LEUKEMIA & LYMPHOMA SOCIETY®

Career Development Program
Guidelines & Instructions

Scholar in Clinical Research

August 1, 2022 – June 30, 2023

Application Deadlines	
Eligibility Phase deadline:	November 1, 2022; 3:00 PM (ET)
Abstract Phase deadline:	November 8, 2022, 3:00 PM (ET)
Full Application Phase deadline:	December 16, 2022, 3:00 PM (ET)
Award Start date:	July 1, 2023

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What's New for 2022

Starting the prior application cycle, the approach to the application and review process has <u>fundamentally</u> changed. The Scholar in Clinical Research award has always had the intention of supporting researchers who are on a trajectory for leadership in blood cancer clinical research. To better capture this, we have modified the application process to better emphasize all the clinical research activities of the applicant. Therefore, the total research portfolio of the applicant will be assessed by the review committee. These changes better align the application, review process, and funding decisions with the intent of the Scholar in Clinical Research award.

We have changed the formula for calculating indirect costs. The calculation is now with respect to the total award amount.

The eligibility requirements have changed. Starting this cycle, all non-mentored, faculty-level positions are considered independent for eligibility determination. In addition, those with a title of Full Professor (or equivalent) at the award start date (July 1 of the upcoming year) are no longer eligible for this program.

2022 Update: Application Compliance

In prior award cycles, ~20-30% of eligibility requests were rejected. We have updated the eligibility form to make rejections far less likely, but it takes much more time to complete. To avoid eligibility rejection, read these Guidelines & Instructions carefully and fill out the eligibility form completely. ***Be sure to start this process early.***

A rejected applicant can only re-submit an eligibility request once.

In recent years, approximately 10-15% of all full applications had serious structural flaws. These include non-adherence to section lengths, font size, or missing attachments (e.g., a Sponsor Letter or Biosketch), or critical sections not completed. **Applications with such flaws run the risk of administrative disqualification.**

Carefully check the final version of your application prior to upload (even if someone else uploads for you).

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 the CDP Scholar in Clinical Research Award

Through the Career Development Program, LLS supports talented blood cancer researchers in the early/mid phase of their careers. CDP continues to provide a pool of dedicated researchers to advance the understanding and diagnosis of blood cancer, as well as the development of

treatment and prevention options that will ultimately lead to a higher quality of life for blood cancer patients as well as potential cures.

Scholar in Clinical Research applicants must have significant clinical duties. Their research must relate to their clinical activities and the research must involve direct patient contact. This usually involves investigator-initiated clinical trials, but in some cases may involve other clinically related research involving patients. **Investigators who are primarily laboratory-based, and/or who are working on primarily blood cancer model systems rather than blood cancer patients are not eligible for the Scholar in Clinical Research Award and should consider applying for the Scholar Award instead.**

The **Scholar in Clinical Research Award** is for 5 years and supports independent, junior faculty who have *already* established themselves as blood cancer researchers and are on a trajectory of leadership in the field.

The maximum award per year is $125,000 and includes the salary and fringe benefits for the Applicant and an assistant. Salaries may be supplemented by funds from other sources. Any assistant supported by this award **_must_** have a direct role in the described research program. Indirect costs may be included and cannot exceed 5% of the total award amount requested in the proposal. Expenditures for clinical and/or laboratory costs/equipment, travel, etc. are not permitted. The awarded value will be limited to the amount requested in the submitted proposal even if that amount is less than $125,000/year. The applicant's research program described should occupy all the applicant's research time though there are no requirements for a certain percent effort in our budget template. Scholar in Clinical Research applicants are typically assistant or associate professors. Scholar in Clinical Research applicants **_must_** hold an independent position. However, this award is not intended for well-established and/or senior investigators.

The Leukemia & Lymphoma Society honors those CDP awardees whose awards are ending and who have done the most impactful work. One Scholar/Scholar in Clinical Research awardee will be honored with the **CDP Achievement Award**. This high honor will be given to the Scholar/Scholar in Clinical Research awardee who is a leader/emerging leader and has had the three most impactful publications of direct relevance to blood cancer over the course of their funding period. An absolute requirement for consideration is that those publications must acknowledge support of The Leukemia & Lymphoma Society (preferably as a specific acknowledgement of this funding mechanism*). Since we consider a CDP awardee to always be an awardee while funded, **_all_** publications should acknowledge our support.* A secondary consideration is the total publication record and productivity during the award period as well as career trajectory. *Though not guaranteed, we hope to continue the CDP Achievement Awards indefinitely.*

*Use this format when acknowledging The Leukemia & Lymphoma Society: "…was supported by a Scholar in Clinical Research award from The Leukemia & Lymphoma Society."

