# Cannonball Kids' cancer Foundation
# 2023 Research Grants


**LOI Deadline:** June 1, 2023
**Application Deadline:** August 15, 2023
**Funding Available:** January 1, 2024

## Questions

Should you have any questions throughout the application or award process, please contact Matt Kopkin, Grants Administrator, at grants@cannonballkidscancer.org.

To learn more about us, visit our web site at cannonballkidscancer.org.

# Contents

# Overview

## Mission

Cannonball Kids' cancer (CKc) Foundation's mission is to fund innovative and accessible research for children fighting cancer to provide better treatments and quality of life, and to educate for change.

## About CKc

Cannonball Kids' cancer Foundation (CKc) was founded in June 2014 by Michael and Melissa Wiggins, parents of Cannon Wiggins, who was diagnosed with Stage IV high-risk neuroblastoma when he was just 20 months old. During Cannon's treatment, Michael and Melissa learned very little time, effort and funding is devoted to finding cures for children's cancer compared to adult cancers, and as a result, children are unnecessarily and unjustly lost. CKc aims to stop the tragic reality of children suffering and dying because of the lack of research in the world of children's cancer treatments. CKc believes "Research is the Key" that will unlock a cure, and the foundation has now awarded more than $3.3 million in research grants, providing an option for over 680 children who were told they had "no more options". The majority of those studies are first-of-their-kind and are dispersed throughout 32 U.S. states, plus Washington, DC, Scotland and Switzerland.

## 2023 Funding Priorities

For the 2023 Grants Cycle, CKc will prioritize funding clinical trials, research that is nearing translation to a clinical trial, and young investigator grants.
Grants funded by CKc must be innovative and provide better quality of life or symptom relief than current treatments.
Whenever possible, CKc will prioritize funding **research**:

- with a focus on cancers that are under-funded or under-researched,
- with a focus on patient populations who are traditionally underserved.

Whenever possible, CKc will prioritize funding **researchers** of diverse backgrounds.

For CKc, "innovation" means the invention or application of novel methods or treatments, specifically treatments that have fewer side-effects than standard care, increase a child's quality of life, and/or create an option for care where there otherwise were few or none (either on primary diagnosis, relapse, or for recalcitrant cancers).

## Types of Awards

CKc offers three types of research grants: Clinical Trial, Young Investigator and Program. The maximum award amounts and durations for the 2023 cycle are as follows:

- Clinical Trial: $200,000 over 3 years
- Young Investigator: $100,000 over 3 years
- Program: $65,000 over 2 years

## Application Schedule

A Letter of Intent (LOI) must be submitted and approved by the SAB to access the application. LOI's and Applications are to be submitted online via Proposal Central.

| | |
|---|---|
| June 1, 2023 | LOI's Due |
| August 15, 2023 | Applications Due |
| December 15, 2023 | Award Notifications |
| January 1, 2024 | Funding Begins |

# Research Grants

## Clinical Trial Grant

**Award Amount & Duration**

- Up to $200,000 over 3 years

**Goals**

The goal of CKc's Clinical Trial Grant is to fund trials that:

- Are innovative.
- Focus on cancers that are either underfunded or under-researched.
- Provide better quality of life or symptom relief than current treatments.

**Eligibility Criteria**

- The Principal Investigator (PI) for the proposed clinical study must hold an academic appointment at the Assistant Professor level or higher, and must be affiliated with a clinical department that supports the proposed research
- The PI must have a medical doctoral degree: MD, DO, MD/PhD, or equivalent
- The PI must demonstrate the potential to successfully conduct and complete the proposed clinical study
- The Institution must have the infrastructure and resources necessary to support the proposed clinical research
- Preclinical studies must be complete
- If an FDA Investigational New Drug (IND) application is necessary for the proposed clinical study, the IND application should already have passed FDA initial review and be active;
- Institutional Review Board (IRB) approval may be pending at the time of application, but the proposed clinical study must have current IRB approval before any funds are expended;
- If the PI has recruited additional patient enrollment sites, local IRB approval must be obtained for each site.

**Proposal Evaluation Criteria**

- Innovation and potential impact for children with cancer
- Scientific validity, quality, and significance
- Medical applicability and feasibility, including plan to complete study accrual
- Investigator qualifications
- Institutional infrastructure and support
- Preference will be given to highly innovative and potentially impactful proposals from institutions that have the necessary infrastructure and scientific environment.

## Young Investigator Grant

**Award Amount & Duration**

- Up to $100,000 over 3 years

**Goals**

The goal of CKc's Young Investigator Grant is to fund research that:

- Is within 2-3 years to translation to a clinical trial or is already associated with a clinical trial.
- Is innovative.
- Focus on cancers that are either underfunded or under-researched.
- Provide better quality of life or symptom relief than current treatments.

