



LEUKEMIA &  
LYMPHOMA SOCIETY®  
fighting blood cancers

Career Development Program  
Guidelines & Instructions:  
Fellow

Revised June 30, 2015

## What's New

The application process is changing from two steps to three steps. **Please note the change in deadlines.**

### **Step 1: Eligibility Phase**

This phase is a non-scientific evaluation of eligibility. LLS staff will determine eligibility using the criteria set forth by our independent oversight committees and described in the “Eligibility Criteria” and “Eligibility Details” sections below. Though LLS’s online grants management portal requires Applicant information in each section of the eligibility form, there is no requirement for scientific information during this phase. For those sections asking for scientific details (such as Title and Summary), please state N/A. In addition, any eligibility question not applicable to you must be answered with “N/A.”

**To be eligible for a Fellow Award, Applicants must have had their oral thesis defense, or the end of their clinical education or training, on or more recent than July 1, 2014.**

The Justification section provides the opportunity to detail reasons why Applicants are eligible, despite being outside the eligibility window. Scientific discussions, including the need for more training (current or past), are not a part of the eligibility process, and thus are not allowed in this section. Any gaps in training/experience must be explained.

Your current Sponsor or former supervisor may be asked to provide a signed letter attesting to your eligibility justification. Your eligibility may be provisionally accepted and you will have access to the next phases of the application process. However, any eligibility justification letters from your current Sponsor or former supervisor must be received no later than October 1, 2015 at 3 pm ET. If an Applicant has a provisional acceptance of eligibility, and LLS does not receive a letter by the deadline, the application will be administratively triaged.

**The Eligibility Phase opens in July 2015, and ends on September 1, 2015 at 3 pm ET.**

### **Step 2: Abstract Phase:**

Once eligibility is approved by LLS, applicants may move immediately to the Abstract Phase. Applicants will provide project title, abstracts, and other information, as described below. Scientific information is required at this phase.

**The Abstract Phase opens upon eligibility approval and ends on September 15, 2015 at 3 pm ET.**

### **Step 3: Full Application Phase**

Upon submission of Abstract Phase components, applicants may begin working on the full application.

**The Full Application Phase opens upon submission of Abstract Phase materials and ends on October 1, 2015 at 3 pm ET.**

## **Table of Contents**

### **1. Guidelines**

- a. About the Leukemia & Lymphoma Society
- b. Description of Awards
- c. Who can Apply
- d. Application Process and Deadlines
- e. Review Process and Applicant Notification

### **2. General Instructions**

- a. General Information
- b. Requirements

### **3. Application Phases**

- a. Eligibility Phase
- b. Abstract Phase
- c. Full Application Phase
- d. Peer Review of the Full Application

## 1. Guidelines

### **About the Leukemia & Lymphoma Society**

The Leukemia & Lymphoma Society (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.

The research projects funded by LLS's Career Development Program (CDP) must be of the highest quality and clearly related to this mission. These would include basic and translational research projects using normal hematopoietic and blood cancer model systems as well as immunological studies that are relevant to cancer. A description of LLS's grant portfolio is found by following this link: [LLS Grants](#).

### **Description of Awards**

With a tradition spanning over 50 years, LLS continues to support talented blood cancer researchers in the early phase of their careers. Many of our former CDP recipients have become leaders in the blood cancer field. LLS's support of young investigators will continue to provide the foundation for 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 limited to salary support for the Applicant, but may be supplemented by funds from other appropriate sources as determined by the Grantee's Sponsoring Institution. Support for research-associated costs must be certified as provided by another appropriate source.

The Fellow Award is for 3 years. The maximum award per year is \$55,000 and includes the Applicant's salary and fringe benefits, and indirect costs which cannot exceed 5% of the total direct costs. The final value of the Award may be limited by the Applicant's Sponsoring Institution's allowable salary range. Fringe benefits, including insurance and retirement benefits, may be paid from a Grantee's Award as mutually determined by the Sponsoring Institution and Grantee. Expenditures for laboratory costs/equipment, travel funds, tuition, etc. are excluded. The awarded value will be limited to the amount requested in the submitted proposal.