<u>Eligibility</u>

Scholar in Clinical Research applicants must…

- Have a Sponsor who will attest to institutional support for the applicant. An appropriate Sponsor may be a department head, chief of service, or program chair.
- Be an independent investigator of at least an assistant professor position or equivalent; this includes any permanent, independent clinical faculty who are not on a laboratory-based, tenure-track career path (see Experience/eligibility clock).
- ***Have clinical training in blood cancer.***
- Have adequate funding to support the proposed research (see Research Support Requirement).
- Have started their ***first*** independent position no less than 4 years but not more than 10 years before the time of review (see Experience/eligibility clock). Instructor-level positions are not counted as independent for eligibility purposes. However, all non-mentored positions are considered independent for this calculation.
- Have protected time for research after the funding start date in the range of 20-40%. Deviations from this may be allowed and will be determined on a case-by-case basis by LLS scientific staff. If an investigator is more laboratory-based than clinic-based, they cannot apply for this award; they should consider the Scholar subcategory.
- Have a least one first author, full length (which may include short reports), peer-reviewed, primary research publication available on PubMed by the full application due date* (***Not*** including reviews, perspectives, conference/meeting presentations or abstracts, etc.). Note that those applicants with no corresponding author publications are eligible but are less likely to be competitive.
- ***Be performing clinical research involving patients (generally clinical trials), which is related to their clinical duties. Laboratory correlative studies are welcome and any laboratory studies must directly relate to the clinical studies.***

<u>Citizenship</u>
The program welcomes applications worldwide from appropriate academic institutions and investigators of any nationality.

<u>Degree and Training</u>
Applicants must generally hold an MD or equivalent, but in some cases, we may consider those with other advanced degrees if they are clinicians who have undergone rigorous clinical training. All Scholar in Clinical Research applicants must have formal clinical training in blood cancer.

<u>Experience/eligibility clock</u>
Applicants must currently hold an independent, faculty-level position (or equivalent). As a new policy starting in the 2022-2023 cycle, those with the title of full professor (or equivalent) are ineligible to apply. The eligibility window is 4 to 10 years in an independent position (see Eligibility Outline table). All such positions are counted in the 10-year total. Instructor-level positions are not counted as independent for eligibility purposes. In some cases, LLS may ask for a letter from any applicable institution confirming employment start date(s). As a new policy starting in the 2022-2023 cycle, all non-mentored positions will be considered as independent for purposes of the eligibility window. Therefore, research assistant professor and similar positions will count towards the eligibility window. For example, if you were a research assistant

professor for 5 years and a tenure-track assistant professor for 6 years, you would have 11 years of experience and you would therefore be ineligible to apply. One criterion is publishing (or the ability to publish) in the non-mentored position, in which case this type of position will be considered as part of the 4-10 year eligibility window.

CDP Eligibility Outline for 2022-2023 Application Cycle

	Scholar	Scholar in Clinical Research	Special Fellow (2-year)	Special Fellow (3-year)	Fellow
Degree	MD, PhD, DVM, or equivalent	MD, PhD, DVM, or equivalent	MD, PhD, DVM, or equivalent	MD, PhD, DVM, or equivalent	MD, PhD, DVM, or equivalent
Earliest oral thesis defense date	N/A	N/A	June 30, 2018	June 30, 2019	June 30, 2020
Most recent oral thesis defense date	N/A	N/A	June 29, 2019	June 29, 2020	Full application due date
***Total* postdoctoral experience as of the funding start date**	N/A	N/A	5 years	4 years	3 years
Independent faculty position required?[a]	Yes	Yes	No	No	No
Earliest start date of independent position[a]	January 1, 2015	January 1, 2013	N/A	N/A	N/A
Most recent start date	January 1, 2021	January 1, 2019	N/A	N/A	N/A
Applicant R01-level funding required?[b]	Yes	No[c]	No	No	No
Sponsor R01-level funding required? (For Sponsors with *more* than 5 years of experience)	N/A	N/A	Yes	Yes	Yes
Sponsor R01-level funding required? (For Sponsors with *less* than 5 years of experience)	N/A	N/A	No[d]	No[d]	No[d]
At least 1 first author publication required?[e]	Yes[f]	Yes[f]	Yes[f]	Yes[f]	Yes[f]

	Scholar	Scholar in Clinical Research	Special Fellow (2-year)	Special Fellow (3-year)	Fellow
At least 1 corresponding author publication required?[e]	Yes[f]	No	No	No	No

[a] Mentored faculty positions (e.g., Instructor) do not count as independent; all non-mentored positions *do* count as independent (see Experience/eligibility clock section)
[b] See Research Support Requirement section
[c] Funding may come from any source, but must be able to fund the active/proposed studies
[d] For Sponsors with less than 5 years of experience, adequate funding may come from an R00, institutional startup funds, or other grants to sufficiently support the research.
[e] Full length, primary research publication (no reviews, perspectives, conference/meeting presentations, or abstracts)
[f] Peer reviewed manuscripts that are *fully* accepted by the eligibility due date are acceptable. (see Eligibility section)

Career Trajectory
The Scholar in Clinical Research award applicant must be in the early/mid stages of a career in blood cancer clinical research. The anticipation is that Scholar in Clinical Research awardees will eventually be leaders in clinical blood cancer research and/or treatment.

