

# Career Development Program Guidelines & Instructions: Scholar in Clinical Research

Revised June 30, 2015 Expires December 31, 2015 New Version Available July 2016

# 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 Scholar in Clinical Research Award, Applicants must have been appointed to their independent, tenure-track faculty position on or more recent than January 1, 2006.

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.

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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. 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 Scholar in Clinical Research Award is for 5 years. The maximum award per year is \$110,000 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, 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 held a faculty-level, tenure-track position for less than or equal to 10 years at the time of review (January 1, 2016).

#### **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. An appropriate Sponsor is the department head, chief of service, or program chair who can describe the department's and institution's commitment to the Applicant.

#### **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 Scholar in Clinical Research Award, the LLS Award must be relinquished.

### Eligibility Criteria for Scholars in Clinical Research

- Must have shown a capacity for independent, sustained, original clinical investigation in a field directly relevant to hematologic malignancies as documented in significant corresponding author publications in first tier, peer-reviewed journals.
- Must be in a faculty-level, tenure-track (or equivalent) position, held for less than (or equal to) 10 years at the time of review (January 1, 2016).
- Must be the principal investigator on a peer-reviewed research grant from a national agency (e.g., NIH, NSF, ACS) or other independent source that supports the research costs of the proposed work.
- The Scholar in Clinical Research Award is intended to further develop the independent research careers of highly qualified investigators, not to support well-established or senior investigators.
- Must have time to commit to the proposed research (versus teaching, administrative, or clinical responsibilities) as documented in the Sponsor's Letter of Support.
- The proposed studies should translate new concepts in the biomedical, epidemiological, or preventive 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 independently developed and implemented by the Applicant. Ongoing collaborations and sponsorships of clinical research by an industry source are acceptable.
- Other research support information from the Sponsor is not required.

# **Application Process and Deadlines**

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

# **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	
Reference Letters due	September 25, 2015	11:59 pm ET
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

<sup>\*</sup>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.

<u>The submission deadlines will be strictly enforced.</u> <u>Please note that all times are Eastern Time (ET).</u> 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 his or her environment, as well as the scientific quality of the proposal. This score also reflects the likelihood of the Applicant to continue developing a career where he/she will make significant contributions to the understanding and treatment of blood cancer. 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 <u>not</u> 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: <a href="https://ils.fluxx.io">https://ils.fluxx.io</a>. 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.

#### **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 <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a>.

#### **Data Entry**

Applications may be accessed and changed multiple times as needed prior to the submission deadlines. However, <u>no changes can be made once the deadline has passed or the application has been finally submitted.</u> 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

# **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

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

#### **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 <u>not</u> based on scientific merit; therefore, any justification should <u>not</u> 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

#### **Sponsor Name and Institution**

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

#### **Research Support**

The CDP Award only supports salary. Therefore, Applicants must demonstrate that they have substantial funding to support the proposed or closely related research. Generally, Applicants who do not have R01-level funding are not 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.

#### Date of independent faculty appointment

Provide the date of independent faculty appointment (month, day, year). The applicant must be in a faculty-level, tenure-track position held for less than (or equal to) 10 years as of January 1, 2016. This 10 year limit is the cumulative total of all independent faculty positions held.

#### **Justification**

If needed, please provide a <u>brief</u> justification as to why the Applicant should be considered eligible, even though he or she is outside the 10 year time limit. Any justification considered by LLS and the Review Panel is very narrow, and includes family leave, personal illness, or military service. There may be limited circumstances that will be considered beyond these listed, but they must be of a similar level of importance.

#### **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.** 

#### **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.

#### **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 \$110,000.

#### **Proposed Start Date**

All CDP Awards will start July 1, 2016.

#### **Proposed End Date**

The grant length will be 5 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. <u>Once submitted, changes may only be made after receiving prior approval from LLS.</u> The Applicant should email LLS (<u>researchprograms@lls.org</u>) 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. <u>Information submitted in the Abstract Phase must not be modified</u>, 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 should not exceed two pages per person. It is acceptable for the Applicant 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 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 \$110,000.

#### **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 11 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 description of institutional support for the Applicant's research.
- 3. Future plans for the Applicant's career development at the institution.
- 4. A discussion of how the Applicant's time will be divided among research and other responsibilities (such as clinical work, teaching and administration).
- 5. How the Award will help the Applicant develop his/her career.

The Sponsor's letter of support should be included after the Project Description, 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 September 25, 2015. Any letters received after this 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.
- 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.

#### **Current LLS funding**

Indicate the number of current and pending LLS grants on which you are a PI.

#### **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: Applicant's Biographical Sketch and Other Research Support, Budget, Project Description, Sponsor's Letter of Support, 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. Preference will be given to those Scholar in Clinical Research Applicants whose research involves an early phase clinical trial of new or innovative therapies.

\*\*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 (<a href="https://lls.fluxx.io">https://lls.fluxx.io</a>). 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.

# **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.

