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Career Development Program Guidelines & Instructions

Special Fellow

Effective dates: July 1, 2017 - June 30, 2018

2017 updates

CDP and NIH K99 awards

LLS has made several changes regarding K99 awards:

- Special Fellows who receive a K99 award may keep their CDP award pending LLS approval.
- Current K99 awardees may apply for a Special Fellow award (if otherwise eligible).
- Dual K99/CDP recipients may convert part or all of their CDP award to non-salary expenses related to the project.

The purpose of this change is to broaden the pool of high quality applicants that will help LLS achieve its mission to cure blood cancers. See the *Other Career Development Support* section.

Blood cancer relevance

The purpose of the Career Development Program (CDP) is to enhance the careers of scientists researching blood cancer or normal blood biology that has relevance to blood cancer. Continuing from last year, there is an enhanced emphasis on this purpose. The proposal's blood cancer relevance and the Sponsor's (or co-Sponsor's) experience in blood cancer will both be important criteria of the review process. In addition to translational research, The Leukemia & Lymphoma Society (LLS) encourages basic research, technological development, and informatics pipeline development; however, all approaches must have direct blood cancer relevance.

To be sure to adhere to this policy, please carefully read the following sections: *Sponsor* Requirement, Optional co-Sponsor, Blood Cancer Relevance, Key Publications of Sponsor(s), and the Mission Score discussion in Review Process and Applicant Notification.

Competitive **Special Fellow** applicants will typically follow the same path of blood cancer-relevant research they have pursued in the first part of their postdoctoral training. In some cases, a Special Fellow may apply his/her former experience in a new direction, but this must be well-justified.

Lay abstracts

Lay abstracts are not asked for during the application process. Lay abstracts will be required of those selected for funding following Award notification. *The lay abstract is essential for LLS to continue successful fundraising to support our current and future grantees.* Thus, a well-written lay abstract suitable for the general public is required post-award. After the review meeting, LLS will contact top-ranked applicants regarding lay abstract submission. Wording modifications may be asked for in cases where LLS determines that improvements are warranted.

Key Points for Special Fellow Applicants

- Must be between 2 years and 4.5 years of the oral thesis defense as of January 1, 2018. Time in clinical training does not count towards this time for eligibility purposes. See the *Experience/Eligibility Clock* section for more details.
- Must have a Sponsor (or Sponsor/co-Sponsor pair) that has significant experience in blood cancer-relevant research. See the *Sponsor Requirement* and *Optional co-Sponsor* sections for more details.
- Research must be performed in a laboratory different from where the graduate research was performed and with a Sponsor different than the graduate mentor.
- Must have a training plan for career development in blood cancer research, which is outlined in the Sponsor Letter.
- Must have a Sponsor with adequate funding that supports the research proposed (see the *Research Support Requirement* section).
- Must propose research directly relevant to blood cancer.
- Must be on a clear trajectory to an independent career.
- Must demonstrate the need for continued funding.

Helpful pointers:

- Special Fellows who have established a research program within their Sponsor's laboratory, and who are approaching an independent career, will be most competitive.
- As it is required that the applicant's Sponsor have current grants to fund the proposed research (Special Fellow Awards are for salary support), it is expected that there will be some overlap with current research support. Applications that include writing and figures directly from their Sponsor's prior grant submissions will be unfavorably reviewed; the exception are figures in the Background section of the full application.
- It is highly recommended to access the LLS grants management portal to begin the application process well in advance of any deadlines.
- It is recommended that final submissions at each stage be completed the day prior to the deadline. No changes will be accepted past the deadline. The exceptions to this rule are

regulatory updates, significant updates to clinical trials and manuscripts accepted for publication (described in the *Submission and Confirmation* section).

General Information

About the Leukemia & Lymphoma Society, Inc.

The Leukemia & Lymphoma Society, Inc. (LLS) is a national voluntary health agency dedicated to the conquest of hematologic malignancies and relevant premalignant conditions. LLS supports research, patient aid, community service programs, advocacy, and public and professional education.

Description of Awards

Through the Career Development Program, LLS supports talented blood cancer researchers in the early phase of their careers. CDP continues to provide a pool of dedicated researchers to advance the understanding and diagnosis of cancer, as well as the development of treatment and prevention options that will ultimately lead to cures for blood cancer patients.

The **Special Fellow** Award is for 2 or 3 years depending on eligibility. The maximum award per year is \$67,000 and includes the applicant's salary and fringe benefits. A Special Fellow's salary may be supplemented by funds from another source. Indirect costs may be included, and cannot exceed 5% of the total direct costs requested in the proposal. The final value of the Award may be limited by the applicant's Sponsoring Institution's salary range. Expenditures for laboratory costs/equipment, travel, tuition, etc. are not permitted (some exceptions to this rule apply in the case of K99 recipients). The awarded value will be limited to the amount requested in the submitted proposal. It is anticipated that the proposed research will occupy a majority of the applicant's research time. However, there are no requirements for a certain percent effort in our budget template.

Who Can Apply

Citizenship

LLS welcomes applications from US citizens and non-US-citizens, as well as applicants who are performing research outside the United States.

Degree

Applicants must hold a PhD, MD, DVM, or equivalent degree by the award start date. Applicants may not be in a degree-granting program at the award start date.