Institution Affiliation
Applicants must be affiliated with a non-profit academic institution at the time funding commences and for the duration of the award.

Research Support Requirement
The Scholar in Clinical Research Award supports only salary for the awardee and an assistant. Applicants must have funding for their research program. This funding may come from the NIH, foundations, industry, or from the applicant's institution. The presence of funding will be assessed at the eligibility phase, while the details of that funding will be assessed after full application submission (evidence of adequate funding will be a major aspect of the review process). In cases where funding starts after the eligibility due date, the applicant must send evidence to researchprograms@lls.org from the funding agency of the award details (including funding agency, type, total and annual award amounts, start date, and end date). This must be received by LLS by the full application due date.

Research support that ends prior to the Award start date may not be used as evidence of research support.

Application Limitations
Applicants may only submit one application. There is no limit to the number of applications submitted from a specific institution, nor is there a limit to the number of Scholar in Clinical Research (or Scholar) applications on which a Sponsor is listed.

Other Career Development Support
No other equal or better career development-type award (as measured by the total award amount) may be held at the time of the award start date. If an equal (or better) career development-type award is activated after receiving a Scholar in Clinical Research Award, the LLS award must be relinquished. Those who have previously held an equal (or better) career development-type award **may** apply for a CDP Award.

If a career development-type award (of lower total value) is held by the applicant, this funding may be held concurrently with the LLS award at LLS's discretion, should the LLS award be funded. In all such cases, the LLS funding may only be used to support the applicant/awardee's salary (and that of an assistant who is directly involved in the clinical research). In addition, an absolute requirement is that the other funding must support blood cancer research. Career development-type funding from organizations that are focused on diseases other than blood cancer may not be held concurrently with the Scholar in Clinical Research award. This requirement reflects the necessity that the research of a Scholar in Clinical Research should be fully (or largely) focused directly on blood cancer.

Transfers
The application must be designed from the perspective of where the research will be performed. If a transfer is being considered, notify LLS at least 30 days prior to the transfer date by contacting researchprograms@lls.org. **Since applicants are judged in part on their institutional environment, a change to a new institution may affect the review of your application.** If a transfer is agreed upon by the applicant and a new institution after the in-person review meeting (or if LLS is notified of such a transfer after the in-person review meeting), the award may be re-reviewed by both LLS staff and select members of the review panel. If LLS staff and the review panel members agree that this move is beneficial, funding will be awarded. ***However, there may be cases where the award may not be funded.***

Change in Applicant or Awardee's Status
Applicants must be full-time, independent investigators at an academic institution. If this status changes at any time, LLS must be notified immediately. In some cases, the Scholar in Clinical Research award may continue, but only if the awardee's other work is clearly Mission-relevant and associated with a non-profit entity. However, a significant portion of the time must still be spent as an investigator at an academic institution. Should an applicant or awardee obtain a position at a for-profit entity, even part-time, they are no longer eligible to hold the Scholar in Clinical Research Award. Any funds dispersed after this change in status making the awardee no longer eligible must be returned to LLS.

Clinical Relevance

Supported Scholars in Clinical Research are seeking to translate new concepts in the biomedical, epidemiological, or preventative sciences into clinical practice. The research must **directly** involve blood cancer patients (and/or survivors), and generally involves investigator-initiated clinical trials. Research that is mostly laboratory-based using model systems is not appropriate for the Scholar in Clinical Research Award (but may be appropriate for the Scholar Award). Preference will be given to those whose clinical research is being developed and

implemented by the applicant. Ongoing collaborations and sponsorships of clinical research by industry sources are acceptable.

Review Process & Applicant Notification

CDP applications are reviewed by an independent, voluntary panel of experts.

Review criteria for **Scholar in Clinical Research** applications include:
- Likelihood of the applicant becoming a leader in the clinical blood cancer research field
- Likelihood that success in the applicant's research program will positively impact the treatment of blood cancers
- Accomplishments of the applicant, including demonstrated record of blood cancer clinical research engagement
- Innovation of current and future research program
- Access to applicable key materials and models, including patient materials, animal models, drugs, etc., to demonstrate feasibility of research program
- Clarity of presentation
- The institution's support for the applicant's research program and career advancement, as demonstrated in the Sponsor Letter
- Clear evidence of funding to support the clinical research program

Based on these criteria, the application receives a Priority Score based on the NIH scoring system.

