LEUKEMIA & LYMPHOMA SOCIETY®
fighting blood cancers

Career Development Program Guidelines & Instructions: Special Fellow

Revised July 1, 2014

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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. Details on LLS's grant portfolio may be found on our website by following this URL: http://www.lls.org/#/researchershealthcareprofessionals/academicgrants/grantsfinder/.

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 Special Fellow Award is for 2 or 3 years, depending on eligibility (see below). The maximum award per year is $65,000 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. Benefit charges applied against the Grantee's award requires that he or she is eligible to participate in such programs. Expenditures for laboratory costs/equipment, travel funds, etc. are excluded as fringe benefits. The awarded value will be limited to the amount requested in the Applicant's submitted proposal.

Who Can Apply

Citizenship

Applicants need not be United States (U.S.) citizens nor associated with U.S.-based Sponsoring Institutions. LLS welcomes applications from qualified investigators outside the U.S.

Degree and Experience

Applicants should hold a PhD, MD, DVM, or equivalent degree and have at least 2 years postdoctoral experience, but less than 4.5 years of experience at the time of review (January 1, 2015).

For PhD applicants, the eligibility clock starts the day of the successful oral thesis defense (*not* the date at which the graduate degree is conferred by their university or the date at which postdoctoral training begins). Applicants from foreign institutions may use the eligibility justification section of the Letter of Intent to explain their eligibility.

For MD applicants, the eligibility clock starts at the date of MD degree conferral, ***or*** the end date of a clinical fellowship (if applicable), ***or*** at the beginning of postdoctoral training (if applicable), whichever date is later.

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 will 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 Special Fellow's application, or funds related work.

Application Limitations

Applicants may submit only one application. In addition, no more than one application in the Fellow, Special Fellow, or Special Fellow in Clinical Research categories will be accepted from any one Sponsor in any one calendar year. We do not limit the number of applications submitted from a specific institution, nor do we limit the number of Scholar applications from any one Sponsor. Failure to follow this rule will result in disqualification of all Applicants with that Sponsor.

Other Career Development Support

No other comparable (or better) career development award may be held ***prior*** to the review panel meeting (January 1, 2015). **However, Grantees may receive other career development awards (e.g. NIH K Awards) during their time as a Special Fellow.**

Eligibility Criteria for Special Fellows

- Must have shown a capacity for independent, original investigation in a field directly relevant to hematologic malignancies as documented in significant first author/last author publications in first tier, peer-reviewed journals.
- Applicants should hold a PhD, MD, DVM, or equivalent degree and have at least 2 years postdoctoral experience, but less than 4.5 years of experience at the time of review (January 1, 2015).
- Must be on a trajectory to an independent career. It is expected that Special Fellows will be competitive for an independent position by the end of the grant period. The research should ***not*** be a completely new direction, nor should it be broad-based screening. The Applicant should be building a research portfolio which will enable him/her to be competitive for an R01 proposal by the end of the grant period.
- A major consideration for the Applicant is that his/her application will be judged in part on 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.

- Acceptance of a Special Fellow Award requires that the recipient spend at least one year in the Sponsor's laboratory as a research fellow (July 1, 2015 – June 30, 2016) before moving to another position. If the Special Fellow leaves the Sponsor's laboratory (or is appointed to a faculty-level tenure-track position) before one year, the grant must be relinquished and funding returned to LLS.
- If the Special Fellow obtains an independent position **after** one year, he/she may bring the Award to his/her new institution.
- Grantees may receive other career development awards (e.g. NIH K Awards) during their time as a Special Fellow. However, they may not have such an award at the time of review (at or prior to January 1, 2015).
- Grantees are encouraged to obtain research grants during the Special Fellow Award period.
- Must not request LLS support that would extend postdoctoral research training (excluding clinical training) beyond 7 years. **Applicants can apply for either two or three years of funding** to comply with the requirement that applicants cannot exceed 7 years of postdoctoral training at the end of the funding period. In a small number of cases, this training may extend beyond 7 years, but must be approved by LLS after providing explicit and compelling justification in the "Applicant Eligibility Justification" section of the Letter of Intent. Compelling justification is restricted to some major life events, military service, and some medical emergencies.
- **The Applicant must explain why he or she needs to continue his or her postdoctoral training and how the Special Fellow award will help the Applicant to achieve his or her career goals.** The Sponsor should provide a similar explanation in his or her letter. Insufficient justification by both the Applicant and the Sponsor may result in administrative triage or disqualification at the review meeting.

