



THE TRANSLATIONAL RESEARCH
PROGRAM
GUIDELINES & INSTRUCTIONS

FOR

NEW
LETTER OF INTENT
&
FULL APPLICATION

November 8, 2013

What's New:

- The Leukemia & Lymphoma Society (LLS) has revised its priority scoring policy to reflect the numerical scale of the NIH. Individual priority scores will range from 1 to 9 (1 being the most exceptional and 9 indicating a poor proposal).

Each application will receive two scores: The **Priority Score**, with a range from 1-9, will be based on a clear plan for the clinical exploitation of the studies proposed and the results expected. Proposals should be based on molecular, cellular or integrated systems findings and be conceptually innovative. This feature of the proposal will be an important consideration of the review process. While work directed at a further elucidation and understanding of the fundamental cellular and molecular biology of neoplastic lymphohematopoietic cells is a research priority of LLS, the Translational Research Program is specifically intended for the support of work which is clearly clinical in orientation and will be scored in a manner that is reflective of that premise.

Reviewers will also assign a **Mission Score** based on the following categories:

Mission Score of 1 – There is a very high degree of integration between basic and translational research with strong potential to lead to a clinical trial in the field of blood cancer during the duration of the award.

Mission Score of 2 – There is a very high degree of integration between basic and translational research with a moderate potential to lead to a clinical trial in the field of blood cancer during the duration of the award.

Mission Score of 3 – There is a moderate degree of integration between basic and translational research with a low potential to lead to a clinical trial in the field of blood cancer during the duration of the award.

TRP applications will be rank ordered based on their Overall Priority Score (10-90; which reflects the average of all the reviewers' priority scores multiplied by ten). **When scores are close in value**, applications with a Mission Score in category 1 may be funded despite the fact that their Priority Score is slightly less meritorious than those of other applications in Mission categories 2 and 3. Only applications with scores in the excellent to exceptional range (Overall Priority Score between 10 and 39) will be funded, regardless of mission category rankings.

******SPECIAL RFP****:**

LLS will continue to pursue proposals in several specific research areas that we consider “high need”. Applications that are focused on one of these topics will be given some funding priority within our Translational Research Program (TRP):

- 1. Define genetic/molecular predispositions to long-term and late-term effects associated with standard therapies in pediatric ALL and apply this information to improve patient outcomes.**
- 2. Development of novel therapeutic strategies for patients with non-cutaneous T-cell lymphoproliferative disorders.**
- 3. Develop novel targeted therapies for CLL patients, with real curative potential.**
- 4. Develop novel treatment strategies for MDS patients for whom hypomethylating agents have failed.**
- 5. Develop novel targeted therapies for patients with high-risk myeloma.**
- 6. Development of new-targeted therapies for indolent lymphoma patients.**

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GUIDELINES

ABOUT THE LEUKEMIA & LYMPHOMA SOCIETY

The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health agency dedicated to funding blood cancer research, education and patient services. LLS's mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

The Translational Research Program (TRP) was developed to encourage and provide early-stage support for clinical research in leukemia, lymphoma and myeloma, which is intended to develop innovative approaches to treatment, diagnosis or prevention.

DESCRIPTION OF AWARDS

The formation of the TRP program was to foster collaboration between basic and clinical scientists with the intent of enhancing the transfer of basic research findings to clinical usefulness.

Applications are sought proposing novel approaches to the prevention, diagnosis or treatment of leukemia, lymphoma and myeloma. Proposals should be based on molecular, cellular or integrated systems findings and be conceptually innovative. The application should have a clear plan for the clinical exploitation of the studies proposed and the results expected. This feature of the proposal will be an important consideration of the review process. While work directed at a further elucidation and understanding of the fundamental cellular and molecular biology of neoplastic lymphohematopoietic cells is a research priority of LLS, the Translational Research Program is specifically intended for the support of work which is clearly clinical in orientation with an overall goal to result in a clinical trial and/or TRP renewal.

