RTFCCR/LLS Patient-Focused Immunotherapy Research Grant for Blood Cancer

Funded by Rising Tide Foundation for Clinical Cancer Research and the Leukemia & Lymphoma Society

GUIDELINES & INSTRUCTIONS

FOR

LETTER OF INTENT
&
FULL APPLICATION

December 2015

RISING TIDE FOUNDATION FOR CLINICAL CANCER RESEARCH

LEUKEMIA & LYMPHOMA SOCIETY fighting blood cancers

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GENERAL INFORMATION

1. ABOUT

The **Rising Tide Foundation for Clinical Cancer Research (RTFCCR)**, a private foundation in Switzerland, is focused on funding promising, innovative translational studies and clinical trials that hold the promise of delivering hopeful, encouraging and immediate options for cancer patients to prevent, diagnose, treat or improve quality of life.

The **Leukemia & Lymphoma Society (LLS**) is a US-based foundation focused on developing, and providing access to, therapies to cure or control leukemia, lymphoma, Hodgkin's disease and myeloma as well as improve the quality of life of patients and their families. The organization has funded blood cancer research for the past 60 years to strive toward these goals.

2. DESCRIPTION OF AWARDS

In a joint collaboration, the RTFCCR and LLS aim to stimulate innovative and clinically relevant cancer research that has the highest potential for near-term patient impact in terms of clinical application, therapeutic outcomes and quality of life. With this competitive grant, the RTFCCR and LLS aspire to advance clinical cancer research worldwide that aims to "educate" a person's immune system to fight blood cancers.

Great strides have been made in recent years to advance new therapies that either directly activate the immune system in blood cancers or release the inhibitory mechanisms that prevent such activation in solid tumors. The profound clinical efficacy of a few emerging immune-therapeutics for blood cancer and solid tumors, along with a deeper understanding of the ability of tumors to evade the immune system, hold the greatest potential for cures today. The two organizations (RTFCCR and LLS) have joined forces to build upon previous successful application of immune-oncology therapeutics for cancer to achieve future cures for blood cancers.

This award program will provide each awarded application with a maximum of $600,000 (USD) over a 3-year period. RTFCCR and LLS will equally co-fund the successful application and will require that contracts with each organization be executed prior to initiation of the grant. Applications are accepted globally. We seek to fund innovative clinical projects that apply an understanding of the immune system or to use novel therapeutic approaches to engage the immune system in clinical trials for blood cancers. A direct patient benefit as a result of the conducted study is desired, which would have clinical impact during the course of this 3 year grant or potentially within 3 years after completion of the grant.

Potential projects are expected to include, but not be limited to, the following points of interest:

1. Characterization of the status of the immune system in blood cancers patients with the purpose of stratifying them on conventional or emerging immunotherapies for the treatment of blood cancers; understand how or if immune system impairment can lead to blood cancers.

2. Development of novel immunotherapeutics including conventional antibodies, immunocheckpoint inhibitors, bi-specific T-cell engaging biologics, adoptive cell therapies, and vaccines for use in clinical trials.

3. Development of repurposed agents that engage the immune system.

4. Examine improvements to the quality of life during or after immunotherapy for the treatment of blood cancers.

Applications from any discipline will be encouraged to apply. Applicants with specialization in immuno-oncology, including those applicants with experience in solid tumors, are especially encouraged to apply.

Eligible Focus of Proposals

The purpose of the call for proposal is to solicit high quality research proposals from medical and academic research institutions and hospitals globally to find new immunotherapies to treat blood cancers.

Of special interest will be clinical trials that demonstrate a truly patient-centered approach in terms of potential benefits to patients enrolled in the study and seeking patient report outcomes to measure quality of life issues.

Preference will be given to international collaborative projects and/or projects that use methods to accelerate the pace of the study (i.e. use effective, novel clinical trial designs, such as biomarker-driven patient selection, pharmacodynamic endpoint assessment, etc.).

New projects may be an extension of other work, but cannot overlap any funded projects unless the applicant clearly demonstrates that new funding will not duplicate existing support. Principal investigators will be encouraged to submit proposals with multiple funding sources, so long as the projects are novel and distinct.

Extensions of conventional or traditional chemotherapy such as phase III/IV trials will not be supported. Applications that have solely basic and pre-clinical research without an anticipated clinical trial or outcome will not be considered. Placebo-only agent arms will be avoided.

