Hairy Cell Leukemia Foundation-Leukemia & Lymphoma Society HCL2025 Initiative (HCL2025)
Guidelines & Instructions

Synergistic Team Award (STA)

Effective dates:
November 2, 2020 – June 30, 2021

Key Points

- Follow this link (https://lls.fluxx.io) to access the LLS Research Portal 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 Hairy Cell Leukemia Foundation

The mission of the Hairy Cell Leukemia Foundation (HCLF) is to improve outcomes for patients through high-caliber research in hairy cell leukemia, by advancing knowledge about HCL among oncologists and hematologists, and by providing educational resources, comfort and support to patients and families. HCLF funds the most promising research to expand scientific and medical advances in hairy cell leukemia. HCLF also promotes collaboration and cooperation across an international network of institutions and convenes researchers and healthcare professionals to improve understanding and treatment of this disease. HCLF provides a range of educational initiatives and resources for patients and families around the world.

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

The Hairy Cell Leukemia Foundation and LLS have joined forces to invest up to $10 million over 5 years in targeted research to build a more comprehensive foundational understanding of the molecular basis of hairy cell leukemia, develop better therapies, and optimize outcomes for patients with HCL. This initiative is called The Hairy Cell Leukemia Foundation-Leukemia & Lymphoma Society HCL2025 Initiative (HCL2025).

Research Focus Areas

While investigators are encouraged to submit proposals in any clinical or biological topic related to hairy cell leukemia, certain research areas will be prioritized. On the clinical side, these include a) studies of innovative treatments for situations of high unmet medical need that require accurate diagnosis and characterization of the HCL-like disease spectrum, including classical HCL (cHCL) and variant HCL (HCLv); b) novel strategies to treat infections associated with HCL; and c) risk stratification and development of targeted treatments. Equally important, we also seek a deeper understanding of the disease and will support studies focused on a) uncovering novel features of HCL biology and cellular vulnerabilities; b) investigations into mechanisms of HCL relapse and therapy resistance; and c) efforts to establish and validate *in vitro* and *in vivo* models of the disease. Such fundamental studies should be focused toward translational potential and driven ultimately by the goals of improved patient outcomes and reduction or elimination of disease.

For a more detailed description of HCL, as well as potential laboratory and clinical research avenues, please follow this link for the document entitled "***Statement on Future Research and Therapeutics for Hairy Cell Leukemia***."

Grant Funding Mechanisms

HCLF and LLS are activating a global call for inventive proposals that have the potential for high impact in the field of HCL. Additional funding for projects that are successful may be granted in later years of the grant term. There are three funding mechanisms under HCL2025: Synergistic

Team Award (STA), Translational Grants (TRL), and Exploratory Awards (EXP). These guidelines explain the STA mechanism.

Please review the links below regarding the other HCL2025 programs to ensure you are applying to the program that best suits your research.

TRL Guidelines and Instructions

EXP Guidelines and Instructions

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

Synergistic Team Award (STA)
One will be awarded. This multi-investigator grant will focus on novel clinical trial(s) in HCLv or cHCL; the group may be from multiple centers. The group must have the knowledge and capacity to perform biomarker/PD assessment and/or basic HCL biology research. Additional features of this grant 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)
- Funding for Core facilities (e.g. clinical trial services, genomics, animal models, registries, or computation) may be included; Cores serve a supportive function for the Projects and therefore should not be research-oriented
- 4 years of support
- $625,000/year ($2,500,000 total)
- Our goal is to maximize funds directed to actual research so more consideration will be given to grant applications with no or minimal indirect costs; in no event will indirect costs greater than 11.1% be considered or approved
- Annual site visits with assessments will be required

Maximum Award Duration & Value

	Duration	***Maximum Annual Total Costs***	***Maximum Total for Duration***
STA	4 years	$625,000	$2,500,000

The budget must align with the actual costs of the research; this will be reviewed by the HCLF/LLS Joint Leadership Group composed of HCLF leadership and LLS scientific 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 Program

- 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 Sponsoring 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. Applications may involve multiple institutions; however, the Applicant will be responsible for signing off on all terms of the Grant Agreement.

- Application Limitations: An Applicant may submit only one application per cycle as a Program Director or Principal Investigator in any of the HCL2025 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/Core Leader may serve as a Co-Principal Investigator or STA Project/Core 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.