After the review panel meeting, applications will be rank-ordered based on their Priority Score and those at or near the payline will be presented to LLS's oversight committees for approval. Funding will be based on ranking and LLS priorities. Funding status is relayed by email only and is not available by phone. All Priority Scores are confidential and are available only to LLS oversight committees and staff. Brief, anonymous feedback from the review panel may be provided, but only when available.

Applicants can see the status of their application on the [LLS Research Portal](#). Up until final decisions are made, the status will be "Under Review." After final decisions are made, the status will either be "Awarded," "Waitlist" or "Not Funded." Please do not call or email regarding status updates.

Key Dates

Applicants can begin the application process once the program is open and can move through each step up until the deadline. Note that each step can be submitted early. As long as each step is done thoughtfully and meticulously, there may be an advantage to progressing through the steps well ahead of the deadlines.

Phase	Date
Eligibility Phase: open	August 1, 2022
Eligibility Phase: close	November 1, 2022, 3:00 PM (ET)
Eligibility determination by LLS staff	Rolling
Notification of eligibility	By November 4, 2022 (Starting October 1, within 5 business days after submission)
Abstract Phase: open	Immediately after eligibility is approved
Abstract Phase: close	November 8, 2022, 3:00 PM (ET)
Full Application Phase: open	Immediately after Abstract Phase submission
Reference letters due	December 16, 2022, 3:00 PM (ET)
Full Application Phase: close	December 16, 2022, 3:00 PM (ET)
Award Notification*	May 2023
Award Start Date	July 1, 2023

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

The 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 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. Every year, a few applicants get caught with difficulty near the deadline. Some people who tried to submit after the deadline did not have their application reviewed. ***The best way to avoid this problem is to submit every phase well ahead of the deadline.*** In addition, those who are working on their grant right up until the deadline are more likely to make mistakes that may reduce the fundability of the grant.

General Application Instructions

The CDP application process consists of 3 distinct phases: Eligibility*, Abstract*, and Full Application.* Below are step-by-step instructions for applying:

1. Read these Guidelines & Instructions in full.
2. Log in to the LLS Research Portal (https://lls.fluxx.io/) and select Career Development Program. Click "Apply Now" to begin the application process (well ahead of the deadline).
    o If you have applied to LLS in the past, you do not need to create a new registration and can log-in with your username (email address associated with your account) and your password. If you forgot your password, 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.
    o If you are a first-time user to the LLS Research Portal, please complete the intake form located at this link: Account Creation Request so an account can be created for you.
3. Familiarize yourself with the LLS Research Portal.
4. Follow the instructions on the LLS Research Portal and this document to complete and submit your Eligibility Phase components. The Eligibility Phase requires completion of both the web form and the current eligibility form, which should be downloaded from the Project Document section of the web form.
5. You will receive an email notifying you of your Eligibility approval status. Starting October 1, this email will typically be sent within 5 business days. Once your Eligibility is approved, return to the LLS Research Portal, select "New or Pending" under Requests on the left panel and follow the instructions on the site and in this document to submit your Abstract Phase components.
    o You may be contacted by an LLS staff member if the information provided on your eligibility request suggests that you may be better suited for a different award category.
    o LLS staff will determine eligibility on a rolling basis using the criteria described in this document.
6. Reference letters requests are required during the Abstract Phase. Applicants are responsible for making sure that all required reference letters are submitted by their letter-writers by the Full Application deadline.
7. Once you have submitted your Abstract Phase information, you may immediately begin the Full Application Phase. Please carefully follow the instructions on the LLS Research Portal and this document. The Full Application Phase requires completion of both the web form and the current application template, which should be downloaded from the Project Document section of the web form. **Failure to follow all application instructions may result in administrative disqualification of your application.**
    o Contact researchprograms@lls.org with any questions about the application that are not addressed in the LLS Research Portal or this document.
8. Submit your Full Application to LLS prior to the Full Application deadline. We strongly recommend submitting well before the deadline, as site traffic on the day of and days leading up to the deadline will be heavy.
9. 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 rejected.*

10. 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 rejection of your application.***

11. 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, <u>even if someone else submits on your behalf</u>.

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.

*Information provided at the earlier phases must match that provided at later phases. *Divergence between information provided at the Eligibility and/or Abstract Phases and information provided at the Full Application Phase **may result in administrative disqualification; if not disqualified, any divergence may be shared with the review committee.***

<u>Detailed Eligibility Phase Instructions</u>

Applicants may submit Eligibility Phase components upon opening of the program. There are both webform components and an eligibility template that you must obtain from the LLS Research Portal. Your completed eligibility template must be uploaded onto the LLS Research Portal. Eligibility will be evaluated by LLS scientific staff on a rolling basis (see the Eligibility Review section below). If eligibility is approved, the applicant may proceed to the next phase of the application process. If eligibility is rejected, the applicant may submit one more time if new information is provided and the eligibility deadline has not passed.