This program is intended to provide support over an initial three year period and two additional years may be available through the Renewal application to solidify progress made in the initial award and further support a clinical trial. A Renewal application is not a guarantee of additional funding but competes with other Renewal applications in the same year.

The Translational Research Program was developed in consultation with the National Cancer Institute. As part of this collaboration, representatives from the Institute are invited to participate in an annual review of LLS's Translational Research Program awards.

Table 1: Maximum TRP Award Duration & Value

***Please note: The TRP award amount you are given will reflect the amount you request in the budget section of your application. Any requests to increase funding must be in writing to LLS and are subject to the availability of funds.**

Duration	Maximum Annual Direct Costs	Maximum Annual Indirect Costs	Maximum Total Costs	Maximum 3 Years
3 yrs	\$180,018	\$19,982	\$200,000	\$600,000

WHO CAN APPLY

General Eligibility Criteria

Citizenship and Degree - Applicants (Principal Investigator) must hold an M.D., Ph.D., or equivalent degree, and work in domestic or foreign non-profit organizations, such as universities, colleges, hospitals or laboratories. Applications may involve multiple such institutions and the Applicant (Principal Investigator) should have an independent research or academic position. Applicant (Principal

Investigator) need not be U.S. citizens, and there are no restrictions on Applicant (Principal Investigator) age, race, gender or creed. Applications from non-academic facilities and the National Institute of Health are not eligible. Current TRP Grantees are eligible to reapply for an extension of similar research by submitting a Renewal Application (see Renewal Guidelines and Instructions). An Applicant (Principal Investigator) may only submit one application at a time.

LEADERSHIP AND STAFFING

The Application will require one Principal Investigator who is responsible for the preparation and submission of the proposal including budget, the conduct of the research programs and adherence with all stipulations made by LLS in this document, the [Policies & Procedures](#) document, and in the grant contract if funded. Modifications to Leadership and Staffing are subject to the *Relocation or Transfer* and *Interruption, Abandonment or Leave of Absence* section of LLS's [Policies & Procedures](#) document.

APPLICATION PROCESS AND DEADLINES

The Applicant (Principal Investigator) and Sponsoring Institution must register independently with the FLUXX site in order for Applicant (Principal Investigator) to apply (*see Instructions / General / Using FLUXX*). Each Applicant (Principal Investigator) must submit a Letter of Intent (LOI; previously referred to as a Preliminary Application in Society documents) on the FLUXX website (*see Instructions /General / Using FLUXX*).

REVIEW PROCESS OF LOI

LOIs are reviewed and approved by LLS at the time of submission. Once the LOI has been approved, the Full Application will be available to the Applicant (Principal Investigator) on FLUXX for submission by March 1st.

Full Applications will only be accepted via FLUXX. The submission deadlines will be strictly enforced. Please note that all times are Eastern Standard Time (EST). If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

Table 3: TRP Grant Application Deadlines

Application Phase	Date	Time
Letter of Intent – open	November	3:00pm EST
Letter of Intent – close	February 15	3:00pm EST
Full Application – close	March 1	3:00pm EST

REVIEW CRITERIA

An application will be judged on these criteria:

- The probability of an advance in prevention, diagnosis or treatment in the near-term.
- The conceptual basis upon which the proposal rests.

- The novelty of the concept and strategy.
- Thoughtful and clear presentation.
- The overall plan for bringing the research findings to clinical application.
- Experience, background, and qualifications of investigators.
- Adequacy of resources and environment (facilities, patient population, data management, and data analysis).
- Adequacy of provisions for protection of human subjects.

REVIEW PROCESS OF FULL APPLICATIONS

Full Applications will be reviewed after the March 1st submission deadline by the TRP Subcommittee of the Medical & Scientific Affairs Committee. If an application does not meet the program goals, scope, or guidelines, it will be administratively disqualified. Once ranked, a priority score and funding recommendations of the TRP Subcommittee will be presented to the Medical & Scientific Affairs Committee and Mission Oversight Committee for final determination of awardees (in June). The Mission Oversight Committee will determine the number of awards funded, based on scientific merit and the budget approved by LLS's National Board of Directors.