- Sponsoring Institution's Acceptance of the Terms and Conditions: Applicants who are offered an HCL2025 grant will be sent a Grant Agreement. This must be accepted and signed by the Applicant and by responsible institutional officials.

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

  The Program Director must be an independent investigator, 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 Program Director must demonstrate a significant track record in the area of hematology and/or blood cancer research. If the scientific achievements and expertise of the Program Director are in another scientific area, they must have at least one Project Leader who has the required significant track record in the area of hematology and/or blood cancer research.

- Relevance: Proposed research must be directly aimed toward advancing our understanding of and/or treatments for HCL. Projects must be concerned with understanding properties and vulnerabilities of HCL and/or focused on developing and testing novel HCL therapies. Applications that do not meet the relevance requirement will be disqualified without full review.

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 Sponsoring 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 HCL, 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 HCL patients. The HCLF/LLS Joint Leadership Group will make final funding decisions based on the committee evaluation, program priorities, and the availability of funds.

Key Dates

Phase	Date
Call For Proposals	November 2, 2020
Letter of Intent Due	January 29, 2021 at 3 PM ET
Notification of Full Application Invite	February 5, 2021
Full Application Deadline	April 16, 2021 at 3 PM ET
Review Panel Meeting	June 2021
Notification of Awards	August 1, 2021
Grant Term Begins	October 1, 2021

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 January 29, 2021 at 3 PM ET. ***LOIs will be reviewed by the HCLF/LLS Joint Leadership Group for eligibility and relevance so it is imperative that LOIs are clearly presented with all the required information provided (See "Eligibility of Applicant and Program" 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. 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 April 16, 2021 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 STA Full Application

An application will be judged on these criteria:

- The potential of preclinical development to lead to novel clinical trials in the near- to medium-term, or the potential for novel clinical trials to significantly advance survival and/or quality of life of HCL patients
- Overall scientific quality of the proposal
- The qualifications of the Program Director, who must have experience and expertise relevant to HCL
- The qualifications of the Project Leaders; all need not have experience with HCL, but must have clear and demonstrated experience to significantly contribute to the overall approach of the team towards HCL preclinical and/or clinical development
- The synergy resulting from contributions from each Project to the overall goals of the STA
- The quality of the resources and environment
- Access to applicable key materials and models, including patient materials, animal models, drugs, etc., to demonstrate feasibility of proposed approaches; this will be critical for the initial aims of the Projects, but this is not required for more distal aims
- Clarity of presentation

Full Applications received by the April 16, 2021, 3 PM ET submission deadline will be reviewed by the HCLF/LLS Joint Leadership group for adherence to the HCL2025 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 HCL, blood cancer biology, and cancer therapeutics.

Applications will be ranked by final scores and funding recommendations will be presented to the HCLF/LLS Joint Leadership Group. Funding decisions of the HCLF/LLS Joint Leadership Group will be submitted to the Oversight Boards of both the HCLF and LLS for final approval.

Any Applicant selected for funding will be notified by the date indicated in the Key Dates section**.** Please do not call or email the HCLF or 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 HCLF Board of Directors and administrative staff, LLS staff, LLS's Medical & Scientific Affairs Committee and its Research Subcommittee, and LLS's National Board of Directors.

General Application Instructions

All submissions must use the LLS Research Portal. It is recommended that you familiarize yourself with this portal well in advance of any deadlines.

Registration

Both the Applicant and Sponsoring Institution must be registered in the LLS Research Portal. Contact researchprograms@lls.org to create a new account 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
The Project Director (Applicant) should create their profile from the standpoint of their institution. The Applicant must indicate the names of the Sponsoring 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 in 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 in 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 "Hairy Cell Leukemia Foundation-Leukemia & Lymphoma Society HCL2025 Initiative."

Click "Apply to HCL2025!" and select the STA 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 (Fluxx). 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 biosketches and Other Support forms)**, so delete any other documents uploaded during the process.

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

Detailed Letter of Intent Phase Instructions

The LOI must be submitted by **January 29, 2021 at 3:00pm ET** via the LLS Research Portal 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 the HCLF/LLS Joint Leadership Group. If the LOI is approved, the Applicant will be notified by an automated email from the LLS Research Portal (Fluxx) 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

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

Program Director (PD): See "Leadership and Staffing" in the "Eligibility" section.

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

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

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

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

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

Grant Information

Project Title: 100 character limit including spaces.

Projects: Provide the title, Project Leader(s) and Institution(s) of each Project Leader(s). Use full names.