Experience/Eligibility Clock

Applicants must have had their oral thesis defense at least 2 years, but no more than 4.5 years, at the time of review (January 1, 2018). When there is no required oral thesis defense, other events signaling the end of graduate training will be considered. In these cases, details must be provided in the Justification section of the eligibility form. In all cases, but typically after a successful oral thesis defense, LLS starts the eligibility clock as soon as an institution considers a former graduate student as having a PhD (officially conferred or not).

For MDs, the eligibility clock starts at the beginning of postdoctoral research training or at the end of clinical training, whichever comes first. Time in clinical training, where applicable, does not start the eligibility clock. Details of this training, with associated dates (including the month and day), must be clearly explained in the eligibility form. Any research training after medical school, but prior to clinical training, is considered postdoctoral training.

There should be no unexplained gaps in training.

In some cases, LLS may ask for a letter from any applicable institution confirming date(s).

For those who have spent time in any laboratory as a postdoctoral fellow (or equivalent), the eligibility clock does <u>not</u> start with the start date in your current laboratory.

LLS support for Special Fellows may not extend postdoctoral research training (excluding clinical training) beyond 7 years. Applicants who receive a Special Fellow Award will receive either two or three years of funding to comply with this requirement.

Pauses to the eligibility clock

The following events may be used as a pause in the eligibility clock:

- Parental leave.
- Military service.
- Visa delays that are caused by governmental agencies.

These events, including dates, must be stated in the Justification section of the web form. A letter from your current Sponsor or former advisor stating the nature of the leave or Visa delays and the dates should be sent to researchprograms@lls.org by the full application deadline.

There are no other acceptable pauses to the eligibility clock.

Career Trajectory

In general, Special Fellow applicants must have a recent track record that is directly relevant to blood cancer. In some cases, LLS and the review panel may consider Special Fellow applicants with little to no prior blood cancer experience, but there must be clear evidence of a path forward in a career in blood cancer. The Sponsor (or Sponsor/co-Sponsor pair) must be appropriate for this career path (see *Sponsor Requirement* and *Optional co-Sponsor* sections). The Sponsor Letter should detail the training plan for this career path.

Institution Affiliation

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

Sponsoring Institution's Acceptance of Contract Terms

Applicants who are offered a CDP Award will be sent a contract. The Sponsoring Institutional representatives must agree to these terms and return the signed contract by the deadline (May 1, 2018). Currently, the NIH does not accept LLS's contract terms.

Sponsor Requirement

All Special Fellow applicants must have a Sponsor who provides mentorship and research funding support for the proposed project. The Sponsor must be the head of the laboratory in which the applicant is performing, or will be performing, the proposed research. The Sponsor must be different than the applicant's graduate advisor and different from the head of the laboratory where the applicant's graduate research was performed.

Optional co-Sponsor

Applicants may have a co-Sponsor who will serve as a second mentor to their research project and career. A co-Sponsor is necessary in cases whereby the applicant's Sponsor does not have experience directly applicable to blood cancer or normal blood biology that has relevance to blood cancer. Conversely, a co-Sponsor may provide basic scientific or technical expertise to an applicant who's Sponsor does not have that expertise. Ultimately, it is up to the applicant as to whether a co-Sponsor is needed. When an applicant has both a Sponsor and a co-Sponsor, a Sponsor letter is required from both (see *Sponsor Letter* section). The review panel will look favorably on applicants with the most qualified mentorship, whether that be from a single Sponsor or a Sponsor/co-Sponsor pair. The co-Sponsor must be declared at the eligibility stage; any changes regarding a co-Sponsor after the eligibility stage must be approved by LLS.

CDP awardees will require letters from their Sponsor, and, where applicable, from their co-Sponsor as part of the annual progress reports.

The role of the co-Sponsor is <u>not</u> to provide an appropriate level of research funding support that is lacking with the primary Sponsor. If the primary Sponsor does not have adequate research funding, the applicant is not eligible.

Research Support Requirement

Fellow Awards generally fund only salary (see the K99 discussion in the *Other Career Development Support* section for an exception). Applicants must have Sponsors with active grant(s) (peer-reviewed, national-level; R01-equivalent) to support the research proposed in the application (or related research). This funding must not be a transitional award. In some cases, research support may come from substantial and sustained institutional support beyond a startup package when other funding is not available. The presence of funding will be assessed at the

eligibility phase, while the details of the blood cancer relevance of that funding will be assessed after full application submission. **Research support that ends prior to the Award start date** may not be used as evidence of adequate support.

Application Limitations

Applicants may only submit one application. There is a limit of one Fellow application per application cycle for each Sponsor, as well as one Special Fellow application per application cycle for each Sponsor. A Sponsor may have one Fellow applicant and one Special Fellow applicant in the same application cycle. There is no limit to the number of applications submitted from a specific institution, nor is there a limit to the number of Scholar applications from any Sponsor. It is also acceptable for a Sponsor who currently has an active Fellow and/or Special Fellow Awardee in his/her lab to sponsor a Fellow and/or Special Fellow applicant during another award cycle. It is highly recommended to coordinate this with your Sponsor, to be sure that there are no other Special Fellow applications coming from the same lab during this application cycle.

Other Career Development Support

No other comparable or better career development award (as measured by the total award amount) may be held prior to, or at the time of the Award start date. If such an award is activated after receiving a Special Fellow Award, the LLS Award must be relinquished.

