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# **CureSearch Acceleration Initiative 2 (AI-2) International Grand Challenge Awards in Pediatric Cancer**

***2015 Request for Applications (RFA)***

***Funded in partnership with the  
Rising Tide Foundation for Clinical Cancer Research (RTFCCR)***

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

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

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## KEY DATES

<b>Request for Applications Opens</b>	March 2, 2015
<b>Letter of Intent Deadline</b>	April 15, 2015
<b>LOI Notification</b>	June 1, 2015
<b>Full Applications Due</b>	July 15, 2015
<b>Award Notification</b>	October 1, 2015
<b>Funding Timeframe</b>	January 2016 - December 2018

## BACKGROUND ON CURESEARCH'S RESEARCH PROGRAM

Despite overall improvements in the survival rates of children's cancer, many types of children's cancer remain difficult to treat and account for more than their share of deaths. Leukemia and central nervous system tumors remain prevalent and account for over half of diagnosed cancers among children. These cancers have benefited from decades of research, yet survivors continue to face significant late effects when they finish treatment. Other cancers, despite advances in research, continue to show only modest progress in outcomes, with cure rates of only 50%. Survival rates for some cancers are still as low as 30% within two years of diagnosis. So while the overall odds have improved, the degree to which childhood cancer research has progressed varies greatly depending on the disease diagnosis. The growing population of childhood cancer survivors (estimated at 379,112 in the U.S. as of 2010) continues to face significant challenges related to their cancer treatments, with over 225,000 of these individuals facing significant adverse late effects due to their cancer treatments.

By joining together, CureSearch for Children's Cancer (CureSearch) and Rising Tide Foundation for Clinical Cancer Research (RTFCCR) have joined forces to advance pediatric cancer research worldwide and address the most challenging problems facing childhood cancer research in order to accelerate the field toward a cure. Through the Acceleration Initiative (AI-2), CureSearch and RTFCCR will fund promising research that addresses these barriers in the field and has the potential to save lives in the near term. We support innovative, evidence-based translational and clinical cancer research that has a high potential to improve the therapeutic options for children with cancer. Our



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research pathway is collaborative, interdisciplinary, and demands measurable results.

CureSearch's first Acceleration Initiative 1 (AI-1) funds major research initiatives with the potential to reach children in a shortened time period. As we look forward to Acceleration Initiative 2 (AI-2), funded in conjunction with RTFCCR, we remain committed to changing outcomes for patients and families through novel, innovative research. AI-2 grants will require rigorous milestones and careful reporting from its grantees, and we measure success by outcomes in the research program as well as with patients. This is a new day of measurable results in scientific research and AI-2 will lead the way by sharing outcomes with donors, patients, families and the scientific community. The ultimate goal of AI-2 is to improve childhood cancer treatment and cure rates so that childhood cancer patients are able to lead long, healthy lives.

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## GRAND CHALLENGE AWARDS IN PEDIATRIC CANCER

### BACKGROUND

Acceleration Initiative grants are intended to fund translational and clinical cancer research with the greatest potential of measurable, patient-centric outcomes within an accelerated time period.

*A CureSearch “Grand Challenge” is a call for a specific scientific or technological innovation that will remove a critical barrier or identify a breakthrough toward improving childhood cancer outcomes—all with a high likelihood of becoming a feasible and impactful therapeutic option for children in the near term (meaning it has to reach clinical applicability within 3 years or less).*

### Novel Approaches to Childhood Cancer Survivorship

Grand Challenge 1: Develop interventions to prevent or reduce the late effects of pediatric cancer treatments or improve long-term survivorship health. Preference will be given to projects with the potential to reach patients in an accelerated timeframe, applicability to multiple cancers and/or applicability to multiple patient populations.

Critical barriers: New treatments for childhood cancers have dramatically improved the prognosis and outcomes for many pediatric cancers, from 10% fifty years ago to almost 90% today in some cases. Long-term survival into adulthood is the expectation for most children with access to contemporary therapies for pediatric cancer, on average. However, the therapy responsible for this survival can also produce adverse long-term health consequences that manifest months to years after completion of cancer treatment. There is potential for interventions that improve the quality of life of survivors, reduce the severity of long-term effects, and advance clinical and preclinical interventions to improve long-term outcomes.

### Accelerating the Delivery of Novel Agents and Clinical Trial Design

Grand Challenge 2: Develop approaches to accelerate the delivery of new therapeutic agents for pediatric cancer. There is potential for applying new clinical study design using personalized medicine, biomarker screening, or innovative study design to accelerate new drug development and/or improved treatment standards. Preferences will be given to international collaborative projects and/or projects that leverage existing regulatory guidelines or governmental programs that require or reward research into the development of new therapies for pediatric patients.



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Critical barriers: Drug development in pediatric cancer is slowed by regulatory barriers, differences between academic and pharmaceutical incentives, and clinical study design. This grand challenge presents an opportunity for projects that apply insights about molecular targets and cellular disease processes to developing novel agents. Other potential projects might develop biologically-based studies for testing existing adult drugs on pediatric populations, for multi-cohort study design, designs that incorporate single agent and combination therapy study phases, Phase I + II designs, multi-site (consortia) or multi-national studies, or other approaches.

