

Career Development Program Guidelines & Instructions

Special Fellow

Effective dates: May 1, 2018 - April 30, 2019

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What's New for 2018-2019

Starting in this award cycle, the eligibility window for Special Fellow applicants has been changed from a minimum of 2 years to a minimum of 2.5 years. Those who are between 2 and 2.5 years from their advanced degree are now eligible to apply in the Fellow subcategory. See Experience/Eligibility Clock section for more details, and, if applicable, see the Fellow Guidelines & Instructions.

2018 - 2019 Update: Application Compliance

In the 2017-2018 cycle, more than 8% of CDP applications submitted (from Fellow, Special Fellow and Scholar subcategories) were triaged without full review based on non-compliance with the Mission Score and Blood Cancer Relevance.

In recent years, approximately 10-15% of all applications had serious administrative/structural flaws. These include non-adherence to page numbers, font size, or missing sections (e.g. a Sponsor Letter or Biosketch). Applications with such flaws run the risk of administrative triage.

Carefully check the final version 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 CDP Special Fellow Award

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 and supports postdoctoral fellows and instructors. 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.

Eligibility

Special Fellow applicants must...

- Must have an appropriate Sponsor:
 - Head of a laboratory at a non-profit institution where applicant's research will be performed.
 - o 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, 2019).
- Must not be in a graduate program at the award start date (July 1, 2019).
- 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, 2019).
- Must not have, nor have had, other career development support that has a higher award amount than the Special Fellow Award (except a K99).
- Must not have any unexplained gaps in training.
- All positions and titles from the end of graduate or medical training must be explained in the Justification section. This is particularly critical for training that does not follow the standard US-based training and for unusual position titles.
- Where appropriate, the Justification section may be used *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.
 - o To explain training history not adequately explained previously, particularly for those who have trained outside the US.

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 2.5 years ago, but no more than 4.5 years ago, at the time of review (January 1, 2019). 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. Special Fellow applicants must be on a clear trajectory to an independent career, and must demonstrate a need for continued funding and training to achieve independence.

Institution Affiliation

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

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 review panel may look unfavorably upon an applicant who appears to include a co-Sponsor for the purposes of Mission-relevance, rather than for a true mentorship purpose. 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

Special Fellow Awards generally fund only salary (see the K99 discussion in the <u>Other Career Development Support</u> 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. In cases where funding starts after the eligibility due date, the applicant must send evidence from the funding agency of the award details (including funding agency, type, award amount, and start date; send to researchprograms@lls.org.

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 cycle for each Sponsor, as well as one Special Fellow application per 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 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 obtain 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:

Special 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:

Special 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 (particularly for the selection of publications), but it must be written by the applicant.

Review Process & 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 within a few years.

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 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" 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

| Phase | Date |
|--|--|
| Eligibility Phase: open | May 2018 |
| Eligibility Phase: close | September 1, 2018, 3:00 PM ET |
| Eligibility determination by LLS staff | Rolling: May through September 8, 2018 |
| Notification of eligibility | By September 8, 2018 (typically within 2 business days after submission) |
| Abstract Phase: open | After eligibility is approved |
| Abstract Phase: close | September 15, 2018, 3:00 PM (ET) |
| Full Application Phase: open | After Abstract Phase submission |
| Reference letters due | October 3, 2018, 3:00 PM (ET) |
| Full Application Phase: close | October 3, 2018, 3:00PM (ET) |
| Panel Review Meeting | January 2019 |
| Award Notification | February 2019 |
| Final version of Lay Abstract due | May 1, 2019 |
| Award Start Date* | July 1, 2019 |

^{*}LLS's non-negotiable Grant Agreement Terms & Conditions are available on www.lls.org.

<u>The submission deadlines will be 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.

<u>It is highly recommended that submissions are done the day prior to the deadline.</u> Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. The LLS Research Portal automatically shuts down submissions after the deadline has passed. Late

submissions due to technical difficulties will not be accepted. Every year, a few applicants get caught with difficulty near the deadline; some are unable to submit because of these issues. The best way to avoid this problem is to submit every section well ahead of the deadline.