Any Applicant (Principal Investigator) selected for funding will be notified within 45 days of the funding decision. **Funding decisions are relayed by email only and are not available by telephone.** All priority scores are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, LLS's Mission Oversight Committee, its Research Subcommittee and administrative personnel only. **Written critiques of the application are not formally provided to an Applicant (Principal Investigator).**

GENERAL SUMMARY OF AWARD TERMS AND CONDITIONS

The Applicant (Principal Investigator) and Sponsoring Institution officials should reference LLS's [Policies & Procedures](#) document for a full description of award terms and conditions, and to assist in the completion of the LOI and Full Application. This document can be downloaded from the FLUXX website (*see Instructions /Full Application / Download Templates & Instructions*) and is also available on LLS's website on the [Grants Information](#) page under the TRP program. The following is meant to provide a brief summary of selected sections from this document.

Grant Payments

If an Applicant (Principal Investigator) is selected for funding, a contract will be forwarded for signing by the Applicant (Principal Investigator) and Sponsoring Institution representatives. 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 (Principal Investigator) and Sponsoring Institution's Fiscal Officer. 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 Applicant (Principal Investigator) during the term of the award. The final grant payment shall be made only after the receipt by LLS of a satisfactory and complete final Annual Report.

Annual Renewal of Funding

Although contracts are issued for the full term of the award, continuation of funding is **contingent upon timely submission of satisfactory and complete Annual Reports** (*see LLS's Policies & Procedures for specific details and submission deadlines*) **and the funding available. In general, every Annual Report includes 1) a research progress report 2) an intellectual property & invention disclosure report, and 3) a financial accounting report.** Report templates are posted on LLS's [Grant Reporting & Requests](#) page. Once completed, reports must be submitted to LLS's Research and Medical Affairs Department electronically (via [FLUXX](#)) and in hard copy.

Research progress reports should briefly review research accomplishments and list any publications and clinical trials that derived from the research, as stipulated in the report template. These reports shall be reviewed by LLS in order to evaluate the research progress and will be the basis for continued funding each year the grant is in effect.

Financial reports should include details and summary of all allowable costs for the Project per year. A cumulative report will be required at the end of the grant period.

An intellectual property & invention report must be submitted by the Applicant (Principal Investigator), and signed by their respective institution.

LLS reserves the right to terminate any grant if, at its sole discretion, it determines that there has been inadequate research progress or a failure to adhere to the original research plan in the grant application. **Annual Reports that are more than thirty (30) days late or are incomplete or unsatisfactory will result in suspension of funds.**

Withholding of Funds

The failure of the Applicant (Principal Investigator) 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 ninety (90) days written notice, if the deficiency cannot be corrected. In such case, any unexpended balance of funds must be returned to LLS.

INSTRUCTIONS

GENERAL

This section contains instructions for the submission of a LOI to The Translational Research program. When completing a LOI, please keep the following in mind:

Using FLUXX

LLS uses [FLUXX](https://lls.fluxx.io) (<https://lls.fluxx.io>) for electronic submission of LOIs (and Full Applications). LLS will **not accept fax or hard copy submissions.**

Registration

Registration of Applicant (Principal Investigator) and Sponsoring Institution is required in order to submit a LOI.

- Applicant (Principal Director):

It is the responsibility of the Applicant (Principal Investigator) to register with FLUXX. If an account was already created with proposalCENTRAL, there is no need to create a new account with FLUXX. If you are a new user, click "Create an account now" on the FLUXX home page. After completing your profile,

click “submit request”. You will receive an email requesting that you confirm your account and create a password. Once your account is created, log in and click “View/Apply to Open RFPs”. To the right of the Translational Research Program, click “Create Request”.