## ELIGIBILITY

AI-2 grants are open to applicants from academic research institutions involved in the development of novel cancer therapeutic approaches with pediatric oncology applications. Applicants and institutions must conform to the following eligibility criteria to apply for an AI-2 grant. Eligibility requirements must be met at the time of full application submission. Applicants with questions about eligibility should contact CureSearch or the RTFCCR before submitting a Letter of Intent.

### APPLICANTS (PRINCIPAL INVESTIGATOR)

- The applicant must be the principal investigator (PI). The PI must be an independent investigator at any level who is affiliated with an academic institute. Applications are open to North American, European Union, and international applicants. Non-U.S. applicants must comply with U.S. anti- terrorism financing laws.
- Must have a doctoral degree, including MD, PhD, DrPH, DO or equivalent.
- Laboratory scientists and clinical investigators must have adequate space to conduct proposed research and protected time for research, verified by the Letter of Institutional Support.
- For applicants seeking support of USD 500,000 or greater, a minimum committed effort of 10% from the PI is required.
- Must not hold an active CureSearch or RTFCCR grant.
- All applications must be written in English.

### INSTITUTIONS

- Open to nonprofit, academic institutions. Collaborative efforts with different disciplines, institutions, nationalities or biotechnology and pharma companies are encouraged.

## FUNDING INFORMATION AND GRANT TERM

The AI-2 is funded in conjunction with RTFCCR, a Swiss-based foundation dedicated to supporting promising, innovative clinical cancer and scientific studies to provide hopeful, encouraging, and immediate options for cancer patients. Awards are contingent upon the availability of funds and the receipt of a sufficient number of applications of high scientific merit and potential impact. We are likely to fund **one to three proposals for a total of up to USD 2 million.**

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There is no set budget limit per project. However, no application may exceed a project period greater than three years (01/01/16-12/31/18) and budgets must be efficient and appropriate for the work performed. Budgets are not required to be equivalent across each year of the project, but rather should reflect the costs appropriate to support the research project each year.

## **BUDGET GUIDELINES**

- Personnel on the project are limited to a base salary at or below USD 200,000 per year.
- Equipment costs are limited to no more than 20% of total direct costs and only if it is an integral part of the proposed project (specific approval RTFCCR and CureSearch required).
- Reasonable travel costs are allowable only if such costs are an integral part of the proposed project (specific approval RTFCCR and CureSearch required).
- Publication and meeting-related poster printing costs are allowable.
- Graduate and postdoctoral fellow tuition costs are not allowable.
- Visa costs are not allowable.
- Professional membership dues are not allowable.

## **GENERAL GUIDELINES**

### **COLLABORATIONS**

AI-2 grants are intended to leverage the power of collaboration, through multi-institutional, interdisciplinary approaches that address the greatest barriers to improving outcomes for infants, children, adolescents, and young adults suffering from cancer. As one institution or researcher cannot possess the necessary expertise in all steps of a particular project, multi-national collaborations among a team of investigators and/or partnerships with industry in addressing the “grand challenges” are strongly encouraged and will be reviewed favorably. However, Acceleration Initiative funding is for the sole use of grantees as described in the ‘Eligibility’ section above, and may not be used to directly support commercial or industry projects or initiatives.

### **MEASURING SUCCESS, CREATING IMPACT**

Applicants are required to propose time-dependent, measurable milestones to ensure completion of study objectives and clearly state how results at each milestone will be used in measuring research outcomes. The project budget should closely reflect the milestones. Continuation of funding will be dependent upon successful completion of each milestone. Additionally, multi-year support is not automatic and is contingent upon favorable review of the grantee's progress reports by the Scientific Review Committee appointed by CureSearch and RTFCCR. After the grant term is complete,

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CureSearch and RTFCCR require periodic (every 1-5 years) survey responses to gauge the long-term effects of its investment and research outcomes.

## REVIEW PROCESS

CureSearch and RTFCCR employ a multi-step approach to application and review that invites submission of a Letter of Intent (LOI), the success of which will result in an invitation to submit a full application. LOIs are first reviewed for eligibility, adherence to formatting requirements, and responsiveness to the research focus and Grand Challenges specified in this RFA. Applications that do not meet the aforementioned requirements will be withdrawn and will not undergo scientific review.

Each qualifying LOI is reviewed by a panel of international scientific experts appointed by CureSearch and RTFCCR. Reviewers will assess the strengths and weaknesses of each application based on the defined review criteria described below. Only applicants with LOIs deemed most meritorious and aligned with the program's primary goals will be invited to submit full applications.

Applicants will be notified of LOI review decisions via email. Applicants invited to submit a full application will be granted access to the full application site.





