



2022 Grant Application Guidelines for *RUNX1* Early Career Investigator Grant Program

Application Deadline: December 20, 2021 (8:00 PM ET)

Table of Contents

About the RUNX1 Research Program (RRP) and Alex’s Lemonade Stand Foundation (ALSF) 3

About RRP 3

About Alex’s Lemonade Stand Foundation 3

RUNX1 Early Career Investigator Program 3

Key Objective 3

Program Description 3

Application Review and Funding Decisions 4

Applicant Eligibility 4

Scope of Proposal 5

Budget 5

Resource and Data Sharing Error! Bookmark not defined.

Resubmissions 6

Restrictions 6

Grant Reporting Requirements 6

Application Package Instructions 7

 Format Instructions 7

 Section Descriptions 7

Application Submission Instructions 10

Contact 10

About the *RUNX1* Research Program (RRP) and Alex's Lemonade Stand Foundation (ALSF)

About RRP

A research and advocacy venture committed to funding world-class, innovative, and cross-disciplinary cancer research to develop a cancer prevention therapy for *RUNX1* familial platelet disorder (*RUNX1*-FPD) with predisposition to blood cancer. The program also aims to support, inform, educate, and connect patients, healthcare providers, researchers, and other stakeholders in the *RUNX1* community.

About Alex's Lemonade Stand Foundation

A non-profit changing the lives of children with cancer by funding impactful research, raising awareness, supporting families, and empowering everyone to help cure childhood cancer.

RUNX1 Early Career Investigator Program

The *RUNX1* Research Program and Alex's Lemonade Stand Foundation are delighted to continue their partnership and funding opportunity for early career investigators: **the RRP and ALSF *RUNX1* Early Career Investigator Program.**

Key Objective

To promote the establishment of a new generation of translational and clinical researchers interested in tackling inherited hematologic malignancy predisposition disorders with a focus on *RUNX1*-familial platelet disorder. We believe that providing capital to early career investigators not only injects funding to where it is needed most, but also cultivates a new cohort of investigators who will be invested in an area of research that historically has had limited attention.

Program Description

The *RUNX1* Early Career Investigator grant is a three-year award designed to fund research investigating strategies that will lead to the development of therapies that will prevent the transition from pre-leukemia to leukemia for patients with *RUNX1*-FPD.

The *RUNX1* Research Program and ALSF host an annual scientific meeting that brings together grant recipients and other scientists. Grant recipients are expected to present their progress as part of the annual review.

A *RUNX1* Early Career Investigator Grant is **\$180,000 over 3 years** (maximum \$60,000 per year may be requested).

Application Review and Funding Decisions

- A full proposal must be submitted, and all eligibility criteria met to be considered for review.
- Grants will be reviewed by an independent panel of experts according to the NIH recognized peer-review process.
- Selection criteria include the following:
 - Training/Education record
 - Publication record
 - Grant awards and research awards/recognition
 - Quality and overall ranking of research proposal based on the NIH 9-point scoring system
 - Alignment to overall goal of preventing hematologic malignancies in *RUNX1*-FPD and the feasibility of translating findings into the clinic.

Application Due Date	December 20, 2021 (8:00 PM ET)
Award Notification Date	May 2022
Project Start Date	July 1, 2022 (contingent upon receipt and approval of new award requirements)
Project End Date	June 30, 2025
Progress Reports	Interim, 6-month check-in based on project start date
Final Report	Two months after project end date
RPP Scientific Meeting	Annual

Applicant Eligibility

- Applicants must have an MD, PhD, or MD/PhD (DO, MBBS or equivalent) and be within five years of their first faculty appointment as an Assistant Professor or equivalent tenure-track position. Associate and Full Professors are ineligible. If at the Instructor level, the applicant must submit a letter of support from their mentor at the sponsoring institution.
- A minimum of 75% of the applicant’s time during the award period must be allocated as protected time for *all* research activities. This percentage of time includes both activities on this grant and the applicant’s other research responsibilities.

