



2023 Grant Application Guidelines for *RUNX1* Early Career Investigator Grant Program

Application Deadline: December 21, 2022 (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 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 – Basic and Translational Science

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 basic and translational scientists 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-malignancy to overt hematologic malignancy in 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 that meets all guideline criteria as well as all eligibility criteria; otherwise, applications will be administratively rejected.
- Proposals 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 21, 2022 (8:00 PM ET)
Award Notification Date	February, 2023
Project Start Date	April 2023 (contingent upon receipt and approval of new award requirements)
Project End Date	April 2026
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: must be met at the time of application

- Applicant institutions must be based in the United States or Canada. Applicants need not be United States citizens. Funds must be granted to nonprofit institutions or organizations.
- 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
- 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 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:
 - Characterize the role of *RUNX1* in DNA damage repair and the impact germline *RUNX1* mutations may have on acquisition of somatic mutations in the blood.
 - Determine the functional differences of human *RUNX1* mutant proteins and their role in conferring risk of hematologic malignancies.
 - Define the effects of germline *RUNX1* mutations on specific immune cells, especially T and B cells, and the potential contribution to clonal evolution to HM
 - Identify druggable mechanisms, with a focus on drug repurposing, that drive clonal hematopoiesis, clonal expansion, and ultimately malignant transformation in *RUNX1*-FPD patients.
 - Develop drug screening programs aimed at raising normal *RUNX1* activity to improve hematopoietic function and reduce HM risk.
 - Investigate feasibility of targeting RNA splicing for disease therapy in patients with splice-site mutations.
 - Investigate potential for mRNA vaccine for *RUNX1*-FPD hematologic malignancy prevention.

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:

- RRP/ALSF adheres to the NIH salary cap for principal investigator(s).
- Indirect costs are not allowed.
- The grant may not be renewed; one no-cost extension request is allowed.
- Other budget items may include fringe, travel, supplies and small pieces of equipment. RRP/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 [Resources for Grant Applicants](#) page.

Childhood Cancer Data Lab Collaboration (optional)

Applicants may elect to work with [the Childhood Cancer Data Lab](#), at no cost to the investigator(s), as part of this award. This is not required and is meant to serve as a benefit. If you are interested in collaborating with the Data Lab, please fill out [this form](#) and indicate your submission is associated with an Alex's Lemonade Stand Foundation grant application.

Please note: There are a limited number of grant applications per cycle that can request effort from the Data Lab. Data Lab staff will evaluate collaboration requests on a rolling basis. Requests to collaborate must be submitted to the CCDL not later than 4 weeks before the grant application deadline. Requests submitted after this time frame will not be considered.

- Requests will be evaluated based on the expertise required to carry out the work and priority will be given to investigators: Seeking to improve reproducible research and analytical code practices through

collaboration with the Data Lab (e.g., learning to use version control services for source code or workflow managers for data processing)

- Making existing scientific software more usable or accessible (e.g., through construction of a web portal)

Data Lab staff will notify investigators of the status of their request within 5 working days. If your request is approved, the Director of the Childhood Cancer Data Lab will provide a Letter of Support to be included as part of your application.

The Data Lab is also available for consultations regarding the management and sharing of your research data which is a required element of this award. For applicants interested in consultations regarding data management and sharing, please contact the Data Lab team at collaborations@ccdatalab.org.

Resubmissions

One resubmission of an application previously reviewed by RRP/ALSF's Review Board is permitted. Applicants should respond to the 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.
- RRP/ALSF does not fund proposals 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 the Grant Policies, including Budget Expenditures, Resource Sharing, found on the [Resources 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; 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 (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 [Resources 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. Project Information

- a. **Cover Page (1 page):** Download and complete 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):

- i. **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.
 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 (1.5 pages):** Include a narrative for the following. Use N/A in sections as needed:
1. Personnel
 2. Subcontractors/Subawards/Consultants
 3. Equipment (for equipment costs above \$5000)
 4. Travel
 5. Computer and Software
 6. Other
3. **Biographical Sketch(es):** Use the NIH five-page biographical sketch (SF424) format for the principal investigator and all key personnel. **Please list all current and pending funding that would support financial productivity of the PI in Section A (Personal Statement).**
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 must include but is not limited to:
 - i. Feasibility of the approach to reach project goals; if available, include PI's preliminary studies pertinent to the project.

- ii. Key milestones with expected outcomes, details of potential problems, and plans to address these issues.
 - iii. A timeline
5. **Resource Sharing (1-2 pages):** 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 way 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. **Childhood Cancer Data Lab Letter of Support (optional):** If you have requested support from the CCDL and received a LOS from the Director of the CCDL, please insert the letter here. This resource does not have a cost associated with it and should not be included in the budget.
7. **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.
8. **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.
9. **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.
10. **Literature Cited:** A maximum of 30 references are allowed. Use Vancouver format (numbered citations within text).
11. **Collaborators and/or Consultants:** Include any appropriate letters from individuals confirming their roles in the project.
12. **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.
13. **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 apply for a Research Grant. Complete the online form with applicant contact and project information.

TIPS:

- a. Enter the Project Title first, even if it is tentative. Then Save.
 - b. If someone other than the PI is entering information into the portal, the “Contact Person” name entered **must** be the PI’s name.
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 the left to edit your application in progress.
 5. Once completed, submit the application by clicking Review & Submit. You will see error messages for any required fields that need to be completed. Review all information and click Submit again.
 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 Margaret Poore at M.Poore@AlexsLemonade.org.