The exception to this rule is regarding the K99 Award. Current K99 awardees may apply for a Special Fellow award, and current Special Fellow awardees may accept a K99 Award and keep the CDP Award, pending LLS approval. The aims of the K99 Award must be provided to LLS to ensure that the K99-funded research is relevant to LLS's Mission. If approved, funding from the Special Fellow Award may be used for any purpose related to the CDP application/award, whether it be awardee salary, technician salary, or research supplies, pending LLS approval. It is recommended that Special Fellow applicants and Special Fellow Awardees notify LLS of any developments in the K99 applicant process. Contact LLS at researchprograms@lls.org for questions about LLS's approval process for holding both awards.

Transfers

The application must be designed from the perspective of where the research will be performed. If a transfer is being considered, the applicant must submit the application based on work that will be performed in the new laboratory and contain the appropriate signatures from the new destination. In addition, the Special Fellow Award is issued to an individual, and thus is not transferable to another person.

It is anticipated that Special Fellow applicants will be contemplating applying for independent positions, and LLS encourages this career progression. Special Fellow Awardees who have been in their Sponsor's laboratory as a research fellow for one year (after the Award start date) are allowed to carry their funding with them should they receive a faculty-level position.

Blood Cancer Relevance

General

LLS encourages scientists of various disciplines to ask questions relevant to hematologic malignancies and/or relevant premalignant conditions/states. **Relevance is determined by the experimental approach.** Correlation of a biological phenomenon with blood cancer is *not* sufficient evidence of relevance to LLS's Mission, unless there are experiments to directly address this correlation. The proposed experiments must seek to answer questions about blood cancer or normal blood cell function of relevance to cancer. There must also be research funding support for this research (see *Research Support Requirement* section).

The intent of LLS's Special Fellow Award is to encourage early-stage scientists to pursue a career in blood cancer. Thus, the experimental plan and the career trajectory must indicate this desire. LLS encourages applicants with diverse scientific training to pursue careers in blood cancer. In general, Special Fellow applicants must have a recent track record that is directly relevant to blood cancer. In some cases, LLS and the review panel may consider Special Fellow applicants with little to no blood cancer experience, but there must be clear evidence of a path forward in a career in blood cancer, including being in the appropriate laboratory.

Post-Award Adherence to Aims

CDP Awards are selected in part based on the aims in the application. LLS requires any substantial change to aims of funded Awards to be approved in order to continue receiving funding. LLS understands that science does not progress in a direct path, and thus minor changes to the aims need not be approved by LLS (but should be described in annual progress reports). Changes to the aims that substantially reduce the impact of the research on LLS's Mission will not be approved and funding may be reduced or eliminated. Therefore, it is highly recommended that aims be carefully crafted in terms of feasibility and blood cancer relevance. Careful consideration of aims during the application process will enhance the ability to modify research directions in a Mission-relevant fashion, should the need arise after funding commences.

Key Publications of Sponsor(s)

For applicants with one Sponsor:

Fellow applicants must provide a description of publications that best highlight their Sponsor's contributions to the understanding of blood cancer or normal blood biology having relevance to blood cancer. Three to five publications must be presented in the full application template. The Sponsor must have expertise in blood cancer. This information will be used to determine the qualifications of the Sponsor to mentor the applicant's blood cancer-relevant research career.

For applicants with a co-Sponsor:

Fellow applicants must provide a description of publications of their Sponsor *and* co-Sponsor that best highlight the contributions to science that are relevant to the applicant's research and career development. At least one of the Sponsor/co-Sponsor team must have contributions to the understanding of blood cancer or normal blood biology having relevance to blood cancer. Three

to five publications in total must be presented in the full application template. This information will be used to determine the qualifications of the Sponsor/co-Sponsor pair to mentor the applicant's blood cancer-relevant research career.

The applicant should get input from the Sponsor/co-Sponsor for this section, but it must be written by the applicant.

Review Process and Applicant Notification

CDP applications are reviewed by an independent, voluntary panel of experts. Review criteria for **Special Fellow** applications include:

- Prior accomplishments of the applicant (*graduate* research of the applicant need not be blood cancer-based).
- Qualifications of the Sponsor (or Sponsor/co-Sponsor pair) to mentor the applicant in blood cancer research or normal blood biology that is relevant to blood cancer.
- Scientific quality of the proposal.
- Access to applicable key materials and models, including patient materials, animal models, drugs, etc., to demonstrate feasibility of proposed experiments.
- Clarity of presentation.
- Direct relevance of proposed research to blood cancer.
- Likelihood of the applicant pursuing a career in blood cancer research.
- Clear and robust training plan from the Sponsor (and co-Sponsor, where applicable).
- Demonstrated need for continued funding with a clear trajectory to an independent career.

Based on these criteria, the applicant receives a priority score based on the NIH scoring system.

The applicant also receives a **Mission Score** to measure adherence of the application to LLS's Mission of curing blood cancer. CDP Awards must focus on those questions of direct relevance to blood cancer, which may include questions of normal blood biology. Research on normal blood biology must have a clear relevance to blood cancer.

Proposals that do not have clear relevance to blood cancer will be triaged without full review.

Mission Score of 1: The experimental plan must address mechanisms directly relevant to the pathogenesis, diagnosis, or treatment of hematologic malignancies and/or relevant premalignant conditions/states. In addition, at least some experiments must include patients, patient materials, or the most appropriate animal model system.

