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## Career Development Program Guidelines & Instructions

# **Scholar in Clinical Research**

**Effective dates:**

**July 1, 2017 - June 30, 2018**

## **2017 Updates**

### **Significant changes to the Scholar in Clinical Research Award:**

These changes are meant to better align this award to support early-stage physician-scientists who are conducting clinical research.

- Eligibility is expanded to include any permanent, independent clinical faculty who are not on a laboratory-based, tenure-track career path.
- The research support requirement is expanded to include funding from any source that adequately supports the research.
- Protected time for research is now defined to be in the range of 20-40%. Deviations from this may be allowed, and will be determined on a case by case basis by LLS staff. If an investigator is more laboratory- based than clinic-based, then they cannot apply for this award; they should consider the Scholar CDP subcategory.
- The award amount is increased to \$125,000/year.
- Some of the award may be used for salaries of other personnel who are directly connected with the clinical research activities of the applicant.

### **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 Scholar in Clinical Research Applicants**

- Must hold an independent position, and have held an independent position for less than or equal to 10 years as of January 1, 2018; all independent positions are counted (Instructor-level positions are *not* counted as independent for eligibility).
- Must have clinical training in blood cancer.
- Must propose research directly related to the clinic.
- Must demonstrate availability of research funding for the research proposed.
- Must have a Sponsor who will attest to the Sponsoring Institution's commitment to the applicant's clinical research and overall career.

### **Helpful pointers:**

- As it is required that the applicant have current funding (Scholar in Clinical Research Awards are salary support only), it is expected that there may be some overlap with current funding.
- The Scholar in Clinical Research Award is intended to further develop the careers of early-stage investigators; this Award is not intended for well-established and/or senior investigators.
- It is highly recommended to access the LLS grants management portal to begin the application process well in advance.
- It is recommended that final submissions at each stage are 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.

CDP funding is for the Applicant's salary, but a portion may also be allocated to for salary of others who are directly involved in assisting the clinical research. Salary may be supplemented by funds from other appropriate sources as determined by the Grantee's Sponsoring Institution. Support for research-associated costs must be provided by another source.

The **Scholar in Clinical Research** Award is for 5 years. The maximum award per year is \$125,000 and includes the salary and fringe benefits for the Applicant and an assistant. Any assistant supported by this award must have a direct role in the research. Indirect costs may be included, and cannot exceed 5% of the total direct costs requested in the proposal. Expenditures for laboratory costs/equipment, travel, etc. are not permitted. 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 both US citizens and non-citizens, as well as applicants who are performing research outside the U.S.

#### **Degree**

Applicants must hold a PhD, MD, DVM, or equivalent degree.

#### **Experience/eligibility clock**

Applicants must have held an independent, faculty-level, position (or equivalent) for less than or equal to 10 years at the time of review (January 1, 2018). The present position does not need to

be tenure-track, but must be independent. All such positions are counted for the 10 year total. Instructor-level positions are not counted as independent for eligibility purposes. In some cases, LLS may ask for a letter from any applicable institution confirming employment start date(s).

### **Career Trajectory**

The Scholar in Clinical Research award applicant must be in the early stages of a clinical research career in blood cancer, and the anticipation is that they will eventually be leaders in clinical blood cancer research and treatment.

### **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 Scholar in Clinical Research applicants must have a Sponsor with a full time appointment at the applicant's institution. Sponsors will document the departmental and institutional commitment to the applicant. In annual Progress Reports, the Sponsors of a Scholar in Clinical Research will document the Scholar in Clinical Research awardee's career progress as an emerging leader in the field, contributions to blood cancer research and treatment, and the Sponsoring Institution's continued commitment to the Awardee's career. An appropriate Sponsor may be a department head, chief of service, or program chair.

### **Research Support Requirement**

CDP Awards support only salary for the awardee and an assistant. Applicants must have documentation demonstrating funding for the proposed research. This funding may come from the NIH, foundations, industry, or from the applicant's institution. The presence of funding will be assessed at the eligibility phase, while the details of that funding will be assessed during the review process. **Research support that ends prior to the Award start date may not be used as evidence of research support.**

### **Application Limitations**

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

### **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 another career

development award, which has the same or higher total award amount, is activated after receiving a Scholar in Clinical Research Award, the LLS Award must be relinquished.

### **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 this move, and must contain the appropriate signatures from the new destination. In addition, the Scholar in Clinical Research Award is issued to an individual and is not transferable to another person.

### **Clinical Relevance**

The proposed studies should translate new concepts in the biomedical, epidemiological, or preventative sciences into clinical practice. Preference will be given to applicants whose research involves an early phase clinical trial of new or innovative therapies. Any proposed clinical research should be developed and implemented by the applicant. Ongoing collaborations and sponsorships of clinical research by an industry source are acceptable.

### **Review Process and Applicant Notification**

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

Review criteria for **Scholar in Clinical Research** applications:

- Accomplishments of the applicant, including demonstrated record of clinical research engagement
- Scientific/clinical quality of the proposal
- Clarity of presentation
- Likelihood of the applicant becoming a leader in the clinical translation of blood cancer research

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

After the review panel meeting, applications will be rank-ordered based on their Priority Score and those at or near the payline will be presented to LLS's oversight committees for approval. Applicants will be notified of the final decision on their application by late February. 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 status change is typically made by late February. Please do not call or email regarding status updates. Notification by email will also happen by 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	

**The submission deadlines will be strictly enforced.** Please note that all times are Eastern Time (ET). If any date falls on a weekend or US holiday, the deadline becomes the next business day.

