

## **Discovery Grant Program (DGP)**

**Guidelines & Instructions** 

Effective dates: August 17, 2023 – October 1, 2024





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## **Application Compliance**

- It is highly recommended to access the LLS Research Portal, Fluxx, at
   https://lls.fluxx.io
   to begin the application process well in advance of any deadlines. In
   addition, each stage of the application process (letter of intent/full application should
   be completed well before the deadlines.
- No aspects of the application, except regulatory approvals, will be accepted past the deadline.
- All components of the application must be presented in the order indicated in these guidelines.
- Character limits include spaces. Character and other length limits are strictly enforced
  on the web form and the uploaded project description template. Font must be black
  Arial 11 pt. including figure legends, which should be text boxes separate from the figure
  itself. If character limits and font restrictions are not adhered to, or the preset
  margins are altered, the application may be administratively disqualified.
- Line spacing is preset in the Word document. **Do not change this setting**. Pasting text from another document into the template may result in a change in the line spacing. Check the line spacing in the template before pasting, and if there is a change after pasting, return the line spacing to the original setting. Any modifications in line spacing, particularly if the change allows for more text to fit into the page, **may result in administrative disqualification of your application.**
- Do not attach documents to the application that are not specifically called for. **The application may be administratively disqualified if this rule is violated.**
- <u>The PI and/or Co-PI</u> may apply to more than one grant program during an application cycle if the aims do not substantially overlap with the aims of any other application across all programs. You may not be on a different project within the same grant program unless you are a Collaborator.
- <u>Collaborators or Key Personnel</u> may be part of other DGP projects or any other grant program applications-provided the aims differ.
- 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 <a href="researchprograms@lls.org">researchprograms@lls.org</a> with any questions about this policy or to discuss with LLS scientific staff any questions concerning potential overlap.
- Completion of several steps in the process initiates emails sent from the <u>LLS Research</u>
   <u>Portal</u>. 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 these guidelines or if you have any questions not clarified in this document.

## About the Leukemia & Lymphoma Society, Inc.

The Leukemia & Lymphoma Society, Inc. (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.

## **Program Description**

The Leukemia & Lymphoma Society (LLS) is pleased to announce the 2023-2024 application cycle of the Discovery Grant Program (DGP). DGP is a research award program designed to encourage basic research, technological innovation, and informatics pipeline development. Also known as the Blood Cancer Discoveries Grant Program, DGP hopes to gain better understanding of blood cancer disease mechanisms, to help develop improved methods for detecting and monitoring cancer progression, and to help identify 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.

The Discovery Grant Program (DGP) is aimed at supporting cutting edge, discoveryoriented innovation research, 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 **not** 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 10% of the total award. Please note that LLS does not follow NIH guidelines for budgets.

Maximum	Maximum Annual	Maximum Annual	Maximum Annual	Maximum Total for
Duration	Indirect Costs	Direct Costs	Total Costs	3 Years
3 years	\$25,000.00	\$225,000.00	\$250,000.00	\$750,000.00

Please note: The 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 <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a> and are subject to the availability of funds. In addition, the PI and Co-PI's salaries 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.

## **Who Can Apply**

#### 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 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. Applications may involve multiple institutions and collaborators; however, the applicant (principal investigator) will be responsible for signing off on all terms of the funding agreement.

#### **Application Limitations**

An applicant (PI) may only submit one DGP application per cycle. However, if you currently hold a Discovery Grant Program (DGP) or Blood Cancer Discoveries Grant Program (BCDG) award, you may not apply to DGP in this cycle unless your current award is scheduled to end before October 1, 2024.

#### Overlapping aims in grant proposals submitted to LLS

- <u>The PI and/or Co-PI</u> may apply to more than one grant program during an application cycle if the aims do not substantially overlap with the aims of any other application across all programs. You may not be on a different project within the same grant program unless you are a Collaborator.
- <u>Collaborators or Key Personnel</u> may be part of other DGP projects or any other grant program applications provided the aims differ.

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 <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a> with any questions about this policy or to discuss with LLS scientific staff any questions concerning potential overlap between applications.

#### **Institution's Acceptance of the Terms and Conditions**

Applicants who are offered a Discovery Grant will be sent a funding 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 funding agreement, if funded.

