LEUKEMIA & LYMPHOMA SOCIETY®
fighting blood cancers

THE TRANSLATIONAL RESEARCH PROGRAM
GUIDELINES & INSTRUCTIONS

FOR RENEWAL APPLICATIONS

LETTER OF INTENT
&
FULL APPLICATION

November 15, 2012

What's New:

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

  The **Priority Score** will be based on a clear plan for the clinical exploitation of the studies proposed and the results expected. Evidence that a clinical trial will be carried out as a result of the renewal of funding is required. An approved clinical protocol is considered strong evidence of a grant's translational potential. It must also be shown that the IRB-approved Phase I or II clinical trial is based on the initial LLS translational grant. While work directed at a further elucidation and understanding of the fundamental cellular and molecular biology of neoplastic lymphohematopoietic cells is a research priority of LLS, the Translational Research Program is specifically intended for the support of work which is clearly clinical in orientation and will be scored in a manner that is reflective of that premise.

  TRP renewal applications will be rank ordered based on their Overall Priority Score (10-90; which reflects the average of all the reviewers' priority scores multiplied by ten).

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

  Mission Score of 1 – The clinical trial proposed in this renewal has strong potential for scientific advancement or patient impact in the field of blood cancer.

  Mission Score of 2 – The clinical trial proposed in this renewal has moderate potential for scientific advancement or patient impact in the field of blood cancer.

  Mission Score of 3 – The clinical trial proposed in this renewal has low potential for scientific advancement or patient impact in the field of blood cancer.

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

- There will be a separate peer review panel for TRP renewals that focus on eligibility, trial design and potential patient impact. The review panel may provide feedback and comments for the investigator.

- The award amount has increased ***if needed*** with a cap of $ 500,000 /year for 2 years to allow for enhanced trial designs with an emphasis on patient impact.

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GUIDELINES

ABOUT THE LEUKEMIA & LYMPHOMA SOCIETY

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

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

DESCRIPTION OF AWARDS

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

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

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

Renewal applications will be accepted during the third year of the initial award or up two grant cycles after the expiration date of the initial award. For example, those grantees whose awards terminate in the Fall of 2013 can apply for renewal in 2013, 2014, or 2015, **if an IRB-approved Phase I or II clinical trial based on the initial translational grant is in place.**

Table 1: Maximum TRP Renewal Award Duration & Value

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

Duration	Maximum Annual Direct Costs	Maximum Annual Indirect Costs	Maximum Total Costs	Maximum 2 Years
2 yrs	$450,045	$49,955	$500,000	$1,000,000

WHO CAN APPLY

General Eligibility Criteria

Citizenship and Degree - Applicants (Principal Investigator) must hold an M.D., Ph.D., or equivalent degree, and work in domestic or foreign non-profit organizations, such as universities, colleges, hospitals or laboratories. Applications may involve multiple such institutions and the Applicant (Principal Investigator) should have an independent research or academic position. Applicant (Principal Investigator) need not be U.S. citizens, and there are no restrictions on Applicant (Principal Investigator) age, race, gender or creed. Applications from non-academic facilities and the National Institute of Health are not eligible.

Current TRP Grantees are eligible to apply for a renewal of similar research by submitting a Renewal Application (see Renewal Guidelines and Instructions). An Applicant (Principal Investigator) may only submit one application at a time.

LEADERSHIP AND STAFFING

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

APPLICATION PROCESS AND DEADLINES

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

REVIEW PROCESS OF LOI

LOIs are reviewed and approved by LLS at the time of submission. Once the LOI has been approved, the Full Application will be available to the Applicant (Principal Investigator) on proposalCentral for submission by March 15th.

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

Table 2: TRP Grant Application Deadlines

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

REVIEW CRITERIA

An application will be judged on these criteria:

- The probability of an advance in prevention, diagnosis or treatment in the near-term.
- Evidence of productivity through the initial award period of the Translational Research Grant.
- Evidence that a clinical trial will be carried out as a result of the renewal of funding. An approved clinical protocol is considered strong evidence of a grant's translational potential.
- The conceptual basis upon which the proposal rests.
- The novelty of the concept and strategy.
- Thoughtful and clear presentation.
- The impact of the research on disease prevention, diagnosis or management.
- Experience, background, and qualifications of investigators.
- Adequacy of resources and environment (facilities, patient population, data management, and data analysis).
- Adequacy of provisions for protection of human subjects.