Mission Score of 2: The experimental plan must address mechanisms directly relevant to the pathogenesis, diagnosis, or treatment of hematologic malignancies and/or relevant premalignant conditions/states. In addition, at least some experiments must use cell lines and/or animal

models that are directly relevant to hematologic malignancies and/or relevant premalignant conditions/states.

Mission Score of 3: The experimental plan must address basic mechanisms directly relevant to normal blood cell development, hematopoietic stem/precursor cell function, or immune responses. These studies must have clear relevance to blood cancer and must use appropriate models to understand these mechanisms in blood cells.

Mission Score of 4: Does not address mechanisms directly relevant to normal blood cell development/function, hematologic malignancies and/or relevant premalignant conditions/states. Applications with a Mission Score of 4 will be triaged.

After the review panel meeting, Mission-relevant applications (Mission Scores 1, 2 and 3) will be rank-ordered based on their Priority Score and those within or near the payline will be presented to LLS's oversight committees for approval. Funding status is relayed by mail and/or 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 grants management portal. Up until final decisions are made, the status will be "Under Review." After final decisions are made, the status will either be "Awarded" or "Waitlist" or "Not Funded." The final status change is typically made by late February. Please do not call or email regarding status updates. Notification by email will also happen beginning in late February.

Key Dates

	Date	Time
Eligibility Phase: open	July 2017	
Eligibility Phase: close	September 1, 2017	3:00 PM ET
Eligibility determination by LLS staff	July 17 – September 8, 2017	
Notification of eligibility	By September 8, 2017 (typically within two business days after submission)	3:00 PM ET
Abstract Phase: open	After eligibility is approved	
Abstract Phase: close	September 15, 2017	3:00 PM ET
Full Application Phase: open	After Abstract Phase submission	
Reference letters due	October 3, 2017	3:00 PM ET
Full Application Phase: close	October 3, 2017	3:00 PM ET
Panel Review Meeting	January 2018	
Award Notification	February 2018	
Final version of Lay Abstract due	May 1, 2018	
LLS's receipt of signed contract	May 1, 2018	
Award Start Date	July 1, 2018	

<u>The submission deadlines will be strictly enforced.</u> 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. Our grants management portal automatically shuts down submissions after the deadline has passed.

General Instructions for Applying

All submissions must use LLS's online grants management portal at https://lls.fluxx.io/. It is recommended that you familiarize yourself with this portal well in advance of any deadlines.

If you do not have an account with LLS, contact <u>researchprograms@lls.org</u> with your full name and organization contact information. A new account will be created for you and your log in credentials will be emailed to you by an LLS staff member.

Under "Information" on the left navigation bar, click "Career Development Program."

Click "Apply to CDP!" and you will be directed to the eligibility form.

Follow the instructions for each web form field. Bold font indicates required information.

Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be triaged.

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

Once your eligibility is approved, you will receive an automated email from the system. Consider that these emails may end up in your spam filter.

Log back in to submit your Abstracts (your access to the Abstract Phase happens automatically upon eligibility approval). Once submitted, you will have immediate access to the full application. Under "New or Pending," click on your request to continue with your application.

Download and complete the project description template, including all required signatures, and upload to the "Project Document" section towards the bottom of the web form. Margins are preset and must not be changed. Text must be written single spaced in Times New Roman 12pt. Only one PDF file is accepted in this section, so delete any other documents uploaded during the process.

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

Specific Instructions for Applying

Three-step application process

There are three phases to the application process:

- Eligibility Phase.
- Abstract Phase.
- Full Application Phase.

In the **Eligibility Phase**, a broad overview of the applicant is asked for in a brief series of questions (years since oral thesis defense, Sponsor's funding, etc.). The answers to these questions will be used by LLS staff to determine eligibility. This step determines broad eligibility; Mission-relevance is determined later. Eligibility will be evaluated on a rolling basis. Notification of eligibility will be emailed to the applicant, typically within a few days of submission.

The eligibility criteria are straightforward and it is expected that 100% of applicants who follow these guidelines will be deemed eligible. See *Key Criteria for Eligibility* section for a summary.

Applicants whose eligibility is rejected may resubmit for eligibility determination two more times during this application cycle if there is more information to present and if submitted prior to the Eligibility Phase deadline.

After eligibility is accepted, the **Abstract Phase** begins, at which point the applicant will have access to the Abstract Phase portion of LLS's grants management portal.

The purpose of the **Abstract Phase** is to provide LLS with information that will be used for reviewer selection and assignment. In addition, LLS staff use this information to evaluate the subject matter of our grant applications, which will help with strategic decisions on LLS programs going forward. The information at this phase may be checked with information in the full application. It is imperative that they match.

Besides minor wording/stylistic changes (which must be approved by LLS), no changes may be made to the Abstract Phase components after the deadline.

The **letters of reference** may be uploaded by the letter writers during the Abstract Phase, but must be uploaded by the full application deadline. (See the *Letters of Reference* subsection in the *Abstract Phase Details* section).

The **Full Application Phase** opens when the applicant passes through the Abstract Phase. The full application template is uploaded during this phase, and letters of reference are also uploaded (by the letter writers) by the full application due date. LLS staff will review full applications to

ensure compliance with the guidelines, which may include re-checking eligibility criteria. *Applications may be administratively triaged due to non-compliance with the policies stated in these guidelines.* After LLS staff review, full applications will be provided to the independent peer review panel.

Details for each Phase are described following the next section.

