

RTFCCR/LLS Cancer Prevention 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

Funding Start Date:
July 1, 2018

Funding Date Range:
3 to 5 years

Funding Amount:
Up to \$1.2M US

May 2017

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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 LLS and RTFCCR 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. These grants aspire to advance clinical cancer research worldwide that aims to prevent blood cancers from either occurring initially in healthy individuals (no neoplasm detected), advancing to full-blown blood cancers in patients with benign conditions, or blocking reoccurrence of blood cancer after therapy.

Great strides have been made in recent years to understand the molecular basis of either smoldering disease or mutations found in the blood of otherwise healthy individuals. Moreover, new therapeutics including immunotherapy have been recently developed that may have a sufficient safety window to prevent disease emergence or re-emergence after disease clearance. LLS and RTFCCR have joined forces to build upon previous knowledge in blood cancer research to achieve future cures and disease interception for blood cancers.

Applications considered for funding for each proposal can amount up to USD 1.2 M for 3 to 5 years. LLS and RTFCCR will mutually agree on the applications to be funded and then will determine the exact funding period based on the merit of the application, requested funds, and length of time funds are needed. It is anticipated that the program could fund 3 to 4 awardees.

The Parties seek to fund innovative clinical projects that apply an understanding of blood cancer prevention. A direct patient benefit as a result of the conducted study is desired, which would have clinical impact during the course of this 3-5 year grant or potentially within 3 years after completion of the grant.

Potential projects in prevention will include, but not be limited to, the following points of interest:

- **Clinical Trials:** Perform prospective studies using pharmaceuticals or nutraceuticals or lifestyle changes in people who have blood cancer precursor conditions, conditions that remain after apparent disease clearance, or otherwise healthy individuals, such as those who have clonal hematopoiesis of indeterminate origin (CHIP) and are at high risk of developing blood cancers. Retrospective studies may also be considered if they are science-based.
- **Biomarker evaluation:** Develop and apply sensitive methodologies, including liquid biopsies, to know when all precursor cells are eliminated and therefore, therapy can be terminated. Explore clonal evolution using sensitive detection methods.
- **Use experimental systems** to identify safe and effective therapeutic strategies to eliminate mutant clones early in disease stages or prevent recurrence of disease that could justify a clinical trial in prevention.
- **Drug the “undruggable”:** Develop novel inhibitors of “drivers” that mediate progression to full blown disease (e.g. epigenetics and spliceosome factors) or leverage synthetic lethality strategies that achieve the same goal. Translate new therapeutics to clinical development and ultimately clinical trials.

Applicants from any discipline will be encouraged to apply. Applicants with specialization in immuno-oncology and sensitive detection strategies, including those applicants with experience in solid tumors, are especially encouraged to apply. The applicant is encouraged to recruit co-PIs or other alliances that will strengthen the proposed work.

3. Eligible Focus of Proposals

- The purpose of the call for proposals 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. Proposals 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 proposals are expected to be based on previously published work, they 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.

4. Grant Administration

- Under each of its Grant Contracts, Rising Tide will pay the grant recipient on a bi-annual basis the amount due as defined in their award letter during each year of the Term once the grant recipient has demonstrated sufficient progress against pre-set milestones (more fully described in the Grant Contract) as reflected in a written research progress report prepared by the grant recipient (each, a “Progress Report”). Under each of its Grant Contracts, LLS will pay the grant recipient on a quarterly basis the amount due during each year of the Term as more fully described the Grant Contract. Rising Tide and LLS will have the right to withhold such funding to each grant recipient if the grant recipient has not made sufficient progress against pre-set milestones more fully described in the Grant Contract as reflected by the Progress Report.
- 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 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 Term, each grant recipient will be required to provide a written summary of his/her research project and plans for publication in a peer-reviewed journal naming the Parties as funders.

5. 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 proposals (“**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 ProposalCENTRAL grant system (<https://proposalcentral.altum.com/opportunities.asp?GMID=128>). 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.

6. Budget and Use of Funds

Applications considered for funding can amount up to USD 1.2 M for 3 to 5 years. LLS and RTFCCR will mutually agree on the applications to be funded and then will determine the exact funding period based on the merit of the application, requested funds, and length of time funds are needed. It is anticipated that the program could fund 3 to 4 awardees.

The funds must be used for research-related costs while overhead/indirect costs strictly should be kept at a minimum as further described below.

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 or less.

Deadline for the submission of the LOIs is **October 1, 2017 at 3 PM ET**. All LOIs must be submitted via ProposalCENTRAL system.

7. 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, postdoctoral 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.

8. 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 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 Cancer Prevention Research Grant for Blood Cancer 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.