#### The Principal Investigator (PI):

- MUST be a person (companies or institutions are not eligible)
- MUST be an <u>independent investigator at the time of the Letter of Intent</u>, 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
- MUST be an <u>established investigator</u>, defined as a researcher with more than 3 years in an independent faculty appointment at the time of the Letter of Intent
- may only submit ONE application per cycle and cannot serve as a PI OR Co-Principal Investigator on more than ONE application per cycle
- CAN serve as a Collaborator on other applications provided aims differ
- if the applicant can demonstrate a <u>significant track record in malignant hematology</u> and/or blood cancer research, a co-PI may strengthen the proposal but is not required
- if the applicant has scientific achievements and <u>significant expertise in another</u> <u>scientific area and no track record in blood cancer research</u>, they MUST have a Co-

Principal Investigator who has the required significant track record in hematology and/or blood cancer research

#### NOT eligible to apply for a grant in this program:

- predoctoral scientists or postdoctoral fellows
- junior principal investigators (within the first 3 years of initial independent faculty appointment)
- current Discovery Grant Program (DGP) or Blood Cancer Discoveries Grant Program (BCDG) awardees, unless the current award is scheduled to end before October 1, 2024

#### A Co-Principal Investigator (Co-PI):

- MUST be a person (companies or institutions are not eligible)
- MUST be an established, independent investigator with more than 3 years in an independent faculty appointment at the time of the Letter of Intent
- if the PI has the necessary track record in blood cancer research, a co-PI may strengthen the proposal but is not required
- if the PI has no expertise or proven track record in any of the blood cancers, an expert Co-PI is REQUIRED
- only ONE Co-PI is allowed
- at least one research aim of the proposal fully depends on their expertise, typically performed in their laboratory and/or facility
- MUST be designated <u>at the LOI phase</u> detailing the nature and extent of the scientific interaction
- MUST be included in the "Interaction with Other Investigators" section <u>as part of the</u> Full Application
- the Co-PI MUST provide a letter detailing the scientific interaction <u>as part of the Full</u> Application

#### A Named Collaborator or Collaborators

- MUST be a person or persons (companies or institutions are not eligible)
- a maximum of TWO NAMED collaborators are allowed
- may NOT be named at the LOI phase
- may ONLY be designated <u>at the Full Application phase</u> by being included in the "Interaction with Other Investigators" section
- each Named Collaborator MUST provide a letter of support detailing the nature of the scientific interaction
- may strengthen the work proposed but is not required
- may supply the PI with a rare reagent that is not available commercially
- may provide expert insight, guidance, or feedback on research progress
- CAN serve as a Collaborator on other Applications in this program in the same cycle

#### An "unofficial" collaborator or collaborators

• may be a person, an institution or a company supplying practical support, such as access to a single rare reagent or an instrument





- may not provide scientific expertise, that role is reserved for the Co-PI and the Named Collaborator(s)
- may strengthen the work proposed but is not required
- there is no limit on the number of unofficial collaborator(s)
- may not be included in the "Interaction with Other Investigators" section, only provide a letter of support
- CAN serve as a Collaborator on other Applications in this program in the same cycle

#### 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 & Applicant Notification**

The application process will occur in two phases, the Letter of Intent (LOI) phase and Full Application phase. Applicants will be notified via an automated email whether they are invited to submit a full application or whether their LOI was declined. If the applicant is invited to submit a full application, immediate access to the full application phase is enabled in the <u>LLS Research Portal</u>. If you have not received an email regarding your LOI approved by January 26, 2024, contact <u>researchprograms@lls.org</u>.

## **Key Dates**

Phase	Date
Call For Proposals	August 17, 2023
Letter of Intent Due	September 29, 2023, 3:00 PM (ET)
Notification of Full Application Invite	Late January 2024
Full Application Deadline	March 4, 2024, 3:00 PM (ET)
Notification of Awards	June 2024
Award Start Date	October 1, 2024

<u>All submission deadlines will be enforced.</u> 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 *prior* to the deadlines. Internet traffic may be slow near the deadlines, which may result in difficulties in submissions. In addition, LLS's response time to questions may be delayed by the high volume received near the deadlines. Therefore, it is imperative that any submissions or questions be posed to LLS well ahead of any deadlines.