Key Points Regarding the Application Process

- The application process consists of three phases: Eligibility, Abstract and Full Application.
- The application process is done on a rolling basis; if one phase is completed, the applicant may move to the next phase.
- It is recommended to start the application process early.
- All components of the application must be present in the order indicated in these guidelines.
- All formatting must adhere to the policy stated in these guidelines.
- Letters of reference submission status is viewable by the applicant on the grants management portal; the letters themselves are not viewable by the applicant.
- Completion of several steps in the process initiates emails sent from LLS's grants
 management portal, including emails sent to those who will write letters of reference.
 LLS staff may also send emails during the application process. Spam filters should be
 monitored for these emails.
- Contact <u>researchprograms@lls.org</u> if expected emails are not received by the times indicated in these guidelines.
- No changes/updates may be made after full application submission. The exceptions to this rule are regulatory updates, significant updates to clinical trials, and manuscripts accepted for publication (described in the *Submission and Confirmation* section).
- Check your application package carefully prior to submission. The deadlines stated in the *Key Dates* section are strictly enforced. No exceptions are made to this policy.

Eligibility Phase Details

Only organizational details and general eligibility information are entered at this phase. Applicants may submit eligibility immediately after the program opens. Eligibility will be evaluated by LLS 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. If eligibility is rejected, the applicant may submit two more times if new information is provided and the eligibility deadline has not passed.

Organization Information

Institution

Indicate the institution where the proposed research will be performed.

Principal Investigator

The Principal Investigator of this application is the applicant (*not the Sponsor*).

Institutional Signing Official (ISO)

The ISO is the institutional representative responsible for signing and agreeing to the accuracy of the application and the terms of the award, should the application be funded.

Financial Officer

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

Technology/Transfer Officer (TTO)

The TTO is responsible for the contractual and business-related aspects of any patentable discoveries resulting from the Grantee's research activities. Contact information for the TTO will be asked for from those applicants selected for funding.

Sponsor

The Sponsor is the head of the laboratory where the applicant is performing, or will be performing, the proposed research.

Co-Sponsor

A co-Sponsor is optional. See the *Optional co-Sponsor* section. The co-Sponsor must be declared at the eligibility stage; any changes regarding a co-Sponsor after the eligibility stage must be approved by LLS.

Zip Code (of Institution)

Eligibility Information

This section asks for a broad overview of the applicant which will be used by LLS staff as an initial eligibility screen.

Position Title/Academic Rank

This is the position that you will have at the funding start date.

Program and Subprogram Sections

Choose "Career Development Program" then "Special Fellow" for Special Fellow-specific eligibility questions.

Research Support

Applicants must demonstrate that their Sponsor has substantial funding to support the proposed or closely-related research. This can be in the form of R01-level funding from private foundations or the NIH, or substantial and sustained institutional support beyond a startup package. This funding must not be transitional funding. Provide the grant PI, full name of the funding source (including grant subtype), grant number, amount of the award, and years of funding period. This research support must be active by the Eligibility Phase deadline, or a letter from the funding agency must be provided that indicates a start date prior to the CDP Award start date. Research support that ends prior to the Award start date may not be used as evidence of adequate support.

The presence of funding is determined by LLS staff during the eligibility phase while the appropriateness of that funding to support blood cancer-relevant research will be determined by the review panel after full application submission.

Other Salary Support

Provide details of other salary support for the applicant, including the amount of that support. If your salary comes from the same source as the research support, write "Same as above" in this section.

Oral Thesis Defense

Provide the date of the oral thesis defense. If no oral thesis defense was required for a PhD at the conferring institution, provide a description of the PhD evaluation process in the Justification section (see below). Applicants with an MD (and no PhD) should leave this section blank.

Date of Doctoral and/or Medical Degree Conferral

Provide the date of degree conferral for each doctoral-level degree.

Degree-Granting Institution and Name of Thesis Supervisor

Provide the name and location of the degree-granting institution and the full name and title of your thesis supervisor from that institution.

Thesis Research Laboratory Location and Name of Laboratory Principal Investigator

Provide the name and location of the institution where the thesis research was performed and the full name and title of the head of that laboratory. These may be the same as the degree-granting institution and thesis supervisor.

Post-Degree Clinical Training

Provide the dates and general description of any clinical training, including percentage of time devoted to research. Account for all the time since degree conferral.

There should be no unexplained gaps in training.

Justification (Optional)

This section is optional and is used to provide <u>only</u> the information listed below. The first three bullet points describe possible extensions to the eligibility window. If any of the first three bullet points are indicated in the Justification section, a letter from the Sponsor (or thesis advisor) confirming these events and dates must be submitted by the full application due date (to be sent directly to LLS at <u>researchprograms@lls.org</u>). This letter must be signed and on institutional letterhead.

- Dates of parental leave.
- Dates of military service.
- Dates related to Visa issues caused by governmental delays; the eligibility window may be extended, but only if the delays were not caused by the applicant.
- Explanation of the degree-conferring institution's PhD evaluation process if there is no oral thesis defense and/or if the graduate training is distinct from a typical USA-based program.
- Any explanations of your training history that were not adequately addressed in prior sections.

Note: This section must <u>not</u> contain any descriptions of time spent in the thesis advisor's laboratory after the oral thesis defense and/or after you are considered a PhD recipient. This information will not be considered for any extensions of the eligibility window.

Total Amount Requested

Please enter your estimated total amount requested for the life of the grant. You may change this amount during the Abstract and Full Application Phases. This amount must not exceed \$67,000, which includes both direct and indirect costs, per year. The amount requested will be the amount awarded, should the Award be approved for funding.

