



# **CureSearch Young Investigator Awards in Pediatric Oncology Drug Development**

***2018 Request for Applications***

***Accelerate the Search: Find the Cure***

*Driving research to improve the odds for those children most at risk.*



## Timeline

<b>Request for Applications Opens</b>	October 5, 2018
<b>Letter of Intent Deadline</b>	November 16, 2018
<b>LOI Notification/Full Applications Invited</b>	December 21, 2018
<b>Full Applications Due</b>	February 1, 2019
<b>Award Notification</b>	April 8, 2019
<b>Earliest Award Start Date</b>	May 15, 2019

## Young Investigator Program Overview

CureSearch for Children's Cancer supports the recruitment of promising early career scientists to a research career in pediatric oncology. Early career investigators are the most vulnerable to the shortfalls in federal research funding. The CureSearch Young Investigator program helps early career scientists begin their research programs and provides a pathway to independence. Since 2012, CureSearch has invested \$2.8M in Young Investigator awards to 20 grantees in research areas with high-risk and poor outcomes for children with cancer: relapsed ALL, AML, brain tumors, Ewing sarcoma, hepatoblastoma, Hodgkin disease, neuroblastoma, non-Hodgkin lymphoma, rhabdomyosarcoma, and Wilms tumor.

CureSearch's mission is to drive innovative research to clinical impact to accelerate the delivery of novel therapeutics to pediatric cancer patients. A key component of this mission is to ultimately drive outstanding basic and translational research to clinical trials and beyond towards commercialization. CureSearch for Children's Cancer will review and fund projects advancing promising research. The 2018 Young Investigator Program is designed to provide support and training for exceptional young investigators in pediatric oncology drug development. The award is intended for investigators who have completed post-doctoral training and are transitioning to a full-time academic position. Up to four awards are available, contingent on the availability of funds, and will be based on the merits of the research proposed, the applicant's previous productivity, ongoing mentorship during the transition, and the research environment. The applicant will receive funding up to \$75,000 direct costs per year for up to three years (including a 10% indirect cost). Continued support for second and third year funding is contingent upon a noncompetitive review and demonstration of satisfactory and timely completion of milestones.



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Projects should be focused on **pediatric oncology drug development**. Basic research studies leading to drug discovery and pre-clinical testing of new therapies that have a high potential to translate into the clinic and eventual commercialization will be given priority. Applicants are encouraged to submit projects addressing areas of high unmet need in pediatric cancer research including high-risk, relapsed, or metastatic disease, adolescent and young adult patient populations, and/or the use of novel immunotherapy targets or modalities for pediatric cancer treatment. Funding decisions will be based on scientific merit and the project's drug development potential.

### Award Criteria

Applicants will be reviewed based on the following criteria:

- The applicant's previous productivity, research environment, and ongoing mentorship during the transition to independence.
- Extent to which the proposed research has potential for pediatric drug development. Basic research studies leading to target and drug discovery and pre-clinical testing of new therapies that have a high potential to translate into the clinic and eventual commercialization will be given priority.
- Scientific merit and potential for clinical development and commercialization. Proposals will be reviewed for scientific merit by CureSearch's Scientific Review Committee and for clinical development/commercialization potential by the Industry Advisory Council.
- Continued support for second and third year funding is contingent upon a non-competitive review and demonstration of satisfactory completion of proposed research objectives **and meeting the following expectations:**
  - Submission of biannual progress reports and completion of stated milestones, unless modified based on direction of research
  - Attendance and participation in the annual CureSearch Summit, travel stipend to be provided by CureSearch

### Eligibility Criteria

Applicants should meet the following eligibility criteria:

- MD (or equivalent), PhD, MD-PhD with no more than six years beyond completion of post-doctoral training
- Applicants must have an academic appointment at a US or European Union medical institution at the Instructor or Assistant Professor level; non-US applicants must comply with the US anti-terrorism financing laws



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- Applicants may not hold an independent NIH “R” or “P” award at the time of application
- Applicants may concurrently have an NIH “K” award
- Applicants must have an academic mentor identified and the application must include a letter/statement from the mentor documenting his/her involvement in the proposed research

### LETTER OF INTENT SUBMISSION INSTRUCTIONS

All LOIs must be submitted in accordance with the requirements and instructions of this RFA.

**LOIs must be completed by November 16, 2018 11:59 PM** 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”. In the upper left-hand corner, select “Filter by Grant Maker” and select CureSearch for Children’s Cancer in the drop-down menu. Find “**Curesearch for Children’s Cancer Young Investigator Award in Pediatric Oncology Drug Development**” and click the “apply now” link to create your LOI.

Complete all fields in the application and all templates that are provided. 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](mailto:pcsupport@altum.com).