### **Who Can Apply**

#### **Citizenship**

LLS welcomes applications from qualified investigators who are not US citizens as well as Applicants who are performing research outside the U.S.

#### **Degree and Experience**

Applicants should hold a PhD, MD, DVM, or equivalent degree and have less than or equal to 2 years postdoctoral experience at the time of review (January 1, 2016). Postdoctoral experience begins on the date of the oral thesis defense (or date of degree conferral, whichever comes first), or at the end of clinical education or training. Time spent in the thesis advisor's laboratory following the thesis defense is considered postdoctoral experience. Postdoctoral experience is **not** defined by the start date in the current laboratory.

### **Institution Affiliation**

Applicants must be affiliated with a non-profit Sponsoring Institution at the time funding is to commence and for the duration of the award. A non-profit Sponsoring Institution includes but is not limited to the following: academic institution, university, medical center, research hospital, medical research institute, research institution or laboratory.

### **Sponsor Requirement**

Each Applicant must secure a Sponsor for the proposed research project. The Sponsor must be the head of the laboratory where the Applicant's research will occur, and will provide supervision and necessary support for the proposed research project. Research support must be demonstrated by active grant(s) to the Sponsor from the NIH, ACS, or a similar competitive, peer-review agency that funds the work described in the Fellow's application, or funds related work.

### **Application Limitations**

Applicants may submit only 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. Failure to follow this rule will result in disqualification of all Applicants with that Sponsor. 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.

### **Other Career Development Support**

No other comparable (or better) career development award may be held prior to, or at the time of the grant start date (July 1, 2016). If a comparable (or better) career development award is obtained after receiving a Fellow Award, the LLS Award must be relinquished.

### **Eligibility Criteria for Fellows**

- Must have a qualified Sponsor. See "Sponsor Requirement" above and sections pertaining to Sponsors in the "Full Application" section below.
- The Sponsor must be the head of the laboratory where the Applicant's research will be performed.
- An Applicant's postdoctoral research must be in a laboratory different than where they performed their thesis research. In addition, their Sponsor must be different than their graduate supervisor.
- A major consideration for the Applicant is the Sponsor's record of training individuals who go on to become independent biomedical researchers and on a training plan specific to the Applicant. Both should be addressed in the Sponsor's Letter of Support.
- Applicants should hold a doctoral-level degree and the appropriate amount of experience. See "Degree and Experience" above.
- The application should be designed from the perspective of where the research will be performed. Applicants who transfer between full application submission (October 1, 2015) and the Award start date (July 1, 2016) are not eligible for a Fellow Award.

### **Application Process and Deadlines**

All submissions must use our online management system, Fluxx (<https://lls.fluxx.io>). A tutorial for using Fluxx is found on the Fluxx landing page, or can be obtained by emailing [researchprograms@lls.org](mailto:researchprograms@lls.org).

## Key Dates:

	Date	Time
Eligibility Phase – open	July 2015	
Eligibility Phase – close	September 1, 2015	3:00 pm ET
Notification of eligibility	By September 8, 2015	5:00 pm ET
Abstract Phase – open	After eligibility is approved	
Abstract Phase – close	September 15, 2015	3:00 pm ET
Full Application phase – open	After Abstract Phase submission	
Full Application phase – close	October 1, 2015	3:00 pm ET
Panel Review	January 2016	
Notification of Awards	Late February 2016	
LLS's receipt of signed contracts*	May 1, 2016	3:00 pm ET

\*There is a strict deadline for returning the signed contract. In the event that a contract is not returned by this deadline, LLS reserves the right to rescind the Award offer.

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

## **Review Process and Applicant Notification**

The Medical & Scientific Affairs Committee, a standing committee of the Board of Directors, oversees LLS's research grant programs. Review of applications is delegated to the Career Development Program Grant Review Subcommittees. Members of these Subcommittees, comprised of experts in the relevant fields of science and medicine, serve on a voluntary basis.