Submission and Confirmation

After clicking the "Submit" button, you will receive an automated email stating that your information was successfully submitted.

If you do not receive the email confirmation within 2 business days of submission, contact LLS at researchprograms@lls.org.

Eligibility Review

LLS staff will review eligibility on a rolling basis. If you submit prior to July 17, you will receive notification by July 21. If you submit between July 17 and August 31, you will receive notification within 5 business days of your submission (typically less than 5 days). If you submit on September 1, you will receive notification by September 8 at 3 PM ET. If you have not received notification within this time frame, contact LLS at researchprograms@lls.org.

If eligibility is accepted, you will have access to the next phase (Abstract Phase).

During the eligibility phase, the applicant should carefully consider who will write letters of reference on their behalf and alert them of the due date for these letters (See *Letters of Reference* subsection in the *Abstract Phase Details* section). Letters submitted past the deadline will not be accepted.

Key Criteria for Eligibility:

- Must have an appropriate Sponsor:
 - Head of a laboratory at a non-profit institution where applicant's research will be performed.
 - Assistant Professor or above (or equivalent).
 - Not applicant's thesis advisor or the head of the laboratory where applicant's thesis research was performed.
- Must be a postdoc at the award start date (July 1, 2018).
- Must not be in a graduate program at the award start date (July 1, 2018).
- Must have a Sponsor with access to adequate funding to support the proposed research:
 - o R01-level funding from private foundations or the NIH.
 - Substantial and sustained institutional support beyond a startup package when other funding is not available.
 - o Funding must not be transitional.
 - o Funding listed must not end prior to the award start date (July 1, 2018).
- Must not have, nor have had, other career development support that has a higher award amount than the Special Fellow Award (except a K99).
- For PhDs, an oral thesis defense date that is on or after June 30, 2013 (2 year award) or June 30, 2014 (3 year award).*
- For MDs, the date of their first postdoctoral training must be on or after June 30, 2013 (2 year award) or June 30, 2014 (3 year award).*

- *For applicants whose training is not typical of most US-based institutions, a detailed explanation of their degree-conferring institution's degree criteria must be provided in the justification section; eligibility will be reviewed on a case by case basis.
- Must not have any unexplained gaps in training.
- Where appropriate, the Justification section may be used for *only*:
 - o To expand the window of eligibility describing the following:
 - Dates of parental leave.
 - Dates of military service.
 - Dates related to Visa issues caused by governmental delays.
 - To explain training history not adequately explained previously, particularly for those who have trained outside the USA.

Abstract Phase Details

There are two main aspects of the Abstract Phase:

- Letters of Reference.
- Project Information.

The letter of reference information can be added as soon as the application moves to the Abstract Phase. It is recommended to complete the letter of reference 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 letters of reference section must happen prior to final submission of all Abstract Phase components.

Letters of Reference

The applicant must have three reference letters submitted on their behalf. These letters must be submitted directly by the letter writers to our grants management portal. (See *Initiating Blind Reference Letters* below).

It is the responsibility of the applicant to ensure that the letters are received by LLS by the deadline.

Letter policies

- Three letters are required.
- No more than four letters will be accepted.
- Two letters must be from outside the Sponsoring Institution.
- One letter must be from the applicant's PhD advisor; if a letter from the advisor is not available, the Sponsor should provide an explanation in the Sponsor letter.

- The Sponsor Letter (and co-Sponsor letter, where applicable) is separate from the letters of reference and therefore is not considered one of the three letters of reference.
- Letters are blinded to the applicant and must be uploaded directly by the writer.

Initiating Blind Reference Letters

The applicant must contact those who will write their references letters well before the deadline.

A section called "Request Blind Reference Letters" is available on LLS's grants management portal 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 grants management portal. This process is repeated for each of the letter writers.

Each letter writer will receive a unique link (from a unique email address) for letter uploading. The email containing this link may end up in the letter writer's spam. Therefore, after the letter writer's information is added in the grants management 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 24 hours, 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 the letter's status on the grants management portal. Prior to the letter being submitted, 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 completion of the initiation of blind reference letters.

Project Title

Limited to 150 characters (including spaces).

Specific Disease or Subject Focus of Your Experiments

Indicate the disease or cell type that *directly* forms the basis of your experiments (e.g. CLL, normal B cell development, etc.). Limited to 75 characters (including spaces).

Technological Approaches used by Your Experiments

Indicate the overall technological approaches used in your experiments (e.g. next-generation sequencing, crystallography, etc.). Limited to 75 characters (including spaces).

Model Systems used in your Experiments

Indicate the model systems used in your experiments (e.g. cell lines, mouse models, patient samples, etc.). Limited to 75 characters (including spaces).

Scientific Abstract

Describe your proposed research, including blood cancer relevance, problem/question to be addressed, specific aims, and anticipated results. Scientific/Greek characters must not be used. Limited to 1500 characters (including spaces).

Proposed Start Date

All CDP Awards start on July 1, 2018.

Proposed End Date

Special Fellow Awards end June 30, 2020 or 2021, depending on years of experience. LLS support for Special Fellows may not extend postdoctoral research training (excluding clinical training) beyond 7 years. See the *Experience/Eligibility Clock* section.

Previous submission

Indicate if you have previously submitted a similar application to LLS's CDP award mechanism.