REVIEW PROCESS OF FULL APPLICATIONS

Full Applications will be reviewed after the March 15th submission deadline by the TRP Subcommittee of the Medical & Scientific Affairs Committee. If an application does not meet the program goals, scope, or guidelines, it will be administratively disqualified. Once ranked, a priority score and funding recommendations of the TRP Subcommittee will be presented to the Medical & Scientific Affairs Committee for final determination of awardees (in June). The Medical & Scientific Affairs Committee and Mission Oversight Committee will determine the number of awards funded, based on scientific merit and the budget approved by LLS's National Board of Directors.

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

GENERAL SUMMARY OF AWARD TERMS AND CONDITIONS

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

Grant Payments

If an Applicant (Principal Investigator) is selected for funding, a contract will be forwarded for signing by the Applicant (Principal Investigator) and Sponsoring Institution representatives. The funds awarded shall be used solely for the purposes specified and in strict compliance with the budget submitted in the application to LLS and executed by the Applicant (Principal Investigator) and Sponsoring Institution's Fiscal Officer. All grant payments will be made pro rata at the end of each quarter. It is the Sponsoring Intuition's responsibility to disburse funds to the Applicant (Principal Investigator) during the term of the award. The final grant payment shall be made only after the receipt by LLS of a satisfactory and complete final Annual Report.

Annual Renewal of Funding

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

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

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

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

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

Withholding of Funds

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

INSTRUCTIONS

GENERAL

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

Using proposalCENTRAL

As of July, 2007, LLS is using proposalCENTRAL (https://ProposalCENTRAL.altum.com) for electronic submission of LOIs (and Full Applications). LLS will **not accept fax or hard copy submissions**.

Registration

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

- Applicant (Principal Director):

It is the responsibility of the Applicant (Principal Investigator) to register with proposalCENTRAL. Once registered, the Applicant (Principal Investigator) should complete the Professional Profile section (*see Professional Profile below*). Applicant (Principal Investigator) can reference tutorials provided on the proposalCENTRAL website such as: "*How to register as a proposalCENTRAL User*", "*How to create an application using proposalCENTRAL*".

- Sponsoring Institution:

It is the responsibility of institution officials (i.e. Grants and Contracts Officials) to register the Sponsoring Institution. The information provided by the Sponsoring Institution is important for Applicant (Principal Investigator) eligibility verification and will automatically populate sections of the LOI (and Full Application). Sponsoring Institution officials can reference tutorials provided on the proposalCENTRAL website such as "*How to register your institution with proposalCENTRAL*".

Professional Profile

It is imperative that the Applicant (Principal Investigator) carefully complete the Professional Profile section, once registered. Much of the information from this Profile will automatically populate sections of the LOI (and Full Application). Please keep the following in mind when completing the Profile:

- The Profile should be created with reference to the institution at which the Applicant (Principal Investigator) will perform the research, regardless of their institutional residence at the date of submission.
- The Applicant (Principal Investigator) must indicate the Sponsoring Institution. If the Applicant's (Principal Investigator) Sponsoring Institution is not provided in the drop down menu, the Applicant (Principal Investigator) should contact their institute officials (i.e. Grants and Contract Officials) and request institutional registration.

Data Entry

An Applicant (Principal Investigator) is not required to complete the online LOI (or Full Application) in one sitting. The LOI may be accessed and changed multiple times as needed prior to the submission deadlines. However, **neither the LOI nor Full Application can be changed once the deadline has passed or applications have been finally submitted.** Moreover, some fields may not be

modified in the Full Application following submission of the LOI (*see Instructions/Letter of Intent/Changes*).

Assistance with Applications

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

Contacting proposalCENTRAL

The Applicant (Principal Investigator) should address questions regarding the guidelines, requirements, instructions and assistance to:

Customer Service
8:30am - 5:00pm Eastern Standard Time
Available Monday through Friday
Telephone (toll-free): (800) 875-2562 x227
or Direct dial: (301) 916-4557 x227
Email: pcsupport@altum.com

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

Contacting LLS

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

Director of Research Administration
The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue, Suite 310
White Plains, New York 10605
Telephone: (914) 821-8290/ 8301
Fax: (914) 821-3301
Email: researchprograms@lls.org

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

Requirements

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

Relevance

A**n IRB-approved Phase I or II clinical trial based on the initial translational grant must be in place.** Renewal projects currently funded by LLS can be viewed on www.lls.org under the Grants in Force section.

