CURESEARCH
FOR CHILDREN'S CANCER

CureSearch Acceleration Initiative

International Award in Pediatric Cancer Drug Development

2024 Request for Applications

Accelerate the Search: Find the Cure

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

2024 FUNDING CYCLE TIMELINE

Request for Applications Opens	September 1, 2024
Letter of Intent Deadline	October 7, 2024
LOI Notification/Full Applications Invited	November 10, 2024
Full Applications Due	January 18, 2025
Earliest Award Notification*	March 2025

*Awards will be made on a rolling basis, pending the availability of funds.

ACCELERATION INITIATIVE PROGRAM OVERVIEW

The CureSearch for Children's Cancer Acceleration Initiative (AI) advances pediatric cancer research worldwide to address the most challenging problems facing childhood cancer research in order to accelerate progress in the field toward a cure. CureSearch will review and fund promising research that addresses barriers in areas of high unmet need in pediatric cancer research. We support innovative, evidence-based translational and preclinical cancer research that has a high potential to improve therapeutic options through research pathways that are collaborative, interdisciplinary, and generate measurable results.

CureSearch's first ten Acceleration Initiative awards funded major research projects with the potential to reach children in a shortened time period. As we look forward to the next phase, we remain committed to changing outcomes for patients and families through innovative research. To date, 60% of the completed AI awards have ultimately led to a clinical trial. AI awards will require rigorous investigator-defined milestones and careful reporting from its grantees. The ultimate goal is to improve childhood cancer treatment and cure rates so that patients are able to lead long, healthy lives.

The 2024 AI solicitation is seeking translational and preclinical projects that focus on addressing areas of high unmet need and are designed to lead to clinical studies of therapies for children within a three-year timeframe. **While all applications addressing unmet needs in pediatric oncology are welcome, this solicitation includes a Notice of Special Interest for projects specifically aimed at developing therapies for neuroblastoma.** Applicants are encouraged to detail how their proposal will address critical challenges and overcome significant barriers in pediatric oncology treatment.

2024 LETTER OF INTENT CHECKLIST:

- ☐ Title Page Information (*Completed in proposalCentral*)
- ☐ Download Templates & Instructions (*Completed in proposalCentral*)
- ☐ Applicant/Principal Investigator Information (*Completed in proposalCentral*)
- ☐ Organization/Institution & Contacts (*Completed in proposalCentral*)
- ☐ Abstract & Keywords (*Completed in proposalCentral*)
- ☐ Project Impact (*Completed in proposalCentral*)
- ☐ Clinical Application/Commercialization (*Completed in proposalCentral*)
- ☐ Scientific Approach, Feasibility, and Innovation (*Attachment, Template provided*)
- ☐ Cited Publications (*Attachment*)
- ☐ Biosketches for Key Personnel (*Attachment, Template provided*)

☐ Letter(s) of Support (*Attachment*)
☐ Other Supporting Document(s) (*Attachment*)

ELIGIBILITY

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

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks/African Americans, Hispanics/Latinos, Indigenous Peoples/Native Americans, Alaska Natives, Native Hawaiians, and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting. CureSearch encourages applicants from diverse populations to enhance the participation of researchers identified as nationally underrepresented in the biomedical and clinical sciences.

APPLICANT (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 institution. Applications are open to applicants in North America, the European Union, Japan, the United Kingdom, China, and Australia. Non-U.S. applicants must comply with U.S. anti-terrorism financing laws.
- The applicant must have a doctoral degree, including MD, PhD, DO, or equivalent.
- Laboratory scientists and clinical investigators must have adequate space to conduct proposed research and protected time for research, verified by a Letter of Institutional Support.
- For applicants seeking support of $500,000 or greater, a minimum committed effort of 10% from the PI is required.
- Applicants must not hold an active CureSearch grant or apply for funding through another CureSearch program during the same cycle.
- All applications must be written in English.

INSTITUTIONS

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

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. CureSearch will not accept duplicate or highly overlapping applications under review at the same time. This means that CureSearch will not accept:

- A new application that is submitted before issuance of the summary statement from the review of an overlapping new or resubmission application.
- A resubmission application that is submitted before issuance of the summary statement from the review of the previous new application.
- An application that has substantial overlap with another application pending appeal of initial peer review.

RESUBMISSION POLICY

Applicants may resubmit an application that advanced to the full proposal stage in a previous RFA cycle but was not selected for funding. The LOI must be marked as a resubmission within the Proposal Central site. If invited to submit a full application, applicants will be asked to include a cover letter that addresses reviewer comments and outlines specific revisions. Resubmissions will compete with new proposals for funding consideration.

FUNDING INFORMATION AND GRANT TERM

AI awards are contingent upon the availability of funds and the receipt of applications of high scientific merit and potential impact. CureSearch is likely to fund one to three proposals.

The budget should reasonably reflect the direct costs needed to carry out the project and **should not exceed $1.5M total costs over the three-year project period (including 10% indirect costs.** The budget should be as evenly distributed across the requested years of support as possible.