Collaborators Information

Indicate any personnel, outside of your institution, with whom you have a significant and current interaction regarding your project or your career development. Only include those people who are at or above tenure-track level (or equivalent). List up to 5 people. 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 stating that your information was successfully submitted. If you do not receive the email confirmation within 2 business days of submission, contact LLS at 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 next phase. If submitted prior to the deadline, changes may be made with LLS approval. Email researchprograms@lls.org requesting any change and identify the elements to be changed. No changes may be made after the Abstract Phase deadline has passed. Failure to follow this policy may result in disqualification of the application.

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

Full Application Phase Details

Some sections of the full application will carry through from the Abstract Phase. Information that carries through must not be modified. The remainder of the full application consists of web form components and elements to be uploaded as a single PDF.

All sections in the full application template must use **Times New Roman 12pt font**, except figure legends, which may use 10pt font.

<u>Failure to submit as a single PDF in the order below will result in disqualification of the application.</u>

Project Description Template (downloaded from LLS's grants management portal)

The full application has two sections.

Section 1:

The downloadable project template consists of the following required elements:

a. Applicant/Institution/Project Title/Abstract

Copy and paste the title and abstract from the Abstract Phase.

b. Key Publications (2 page maximum)

Describe 3-5 publications from your Sponsor (and co-Sponsor, where applicable) that best demonstrate their contributions to the understanding of blood cancer, or normal blood biology having relevance to blood cancer. Your Sponsor must be the corresponding author on these publications (same with co-Sponsor publications, where applicable). Use the Blood citation format. In addition, indicate who the corresponding author is. Follow this with a description of how each publication has impacted our understanding of blood cancer. See *Sponsor* and *co-Sponsor* subsections in the *Who Can Apply* section as well as the *Blood Cancer Relevance* section. The applicant should get input from the Sponsor/co-Sponsor for this section, but it must be written by the applicant. Use Times New Roman 12pt font.

The applicant should get input from the Sponsor/co-Sponsor for this section, but it must be written by the applicant.

c. Statement of Direct Blood Cancer Relevance (0.5 page)

Briefly describe how your proposed research is *directly* relevant to blood cancer (which may include normal blood biology that has relevance to blood cancer). Include the titles of each of your aims. In addition, describe how performing research in your Sponsor's laboratory will help your career development as someone who contributes to improving the lives of blood cancer patients. Where applicable, indicate how your co-Sponsor will enhance your career

development. The research described here and in the Project Description section must clearly fit within either Mission Score 1, 2 or 3. Use Times New Roman 12pt font.

d. Statement of Need for Continued Training (0.5 - 1 page)

Demonstrate how you need more time to continue with your research project's development so that you will be competitive for an independent position near the end of the Special Fellow Award term. Generally, competitive Special Fellow applicants will *not* be proposing a completely new direction in their research. For applicants who are current or former LLS Fellows, include a description of how you have made progress on the aims of your original application, or how those aims have been modified. Use Times New Roman 12pt font.

e. Project Description (6 page maximum, including figures)

The following information should be provided in this order:

- Background; this section may contain unpublished data from others in the lab.*
- Specific Aims.
- Previous Work/Preliminary Data, including figures;** this section may *only* contain data generated by the applicant; in addition, the Sponsor must indicate in the Sponsor letter that data in this section was generated by the applicant.
- Experimental Design and Expected Outcomes, including figures.**
- Potential Pitfalls and Alternative Approaches.
- Resources and Environment; this section must include a description of access to applicable key materials and models, including patient materials, animal models, drugs, etc.

Use Times New Roman 12pt font, except figure legends, which may use 10pt font.

*Applicants should provide credit for unpublished data/figures primarily generated by others.

**Figure legends should be formatted with a font size equivalent of 10pt or above.

The figure legends and the Experimental Design and Expected Outcomes section must clearly identify the model system(s) used (e.g cell line name, what type of cell, etc.).

Applications that include writing and figures directly from their Sponsor's prior grant submissions will be unfavorably reviewed; the exception are figures in the Background section.

f. References (4 page maximum)

Use the Blood citation format. Use Times New Roman 12pt font.

g. Budget

The following information should be provided in the budget template (and on the web form):

• Current salary, wage or stipend

- Fringe benefit expense
- Cost of living increases should be included in all out years

The amount requested must not exceed \$201,000 for 3 year Awards or \$134,000 for 2 year Awards (\$67,000/year). Should the application be funded, the amount requested will be the amount awarded, even if the requested amount is less than \$201,000 (3 year Awards) or \$134,000 (2 year Awards).

h. Signature Page

This form must be completed, including the indicated signatures.

i. Sponsor Mentor Table

The Sponsor should complete this table. No mentor table is needed for the co-Sponsor, if applicable.

Section 2:

The following sections must be attached in this order to the end of the template (from Section 1) to create a single PDF.

a. Applicant's Biosketch

Use the most recent NIH format. Adhere to the 5 page limit. Do <u>not</u> use the postdoctoral fellowship version. Publications submitted and under review may be indicated on the biosketch. An eRA Commons User Name is not required. Do <u>not</u> use the postdoctoral fellowship version.

b. Sponsor's/co-Sponsor's Biosketch

Use the most recent NIH format found on the NIH website. Adhere to the 5 page limit. Publications submitted and under review may be indicated on the biosketch. If an applicant has a co-Sponsor, a biosketch must be provided for that person as well. An eRA Commons User Name is not required.

c. Sponsor Letter

The Sponsor Letter must be on institutional letterhead must contain the following:

- Description of the applicant's position and how the applicant's research is integrated in the overall laboratory.
- Brief description of how much of the application was written by the applicant; this should include certification that the "Previous Work/Preliminary Data" section includes *only* data generated by the applicant.
- The Sponsor's experience in mentorship, which summarizes the information contained in the Sponsor Mentor Table.
- Source of funding for the applicant's research.
- Training plan to develop the applicant into an independent researcher, clinician, or other professional whose major function will be to directly or indirectly enhance the lives of blood cancer patients; *this is an integral component of the review process*.

