



PROGRAM OVERVIEW

I. PURPOSE

The purpose of the **Cancer and Blood Disorders Center (CBDC) Research Pilot Funds Program** is to cultivate outstanding new research, stimulate preliminary data in novel research directions, and ultimately launch new, nationally-funded clinical research programs within Seattle Children's Research Institute.

CBDC Research Pilot Funds are intended for junior faculty (Instructor, Assistant Professor) with limited funding, although more senior faculty with new research interests can also apply. Proposals addressing clinical and/or translational research involving childhood cancer and blood disorders will be considered. Proposals must involve clinical trials or outcomes research. Proposals that reflect collaborations within the Hematology/Oncology Division or across the Cancer Consortium are encouraged. In addition, use of shared resources, including research nurses and clinical research associates, among multiple related clinical projects are encouraged. Proposed laboratory components must be integral to the conduct of a clinical trial or outcomes research.

II. PEDIATRIC PILOT FUNDING DETAILS

A. Funding

1. Amount awarded will be a maximum of \$50,000 yearly for up to two years. Payment of indirect costs is not allowed for this award.
2. Projects will be no more than two years in length.
3. The CBDC Pilot Funds are intended to support the direct costs of research at Seattle Children's. CBDC Pilot Funds will not fund work occurring at an external institution and subaward contracts are not allowed.
4. The number of projects to be funded annually will depend upon the quality of the applications and the availability of funds.

B. General Principal Investigator (PI) Eligibility

1. Applicants must be Seattle Children's Hospital or Fred Hutchinson Cancer Research Center-based investigators.
2. The applicant must have a faculty appointment. Fellows or other trainees may be a co-investigator; however, a faculty mentor must serve as the PI.

C. Allowable Costs

1. Research nurse, clinical research associate, pharmacist, clinical dietician, psychologist, or other research personnel salary; investigator salary is not allowed,
2. Supplies and research equipment,
3. Specimen collection or processing, correlative laboratory testing,
4. Per patient reimbursement to collaborating sites, and

5. Other expenses, such as fees for core services including biostatistics

III. KEY DATES 2018 - 2019

RFA Released	November 15, 2018
Deadline to Email Intent to Submit	December 28, 2018
Request for Budget Overview	January 18, 2019
Application Deadline	January 25, 2019 by 5:00 PM PST
Award Announcement	March 1, 2019
Funding Begins	June 1, 2019

IV. REVIEW PROCESS

1. CBDC Research Pilot Funds applications will be reviewed by members of the CBDC Research Pilot Funds Review Committee as well as additional ad hoc reviewers as required for expertise. All reviewers are experienced investigators.
2. At least two reviewers will be assigned to an application. Top scoring applications will be discussed in detail by the Committee. Any application will be discussed in detail at the request of any Committee member.
3. All applicants will receive a summary of reviews conducted on their applications. Applicants who are not funded are encouraged to set up an appointment to meet with a reviewer of their application.
4. Final funding decisions will be made by the leadership of the Center for Clinical and Translational Research (CCTR).

V. REVIEW CRITERIA

A. Significance and Feasibility of the Proposed Research for Clinical Cancer and Blood Disorders Research (40%)

1. Is the proposed research readily identifiable as addressing important issues in Pediatric Cancer or Blood Disorders?
2. If the aims of the project are achieved, will scientific knowledge and/or clinical practice be advanced?
3. Will the project result in later phase trials or expanded to larger patient cohort?
4. Will the preliminary data obtained from the proposed service be likely to contribute to a grant application (from NIH or other external sources)?
5. Is the proposed research feasible, including confirmation of the availability of an investigational agent, intervention, etc.?

B. Methods/Approach (20%)

1. Are the conceptual framework and specific aims, study design, methodology, data analysis and interpretation, feasibility, etc. of high scientific quality?
2. Is the technique or service the most appropriate means to address the question?
3. Will the method/approach yield meaningful results in the timeframe (two years) and budget available? For clinical trials, the two-year timeframe does not assume completion, but initiation and substantial recruitment.