BUDGET GUIDELINES

- Personnel on the project are limited to a base salary at or below the NIH Salary Cap, which is currently $221,900 per year.
- 10% indirect costs are allowed.
- Equipment costs are limited to no more than 20% of total direct costs for equipment that is an integral part of the proposed project (if additional equipment costs are required, prior approval by CureSearch is required).
- National and international travel costs are allowable, limited to no more than $5,000 per year of the award.
- Publication and meeting-related costs are allowable.
- Graduate and postdoctoral fellow tuition costs, visa costs, and professional membership dues are not allowable.

GENERAL GUIDELINES

COLLABORATIONS

AI awards 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, collaborations among a team of investigators, consortia, and/or partnerships with industry are strongly encouraged and will be reviewed favorably. However, AI 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

The ultimate outcome of AI funding is to have a clinical impact within a three-year timeframe. Applicants are required to propose time-dependent, measurable milestones and deliverables to ensure the completion of study objectives. The project budget should closely reflect the milestones and deliverables. Continuation of funding will be contingent upon the successful completion of each milestone. Multi-year support is dependent upon a favorable review of the grantee's progress reports by the Scientific Advisory Council appointed by CureSearch. Folling completion of the award period, CureSearch requires periodic (every 1-5 years) survey responses to gauge the long-term effects of its investment and research outcomes.

REVIEW PROCESS

CureSearch employs a multi-step approach to application and reviews. This RFA invites the 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 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. 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.

LOI SCIENTIFIC PEER REVIEW CRITERIA

Area of Unmet Need and Scientific Barrier/Roadblock	• Identify an area of high unmet need within the pediatric oncology field that will be addressed and describe the scientific barrier or roadblock that this proposal will overcome

Scientific Approach and Feasibility	Description of: • How the proposed study addresses the overarching scientific roadblock/barrier • How the proposed specific aims fully answer the study hypothesis(es) • How the scientific approach effectively addresses each specific aim
Scientific and Patient Impact	• Provide brief support for your proposed timeframe and evidence of the project's ability to produce an impact on patients • Explain clearly, if the proposed project is successful, the pathway to IND submission, product commercialization in pediatrics, and FDA approval
Innovation	Description of: • How the proposed efforts will lead to novel therapeutic strategies or significant improvements on patient outcomes from current existing therapies • 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

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 on October 7, 2024**, and submitted via proposalCENTRAL at https://proposalcentral.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, click on "Filter by Grant Maker" and select CureSearch for Children's Cancer from the drop-down menu. Find the "CureSearch Acceleration Initiative International Award in Pediatric Cancer 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 by phone (800) 875-2562, or email pcsupport@altum.com.

LETTER OF INTENT TEMPLATE

Download the template from proposalCENTRAL and fill in the following sections. The LOI Section E: Scientific Approach and Feasibility is limited to 2 pages. Cited Publications and

LOI supporting documents 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
- 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 Scientific Approach must not exceed 2 pages in length.

Section A: Title, Applicant, & Organization Information

Applicants should enter the title of their proposal,

Section B: Abstracts (500-words each) & Keywords Information

Applicants should enter a scientific abstract, a lay summary, and select their major research interest and keywords from the lists provided.

Section C: Project Impact (3-5 Sentences)

Describe your project and your project's impact in 3-5 sentences. Include how the project would have significant potential to lead to a critical pathway to identify a breakthrough toward improving childhood cancer outcomes.

Section D: Clinical Application/Commercialization (500 Words):

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 and product commercialization in pediatrics

Section E: Scientific Approach, Feasibility, and Innovation (2 Pages)

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:

- Identify the area of unmet need being addressed and describe the scientific barrier or roadblock. Why is removing the scientific barrier important to cancer patients and survivors?
- 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.
- Describe how the proposed study comprehensively addresses the overarching scientific barrier.
- Describe how the proposed specific aims fully answer the study hypothesis(es).
- Describe how the scientific approach effectively addresses each specific aim.

LETTER OF INTENT SUPPORTING DOCUMENTS

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

- **CITED PUBLICATIONS**: References must be numbered. Cited publications are not included in the page limit. Please include in attachments.
- **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/COLLABORATION**: All letters of support/collaboration must be provided at the time of LOI submission and uploaded in PDF format.

FULL APPLICATION SUBMISSION

Only applicants with LOIs deemed most meritorious and aligned with the 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.

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 acknowledgment of the funding provided by CureSearch for Children's Cancer.

INTELLECTUAL PROPERTY/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 via proposalCentral, and reminders will be provided prior to due dates.

If held, Principal investigators are required to attend the annual CureSearch Summit. 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 toward clinical application and commercialization.

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 the termination of funding by CureSearch.

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.)	**CureSearch** Email: researchgrants@curesearch.org Phone: +1-240-235-2215
All technical inquiries related to the online application system, proposalCENTRAL	Email: pcsupport@altum.com Phone: 1-800-875-2562