**It is highly recommended that submissions are done the day prior to the deadline.** Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. 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 [researchprograms@lls.org](mailto:researchprograms@lls.org) 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](mailto: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 Phase Application Process: Overview**

CDP applications are done in three phases:

- 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 first independent position, funding, etc.). The answers to these questions will be used by LLS staff to determine eligibility. This step determines broad eligibility; a more detailed analysis of the applicant's credentials is done by the review panel. 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 [researchprograms@lls.org](mailto:researchprograms@lls.org) 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**

### **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 (required)**

An appropriate Sponsor is the department head, program chair, or chief of service who can describe the departmental and Sponsoring Institution's commitment to the applicant. The appointment of both the applicant and the Sponsor must be at the same institution.

### **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 “Scholar in Clinical Research” for Scholar in Clinical Research-specific eligibility questions.

### **Research Support**

Applicants must demonstrate that they have substantial funding to support the proposed or closely-related research. This funding may come from the NIH, foundations, industry, or from the applicant’s institution. Research support that ends prior to the Award start date may not be used as evidence of research support. Provide, where available, the grant PI, full name of the funding source (including grant subtype), grant number, amount of the award, and years of funding period.

### **Other Salary Support**

Provide details of other salary support, 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.

### **Date of First Independent Faculty Appointment**

Provide the date of the *first* independent faculty appointment. Instructor-level positions are *not* considered independent for eligibility purposes.

### **Justification (Optional)**

This section is optional and is used to provide any information not adequately addressed in the other sections of the eligibility form.

### **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 \$125,000, 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](mailto: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](mailto: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* section). Letters submitted past the deadline will not be accepted.

### **Key Criteria for Eligibility:**

- Must have a Sponsor who will attest to institutional support for the applicant.
- Must be an independent investigator of at least an Assistant Professor position (or equivalent).
- Must have adequate funding to support the proposed research:
  - Funding may be from the NIH, private foundations, industry, or sponsoring institution.
  - Funding must not be transitional.
  - 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 a Scholar Award.
- Must have started the *first* independent position on or after January 1, 2008.
- Instructor-level positions are *not* considered independent for eligibility purposes.

### **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.
- The Sponsor Letter 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](mailto: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**

Scholar in Clinical Research Awards end June 30, 2023.

**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. Do not include fellow or instructor-level people. 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](mailto: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](mailto: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**

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.

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

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

The full application consists of two sections.

### **Section 1:**

The downloadable project template consists of the following required elements:

#### **a. Applicant/Institution/Project Title/Abstract**

Copy and paste the Abstract from the Abstract Phase.

#### **b. Project Description (11 page maximum, including figures)**

The following information should be provided in this order:

- Background.
- Specific Aims.
- Previous Work/Preliminary Data, including figures.\*
- 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.

\*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.).**

**c. References (4 page maximum)**

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

**d. Budget**

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

- The current salary
- Fringe benefit expense
- Cost of living increases should be included in all out years
- Justification

The amount requested must not exceed \$625,000 (\$125,000/year). Should the application be funded, the amount requested will be the amount awarded, even if the requested amount is less than \$625,000.

**e. Signature Page**

This form must be completed, including indicated signatures.

**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. Publications submitted and under review may be indicated on the biosketch. An eRA Commons User Name is not required.

**b. Sponsor Letter**

The Sponsor Letter must contain the following:

- Description of the applicant's position.
- Description of the Sponsoring Institution's support for the applicant's research.
- Future plans for the applicant's career development at the Sponsoring Institution.
- Description of how the applicant's time will be divided among research and other responsibilities to the Sponsoring Institution.
- The Sponsor Letter is separate from the letters of reference; Sponsors may not write a letter of reference.

The Sponsor Letter is not blinded to the applicant.

**c. 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 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 detailed clinical protocol of the proposed research. Include approval date and compliance number. Indicate if IRB approval is pending.

**e. Assurances (Required)**

Human Subjects

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

Laboratory Animals

Indicate if animals will be involved in the proposed research. The status and date of the Institutional Animal Care and Use Committee (IACUC) (or equivalent institutional designation) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of any current or pending approvals must be provided in the full application template. There is also a section on the web form that must be completed. An application may be submitted with approval pending, but approval must be obtained and provided to LLS prior to the Award start date.

Recombinant DNA

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

Biohazard Statement

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

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

### **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 confirmatory email within 2 business days of submission, contact LLS at [researchprograms@lls.org](mailto:researchprograms@lls.org).**

If extra documents remain after submission and before the deadline, email [researchprograms@lls.org](mailto: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](mailto: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:
  - IRB updates.
  - Opening of the trial.
  - Patient enrollment.
  - Opening of new clinical sites.
  - Efficacy and/or safety updates.
- Manuscripts that have been accepted for publication; the following must be provided:
  - List of authors.
  - Title.
  - Journal.
  - A copy of the acceptance letter from the journal.

***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](mailto:researchprograms@lls.org), so that they can be removed).
- All sections should be complete, including:
  - Applicant biosketch attached to the full application template.
  - A signed Sponsor Letter 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.