

Colorectal Cancer Alliance

PROJECT CURE CRC

2024 Request for Proposals

The Colorectal Cancer Alliance (the Alliance) is pleased to announce a Request for Proposals (RFP) for preclinical and clinical translational research with the potential for high impact on diagnosis, treatment, or survivorship of colorectal cancer. Project Cure CRC will prioritize proposals that embrace moving colorectal cancer research to a curative science ASAP. Submitted proposals should focus on projects that are High-Risk/High-Reward and accelerate new therapies and technologies from bench to bedside. Projects that utilize collaborations and/or public-private partnerships are **STRONGLY** encouraged. Proposals will be accepted for Early-Career Investigator Awards, Senior Investigator Awards, Pilot Awards, Team Science Awards, Opportunistic Awards and Strategic Awards from academic and industry researchers. The Alliance plans to award tens of millions in 2024 for new research and infrastructure needs arising from this RFP.

Introduction

About the Alliance

Founded in 1999, the Colorectal Cancer Alliance (the Alliance) is the leading nonprofit dedicated to colorectal cancer (CRC). In 2010, the Alliance established the Chris4Life Research Program in honor of the late Christine Sapienza and for all the families who are affected by colorectal cancer. The research program was a critical driving force in the mission to end colorectal cancer in our lifetime. The Alliance has already invested nearly \$10 million in colorectal cancer research, including nearly \$3 million as early-stage grants to innovative researchers. Please visit www.colorectalcancer.org for more information about the Alliance.

Research Objectives

Based on the Alliance's Research Strategy and priorities identified at the Cure CRC Summit, Project Cure CRC welcomes proposals in the following areas:

- New strategies and technologies in immunotherapy and cellular therapy beyond MSI-H.
- Utilizing ctDNA and other liquid biopsies to improve CRC patient outcomes and early detection.
- Making Clinical Trials more effective for patients using emerging technologies.
- Developing therapies, including vaccines, for prevention of CRC recurrence that are effective for minimal residual disease and adjuvant therapies irrespective of tumor mutational status.
- Leveraging AI using existing large datasets and developing new datasets (molecular and clinical data) to advance precision medicine encompassing diagnostics, development of new treatments, treatment decisions, and longitudinal disease monitoring.

- Targeting cell signaling pathways towards a cure. Leveraging new target and treatment strategies in local and metastatic CRC.
- Developing novel theranostic molecules and its synergy with immunotherapy for localization and treatment of mCRC.
- Expanding the application of local therapies and systemic therapies in Oligometastatic Disease
- Developing infrastructure to support a comprehensive patient data repository to support precision treatment, trial matching, and future research

Special Emphasis Area

The Alliance seeks proposals that accelerate existing preclinical and clinical research that increases therapeutic options, improves adjuvant therapies, delivers novel therapies focused on driver mutations (BRAF, TP53, KRAS, BRCA1, as examples) and investigate strategies to influence the tumor microenvironment (TME) to expand the use of immunotherapy.

Timeline

There are no application deadlines. Applications will be accepted on a rolling basis starting on March 1st, and you should expect to receive a response regarding the proposal within one month of submission. Creative partnerships will be prioritized.

Applicant Eligibility

General eligibility requirements:

- Applications will be accepted from non-profit, for-profit, and academic organizations, and from investigators who hold MD, PhD, or other professional degrees.

If there are any questions about eligibility, please contact dfenstermacher@ccalliance.org before submitting an application.

Types of Awards

Early-Career Investigator Award (Academic Only)

Description: Early-Career Investigator Awards aim to attract early career faculty with original ideas into the field of colorectal cancer research, thereby recruiting and supporting the next generation of CRC research leaders. Awardees will be provided funding to accomplish innovative and original, preclinical, translational, and/or early clinical research projects.

Term: Two years

Amount: Up to \$100,000 per year for two years (up to \$200,000 total)

Eligibility Requirements:

- Applicants must be within the first five years of their first independent, full-time academic faculty appointment.

Senior Investigator Award (Academic Only)

Description: Senior Investigator Awards will fund potentially transformative ideas that will accelerate the translation of new therapies and technologies. Proposals may include investigator-initiated clinical trials and do not require IRB approval at the proposal stage. Collaborations are highly encouraged.

Term: Two years

Amount: Up to \$1,000,000 per year for two years (up to \$2,000,000 total)

Eligibility Requirements:

- Principal Investigator must be a senior researcher, past the initial five years of their first academic faculty appointment.
- Key collaborators are not required to qualify as a senior researcher

Pilot Award (Academic or Industry)

Description: Pilot Awards support investigators who propose potentially transformative ideas that do not have extensive preliminary data but articulate a clear hypothesis and translational goals. Resources for such "high-risk, high-reward" projects are important to establish proof-of-concept, which may then leverage additional funding through more traditional avenues.