- Sponsor signature.
- The Sponsor Letter is separate from the letters of reference; Sponsors may not write a letter of reference.

If the applicant chose a co-Sponsor, there must be a co-Sponsor letter on institutional letterhead containing:

- Description of the role the co-Sponsor will play in the applicant's research and career development.
- Description of any prior interactions between the co-Sponsor and the applicant as well as between the co-Sponsor and the Sponsor.
- Co-Sponsor's signature.
- The co-Sponsor Letter is separate from the letters of reference; co-Sponsors may not write a letter of reference.

The Sponsor/co-Sponsor Letters are not blinded to the applicant.

d. Collaboration/Support Letters (Optional)

When there are significant collaborations, letters of support are helpful. This is particularly important when access to patient samples, animal models, or specialized equipment outside of the Sponsor'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 should accompany the application. The letters must be signed and be on institutional/company letterhead.

e. Clinical Protocol (Required where applicable)

Provide a one page summary of clinical protocols essential to the proposed research. Include approval date and compliance number. Indicate if IRB approval is pending.

f. Assurances (Required)

Human Subjects

Indicate if human subjects will be involved in the proposed research. The status (approved, pending or exempt) of IRB (or equivalent institutional designation) approval must be provided. Documentation of any current or pending approvals must be contained in the full application. There is also a section on the web form that must be completed. An application may be submitted with IRB approval pending, but IRB approval must be obtained and provided to LLS prior to the Award start date.

Laboratory Animals

Indicate if animals will be involved in the proposed research. The status and date of the Institutional Animal Care and Use Committee (IACUC) (or equivalent institutional designation) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of any current or pending approvals must be provided in the full application

template. There is also a section on the web form that must be completed. An application may be submitted with approval pending, but approval must be obtained and provided to LLS prior to the Award start date.

Recombinant DNA

Indicate if the proposed research involves recombinant DNA. Documentation of any current or pending approvals must be contained in the full application template; there is also a section on the web form that must be completed.

Biohazard Statement

Indicate if the proposed research involves the use of biohazards. Documentation of any current or pending approvals must be contained in the full application template. There is also a section on the web form that must be completed.

g. Publications (Optional)

Up to three manuscripts that are not yet available on PubMed may be provided.

Uploading the project document and final submission

Upload the full application components, as a single PDF, in the "Project Document" section on the grants management portal.

All documents must be combined into a single PDF in the order listed above before uploading. <u>Failure to submit as a single PDF in the order above will result in disqualification of the application.</u>

Submission and Confirmation

After clicking the "Submit" button, you will receive an automated email stating that your information was successfully submitted. **If you do not receive the email confirmation within 2 business days of submission, contact LLS at** <u>researchprograms@lls.org</u>.

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, but prior to the deadline, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document.

Once the deadline has passed, only the following updates may be made:

- Significant updates to clinical trials:
 - o IRB updates.
 - o Opening of the trial.
 - o Patient enrollment.

- o Opening of new clinical sites.
- o Efficacy and/or safety updates.
- Manuscripts that have been accepted for publication; the following must be provided:
 - List of authors.
 - o Title.
 - o Journal.
 - o A copy of the acceptance letter from the journal.

No other changes may be made to the application after the full application due date.

Final Helpful Hints

A smooth post-submission review process will be enhanced by paying careful attention to the following:

- Applicants benefit by starting the application process early as well as submitting prior to the deadline.
- Components of the full application should be submitted as one upload of a single PDF (accidental uploads should be brought to the attention of researchprograms@lls.org, so that they can be removed).
- All sections should be complete, including but not limited to:
 - The Key Publications section of the application template which identifies and describes the Sponsor's *corresponding* author publications.
 - The co-Sponsor's *corresponding* author publications are also described in the *Key Publications* section (where applicable).
 - The *Direct Blood Cancer Relevance* section explaining the direct correlation of the research with LLS's Mission.
 - o Statement of Need for Continued Training.
 - Applicant and Sponsor biosketches (and co-Sponsor's biosketch, where applicable) attached to the full application template.
 - A signed Sponsor Letter (and signed co-Sponsor's Letter, where applicable) attached to the full application template.
- Use Times New Roman 12pt font; 10 pt or above for figure legends.
- Use the pre-set template margins.
- Adhere to the page length limitations.

- Have at least three letters of reference, but no more than four; letters must be received by LLS by the full application due date (the Sponsor Letter is separate from letters of reference).
- A Clinical Protocol must be present (where applicable).
- Applicable assurances must be present (human subjects, laboratory animals, etc.).
- Up to three publications, not available on PubMed by the full application due date, may be attached to the application template.
- Check the application prior to submission to be sure everything is in order; no changes to the application are allowed after the deadline, except for those described in the *Submission and Confirmation* section.