LEUKEMIA & LYMPHOMA SOCIETY®

Career Development Program Guidelines & Instructions

Scholar in Clinical Research

July 1, 2023 – June 30, 2024

Application Deadlines	
Eligibility Phase deadline:	October 27, 2023; 3:00 PM (ET)
Letter of Intent Phase deadline:	November 15, 2023, 3:00 PM (ET)
Letters of Reference deadline:	December 1, 2023, 3:00 PM (ET)
Full Application Phase deadline:	December 1, 2023, 3:00 PM (ET)
Award Start date:	July 1, 2024

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What's New

Starting in a prior application cycle, the approach to the application and review process has fundamentally 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.

The application template format has changed. There are new requirements regarding the structure, and these requirements are meant to better capture a 5-year scholarly research program. We encourage applicants to present a thoughtful research plan, and the review panel will reward those with a robust, clear, and scholarly presentation.

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. 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.

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

The Leukemia & Lymphoma Society supports talented blood cancer researchers in the early phase of their careers through the Career Development Program (CDP). 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.

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 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 (or equivalent). Scholar in Clinical Research applicants ***must*** hold an independent position. However, this award is not intended for well-established and/or senior investigators; those who are full professors, or who will be as of the award start date, are no longer eligible to apply.

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 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 further consideration is the total publication record and productivity during the award period as well as career trajectory. Lastly, some consideration will include whether the applicant has complied with reporting requirements as well as reasonable requests from LLS, such as participating in an LLS event.** *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."

**LLS realizes that not all requests can be fulfilled by the CDP awardee, but if multiple requests are either ignored or are not fulfilled, then this information will contribute to the final CDP Achievement Award decision.

Eligibility

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. The Sponsor must be from the same institution and in a supervisory position relative to the applicant.
- 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).
- Not be a full professor as of the award start date.
- ***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 as of January 1 the year of the award start date (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.***

Citizenship

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

Degree and Training

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.

Experience/eligibility clock

Applicants must currently hold an independent, faculty-level position. As a new policy starting in the 2022-2023 cycle, those with the title of full professor (or equivalent) by the award start date 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) as corresponding author 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 2023-2024 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, 2019	June 30, 2020	June 30, 2021
Most recent oral thesis defense date	N/A	N/A	June 29, 2020	June 29, 2021	Eligibility Phase 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, 2016	January 1, 2014	N/A	N/A	N/A
Most recent start date	January 1, 2022	January 1, 2020	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 independence)	N/A	N/A	Yes	Yes	Yes
Sponsor R01-level funding required? (For Sponsors with equal to	N/A	N/A	No[d]	No[d]	No[d]

	Scholar	Scholar in Clinical Research	Special Fellow (2-year)	Special Fellow (3-year)	Fellow
or less than 5 years of independence)					
At least 1 first author publication required?[e]	Yes[f]	Yes[f]	Yes[f]	Yes[f]	Yes[f]
At least 1 corresponding author publication required as an independent investigator?[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
[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 equal to or less than 5 years of independence, 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 and that are published online (PubMed and/or the journal's website) by the full application 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). LLS will not change any aspect of the Scholar in Clinical Research award to accommodate other awards. 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.

Research Subject Matter

CDP applicants must have a research focus on hematological malignancies and relevant premalignant conditions. We are interested in all research studies on any of these subjects. The research may have a basic mechanistic focus to better understand these diseases or may be preclinical/clinical studies using any approach with the goal of achieving better therapeutic outcomes.

Immunotherapy-Specific Request for Proposals

We are particularly interested in funding the next generation of blood cancer researchers with an interest in immunotherapy. Researchers stepping up to the challenge of these important topics in blood cancer preclinical and clinical research are strongly encouraged to apply. All such studies should have the direct intention of improving blood cancer outcomes and must use the appropriate blood cancer models in their research plan.

- **Cellular Therapy**
  We are interested in novel and innovative approaches to advance the next generation of cellular therapies for hematological malignancies. We are looking to go beyond new targets to identify approaches that improve cellular therapies, including armored constructs and other novel vector design. We seek improved CAR T cells as well as other cellular hosts, such as NK cells. In addition, studies to understand and/or address CRS and ICANs are sought.

- **Other Immunotherapies**
  We seek new approaches to the broader spectrum of immunotherapies, including checkpoint inhibitors, vaccines, and antibodies (including bispecifics and ADCs). These approaches should harness biological insights of the immune response to identify more effective ways to approach immunotherapy in hematological malignancies.