- Applicants *may* have research grants from other funding sources during the award period, but there must be clear documentation of mechanisms to avoid scientific and budgetary overlap.
- Applicants must have research experience working in, and a deep understanding of, normal or malignant hematopoiesis and/or immunology.
- Applicant institutions may be based in the U.S. or outside of the U.S. Applicants need not be United States citizens. Funds must be granted to non-profit institutions or organizations.
- One resubmission of a previously unfunded application is allowed. Use the Resubmission section of the application to respond to the prior RRP/ALSF critique of the proposal. The response will be scored in the review process in addition to the criteria used for new applications. Resubmissions compete with new applicants for funding.

Scope of Proposal

- Aims of research proposals must be relevant to the ultimate goal of preventing hematologic malignant transformation in *RUNX1*-FPD. Proposals that seek to translate from bench to bedside will receive priority.
- Example areas of research interests include:
 - Determine the precise downstream targets of mutant *RUNX1* that confer hematologic malignancy risk.
 - Evaluate whether there are shared, potentially druggable mechanisms that drive clonal hematopoiesis and malignancy in the general population and in *RUNX1*-FPD patients.
 - Determine whether there are differing cellular and clinical consequences of a *RUNX1* dominant negative mutation versus a loss of function mutation.
 - Define whether the microbiome or macro-environmental exposures influence clonal evolution towards malignant transformation in the bone marrow.
 - Determine the mechanisms by which altered DNA repair promotes clonal hematopoiesis in *RUNX1*-FPD patients.
 - Define the effects of *RUNX1* deficiency on the immune compartment and determine the potential role in initiation and propagation of hematologic malignancy.

Budget

The requested budget should be in proportion to the scope of the proposed project and should be at or under \$180,000 USD in direct costs over 3 years. A maximum of \$60,000 in total costs may be requested per year.

- Restrictions:
 - Proposals must adhere to the NIH salary cap for principal investigator(s).
 - Indirect costs are not allowed.
 - The grant may not be renewed; no cost extension requests are allowed.

- Other budget items may include fringe, travel, supplies and small pieces of equipment. ALSF funds cannot be used for tuition remission. . [View ALSF's complete budget policy.](#)
- If utilizing a subcontract or subaward, you must include this expense in the budget.
 - No indirect costs will be paid.
 - The PI's institution is responsible for disbursing funds for subawards and/or subcontracts.

Resource and Data Sharing

Grant recipients are expected to share unique resources developed under this funding award, and as part of the application, applicants are required to submit a Resource Sharing Plan. Applicants should describe their track record of generating resources that are broadly re-used, the specific resources that will be generated in this proposed project, and the mechanisms by which those resources will be shared. To demonstrate a commitment to sharing that will be actualized, applicants should provide information in their sharing plan that clearly states the type of resource that will be shared, the method, characterization and timing of such sharing, and the anticipated resources (budget, personnel, etc.) required by the applicant and the resource user. Reviewers will consider the extent to which the dissemination of resources produced under the award will enhance or diminish the impact of the proposed work. For a full description and an example, see [the Resource Sharing Form](#). For the full Resource Sharing Policy visit our [Information for Grant Applicants](#) page.

Resubmissions

One resubmission of an application previously reviewed by ALSF/RRP's Review Board is permitted. Applicants should respond to prior critique of the proposal in the Resubmission section of the application. The response to critique will be scored in the review process, and resubmissions compete with new applicants for funding.

Restrictions

- The RUNX1 Early Career Grant is not transferable to another investigator.
- Funds may not be used for research utilizing human embryonic stem cells or non-human primates. Research with human induced pluripotent stem cells is permissible.

Grant Policies & Reporting Requirements

- Please review ALSF's Grant Policies, including Budget Expenditures, Resource Sharing and Grant Agreement with IP, found on the [Information for Grant Applicants](#) page.
- Six month Interim and Annual Progress reports are required. Continued funding is contingent upon demonstration of satisfactory progress toward the completion of proposed research objectives and appropriate budget expenditures.