### Letter of Intent Template

Use a blank Word document with the following sections. The LOI Narrative (Sections A-F) is limited to 5 pages. Cited Publications and LOI supporting documents (i.e. Biosketch, Letters of Support, Letters of Collaboration) are not included in this page number limit. A budget is not required at the LOI stage.

### Document Format

Please adhere to the following formatting requirements:

- PDF file format



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- Font size: 12 point
- Font type: Times New Roman
- Page Size: No larger than 8.5 inches x 11.0 inches
- Margins: 0.5 inch in all directions
- The complete LOI Narrative **must not exceed 5 pages** in length.

## **Section A: Title**

Applicants should enter the title of their proposal exactly as it is entered in proposalCENTRAL.

## **Section B: Scientific Approach and Feasibility (3 pages recommended)**

Clearly and concisely outline the hypothesis(es), specific aims, and approaches that will be taken to address each aim. In this section, address the following questions:

- Describe how the proposed study comprehensively addresses an overarching scientific roadblock/barrier.
- Describe how the proposed specific aims fully answer the study hypothesis(es).
- Describe how the scientific approach effectively addresses each specific aim.
- Describe the specific outcomes/deliverables of the proposed research plan and how those outcomes will be measured.

## **Section C: Scientific and Patient Impact (0.5 page recommended)**

Clearly and concisely answer the following questions using non-scientific language appropriate for a lay audience:

- Describe your project and your project's impact as you would explain to a non-scientist, in 3-5 sentences. Include how by removing the scientific barrier/roadblock would have significant potential to lead to a critical pathway to identify a breakthrough toward improving childhood cancer outcomes.
- Why is removing the scientific barrier/roadblock important to cancer patients and survivors?

## **Section D: Potential for clinical application (0.5 page recommended)**

Clearly describe how the project, if successful, will advance to clinical application and FDA approval for pediatric use.

- Describe plans to move the treatment to pediatric clinical trials.
- Briefly delineate the potential pathway for IND submission.



### **Section E: Academic Mentoring Plan (0.5 page recommended)**

A clear plan for career development including strategies for mentorship and future research funding must be articulated.

### **Section F: Innovation (0.5 page recommended)**

- Describe how the proposed efforts will lead to novel therapeutic strategies or significant improvements on existing therapies.
- Describe how the project challenges and seeks to shift current research or clinical practice paradigms by using novel concepts, approaches or methodologies and/or intervention.

### **Cited Publications**

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

### **Letter of Intent Supporting Documents**

The following documentation is required for the LOI, and will not count toward the page limit:

#### **Biosketches**

Complete and upload an NIH Biographical Sketch (maximum five pages each) for all key project personnel, beginning with the Principal Investigator. CureSearch defines “key project personnel” as any individual with an advanced degree who will play an instrumental role in the accomplishment of the research project.

#### **Letters of Support**

Include the following:

1. A letter of support from the applicant's mentor
2. A letter of support from the Division or Department Chair detailing:
  - a. A commitment to the investigator
  - b. The availability of necessary protected research time
  - c. The availability of adequate research facilities (including details of laboratory space for the investigator) to conduct proposed research.

#### **Letters of Collaboration**

All letters of collaboration must be provided at the time of LOI submission and uploaded in PDF format.



### LOI Peer Review Criteria

Review will be based on the inclusion of the following within the LOI:

<p><b>Scientific Approach and Feasibility</b></p>	<p>Description of:</p> <ul style="list-style-type: none"> <li>• how the proposed study addresses the overarching scientific roadblock/barrier</li> <li>• how the proposed specific aims fully answer the study hypothesis(es)</li> <li>• how the scientific approach effectively addresses each specific aim</li> <li>• the specific outcomes/deliverables of the proposed research plan and the timeframe for these deliverables</li> </ul>
<p><b>Scientific and Patient Impact</b></p>	<p>Explanation of:</p> <ul style="list-style-type: none"> <li>• your project and its impact as you would explain to a lay audience, in 3-5 sentences; inclusion of how removing the scientific barrier/roadblock would lead to a critical pathway or identify a breakthrough toward improving childhood cancer outcomes</li> <li>• why removing the scientific barrier/roadblock is important to cancer patients and survivors</li> <li>• your proposed timeline and why this timeframe is required to meet your goals</li> <li>• the project's ability to produce an impact on patients</li> </ul>
<p><b>Innovation</b></p>	<p>Describe:</p> <ul style="list-style-type: none"> <li>• how the proposed efforts will lead to novel therapeutic strategies or significant improvements on patient outcomes from current existing therapies</li> <li>• how the project challenges and seeks to shift current research or clinical practice paradigms by integrating novel concepts, technologies, approaches or methodologies and/or interventions into the proposed scientific and/or clinical research</li> </ul>
<p><b>Clinical Development and Commercialization Potential</b></p>	<ul style="list-style-type: none"> <li>• Explain the molecular feasibility, clinical feasibility, likelihood of regulatory approval, and potential or future commercialization.</li> </ul>



## **Full Application Submission**

Applicants with LOIs deemed most meritorious and aligned with Program's goals will be invited to submit full applications. Instructions on how to submit a full application will be provided at the time of the LOI decision on December 21, 2018.