C. Innovation (20%)

1. How will this application provide results that are novel and likely to open new avenues of investigation within the field?
2. Is the proposed approach advantageous over other approaches and/or provide a unique advantage?
3. Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

D. PI/Investigators Qualifications & Environment (20%)

1. Do the investigators have the appropriate expertise to conduct the study?
2. Is the project a new emphasis or new collaborative team?
3. Is there developmental potential for the PI in the future?
4. Are the resources available to make the project successful?

VI. AWARD TERMS & CONDITIONS

1. Seattle Children's CBDC Research Pilot Funds Program will grant a cost reimbursable award of up to \$50,000 in direct costs. Awardees will receive an account for project-related expenses.
2. CBDC Research Pilot Funds Program awards are non-transferable. They are intended to cultivate and support the scholarship and research of the recipient.
3. CBDC Research Pilot Funds should not be used to hire new staff. If research coordinator support is required, awardees are encouraged to use the Hematology/Oncology clinical research associates or Research Coordinator Core (RCC).
4. If biostatistical support is required, awardees are encouraged to use the Children's Core for Biomedical Statistics (CCBS), which is part of CCTR.
5. It is expected that your research will be conducted within the timeline and as outlined in your submitted proposal. Year 2 funding is contingent upon review and approval of Year 1 progress. Year 1 progress reports are due to the Program Coordinator at least 30 days prior to the Year 2 project start date. Your report will be sent to the Committee Chair for review and approval. Funds not expended by the end of the project date will be returned to the division. **Any re-budgeting greater than 20% or changes to your original proposal requires review and approval of the CBDC Pilot Chair.** Requests for re-budgeting and proposal changes can be sent to Katherine.Painter@seattlechildrens.org to be forwarded to the CBDC Chair for consideration.

6. No-cost extensions require the approval of the CBDC Research Pilot Funds Review Committee. All requests for a no-cost extension should be submitted to the Program Coordinator no less than 30 days prior to the project end date. Only one no-cost extension will be granted and the funds must be expended within one year of the no-cost extension approval.
7. Payment of indirect costs is not allowed for this award.
8. CBDC Research Pilot Funds are intended to support the direct costs of research at Seattle Children's. CBDC Research Pilot Funds will not fund work occurring at an external institution and subaward contracts are not allowed.

The Recipient must ensure that, before the research commences and during the full award period, all the necessary national and local ethical, legal, and regulatory requirements to conduct the research are met; all necessary licenses and approvals must be obtained.

9. International projects involving recruitment of participants, prospective collection of data, or transfer of funds abroad are not allowed. Studies using existing data collected abroad are allowed if there are no transfers of funds abroad. In the unlikely event that Seattle Children's does not have the expertise or resources available, contact the IBO-CTCR Director, Jen Benn, to discuss options at the time of application.
10. Travel and travel costs must abide by Seattle Children's travel and reimbursement policies.
11. Where the Terms and Conditions of the Award have not been observed, the Division of Hematology/Oncology reserves the right to withdraw the remainder of the award.
12. Any publication or presentation of the results of research funded by this award should acknowledge support from *Seattle Children's Cancer and Blood Disorders Research Pilot Program*.



APPLICATION INSTRUCTIONS

I. COMPLETE THE APPLICATION

- A. Complete all required application materials. For a detailed list and specific instructions for each section, see the CBDC Research Pilot Funds Checklist on the next page.
- B. Format Specifications
 - 1. Font: Arial 11
 - 2. Page margins: Use at least one-half inch margins (top, bottom, left, and right) for all pages, including continuation pages
 - 3. Application spacing: Single-spaced
 - 4. Do not exceed page limitations noted for each section on the application
- C. Combine all completed documents. Application materials may be submitted in the following formats: *.doc, *.docx, *.xls, *.xlsx, *.pdf

II. BEFORE APPLICATION SUBMISSION

- A. Contact the Program Coordinator, Katherine Painter, **no later than 30 business days** prior to submission date. The Program Coordinator will assist with the development of your budget and guide you through the internal sign-off process for grant submission. Include the Clinical Research Budget Analyst in your email for review of clinical billable events.
- B. CCTR has several core infrastructure services that may be of use to funded pilot projects (e.g. Clinical Research Center, Biostatistical Services, Research Staff Support Core, Research Lab Services and Investigational Drug Services). The costs for these services should be included in the project budget. Selected core services are offered to Pilot Fund recipients at a subsidized rate. The Clinical Research Budget Analyst can help you in determining the cost of these services.