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**LOI Scientific Peer Review Criteria**

<b>“Grand Challenge” Area and Scientific Barrier/Roadblock</b>	<ul style="list-style-type: none"> <li>• Identify the “challenge” area and describe the scientific barrier or roadblock being addressed.</li> </ul>
<b>Scientific Approach and Feasibility</b>	<ul style="list-style-type: none"> <li>• Describe how the proposed study addresses the overarching scientific roadblock/barrier.</li> <li>• Describe how the proposed specific aims fully answer the study hypothesis(es).</li> <li>• Describe how the scientific approach effectively addresses each specific aim.</li> <li>• Describe the specific outcomes/deliverables of the proposed research plan and the timeframe for these deliverables.</li> </ul>
<b>Scientific and Patient Impact</b>	<ul style="list-style-type: none"> <li>• Describe your project and its impact as you would explain in plain language, in 3-5 sentences. Include how by removing the scientific barrier/roadblock would lead to a critical pathway or identify a breakthrough toward improving childhood cancer outcomes.</li> <li>• Why is removing the scientific barrier/roadblock important to cancer patients and survivors?</li> <li>• Provide brief support for your proposed timeframe and evidence of the project’s ability to produce an impact on patients.</li> </ul>
<b>Innovation</b>	<ul style="list-style-type: none"> <li>• Describe how the proposed efforts will lead to novel therapeutic strategies or significant improvements on patient outcomes from current existing therapies.</li> <li>• Describe 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>

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## 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 **11:59 pm April 15, 2015** 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". Find "**CureSearch for Children's Cancer Acceleration Initiative 2: International Grand Challenges in Pediatric Cancer**" 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

Download the Template from proposalCENTRAL and fill in the following sections. The LOI Narrative (Sections A-E) is limited to 4 pages. Cited Publications and LOI supporting documents (i.e. Biosketch, Letters of Support, Letters of Collaboration and Letter of Commitment from Applicant) are not included in this page number limit.

### Document Format

Please adhere to the following formatting requirements:

- PDF file format
- Font size: 12 point
- Font Type: Times New Roman
- Page Size: No larger than 8.5 inches x 11.0 inches
- Margins: 1 inch in all directions
- The complete LOI narrative must not exceed 4 pages in length.

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### **Section A: Title**

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

### **Section B: Grand Challenge Area and Barrier/Roadblock**

**(.5 page recommended):** Identify the “challenge” area being addressed and describe the scientific barrier or roadblock.

### **Section C: Scientific Approach and Feasibility (1.5 pages recommended):**

Clearly and concisely outline the hypothesis(es), specific aims, and approach that will be taken to address each aim. In this section, address the following questions using non-scientific language appropriate for a lay audience:

- 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 D: Scientific and Patient Impact (1 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 or identify a breakthrough toward improving childhood cancer outcomes.
- Why is removing the scientific barrier/roadblock important to cancer patients and survivors?

### **Section E: Innovation (1 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 interventions.

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### **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 a NIH Biographical Sketch (maximum four pages each) for all key project personnel, beginning with the Principal Investigator. CFF defines "key project personnel" as any individual with an advanced degree who will play an instrumental role in the accomplishment of the research project. NIH Biographical Sketches are acceptable.

## **FULL APPLICATION SUBMISSION**

Only 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 on the LOI decision on June 1, 2015.

## **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

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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 or RTFCCR must be conducted in the public interest. RTFCCR and CureSearch acknowledge 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 RTFCCR and CureSearch have 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 RTFCCR and CureSearch for Children's Cancer.

### **INTELLECTUAL PROPERTY/INVENTIONS**

Ownership of inventions created by AI-2 grant recipients will be determined by the relevant laws applicable to the inventor(s) or his/her / their institution(s). However, the recipient shall promptly notify CureSearch and RTFCCR 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 and RTFCCR shall be entitled to the royalty payment in the event of commercial licensing of an invention specified in the award terms and conditions.

## REQUIREMENTS FOR AWARDEES

- Progress Reports for CureSearch and RTFCCR are due every six months. Progress report forms and instructions will be provided by CureSearch two months before they are due.
- Principal investigators are required to attend annual CureSearch Symposium at which they will report on the progress of their projects, exchange information with other investigators, explore possible collaborative efforts among grantees and identify resources that would enhance productivity of the grantees or the field-at-large.
- Principal investigators will work closely with CureSearch and RTFCCR 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 and RTFCCR.
- Grantees are expected to meet scheduled milestones and submit deliverables on time and 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.

## QUESTIONS?

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

Type of Inquiry	Contact
<b>All programmatic inquiries (including questions related to eligibility, application requirements, etc.)</b>	<b>CureSearch</b> Email: <a href="mailto:researchgrants@curesearch.org">researchgrants@curesearch.org</a> Phone: +1-240-235-2215 <b>Rising Tide Foundation for Clinical Cancer Research</b> Email: <a href="mailto:research@risingtide.ch">research@risingtide.ch</a> Phone: +41-52-630-7087
<b>All technical inquiries related to the online application system, proposalCENTRAL</b>	Email: <a href="mailto:pcsupport@altum.com">pcsupport@altum.com</a> Phone: 1-800-875-2562



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