- **Sponsoring Institution:**

It is the responsibility of institution officials (i.e. Grants and Contracts Officials) to register the Sponsoring Institution. The information provided by the Sponsoring Institution is important for Applicant (Principal Investigator) eligibility verification and will automatically populate sections of the LOI (and Full Application).

Professional Profile

Please keep the following in mind when completing the Applicant Profile:

- The Profile should be created with reference to the institution at which the Applicant (Principal Investigator) will perform the research, regardless of their institutional residence at the date of submission.
- The Applicant (Principal Investigator) must indicate the Sponsoring Institution. If the Applicant’s (Principal Investigator) Sponsoring Institution is not provided in the drop down menu, click “Add New”.

Data Entry

An Applicant (Principal Investigator) is not required to complete the online LOI (or Full Application) in one sitting. The LOI 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 applications have been finally submitted.** Moreover, some fields may not be modified in the Full Application following submission of the LOI.

Assistance with Applications

Each Applicant (Principal Investigator) is strongly encouraged to first read the Guidelines & Instructions as well as the Policies & Procedures document before asking for further assistance:

Contacting LLS

The Applicant (Principal Investigator) should address questions regarding the guidelines, requirements, instructions and assistance to researchprograms@lls.org.

The Applicant (Principal Investigator) should not contact local chapters or any other department within LLS regarding technical assistance with grant applications.

All questions concerning eligibility that are not clarified in this document should be addressed to:

*Director of Research Administration
The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue, Suite 310
White Plains, New York 10605
Telephone: (914) 821-8301
Fax: (914) 821-3301
Email: researchprograms@lls.org*

The Applicant (Principal Investigator) should not contact the local chapters or any other department within LLS regarding eligibility.

Requirements

The following are some additional requirements that the Applicant (Principal Investigator) needs to consider while completing the LOI (and Full Application).

Relevance

The proposed research should be early stage clinical research in leukemia, lymphoma and myeloma that is intended to develop innovative approaches to treatment, diagnosis, or prevention. Projects currently funded by LLS can be viewed on www.lls.org under the Grants in Force section.

Forms and Format

Templates/forms are provided for the Applicant (Principal Investigator) on the FLUXX website. Failure to use provided templates/forms may result in the disqualification of the application. All information must be typed in English. Some information will be captured when Applicant (Principal Investigator) populates fields on the FLUXX website. Other information will also be captured using provided templates/forms. Fields in **bold** are required. All documents must use single-spaced text and one of the following fonts: Arial 11 pt or Times New Roman 12 pt. The Applicant's (Principal Investigator's) name should be typed in the upper right corner of each page. Care should be taken to ensure all documents and fields are accurately completed and use commonly accepted grammar and punctuation. Page limitations must be observed, as described below.

Compliance

The Applicant (Principal Investigator) must carefully follow the [Guidelines & Instructions](#) and [Policies & Procedures](#) or risk the proposal being disqualified.

LETTER OF INTENT (LOI)

The LOI was previously referred to as the Preliminary Application in LLS's research grant program materials. Each Applicant (Principal Investigator) must submit an LOI by **February 15th at 3:00pm EST** via FLUXX website, or the following business day if this date falls on a weekend or a U.S. holiday. All information required of the Applicant (Principal Investigator) for the LOI will be captured electronically on the FLUXX website. The LOI consists of several sections. The following provides instructions for completing each section. The Applicant (Principal Investigator) 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.

Completing the LOI

Organization Information

If the Sponsor Institution already exists in the system, it will appear in a drop-down menu as its name is typed. If it does not appear, click "Add New". The same is true for all other fields in this section.