Application Process and Deadlines

All Applicants must submit the Letter of Intent (LOI) and application using our new 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.

Once the LOI is processed by LLS, the Applicant will have access to the full application. Applicants and Sponsoring Institutions must register independently with Fluxx in order for Applicants to apply. 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 then becomes the following business day.

Key Dates:

	Date	Time
Letter of Intent – open	July 2014	
Letter of Intent – close	September 8, 2014	3:00 pm ET
Notification of eligibility	By September 12, 2014	3:00 pm ET
Full Application – close	October 1, 2014	3:00 pm ET
Panel Review	January 2015	
Notification of Awards	Late February 2015	
LLS's receipt of signed contracts*	May 1, 2015	3:00 pm ET

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

Review Process and Applicant Notification

The oversight of the LLS research grant program is the responsibility of the Medical & Scientific Affairs Committee, a standing committee of the Board of Directors. 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. Reviewers will also assign a **Mission Score** based on the following 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 (10-90, reflecting the average of all the reviewers' priority scores, multiplied by ten). Only applications with scores in the exceptional to excellent range (Priority Score = 10 to 39.9) are eligible for funding. Applications eligible for funding are presented to the Medical & Scientific Affairs Committee. The Medical & Scientific Affairs 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 considered 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 administrative personnel. 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.**

General Summary of Award Terms and Conditions

The following is a brief summary of selected sections of the terms and conditions of this award.

Grant Payments

The funds awarded shall be used solely for the purposes specified and in strict compliance with the budget submitted in the application to LLS and executed by the Applicant, Sponsor, Sponsoring Institution and Officers. All grant payments will be made pro rata at the end of each quarter. It is the Sponsoring Institution's responsibility to disburse funds to the Grantee during the term of the award. The final grant payment shall be made only after the receipt by LLS of satisfactory and complete final Annual Progress, Patent, and Financial Reports (see the following paragraph for an overview).

Annual Renewal of Funding

Although contracts are issued for the full term of the Award, continued funding is **contingent upon timely submission of satisfactory and complete** Annual Progress, Patent, and Financial Reports and LLS's ability to continually raise funds. **The annual progress report is due 60 days before the grant anniversary date. A financial accounting report is due 60 days after the grant anniversary date.** Report templates are on the Fluxx website (https://lls.fluxx.io), and are to be re-uploaded on this site. Reports will be reviewed by LLS staff to evaluate the research progress of each Grantee. LLS reserves the right to terminate any grant if, in its sole discretion, it determines that there has been inadequate research progress or a failure to adhere to the original proposal. **Annual Reports that are more than 30 days late or are incomplete or unsatisfactory will result in suspension of funds until the delinquency is resolved. If delinquency persists beyond 90 days, LLS reserves the right to terminate the award with prior written notice provided to the Grantee and their research administrator.**

Withholding of Funds

The failure of the Grantee, the Sponsor, and/or the Sponsoring Institution to adhere to any of the terms and conditions in the contract shall constitute sufficient grounds for LLS, in its sole discretion, to withhold any or all funds due until the deficiency is corrected to LLS's satisfaction. Either LLS or the Sponsoring Institution may then terminate the contract upon giving 90 days written notice, if the deficiency cannot be corrected. In such a case, any unexpended funds must be returned to LLS.

2. General Instructions and LOI

General Information

LLS is using a new system to manage our grants online. This system, called Fluxx, is accessed using this URL: https://lls.fluxx.io. **Only online submissions through the Fluxx website will be accepted.**

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, the Applicant can begin the LOI. Applicants needing assistance with the Fluxx registration process can email researchprograms@lls.org.