All information requested on the eligibility form must be provided.

<u>The eligibility template is lengthy</u>, and you must sign this form prior to uploading. Therefore, it is highly recommended that this process is started <u>well before</u> the eligibility deadline.

Submission and Confirmation

You will receive an automated email stating that your information was successfully submitted within 2 business days of submission. If you have not received this email within 2 business days, contact researchprograms@lls.org. **It is recommended that you confirm each stage of the application process by checking your application status on the LLS Research Portal; submitted eligibility, abstract phase, and full application phases will be located in the "Submitted" Requests on the left side of the screen.**

Eligibility Review

LLS scientific staff will review eligibility on a rolling basis, and you will generally receive notification within a few days, though there may be delays in August and September. Starting October 1, you should receive notification within 5 business days. Refer to Key Dates for details. **If you have not received notification within 10 business days for August or September submissions, or if you have not received notification within 5 business days starting October 1, contact** researchprograms@lls.org.

If eligibility is accepted, you will have access to the Abstract Phase.

During the Eligibility Phase, the applicant should carefully consider who will write reference letters on their behalf and alert them of the due date for these letters (See Reference Letters subsection in the Detailed Abstract Phase Instructions). Letters submitted past the deadline will not be accepted. It is therefore beneficial to have a backup letter-writer in case one of your original writers is not able to submit on time.

Detailed Abstract Phase Instructions

There are two main aspects of the Abstract Phase:
- Reference Letters
- Project Information

The reference letter information can be added as soon as the application moves to the Abstract Phase. It is recommended to complete the reference letters information before starting the Project Information components, so that the writers get their submission instructions early (more details are found in the next section). Completion of the reference letters section by the applicant must happen prior to final submission of all Abstract Phase components.

Reference Letters

The applicant must have reference letters submitted on their behalf. These letters must be submitted directly by the letter-writers to the LLS Research Portal. (See Initiating Blind Reference Letters below).

It is the responsibility of the applicant to ensure that the letters are submitted in the LLS Research Portal and received by the deadline. Letters received by LLS after the deadline will not be accepted.

If there are not at least 3 letters of reference received by the full application deadline, the application will be administratively disqualified.

Reference Letter Policies
- Three letters are required
- It is beneficial to have a backup letter-writer in case one of your original writers is not able to submit on time
- No more than four letters will be accepted
- Though not required, it is beneficial to have two of the letters coming from outside your institution
- Letters are blinded to the applicant and must be uploaded directly by the writer
- **The Sponsor Letter is separate from the reference letters and therefore is <u>*not*</u> considered one of the three reference letters; Sponsor information should <u>not</u> be provided in the reference letters section on the <u>LLS Research Portal</u> (see Sponsor Letter section)**

Initiating Blind Reference Letters

During the Abstract Phase, the applicant must contact those who will write their reference letters. A section called "Request Blind Reference Letters" is available on the <u>LLS Research Portal</u> during the Abstract Phase. For each letter-writer, press the green "+" button on the right side. A pop-up window will appear. Copy and paste the first name, last name, and email address of the letter-writer into the designated spaces. After adding this information, press "Create Recommendation." The pop-up will disappear, and an email will be automatically sent to the letter-writer. The email will contain a unique link that allows the writer to directly upload the letter to the <u>LLS Research Portal</u>. This process is repeated for each of the letter-writers.

The email may end up in the letter-writer's spam. Therefore, after the letter-writer's information is added in the <u>LLS Research Portal</u>, **it is critical for the applicant to follow up with each writer to be sure they received the email.** If they have not received this email within 2 business days, email <u>researchprograms@lls.org</u>, and the link will be re-sent to them.

The letters will not be viewable by the applicant. However, the applicant can view reference letter status on the <u>LLS Research Portal</u>. Prior to each letter's submission, a note will be visible to the applicant indicating that no letter is uploaded. After the letter is uploaded, this note will change to indicate that the letter has been submitted.

<u>Project Information</u>

Provide the following after completing the initiation of blind reference letters. All information provided here must remain consistent in the full application. ***Significant divergence between information in this section and in the full application may negatively affect your funding chances.***

Project Summary

For funded applications, we post awardee information on our website. Together with the applicant's biographical information, there is a short Project Summary of the applicant's research. From there, a reader may choose to look at the longer Lay Description. Therefore, please provide a 3-5 sentence Project Summary describing your work. The total of all

sentences should be no more than 500 characters, including spaces. Use this guide to structure the short paragraph:

- Overall question/focus of your research (1 sentence)
- High-level approach you will use to address this question (1 to 2 sentences)
- Outcome/goal of your research (1 to 2 sentences)

The overall goal is to provide a succinct overview of your research in a short, cohesive paragraph.