Forms and Format

Templates/forms are provided for the Applicant (Principal Investigator) on the proposalCENTRAL website. Failure to use provided templates/forms may result in the disqualification of the application. All information must be typed in English and a margin of .5 inches is required. Some information will be captured when Applicant (Principal Investigator) populates fields on the proposalCENTRAL website. Other information will also be captured using provided templates/forms. Fields marked with an asterisk

are required. All documents must use single-spaced text and one of the following fonts: Arial 11 pt or Times New Roman 12 pt. The Applicant's (Principal Investigator's) name should be typed in the upper right corner of each page. Care should be taken to ensure all documents and fields are accurately completed and use commonly accepted grammar and punctuation. Page limitations must be observed, as described below.

Compliance

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

LETTER OF INTENT (LOI)

The LOI was previously referred to as the Preliminary Application in LLS's research grant program materials. Each Applicant (Principal Investigator) must submit an LOI by **March 1 at 3:00pm EST** via the proposalCENTRAL website, or the following business day if this date falls on a weekend or a U.S. holiday (*see Instructions / General / Using proposalCENTRAL*). All information required of the Applicant (Principal Investigator) for the LOI will be captured electronically on the proposalCENTRAL website. The LOI consists of several sections. The following provides instructions for completing each section. The Applicant (Principal Investigator) should carefully craft the information requested in the LOI as this information is automatically populated into the Full Application and is subject to the Changes clause listed below.

Completing the LOI

Title Page

Project Title: Provide a concise title for the proposed Project, adhering to the stated character limitation. Once the LOI has been submitted, the Applicant (Principal Investigator) cannot change the title.

Resubmission and date (if applicable): Please indicate if the Applicant (Principal Investigator) has previously submitted a TRP Renewal grant application. This is a required field. Provide the date if known.

A title needs to be entered in order to continue to the next step of the application.

Download Templates & Instructions

This section provides a single location for the Applicant (Principal Investigator) to access and download all forms. The following is a list of the available documents:

Document Name	**Document Type**	**Document Format**
Guidelines & Instructions	Instructions	PDF
Policies & Procedures	Instructions	PDF

**no templates are needed at the LOI stage*

Enable Other Users to Access this Proposal

This section is not utilized in determination of the Applicant's (Principal Investigator's) eligibility or in administrative or programmatic review of applications. This screen allows the Applicant

(Principal Investigator) to give other users in the Sponsoring Institution, access to the application to assist with completing sections of the LOI.

Applicant (Principal Investigator)

The majority of this section is populated from the Applicant (Principal Investigator) Professional Profile. If there are required fields that do not contain information, the Applicant (Principal Investigator) should click on the Edit Professional Profile button and complete the requested information.

Institution & Contacts

This section is automatically populated from the Sponsoring Institution's Profile. The Applicant (Principal Investigator) cannot modify Sponsoring Institution Profiles. However, the Applicant (Principal Investigator) should confirm that the appropriate Sponsoring Institution is listed. If a Sponsoring Institution is not listed or listed incorrectly, the Applicant (Principal Investigator) should select the correct Sponsoring Institution from the list provided. If the Applicant's (Principal Investigator's) Sponsoring Institution is not on the provided list, the Applicant (Principal Investigator) should contact the Sponsoring Institution Official (i.e. Grants and Contracts Office) to request registration by the Sponsoring Institution.

General Abstract

In the space provided, the Applicant (Principal Investigator) must clearly state in lay language the proposed research in 3000 characters or less. Once the LOI has been submitted the lay abstract may not change.

Technical Abstract

Briefly describe the proposed research in 3000 characters or less using technical language. Once the LOI has been submitted, the technical abstract may not change.

Validate

It is required that the Applicant (Principal Investigator) validate the LOI. The Validate function is a safety measure for the Applicant (Principal Investigator) to ensure that all required fields of information are completed. If required fields are empty, the system identifies and notifies the Applicant (Principal Investigator) of fields that require information.

Submit

The Applicant (Principal Investigator) can formally submit the LOI using this function. Signatures of the Applicant (Principal Investigator), and Sponsoring Institution are not required for submission of the LOI.

Changes

Information collected in the LOI will automatically populate fields in the Full Application. Once submitted, changes may only be made after receiving prior approval from the Director of Research Administration. The Applicant (Principal Investigator) should email LLS requesting any change and identifying the elements to be changed (at researchprograms@lls.org; *see Instructions / General / Assistance with Applications*). Any changes made without the prior approval of LLS may result in the disqualification of the application.