Term: Two years

Amount: Up to \$100,000 per year for two years (up to \$200,000 total)

Eligibility Requirements:

- Applicants must have an academic or industrial research appointment and will be considered on a case-by-case basis.

Team Science Award (Academic and/or Industry)

Description: The Team Science Award will support team science, including public-private partnerships, that will drive CRC research to curative science. Research proposals that accelerate new innovations from bench to bedside and address current unmet clinical needs will be prioritized.

Term: Two years

Amount: Up to \$2,000,000 per year for two years (up to \$4,000,000 total)

Eligibility Requirements:

- Principal Investigator of Team Award proposal must be a senior investigator with more than five years of active research in colorectal cancer.
- Research teams may be from a single institution or multiple institutions.
- Research teams may include both academic and industry (biotech/pharma) researchers

Opportunistic Award (Small Startup Companies)

Description: The Opportunistic Award are seed grants to fund novel research from small startup companies that will drive CRC research towards a curative science.

Term: One year

Amount: Up to \$500,000 per year for one year (up to \$500,000 total)

Eligibility Requirements:

- Small startup companies are defined as one or less rounds of fundraising.

Strategic Award (Small Biotechnology or Small Pharmaceutical Companies)

Description: The Strategic Award supports Phase II and III clinical trials initiated by small biotechnology or pharmaceutical companies that will accelerate new therapies, addressing current unmet clinical needs.

Term: One year

Amount: Up to \$5,000,000 per year

Eligibility Requirements:

- Principal Investigator of Strategic Award proposal must be a senior clinical investigator with more than five years of active clinical research
- Proposed research must include a clinical trials protocol that does not require approval by an IRB upon proposal submission, but IRB approval is required prior to any payments

Application Format and Instructions (all awards)

Please apply online via **ProposalCENTRAL** using the requirements therein. **All Applications, Letter of Intent and Full Proposal must be submitted in PDF or Word format using Font: Arial, and Size: 11 or larger.**

Applications: Letter of Intent

Letter of Intent should include the following components:

1. Early-Career Investigator Awards, Senior Investigator Awards, Pilot Awards, Opportunistic Awards:
 - a. 1-page description of research proposal that should include information about the Principal Investigator (name, title, contact info) and institution, a brief overview of the project with specific aims, the impact to CRC research, timeline, and overall cost of the project.
2. Team Awards:
 - a. Up to a 2-page description of research proposal that should include information about the Principal Investigator and key team members (name, title, contact info) and institution/s, brief overview of the project with specific aims, description of team expertise and relevance to specific aims, the impact to CRC research, timeline, and overall cost of the project.
3. Strategic Awards
 - a. Up to a 2-page description of research proposal that should include information about the Principal Investigator and key team members (name, title, contact info) and institution/s, a brief overview of the clinical trial, description of team expertise and roles, the impact to CRC research, timeline, and overall cost of the clinical trial.

All Letters of Intent must be submitted to [ProposalCENTRAL](#). Upon submission, proposals will be reviewed to determine if the proposal has adhered to Project Cure CRC RFP instructions. Proposals submitted that have not adhered to RFP instructions will be rejected and not reviewed further. Proposals that have adhered to RFP instructions will be reviewed by the Project Cure CRC scientific review panel that is comprised of CRC scientists and patient advocates within 1 month after submission. The review panel will have the option to invite the Principal Investigator and research team to submit a Full Proposal, as described below.

Principal Investigators of selected proposals should submit the following for review by the Project Cure CRC scientific review committee (review timeline is dependent on submission of Full Proposal and will be no longer than 2 months).

Please submit the following sections for a complete grant application (please use forms on submission page to complete parts of application and to upload Full Proposal):