Lay Description
The Lay Description should clearly describe your overall research program, its relevance to blood cancer, and how success in your overall program will improve the treatment of blood cancer. Use 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 minimum of 2,000 characters and a maximum of 2,500 characters, including spaces.**

Helpful hints:
- Consider how you would communicate your research to a friend or family member who is educated *but is not a scientist.*
- Limit the use of scientific terms that are specific to your field.
- When specific scientific terms are necessary, be sure to include a brief definition.
    - When in doubt, err on the side of over-explaining.
- Avoid using too many acronyms and always define acronyms before using (except for common acronyms like "DNA").

Use the following list of questions as a guide for creating your Lay Description:
- What are the overall problems that your research program is addressing?
- What are the goals of your program? How does if fit into the overall problem?
- What is unique about *your* research? You must describe the specifics of your research and approach while avoiding being overly generic.
- What will be the indicators for success of your research program?
- How will your research benefit blood cancer patients now or in the future?

Scientific Abstract
The Scientific Abstract should accurately reflect your overall research program. Though putting your research in a broader context may be useful, it is also important to avoid overstating your research beyond your actual research activities. Do not use disease names or other terms that are not directly relevant to your research. **1,500 characters maximum, including spaces.**

Brief Biography
Provide a brief, professional biography introducing the applicant to a lay audience. **1,000 characters maximum, including spaces.**

Submission and 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, contact researchprograms@lls.org.

Immediately after Abstract Phase submission, you will have access to the Full Application Phase and may proceed with the application.

Changes

Information collected in the Abstract Phase will automatically populate fields in the Full Application Phase. Changes may be made with LLS approval if requested prior to the Full Application Phase deadline. Email researchprograms@lls.org requesting any change and identify the elements to be changed. No changes may be made after the Full Application Phase deadline has passed. Abstract Phase components must accurately reflect the focus of the full application. Furthermore, the exact wording of the Project Summary, Lay Description, and Scientific Abstract must be provided in the full application. **Failure to follow these policies may result in disqualification of the application.** See the first paragraph in the Project Information section above.

At this stage, the applicant should follow up with those chosen to write reference letters to remind them of the upcoming deadline for letter submission.

Detailed Full Application Phase Instructions

Some sections of the full application will carry through from the Abstract Phase. Information that carries through must not be modified; changes made to the Abstract Phase components after the Abstract Phase deadline without LLS approval may result in administrative disqualification of the full application. The remainder of the full application consists of web form components and elements to be uploaded as a ***single PDF.***

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

Two sections are required for the uploaded PDF:
- Section 1: Project Description Template
- Section 2: Attachments

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

The template consists of the required elements listed in the Project Description Template Components section. You will find detailed instructions for each element on the full application template. Please ensure that you provide all requested information. If you have any questions regarding these elements, please contact researchprograms@lls.org. **No information may be attached to the beginning of this template; such added information may result in administrative disqualification of the application.**

Use Arial 11 pt. black font. ***The figure legends must be a separate text box that uses Arial 11 pt. black font.***

Should any font be smaller than Arial 11 pt., the application <u>may be administratively disqualified without review</u>.

The figures themselves *may* have smaller text size and/or a different font. However, it is to **your advantage** to have figures that are easily readable by the reviewers. Reviewers who have difficulty understanding your figure, which often happens with small text within the figure, will more likely downgrade the score of your application.

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 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 rejection of your application***. (We also anticipate very little pasting from other sources).

<u>**Project Description Template Components**</u>

- o **Applicant and Project Information:** Provide Name, Institution, Research Program Title, Project Summary, Lay Description, and Scientific Abstract. **Note**: This information must be directly copied directly from the Abstract Phase.
- o **Protected Time for Research:** This section lists time allocated for all duties (clinical, administrative, teaching, research, etc.) both currently and if funded. It is critical that protected time for research, if funded, is sufficient to make research contributions (~20-40% protected time for research). Also indicate how receipt of the Scholar in Clinical Research award will enhance your clinical research activities.
- o **Research Funding to Support Research Program:** Describe your funding sources that are/will support your current and research described in the application. This information should be readily verifiable and will form a critical component of the review panel's assessment of the feasibility of your research program.
- o **Education and Mentorship:** Describe your education and mentorship responsibilities.
- o **Prior Research List*:** List up to 3 of your most recent publications (first and/or corresponding author) in chronological order.
- o **Prior Research Accomplishments*:** Brief description of your most significant contributions to science.
- o **Current Non-Blood Cancer Research:** Brief description of all current research activities that are not directly related to blood cancer (and that do not use blood cancer patients and/or models).
- o **Current and Future Research Program and Graphical Abstract***
    - **Description of Models, Reagents, and Trials:** All model systems, reagents, and trials mentioned in your current and future research program, including figures, must be described here. ***Any drug used in a clinical trial associated with your research <u>must be listed here</u>.*** This provides reviewers with an easily accessible reference source and demonstrates feasibility of your research plans.

