Blood Cancer Discoveries Grant Program (BCDG)

Guidelines & Instructions

Effective dates:
September 22, 2021 – October 1, 2022

Contents

<u>Key Points</u>

- It is highly recommended to access the **LLS Research Portal or "Fluxx" at** https://lls.fluxx.io to begin the Application process well in advance of any deadlines.

- It is recommended that final submissions at each stage (Letter of Intent/Full Application) be completed prior to the deadline. No aspects of the Application, except regulatory approvals, will be accepted past the deadline.

- All components of the Application must be present in the order indicated in this document.

- All formatting must adhere to the policy stated in this document.

- Completion of several steps in the process initiates auto generated emails sent from the LLS Research Portal. LLS staff may also send emails during the Application process. Spam filters should be monitored for these emails.

- Contact researchprograms@lls.org if expected emails are not received by the times indicated in this document.

- The deadlines stated in the Key Dates section are strictly enforced. No exceptions are made to this policy.

- Please do not attach documents to the Application that are not specifically called for such as papers in press or published papers. The Application may be administratively disqualified if this rule is violated.

<u>Introduction</u>

The Leukemia & Lymphoma Society (LLS) is proud to announce the second year of the Blood Cancer Discoveries Grant Program, a research award program designed to encourage basic research, technological innovation, and informatics pipeline development that can lead to an understanding of blood cancer disease mechanisms, the development of improved methods for detecting and monitoring cancer progression, and the identification of novel therapeutic targets.

LLS is sponsoring and issuing this Request for Applications (RFA) from **established** independent academic investigators for support of foundational, discovery-stage research that can lead to advances in the treatment and cure of blood cancers. LLS recognizes the need for a dedicated mechanism to encourage established investigators to explore the biology of blood cancer and support proof-of-concept studies that could initiate completely novel approaches to treatment.

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.

<u>Program Description</u>

The Blood Cancer Discoveries Grant Program (BCDG) is aimed at supporting cutting edge, innovative research that is discovery oriented, concerned with understanding blood cancer properties and vulnerabilities and aimed toward advancing treatments for blood cancers.

Examples of projects of potential interest include:
- cellular activities that underlie the behavior and vulnerabilities of blood cancer cells including phenomena or processes such as clonal evolution, autophagy, unique metabolic vulnerabilities, inflammation/inflammasomes, DNA damage responses, organellar changes, and poorly understood cellular regulatory mechanisms
- resistance mechanisms including immune evasion, resistant clone evolution and cellular changes underlying development of resistance to chemotherapies
- novel biomarkers or techniques to detect and monitor blood cancer development and progression
- blood cancer cell interactions with the microenvironment and with the immune system, including exploration of novel immune synapses

This program is **<u>not</u>** meant to support:
- clinical trials or correlative studies associated with clinical trials
- development of a drug or treatment that already has shown proof of concept
- research that is primarily confirmatory or minimally incremental
- research into cellular behavior, mechanisms or development not in the context of blood cancer

- studies of normal hematopoiesis

Applicants must submit a proposed work plan (subject to modification by LLS upon review) and a proposed budget with justification for its relationship to the work plan. The budget submitted should reflect the actual needs of the project but cannot exceed $250,000 USD per year / $750,000 USD total for the three (3) years of the grant. This budget ceiling includes all costs associated with the grant including indirect costs (often referred to as Institutional Overhead), which will be capped at 11.1% of the total direct costs.

Maximum Duration	Maximum Annual Indirect Costs	Maximum Annual Total Costs	Maximum Total for 3 Years
3 years	$24,977.50	$250,000.00	$750,000.00

*Please note: The grant amount awarded will reflect the amount requested in the budget section of the Application. Any requests to increase funding after submission of the Application must be in writing to researchprograms@lls.org and are subject to the availability of funds.

Eligibility

Citizenship
The program welcomes Applications from US citizens and non-US citizens, as well as Applicants who are performing research outside the United States.

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

Institutional Affiliation
Applicants must be independent investigators affiliated with a non-profit Sponsoring Institution at the time funding commences and for the duration of the award. Applications from non-academic facilities are not eligible.

Research Environment
Investigators must demonstrate that their research environment is equipped and suitable for all aspects of the work. Collaborations between multiple investigators to strengthen the work proposed will be considered favorably but are not required. Applications may involve multiple institutions; however, the Applicant (principal investigator) will be responsible for signing off on all terms of the Grant Agreement.