9. Announcement and Communication

The invitations for the submission of full grant applications will be communicated to selected applicants after **November 1, 2017**. Parties will accept full applications until **February 1, 2018**.

10. Award ceremony

Funded proposals will be announced publicly by the Parties. The grants will be awarded at a reception to coincide with a large blood cancer conference (e.g. American Society of Hematology – December 2018) 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 each Party's website.

11. 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.

12. APPLICATION PROCESS AND DEADLINES

The deadline for submission of the **letter of intent is October 1, 2017 at 3 PM ET**. Submissions must be made electronically to the RTFCCR grants management portal powered by proposalCENTRAL (<https://proposalcentral.altum.com/opportunities.asp?GMID=128>).

Table 2: Grant Application Deadlines

Application Phase	Date
Letter of Intent – open	June 1, 2017
Letter of Intent – close	October 1, 2017
Full Application – open	November 1, 2017
Full Application – close	February 1, 2018
Award Notification	April 16, 2018
Award Start Date	July 1, 2018

Registration

Both the Applicant and Sponsoring Institution must be registered in proposalCENTRAL (RTFCCR grant management system). If you have applied to RTFCCR 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 proposalCENTRAL registration process could email pcsupport@altum.com, or call (toll-free U.S. and Canada): 800 875 2562 or +1 703 964 5840 (Direct Dial International).

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. proposalCENTRAL currently has a list of organizations registered. To register a new institution, contact pcsupport@altum.com.

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 RTFCCR Regarding Filing of Application

Questions that are not clarified in this document or in the documents available on the proposalCENTRAL site should be addressed to grants@risingtide-foundation.org.

Forms and Format

An application template is provided on the proposalCENTRAL 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 proposalCENTRAL 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.

13. REVIEW PROCESS

Review of LOI

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 proposals (“**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 proposalCENTRAL grant system (<https://proposalcentral.altum.com/opportunities.asp?GMID=128>). 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, and 5) CV for the principal investigators and co-principal investigators (if applicable) with list of publications.

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.

Review of Full Applications

- The Parties will establish a Scientific Review Committee (“**SRC**”) that will process and review grant proposals as further described below. Each Party will be solely responsible for paying the costs incurred by its appointees to the SRC and the panel of scientific experts more fully described below.

- The SRC will consist of 4 appointees, which will include 2 appointees from Rising Tide and 2 appointees from LLS. Each Party will appoint members to the SRC in its sole discretion. Each appointee to the SRC must be a scientist respected for his or her accomplishments in cancer research and/or clinical cancer research. Each Party may replace its appointees to the SRC upon reasonable advance notice to the other Party.
- The SRC will meet via telephone on a schedule to be determined by the SRC.
- The SRC will conduct an initial assessment of all LOIs by **October 15, 2017**.
- Only the most promising LOIs that have the highest potential for patient impact will be invited to fill out a full application by the SRC, which has to be submitted no later than **February 1, 2018**.
- Full applications will be reviewed by the SRC on or about **March 15, 2018**. The SRC will select a primary and secondary reviewer for each full application, who will be responsible for evaluating the applicable grant in detail and presenting their opinions to a panel of scientific experts. After the panel of experts hears these presentations, the experts will submit their scores for each full application. The NIH scoring system will be used (10 = most desirable; 90 = least desirable). The three highest ranking full applications will be recommended to the Rising Tide Board of Directors and the LLS Medical and Science Affairs Committee for final approval.
- The SRC and the panel of experts will judge the full applications 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's Medical and Science Affairs and Mission Oversight Committees approve the grant recipients, the Rising Tide and LLS will inform the award winners on **April 16, 2018**. The SRC will also inform all applicants who were not chosen for funding. If not enough quality projects worthy of this award are found, less than 3 winners may be awarded. If no winning projects are identified or approved by Rising Tide's Board of Directors and the LLS Medical and Science Affairs Committee, this contract shall immediately terminate.
- The start date of the awarded grants is **July 1, 2018**. Funding terminates for 3 year grants on **June 30, 2021** and for 5 year grants on **June 30, 2023**.



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

All LOIs must be submitted in accordance with the requirements and instructions of this RFA. LOIs must be completed by **3 pm on October 1, 2017** and submitted via proposalCENTRAL at <https://proposalcentral.altum.com/>

You must establish a user account to submit a grant application. If you have a user account with proposalCENTRAL, simply log in. To begin a LOI, select “Grant Opportunities”. Find “**Rising Tide Foundation for Clinical Cancer Research**” and click the “apply now” link to create your LOI.

At the “Title page” select RTFCCR/LLS request for proposals as type of submission. Complete all fields in the application page and LOI template. Upload all requested documents in PDF format. See the proposalCENTRAL FAQ section, for more information.