Submission of the LOI

LLS will not accept fax or hard copies of the LOI. Each Applicant (Principal Investigator) must submit a LOI by **March 1 at 3:00pm EST** via the proposalCENTRAL website or the following business day if this date falls on a weekend or a U.S. holiday. The Applicant (Principal Investigator) will receive an email from proposalCENTRAL stating that the LOI was successfully submitted.

Review of the LOI

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

INSTRUCTIONS

FULL APPLICATION

Applicants (Principal Investigators) must submit a Full Application by **March 15 at 3:00pm EST via the proposalCentral website** or the following business day if this date falls on a weekend or a U.S. holiday. Some sections of the Full Application will be captured electronically on the proposalCentral website from the Applicant's (Principal Investigator's) profile or are captured during the LOI phase. Other vital pieces of information will be captured in documents that must be downloaded, completed and then uploaded by the Applicant (Principal Investigator). The Full Application consists of several sections and the following provides instructions for completing each section. ***The Applicant (Principal Investigator) may not modify any information provided in the submitted LOI as this information is subject to the Changes clause posted in the LOI and may result in disqualification of the application.***

Completing the Full Application

Title Page

- Title: This information was provided during the LOI phase. Do not change this field.
- Resubmission: Please indicate if the Applicant (Principal Investigator) has previously submitted a TRP renewal grant application. This is a required field.
- Date of Previous Submission:
  Provide the date, if known, in the format of mm/dd/yyyy.

Download Templates & Instructions

This section provides a single location for the Applicant (Principal Investigator) to access and download all necessary templates/forms. The Applicant (Principal Investigator) should download a copy of each document and complete the information in the templates/forms provided. Please reference the *Proposal Attachments* section below for detailed guidance regarding the information to include. The following is a list of the available documents:

Table 4: Templates & Instructions for Full Application

Document Name	Document Type	Document Format
Guidelines & Instructions	Instructions	PDF
Policies & Procedures	Instructions	PDF
Project Information with Budget	Template	Word Document
Appendices Table of Contents	Template	Word Document
Signature Page	Template	Word Document

- The Project Information with Budget Template includes five (5) parts as follows: a) the Project Description b) the Applicant's (Principal Investigator's) Biosketch c) Other Research Support, d) the Budget and e) the Budget Justification. For additional details on the upload attachments, see the Upload Attachments section.

Enable Other Users to Access this Proposal

This section allows the Applicant (Principal Investigator) to provide other users access to the proposal. Administrative assistants and collaborating institutions would be suitable "users" for accessing sections of the Full Application.

Applicant (Principal Investigator)

The information that the Applicant (Principal Investigator) provided in the Professional Profile will automatically populate this section. No additional information is required. Modification of this information from that provided in the LOI can result in the disqualification of the application.

Institution and Contacts

The first part of this section is automatically populated from the Sponsoring Institution's Profile. The Applicant (Principal Investigator) cannot modify the Sponsoring Institution's Profile. The remainder of this section is designed to capture contact information for various individuals that LLS may need to speak to if the Applicant (Principal Investigator) is selected for funding. The Applicant (Principal Investigator) should reference the "Instruction" button on the page for detailed directions. Below is a list of the required contacts. If the Applicant (Principal Investigator) does not know who the appropriate individual is, the Applicant (Principal Investigator) should contact the Sponsoring Institution's Grants and Contracts officials (or equivalent) for guidance. (This information was filled in at the LOI stage and it needs to be completed for the Full Application step as well).

- Signing Official:
  The Signing Official is the institutional representative responsible for signing and agreeing to the accuracy of the application and the terms of the award, if funded.
- Fiscal Officer:
  The Fiscal Officer is the institutional representative responsible for the financial administration of externally funded research.
- Research Administrator:
  The Research Administrator is the institutional representative responsible for the day-to-day administration of externally-funded research.
- Communications Officer:
  The Communications (or Public Relations) Officer is the institutional representative responsible for communications of newsworthy accomplishments made by investigators at the Sponsoring Institution.

Key Personnel:

The Applicant (Principal Investigator) or staff can add a new contact(s) to the key personnel table at this point. Adding an investigator or researcher here will allow that contact to alter areas in the Full Application if they are permitted in the section labeled Enable Other Users to Access the Proposal.