## **Review Process for the Letter of Intent and Full Application**

Letters of Intent for the Discovery Grant Program are reviewed and approved by LLS after submission. Once the LOI has been reviewed, the applicant will be notified via e-mail as to whether 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 <a href="LLS Research Portal">LLS Research Portal</a>. If you have not received an email regarding your LOI by January 26th, 2024, contact researchprograms@lls.org.

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 June 2024 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 <a href="LLS Research Portal">LLS Research Portal</a> 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
- **DEI**: the applicant demonstrates understanding of any health disparities associated with the disease

## **General Application Instructions**

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

#### Registration

Both the applicant and institution must be registered in the <u>LLS Research Portal</u>. 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, 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 updated, the applicant can begin the LOI. If you are a first-time user to the LLS Research Portal, please complete the intake form located at this link: <u>Account Creation Request</u> so an account can be created for you. 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 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, you may contact <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a> to have it registered in the system. Please provide the official's full name and email address.

#### **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 final application has been 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 <u>LLS Research Portal</u> at the LOI phase; there is no other template necessary at this phase. For the full application phase, a template will be provided on the 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. <u>Fields in bold are required.</u> Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template.

Font must be black Arial 11 pt. including figure legends, which should be text boxes separate from the figure itself. If character limits, font restrictions, margins and/or page limitations are not adhered to, the application may be administratively disqualified.

In case there is a discrepancy between the application template and the guidelines document, the downloadable template supersedes the guidelines.

#### **Contacting LLS**

Questions that are not clarified in this document, on the <u>Discovery Grant Program webpage</u>, or the <u>LLS Research Portal</u> should be addressed to <u>researchprograms@lls.org</u>.

#### 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 in full and familiarize yourself with the <u>LLS</u> Research Portal.
- 2) Log into the <u>LLS Research Portal</u>, and under "Information" in the left navigation bar, select Discovery Grant Program. Click "Apply to DGP!" to begin the application process (well ahead of the deadline).
- 3) Click "Edit" and follow the instructions for each web form field. Bold font indicates required information.
  - Character limits include spaces. Character and other length limits are strictly
    enforced on the web form and the uploaded project description template. If
    character limits are not adhered to, the application may be disqualified.
  - 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 <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a> if you submit in error (must be before the deadline).
- 4) Once your LOI is submitted, you will receive an automated confirmation email within two business days from the <u>LLS Research Portal</u>. Consider that these emails may end up in your spam filter.
- 5) 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.
- 6) Please carefully follow the instructions on the <u>LLS Research Portal</u> 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 disqualification of your application.**
- 7) Submit your full application to the <u>LLS Research Portal</u> prior to the full application deadline. We strongly recommend submitting well before the deadline, as site traffic on the day of and days leading up to the deadline will be heavy.
  - Contact <u>researchprograms@lls.org</u> with any questions about the application phases that are not addressed in the LLS Research Portal, the FAQ, or this document.
- 8) To create a fair process to all applicants, these Guidelines & Instructions and



information on the LLS Research Portal must be followed. **Do not ask for** exceptions to these policies, including but not limited to exceptions to deadlines or making corrections to your document past the deadline.

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 into the <u>LLS Research Portal</u>, 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 <u>LLS Research Portal</u>, please contact <u>researchprograms@lls.org</u>.

### **Detailed Letter of Intent Phase Instructions**

Each applicant must submit the LOI using the webform available on the <u>LLS Research Portal</u>. There is no LOI template available for download and the LOI abstract must be typed or copied/pasted directly into the respective text fields. Only characters available in the standard Latin alphabet may be used, and no images nor references are allowed.

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.

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.

Please note that if the PI does not have blood cancer expertise and it is determined that the Co-PI is not a malignant hematology expert either, the LOI will be administratively disqualified. Including a Co-PI without proper justification in section "d" of the structured abstract may also result in administrative disqualification. Please ensure the requirements of the PI and Co-PI are met as described above.

The deadline is **September 29, 2023, at 3:00pm ET**, or the following business day if this date falls on a weekend or a U.S. holiday. If the LOI is approved, the applicant will be notified by an automated email from LLS Research Portal stating that he/she/they may proceed to the full application phase. Applicants may also check the status of their LOI on the LLS Research Portal.