While the application is expected to be based on previously published work, it must contain novel, unpublished findings to justify consideration for the grant.

Grant activation is expected within three months after the award notification. Therefore, if clinical trials are contemplated at the outset of the grant, submission of advanced or fully developed protocols are recommended.

Grant Administration

Grants will be issued under separate contracts with the LLS and RTFCCR. Payments by RTFCCR will be provided bi-annually and triggered by demonstration of sufficient progress against pre-set milestones. Payments provided by LLS will be issued quarterly. Payment every other quarter from LLS will rely on the same bi-annual research progress updates.

Progress Reports must address findings to-date against predetermined project goals and include scientific and lay abstracts as well as a short synopsis of the data used to support conclusions in these abstracts. Progress Reports must also include any new publications (in whatever form and stage of publication) and any new patent applications filed by the grant recipient during the applicable progress report period.

Principal investigators will be required to present their work to their peers and the Parties at an annual progress review meeting, which typically is held in October. Rising Tide and/or LLS may invite principal investigators and clinical trial participants to share their experiences with respect to the applicable project with Rising Tide's and/or LLS' governing committees.

At the conclusion of the award, the grantee is expected to provide a written summary of his/her research project and plans for publication in a peer-reviewed journal naming LLS and RTFCCR as funders.

Submission of Proposals

Proposals will consist of two phases: the letter of intent ("**LOI"**) and the full application with all documents in English.

The purpose of the LOI is to determine eligibility and compliance with the request for proposal ("**RFP**"). If an LOI does not address the RFP, the author shall indicate why the LOI falls outside the RFP topics yet merits further consideration. An exceptional proposal could be funded even if it does not adhere to any of the RFP topics.

Details related to preparation of the LOI can be found in the FLUXX grant system (https://lls.fluxx.io). LLS will supply Rising Tide with a link to this system. In addition, the Principal Investigator will submit a pdf version of the LOI directly to Rising Tide. Information in the LOI must contain 1) contact information (Institution, Principal Investigator), 2) grant information (project title, scientific and lay abstract, which RFP it addresses), 3) amount requested, 4) proposed start/end date, 5) CV for the principal investigators and co-principal investigators (if applicable) with list of publications, and 6) Clinical trial information.

If the LOI is accepted, the applicant will be notified to submit the full application, which will contain information and instructions for submitting the full application.

Table 1: Maximum Award Duration & Value

*Please note: The 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 Rising Tide Foundation, and are subject to the availability of funds.

Duration	Maximum Annual Direct Costs	Maximum Annual Indirect Costs	Maximum Total Costs	Maximum 3 Years
3 yrs	$90,909	$9,091	$100,000	$300,000
3 yrs	$90,909	$9,091	$100,000	$300,000
Total	$181,818	$18,182	$200,000	$600,000

Budget and Use of Funds

The funds must be used for research-related costs while overhead/indirect costs strictly should be kept at a minimum as further described below. (Detailed instructions for budget and justification can be found in the guidelines available within the FLUXX grant system).

Permissible Direct Costs include the following:

- Personnel Expenses including salary, wage, or stipend with fringe benefits. In total, no more than forty percent (40%) of the direct costs may be requested for the salary and fringe benefit expenses of professional staff with a post-graduate degree (i.e. M.D., Ph.D., D.V.M.) regardless of function or role in the proposal. This restriction does not apply to technical staff (lab assistants, nurses, etc.).
- Supplies and Materials requests should be itemized by category.
- Equipment purchase requests must identify each item of equipment with an acquisition cost of more than $500. The applicant must demonstrate that the equipment is directly used and vital for the conduct of this project. Equipment requests may be denied upon further review of the full application and will be funded only upon approval from Rising Tide and LLS.
- Other Direct Cost requests can include patient care costs.
- Travel costs are not supported

Permissible Indirect Costs **are limited to (10%) of total direct costs.**

Deadline for the submission of the LOIs is Jan 25th, 2016. All LOIs must be submitted via email to grants@risingtide-foundation.org and uploaded using the FLUXX system.

3. WHO CAN APPLY

Citizenship and Degree

Applications are accepted from any nation where general grant oversight is possible. Principal investigators must hold an M.D., Ph.D., or equivalent degree, and work in non-profit organizations, such as universities, colleges, hospitals or laboratories. Principal investigators may be affiliated with various non-profit institutions. Principal investigators should have an independent research or academic position within at least one non-profit institution. International collaborations will be accepted and encouraged. Accordingly, principal investigators from any country will be encouraged to apply, and there will be no restrictions on any such party's age, race, gender or creed. Principal Investigators from non-academic facilities, post doctoral positions and the National Institutes of Health are not eligible. Principal investigators requesting pilot funding should show how their project is a departure from ongoing, funded work and why it has promise.

