

2025 Grant Application Guidelines for *RUNX1* Early Career Investigator Grant Program

Application Deadline: **December 19, 2024** (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 Timeline and Review

• 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 peerreview 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 TIMELINE

FULL PROPOSAL DUE	December 19, 2024, 8 PM EST
AWARD NOTIFICATION	March 2025
PROJECTED START/END	April 2025

Applicant Eligibility: must be met at the time of application

- 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.
- 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 and potential contribution to the process of clonal evolution to HM.
 - Address the contribution of increased levels of inflammatory cytokines present in *RUNX1*-FPD bone marrow to somatic evolutionary processes that result in clonal hematopoiesis and its transformation to HM.
 - Investigate feasibility of developing therapies that target specific germline *RUNX1* mutation types. For example, for nonsense mutations test compounds that promote read-through of mRNA transcripts bearing nonsense mutations or for splice-site mutations develop antisense oligonucleotide-based therapies that target pre-mRNA fragments and can modulate aberrant splicing.

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 <u>cannot</u> be used for tuition remission. View ALSF's complete <u>budget policy</u>.
- \circ $\;$ 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 using <u>ALSF's</u> <u>Resource Sharing Form.</u> 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.

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 <u>Resources for Grant Applicants</u> 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. Maximum NCE request is 12 months.
- 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 <u>Grants@AlexsLemonade.org</u>.



• Investigators must present project progress at the annual *RUNX1* Research Program scientific meeting and complete an RRP-generated survey at the end of the grant term.

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 <u>Resources for Grant Applicants</u> 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 <u>Cover Page Template</u>.
- 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 patients?
- 2. Budget/Justification (3 pages):
 - Budget Template (1.5 pages): Complete the <u>ALSF budget template</u>. The signature from an institutional representative on the cover page of this grant application specifically acknowledges and accepts this budget and acknowledges that <u>no indirect costs will be</u> <u>paid</u>.
 - 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 <u>NIH Salary Cap</u> for principal investigator(s).
 - 3. Indirect costs 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 <u>NIH five-page biographical sketch (SF424)</u> format for the principal investigator and all key personnel.
- 4. Research Plan
 - a. **Resubmissions (1 page, if applicable):** If this proposal was previously submitted to RRP/ALSF and did not receive funding, describe any changes in response to the reviewer critiques (e.g., changes in experimental design, scope, new data)
 - 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 and how this could potentially translate to the clinic in the near or long term.
 - 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. Images, graphs, and charts that are critical to the project should be included within this section, not in the appendix. They will count against the page limit. 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 <u>Resource Sharing Form</u> 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. **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. 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 addressing 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.
 - Appendices should be included only if essential to the understanding of the application.
 Appendices are limited to one accepted but not yet published manuscript OR two pages of additional information such as a summary of the protocol and supplementary figures.
 (*Reminder: tables and figures noted in the text should be embedded in the body of the proposal.*)
 Reviewers are not required to read the appendix.

Application Submission Instructions

Application Submission Instructions:

ALSF has migrated to Proposal Central for submitting grant applications!



- 1. To start an application, navigate to <u>Proposal Central</u> and select I am an... Applicant or Awardee
 - a. <u>Returning applicants (with an existing Proposal Central)</u>: log in with your Proposal Central ID.
 i. A password reset request can be sent using the following link:
 - https://proposalcentral.com/ForgotPassword.asp
 - b. First time applicants (using Proposal Central): click "Need an Account?" under the Login Button or use the following link: <u>https://proposalcentral.com/register.asp</u>. Enter all the required fields and click "Submit."
 - c. <u>ORCID Registrants</u>: you can login using your ORCID. If you don't have one, you can obtain one by registering through the link <u>https://orcid.org/register.</u>
- 2. After you've logged in to Proposal Central, navigate to the Grant Opportunities tab and you can search *Alex's Lemonade Stand Foundation* in the search bar to find our active grant application cycles. Click the "Apply Now" button to start an application.
- 3. The application document must be uploaded as **one PDF** (maximum of 20 MB), in the Attachments tab. Please see the guidelines for specific format and section instructions.
- 4. You may save your application to finish later. Just click "Save".
 - a. When you return to Proposal Central, click the "Proposals" tab at the top to navigate to your applications. You can filter your application based on Proposal Status in the upper right-hand corner. Click "In Progress" to return to your existing applications.
- 5. Once completed, click "Submit". Within 10 minutes you will receive a confirmation email. As long as the deadline has not passed, you may unsubmit your application to make changes by clicking the "Unsubmit" button on the "Proposals" tab.

If you have any questions regarding your Proposal Central account, please contact pcsupport@altum.com.

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 <u>M.Poore@AlexsLemonade.org.</u>