#### **Completing the LOI**

#### 1) Organization Information

**Institution:** Indicate the name of the institution where the research will be performed. If this institution is not listed, please contact <u>researchprograms@lls.org</u> with the institution name and address so an account can be created.

**Principal Investigator:** The Principal Investigator (or PI) is the applicant who typically has the academic title assistant/associate or (full) professor. If his or her academic title does not follow this convention, please upload a letter from the institution verifying eligibility to serve as a PI (Letter of Investigator Eligibility). The following criteria must be satisfied: an independent investigator 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.

**Institutional Signing Official (ISO):** The ISO is the institutional representative responsible for 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.

**Additional Contact (Assistant)**: This is optional and may be a personal representative of the principal investigator, such as an administrator, an assistant, or a laboratory manager to be used as an additional point of contact, typically in the post-award phase. The Additional Contact will not have access to the application in Fluxx.

**Zip Code of the Institution**: Enter the zip code of the institution if located within the United States. You will need to select the zip code from the drop-down menu to ensure it is captured in the zip code field. If not located within the US, this can be left blank.

**Co-PI:** Please refer to the Co-PI section of this document to see who can serve as Co-PI and to understand if the applicant must have a Co-PI or not. Only one Co-PI is permitted on the application. The designated Co-PI cannot be changed, or a new Co-PI cannot be added after submitting the Letter of Intent. The Co-PI typically has the academic title assistant/associate or (full) professor. If his or her academic title does not follow this convention, please upload a letter from the institution verifying eligibility to serve as a Co-PI.

#### 2) Project Information

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

**Project Summary**: Please enter N/A on the Fluxx webform as this information will be requested at the full application phase.

**Structured Scientific Abstract:** Briefly describe the overall proposed research in **6,000** characters (including spaces) or less using technical language in the following sections:

- a. **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)
- b. **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)
- c. **Expected Outcomes 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)
- d. **Role of the Co-PI (Optional):** If applicable, describe the nature of the scientific interaction, i.e., which aim depends fully on the Co-PI and how. (Maximum 1,500 characters)

Once the LOI has been submitted, the Structured Scientific Abstract may not be changed without approval. If awarded, sections a-c will serve as a scientific abstract.

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 <a href="LLS Research Portal">LLS Research Portal</a> should match the budget section of the full application template. Please note that LLS does not follow NIH guidelines for budgets. Please adhere to the LLS rules as outlined in this document.

**Key Scientific Terms:** Please check the appropriate or relevant option(s) in the following categories. You may check multiple options, but please be thoughtful when selecting your answers:

- Relevance to Blood Cancer
- Disease Key Words
- Experimental System
- Specialized Experimental Approaches & Areas of Study
- Area of Study



#### 3) Supporting Documentation for the PI and Co-PI

The documents described below must be uploaded for both the PI and the Co-PI at the LOI phase as one consolidated PDF file. These documents must also be included during the Full Application phase.

- a) Biographical Sketch: use the most recent NIH biosketch format found on the NIH website. Publications submitted and under review should be indicated on the Biosketch. An eRA Commons Username is not required.
- b) NIH Other Support Form: use the most recent NIH Other Support Document format found on the NIH website. <u>Must contain all current and pending support from any source</u> and completed support should not be included. **In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap with the LLS application.** This includes any grants or portions of grants submitted to any organization, including LLS.
- c) Letter of Investigator Eligibility: If the PI or Co-PI does not have the appropriate academic title, please provide an eligibility letter as described above and at the end of this document.

If funding decisions about potentially overlapping, pending grants become available following submission of an LLS application, LLS must be notified within (5) five business days of the applicant's receipt of that information. Please e-mail researchprograms@lls.org.

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 **September 29, 2023, at 3:00 pm ET** via the <u>LLS Research Portal</u>, 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 automated email from the LLS Research Portal stating that the LOI was successfully submitted. If you did not receive the confirmation email from the LLS Research Portal within two business days of LOI submission, please e-mail <u>researchprograms@lls.org</u>. Signatures of the applicant and institution officials are not required for submission of the LOI.