Abstract, Keywords, and Descriptors

The Technical and General Abstracts will be populated from the LOI. Do not change these fields as it may result in the disqualification of your application.

- Research Descriptors
  The descriptors provide information that assists in reviewer assignment and portfolio management.
- Keywords:
  The Applicant (Principal Investigator) should chose from the following keywords that are most relevant to the proposed research. This information will assist LLS in reviewer assignment. While there is no limit on keyword selection, the Applicant (Principal Investigator) should only chose keywords that are specifically relevant to the application.

- Acetylation, histone deacetylases, histone deacetylase inhibitors
- antibody-based therapeutics, immunotoxins
- AML1, AML1-ETO, incl Runt domain, TEL-AML1
- Antisense oligodeoxynucleotides
- apoptosis, cell survival, incl Bcl-2, XIAP, caspases
- autophagy
- BCR-ABL
- C. elegans worm models
- CBFß
- carcinogenesis, incl. leukemogenesis, lymphomagenesis, oncogenes, tumor suppressors, cancer stem cells
- cell adhesion, motility, migration, cytokinesis, cytoskeleton, scaffold
- cell cycle, incl. cyclins, CDKs, checkpoints
- cell division, mitotic spindle, mitotic checkpoint
- cell growth, proliferation regulation
- cellular aging/senescence
- chemotherapy, incl. drug resistance, drug discovery
- chromosome biology, incl. segregation, centromeres, telomeres, chromosome translocations, karyotypes
- clinical trials
- cytotoxic T lymphocytes (CTLs)
- D. melanogaster fly models
- DNA damage/mutations/repair, incl. genomic stability
- DNA methylation, DNA methyltransferase
- DNA recombination
- DNA replication
- embryology
- embryonic stem cells
- endocytosis, internalization, trafficking, clathrin-coated vesicles, intracellular transport, chaperones
- epigenetics, incl. chromatin, nucleosomes, histone modification, histone deacetylatases, DNA methylation
- extracellular matrix incl integrins, cadherins, stromal cell interactions
- familial inheritance
- FLT3
- gamma secretase
- genomics
- Hematopoiesis / Immunology, incl. Ab and TCR Class Switch, B cell, T cell, dendritic cell
- NK cell and myeloid cell biology, differentiation, costimulatory molecules
- High throughput chemical/peptide/antibody screening
- immunotherapy, including adoptive, vaccines
- interleukins
- JAK2, JAK/STAT
- metabolomics, mitochondria, electron transport, glycolysis
- M.musculus models, including transgenics, knockouts, knock-ins
- microenvironment
- microRNAs, siRNA, RNA interference
- minimal residual disease
- MLL
- Myc
- NFκB, IKK

- Notch
- p53
- pediatric cancers
- peptide therapeutics
- pharmacogenomics
- pharmacokinetics, pharmacodynamics
- phosphodiesterases (PDE)
- phosphatases
- proteasome, protein folding, ubiquitin, proteasome inhibitors
- protein modification (not histones), incl. farnesylation
- proteomics
- Ras
- RNA folding
- RNA Polymerase
- S. Cerevisiae, S. Pombe yeast models
- signal transduction, incl. cytokines, growth factors / interleukins, interferons, kinases
- protein phosphorylation, phosphatases, glucocorticoids, ligand/receptor biology, lipid metabolism
- phospholipase, GTPase
- stem cell biology, incl niche, self-renewal
- stem cell transplantation, incl autologous, allogeneic, non-myeloablative, cord blood, bone marrow
- structural biology
- transcription, transcription factor, pocket proteins, mRNA processing, stability
- translation
- transplants, including allogeneic, autologous, bone marrow, cord blood stem cell, and graft-versus-tumor graft-versus-host disease
- virology, incl. viral-assd. cancers
- Wnt
- WT1
- X. Laevis frog models

- Disease Relevance:

The Applicant (Principal Investigator) can identify two (2) diseases that are most relevant to the proposed research. Choosing more than two (2) may result in disqualification of the application. The list of options is provided here in more detail for clarity.