Application Limitations
An Applicant may only submit one Application per cycle.

Overlapping aims in grant proposals submitted to LLS
This policy applies to proposals submitted within the same Application cycle, which is defined as all LLS calls for proposals – across all grant programs – that open within the same calendar year. An Application to any LLS grant program may not have aims that substantially overlap with the aims of any other Application (either to the same program or to a different program) that includes the same investigator(s) as PI(s), Co-I(s), Project or Core Leaders, or collaborator(s). All such duplicate grant proposal submissions with substantially overlapping aims are subject to administrative disqualification, and such proposals will not be reviewed further or considered for funding. Contact researchprograms@lls.org with any questions about this policy or to discuss with LLS scientific staff any questions concerning potential overlap between Applications.

Sponsoring Institution's Acceptance of the Terms and Conditions
Applicants who are offered a Blood Cancer Discoveries Grant will be sent a Grant Agreement. Currently, the NIH does not accept LLS's Terms and Conditions.

Leadership and Staffing
The Application will require one Principal Investigator (PI) who is responsible for the preparation and submission of the proposal including the budget, the conduct of the research programs and adherence with all stipulations made by LLS in this document, the LLS Policies & Procedures document, and the Grant Agreement, if funded.

The PI must be an independent investigator, which is defined as a scientist who has dedicated laboratory space, directly hires and supervises laboratory personnel (technicians, graduate students, postdocs and staff scientists) and makes all decisions concerning research activities and use of the grant funds. Additionally, the PI must be an established investigator, which is defined as a researcher with more than 3 years in an independent faculty appointment. Predoctoral scientists, postdoctoral fellows and junior principal investigators (within the first 3 years of initial independent faculty appointment) are not eligible to apply for a grant in this program.

The Principal Investigator must be able to demonstrate a significant track record in the area of hematology and/or blood cancer research. Co-Principle Investigators are not acceptable in this program, except as described below. Collaborator(s) (also known as Co-Investigator) may be named in the Application.

We warmly welcome Principal Investigators whose scientific achievements and expertise are in another scientific area. In this case, he or she <u>must</u> have a Co-Principal Investigator who has the required significant track record in hematology and/or blood cancer research.

A Principal Investigator may only submit ONE Application per Application cycle and cannot serve as a Principal Investigator OR Co-Principal Investigator on more than ONE Application per cycle. A Co-Investigator (also known as a Collaborator) CAN serve as Co-Investigator on more than one Application. A Principal Investigator or Co-Principal Investigator can serve as a Collaborator on other Applications. Members of the peer review committee cannot apply for a Blood Cancer Discoveries Grant.

Relevance

Proposed research must be discovery oriented, concerned with understanding blood cancer properties and vulnerabilities and aimed toward advancing treatments for **blood cancers**.
Applications that do not meet the relevance requirement will be disqualified without full review.

Application Process

The Application process will occur in two phases. The first phase is submission and consideration of a Letter of Intent (LOI). The second step is the invitation for and submission of a Full Application. The Applicant and Sponsoring Institution must register independently with the LLS Research Portal in order for the Applicant to apply. Both LOI and Full Application submissions must be made electronically to the LLS Research Portal.

Key Dates

Phase	Date
Call For Proposals	September 2021
Letter of Intent Due	November 4, 2021, 3:00 PM (ET)
Notification of Full Application Invite	after January 17, 2022
Full Application Deadline	March 14, 2022, 3:00 PM (ET)
Notification of Awards	July 2022
Award Start Date	October 1, 2022

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

It is highly recommended that submissions are done well before the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be submitted to researchprograms@lls.org as far ahead as possible. The LLS Research Portal automatically shuts down submissions after the deadline has passed.

Letter of Intent (LOI)

Each Applicant must submit an LOI that will include a structured abstract describing the overall proposal in the following sections with a total character limit of 4,500.
1. Background and Preliminary Data
2. Goals and Objectives
3. Expected Outcomes and Scientific Significance.

LOIs should provide brief descriptions of how the goals and/or approaches are novel and innovative, and what impact the research may have on blood cancer. All LOIs will be reviewed, and those judged to be the most promising, competitive and responsive to the goals of the program will be invited to submit a Full Application. Letters of Intent are due **November 4, 2021 at 3PM ET**.