Request for Proposals

This year there are six RFP topics in research areas that highlight unmet need. If your proposed research falls within a topic listed, please choose "Yes" from the selections. Otherwise, choose "No". Choosing "No" for all topics does not disqualify your application from review. The research topics are as follows:

- 1. Define genetic/molecular predispositions to long-term and late-term effects associated with standard therapies in pediatric ALL and apply this information to improve patient outcomes**
 - The success in the treatment for acute lymphoblastic leukemia (ALL) over the last 30 years has led to numbers of pediatric cancer survivors. However, evidence is increasing that the cure from the

primary malignancy is not without long-term physical complications as well as challenges with mental and cognitive health, including brain function/learning skills. LLS seeks to support the translational research needed to identify the molecular components that may predispose a patient to developing long-term and/or late-term effects from cancer chemotherapy, and to develop diagnostic and intervention strategies based on these new understandings.

- 2. Development of novel therapeutic strategies for patients with non-cutaneous T-cell lymphoproliferative disorders** - Non-cutaneous T-cell lymphoproliferative disorders represent a diverse set of diseases from the relatively rare and chemo-responsive T-cell lymphomas to the more aggressive and difficult to treat adult T-cell acute lymphocytic leukemias. LLS seeks to support research that will enable a better understanding of the intrinsic biological differences among non-cutaneous T-cell lymphoproliferative disorders that may present therapeutic opportunities, with the goal of developing more effective, tumor-specific treatment strategies. .
- 3. Develop novel targeted therapies for CLL patients, with real curative potential** - BTK is predominately expressed in B-cells and is essential for B-cell receptor signaling, chemokine-mediated migration and adhesion, and TLR signaling. The emergence of BCR/BTK inhibitors has increased our understanding of this pathway and has demonstrated its clinical importance. With that said, BTK inhibitors are not curative and escape mechanisms remain a concern. LLS seeks to support translational research that will identify additional novel targets for CLL and elucidate new therapeutic strategies including, but not limited to, immunotherapy and immunocheckpoint therapy. LLS is particularly interested in studies that use combinations of novel therapies to potentially achieve a cure for this patient population.
- 4. Develop novel treatment strategies for MDS patients for whom hypomethylating agents have failed** - MDS is difficult to treat. While the use of hypomethylating agents as a treatment option appears promising, the lack of response/relapse rate is still too high. Therefore, there are few viable treatment options for these patients. LLS seeks to support the translational research needed to identify targets in MDS patients that have failed hypomethylating agents, with the goal of developing new therapeutic strategies for this patient population.
- 5. Develop novel targeted therapies for patients with high-risk myeloma** - Approximately 20% of myeloma patients are considered at high-risk of treatment failure as defined by specific cytogenetics, plasma cell leukemia presentations and/or early disease progression. LLS seeks to support the translational research needed to identify key targets in high-risk cases, with the goal of developing more effective therapies including, but not limited to, immunotherapy and immunocheckpoint therapy for this patient population. LLS is particularly interested in studies that use combinations of novel therapies to achieve breakthroughs for this patient population.
- 6. Development of new-targeted therapies for indolent lymphoma patients** - Despite advances in treatment, indolent lymphomas are still considered non-curable and available options are primarily cytotoxic agents with significant acute and long-term adverse affects. LLS seeks to support the research needed to identify therapies that target the underlying (and varied) pathophysiology of the disease.

Grant Information

A project title must be entered and cannot be changed once the LOI is submitted. The same is true for the project summary section. Charts and graphs should not be included in the project summary section as this section is limited to 2 to 4 sentences in length.

Enter the amount of funding requested. Please note that, should your application be funded, LLS will issue the budget as requested in your application, up to a maximum of \$200,000 per year.

Please note that the grant start and end dates are as follows and are not flexible:

Start Date: October 1, 2014

End Date: September 30, 2017

Narratives

Technical Summary (Scientific Abstract)

Briefly describe the proposed research in 3,000 characters or less using technical language. Once the LOI has been submitted, the technical abstract may not change.

General Audience Summary (Lay Abstract)

In the space provided, the Applicant (Principal Investigator) must clearly state in lay language the proposed research in 3,000 characters or less. Once the LOI has been submitted the lay abstract may not change.