III. APPLICATION SUBMISSION

- A. Email completed application materials to Katherine.Painter@seattlechildrens.org
- B. Submissions must be received **no later than 5:00 PM PST on January 25, 2019**.
- C. Submissions will be reviewed and applicants notified of award status within two months of the application deadline.
- D. Unsuccessful applicants may resubmit their applications for the next round up to a total of three times, unless the reviewers determine that the application does not meet the intent of the program. If the application is a resubmission of a previously unfunded CBDC Research Pilot Funds application, an additional page(s) should be added to the cover page (limit – three pages) describing how the application has been modified in response to the previous review.



CBDC RESEARCH PILOT FUNDS APPLICATION CHECKLIST

- Cover page** (use form provided)
 - Current PI information
 - Department/Division information
 - Title of proposed project
 - Abstract (limit 15 lines)
 - Applicant's signature (electronic signature is acceptable)
 - Department/Division Chair signature (electronic signature is acceptable)
 - Reviewers
Provide the names and contact information for at least three possible reviewers who would be qualified to provide a review of your application.
- Budget and Budget Justification** (limit two pages, use form provided)

Provide a detailed budget justification that includes an explanation for why support is needed for each expenditure.
- Biosketch** (limit five pages for each)

Use NIH Biosketch form for PI and each Co-PI
- Aims, Significance, and Methods** (limit 5 pages)

Include the following sections:

 - Question to be studied
 - Specific aims
 - Background and significance
 - Research design and methods (include the approach to statistical analyses, power estimates, etc.)
- Future Plan** (limit one page)

Explain how pilot funding will be used for conducting research activities designed to prepare and support full-scale clinical or translational research. Also include how these funds will lead to future funding.
- Timetable** (limit one page)

Timetable for development of work
- References** (limit one page)
- Appendix** (optional)

Include additional materials, instruments, etc.; avoid lengthy appendices

FREQUENTLY ASKED QUESTIONS

1. Who can answer my questions?

For inquiries regarding the application, budget review, and administrative questions:	Katherine Painter Program Coordinator	Katherine.painter@seattlechildrens.org 206-884-4872
For review of clinical billable events in your budget:	Michelle Palmer Clinical Research Budget Analyst	Michelle.palmer@seattlechildrens.org 206-884-5617
For questions about available resources or expertise at Seattle Children's:	Jen Benn Director, IBO-CTCR	Jennifer.benn@seattlechildrens.org 206-884-1255

2. Are subcontracts/subawards from other institutions allowed?

No, subcontracts are not allowed. CBDC Pilot Funds are intended to support the direct costs of research. Indirect costs are not allowed. CBDC Pilot Funds should not be used to fund work occurring at an external institution and subaward contracts will not be approved. In some cases, Seattle Children's may not have the necessary expertise or resources required to provide the required service to complete a project. In this case, please contact the IBO-CTCR Director, Jen Benn, prior to submission for discussion.

3. Am I allowed to travel to present at a conference or meeting?

Yes, if your travel is related to presenting and promoting your CBDC Pilot project, then it is an allowable budget item. Travel must abide to Seattle Children's travel and reimbursement policies. The award may not be used to pay for society membership dues. You will be required to attach your abstract that you will be presenting to the travel authorization.

4. Are international projects funded?

International projects involving recruitment of participants, prospective collection of data, or transfer of funds abroad will not be funded. Studies using existing data collected abroad are allowed if there are no transfers of funds abroad.