Review Process for LOIs

Letters of Intent for the Blood Cancer Discoveries Grant Program are reviewed and approved by LLS soon after submission. Once the LOI has been reviewed, the Applicant will be notified via e-mail as to whether or not they have been invited to submit a Full Application. The LOI stage is a competitive step; all LOI's will be reviewed for eligibility as well as for relevance and responsiveness to the goals of the program. If invited for Full Application submission, the Applicant will immediately have access to the Application submission capability in the [LLS Research Portal](#). If you have not received an email regarding your LOI approval within no more than fourteen business days, contact [researchprograms@lls.org](#).

Full Application

The project description is limited to thirteen (13) pages or less (including figures and references).
- the described project must have a clear and strong connection to or implications for understanding and/or treating blood cancer
- compelling preliminary data are required
- the proposal must contain a lucid and succinct description of how project success can be translated to clinical application
- proposals must include the description of a distinct and quantifiable milestone (goal) to be achieved by the end of the second grant year; the significance, appropriateness and impact of this milestone will be a key rating criterion during the review of the proposal; if the grant is awarded, the third year of funding will depend on the successful achievement of this goal

The deadline to submit all Full Applications is **March 14, 2022 at 3 PM ET**. Full Applications will only be accepted via the [LLS Research Portal](#). The submission deadlines will be strictly enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

Review Process for Full Application

Full Applications will be reviewed by a peer review committee composed of a diverse group of external experts. An Application that does not meet the program goals, scope or guidelines will be administratively disqualified. Applications will be assigned an initial score by the primary and secondary reviewers. Only Applications that fall above a scoring level determined by program staff and the committee chair will be discussed in detail for final ranking by the entire committee. Applications will be evaluated for potential significance, novelty, innovation and feasibility. Once ranked by the peer review panel, the highest scoring proposals will be reviewed by LLS research staff. LLS will identify those proposals to be funded based on scientific merit, responsiveness to programmatic goals and budget availability. Final approval of funding will be made by the LLS Board of Directors.

Any Applicant selected for funding will be notified in July 2022 of the funding decision. 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. Funding decisions are relayed by email only and are not available by telephone. Please also check the LLS Research Portal for the status of your Application. All priority scores are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, LLS's National Board of Directors, and Research and administrative personnel only. Feedback may only be provided for Applications discussed by the full review committee. Written critiques of the Application are not formally provided to Applicants.

Review Criteria for Full Application

An Application receives a Priority Score based on a 9-point rating scale (1=most meritorious; 9 = least meritorious) using these criteria:
- the conceptual basis upon which the proposal rests
- the novelty of the concept and strategy
- innovation in focus and/or approach
- the quality and relevance of the preliminary data
- the feasibility of the proposed experimental approaches
- thoughtful and clear presentation
- the probability that the investigation will yield discoveries that can lead to clinical translation
- the feasibility and appropriateness of the proposed milestone to be completed by the end of year 2
- experience, qualifications and track-record of investigators
- adequacy of resources and environment (facilities, access to patient samples if needed, data management and data analysis)
- adequacy of provisions for protection of human subjects

General Application Instructions

All submissions must use the LLS Research Portal or "Fluxx" at https://lls.fluxx.io. It is recommended that you familiarize yourself with this portal well in advance of any deadlines.

Registration
Both the Applicant and Sponsoring Institution must be registered in the LLS Research Portal. If you have applied to LLS in the past, you do not need to create a new registration. Simply log in with your username and password. If you forgot your password, please use the password reset functionality on the LLS Research Portal log-in page. Once updated, the Applicant can begin the LOI. Email researchprograms@lls.org for assistance creating a new account in the LLS Research Portal if you do not already have one or to update information on your existing account. Only LLS staff members have administrative permission to create new accounts.

Institutional Designation
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. If your institution is not displayed as an option under this field of the Application, contact researchprograms@lls.org to have it registered in the system.

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

Forms and Format
Applicants will provide information on the LLS Research Portal website at the LOI phase; there is no other template necessary at this phase. For the Full Application phase, a template will be provided in LLS Research Portal. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the LLS Research Portal. Fields in bold are required. All Applicants must use single-spaced Arial, size 11 font. Figure legends may use size 9 font (figures which are illegible or too small will impact the ability of reviewers to evaluate your Application and may reflect in the final scoring). Margins are preset in the template and must remain as set. 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 will result in the disqualification of the Application. In addition, applicants must adhere to character or space limitations.