- **Neoantigens**
  We seek to use the current knowledge of neoantigens to identify novel approaches to harness neoantigens for therapeutic development. The use of approaches that can rapidly go from individual patients to personalized therapies for each patient is encouraged. We are also interested in the novel use of broadly expressed neoantigens for new therapeutic approaches in hematological malignancies.

- **Tumor Microenviroment**
  We seek studies that use the current knowledge of the complex tumor microenvironment to identify novel therapeutic approaches that overcome the tumor suppressive aspects of the microenvironment. Further understanding of the biology of the tumor

microenvironment is welcome, but we will give greater consideration to strategies to overcome the tumor suppressive effects of the microenvironment.

- **Resistance**
  We are interested in a more complete understanding of resistance to all immunotherapies as well as innovative approaches to overcome this resistance. The use of samples from patients who have developed resistance to current immunotherapies, including those in clinical trials, is of high importance. Alternatively, the development and study of novel animal models of immunotherapeutic resistance is encouraged as well.

- **Combination Therapies**
  We are interested in studies that provide more effective outcomes using immunotherapy combinations. This research must be mechanistically well justified. The strategies may include combining immunotherapies to different targets based on tumor expression but may also include combinations intended to overcome resistance mechanisms.

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
- Quality of the scholarly presentation, including the ability to logically weave together a multi-project research program while making effective use of the space provided
- Access to applicable key materials and models, including patient materials, animal models, drugs, etc., to demonstrate feasibility of the 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	July 1, 2023
Eligibility Phase: close	October 27, 2023, 3:00 PM (ET)
Eligibility determination by LLS staff	Rolling
Notification of eligibility	By October 31, 2023
Letter of Intent Phase: open	Immediately after eligibility is approved
Letter of Intent Phase: close	November 15, 2023, 3:00 PM (ET)
Full Application Phase: open	Immediately after Letter of Intent Phase submission
Reference letters due	December 1, 2023, 3:00 PM (ET)
Full Application Phase: close	December 1, 2023, 3:00 PM (ET)
Award Notification*	May 2024
Award Start Date	July 1, 2024

**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 tried to submit after the deadline but 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 rushing 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*, Letter of Intent*, and Full Application.*

*Information provided at the earlier phases must match that provided at later phases. *Divergence between information provided at the Eligibility and/or Letter of Intent 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.***

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).
    - 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.
    - 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, which happens after LLS staff review. It typically occurs within 24 hours, but may take up to 10 business days, which means you will benefit by doing this step early. 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 Letter of Intent Phase components.
    - 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.

- LLS staff will determine eligibility on a rolling basis using the criteria described in this document.

6. Reference letters ***requests*** are required during the Letter of Intent 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 Letter of Intent 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 must 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.**
   - 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, even if someone else submits on your behalf.

You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your application and prevent further modification at that stage. Contact researchprograms@lls.org if you submit in error (must be at least one hour prior to the deadline).

At any time during the application process, including after submitting your Full Application, you can check the status of your application by logging in to the LLS Research Portal, selecting your application (under Requests in either "New or Pending" or "Submitted"), and referring to the Status in the yellow box at the top of the page.

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

Detailed Eligibility Phase Instructions

Applicants may submit Eligibility Phase components upon opening of the program. It is recommended to submit as soon as possible, as there is no benefit to waiting. 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. Write "N/A" for anything not applicable to you.

The eligibility template is lengthy, and you must sign this form prior to uploading. Therefore, it is highly recommended that this process is started well before 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, Letter of Intent, 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 24 hours, but the process may take longer. Refer to Key Dates for details. **Contact researchprograms@lls.org if you have not received notification within 10 business days.**

If eligibility is accepted, you will have access to the Letter of Intent Phase.

Prior to the Eligibility Phase deadline, 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 Letter of Intent 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 Letter of Intent Phase Instructions

Applicants may access Letter of Intent Phase components as soon as their eligibility request is approved by LLS. The components on our grants management system must be completed by the Letter of Intent Phase deadline. This includes reference letter writer request information, which must be input into our grants management system by this deadline (however, reference letter writers should be contacted well before this time). Once these components on our grants management system are submitted, the applicant will have immediate access to the Full

Application Phase components. Note that reference letters must be uploaded by the letter writers by the Full Application Phase deadline.

