



The RUNX1 Research Program and Alex's Lemonade Stand Foundation

2021 Grant Application Guidelines for *RUNX1* Early Career Investigator Grant Program

Application Deadline: December 16, 2020 (8:00 PM ET)



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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 cure for *RUNX1*-FPD, a familial platelet disorder (FPD) with a predisposition to blood cancer. The program also aims to support, inform, educate, and connect patients and healthcare providers in the *RUNX1* community.

About ALSF

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 3-year award designed to fund research in strategies leading to the development of therapies to prevent the transition from pre-leukemia to leukemia for patients with *RUNX1*-FPD.

Collaboration and data sharing are a priority for this research program. 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).



Eligibility

- Applicants must have an M.D., Ph.D. or dual M.D., Ph.D. (D.O., MBBS or equivalent) and be within 5 years of their first faculty appointment as an Assistant Professor or equivalent. Associate and Full Professors are ineligible. If still 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.

Mission Relevance

- 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:
 - Hematopoietic stem cell gene correction strategies that optimize gene editing efficiency, precision and limit off-target effects.
 - Determining the drivers of clonal hematopoiesis and progression to overt malignancy.
 - Identifying strategies to lower the risk of hematologic malignancy in *RUNX1*-FPD.
 - Understanding the cellular and molecular mechanisms that underlie the inflammatory manifestations of *RUNX1*-FPD such as eczema, reactive airway disease and GERD.
 - Defining the role of inflammation in leukemic progression in *RUNX1*-FPD.
 - Determining whether impaired *RUNX1*-regulated DNA damage response contributes to acquisition of somatic mutations and clonal evolution.
- Resource sharing is an expected outcome of a completed project. The review will consider how outputs will be shared as a component of impact. For a full description see the [Resource Sharing Form](#).

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.

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 and a funding decision made within 3 months of the submission deadline.
- 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 malignant transformation in *RUNX1*-FPD and the feasibility of translating findings into the clinic.

Grant Reporting Requirements

- Six month Interim and Annual Progress reports are required. A second and third year of 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 is permitted with justification. Each year’s budget will be approved subsequent to the review of project progress.
- 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; no cost extensions must 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.” ALSF requests copies be sent via email to Grants@AlexsLemonade.org.
- Investigators must present project progress at the annual *RUNX1* Research Program scientific meeting.

Important Dates

Application Due Date	December 16, 2020 (8:00 PM ET)
Award Notification Date	Notification within 3 months of submission deadline
Project Start Date	1-2 months after award notification; contingent upon receipt of new award requirements



Project End Date	Three years from project start date
Progress Reports	Interim, 6-month check-in based on project start date
Final Report	Two months after project end date
RRP Scientific Meeting	Annual

Application Instructions

Part I: Online Form

- All applications must be submitted using ALSF’s online portal (<https://alsfapps.force.com>). A one-time registration is required to create a user account.
- Applicants must not use the IE browser as it is not compatible with the online portal. Chrome and Firefox browsers are recommended.

Contact Information

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.

Project Overview and Lay Summary

In the respective sections enter the project title, request amount, state how aims of research are relevant to the ultimate goal of preventing hematologic malignant transformation in *RUNX1*-FPD, 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 should the proposal be funded. The applicant may copy and paste information from other documents into these sections.

Part II: Application Package

- All sections described below should be combined into **one** PDF (max 10 MB) and uploaded to the ALSF online application form. Include the scanned signed Cover Page.
- 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.

Section Descriptions

1. **Cover Page (one page):** Download and complete the [Cover Page template](#).
2. **Table of Contents (one page):** Provide a Table of Contents with page numbers to the corresponding sections.
3. **Project Information**
 - a. **Scientific Abstract (half page):** Summarize the research objectives and rationale.
 - b. **Impact Statement (half page):** How will this project impact *RUNX1*-FPD?
 - c. **Budget/Justification (three pages):**
 - i. **Budget Template (one and one half pages):** Complete the [ALSF Standard Grant Budget template](#). The signature from an institutional representative on the cover page of this grant application specifically acknowledges and accepts this budget.
 1. 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.
 2. RRP and ALSF adhere to the NIH salary cap for principal investigator(s).
 3. Indirect costs (including tuition remission) are not allowed.
 4. If utilizing a sub-contractor, you must include their budget. No indirect costs will be paid to the sub-contractor.
 5. 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.
 - ii. **Budget Justification (one and one half pages)**
 - d. **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 (one page):** 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 (one 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. **Research Strategy**
 - i. **Significance (half 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.

- ii. **Innovation (half page):** Describe how the proposed research challenges and shifts paradigms or introduces a novel concept, approach or technology.
- iii. **Approach (four 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. **Plans for Clinical Translation (one page):** If the specific aims described above are successfully met, state in detail how you will move your research forward to a clinical therapy. Describe your plan in as best detail as you can including a **timeline with milestones** and estimated budget (general categories).
6. **Care of Human Subjects (half 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.
7. **Care of Vertebrate Animals (half 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.
8. **Literature Cited:** A maximum of 30 references are allowed. Use Vancouver (numbered citations within text) format.
9. **Collaborators and/or Consultants:** Include any appropriate letters from individuals confirming their roles in the project.
10. **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.
11. **Resource Sharing (one page):** Describe the outputs from the proposed project and how they will be shared. Reviewers will be asked to consider the manner in which resources will be shared and the extent to which this plan will increase or decrease the impact of the proposed project. Download and use the [Resource Sharing Form](#) to complete this section of the application.
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

1. Applications must be submitted through ALSF's online portal.
2. To start an online 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. If you are new to ALSF's portal, here is a [step-by-step guide](#) with screen shots!
3. After you've logged in, select *RUNX1 Early Career Investigator Grant Application* to submit your application. Complete the online form with applicant contact and project information. *Make sure your information is correct before the next step because you will not be able to change it!*
4. The application document must be uploaded as **one PDF** (maximum of 10 MB).
5. 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.
6. Once completed, submit the application by clicking Review & Submit. You will see error messages for any required fields that need to be completed.
7. 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 the Executive Director at RRP directly at kericson@runx1-fpd.org.
- All other questions can be submitted to Carrie Peck at 866-333-1213 or by email Grants@AlexsLemonade.org.