- Year Two & Three: Minor carry-over of funds (25% or less) is permitted each year with justification. Each year's budget will be approved subsequent to the review of project progress and milestones.
- RRP and ALSF may elect to partially fund or to hold new funds if a carry-over is excessive.
- A Final Report is required at the conclusion of funding. Report must state findings, expenditures, as well as publications and presentations which acknowledge RRP and ALSF funding.
- The grant may not be renewed; one no-cost extension may be requested in the Final Report.
- Publications, presentations, and posters featuring results of the experiments funded by this grant mechanism should acknowledge "The *RUNX1* Research Program and Alex's Lemonade Stand Foundation (Grant #)". ALSF requests copies be sent via email to Grants@AlexsLemonade.org.
- Investigators must present project progress at the annual *RUNX1* Research Program scientific meeting.

Application Package Instructions

- All sections described below should be combined into one PDF (max 20 MB) and uploaded to the ALSF online application form ([see Application Submission Instructions](#)).
- All templates mentioned can be found at ALSF's [Information for Grant Applicants](#) page.

Format Instructions

- PAGE HEADER: All pages of the application should be numbered; the name of the principal investigator should appear in the upper right-hand corner of each page.
- FORMAT: Follow NIH format guidelines: Arial, Helvetica, Palatino Linotype, or Georgia fonts with a font size of 11 points or larger with a minimum of ½ inch margins.
- ORDER & LENGTH: The order of the application should be followed, adhering to the maximum number of pages allowed for each subsection indicated in parentheses.
- Appendices are not allowed.

Section Descriptions

1. Project Information

- a. **Cover Page (1 page):** Download and cocomplete the [Cover Page Template](#).
- b. **Table of Contents (1 page):** Provide a Table of Contents with page numbers to the corresponding sections.
- c. **Scientific Abstract (0.5 page):** Summarize the research objectives and rationale.
- d. **Impact Statement (0.5 page):** How will this project impact *RUNX1*-FPD?

2. **Budget/Justification (3 pages):**

- a. **Budget Template (1.5 pages):** Complete the [ALSF budget template](#). The signature from an institutional representative on the cover page of this grant application specifically acknowledges and accepts this budget and acknowledges that no indirect costs will be paid.
- The award amount is up to \$180,000 over three years. A maximum of \$60,000 in total costs will be awarded to applicants annually.
 - RRP and ALSF adhere to the NIH salary cap for principal investigator(s).
 - Indirect costs (including tuition remission) are not allowed.
 - If utilizing a sub-contractor, you must include their budget. No indirect costs will be paid to the sub-contractor.
 - Reasonable travel expenses to national/international research meetings to disseminate findings may be budgeted. Travel to the RRP annual conference will be at no cost to the grant recipient.

b. **Budget Justification (1.5 pages)**

3. **Biographical Sketch(es):** Use the NIH five-page biographical sketch (SF424) format for the principal investigator and any key personnel.

4. **Research Plan**

- a. **Resubmissions (1 page, if applicable):** If this proposal was submitted previously and did not receive funding, describe any changes in the application (i.e., respond to the reviewers' critique in terms of changes in experimental design or new data). Only one resubmission of a previously reviewed, unfunded application is permitted.
- b. **Specific Aims (1 page):** List the goals, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypothesis to be tested and relevance to *RUNX1*-FPD research.
- c. **Significance (0.5 page):** Describe the relevant background for the current research plan. State the significance and importance of your proposed project with respect to *RUNX1*-FPD research (must be aligned with *RUNX1* Research Program & ALSF mission). Relate the specific aims to the goals and long-term objectives.
- d. **Innovation (0.5 page):** Describe how the proposed research challenges and shifts paradigms or introduces a novel concept, approach, or technology.
- e. **Approach (4 pages):** Describe the experimental approach to the research question and how the research will be realistically accomplished within the proposed funding period. This section should include *but is not limited to* –
1. Timeline and deliverables

