Children's Clinical Research Advisory Committee (CCRAC)
Children's Health[SM]

Senior Investigator Bridge Award Guidelines
(seeking bridge or gap funding)

Introduction

The advancement of medical knowledge through clinical research is a core mission of Children's Medical Center Dallas. In support of this mission, Children's Health will support research designed to improve the understanding, prevention, diagnosis, or treatment of childhood diseases. In particular, Children's Health seeks to provide ***one year*** of funding for innovative research ideas with high potential for sustainable extramural support in the future.

Funding will be awarded following a rigorous Peer Review process conducted by the Children's Clinical Research Advisory Committee (CCRAC). This process is intended to identify the most meritorious and innovative projects that support our aim of improving child health across a wide range of disciplines. Children's Health encourages applications from all areas of scientific and clinical inquiry.

Eligibility

Applicants applying under the **Senior Investigator Bridge Award** category should be an Assistant Professor (beyond 5 years of the initial faculty appointment), Associate Professor, or Professor. The applicant should be seeking funding for a worthy research project but suffer from a gap in funding. The quality and importance of the project should support the likelihood that the gap will be of short duration.

Applicants must be members in good standing of the Children's Health medical, dental, nursing, or other health professional staff. Individuals who are being recruited from other institutions are also eligible provided that at the time the funding becomes effective they are members of the faculty of UT Southwestern or the professional staff at Children's Health.

Amount: The awards for gap funding are designed primarily as *bridge money* for clinical or translational research studies. These awards are **limited to one year** of bridge funding at a maximum level of $75,000.

> To be eligible for the award, the applicant must have submitted a grant application to the NIH or other "high profile" granting agency (e.g., American Diabetes Association, American Heart Association, American Cancer Society, March of Dimes, Gates Foundation) that was favorably reviewed but is NOT expected to be funded. For NIH grants applications, those grants that were triaged (i.e., did not make the top 50th percentile) will not be eligible. Grant applications to these agencies must have been submitted within the previous 18 months from the CCRAC announcement for request for applications.
>
> Grants that have been resubmitted and are under review are eligible. Applicants who have submitted a renewal application that meets the above criteria can submit

for funding even if the current funding has not yet expired, in the event there may be a gap in funding. In this case, the CCRAC funding start date may be delayed coinciding with the expiration date of the currently funded grant. In the event that the applicant successfully secures extramural funding for the proposed work during the CCRAC funding period, the duration and amount of the CCRAC award may be reduced such that the CCRAC award terminates upon the start date of the extramural funding.

Grants will be reviewed by the Research Advisory Committee (RAC). The review process will be based largely on the feedback of the external review committee, specifically regarding the scientific merit of the proposed project. Since the grant will have already been reviewed by qualified reviewers, the role of the RAC will be to ensure that the reviews were "favorable" and that the grant did not include "fatal flaws". The grant application must also address the comments of the external review committee or otherwise include a rebuttal to the committee's feedback. Grant applications will be ranked by the RAC. The RAC may or may not agree with the external reviews and may or may not consider the grant for bridge funding.

Senior Investigator applicants who have received bridge funding in the last 3 years will not be eligible. Each Senior Investigator Bridge Award candidate is allowed to submit one grant application per cycle. Combined grant applications will not be accepted.

Criteria for Funding

The main criteria for funding will be scientific quality of the project and its sustainability through future extramural funding. This will be specifically assessed by review of the critiques provided by the review committee of the external grant application. The RAC will also take into consideration the applicant's track record and ability to acquire independent extramural support.

The RAC will consider each study proposal and its budget in comparison to the others on a cost benefit basis, weighing in particular the scientific merit, potential impact, and likelihood for future funding against the overall cost of the project. While funding requests at all levels will be considered, preference will be given to those projects likely to produce the greatest benefit at the lowest relative cost.

Human Subjects, Animals, and Recombinant DNA

If the proposed research program involves humans as research subjects, the use of warm-blooded animals or experiments involving recombinant DNA techniques, the investigators will be expected to comply with the current guidelines of the Department of Health and Human Services concerning such matters. Evidence of compliance, as well as an approved protocol from the appropriate institutional review board of the sponsoring institution (usually UT Southwestern), will be required before funding. *Note*: pending protocol approval is acceptable, but IRB approval must be obtained within 90 days of award notification or the award will be forfeited.

Organization and Submission of Applications

Duration of Funding - The project time frame will be one year.

Deadlines and Review Schedule - Applications will be accepted 4 times per year on the following schedule:

January 1st	April 1st	July 1st	October 1st

Note: For applicants submitting a renewal application, the funding start date may be delayed coinciding with the expiration date of the currently funded grant.

Address for Submission

The letter of intent and complete application should be submitted electronically in PDF format to CCRAC@childrens.com and Jeffrey.kahn@utsouthwestern.edu

The deadline for all materials is 5 PM on the dates listed above. Applications received after this deadline will not be considered. Note: under extraordinary circumstances the deadline may be extended, but only with prior approval from the Medical Director for Research.