Contacting LLS

Questions that are not clarified in this document, on the Blood Cancer Discoveries Grant webpage or the LLS Research Portal should be addressed to researchprograms@lls.org.

Beginning an Application

The Application will be completed in two phases: Letter of Intent and Full Application. Below are step-by-step instructions for applying:

1) Read the Guidelines & Instructions (this document) in full.

2) Log in to the LLS Research Portal and select Blood Cancer Discoveries Grant. Click "Apply Now!" to begin the Application process (well ahead of the deadline).
   - if you need a new account or have updates to an existing account, contact researchprograms@lls.org

3) Familiarize yourself with the LLS Research Portal.

4) Click "Edit" and follow the instructions for each web form field. Bold font indicates required information.
   - Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the Application may be triaged.
   - You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your Application and prevent further modification at that stage. Contact researchprograms@lls.org if you submit in error (must be before the deadline).

5) Once your LOI is submitted, you will receive an automated email within two business days from the LLS Research Portal. Consider that these emails may end up in your spam filter.

6) If your LOI is selected, you will have access to the Full Application. Click on your request, found in *New* or *Pending*, to continue with your Application.

7) Please carefully follow the instructions on the LLS Research Portal and this document. Full Applications require completion of both the web form and the Application template, which should be downloaded from the *Applicant and Collaborators Documentation* section of the LLS Research Portal. **Failure to follow all Application instructions may result in administrative triage of your Application.**

8) Submit your Full Application to the LLS Research Portal prior to the Full Application deadline. **We strongly recommend submitting at least 1 week in advance of the deadline, as site traffic on the day of and days leading up to the deadline will be heavy.**
   - Contact researchprograms@lls.org with any questions about the Application that are not addressed in the LLS Research Portal, the FAQ or this document.

Carefully check every page of your Application prior to submission. You are ultimately responsible for this submission, even if someone else submits your final Application.

At any time during the Application process, including after submitting your Full Application, you can check the status of your Application by logging in to the LLS Research Portal, selecting your Application (under *Requests* in either "New or Pending" or "Submitted") and referring to the Status in the yellow box at the top of the page.

If you have any technical difficulties with the LLS Research Portal, please contact researchprograms@lls.org.

<u>Letter of Intent Phase Instructions</u>

Each Applicant must submit the LOI by **November 4, 2021 at 3:00pm ET** via the LLS Research Portal 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. If the LOI is approved, the Applicant will be notified by an automated email from LLS Research Portal stating that he/she may proceed to the Full Application phase. Applicants may also check the status of their LOI on LLS Research Portal.

<u>Completing the LOI</u>

1) **Organization Information**

Sponsor Institution: Indicate the name and full mailing address of the institution where the research will be performed. If this institution is not listed, please contact researchprograms@lls.org.

Principal Investigator: The Principal Investigator (or PI) is the Applicant. If his or her academic title is not assistant/associate or (full) professor, please upload a letter from the sponsor institution verifying eligibility to serve as a Principal Investigator (PI) on externally funded research.

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.

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

Additional Access (Admin/Assistant): Access may be given to personnel to assist in the Application process. This is the institutional representative responsible for the day-to-day administration of externally funded research (or the Research Administrator).

Technology/Transfer Official (TTO): The TTO is the institutional representative responsible for overseeing Intellectual Property.

Key Personnel or Collaborators Information: New collaborator or key personnel contacts may be added to the collaborator section by typing the name(s) into the box. These include Co-Principal Investigators and Co-Investigators. This section helps LLS identify conflicts with reviewer assignments.

2) **Grant Information**

Project Title: Provide a title adhering to the 150-character limitation (which includes spaces).

Structured Scientific Abstract: Briefly describe the overall proposed research in <u>4,500</u> characters (including spaces) or less using technical language in the following sections:

Background and Preliminary Data: Describe the background and overall purpose of your proposed study, including a brief description of the preliminary data the study is based on. (Maximum 1,500 characters)

Goals and Objectives: Succinctly state the Specific Aims. Summarize your study design and approach to analyzing your findings. Briefly describe what you expect to find or achieve. (Maximum 1,500 characters)

Outcome and scientific significance: Describe the potential impact of your study on blood cancers. How will your study translate scientific discovery into a solution for a problem in the diagnosis, prevention, or treatment of blood cancers? (Maximum 1,500 characters)

Once the LOI has been submitted, the Goals and Objectives section of the scientific abstract may not change. Greek characters or symbols must not be used.