The applicant is ultimately responsible for the submission, regardless of who actually is uploading information on the <u>LLS Research Portal</u>. Every year, LLS has a small number

of people that notice problems with their letter of intent after the deadline. The solution to this problem is very simple and in the hands of the applicant:

- Check your letter of intent prior to final submission.
- Submit well ahead of the deadline.
- We are not responsible if any applicants are unable to submit by the deadline if our system indicates that:
  - a. the letter of intent procedure was started less than 24 hours before the deadline, or
  - b. <u>a previously started letter of intent file was then only picked up again less</u> than 3 hours before the deadline

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

## **Detailed Full Application Phase Instructions**

Each invited applicant must submit a full application by **March 4, 2024, at 3:00 pm ET** via the **LLS Research Portal** at <a href="https://lls.fluxx.io">https://lls.fluxx.io</a> or the following business day if this date falls on a weekend or a U.S. holiday. Most sections of the full application will carry through from the LOI Phase. Information that carries through must not be modified; changes cannot be made to the LOI components after the LOI Phase deadline. 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**. Margins are preset and must not be changed.

<u>Failure to submit as a single PDF in the order below may result in disqualification of the application.</u>

- **1. Cover page** (1 page)
  - Name of Applicant and Co-PI (if applicable)
  - Project Title
  - Specific Aims

#### 2. Public Grant Information

If awarded, your information will be featured 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**: Provide a short summary (approximately 2-4 sentences) in lay language. Charts and graphs cannot be included in the project summary section of the LLS Research Portal.

- Lay Description: The Lay Description should clearly state the relevance of your research to blood cancer and describe your current/proposed research, including the problem/question to be addressed, specific aims, and anticipated results using non-technical language that is easily understood by the lay community. Scientific/Greek characters or symbols must not be used. The Lay Description is essential for LLS to continue successful fundraising to support our current and future grantees, including the later years of your award, should it be funded. Thus, we require a well-written Lay Description, with sufficient detail and suitable language for non-scientists. Be aware of your confidential information, as the Lay Description (and Project Summary) will be shared with others. The Lay Description has a maximum of 3,000 characters, including spaces.
- Brief Biography (for both PI and Co-PI): Provide a brief, professional biography introducing the PI and Co-PI (if applicable) to a lay audience. Approximately 1,000 characters including spaces.
- **Public Project Tags:** Please check the appropriate or relevant option(s) in the following categories. You may check multiple options, but please be thoughtful when selecting your answers:
  - o Major Diseases
  - Specific Disease Types
  - Other Key Search Terms

# **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 and Reagents (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** (14 pages total)

The project description is limited to fourteen (14) 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



In addition, the project description must include the following sections in the following order (suggested length for each is indicated):

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

#### 6. 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 and Co-PI's salaries 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 \$3,000 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 Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. *Indirect costs are limited to 10% of the total award value of \$750,000, or \$250,000 per year*. For 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.



**Please note**: The 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 <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a> and are subject to the availability of funds.

#### 7. Appendix

This section should include, in this order:

- **a.** *Table of contents:* Please list the contents of your Appendix section in the format of your choosing. List each individual document separately (i.e., support letter from each collaborator).
- b. Biosketches and Other Support (Required for the PI and Co-PI only): Although these were provided at the LOI phase, we are asking that you include them again as part of the full application phase. Use the NIH Biosketch format and include the NIH Other Support form. ERA Commons username is not required. The Other Support section must contain all current and pending support from any source. 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 with your Discovery Grant Program 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; please e-mail researchprograms@lls.org.

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.

**c.** Letters of support or collaboration are required from all personnel listed and described in the "Interaction with Other Investigators" project description section above. As a reminder, one Co-PI and a maximum of two Named Collaborators are

allowed. Further letters of support may be added from other investigators, institutions, or companies; however, these are considered unofficial collaborators. As a reminder, if the applicant has scientific achievements and significant expertise in another scientific area and no track record in blood cancer research, the Co-PI MUST provide a letter detailing the scientific interaction <u>as part of the research proposal</u>.

d. Organizational Assurances (Required) Projects for which IRB approval is pending must be accompanied by a signed letter from the appropriate institutional official. The applicant should notify LLS of IRB approval prior to the grant review. <u>Any application without these letters attached may not be reviewed</u>.