There are three main aspects of the Letter of Intent Phase:

- Reference letter requests (letter writer information added to our grants management system)
- Project information
- Collaborator information

The reference letter information can be added as soon as the application moves to the Letter of Intent Phase (after eligibility is approved). 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 Letter of Intent 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). Reference letter requests must be done by the applicant during the Letter of Intent Phase, but the letters must be submitted by the letter writers by the Full Application deadline.

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

- Reference letter information must be provided by the applicant at the Letter of Intent stage, but the letters are not due until the full application deadline
- Three letters are required
- No more than four letters will be accepted
- It is beneficial to have a backup letter-writer in case one of your original writers is not able to submit on time
- It is beneficial to add letter writer information to our grants management system as early as possible as well as to contact the letter writers early
- 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 *not* considered one of the three reference letters; Sponsor information should not be provided in the reference letters section on the LLS Research Portal (see Sponsor Letter section)

Initiating Blind Reference Letters

During the Letter of Intent Phase, the applicant must contact those who will write their reference letters. A section called "Request Blind Reference Letters" is available on the LLS Research Portal during the Letter of Intent 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 LLS Research Portal. This process is repeated for each of the letter-writers. If a name is added in error, such as your Sponsor's name (which does not belong here), it cannot be deleted. Simply move on and add the name(s) that are needed here.

The email may end up in the letter-writer's spam. Therefore, after the letter-writer's information is added in the LLS Research Portal, **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 researchprograms@lls.org, 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 LLS Research Portal. 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.

Project Information

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

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 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.

Title

Provide a succinct title to describe your research; 150-character limit, including spaces.

Research focus and details

Provide the following details that form the basis of your research. Only state information that is ***directly*** related to **your** research. This information must reflect what will be in your full application; significant divergence may negatively affect your funding chances.

For each section, provide brief details using these criteria:

- Only provide information of direct relevance to your research
- Provide either the full name or the acronym but do ***not*** include both
- For multiple items, separate each by a comma; do not hit enter within the text box

Provide details for these items:

- Disease or Subject Focus
- Technological Approaches
- Model System(s); if you are working with human patients, put "human patients" or "human patient samples"

Collaborators

List the names and institutions of all investigators, outside of your institution, with whom you have significant and current interaction regarding your research project/program or your career development. Individuals listed here may be contacted by LLS to verify their connection to your research.

- Include those who are outside your institution who you are collaborating with or who have a significant role in your career development
- Include only researchers who are at or above tenure-track level (or equivalent)
- Include only full names and institutions with no additional information
- Do not list their full institutional titles
- Do not include the names of those who are writing letters of reference

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 Letter of Intent Phase submission, you will have access to the Full Application Phase and may proceed with the application.

Changes

Information collected in the Letter of Intent Phase will automatically populate fields in the Full Application Phase. Carefully and thoughtfully complete these sections as the fields are locked after the Letter of Intent Phase is completed. Letter of Intent Phase components must accurately reflect the focus of 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 Letter of Intent Phase. Information that carries through must not be modified; changes made to the Letter of Intent

Phase components after the Letter of Intent Phase deadline 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.

Three sections are required in this phase:

- Section 1: Abstracts and Brief Biography (webform and template in Section 2)
- Section 2: Project Description Template
- Section 3: Attachments

Section 1: Abstracts and Biography

Lay Description

The Lay Description should clearly state the relevance of your research to blood cancer and describe your current/proposed research, including the problem/question to be addressed, approaches, and anticipated results using non-technical language that is easily understood by the lay community. Scientific/Greek characters or symbols must not be used. The Lay Description is essential for LLS to continue successful fundraising to support our current and future grantees, including the later years of ***your*** award, should it be funded. Thus, we require a well-written Lay Description, with sufficient detail and suitable language for non-scientists. Be aware of your confidential information, as the Lay Description (and 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 nor a clinician.*
- Limit the use of scientific/medical 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 them before using (except for common acronyms like “DNA”).

Use the following list of questions as a guide for creating your Lay Description:

- What is the overall problem?
- What are the goals of your research program? How do these 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 in your program?
- What are the longer-term goals of your program?
- How will your research benefit blood cancer patients now or in the future?

Scientific Abstract

The Scientific Abstract should accurately reflect your research (current/proposed). Though putting your research in a broader context may be useful, it is also important to avoid

overstating your research beyond what you are actually doing. 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.**

Section 2: 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 (as well as below). 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 in each section of the application. This includes figure legends, which must be a separate text box that uses Arial 11 pt. black font.

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.

Outside of the figures themselves, should any font be smaller than Arial 11 pt., the application may be administratively disqualified without review.