If you have difficulties registering, logging in, or creating your application, contact proposalCENTRAL Customer Support: Phone (800) 875-2562 or email pcsupport@altum.com.

Letter of Intent Template

Download the Template from proposalCENTRAL(Letter of Intent Template-RTFCCR/LLS Applicants Only available in the “download templates and instructions” section; See picture

LOI Sections
 Complete each section of the LOI below. Click the Next button to save and go to the next section or click directly on the sections listed below.

- 1) [Title Page](#)
- 2) [Download Templates & Instructions](#)
- 3) [Enable Other Users to Access this Proposal](#)
- 4) [Applicant/PI](#)
- 5) [Organization/Institution](#)
- 6) [Main Stakeholders](#)
- 7) [Project Overview](#)
- 8) [Upload LOI Documents](#)
- 9) [Validate](#)
- 10) [Submit](#)

<<Previous Next>> Cancel Exit

Please download the templates below

Download	Template Type	Description	File Type	File Size
Download	Letter of Intent	Letter of Intent Template- Spontaneous Applicants Only	.DOCX	73859
Download	Letter of Intent	Letter of Intent Template- RFTCCR/LLS Applicants Only	.DOCX	85390
Download	Letter of Intent	Letter of Intent Template- RFTCCR/SAKK Applicants Only	.DOCX	113181

Many of the grantmakers in proposalCENTRAL request or require that applicants submit their attachments as portable document format (.pdf). In order to save your documents as PDFs, you will need to use PDF generator software. [Click here for a list of PDF generators.](#)

below) and fill in the following sections. The LOI Narrative (Sections A-E) is limited to 5 pages. Cited Publications and LOI supporting documents (i.e. Biosketches, Letters of Support, Letters of Collaboration and Letter of Commitment from Applicant) are not included in this page number limit.

Document Format

Please adhere to the following formatting requirements:

- Word or PDF file format
- Font size: 12 point
- Font Type: Times New Roman
- The complete LOI narrative must not exceed 5 pages in length

Cited Publications

References must be numbered. Cited Publications are not included in the page limit.

GUIDELINES - FULL APPLICATION

Only selected LOIs will be invited for Full Applications. Applicant must submit a full application via the proposalCENTRAL website by **February 1, 2018 at 11:59 pm Eastern Time**. Some sections of the full application will be automatically captured electronically 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.

All applications should include the following

- ‘Guidelines’ document signed in entirety [to be submitted online as pdf]
- ‘Full Grant Application’ filled out and signed in entirety [to be submitted online as pdf]
- The curriculum vitae of the principal investigator and co-investigators limited to a MAXIMUM of 2 pages per individual. All CVs should be included in one pdf file to be uploaded online.
- A description of the proposed research project. The description of the proposed research project should be organized in a manner similar to that required by the US National Institute of Health [PHS 398], including:
 - Specific aims
 - Background and significance
 - Preliminary results, studies explaining the significance and potential for success
 - Experimental design and methods
 - Statistical analysis section outlining approach taken to make it scientifically valid
 - Statement of your objectives regarding how your study can change the current standard-of-care for today’s patients or how it will create evidence to improve prevention and early detection of cancer
 - How much time will elapse between your approval for funding and opening of your proposed study
 - Statement of next steps for your research upon achieving positive or negative results
 - Description of how milestone achievements for this study are achieved
 - List of other sources of financial support for this project; please include all sources *applied, pending, and/or active* with dates of start and expected end (see page 10)
 - Industry letter stating permission for the use of the investigational agent [provide where applicable] and list literature cited.

If the proposed study is a clinical trial, please include the following in addition to the above referenced information:

- Number of patients enrolled to achieve statistical significant findings
- Enrollment inclusion and exclusion criteria
- A detailed schedule of activities for a patient in this study
- Explain why this treatment may be helpful to those patients enrolled

- Describe criteria used in determining positive results and how you will be quantifying quality-of-life improvements
- A copy of the Patient Consent Form, if available, acknowledging funding in whole or in part by Rising Tide, including a statement to the effect of “If you are interested, Rising Tide would like permission to communicate with you regarding your experience and any other information you would like to share regarding the treatments received while participating in this clinical trial. Please acknowledge yes by checking here _____” must be included on the form.
- Timeline for patient treatment, including milestones for completing this study as a “fee per patient” study
- Current, active IRB Approval letter for this study. If your application is reviewed and considered “approved pending IRB approval” by Rising Tide’s Board of Directors, you acknowledge that proof of IRB approval must be in the hands of Rising Tide prior to any payment of Rising Tide’s funds.

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 (LLS). 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.

Applications to this award will be rank ordered based on their Overall Priority Score (1-9; which reflects the average of all the reviewers' priority scores). Only applications with scores above 6 will be considered for funding.