Cores: Provide the title, Core Leader(s) and Institution(s) of the Core Leader(s).

Project Summary: 1,500 character limit including spaces. Provide an overall summary of the STA Program using lay language. The purpose of this section is to give a brief overview of your program, which should serve as a summary of the lay abstract.

STA Program Statement: 5,000 character limit including spaces. Describe the overall proposed research and a brief overview of each Project and Core. Discuss the interactions between the components that will create synergy. Discuss plans for clinical translation of findings. Proposed research must be directly aimed toward advancing our understanding of and/or treatments for HCL. The *direct* relationship to HCL of the research must be clearly stated and will form an essential component of the review of the LOI.

Lay Abstract: 3,000 character minimum and 3,500 characters maximum including spaces. The lay abstract should clearly state the relevance to HCL and describe the STA program, 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 grantees. 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.

Project Details: 1,500 character limit including spaces. Provide a brief description, including the specific aims and anticipated results for each Project. Scientific/Greek characters or symbols must not be used.

Core Details: 1,500 character limit including spaces. Provide a brief description for each Core and the role each plays in the various Projects and the overall SCOR. Scientific/Greek characters or symbols must not be used. Note that the Cores serve a supportive function for the Projects and therefore should not be research-oriented.

Investigator Qualifications: 1,000 character limit including spaces. Describe how the Program Director, Project/Core Leaders, and collaborators are uniquely qualified to address the research proposed.

Amount Requested: Enter the total amount of funding requested over the life of the grant (maximum $2,500,000). 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 STA is October 1, 2021.

Proposed End Date: The end date for STA is September 30, 2025.

Collaborators Information: Provide information for all investigators with whom you have significant interactions (including those not associated with the proposed 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 Program Director and all Project and Core Leaders must each provide a biosketch and an Other Support form using the current NIH format. eRA Commons user name 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.

HCLF and LLS recognize 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, HCLF/LLS will consider an applicant's other current grant support in its funding decisions. This may result in HCLF/LLS funding only part of the grant or none of the grant, depending on the level of overlap. In addition, HCLF/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.

Submission of the LOI

Each Applicant must submit the LOI by **January 29, 2021 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. After clicking

the "Submit" button, the Applicant will receive an email from the LLS Research Portal (Fluxx) stating that the LOI was successfully submitted. **If you did not receive the confirmatory email from the LLS Research Portal (Fluxx) within two business days of LOI submission, please e-mail** researchprograms@lls.org**.**

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

Changes: Information collected in the LOI will automatically populate fields in the full application. Once submitted, changes may only be made after receiving prior approval from LLS. The Applicant must email 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 **April 16, 2021 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 Project Director's name and institution and copy/paste the title and abstracts from the LOI Phase.

b. Project and Core Details: Provide the required information in the form.

c. Collaborators Information: Provide information for all investigators with whom you have significant interactions (including those not associated with the proposed 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. 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. 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.***

f. 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.

g. Projects/Cores Description:

Projects: Each Project should be listed as a separate section and included in this order (6 page maximum for ***each*** Project, not including citations):

- 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 (when applicable)
    - Resources and environment

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

Each Project description must have a minimum of 3 figures.

Cores: Each Core should be listed as a separate section and included in this order (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 2 pages (Arial, 11 pt. font, Blood citation format).

h. Other Grant Applications: Indicate other grants that the applicant is currently applying for or is awaiting a funding decision using the format provided.

i. Budget 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 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 having an acquisition cost of more than $1,000
- Travel Expense requests cannot exceed $5,000 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 the HCLF/LLS Joint Leadership Group

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 Uniform Administrative Requirements, Cost Principals, and Audit Requirements for Federal Awards documents. Our goal is to maximize funds directed to actual research. More consideration will be given to grant applications with no or minimal indirect costs. In no event will indirect costs greater than 11.1% be considered or approved.

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

j. Budget Justification: 2 page maximum for Projects and 2 page maximum for Cores.

k. 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. Program Director's NIH Biosketch and Other Support forms: Follow the instructions in the "*Biosketches and Other Support"* section for the LOI.

b. Project and Core Leaders NIH Biosketches and Other Support forms: Follow the instructions in the "*Biosketches and Other Support"* section for the LOI.

c. Collaboration/Support Letters (Optional): 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 or Supporting Documentation" section on the web form.

Failure to submit as a single PDF in the order listed 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