- **Graphical Abstract:** Provide up to two graphical abstracts to describe some aspect of your research program, such as signaling pathways, overall approach, etc. This provides reviewers (and others) with a quick overview of your research. This is similar to the graphical abstract in a Cancer Cell paper. Graphical abstracts must not be professionally developed. They must be developed primarily by the applicant using tools readily available in a typical lab (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. Do not rotate the image; it must be viewable by the reviewer without rotating the page. ***Do not simply have a diagram of a clinical trial as the major aspect of your graphical abstract.*** Avoid excessive use of words.
- **Current and Future Research Program:** Provide all current clinical research projects you are leading and integrate with your future plans. This provides the opportunity for reviewers to assess your innovative approaches and the impact they may have on blood cancer treatment.
    - If you do not have direct and demonstrable access to materials, access should be confirmed through letters of collaboration/support from the supplier. Lack of clear access to materials may indicate feasibility issues which may negatively affect the review of your application.
    - The text (and figure legends) in this section must clearly identify the model system(s) with enough description so that the reviewer understands the system. Use appropriate descriptors which may then refer to details in the Description of Models, Reagents, and Trials section.
    - Applicants may ***not*** refer to any attached manuscripts for "extended data." Any data discussed in the research program must be a figure, a citation referring to a published paper, labeled as "manuscript under review" or "data not shown."
- **References:** Refer to the application template.
- **Applicant's Corresponding Author Publications****
- **Access to Non-Commercially Available Reagents, Drugs, and Models:** Confirm that you have (or will have) access to all reagents, drugs, and models necessary for your research. This will be another component to assess the feasibility of your research.
- **Other Grant Applications:** List other grants or awards that you are currently applying for or are awaiting a funding decision. If funding decisions on other grant/award applications occur during the application or review phases, you must inform LLS. If your Scholar in Clinical Research Award is funded, you must also indicate whether other award notices occur for grants/awards that may overlap or conflict with the Scholar in Clinical Research Award.
- **Budget:** Refer to the application template.
- **Budget Justification:** Use this section when salary for an assistant is requested. The assistant salary must be directly tied to the clinical research activities presented. The assistant must be an employee of the applicant's institution and must directly interact with the applicant.
- **Signature Page:** Please ensure all signatures requested are complete. *Electronic signatures are acceptable.*

*Prior, current, and future research will form an essential part of the review process. Reviewers will use these sections to assess the quality of your clinical research and the likelihood that you will become a leader in blood cancer research.

**Applicant's Corresponding Author Publications
Using the *Blood* citation format, list all primary research, corresponding-author publications following the instructions on the template.

> **Include:**
> • Corresponding author publications, including multiple corresponding author publications (corresponding authorship must be verifiable on the manuscript)
> • Primary research-oriented publications, including clinically oriented publications (must be primary observations/analyses)
> • Peer-reviewed publications that are available on PubMed or the journal's website by the full application due date (full text must be available in one or both locations)
> • Peer-reviewed manuscripts that have been accepted for publication; accepted manuscripts that are not yet published must be provided as an attachment and must also be accompanied by a copy of the correspondence from the journal indicating acceptance

> **Do <u>not</u> include:**
> • Publications on which you are not corresponding author
> • Non primary research-oriented publications (reviews, perspectives, etc.)
> • Methods papers
> • Conference presentations
> • Manuscripts submitted, under review/revision, or those only found on a preprint server
> • Manuscripts accepted that are not accompanied by correspondence from the journal (see prior section)

Applications will be checked by LLS scientific staff for accuracy. **Significant deviations from publicly available information may result in administrative disqualification.** An example includes, but is not limited to, the inclusion of a publication where the applicant indicates corresponding authorship, but the manuscript does not indicate corresponding authorship, co/dual corresponding authorship, etc. *In addition, inclusion of papers not verifiably accepted for publication, or the inclusion of reviews or conference presentations, may cause an administrative disqualification of the application.*

<u>Section 2: Attachments</u>
The following sections must be attached to the end of the template (from Section 1) to create a single PDF. Attach in the order stated on the application template. No other information may be provided in this section.