**Eligibility Criteria**

- The Young Investigator Applicant for the proposed research must:

    - have a medical doctoral degree: MD, DO, MD/PhD, or equivalent;
    - be within 5 years of completing a training fellowship in Pediatric Hematology/Oncology or a closely related discipline that has direct clinical contact with pediatric cancer patients;
    - hold an academic appointment at the instructor level or higher; and be affiliated with a clinical department capable of supporting the proposed research
- The Applicant must demonstrate the potential to successfully conduct and
- complete the proposed research
- The Institution must have the infrastructure and resources necessary to support the proposed research
- If necessary, approvals by Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) may be pending at the time of application, but the proposed research must have current approval before any funds are expended.

**Proposal Evaluation Criteria**

- Evidence of Mentor's commitment to the Applicant's career development plan
- Innovation and potential impact for children with cancer
- Scientific validity, quality, and significance
- Translational potential
- Applicant's qualifications
- Institutional infrastructure and support
- Preference will be given to highly innovative and potentially impactful proposals from institutions that have the necessary infrastructure and scientific environment.

## Program Grant

**Award Amount & Duration**

- Up to $65,000 over 2 years

**Goals**

The goal of CKc's Program Grant is to fund programs that expand and enhance a clinical trial's capability to:

- Provide clinical education opportunities
- Provide services/infrastructure for oncology patients in clinical trials
- Expand patient population to ensure diverse and equitable access (please see our Health Equity Statement above for more detail)
- NOTE: While clinical trials associated with Program Grants are not required to be funded by CKc, they must meet the criteria for fundable clinical trial research:
    - Innovation
    - Focus on cancers that are either underfunded or under-researched
    - Provide better quality of life or symptom relief than current treatments

**Eligibility Criteria**

- The Principal Investigator (PI) for the proposed clinical study must hold an academic appointment at the Assistant Professor level or higher, and must be affiliated with a clinical department capable of translating the proposed research
- The PI must have a medical doctoral degree: MD, DO, MD/PhD, or equivalent
- The PI must demonstrate the potential to successfully conduct and complete the proposed research
- The Institution must have the infrastructure and resources necessary to support the proposed research

- If necessary, approvals by Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) may be pending at the time of application, but the proposed research must have current approval before any funds are expended.

**Proposal Evaluation Criteria**

- Innovation and potential impact for children with cancer
- Scientific validity, quality, and significance
- Translational potential
- Investigator qualifications
- Institutional infrastructure and support
- Preference will be given to highly innovative and potentially impactful proposals from institutions that have the necessary infrastructure and scientific environment.

# Process, Reporting, and Applications

## Review Process

CKc accepts applications annually, according to published deadlines. CKc's Scientific Advisory Board (SAB), a panel of scientific and medical experts, will review applications according to the evaluation criteria below and score applications using the NIH scoring system (1 = exceptional; 9 = poor). The application scores, commentary, and funding recommendations will be forwarded to the CKc Board for review and final funding decisions. CKc does not typically provide reviewer critiques to applicants but will consider this upon request.

## Post-Award Reporting

Annual progress reports are required through the completion of the funded project to include updates on overall progress of the study, detailed accounting of expenditures, continued justification of the need for any remaining funds, and listing of work product derived from the grant support (including oral presentation, poster presentation, and journal manuscripts and publications). A full report containing the above items for all budget periods is required at the completion of the grant project.

## Budget Details

Budget proposals, up to the award limits noted above will be considered, with the expectation that funds will be expended over the duration noted for each grant program. Funds are disbursed in equal installments, with Year 2 and 3 (if applicable) funding contingent upon adequate progress demonstrated in the annual report to CKc Foundation. Pro-rated per-encounter costs for investigator fees, nurse practitioner support, data managers, clinical coordinators, etc. are allowed.

Grant funding may vary depending upon the proposed budget, and some studies may be partially funded with agreement of the Principal Investigator. All grant awards will be disbursed to the Principal Investigator's institution to administer for costs related only to the studies proposed in the awarded application.

Multi-site studies will be considered, but funds will be disbursed only to the primary performance site, which is expected to be the Principal Investigator's institution. Payments to secondary sites should be made through subcontract arrangements.

These are one-time awards, and renewals are not guaranteed. Continued funding after the initial period must be applied for as a new grant with progress to date included in the preliminary data. Funding is contingent upon availability, and some studies may be partially funded, with prior agreement of the Principal Investigator and Institution.

**Restrictions**

CKc Foundation Clinical Research Grant funds may not be used for:

- Trainee support;
- Travel;
- Indirect costs or institutional overhead;
- Direct support of consortium costs or cooperative group infrastructure;
- Research that involves the use of human embryonic or fetal tissue.