## **Confidentiality**

CureSearch treats all LOIs, full applications and associated research information (collectively, the "Confidential Information") in confidence using no less than reasonable care in protecting such Confidential Information from disclosure to third parties who do not participate in the grant review process and CureSearch assessments. All Confidential Information will be used by CureSearch and its scientific reviewers only internally for the purposes of reviews and assessments, and will be shared only in accordance with its sharing policy stated herein.

## **Conflicts of Interest**

Principal investigators, co-investigators, sub-contractors or collaborators submitting applications to the RFA will be excluded from serving on the scientific review committee. However, non-applicants who are invited to serve on the scientific review committee may still have a conflict of interest if 1) the application is from the reviewer's own institution regardless of whether or not the reviewer has had any involvement in preparing the application, 2) the reviewer, his/her immediate family, or close professional associate(s) has a financial interest or vested interest in the outcome of the proposed research, or 3) the reviewer has been involved in discussions regarding the application, is a provider of services, cell lines, reagents or other materials, or writer of a letter of support for the applicant. When a conflict of interest is deemed to be present, the reviewer will be ineligible to review the proposal and be asked to recuse themselves from the deliberations.





## Special Requirements

### **SHARING POLICY**

Being a public, philanthropic charity, research conducted with funds from CureSearch must be conducted in the public interest. CureSearch acknowledges that any discoveries and related regulatory approvals made by researchers through the funded research are the property of those conducting and responsible for the research and that unless otherwise agreed to by the parties; such researchers have the first opportunity to exploit the research commercially or otherwise. However, subject to intellectual property protection considerations, each applicant acknowledges that CureSearch has the right, after reasonable consultation to release a summary of findings of the research to the general public.

### **PUBLICATION**

It is also required that the results of the research will be published as rapidly as possible in the open scientific literature. Publications should be consistent with high standards of scientific excellence and rigor and include acknowledgement of the funding provided by CureSearch for Children's Cancer.

### **INVENTIONS**

The recipient of this Award or his/her institution shall own any invention. However, the recipient shall promptly notify CureSearch of any invention and associated patent filing resulting from the research. If the recipient or his/her institution grants any right to the invention to a third party for commercial application and receives any amounts from the invention, CureSearch shall be entitled to receive a share calculated by multiplying the amounts received by a fraction, the numerator of which is the amount of the Award, and the denominator of which is the direct cost incurred by the recipient and his/her institution in developing the invention, except in no event shall the CureSearch share of any such amount received that exceeds 30%.

### **REQUIREMENTS FOR AWARDEES**

- Progress Reports for CureSearch are due every six months. Progress report templates and instructions will be provided by CureSearch at the time of the award and reminders will be provided two months prior to due dates.



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- Principal investigators are required to attend the annual CureSearch Summit to be held during the first quarter of the year. Grantees will have the opportunity to network with other investigators, industry and other stakeholders, explore possible collaborative efforts, and identify strategies/resources to advance projects towards clinical application and commercialization. A travel stipend will be provided by CureSearch to attend this event.
- Principal investigators will work closely with CureSearch to translate complex science, findings and outcomes for donors and constituents. This will be done by conducting interviews for videos, podcasts, webinars, newsletters and/or other written updates.
- Grantees are expected to account for the monies expended under the Award; any monies spent either not in accordance with the approved research project or prior to pre-approval of any material change in the project are not recoverable and may be cause for immediate termination of funding by CureSearch.
- Grantees are expected to meet scheduled milestones and submit deliverables on time. Failure to meet milestones, furnish scheduled deliverables, including the aforementioned reports or to comply with the terms of the grant may serve as a base for termination of funding by CureSearch.



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## QUESTIONS?

Contact information for all inquiries about application submission is provided below.

Type of Inquiry	Contact
All programmatic inquiries (including questions related to eligibility, application requirements, etc.)	<b>CureSearch</b> Email: <a href="mailto:researchgrants@curesearch.org">researchgrants@curesearch.org</a> Phone: +1-240-235-2215
All technical inquiries related to the online application system, proposalCENTRAL	Email: <a href="mailto:pcsupport@altum.com">pcsupport@altum.com</a> Phone: 1-800-875-2562