Each application receives two scores: The **Priority Score**, which follows the NIH scoring system, ranges from 1-9 and is based on the quality of the applicant and training environment, as well as the scientific quality of the proposal. This score also reflects the likelihood of the applicant becoming a dedicated blood cancer researcher. A **Mission Score** is also assigned to one of these categories:

**Mission Score of 1:** Addresses mechanisms pertinent to the pathogenesis, diagnosis, or treatment of hematologic malignancies and relevant premalignant conditions involving patients, patient materials and/or appropriate animal model systems.

**Mission Score of 2:** Addresses basic biological processes pertinent to hematologic malignancies and relevant premalignant conditions. Has the potential to identify new pathways and clinically relevant targets.

**Mission Score of 3:** Addresses basic mechanisms related to normal blood cell development, hematopoietic stem cell function, or immune responses.

**Mission Score of 4:** Indicates that a proposal does not address mechanisms or basic biological processes relevant to blood cancers or blood cell development and function. If the reviewers assigned to the proposal are in agreement with regard to assigning the application a Mission score of 4, the application will be triaged.

CDP applications will be rank ordered based on their Priority Score and presented to the Medical & Scientific Affairs Committee. This Committee creates a funding recommendation based on the overall quality of applications (Priority Score), relevance to the LLS mission (Mission Score), programmatic review, and funds available (LLS Board of Directors determines the budget available for research grants each year). This recommendation is presented to the Mission Oversight Committee for final approval.

Applicants selected for funding will be notified as soon as possible, usually late February. Funding status is relayed by mail or email only and is not available by telephone. All Priority Scores are confidential and are available only to the LLS Medical & Scientific Affairs Committee, the Career Development Program Grant Review Subcommittee, the LLS Mission Oversight Committee, and LLS staff. Brief, anonymous feedback of reviewer critiques may be provided to the Applicant, ***but only when available.***

If an Applicant is selected for funding, a contract will be forwarded for signing by the Grantee, Sponsor, and Sponsoring Institutional representatives (including the Technology Transfer Officer). **There is a strict deadline for returning the signed contract. In the event that a contract is not returned to the LLS by the deadline, the LLS reserves the right to rescind the Award offer.**

## 2. General Instructions

### **General Information**

LLS's grant management system is accessed here: <https://lls.fluxx.io>. **Only online submissions through the Fluxx website will be accepted.**

Please be sure that you, your Sponsor, and the people who will write your letters of recommendation are on the lookout for automated emails from Fluxx regarding your application.

### **Registration**

Both the Applicant and Sponsoring Institution must be registered in Fluxx. If you have applied to LLS in the past, you do not need to create a new registration. Simply click the "[reset or create password](#)" link and enter your email address. The system will send your username and a link to update your password. Once registered, you can begin the application process. Applicants needing assistance with the Fluxx registration process can email [researchprograms@lls.org](mailto:researchprograms@lls.org).

### **Institutional Designation**

During the registration process, you should create your profile from the standpoint of where you will perform your research described in the application. You must indicate the name of the Sponsoring Institution as well as the name of the signing officials for that institution. Fluxx currently has a list of organizations registered. To register a new institution, contact [researchprograms@lls.org](mailto:researchprograms@lls.org).

### **Data Entry**

Applications may be accessed and changed multiple times as needed prior to the submission deadlines. However, **no changes can be made once the deadline has passed or the application has been finally submitted.** Moreover, some fields may not be modified in the full application following Abstract Phase submission.