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).

Project Description Template Components

- **Applicant and Project Information:** Provide Applicant Name, Institution, Research Program Title, Summary, and Scientific Abstract.
- **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.
- **Research Funding to Support Research Program:** Describe your funding sources that are/will support your current and future research program. 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.

- **Education and Mentorship:** Describe your education and mentorship responsibilities.
- **Prior Research List*:** List up to 3 of your most recent publications (first and/or corresponding author) in chronological order.
- **Prior Research Accomplishments*:** Brief description of your most significant contributions to science.
- **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).
- **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 must be listed here.*** This provides reviewers with an easily accessible reference source and serves to demonstrate feasibility of your research plans.
- **Graphical Abstract:** Provide up to two graphical abstracts to describe some aspect of your research, such as signaling pathways, overall approach, etc. This is similar to the graphical abstract in a Cancer Cell paper and provides reviewers (and others) with a quick overview of your research. Graphical abstracts must not be professionally developed. They must be developed primarily by the applicant using tools readily available (e.g., PowerPoint, Photoshop, Adobe Illustrator, BioRender, etc.). You will be judged on your ability to convey information in a simple manner, but you will not be judged on artistic ability. Do not rotate the image; it must be viewable by the reviewer without rotating the page. Avoid excessive use of words. Do not simply have a flow diagram of a clinical trial as the major aspect of your graphical abstract.
- **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.
    - Avoid describing only 1 clinical trial in 3 aims. The intent of this section is to provide a broader overview of your research program, which should likely be larger than 1 clinical trial.
    - Follow the guidance on the template to present a thoughtful discussion of your plans for a 5-year research program.
    - ***Make appropriate use of the space provided. Though being unnecessarily wordy is discouraged, a 5-year research program should be robust, and should likely use much of the space provided. A clear, complete, and scholarly description of your research program is expected.***
    - 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.
    - Applications that appear to include writing and figures directly from the applicant's prior grant submissions will be unfavorably reviewed. Some

exceptions may be in sections describing background and/or previous work (but proper attribution is necessary). In addition, excessive and direct copying/pasting sections from publications is not acceptable. In cases where figures are used from publications, proper attribution must be clear in the figure itself, even if it is from the applicant's publication. Failure to follow these rules will negatively affect your application (as it has in prior application cycles).

- **Trial Diversity/Increasing Equitable Access:** Provide a discussion of the demographics of the patients affected by the disease(s) you are studying based on national data as well as data from your catchment area. This should include gender, race, ethnicity, age, and other categories, where applicable. Discuss how you will attempt to have concordance of any clinical research samples (patient materials and/or information from databases) with the demographic characteristics of the disease. For all clinical trials, state how you will attempt to match the demographic profile of that disease in your catchment area. For larger trials, state how you will also try to broaden the geographical reach of your trials, including to areas not well served by a major academic medical center. We understand that appropriate representation may not always be feasible but plans to address this should be considered. Lastly, integrate this discussion with the latest FDA guidance regarding expanding access to clinical trials.
- **Collaborations for Laboratory Research:** Describe all laboratory collaborations essential to your research program. Include laboratory researchers that are essential for achieving your research goals. This may include core facilities for sequencing and other services.
- **References:** Refer to the application template.
- **Applicant's Corresponding Author Publications Since Independence***
- **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:**
- **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 clinical research.

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

These must be:

- Corresponding author publications, including multiple corresponding author publications (corresponding authorship must be verifiable on the manuscript)
- Publications resulting from your independent career
- 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)

These must not be:

- Corresponding author publications that result from a prior mentored position
- 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 accepted but not yet published
- Manuscripts found only on a preprint server

Applications will be checked by LLS scientific staff for accuracy. **Significant deviations from publicly available information may result in administrative disqualification*. Failure to follow these rules may cause an administrative disqualification of the application.***

Section 3: Attachments

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

NIH Biosketch and Other Support documents.

Biosketch and Other Support documents must be provided and must follow the guidelines provided by the NIH. 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 July 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 at least 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 to prevent their letter from being considered a letter of reference.***

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 not primarily a letter of collaboration and/or a letter stating access to materials and/or other resources may result in administrative disqualification of the application.***

Clinical Protocol Summary (Required where applicable)

Provide a summary (up to two pages for each trial) 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 attach a full clinical protocol.***

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.

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 not 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, Letter of Intent, 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; there are no exceptions to this rule.***

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).