Core Leader(s)' Institution(s) for all proposed Cores. There must be a minimum of one (1) scientific Core (e.g., clinical trial services, genomics, animal models, registries, or computation) and one (1) administrative Core. There can be no more than three (3) Cores. Cores should not be research-oriented, as they serve supportive functions.



Key Personnel or Collaborators Information:

Indicate any personnel, outside of your institution, with whom you have a significant and current interaction regarding your project (list up to five people only). Individuals listed here may be contacted by LLS to verify their connection to your work. *This section helps LLS identify conflicts with reviewer assignments.*

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

Previous Studies/Preliminary Data: Upload the Previous Studies/Preliminary Data (1 page maximum) to the “Project and Supporting Documentation” section of the web form. Text, figure legends, and references must be written single spaced in Arial size 11 font. Text within figures should be easily readable without magnification. Please note that references are not required at the LOI phase but are required at the full application phase. Only one PDF is accepted in this section, so delete any other documents uploaded during the process. **Note:** When uploading this template to the [LLS Research Portal](#), please ensure you choose the correct file name which should read “Previous Studies/Preliminary Data” which you can choose from the document upload drop-down menu. If the file name is incorrect, you will not be able to submit the LOI. In addition, when you name your file, please only use underscores or spaces to separate words.

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 **May 1, 2023, 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 four 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 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 **June 30, 2023 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 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.

Two sections are required in the uploaded PDF:

Section 1: Project Description

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, figure legends, and references must be written single spaced in Arial size 11 font. Embedded figures must be legible.

Upload only one PDF to this section (Project Description Template combined with biosketch(es)). Do not delete the LOI information previously provided.

The template consists of the following required elements:

a. Applicant and Program Information

Provide the Program Director’s name and institution and copy/paste the Project Title, Project Summary, Scientific Abstract, and Lay Description from the LOI phase.

b. Projects’/Cores’ Description

Projects: Each Project should be listed as a separate section and included in this order (seven (7) page maximum for **each** Project, not including citations):

- Graphical Abstract(s) (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 (you will be judged on your ability to convey information in a simple manner, but you will not be judged on artistic ability).
- Project Title
- Project Leader(s)
- Project Description
 - Specific aims
 - Background with scientific and clinical significance
 - 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.
 - Resources and environment



Citations for each Project are limited to two (2) pages (Arial, 11 pt font, *Blood* citation format).

Each Project description must have a minimum of three (3) figures.

Cores: Each Core should be listed as a separate section and included in this order (three (3) page maximum for **each** Core, not including citations):

- Core Title
- Core Leader(s)
- Core Description
 - Goals
 - Function/operation
 - Benefit and relation to other STA components

Citations for each Core are limited to two (2) pages (Arial, 11 pt font, *Blood* citation format).

c. 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 Projects (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.***

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. This will be critical for the initial aims of the Projects; for more distal aims, this is not required at the application phase. For each drug needed during the initial aims, you must provide a letter stating that you have access to these drugs.

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

Indicate that you have access to the reagents and models essential for the immediate aims of your research. This is a critical part of demonstrating feasibility of your proposal.

****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.*** This will be critical for the initial aims of the Projects; for more distal aims, it is not expected that there will be immediate access.

f. Other Grant Applications

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

g. Budgets for Projects and Cores

The Budget and Budget Justification should provide itemized detail for each major category for all years of the Projects/Cores. 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 five (5) years cannot exceed \$5,000,000. The maximum annual total cost (direct and indirect) cannot exceed \$1,000,000.

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 \$10,000 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 10% of total costs requested.** For institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Program Director's stipend or fringe benefits cost.

Subaward budgets should be included within the main budget line items. Indirect costs can be included in the total indirect costs. Please note, LLS will only pay the funded institution, and that funded institution will be responsible for all subcontracting and subsequent payments.

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

h. Budget Justification

Two (2) page maximum for Projects and two (2) page maximum for Cores.

i. 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 2) to create a single PDF. ***No other information may be provided in this section.***

a. Program Director's NIH Biosketch (This document is not required for Senior Staff/Collaborators)



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. Program Director's NIH Other Support Document (This document is not required for Senior Staff/Collaborators)

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 (5) 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. Project Leaders' and Core Leaders' NIH Biosketches

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. Project Leaders' and Core Leaders' NIH Other Support Documents

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 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.

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 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, “STA Project Description/Application” which you can choose from the document upload drop-down menu.

LLS Research Portal Webform Updates

- **Project and Core Details**
Provide the required information within the LLS Research Portal webform.
- **Budgeting Information**
Enter the budgeting information as required on the web form fields.
- **Assurances**
Respond to the assurance questions and indicate if approvals are pending or the date of approval with the approval number.
- **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
- Manuscripts that are accepted for publication; the following must be provided via email to researchprograms@lls.org:
 - Complete list of authors as they appear on the accepted manuscript with your name in bold
 - Manuscript title
 - Journal
 - Date of publication or online ahead of print (if known)
 - A copy of the acceptance letter from the journal

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.