Save and Review

The Save and Review feature is available throughout the LOI process to the left of the screen. **DO NOT CLICK YOUR BROWSER'S "BACK" BUTTON**, as this will cause a loss of any unsaved work.

Submit

The Applicant (Principal Investigator) can formally submit the LOI using this function. Signatures of the Applicant (Principal Investigator) and Sponsoring Institution are not required for submission of the 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 the Director of Research Administration. The Applicant (Principal Investigator) should email LLS requesting any change and identifying the elements to be changed (at researchprograms@lls.org). Any changes made without the prior approval of LLS may result in the disqualification of the application.

Submission of the LOI

LLS will not accept fax or hard copies of the LOI. Each Applicant (Principal Investigator) must submit a Letter of Intent by **February 15th at 3:00pm EST** via the FLUXX website or the following business day if this date falls on a weekend or a U.S. holiday. The Applicant (Principal Investigator) will receive an email from FLUXX stating that the LOI was successfully submitted.

Review of the LOI

LLS will process submitted LOIs. **DO NOT CALL** or **EMAIL** LLS to determine whether the LOI has been received or when it will be processed. Once a LOI is processed, the Applicant (Principal Investigator) will be notified via email and will have access to the Full Application. Such notification will be sent via email to Applicant (Principal Investigator) upon LLS approving the LOI.

INSTRUCTIONS

FULL APPLICATION

Applicants (Principal Investigators) must submit a Full Application by **March 1st at 3:00pm EST 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 captured electronically on the FLUXX website from the Applicant's (Principal Investigator's) profile or are captured during the LOI phase. Other vital pieces of information will be captured in documents that must be downloaded, completed and then uploaded by the Applicant (Principal Investigator). The Full Application consists of several sections and the following provides instructions for completing each section. ***The Applicant (Principal Investigator) may not modify any information provided in the submitted LOI as this information is subject to the Changes clause posted in the LOI and may result in disqualification of the application.***

Completing the Full Application

Log on to the FLUXX site and click the blue link associated with your request to the left. Once the request opens, click "Edit Request" at the top of the page.

The Organization Information, Request for Proposals, Grant Information, and Narratives sections remain the same. Do not change these fields unless prior approval has obtained from LLS. If a change is necessary, contact researchprograms@lls.org.

Grant Details

Download and complete the Project Description and Biosketch template. This section includes 5 fields, as follows: a) Project Description b) Biosketch(s) c) Other Research Support d) Budget and e) the Budget Justification.

Each Project description is limited to seven pages and should be presented in the following sequence: Title and Specific Aims (approx .25 pages), Scientific and Clinical significance of the work (approx. 1 page), Previous Studies/Preliminary Data (approx. 2 pages), Research Methods (approx .75 pages), Interaction with other Investigators (approx. 1 page), Resources and Environment (Major lab items or facilities) (approx. 1 page), and References cited (approx. 1 page).

A biographical sketch is required for the Applicant (Principal Investigator). The format is similar to the NIH biosketch and should not exceed two (2) pages as stated at the top of the template/form. Replicate the provided template (for the biosketch) as needed for key personnel on the project. When listing all government and non government support in the Other Research Support for the Applicant (Principal Investigator) and other key personnel, indicate any overlap of aims or research efforts of proposed work. No more than one biosketch per individual should appear in the application.

The Detailed Budget and Budget Justification should provide itemized detail for each major category for the all years of the program. This budget can be summarized in Year One of the budget and extrapolated for the remaining three years. All Totals and Subtotals should be completed on the form.

Permissible and impermissible costs must adhere to the guidelines provided in the Policies and Procedures document. In brief, the limitations are 1) no more than 40% of the direct costs may be used for professional salaries, 2) travel expenses cannot exceed \$1,000 per year, and 3) indirect costs are limited to 11.1% of the total direct costs. For all expense items, a concise justification should be provided. The justifications should focus on the major expenses, such as salary, laboratory, patient care costs, equipment and travel.

Upload the completed template to the Grant Details section by clicking the green plus sign in the “Request Documents” box.