1. Institution/Organization (Please use Form 6 “Lead Organization” on submission page)
2. Project Name (Please use Form 1 “Title Page” on submission page)
3. Project Period
4. Total Amount of Funding Requested
5. Term of Funding Request
6. Principal Investigator (Please use Form 4 “Applicant/PI” on submission page)
7. Key Personnel (Please use Form 7 “Key Personnel” on submission page)
8. Project Lay Summary (Briefly describe the overall project and its expected impact on patients. This summary will be used by the CCA in donor materials, newsletters, on the website and in press releases.) (Please use Form 8 “Abstracts” on submission page)
9. Technical Abstract (An executive summary for a scientific audience.) (Please use Form 8 “Abstracts” on submission page)
10. Needs Assessment (Provide a brief description of the study’s rationale.)
11. Summary of Goals & Objectives (State the specific goal(s) of the project and list the objectives and milestones necessary to achieve those goals.)
12. Project Plan (Describe a step-by-step plan, with a timeline, for achieving the stated objectives and milestones.)
13. Evaluation Plan (Explain the metrics you will use to measure the project’s success.)
14. Budget and Line-Item Justification Narrative (Project Cure CRC grants can be used to support direct research costs. Include a budget of direct research expenses by line item, including amounts. Provide an item-by-item narrative of each expense for the entire project. The Alliance allows for shared costs with institutions to increase funding for research proposals and considered on a case-by-case basis. CCA funds may be used to support indirect costs of 5% or less on a case-by-case basis.) (Please use Forms 9 and 10 “Budget Period Detail” and “Budget Summary and Justification” on submission page)
15. **Additional Funding (An award from the CCA may not be the only funding source for the proposed project. Please provide information about 1. Needed additional funding; 2. Sources of other funding, secured or pending; 3. Plans for securing other needed funding; and 4. How will you perform this project if the CCA is unable to provide full funding?)**
16. A completed NIH-formatted biosketch or Biosketch for PI form available on “Upload Attachments” is required for the Principal Investigator (not counted towards page limits)
17. For clinical trials, a timeline and milestones must be included in the application package (not counted towards page limits)

Page Limits

The following page limits may not be exceeded to uploaded documents:

- Early-Career Investigator Award – 5 pages total (references/citations not to exceed ½ page)
- Senior Investigator Award – 10 pages total (references/citations not to exceed 1 page)
- Pilot Award – 5 pages total (references/citations not to exceed ½ page)
- Team Award – 15 pages total (references/citations not to exceed 1 page)

- Opportunistic Award – 5 pages total (references/citations not to exceed ½ page)
- Strategic Award – 20 pages total (no page limit for references/citations)

Review Mechanism

All proposals undergo a rigorous review process by members of a distinguished Scientific Review Panel comprising experts in diverse fields. The review panel operates under clear objective guidelines. All proposals will be scored according to Alliance review and selection criteria. All awards are contingent upon ratification by the Alliance Board of Directors.

Weighting of each criterion in the review

	Overall Scientific Merit & Clinical Importance	Rigor and Feasibility	Investigator and Environment	Budget is Reasonable for the Proposed Research Project
Grant Awards	1/4 of score	1/4 of score	1/4 of score	1/4 of score

Award Administration

Award Letter

Upon acceptance of the award, the PI and his/her employing Institution will be required to sign an Award Letter indicating acceptance of the Alliance’s Award Terms and Conditions within 30 days, which can be found on the Alliance website <https://colorectalcaner.org/research>. The Alliance Terms and Conditions are non-negotiable. The Alliance must be notified in advance and approve any significant changes in research objectives, key personnel (including transfer to another employee), or budget.

Approvals

The Alliance requires certification through ProposalCENTRAL of compliance with Human Subjects and Animal Care Assurance as applicable. In cases where ethical/regulatory approval is required to perform the work, such approvals will be required before initial payments are made. This includes local IRB approvals of clinical trials supported by Alliance funding. For clinical trials, a timeline and milestones must be included in the application package. Failure to meet these milestones within a reasonable time frame may result in termination of the award.

Multi-Institutional Projects

For projects including key personnel at other institutions, the PI must verify in advance that funds can be transferred from their institution to the collaborating institution. This requirement can be easily met by attaching a letter from the PI’s sponsored programs office stating a commitment to comply with this requirement (letter does not count towards page limits). Sub-award agreements between collaborating

institutions must be executed within 60 days of the Alliance's execution of the award agreement with the applicant institution.

Funding

For all proposals, the level and duration of funding may be adjusted by the Alliance as appropriate for the scope of the proposal and the funds available. Partial funding will also be considered to obtain proof-of-principle data. **Awards may support indirect costs, overhead costs, or other similar institutional charges up to 5% and will be decided on a case-by-case basis**; fringe benefits for personnel salaries are allowable. **Full-term funding will be contingent upon review of periodic (at least every 6 months) progress reports, submission of the final progress report and other oversight activities conducted by the Alliance** in support of innovative ideas with transformative potential. Multi-year support is not automatic for any Alliance award and is conditioned on submission of complete and accurate progress reports, financial reports, and demonstrated progress on the funded proposal.

Alliance Events

PIs may be invited to attend an annual event for the scientific community. PIs are expected to attend and may be asked to present research findings.

Additional Information and Contacts

Email questions about this RFP, eligibility, or other issues about the Alliance or its awards to David Fenstermacher, Senior Director of Research and Medical Affairs, dfenstermacher@ccalliance.org.

Technical questions about the ProposalCENTRAL submission system should be directed to their customer support at 800-875-2562 (Toll-free U.S. and Canada), +1 703-964-5840 (Direct Dial International) or by email at pcsupport@altum.com. Support is available from 8:30am-5pm Eastern Time, Monday through Friday