## **Contacting LLS**

Questions that are not clarified in this document or in the tutorial on the Fluxx site should be addressed to:

Director, Research Programs  
The Leukemia & Lymphoma Society  
1311 Mamaroneck Avenue, Suite 310  
White Plains, New York 10605  
Telephone: (914) 821-8859  
Email: [researchprograms@lls.org](mailto:researchprograms@lls.org)

## **Requirements**

### **Forms and Format**

An application template is provided on the Fluxx website. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the Fluxx website. Fields in bold are required. Other information will be captured using the provided template. All Applicants must use single-spaced text and Times New Roman 12 pt. Margins are preset in the template and must remain as is. The Applicant's name should be typed in the upper right corner of each page of the template. Failure to use the provided template or to adhere to font size, spacing, margins, and/or page limitations may result in the disqualification of the application.

## **3. Application Phases**

### **Eligibility Phase**

This phase was separated out to make the process more efficient. Only organizational information and eligibility criteria are entered at this phase. Applicants may submit eligibility at the opening of the program in July 2015. Eligibility will be evaluated by LLS staff on a rolling basis. If eligibility is approved, the Applicant may proceed to the next phase of the application process.

The Eligibility Phase ends on **September 1 at 3:00 pm Eastern Time** or the following business day if this date falls on a weekend or a U.S. holiday.

### **Organization Information**

Please complete the required fields. If not applicable, put "N/A."

**a. Institution**

Provide the Institution where the proposed research will be performed.

**b. Principal Investigator**

The Principal Investigator is the Applicant.

**c. Institutional Signing Official (ISO)**

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

**d. Financial Officer**

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



**e. Sponsor**

The Sponsor will be the head of the laboratory where the Applicant's research will be performed.

**Eligibility Details**

This section will be used to verify eligibility. LLS staff will determine eligibility based on criteria set forth above. Applicants deemed ineligible will not be invited to submit a full application. Therefore, it is imperative that all information be filled out completely, but concisely. Eligibility is **not** based on scientific merit; therefore, any justification should **not** include scientific discussions.

**Program**

Choose Career Development Program (CDP)

**Subprogram**

Choose the appropriate subprogram. Subprogram-specific eligibility questions will then display.

**Position Title/Academic Rank**

This is the expected position that you will have at the funding start date (July 1, 2016).

**Sponsor Name and Institution**

The Sponsor will be the head of the laboratory where the Applicant's research will be performed.

**Research Support**

The CDP Award only supports salary. Therefore, Applicants must demonstrate that their Sponsor has substantial funding to support the proposed or closely related research. This can be in the form of private or NIH funding, or substantial institutional support beyond a startup package. Generally, Applicants whose Sponsors have R01-level funding are the most competitive. Please provide the grant PI name, full name of the funding source (including grant subtype), grant number, amount of the award, and years of funding period. For example: Joseph Smith's NIH RO1, CA#####, 2012-2015.

**Salary Support**

Provide the details of any other salary support for the Applicant, including the amount of that support.

**Oral Thesis Defense**

Provide the date (month, day, year) of the oral thesis defense, if applicable.

**Date of Doctoral and/or Medical Degree Conferral**

Provide the date (month, day, year) 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 principal investigator of that laboratory. This may be the same as the degree-granting institution and thesis supervisor.

**Post-Degree Clinical Training**

Provide the dates (month, day, year) and general description of any clinical training, including the percentage of time devoted to research (if applicable).

### **Justification**

If needed, please provide a **brief** justification as to why you should be considered eligible, even though you are technically outside the eligibility guidelines. Any justification considered by LLS and the review panel is very narrow, and includes family leave, serious personal illness, and/or military service. There may be limited circumstances that will be considered beyond those listed, but they must be of a similar level of significance. Examples of **unacceptable** justification include extra time spent in your thesis advisor's laboratory for any reason, or personal reasons beyond those listed above. This section may also be used to concisely explain your training history, particularly when it is complicated or does not reflect the system used in the USA.

### **Save and Review**

Validation will automatically occur after clicking the "Save and Review" button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system provides notification that fields require information. After clicking "Save and Review," you will be directed to review your information. Please ensure all information is accurate, and then click the green "Submit" button (top right corner).