Key Personnel: The Applicant (Principal Investigator) or staff can add a new contact(s) to the key personnel section at this point by clicking the green plus sign.

Signature Page

All applications must be signed by the Applicant (Principal Investigator), the Signing Official, the Research Administrator, and the Fiscal Officer. The signature page is provided as a printable document in the Grant Details section of the application. The Applicant (Principal Investigator) should print the Signature Page, and then obtain the required signatures. The Grants and Contracts Office of the Sponsoring Institution can help ensure appropriate signatures are obtained. Once all signatures are acquired, the document needs to be scanned, converted to a PDF, and then uploaded in the “Request Documents” box by clicking the green plus sign.

- **Signing Official:**
The Signing Official is the institutional representative responsible for signing and agreeing to the accuracy of the application and the terms of the award, if funded.
- **Financial Officer:**
The Financial Officer is the institutional representative responsible for the financial administration of externally funded research.
- **Research Administrator:**
The Research Administrator is the institutional representative responsible for the day-to-day administration of externally-funded research.

Assurances

Provide any information related to IAC, IRB, and Human/Animal Subjects in your proposed work. If any questions in this section are answered in the affirmative, attach documentation in the Grant Details section of your proposal by clicking the green plus sign in the “Request Documents” box.

- **Human Investigation Statement**
Projects that involve human materials/subjects must include the Institutional Review Board (IRB) Approval Date and Compliance Number (or certificate of exemption) as well as the effective dates of approval. IRB approval letters should be included in the “Request Documents” section by clicking the green plus sign. A Project for which IRB approval is pending must include a statement to that effect. 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 (Principal Investigator) notify LLS before review (review takes place in mid-May following March submission) regarding updated IRB status if approval was pending at the time of submission.
- **Laboratory Animals Statement**
For Projects that involve laboratory animals, the Institutional Animal Care and Use Committee (IACUC) Approval Date and Animal Welfare Assurance number must be given. IACUC approval letters should be included in the “Request Documents” section by clicking the green plus sign. An

award will not be made without documented IACUC approval if it was pending the time of application submission. It is recommended that the Applicant (Principal Investigator) notify LLS before review (review takes place mid-May following March submission) regarding IACUC status if approval was pending at the time of submission.

- **Recombinant DNA Statement**

The Applicant (Principal Investigator) must indicate if proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be uploaded with the application in the “Request Documents” section by clicking the green plus sign.

- **Biohazard Statement**

The Applicant (Principal Investigator) must indicate if proposed research involves the use of biohazards. If the Applicant (Principal Investigator) indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be uploaded in the “Request Documents” section by clicking the green plus sign.

- **Clinical Protocol Appendix**

Provide a one page summary and a link to the Cancer.gov website for 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 (Principal Investigator) should notify LLS of IRB approval prior to the grant review.

Save & Review

Click the box in this section that certifies that the information entered is accurate. Then click “Save & Review”. This will save the form as an UNSUBMITTED draft.

Submit

To SUBMIT your full proposal after clicking “Save & Review”, click “Submit” at the top of the page.

Changes

The information collected in the LOI will automatically populate fields in the Full Application. Changes may only be made after receiving prior approval from LLS’s Director of Research Administration. Any changes without prior approval may result in disqualification.

Submission of the Full Application

LLS WILL NOT accept fax or hard copies of the Full Application. Submission of a Full Application is due March 1st at 3:00pm EST via the FLUXX website (<https://lls.fluxx.io>). If any date falls on a weekend or a U.S. holiday, the deadline will be the following business day. The Applicant (Principal Investigator) will receive an email from FLUXX stating that the application was successfully submitted online upon submission.

Review of the Full Application

LLS will review properly submitted applications. Do not call or email LLS to determine whether the application has been received, when it will be reviewed or the result of the review. Results will be emailed to the Applicant (Principal Investigator) and funded grants will be activated on October 1st of the year awarded.