Amount Requested: The total amount, including both direct and indirect costs, cannot exceed $250,000.00/year. Enter the total amount of funding requested over the life of the grant (maximum $750,000.00). The amount requested on the <u>LLS Research Portal</u> should match the budget section of the full Application template.

3) **Biosketches and Other Support (Required for the PI and Co-PI only)**

Use the NIH Biosketch format and include the NIH Other Support form. ERA Commons username is not required. The Other Support section <u>must contain all current and pending support from any source</u>. The section of the Biosketch containing the Research Support section may be used, but all current and pending support must be included; completed support should not be included. As per the NIH format, the goals of each grant must be stated. **In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap your Blood Cancer**

Discoveries Grant Application. This includes any grants or portions of grants submitted to any organization, including LLS.

If you plan to submit an Application or serve as Co-Principal Investigator on an Application, you will not be eligible to serve on the program's review panel for this cycle.

Save and Review: Validation will automatically occur after clicking the "Save" 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" you will be directed to review your LOI. Please ensure all information is accurate, and then click the "Submit" button to submit your LOI to LLS.

Submission of the LOI: Each Applicant must submit the LOI by **November 4, 2021 at 3:00 pm ET** via the LLS Research Portal or the following business day if this date falls on a weekend or a U.S. holiday. After clicking the "Submit" button, the Applicant will receive an email from the LLS Research Portal stating that the LOI was successfully submitted. If you did not receive the confirmatory email from the LLS Research Portal within two business days of LOI submission, please e-mail researchprograms@lls.org. Signatures of the Applicant and Sponsoring Institution Officials 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 LLS. The Applicant must 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.

Full Application Phase Instructions

Each Invited Applicant must submit a full Application by **March 14, 2022, at 3:00 pm ET** via the **LLS Research Portal** at https://lls.fluxx.io or the following business day if this date falls on a weekend or a U.S. holiday. Some sections of the full Application will carry through from the LOI Phase. Information that carries through must not be modified; changes made to the LOI components after the LOI Phase deadline without LLS approval may result in administrative disqualification of the full Application. The remainder of the full Application consists of web form components and elements to be uploaded as a ***single PDF***.

All sections in the full Application template must use **Arial 11-point font,** except figure legends, which may use 9-point font. Margins are pre-set and must not be changed.

Failure to submit as a single PDF in the order below may result in disqualification of the Application.

1. Cover page (1 page)
- **Title**
- **Specific Aims**

2. Public Grant Information
If awarded, your answers may be displayed on LLS.org for the duration of the award. Please do not use any graphical elements, such as figures or charts. The use of Greek characters or symbols is also not permitted in this section.
- **Project Summary**: a very short lay summary of no more than 500 characters including spaces.
- **Lay Summary**: Using lay language, clearly state the proposed research in 3,000 characters (including spaces) or less.
- **Brief biography**: around 1,000 characters with spaces, intended for a lay audience.

3. Graphical abstract (1 page, does not count towards maximum page limit)
Provide a single figure, which will provide a brief overview of the project. This is similar to the graphical abstract in a Cancer Cell paper.

4. Description of Models, Reagents, and Trials (no page limit)
Provide information on the models, reagents, and trials described in your project description. This provides reviewers with an easily accessible reference source and demonstrates feasibility of your research plans.

5. Project Description (13 pages total)
The proposal is limited to 13 pages including figures and references, and must include the following sections in the following order (suggested length for each is indicated):

- **Significance of the Work** (1½ page) with the following sub-sections:
  - Clinical/Scientific significance
  - Innovation
  - Relevance to blood cancers
- **Background and Preliminary Data** (3 pages)
- **Experimental Plan, Potential Pitfalls and Alternative Approaches** (4 pages)
- **End of second year milestone** (½ page)
- **Interaction with Other Investigators (if appropriate)** (½ page)
- **Resources and Environment** (Major lab items or facilities) (1 page)
- **References** (2 ½ pages): Use the *Blood* citation format and Arial 11pt. font

6. Biosketches and Other Support (Required for the PI and Co-PI only)
Use the NIH Biosketch format and include the NIH Other Support form. ERA Commons username is not required. The Other Support section <u>must contain all current and pending support from any source</u>. The section of the Biosketch containing the Research Support section may be used, but all current and pending support must be included; completed support should not be included. As per

the NIH format, the goals of each grant must be stated. **In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap your Blood Cancer Discoveries Grant Application.** This includes any grants or portions of grants submitted to any organization, including LLS.