### **Submission and Confirmation**

You must submit your eligibility information by **September 1st at 3:00 pm ET** via the Fluxx website, or the following business day if this date falls on a weekend or a U.S. holiday. After clicking the green "Submit" button, you will receive an email from Fluxx stating that your information was successfully submitted. **If you did not receive the confirmatory email from Fluxx within 2 business days of submission, please email us at [researchprograms@lls.org](mailto:researchprograms@lls.org).**

### **Eligibility Review**

LLS staff will review eligibility on a rolling basis. If you submit your eligibility details in July or August, you will receive notification within 11 business days. If you submit your eligibility details in September, you will receive notification by September 8, 5 pm ET. Do not call or email LLS to determine whether your information has been received or processed (unless you did not receive either the confirmatory email from Fluxx or the notification email within the timeframe described in this section and the "Submission and Confirmation" section). If eligibility is accepted, you will then have access to the next phase. If you have not received an email regarding your eligibility by September 8, 5 pm ET, contact us at [researchprograms@lls.org](mailto:researchprograms@lls.org).

### **Abstract Phase**

#### **Project Summary and Abstracts**

##### **Project Title**

Please limit to 150 characters.

##### **Project Summary**

Briefly describe the overall purpose of the proposed research in 500 characters or less.

##### **Lay Abstract**

Clearly state the relevance to blood cancer and describe your proposed research, including problem/question to be addressed, specific aims, and anticipated results in 1500 characters or less, using non-technical language that can be easily understood by the lay community. Scientific/Greek characters or symbols must not be used.

### **Scientific Abstract**

Describe your proposed research, including disease relevance, problem/question to be addressed, specific aims, and anticipated results in 1500 characters or less using appropriate technical language. Scientific/Greek characters or symbols must not be used.

### **Additional Grant Details**

#### **Amount requested from LLS**

This amount must not exceed \$55,000.

#### **Proposed Start Date**

All CDP Awards will start July 1, 2016.

#### **Proposed End Date**

The grant length will be 3 years.

#### **Previous Submission**

Please indicate if you have previously submitted an application to the same CDP subprogram in the drop down menu. In the preliminary data section of your full application, you may describe this resubmission in more detail, including changes from the prior submission.

#### **Date of Previous Submission**

Provide the date in the format provided.

### **Save and Review**

Validation will automatically occur after clicking the “Save and Review” button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system provides notification that fields require information. After clicking “Save and Review,” you will be directed to review your information. Please ensure all information is accurate, and then click the green “Submit” button (top right corner).

### **Changes**

Information collected in the Abstract Phase will automatically populate fields in the next phase. Once submitted, changes may only be made after receiving prior approval from LLS. The Applicant should email LLS ([researchprograms@lls.org](mailto:researchprograms@lls.org)) requesting any change and identifying the elements to be changed. Any changes made without the prior approval of LLS may result in the disqualification of the application.

### **Submission**

Abstract Phase submissions are due by **September 15th at 3:00 pm ET** via the Fluxx website, or the following business day if this date falls on a weekend or a U.S. holiday.

### **Full Application**

Each Applicant must submit a full application by **October 1st at 3:00 pm Eastern Time** via the Fluxx website, or the following business day if this date falls on a weekend or a U.S. holiday. Some sections of

the full application will be automatically captured on the Fluxx website. You will provide other information on an application template that must be downloaded, completed, and then uploaded. Information submitted in the Abstract Phase must not be modified, as this is subject to the “Changes” clause listed above, and may result in disqualification of the application.

## **Project Documents**

### **Download Template**

The Applicant should download the template and complete the required information:

#### **a. Biographical Sketch**

A biographical sketch is required for the Applicant and Sponsor and should not exceed two pages per person. It is acceptable for the Applicant and/or Sponsor to use the short version of their NIH biosketch as long as it does not exceed two pages.

#### **b. Other Research Support**

Other research support is defined as any funds or resources that are available to the Applicant or Sponsor in support of the Applicant’s research. This information is an important part of the review process and must be included. The Applicant must list all current and pending research support.