Organization of submission materials

LETTERS OF INTENT AND APPLICATIONS SHOULD BE SUBMITTED IN PDF FORMAT
FILE NAMES SHOULD BE: last name_first name_Sr investigator_CCRAC_2026

Organization of the Letter of Intent
The letter of intent must contain the following:

1. Name of Principal Investigator
2. Title of grant submitted to the external agency
3. Abstract of original grant
4. Name of external funding agency
5. Date of original submission external funding agency
6. Assigned grant number (required for all NIH grants)
7. External funding agency scores (if available). If an NIH grant, provide impact score and percentile (if known)
8. Prior CCRAC funding dates (if applicable)

Organization of the Application
Formatting shall be single-spaced with 12-point Arial (or other equivalent Sans-serif font) and ½ inch margins.

Completed Application Cover Sheet (see attachment A)

One page: ***Cover letter and Prior Funding***
Please include the appropriate Cover Letter which corresponds to the specific grant award Senior Bridge Investigator Research Award). Provide information on prior CCRAC and CTSA funding, if applicable.

Part 1: ***Project Title and Credits***
Principal Investigator, Co-investigators, Department(s), Address and contact information, e- mail, phone and fax; IRB or IACUC status of proposed study. A pending status is acceptable, but the award will not be granted until approval is obtained.

Note:
IRB approval must be obtained within ninety days of award notification or the award will be forfeited.

Part 2: ***Abstract of initial grant submission***.

Part 3: ***Lay abstract or project narrative of initial grant submission***
(written in language understandable by an educated, but non-medical reader).

Part 4: ***Budget and Budget justification***
Applicants should submit the original grant's budget as well as a budget for the one year, $75,000 bridge award.

In preparing the required budget, the investigators should contact Research Finance at research.finance@childrens.com **at least** 10 business **days** prior to full written submission of the application to make sure that all estimated costs at Children's Health are correctly priced. Children's Health Research Administration has both Research Coordinators and Biostatisticians that are available for help in conducting research studies, though there is a charge for these services.

Inaccurately priced or unpriced budgets may negatively impact your review as costs are part of review considerations. If an outside vendor is being used for laboratory tests, this should be explicit within the budget.

PLEASE NOTE: There is ***no*** need to budget for indirect costs. The University of Texas Southwestern Medical Center (UTSW) considers CCRAC grants from Children's Health as "gifts"; therefore, all budget items should be for **direct costs only**. As such, this application and budget are **not routed through UTSW SPA**.

Part 5 ***NIH-style bio sketch of all investigators -*** Bio sketch of collaborators, (if applicable).

Part 6: ***Research Plan (including bibliography) –*** Applicants should submit the original grant that was reviewed by the external review committee and a brief (2-page max) proposal explaining how the bridge money will aid forward progress during the one year of funding.

Part 7: ***Reviews from the external review committee*** (i.e., summary statements or equivalent)

Part 8: ***Investigators response to the critiques of the external review committee*** – Limited to one page unless otherwise specified by the external granting agency.

Part 9: ***Letters of Support***
Please submit all letters of support that were included in the original grant application.

Reporting

Investigators receiving awards will be required to submit a progress report at completion of the 12-month award period. Continuation of the funding is contingent upon satisfactory completion of the report. If extensions are requested and approved, the reporting requirements as previously described still apply. The project template can be downloaded from the Research Administration web page on ChildNet (you must be logged into the Children's network to access the site).

Annual updates on publications and extramural funding resulting from a CCRAC award is required for ten years from the end date of the award after the grant period. Annual reports will be due by January 31 of each year and updates for publications should be made through My Bio Link from PubMed at http://www.ncbi.nlm.nih.gov/books/NBK53595/.

End of Year One report: The PI must submit a maximum of three pages containing a description of the progress made since the beginning of the funding. The investigators should indicate how this progress relates to the specific aims of the proposal, listing any unexpected problems that may prevent completion of the aims in the period designated by the original proposal, and a f in an c i a l statement of expend it u r e s. Plans, and an updated budget, for the second year of funding should be included. **Failure to provide this completed report will disqualify the PI from future awards.**

Final report: The PI must submit a maximum of three pages outlining the following: 1) the findings of the study as they relate to the original aims, 2) publications (submitted or in draft), 3) grant applications emanating from the work (copies of the manuscripts or applications should be included), and 4) A financial statement of expenditures Note: if there are remaining CCRAC funds available an applicant must submit a request to the Medical Director for Research for a no-cost extension, otherwise remaining funds must be transferred back to Children's Health, within thirty days.

Send reports via email and reprints as PDF documents to: jeffrey.kahn@utsouthwestern.edu and copy to CCRAC@childrens.com. Reports are to be submitted in a timely manner. If this is not possible, a written request to extend the reporting deadline must be made. Otherwise, noncompliance may result in termination of the award.