If funding decisions about potentially overlapping, pending grants become available following submission of an LLS Application, LLS must be notified within five business days of the Applicant's receipt of that information.

LLS recognizes that some investigations may require multiple funding sources, so overlap of specific aims with another grant may be appropriate and acceptable. The need for and details about such overlap should be clearly explained in the Application. However, LLS will consider an Applicant's other current grant support in its funding decisions. This may result in LLS funding only part of the grant or none of the grant, depending on the level of overlap. In addition, LLS reserves the right to adjust the level of funding of an awarded grant should another overlapping or potentially overlapping grant that was pending at the time of Application submission be awarded to the Applicant.

Failure to abide by LLS's rules on disclosure of current or pending support may jeopardize the funding of the current Application and may affect future LLS funding decisions.

7. Budget

The Budget and Budget Justification should provide itemized detail for each major category for all years of the project. The budget can be summarized in Year One and extrapolated for the remaining two years unless significant year-to-year change in expenditure is planned. All totals and subtotals should be completed on the form.

The maximum annual total cost (direct and indirect) cannot exceed $250,000.00 per year. The aggregate costs over three (3) years cannot exceed $750,000.00.

Permissible Direct Costs include the following with the specified limitations:

- *Personnel Expenses*: the PI's salary and fringe benefits must be capped at 40% of the total grant amount, except in exceptional circumstances where a higher cap is justified by the applicant
- *Supplies & Materials* requests should be itemized by category
- Other Research Costs (e.g. animal care, pathology services, etc)
- *Equipment Purchase* requests must identify each item of equipment with an acquisition cost of not more than a total of $25,000 annually
- *Travel Expense* requests cannot exceed $1,500 per year of the award
- Other Direct Cost requests can include subcontract costs (e.g. external sequencing service)

Permissible Indirect Costs (often referred to as Institutional Overhead, IDC, M&A, G&A or pooled costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.) as defined in Office of Management and Budget Circular A-21. Indirect costs are limited to 11.1% of the total direct

costs. For Sponsoring Institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Direct Costs.

Impermissible Costs include membership dues, tuition, books, journals, and publication costs.

8. Appendix
This section should include, in this order:

a. *Table of contents*

b. *Letters of support or collaboration*

c. *Organizational Assurances* (signed copies from appropriate institutional representatives, to be uploaded in addition to information provide in the "Assurances" section of the Fluxx web form)

> Human Subjects
> While this award is not meant to support clinical trials or correlative studies associated with clinical trials, the proposed research may include samples from human subjects. Indicate if human subjects will be involved in the proposed research and provide the status (approved, pending or exempt) of IRB approval. Documentation of any current or pending approvals must be contained in the full Application template. There is also a section on the web form that must be completed. An Application may be submitted with IRB approval pending, but IRB approval must be obtained and provided to LLS prior to the Award start date.

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

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

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

9. Signature Page
All Applications must be signed by the Principal Investigator (and Co-Principal Investigator, if applicable) and Institutional Signing Official.

Uploading the project document and final submission
Upload the full Application components, as a single PDF, in the *Applicant and Collaborators Documentation* section on the web form.

All documents must be combined into a single PDF in the order listed above before uploading. Failure to submit as a single PDF in the order above may result in disqualification of the Application.

Submission and Confirmation
After clicking the "Submit" button, you will receive an automated email **within 2 business days** stating that your information was successfully submitted. **If you do not receive the email confirmation of submission, contact LLS at** researchprograms@lls.org.

Only one Application document should be present. If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted, email researchprograms@lls.org, and we will help you upload the correct document if you are unable to delete the incorrect document. ***This email must be received, with the correct document, prior to the deadline; there are no exceptions to this rule.***

The Applicant is ultimately responsible for the submission, regardless of who actually is uploading information on the LLS Research Portal. Every year, LLS has a small number of people that notice problems with their Application after the deadline. The solution to this problem is very simple and in the hands of the Applicant:
- **Check your Application prior to final submission.**
- **Submit well ahead of the deadline.**

Once the deadline has passed, only the following updates may be made:
- manuscripts that have been accepted for publication; the following must be provided:
  - list of authors
  - title
  - journal
  - a copy of the acceptance letter from the journal along with a copy of the manuscript
- updates regarding any transfers to a new institution