**Co-Funding of Proposals**

The CKc Foundation is open to projects that require multiple funding sources to complete. However, the budget justification must make it clear that no budgetary overlap exists between the CKc funds and other funding sources. The grant/contract budgets for other funding sources may be required as documentation, to be provided to CKc in the post-award period.

## Required Acknowledgements

The PI must acknowledge the support of Cannonball Kids' cancer Foundation when presenting data from any CKc-funded project, including oral presentation, poster presentation, and journal manuscripts and publications.

## Human Subject Research

All human subject research and human tissue research must comply with current federal regulations. Prior to disbursement of funds, the applicant must submit the Institution's Human Subjects Assurance Number and the Institutional Review Board's approval letter.

## Application Attachment Requirements

- All documents uploaded to the application must be in pdf format and follow National Institutes of Health (NIH) format guidelines for font and margins:
  Arial, Georgia, Helvetica, Linotype, or Palatino fonts; minimum font size 11 point; minimum one-half inch margins.
- All biosketches should follow the new NIH format with a 5-page maximum length (General format, Version D), as detailed in PHS form 398 instructions (https://grants.nih.gov/grants/forms/biosketch.htm).

## Components of the LOI

1) Title & Request Amount
    a. Years to translation
    b. Relation to existing clinical trial
2) Applicant/PI
3) Institution
4) Abstracts
    a. Lay Abstract (1000 characters)
    b. Scientific Abstract (1000 characters)
5) Required Attachments
    a. Biosketch
        i. Principal Investigator
    b. Proposal Concept (1 page)
        i. Background
        ii. Hypothesis
        iii. Aims
        iv. Research Plan Overview
        v. Feasibility
        vi. Impact

## Components of the Application

1) Title
2) Applicant/PI
3) Institution & Contacts
4) Key Personnel
5) Abstracts & Research Type

a. Lay Abstract (3000 characters)
    i. *Be advised: The Layman's Summary may be published electronically or in other CKc Foundation marketing materials. Please do not include in the Layman's Summary any proprietary information or other information that you intend to keep out of the public domain.*
b. Scientific Abstract (3000 characters)
    i. Include descriptions of impact, innovation, significance, study rationale, study objectives, study design

6) Budget
7) Budget Summary & Justification
8) Organization Assurances
    a. Human Subjects
    b. Vertebrate Animals
    c. IND Approval
    d. Stem Cells
9) Required Attachments
    a. Biosketches
        i. Principal Investigator
        ii. Each co-investigator, collaborator, and consultant
            1. *Note:* Multiple biosketches can be bundled into one pdf document and uploaded together, or each can be uploaded separately as individual pdfs.
        iii. Mentor **(Young Investigator ONLY)**
    b. Research Plan (8 pages max.) **NOTE: include a reference page for any cited figures.**
        i. Background: Include published data or original preliminary/preclinical data and the rationale for the study. For competitive renewal applications, include clear evidence of the progress to date with the preliminary data.
        ii. Experimental Design:
            1. **For Clinical Trial:** Describe or detail the target study population, treatment arms and detailed treatment plan, number of patients needed to enroll on each arm, duration of therapy, study objectives and how they will be assessed, correlative biological studies and their significance, statistical analysis plan including power analysis if warranted.
            1. **For Young Investigator or Program:** Describe or detail the specific aims of the study, specific hypotheses to be tested, mechanistic experiments designed to test relevant hypotheses, relevant specialized methods, expected results, planned analyses and statistical methods.
        iii. Institutional Infrastructure and Support (maximum 1 page of the 8-page Research Plan):
            1. **For Clinical Trial:** Briefly describe the medical and scientific environment, track record and infrastructure for pediatric clinical trials (include information regarding early-phase trials), detailed accrual plan for the clinical trial, and plans for additional sites and collaborators.
            2. **For Young Investigator or Program:** Describe or detail the specific aims of the study, specific hypotheses to be tested, mechanistic experiments designed to test relevant hypotheses,

relevant specialized methods, expected results, planned analyses and statistical methods.

iv. Future Directions (maximum one-half page). Include in this section a statement of the goals, metrics, and milestones for future scientific investigation.

v. Career Development Plan (maximum 1 page): Include in this section a statement of the goals, metrics, and milestones for successful career development across a 3-year timeline, as well as specific contributions from the applicant's Mentor and other key personnel. **(Young Investigator ONLY)**

c. Letters of Support
   i. Institutional Support from Department Chair, Division Director, or Center/Institute Director
   ii. From each co-investigator, collaborator, and consultant
      1. *Note:* Again, these can be bundled into one pdf or uploaded separately.

d. Required Approvals
   i. Current full-text version of the Clinical Trial Protocol **(Clinical Trial and Program ONLY)**
   ii. IRB approval letter
   iii. IACUC approval letter if warranted
   iv. IND approval if warranted

10) Signature Page