Institutional Designation
During the registration process, Applicants should create their profile from the standpoint of where they will perform their research described in the application. The Applicant 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.

Data Entry
Both the LOI and the full application may be accessed and changed multiple times as needed prior to the submission deadlines. However, **neither the LOI nor full application can be changed once the deadline has passed or the application has been finally submitted.** Moreover, some fields may not be modified in the full application following submission of the LOI.

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

Requirements

The following are some additional requirements that the Applicant needs to consider while completing the LOI and full application.

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.

Letter of Intent (LOI)

Each Applicant must submit the LOI by **September 8th 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. The Applicant should carefully craft the information requested in the LOI as this information is automatically populated into the full application and is subject to the Changes clause listed below.

Organization Information
Please complete the required fields.

a. **Institution**
   Provide the Institution where you will be performing your research.

b. Principal Investigator
Please note that 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 is responsible for assuring, on behalf of the Sponsoring Institution, that the scientific aims of the project will be met and for describing the Sponsor's and the Sponsoring Institution's role in the development of the Applicant's career.

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, 2015).

Research Support
The CDP Award supports only salary. Therefore, Applicants must demonstrate that their Sponsor has substantial funding to support the proposed research, or related work. 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, 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.

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 the Applicant should be considered eligible, even though he or she is technically outside the eligibility guidelines. Note that 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 the thesis advisor's laboratory for any reason, or personal reasons beyond those listed above. This section may also be used to concisely explain the training history of the Applicant, particularly when it is complicated or does not reflect the system used in the USA.

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 $65,000.

Proposed Start Date
All CDP Awards will start July 1, 2015.

Proposed End Date
Depending upon eligibility, the grant length will be 2 or 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 in more detail about this resubmission, 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 notifies the Applicant of fields that require information.

After clicking "Save and Review," you will be directed to review your LOI. Please ensure all information is accurate, and then click the green "Submit" button (top right corner) to submit your LOI.

Changes
Information collected in the LOI will automatically populate fields in the full application. Once submitted, changes may only be made after receiving prior approval from LLS. The Applicant should email LLS (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 of the LOI
Each Applicant must submit the LOI by **September 8th 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. After clicking the green "Submit" button, the Applicant will receive an email from Fluxx stating that the LOI was successfully submitted. **If you did not receive the confirmatory email from Fluxx within 2 business days of LOI submission, please e-mail us at researchprograms@lls.org.**

Review of the LOI
LLS staff will process submitted LOIs. Do not call or email LLS to determine whether it has been received (unless you did not receive the confirmatory email from Fluxx) or when it will be processed. Once the LOI is processed, the Applicant will be notified via email and will then have access to the full application. If you have not received an email regarding your eligibility by September 12 at 3 PM ET, contact us at **researchprograms@lls.org.**

3. 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 electronically on the Fluxx website. Other pieces of

information will be captured in the application template that must be downloaded, completed, and then uploaded by the Applicant. The Applicant may not modify any information provided in the submitted LOI as this is subject to the Changes clause listed above, and may result in disqualification of the application.

Completing the Full Application

LOI Phase Components

Some information provided during the LOI phase automatically populates in the full application and should not be modified.

Project Documents

Download Template

The Applicant should download the template and complete the required information. The following information must be completed within the template:

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. **The specific aims for each grant must be listed as they appear in the grant.**

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 $65,000.

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 in this section)
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 six 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. <u>Sponsor's Mentor Table</u>

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

<u>Letters of Reference</u>

The Applicant should use this section of Fluxx to request and monitor the submission of letters of reference. 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.
- Though not required, it is useful to have one of the letters provided by a scientist or clinician who is **<u>not</u>** 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.
- **It is the responsibility of the Applicant to ensure that the letters of reference are submitted by the application deadline. Failure to provide letters by the deadline will result in disqualification of the application.**

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 it 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 it 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 notifies the Applicant of fields that require information.

After clicking "Save and Review," you will be directed to review your application. Please ensure all information is accurate, and then click the green "Submit" button (top right corner) to submit your application.

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 e-mail us at 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.