- acute myeloid leukemias
- chronic myeloid leukemias
- other myeloid diseases (including myelodysplastic syndromes, myeloproliferative diseases)
- acute lymphoid leukemias
- chronic lymphocytic leukemias / small lymphocytic lymphomas (excluded from Indolent non-Hodgkin's lymphoma)
- indolent non-Hodgkin's lymphomas (including follicular, lymphoplasmacytoid, marginal zone, MALT, cutaneous T-Cell / mycosis fungoides / Sezary syndrome)
- aggressive non-Hodgkin's lymphomas (including diffuse large cell, diffuse mixed cell, large cell immunoblastic, lymphoblastic, blastic NK, Burkitt's, mantle cell, primary mediastinal B-cell, anaplastic large cell, various T-Cell except cutaneous, true histiocytic, primary effusion, central nervous system, AIDS-related)
- Hodgkin lymphomas (formerly Hodgkin's disease)
- myelomas (including multiple myeloma, plasmacytoma, MGUS and related lymphoid diseases)
- pediatric blood cancers (including leukemias and lymphomas in children and adolescents)
- basic research (including but not limited to fundamental biological processes / molecules broadly involved in cancer formation and/or progression, with relevance to more than one blood cancer)

- Research Area:

  The Applicant (Principal Investigator) can identify two (2) areas that are most relevant to the proposed research. Choosing more than two (2) may result in disqualification of the application. The list of options is provided here in more detail for clarity.
  - general hematopoiesis / immunology / embryology / cell biology (including but not limited to research focused on DNA / chromosome replication and repair, cell cycle, apoptosis, migration / homing, signal transduction and including model, non-hematopoietic systems for these studies)
  - general blood stem cell biology (including plasticity, lineage commitment)
  - lymphoid, myeloid cell carcinogenesis (including cancer stem cell biology)
  - blood cancer biomarkers (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management)
  - blood cancer therapies, excluding stem cell transplantation (including small molecules, DNA/RNA-based, biologics = antibodies /growth factors / cytokines / other proteins / peptides, cell-based and other non-transplant immunotherapies)
  - stem cell transplantation (including but not limited to allogeneic, autologous, non-myeloablative), cord blood
  - long-term and late effects (including detection / prevention / treatment)

- Steps Toward Improved Outcomes (Development Step):

  The Applicant (Principal Investigator) can identify two (2) most relevant steps towards improving outcomes. Choosing more than two (2) may result in disqualification of the application. The list of options is provided here in more detail for clarity.
  - applied technology development (including assays and animal models)
  - new biomarker / treatment target discovery (including but not limited to diagnosis, prognosis and risk-stratification markers and oncogene, tumor suppressor and immunotherapy targets)
  - pre-clinical biomarker validation (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management)
  - pre-clinical treatment target validation (including chemo-, radio- and immunotherapy targets)
  - pre-clinical treatment validation (including chemo-, radio- and immunotherapy safety and/or activity in animal and other models)
  - pre-clinical treatment development (pharmacokinetics, pharmacodynamics, and/or toxicology in animal and other models)
  - Phase 1 clinical trials (safe / tolerable dose-finding, in humans)
  - Phase 2 clinical trials (preliminary efficacy, in humans)
  - Phase 3 clinical trials (efficacy compared to "standard", in humans)

Attachments

This section provides the Applicant (Principal Investigator) with a central location in which to upload proposal attachments. Please note that all templates/forms must be converted from Word document format to PDF format as this is the only format acceptable. Format conversions can be accomplished using PDF generator software. Links to free or very low cost options are available on the proposalCentral website.

This section also provides a secondary location for the Applicant (Principal Investigator) to access and download any templates/forms and instructions. Attachments are classified as optional or required. The Applicant (Principal Investigator) can view three lists while in this section:

Currently Uploaded Attachments
Required Attachments
Templates & Instructions available for downloading

As each document (regardless of optional or required classification) is uploaded, the document will

be added to the "Currently Uploaded Attachments" list. As each required document is uploaded, the document will be automatically removed from the "Required Attachments" list. The following is a list of the attachments indicating the attachment type, the classification, and whether a template/form is provided. If a template/form is provided, the Applicant (Principal Investigator) must us this form or risk disqualification. If you have any questions about what is acceptable or unacceptable, contact LLS at researchprograms@lls.org

Table 5: Proposal Attachments for Full Application

Attachment Type	Classification	Template Provided
Appendices Table of Contents	Required	Yes
Project Information with Budget	Required	Yes
Human Subject Statement	Required as needed	No
Laboratory Animal Statement	Required as needed	No
Biohazard Statement	Required as needed	No
Clinical Protocol Appendix	Required	No
Signature Page	Required	Yes*

**Can be found immediately following step to "Validate" application.*

The following sections provide guidance to the Applicant (Principal Investigator) for required information in each attachment.