2. Feasibility of the approach to reach project goals; if available, include PI's preliminary studies pertinent to the project
 3. Anticipated potential problems and plans to address these issues
5. **Resource Sharing (1 page):** Use the [Resource Sharing Form](#) to complete this section of the application to describe the outputs from the proposed project and how they will be shared. Reviewers will be asked to consider the manner in which outputs from this project will be shared and the extent to which this plan will increase or decrease the impact of the proposed project.
6. **Plans for Clinical Translation (0.5 page):** If the specific aims described above are successfully met, state what steps you will take to move your research forward to a clinical therapy.
7. **Care of Human Subjects (0.5 page):** If approved, include the IRB approval letter or equivalent. If approval is pending, indicate the expected approval date. Any funds awarded will be held until the letter is received. If IRB approval is not applicable, include a note in this section.
8. **Care of Vertebrate Animals (0.5 page):** If approved, include the IACUC approval letter or equivalent. If approval is pending indicate the expected approval date. Any funds awarded will be held until the letter is received. If IACUC approval is not applicable, include a note in this section.
9. **Literature Cited:** A maximum of 30 references are allowed. Use Vancouver format (numbered citations within text).
10. **Collaborators and/or Consultants:** Include any appropriate letters from individuals confirming their roles in the project.
11. **Three letters of recommendation are required:**

Letters should address the applicant's strengths as they align with the goals of the *RUNX1* Early Career Investigator Grant.

 - a. One letter from applicant's most recent mentor (postdoctoral or fellowship).
 - b. One letter from applicant's Department Chair detailing the level of institutional support (e.g., protected time for physician scientists, startup package, salary, space, administrative support, mentoring).
 - c. One letter from a senior colleague of the applicant's choosing that should address the applicant's potential for success and potential for making an impact in the field.
12. **Appendix:** A brief appendix is allowed with the following limitations.
 - a. Appendices should be included only if they are essential to the understanding of the application, including one accepted but not yet published manuscript or two pages of additional information. Additional information can include a summary of the protocol, the approval number (or CTEP number) if applicable and supplementary figures.
 - b. Excessive appendices will result in the application being rejected.

Application Submission Instructions

Applicants must not use the Internet Explorer (IE) browser as it is not compatible with the online portal. Chrome and Firefox browsers are recommended.

1. To start an application, navigate to the portal at ALSFapps.force.com.
 - a. Returning applicants: login with your username and password.
 - b. First time applicants: click the “New User?” link and complete your one-time registration and then login.
2. After you’ve logged in, follow the directions on the dashboard to submit your application. Complete the online form with applicant contact and project information.
 - a. Enter the Project Title first, even if tentative. Then Save.
 - b. Applicant will be asked for basic contact information for themselves, co-PI(s) if applicable, grant manager and institution. If someone other than the PI is entering information into the portal, the “Contact Person” name entered **must** be the PI’s name.
 - c. In the respective sections enter the project title, budget request amount, type of childhood cancer the project focuses on, as well as a 250-word summary of the research project in lay terms. The applicant will be asked to release this summary for use at ALSF’s discretion (website, press releases etc.) should the proposal be funded. The applicant may copy and paste information from other documents into these sections.
3. The application document must be uploaded as **one PDF** (maximum of 20 MB).
4. You may save your application to finish later. Go to ALSFapps.force.com and login again. You will land on your dashboard. Click “Applications” to edit your application in progress.
5. Once completed, submit the application by clicking Review & Submit, Submit. You will see error messages for any required fields that need to be completed.
6. After your application has been successfully submitted an email confirmation will be sent. You will not be able to amend the application after submission.

Contact

- If you have any questions regarding your eligibility or your research proposal topic, we encourage you to reach out to Katrin Ericson, Executive Director at RRP at kericson@runx1-fpd.org.
- All other questions can be submitted to Gina Dyer at G.Dyer@AlexsLemonade.org.