<u>NIH Biosketch and Other Support documents.</u>
Biosketch and Other Support documents must be provided. Please refer to the NIH guidelines for questions on how to fill out these documents. An eRA Commons User Name is not required. The Other Support document *must be a document separate from the biosketch.* You do not

need to switch to a new version should the NIH update any format during the application process. Therefore, use the most recent format as of August 1 of this application cycle (though you may use a later version if you wish and if one becomes available).

Sponsor Letter
The Sponsor Letter must contain the following:
- Description of the applicant's position
- Description of the Institution's support for the applicant's research and clinical activities
- Description of the potential of the applicant to become a leader in clinical blood cancer research
- Future plans for the applicant's career development at the Institution
- Description of how the applicant's time will be divided among research and other responsibilities to the Institution

The Sponsor Letter is separate from the reference letters; **Sponsors may not write a letter of reference. The Sponsor Letter is not blinded to the applicant.**

Collaboration/Support Letters (Required where applicable)
When there are significant collaborations, letters of support are helpful. This is critical when access to patient samples, animal models, or specialized equipment outside of the applicant's laboratory or department is necessary for the proposed research. If a company asset is required and is not commercially available from scientific supply companies, such as proprietary drugs, a letter from the company supplying this asset ***must*** accompany the application. The letters must be signed and must be provided on institutional/company letterhead. It must be clear that any drugs used in clinical trials described in the application are readily available for this purpose. ***Failure to provide this information will negatively affect the review of your application.***

Collaboration/support letters must be short-typically 1 or 2 brief paragraphs. Each should briefly describe what support will be given to your research program. **These letters should avoid any lengthy description of the positive attributes of you or your research** (a sentence or two is fine), otherwise, they will be considered letters of reference. ***There can only be 4 total letters of reference (submitted separately), otherwise the application may be administratively disqualified; therefore, instruct each writer of a collaboration/support letter to largely restrict their letter to the collaboration and/or service provided <u>to prevent their letter from being considered a letter of reference</u>.***

Letters attached must not be letters of reference. All letters of reference must be uploaded separately by the writer (and blinded to the applicant). ***Outside of the Sponsor Letter, any letter attached to the application that is <u>not</u> primarily a letter of collaboration and/or a letter stating access to materials and/or other resources may be administratively disqualified.***

Clinical Protocol (Required where applicable)
Provide a summary (up to two pages) of any clinical protocols essential to the current/proposed research program, including the NCT number. Include approval date and compliance number.

Indicate if IRB approval is pending and provide a letter from the institutional official regarding IRB status. ***Do not include the full protocol as an attachment.***

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

Assurances (Required)

All assurances that are applicable to your research must be accompanied by a signed letter from the appropriate institutional official, including assurances that are pending. Do not send letters signed by yourself nor from anyone outside of the designated institutional offices.

Any application without these letters attached will not be reviewed.

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.

Manuscripts (Optional)

Manuscripts may be attached using the following rules. ***Applications that do not follow these rules may be administratively disqualified without review.***
- Up to three manuscripts
- You must be first author and/or corresponding author on the manuscript (co-first and/or co-corresponding authorship is acceptable)

- These must be primary research manuscripts and must not be reviews, perspectives, or primarily methods
- Manuscripts must be either under review or accepted but not yet available on PubMed or the journal website by the full application due date
- Each manuscript *must* be accompanied by a copy of correspondence from the journal indicating the status of the review
- Manuscripts that are on a preprint server, but not under review *cannot* be attached; there is a separate section of the template where you may provide a link to preprint manuscripts that are not under review

No attachments besides those listed above should be included, nor should there be any attachments preceding the template (e.g., no cover letters). Applications that include additional documents besides those requested may be administratively disqualified.

Uploading the project document and final submission

Upload the full application components, as a single PDF, in the Project Document section on the web form.

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

Check each page of your PDF before uploading to be sure that everything is present and there are no issues with the text/figures. Changes to your PDF are <u>not</u> allowed past the deadline.

Submission and 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. **It is recommended that you confirm each stage of the application process by checking your application status on the [LLS Research Portal](#); submitted eligibility, abstract phase, and full application phases will be located in the "Submitted" Requests on the left side of the screen.**

Only one application document and one eligibility request 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; <u>there are no exceptions to this rule</u>.***

Check the application prior to final submission. The applicant is ultimately responsible for the submission, regardless of who is uploading information on the [LLS Research Portal](#). Every year, we hear from a small number of applicants that notice problems with their

application after the deadline. Applicants will avoid this problem by carefully checking their application prior to final submission. Submitting well ahead of the deadline is also beneficial.

Once the deadline has passed, only the following updates may be made:
- Significant updates to clinical trials:
  - IRB updates
  - Opening of the trial
  - Patient enrollment
  - Opening of new clinical sites
  - Efficacy and/or safety updates
- 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
- Updates regarding any transfers to a new institution (see Transfers section in Eligibility).