4. LEADERSHIP AND STAFFING

The Application will require one Principal Investigator who is responsible for the preparation and submission of the proposal including budget, the conduct of the research programs and adherence with all stipulations made by LLS in this document, the Policies & Procedures document, and in the grant contract if funded. Co-investigators (also known as Collaborators) are allowed on multiple applications; however one individual is to be designated as the Principal Investigator and this individual is limited to one application only.

An Applicant may only submit one new RTFCCR/LLS Patient-Focused Immunotherapy Research Grant for Blood Cancer application. Note that applicants may also submit an application to LLS's Translational Research Program (running simultaneously with the RTFCCR/LLS grant program), but the TRP application must be distinct from the RTFCCR/LLS application.

A Principal Investigator may only submit ONE application and cannot serve as a Principal Investigator OR Co-Principal Investigator on more than ONE application. A Co-Investigator (also known as Collaborator) CAN serve as Co-Investigator on more than one application with no limit. Members of the peer review committee for the RTFCCR/LLS program cannot apply for a RTFCCR/LLS award. Peer review members for the RTFCCR/LLS program may apply for a TRP or TRP Renewal award if they are not serving on TRP or TRP Renewal committee.

Announcement and Communication

The invitations for the submission of full grant applications will be communicated to selected applicants after February 1, 2016. Parties will begin accepting applications on or about February 7, 2016.

Award ceremony
Funded proposals will be announced publicly by RTFCCR and LLS. The grants will be awarded at a reception to coincide with a large blood cancer conference (e.g. American Society of Hematology- December 2016) or a clinically-oriented Immuno-Oncology meeting. The awardees will present the research project during the ceremony. The award will also be announced in *Science* and/or *Blood* Journals, as well as on the RTFCCR and LLS websites.

Intellectual property
Intellectual property originating from the research done in the framework of the funded grant shall be owned by the applicant and/or institution. Any financial return based on licensing the intellectual property shall be negotiated in good faith between the involved parties and stated in the respective contracts with LLS and with RTFCCR. Scientific and educational ownership of the Investigators as well as transparency amongst all stakeholders shall be respected.

5. Application Process and Deadlines

The deadline for submission of the **letter of intent is January 25th, 2016.** Submissions must be made electronically to the LLS grants management portal powered by Fluxx (https://lls.fluxx.io).

Table 2: Grant Application Deadlines

Application Phase	Date	Time
Letter of Intent – open	December 2015	
Letter of Intent – close	January 25, 2016	3:00pm ET
Full Application – open	February 7, 2016	
Full Application – close	March 15, 2016	3:00pm ET
Award Notification	June 30, 2016	
Award Start Date	October 1, 2016	

Registration
Both the Applicant and Sponsoring Institution must be registered in Fluxx (LLS grant management system). If you have applied to LLS in the past, you do not need to create a new registration. Simply click the "reset or create password" link and enter your email address. The system will email your username and a link to update your password. Once registered, the Applicant can begin the LOI. Applicants needing assistance with the Fluxx registration process could email researchprograms@lls.org .

Institutional Designation
During the registration process, Applicants should create their profile from the standpoint of where they will perform their research described in the application. The Applicant must indicate the name of the Sponsoring Institution as well as the name of the signing officials for that institution. Fluxx currently has a list of organizations registered. To register a new institution, contact researchprograms@lls.org.

Data Entry
Both the LOI and the full application 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 the application has been finally submitted.** Moreover, some fields may not be modified in the full application following submission of the LOI.

Contacting LLS Regarding Filing of Application
Questions that are not clarified in this document or in the tutorial on the Fluxx site should be addressed to researchprograms@lls.org .

Forms and Format
An application template is provided on the Fluxx website during the Full Application phase. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the Fluxx website. Fields in bold are required. Other information will be captured using the provided template. All Applicants must use single-spaced text and 12 pt. Times New Roman. Margins are preset in the template and must remain as is. The Applicant's name should be typed in the upper right corner of each page of the template. Failure to use the provided template or to adhere to font size, spacing, margins, and/or page limitations may result in the disqualification of the application.