No-Cost Extension/Re-budgeting

CCRAC Awards include a one-time provision for awardees to re-budget funds and/or extend the final budget period beyond the originally approved timeframe. All such requests must be made to the Medical Director for Research at least 90 days before the original award period ends.

1. No- Cost Extensions (NCE)

Awardees may extend the final budget period for one additional year when the following conditions are met:

- No additional funds are needed to complete the project.
- Additional time beyond the established expiration date is required to ensure adequate

completion of the originally approved project.
- The NCE request is made at least 90 days prior to end of the original award period.

2. Re-budgeting

Awardees are allowed a certain degree of latitude to re-budget within and between budget categories to meet unanticipated needs of the study. Most re-budgeting activity is within the awardees' authority. Exceptions include:

- New budgetary line item(s) not included in the projects originally approved scope.
  - If you anticipate a change in scope from the original project, please contact the Medical Director of Research for prior discussion and approval before previously unbudgeted funds are expended.
- Budgetary adjustments 25% or greater.
  - Anticipated changes of this magnitude must receive prior approval by Children's Health.
- Requests must be made at least 90 days prior to the end of the original award period.

The Research Advisory Committee or designee will evaluate all NCE and re-budgeting requests on a case by case basis.

Funded Projects

If your project is awarded CCRAC funds, and the expenses will not occur at Children's Health, the funds will likely require transfer to a UT Southwestern account. The investigator is responsible for the following steps to ensure that funding is appropriately transferred from Children's Health to UT Southwestern.

- Investigator should provide a copy of their project approval from CCRAC, project application and budget to the appropriate individual (i.e., Grants / Contracts Specialist) in their respective Division.
- A Request for Transfer of Funds letter on UT Southwestern letterhead and project budget must be drafted and submitted to research.finance@childrens.com at Children's Health.

Once Children's Health receives the Request for Transfer of Funds letter and project budget, the award will be verified and a check request will begin processing. Children's Health will transfer the appropriate funds to the address and contact listed on the Request for Transfer of Funds letter.

Acknowledgment

Specific instructions for acknowledgement will be provided in the notice of award letter and all publications resulting from this support must acknowledged accordingly. The support should also be acknowledged as stated in the notice of award letter by the grantee in all public communication of work resulting from the award, including scientific abstracts (where permitted), posters at scientific meetings, press releases or other media communications, and internet-based communications.

Change of Principal Investigator

Children's Clinical Research Advisory Committee must authorize any request for a change of principal investigator. Such a request must be submitted in writing and reasoned thoroughly. Biographical information on the new principal investigator must be sent

to Jeffrey.Kahn@UTSouthwestern.edu before the request can be approved. Note: The committee generally does not allow a change in Principal Investigators as the general purpose of this award is to sustain one investigator through a gap in funding.

Falsification of Scientific Data and Plagiarism

If an individual determines that falsification of scientific data and/or plagiarism has taken place concerning or related to work Children's Health has supported, Children's Clinical Research Advisory Committee must be notified promptly.

Malpractice Liability

It should be understood that Children's Health is not responsible for malpractice or claims of malpractice arising out of, or resulting from, the performance of the investigations carried out under the awards. Children's Health will not provide reimbursement for the cost of malpractice insurance.

Project Termination and Change of Institution

Terms for renewal and/or discontinuance of project are subject to the approval of Children's Clinical Research Advisory Committee. Unexpended funds at the end of one year project period or unexpended funds from prematurely terminated projects must be transferred back to Children's Health, within thirty days, unless a project extension has been granted (see Reporting). CCRAC funds are not transferable to another project or institution.

Other Requirements

By accepting CCRAC funding, each awardee will be expected to present their work in a research forum sponsored by Children's Health.

Attachment A

CHILDREN' S CLINICAL RESEARCH ADVISORY COMMITTEE (CCRAC)

Sr. Investigator Research Award – Bridge Award Application Cover Sheet

DATE:

APPLICANT

: DIVISION:

STUDY

TITLE:

VELOS#:

IRB#:

FACULTY
PARTICIPANTS:

AMOUNT OF FUNDING REQUEST:

One Year Total:

Is this application a re-submission to CCRAC?

Have you received prior CCRAC or CTSA funding? If yes, please provide details on the following page.

CCRAC and CTSA Funding

Please list all prior CCRAC & CTSA funding that you have been awarded:

Year of Award:
Total Amount of Funding Awarded:
Study Title:
Results / Status of Study:

Did the Funding for this study lead to additional extramural funding?
Publications?

Year of Award:
Amount of Award:
Study Title:
Results / Status of Study:

Did the Funding for this study lead to additional extramural funding? Publications?

Year of Award:
Amount of Award:
Study Title:
Results / Status of Study:

Did the Funding for this study lead to additional extramural funding?
Publications?

(Add additional pages if needed)