- Appendices Table of Contents

  Use this form to identify all appended materials. Please indicate a title for each appendix. A detailed description should not be included. The Applicant's (Principal Investigator's) and other key personnel's publications that are directly relevant to the methods or aims of the research may be included however not to exceed three per investigator. All password protection features must be removed by Applicant (Principal Investigator).

- Project Information with Budget

  The Project Information with Budget Template has five (5) sections: a) Project Description b) Biosketch(s) c) Other Research Support d) the Budget and e) the Budget Justification.

  Each Project description is limited to eleven (11) pages and should be presented in the follow sequence: a) Specific Aims for the first renewal year (approximately .5 pages), b) Scientific Background for the first renewal year (approximately 1.5 page), c) detailed progress report, keyed to specific aim(s) of original funded proposal- include a list of *publications* if any from the current grant support (list published papers, papers in press, published abstracts, submitted abstracts or submitted manuscripts (approximately 5 pages), d) summary of clinical trial planned or in progress (approximately 1.0 page), e) significance of research for disease diagnosis, prevention or management (approximately 1.0 page), f) resources and environment (approximately .5 page), g) plans for investigator interaction (approximately .5 page), h) and preliminary data (approximately 1.0 page) and research methods (approximately .5 pages). References must follow the Project description but do not count towards the eleven (11) pages. **A clinical research protocol must be submitted with IRB approval date and compliance number as part of the appendix.**

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

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

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

- Human Investigation Statement

  Projects that involve human materials/subjects must include the Institutional Review Board (IRB) Approval Date and Compliance Number (or certificate of exemption) as well as the effective dates of approval. IRB approval letters should be included in Attachment A. A Project for which IRB approval is pending must include a statement to that effect. An award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant (Principal Investigator) notify LLS before review (mid May following March submission) regarding updated IRB status if approval was pending at the time of submission.

- Laboratory Animals Statement

  For Projects that involve laboratory animals, the Institutional Animal Care and Use Committee (IACUC) Approval Date and Animal Welfare Assurance number must be given. IACUC approval letters should be included in Attachment A. An award will not be made without documented IACUC approval if it was pending the time of application submission. It is recommended that the Applicant (Principal Investigator) notify LLS before review (mid May following March submission) regarding IACUC status if approval was pending at the time of submission.

- Recombinant DNA Statement

  The Applicant (Principal Investigator) must indicate if proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institution approval must be uploaded with the application.

- Biohazard Statement

  The Applicant (Principal Investigator) must indicate if proposed research involves the use of biohazards. If the Applicant (Principal Investigator) indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be uploaded as the Biohazard Statement.

- Clinical Protocol Appendix

  Provide a one page summary and a link to the Cancer.gov website for any clinical protocol essential to the proposed research. Include IRB approval date, IRB compliance number, and effective dates of approval. Projects for which IRB approval is pending must include a statement to that effect. The Applicant (Principal Investigator) should notify LLS of IRB approval prior to the grant review.

- Signature page

  The PDF version of the signatures needs to be uploaded to the Full Application.

Validate

It is required that the Applicant (Principal Investigator) validate the Full Application. This feature ensures that all required application fields are complete. If required fields are empty, the system identifies and notifies the Applicant (Principal Investigator) of fields that require information.

Signature Page

All applications must be signed by the Applicant (Principal Investigator), the Signing Official, the Research Administrator, and the Fiscal Officer. The signature page is provided as a printable document and completing this page is the last step before validating and submitting the application. The Applicant (Principal Investigator) should print the Signature Page, and then obtain the required signatures. The Grants and Contracts Office of Sponsoring Institution can help ensure appropriate signatures are obtained. Once all signatures are acquired, the document needs to be scanned, converted to a PDF, and then uploaded (see *Proposal Attachments* section).

Submit

The Applicant (Principal Investigator) must use this function to submit the completed Full Application for consideration.

Changes

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

Submission of the Full Application

LLS require WILL NOT accept fax or hard copies of the Full Application. Submission of a Full Application is due March 15th at 3:00pm EST via the proposalCentral website (https:proposalCentral.altum.com). If any date falls on the weekend or a U.S. holiday, the deadline will be the following business day. The Applicant (Principal Investigator) will receive an email from proposalCentral stating that the application was successfully submitted online upon submission.

Review of the Full Application

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