6. REVIEW PROCESS

Review of LOI
The Scientific Review Committee composed of members of RTFCCR and LLS will conduct an initial assessment of all LOIs from January 25 – February 1, 2016. Should an LOI not be deemed a good fit for under this competitive grant, such LOIs may be placed in LLS' or Rising Tide's applicant pool for further consideration of funding.

Only the most promising research projects that have the highest potential for patient impact will be invited to fill out a **full grant application**, which must be submitted no later than **March 15, 2016**. Specific instructions will be provided to applicants selected for a full grant application.

Review of Full Applications
Full Applications must be submitted first through Fluxx. The applicant must then send a single PDF of the entire application that was submitted through Fluxx directly to RTFCCR at the following email address: grants@risingtide-foundation.org. Both submissions must occur on or before March 15, 2016 at 3:00 PM Eastern Time (ET). The submission deadlines will be strictly enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

All full grant applications are reviewed in **May** of **2016**. The highest ranking full grant applications are recommended to the RTFCCR Board of Directors and the LLS Medical and Science Affairs Committee for approval and recommendation to LLS Mission Oversight Committee for approval, respectively.

Review Criteria
Full applications will be judged on the following criteria:

- Significance and patient impact
  - The probability of an advance in prevention, diagnosis or treatment in the near-term.

- Novelty and originality:
  - The novelty of the concept and strategy.
  - The conceptual basis upon which the proposal rests.

- Feasibility
  - Thoughtful and clear presentation.
  - Adequacy of resources and environment (facilities, access to patient samples if needed, data management, and data analysis, etc.).
  - Adequacy of provisions for protection of human subjects
  - The overall plan for bringing the research findings to clinical application.

- Experience, background, and qualifications of investigators.

- Reasonable budget

After Rising Tide's Board of Directors and the LLS Medical and Scientific Affairs Committee approve the awardees, RTFCCR and LLS will inform the award winners on **June 30, 2016**. LLS and RTFCCR will also inform all applicants who were not chosen for funding.

The start date of the awarded grants is **October 1, 2016**. Funding terminates on **September 30, 2019**.

For questions, please contact Eveline Mumenthaler, Director of RTFCCR (Eveline.mumenthaler@risingtide.ch) or Lee Greenberger, Chief Scientific Officer of LLS (Lee.Greenberger@lls.org).

GUIDELINES - LETTER OF INTENT

Each Applicant must submit the LOI via the Fluxx website (https://lls.fluxx.io) and email the submitted LOI by PDF to RTFCCR at the following email address grants@risingtide-foundation.org by **January 25th at 3:00pm ET**, or the following business day if this date falls on a weekend or a U.S. holiday. The Applicant should carefully craft the information requested in the LOI as this information is automatically populated into the full application and is subject to the Changes clause listed below.

If the LOI is approved, the Applicant will be notified by automated email from Fluxx that they may proceed to the next phase of the application process.

ORGANIZATION INFORMATION

Sponsor Institution and Department
Indicate the name of the sponsoring institution and department. If this institution is not listed, please contact researchprograms@lls.org.

Principal Investigator
The Principal Investigator is the Applicant.

Institutional Signing Official (ISO)
The ISO is the institutional representative responsible for the signing and agreeing to the accuracy of the application and the terms of the award, should the application be selected for funding.

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

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

Technology/Transfer Official
The Technology Transfer Official is the institutional representative responsible for overseeing Intellectual Property.

Zip Code of Sponsoring Institution

PROJECT OR PROGRAM INFORMATION

The drop-down field for this grant application should be set to “RTFCCR/LLS Patient-Focused Immunotherapy Research Grant for Blood Cancer ”.

RFP TOPICS

The purpose of the LOI is to determine eligibility and compliance with the request for proposal ("**RFP**"). If an LOI does not address the RFP, the author shall indicate why the LOI falls outside the RFP topics yet merits further consideration. An exceptional proposal could be funded even if it does not adhere to any of the RFP topics.

Choose from the following:

1. Characterization of the status of the immune system in blood cancers patients with the purpose of stratifying them on conventional or emerging immunotherapies for the treatment of blood cancers; understand how or if immune system impairment can lead to blood cancers.

2. Development of novel immunotherapeutics including conventional antibodies, immunocheckpoint inhibitors, bi-specific T-cell engaging biologics, adoptive cell therapies, and vaccines for use in clinical trials.