General Application Instructions

The CDP application will be completed in 3 phases: Eligibility, Abstract, and Full Application. Below are step-by-step instructions for applying:

- 1. Read the Guidelines & Instructions (this document) in full.
- 2. Log in to the <u>LLS Research Portal (lls.fluxx.io)</u> and select Career Development Program. Click "Apply to CDP!" to begin the application process (well ahead of the deadline).
 - o If you need a new account or need to reset your password for an existing account, contact researchprograms@lls.org.
- 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.
- 5. You will receive an email notifying you of your Eligibility approval status. Once your Eligibility is approved, return to the LLS Research Portal, select "New or Pending" under *Requests* on the left panel and follow the instructions on the site and in this document to submit your Abstract.
 - 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. Once you have submitted your Abstract, you may immediately begin your Full Application. Please carefully follow the instructions on the LLS Research Portal and this document. Full Applications require completion of both the web form and the current application template, which should be downloaded from the *Project Document* section of the LLS Research Portal. Failure to follow all application instructions may result in administrative triage of your application.
 - o Contact <u>researchprograms@lls.org</u> with any questions about the application that are not addressed in the LLS Research Portal or this document.
- 7. Request letters of reference well in advance of the Full Application deadline. This deadline also applies to reference letters, which are part of your Full Application.
- 8. Submit your Full Application to LLS prior to the Full Application deadline. We strongly recommend submitting at least 1 week in advance of the deadline, as site traffic on the day of and days leading up to the deadline will be heavy.

Carefully check every page of your application prior to submission. You are ultimately responsible for this submission, even if someone else submits your final application.

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 <u>LLS Research Portal</u>, please contact <u>researchprograms@lls.org</u>.

Detailed Eligibility Phase Instructions

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 <u>Eligibility Review</u> 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. Follow instructions on the LLS Research Portal to complete the web form.

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 researchprograms@lls.org. It is also recommended that you confirm each stage of the application process by checking your application status on the LLS Research Portal at lls.fluxx.io.

Eligibility Review

LLS staff will review eligibility on a rolling basis. Refer to <u>Key Dates</u> for details. **If you have not received notification within this time frame, contact <u>researchprograms@lls.org</u>.**

If eligibility is accepted, you will have access to the 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 <u>Letters of Reference</u> subsection in the <u>Detailed Abstract Phase Instructions</u>). Letters submitted past the deadline will not be accepted. It is therefore beneficial to you to have a backup letter writer in case one of your original writers is not able to submit on time.

Detailed Abstract Phase Instructions

There are two main aspects of the Abstract Phase:

- 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 letters 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.

Note: 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, with sufficient detail, and suitable for the general public is required post-award. After award notification, LLS will contact awardees regarding lay abstract submission.

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 the LLS Research Portal. (See <u>Initiating Blind Reference Letters</u> below).

It is the responsibility of the applicant to ensure that the letters are received by LLS by the deadline. Letters submitted past the deadline will not be accepted.

Reference Letter Policies

- Three letters are required.
- No more than four letters will be accepted.
- Though not required, it is beneficial to have two of the letters coming from outside the Sponsoring Institution.
- Letters are blinded to the applicant and must be uploaded directly by the writer.
- The Sponsor Letter is separate from the letters of reference and therefore is not considered one of the three letters of reference; Sponsor information should not be provide in the letters of reference section on the LLS Research Portal.

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 the LLS Research 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 LLS Research Portal. This process is repeated for each of the letter writers.

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 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 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 LLS Research 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 project information after completion of the initiation of blind reference letters. All information must accurately reflect the information in the full application. *Significant divergence between this section and the full application may negatively affect your funding chances.* Examples of significant divergence might be stating that the specific disease focus is CLL when your actual focus is normal myeloid development, or stating that your model systems include patient samples, but your full application indicates no patient samples (or access to patient samples).

The scientific abstract should accurately reflect the actual research that you are proposing. Though putting your research in a broader context may be important, it is also important to avoid overstating your research beyond what you are actually proposing.

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 <u>researchprograms@lls.org</u>.

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

Changes

Information collected in the Abstract Phase will automatically populate fields in the Full Application Phase. If requested prior to the deadline, changes may be made with LLS approval. Email 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. Abstract Phase components must accurately reflect the focus of the full application. See the first paragraph in the Project Information section.

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.

Detailed Full Application Phase Instructions

Some sections of the full application will carry through from the Abstract Phase. Information that carries through must not be modified; changes made to the Abstract Phase components after the Abstract Phase deadline or prior to the deadline without LLS approval, may result in

administrative triage of the full application. 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.

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

Project Description Template (downloaded from the LLS Research Portal)

The full application has two sections:

Section 1:

The downloadable project template consists of the following required elements:

a. Applicant and Project Information

Copy and paste the title and abstract from the Abstract Phase. Use Times New Roman 12pt. font.