Full approval for all assurances that are necessary for the research must be obtained by the award start date.

#### **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. 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 included in the single PDF of the application. The application may be submitted with IRB approval pending but 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 grant review if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be included in the single PDF of the application.

#### 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 or equivalent oversight entity) 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. It is recommended that the applicant notify LLS before the grant review if the IACUC status has changed.

#### 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.

Note: Your institution is required to have assurance procedures in place, so please check with them if you are unsure how to obtain your assurance approval documentation.

No attachments besides those listed above can be included in the Appendix. Applications that include additional documents besides those requested may be administratively disqualified.

#### 8. Signature Page

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

#### <u>Uploading the Project Document and Final Submission</u>

Upload the full application components, as a single PDF, in the *Applicant and Collaborators Documentation* section on the web form. The file upload should be labeled, "DGP Project Description/Application" which you can select from the document upload drop-down menu. **Do not delete the PDF file which included the NIH biosketches and NIH other support forms that were uploaded during the LOI phase.** 

All full application documents must be combined into a single PDF in the order listed above before uploading. <u>Failure to submit as a single PDF in the order above may result in disqualification of the application.</u>

#### **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.

There should be **two** PDF files once the full application is submitted in Fluxx. The LOI phase PDF document which included the biosketches, other support forms and Letter(s) of Investigator Eligibility (if required) and the Full Application phase (steps 1-8 as outlined in the detailed full application phase) PDF file. If extra documents remain after submission and before the deadline, email <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a> 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 <a href="mailto:researchprograms@lls.org">researchprograms@lls.org</a>, 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 <u>LLS Research Portal</u>. 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.
- We are not responsible if any applicants are unable to submit by the deadline if our system indicates that:
  - c. the application procedure was started less than 24 hours before the deadline, or
  - d. <u>a previously started application file was then only picked up again less than</u> 3 hours before 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

If you plan to withdraw your application at any time during the application cycle, please inform LLS staff of your decision by writing to <a href="mailto:researchprogram@lls.org">researchprogram@lls.org</a>.

## <u>List of All Unique Documents Required during the Application</u> <u>Process</u>

Applications with missing or incomplete documents will be subject to administrative triage, both at the LOI and Full Application stages.

- Biographical Sketch: A BioSketch MUST be uploaded from both the PI and the Co-PI.
   Please use the most recent NIH biosketch from the NIH website. Publications submitted
   and under review MUST be indicated on the Biosketch. Please upload this form at the
   LOI Phase and again at the Full Application Phase even if you have no updates. (LOI
   Phase AND Full Application Phase)
- NIH Other Support Form: This form MUST be uploaded from both the PI and the Co-PI. Please use the most recent NIH Other Support Document format found on the NIH website. MUST contain all current and pending support from any source and completed support should not be included. In addition, specific aims MUST be listed for current and pending grants that may overlap or appear to overlap with the LLS application. This includes any grants or portions of grants submitted to any organization, including



LLS. Please upload this form at the LOI Phase and again at the Full Application Phase even if you have no updates. (LOI Phase AND Full Application Phase)

- Letter of Investigator Eligibility: Pls and Co-Pls (where applicable) must be independent investigator(s), typically with any of the following academic titles: assistant, associate or (full) professor. If the Investigator's academic title does not follow this convention, please upload an official letter from the institution verifying eligibility to serve as a Pl or co-Pl. Independent investigator is commonly 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. (LOI Phase)
- Letter of Support from the Co-PI: Co-PIs MUST provide a letter of support detailing the nature of the scientific interaction. As a reminder, only one Co-PI is allowed. (Full Application Phase)
- Letter of Support from a Named Collaborator: Named Collaborators MUST provide a letter of support detailing the nature of the scientific interaction. As a reminder, a maximum of two Named Collaborators are allowed. (Full Application Phase)
- Letter of Support from an "unofficial" collaborator: Further letters of support may be added from other investigators, institutions, or companies; however, these are considered unofficial collaborators. (Full Application Phase)
- Organizational Assurances: Projects for which IRB approval is pending must be
  accompanied by a signed letter from the appropriate institutional official. The
  applicant should notify LLS of IRB approval prior to the grant review. <u>Any application</u>
  without these letters attached may not be reviewed. (Full Application Phase)