3. Development of repurposed agents that engage the immune system.

4. Examine improvements to the quality of life during or after immunotherapy for the treatment of blood cancers.

GRANT INFORMATION

Project Title
Provide a title adhering to the 100 character limitation (which includes spaces).

Project Summary
Provide a title adhering to the 500 character limitation (which includes spaces). Charts and graphs should not be included in the project summary section.

Scientific Abstract
Briefly describe the proposed research in 3,000 characters or less using technical language. Once the LOI has been submitted, the scientific abstract may not change. Greek characters or symbols must not be used.

Lay Abstract
Clearly state in lay language the proposed research in 3,000 characters or less. Once the LOI has been submitted, the lay abstract may not change. Greek characters or symbols must not be used.

Amount Requested
The total amount, including both direct and indirect costs, cannot exceed $200,000/year. Enter the total amount of funding requested over the life of the grant (Maximum $600,000).

Proposed Start Date
The start date for all RTFCCR/LLS Patient-Focused Immunotherapy Research Grant for Blood Cancer grants is October 1st in the year the award is made (i.e. if an award is made to your application in June 2016, the grant start date will be October 1st, 2016).

Proposed End Date
The end date for all RTFCCR/LLS Patient-Focused Immunotherapy Research Grant for Blood Cancer grants is September 30th three years after the year the award is made (September 30th, 2019).

KEY PERSONNEL OR COLLABORATORS INFORMATION
New collaborator or key personnel contacts may be added to the collaborator section by clicking the green plus sign. These include Co-Principal Investigators and Co-Investigators.

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 this cycle.

BIOSKETCH
A biographical sketch is required for the Applicant. It is acceptable for the Applicant to use their NIH biosketch. Include a 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 and other key personnel, **the applicant must indicate any overlap of aims or research efforts of proposed work receiving funding in addition to the RTFCCR-LLS requested funding.** No more than one biosketch per individual should appear in the application. Upload the biosketch(es) to the to the Supporting Documentation section by clicking the green plus sign. Choose "Biosketch" from the drop down menu before uploading.

CLINICAL TRIAL INFORMATION
Download and complete the Clinical Trial template. Upload the completed template to the Supporting Documentation section of the web form by clicking the green plus sign.

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.

SUBMIT
The Applicant can formally submit the LOI using this function. Signatures of the Applicant 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 LLS. The Applicant

must email LLS (researchprograms@lls.org) requesting any change and identifying the elements to be changed. Any changes made without the prior approval of RTFCCR- LLS may result in the disqualification of the application.

SUBMISSION OF THE LOI

Each Applicant must submit the LOI by **January 25th at 3:00 pm Eastern Time** via the Fluxx website (https://lls.fluxx.io) and email the submitted LOI by PDF to RTFCCR at the following email address: grants@risingtide-foundation.org , or the following business day if this date falls on a weekend or a U.S. holiday. After clicking the "Submit" button, the Applicant will receive an email from Fluxx stating that the LOI was successfully submitted. **If you do not receive the confirmatory email from Fluxx within 2 business days of LOI submission, please e-mail researchprograms@lls.org.**

GUIDELINES - FULL APPLICATION

Each Applicant must submit a full application via the Fluxx website (https://lls.fluxx.io) and email the submitted LOI by PDF to RTFCCR at the following email address grants@risingtide-foundation.org by **March 15th at 3:00 pm Eastern Time** , or the following business day if this date falls on a weekend or a U.S. holiday. Some sections of the full application will be automatically captured electronically on the Fluxx website from the LOI. Other pieces of information will be captured in the application template that must be downloaded, completed, and then uploaded by the Applicant. The Applicant may not modify any information provided in the submitted LOI as this is subject to the Changes clause listed above, and may result in disqualification of the application.

PROJECT OR SUPPORTING DOCUMENTATION

- Log on to the Fluxx site (https://lls.fluxx.io), click "New Request" on the left, click on your application, then click "Edit".
- Download and complete the project description template. The project description should be limited 7 pages.

The completed project description, including all appendices, must be uploaded as one single PDF file.

Project Description

The project description section includes 4 fields, as follows: a) Project Description b) Other Research Support c) Budget d) Budget Justification.