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 first or 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 <u>Sponsor</u> and <u>co-Sponsor</u> subsections as well as the <u>Blood Cancer Relevance</u> section. Use Times New Roman 12pt font.

The applicant should get input from the Sponsor/co-Sponsor for this section (particularly on publication selection), 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. The research described here and in the Project Description section must clearly fit within either Mission Score 1, 2 or 3 in order to proceed to full review. A common problem for applicants that do not fit clearly into the criteria set forth in the <u>Blood Cancer Relevance</u> section is an overstatement of relevance by describing indirect relevance (e.g. studying a pathway in non-blood cancer systems and trying to relate to blood cancer by stating that this pathway is important in blood cancer). Use Times New Roman 12pt. font.

d. 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; applications without appropriate and clear credit will be reviewed unfavorably.
- ** Figure legends should be formatted with a font size equivalent of 10pt. or above; figures should indicate the data source (e.g. preliminary data from the applicant's lab or a publication).
- *** If your lab does not have demonstrated access to materials, access should be confirmed through letters of collaboration/support from the supplier. Lack of clear access to materials will negatively affect the review of your application.

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.

e. References (4 page maximum)

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

f. 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 total amount requested must not exceed \$180,000 (\$60,000/year). Should the application be funded, the total amount requested will be the amount awarded, even if the total requested amount is less than \$180,000.

g. Signature Page

This form must be completed, including the indicated signatures.

h. 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 found on the NIH website. Adhere to the 5 page limit. 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 and 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.
- In recent years, LLS has updated the CDP criteria to become more Mission-driven.
 Therefore, if a Sponsor has formerly been involved with a CDP award and this is
 mentioned in the Sponsor Letter, the Sponsor must briefly describe how that CDP
 funding directly impacted our understanding of blood cancer and/or impacted blood
 cancer patients.
- 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 relevant 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.

c. Collaboration/Support Letters (Optional)

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 should accompany the application. The letters must be signed and on institutional/company letterhead.

d. 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. Applications with more than three manuscripts, or that include manuscripts that are available on PubMed by the date of full application submission, may not receive a full review.

Uploading the project document and final submission

Upload the full application components, as a single PDF, in the "Project Document" section on the LLS Research 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 researchprograms@lls.org.

If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document. *This email must be received*, with the correct document, prior to the deadline.

Check the application prior to final submission. The applicant is ultimately responsible for the submission, regardless of who actually is uploading information on the LLS Research Portal. Every year, LLS has a small number of people that notice problems with their application after the deadline. The solution to this problem is very simple and in the hands of the applicant:

- Check your application prior to final submission.
- Submit well ahead of the deadline.

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.
- Updates regarding any transfers to a new institution (see Transfers section in Eligibility).

Tips for Applying

- All submissions must be sent through the LLS Research Portal at https://lls.fluxx.io/.
 - It is highly recommended to access the LLS Research Portal to begin the application process well in advance of any deadlines.
- Carefully follow all instructions on the web forms, templates and this document, including character limitations and font restrictions.
- Text must be written single spaced in Times New Roman 12pt. font. Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. Use the pre-set template margins. If character limits are not adhered to, or the preset margins are altered, the application may not be reviewed.
- Bold font indicates required information.
- The application process is completed on a rolling basis; once submission is approved, the applicant may move to the next phase.
- Letters of reference submission status is viewable by the applicant on the LLS Research Portal; the letters themselves are not viewable by the applicant.
- 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).
- Combine all documents into one PDF for the Full Application submission. Only one PDF file is accepted in this section, so delete any other documents uploaded during the process.
- All components of the application must be present in the order indicated in these guidelines.

- All sections should be complete, including:
 - The <u>Key Publications</u> section of the application template which identifies and describes the applicant's *first and/or corresponding* author publications
 - The <u>Blood Cancer Relevance</u> section explaining the *direct* relevance of the research with LLS's Mission
- Applications must also include:
 - o Applicant biosketch attached to the full application template
 - o A signed Sponsor Letter attached to the full application template
 - 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 the letters of reference)
 - o A Clinical Protocol (where applicable)
 - o Applicable assurances (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.
- Completion of several steps in the process initiates emails sent from LLS's Research 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.
- It is recommended that final submissions at each stage be completed at least the day prior to the deadline. Acceptable post-deadline additions are regulatory updates, significant updates to clinical trials and manuscripts accepted for publication (see Submission and Confirmation).
- <u>Check your application package carefully prior to submission.</u> The deadlines stated in the Key Dates section are enforced.