Because the Career Development Program only provides salary support, it is acceptable that there is overlap between active/pending research support and the proposed research. Applicants with pending research grants at the time of submission must advise LLS of funding prior to the January review date.

#### **c. Budget**

The following information should be provided in the budget template:

1. The current actual salary, wage or stipend of the Applicant and fringe benefits expense.
2. The estimated salary, wage or stipend for the duration of the award.
3. Cost of living increases should be included in all out years.
4. As mutually determined by the Sponsoring Institution and Grantee, full or partial fringe benefits can be included.

### **Personnel Costs**

The salary and fringe benefits cannot exceed \$55,000.

### **Indirect Costs**

The indirect costs are limited to 5% of the total requested direct costs.

**CDP Awards are limited to salary support for the Applicant, and may not be used for laboratory expenses, support for other laboratory personnel, or any other use.** It is acceptable for the Sponsoring Institution to supplement the Applicant’s salary from sources other than the CDP grant. Expenditures for laboratory costs/equipment, travel funds, etc. are explicitly excluded as fringe benefits. The details populated in the budget template will be analyzed by the review panel and will be used by LLS for management of payments should the application be selected for funding.

#### **d. Project Description**

Detailed description of the proposed project must include the following information:

1. Scientific or Clinical Background and Disease Relevancy
2. Specific Aims

3. Previous Work/Preliminary Data for Project (include preliminary data, charts and figures here)
4. Explanation of Experimental Design and Methods (can refer to Clinical Protocol Appendix for additional details, if appropriate)
5. Anticipated Results and Potential Clinical Relevance
6. Potential Problems/Pitfalls and Planned Solutions
7. Resources and Environment
8. References

The project description may not exceed 6 pages (excluding cited references). **Preliminary data, charts and figures are included in this page limitation, and may not be included as appendix material.**

**e. Sponsor's Letter of Support**

A letter of support from the Sponsor must be submitted and should include the following:

1. A full explanation of the Applicant's current position.
2. A plan for the Applicant's training and career development; a summary of the Sponsor's experience as a mentor (as evidenced by the Sponsor's record of training of individuals who go on to become independent biomedical researchers); and the specific sources of funding to support the Applicant's research costs.
3. A discussion of how the Applicant's time will be divided among research and other responsibilities (such as clinical work, teaching and administration).
4. How the Award will help the Applicant develop his/her career.

**f. Sponsor's Mentor Table**

Please indicate the Sponsor's experience in mentorship in the format provided.

**The Sponsor's letter of support should be included after the Sponsor's Mentor Table, all as one PDF.**

**Letters of Reference**

The Applicant should use this section of Fluxx to request and monitor the submission of letters of reference. **It is the responsibility of the applicant to ensure that the letters of reference are submitted by the application deadline. Any letters received after the full application deadline will not be accepted. Please communicate with your letter writers regarding the deadline, and to be sure they have received notification from Fluxx regarding uploading these letters.**

The Applicant should keep in mind the following:

- Three letters are required.
- At least 2 of the 3 letters must be from individuals outside the Sponsoring Institution. One of these letters should be from the PhD thesis advisor. If a letter from the PhD supervisor is not available, the Sponsor should provide an explanation in his/her letter.
- Though not required, it is useful to have one of the letters provided by a scientist or clinician who is **not** a former mentor or collaborator.
- These letters must remain confidential and are not to be viewed by the Applicant. For this reason, the letters must be uploaded by the individual who writes the letter.
- Upon adding each reference writer's information, an email will be sent to each requesting a letter on your behalf.
- The Applicant can use this section to view the submission status of the letters, but cannot view the content of the letters.

- The Applicant's Sponsor may not write a reference letter. The Sponsor's letter should be attached to the template and uploaded directly on Fluxx.

### **Budget**

Complete the information in the required fields from your budget template.

### **Publications**

Indicate the number of your first author publications that are searchable on PubMed. Please do not include non-peer reviewed publications, or publications in preparation or under review. This information will be used for statistical purposes by LLS for retrospective analysis of the grant programs. It will not be seen by the reviewers and will not be used for funding decisions.