Each Project description is limited to 7 pages and should be presented in the following sequence:

- Title and Specific Aims (approx. 0.25 pages)
- Scientific and Clinical significance of the work (approx. 1.0 page)
- Previous Studies/Preliminary Data (approx. 2.5 pages)
- Research Methods (approx. 0.75 pages)
- Interaction with other Investigators (approx. 0.5 page)
- Resources and Environment (Major lab items or facilities) (approx. 1.0 page)
- References cited (approx. 1.0 page)

Budget

The Detailed Budget and Budget Justification should provide itemized detail for each major category for the all years of the program. This budget can be summarized in Year One of the

budget and extrapolated for the remaining three years. All Totals and Subtotals should be completed on the form.

SIGNATURE PAGE

All applications must be signed by the Principal Investigator (and Co-Principal Investigator if applicable), Institutional Signing Official, Research Administrator, Financial Officer, and Technology/ Transfer Official. The signature page is provided in the downloadable application template. The Grants and Contracts Office of the Sponsoring Institution can help ensure appropriate signatures are obtained.

- **Principal Investigator**
  The Principal Investigator is the Applicant.

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

- **Research Administrator**
  The Research Administrator is the institutional representative responsible for the day-to-day administration of externally-funded research.

- **Institutional Signing Official (ISO)**
  The ISO is the institutional representative responsible for the signing and agreeing to the accuracy of the application and the terms of the award, should the application be selected for funding.

- **Technology/Transfer Official**
  The Technology Transfer Official is the institutional representative responsible for overseeing Intellectual Property.

- **Co-Principal Investigator**
  The Co-Principal Investigator is the Co-Applicant.

UPLOAD THE PROJECT TEMPLATE - SUPPORTING DOCUMENTATION

Upload the completed template as one single PDF to the Supporting Documentation section by clicking the green plus sign. Choose “Project Description” from the drop down menu before uploading.

ORGANIZATION ASSURANCES

The Applicant must complete the organization assurances section. The following provides an overview.

Human Subjects

The Applicant must indicate if human materials or subjects will be involved in the proposed research. The status (approved, pending or exempt) of Institutional Review Board (IRB, or equivalent oversight entity) approval must be provided. The Human Subject Assurance

Number (OHRP) must be included. If the research project has received IRB approval, the date must be provided and documentation must be uploaded as the Human Investigation Statement. The application may be submitted with IRB approval pending. However, an award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the May review date if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be uploaded as the Human Investigation Statement.

Laboratory Animals
The Applicant must indicate if laboratory animals will be involved in the proposed research. The status and date of Institutional Animal Care and Use Committee (IACUC, or equivalent oversight entity) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of Sponsoring Institutional approval must be uploaded as the Laboratory Animal Statement. The application may be submitted with IACUC approval pending. However, an award will not be made without documented IACUC approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the May review if the IACUC status has changed.

Recombinant DNA
The Applicant must indicate if the proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be uploaded with the application.

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

Clinical Protocol Appendix (if applicable)
Provide a one page summary and a link to the clinicaltrials.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 should notify LLS of IRB approval prior to the May grant review.

BUDGETING INFORMATION
Enter the budgeting information as required on the web form fields.

APPLICANT ASSURANCE
Check the box to accept the terms as stated on the web form field.

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.

SUBMIT

After clicking “Save” you will be directed to review your application. Please ensure all information is accurate, and then click the “Submit” button to submit your application.

Once submitted, only LLS staff can delete the file. If you need a file deleted from the upload section, contact researchprograms@lls.org for assistance.

If you plan to withdraw your application at anytime during the application cycle, please inform LLS staff of your decision by writing to researchprograms@lls.org.

Application Scoring Overview

This is a special request for proposals sponsored jointly by the Rising Tide Foundation for Clinical Cancer Research (RTFCCR) and the Leukemia & Lymphoma Society. The grants will be administered under the RTFCCR and LLS. Grant applications that adhere to the stipulations highlighted in these guidelines will be reviewed for funding by an expert review committee.

Each application will receive a **Priority Score,** with a range from 1-9 based on a clear plan for the clinically translatable exploitation of the studies proposed and the results expected. Proposals should be based on molecular, cellular or integrated systems findings and be conceptually innovative. This feature of the proposal will be an important consideration of the review process.

While work directed at a further elucidation and understanding of the fundamental cellular and molecular biology of neoplastic lymphohematopoietic cells is important, this special cancer initiative for immunotherapy is specifically intended for the support of work which is clearly clinically translatable and will be scored in a manner that is reflective of that premise.

Applications to this award 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). Only applications with scores in the excellent to exceptional range (Overall Priority Score between 10 and 30) will be considered for funding.