### **Prior Awarded Grants**

Indicate the number of grants, awards, or fellowships which you have been awarded. Do not indicate any that are pending. Please include all current and past grants, awards, or fellowships from any organization. This information will be used for statistical purposes by LLS for retrospective analysis of the grant programs. It will not be seen by the reviewers and will not be used for funding decisions.

### **Organizational Assurances**

The Applicant must complete the organizational assurances section. The following provides an overview.

#### **Human Subjects**

The Applicant must indicate if human materials or subjects will be involved in the proposed research. The status (approved, pending or exempt) of Institutional Review Board (IRB) approval must be provided. The Human Subject Assurance Number (OHRP) must be included. If the research project has received IRB approval, the date must be provided and documentation must be uploaded as the Human Investigation Statement. The application may be submitted with IRB approval pending. However, an award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the January review date if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be uploaded as the Human Investigation Statement.

#### **Laboratory Animals**

The Applicant must indicate if laboratory animals will be involved in the proposed research. The status and date of Institutional Animal Care and Use Committee (IACUC) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of Sponsoring Institutional approval must be uploaded as the Laboratory Animal Statement. The application may be submitted with IACUC approval pending. However, an award will not be made without documented IACUC approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the January review if the IACUC status has changed.

#### **Recombinant DNA**

The Applicant must indicate if the proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be uploaded with the application.

#### **Biohazard Statement**

The Applicant must indicate if the proposed research involves the use of biohazards. If the Applicant indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be uploaded as the Biohazard Statement.

## **Project Documents**

This section provides the Applicant with a central location in which to upload proposal attachments. **Please note that all documents, including the application template, must be converted from Word to PDF format as this is the only acceptable format.**

### **Documents overview**

1. Project template as one PDF, containing the following in this order: Biographical Sketches and Other Research Support for the Applicant and Sponsor, Budget, Project Description, Sponsor's Letter of Support, Mentor Table, and Signature Page.
2. Optional attachments may include: a. Clinical Protocol Appendix;\* b. Publications;\*\* which should be attached before the Signature Page.
3. Organizational Assurances (Human Subjects, Laboratory Animals, Recombinant DNA, and Biohazard Statement) uploaded as separate PDFs.
4. Letters of Reference (to be submitted by the reference writers).

\*Clinical Protocol Appendix: Provide a one page summary of any clinical protocol essential to the proposed research. Include IRB approval date, IRB compliance number, and effective dates of approval. Projects for which IRB approval is pending must include a statement to that effect. The Applicant should notify LLS of IRB approval prior to the January grant review.

\*\*Publications Appendix: Up to 3 publications that are directly relevant to the proposal may be included. Inclusion of more than 3 may result in disqualification. Submitting numerous large files adds to application download times and can delay your submission. If your submission is delayed beyond the deadline, you will not be able to submit your application.

### **Save and Review**

Validation will automatically occur after clicking the "Save and Review" button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system provides notification that fields require information. After clicking "Save and Review," you will be directed to review your information. Please ensure all information is accurate, and then click the green "Submit" button (top right corner).

### **Submission of the Full Application**

**LLS does not accept fax or hard copies of the full application.** Each Applicant must submit a full application by **October 1st at 3:00 pm Eastern Time** via the Fluxx website (<https://lls.fluxx.io>). If any date falls on the weekend or a U.S. holiday, the deadline will be the following business day. The Applicant will receive an email from Fluxx stating that the application was successfully submitted. If you submitted an application and did not receive the confirmatory email from Fluxx within 2 business days, please email us at [researchprograms@lls.org](mailto:researchprograms@lls.org).

### **Peer Review of the Full Application**

An independent committee will review properly submitted applications. You can check Fluxx for the status of your application. Please do not call or email LLS to determine whether the application has been received, when it will be reviewed, or the results of the review. This information will be communicated via email.