Children's Clinical Research Advisory Committee (CCRAC)

Children's Health℠

Children's Medical Center Fellow Research Scholar Award Guidelines

Introduction

The advancement of medical knowledge through basic science, translational, and 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 initial funding for innovative research ideas from Fellows with high potential for sustainable extramural support in the future.

Children's Medical Center Fellow Research Scholar Award

Funding will be awarded following a rigorous Peer Review process conducted by the Children's Clinical Research Advisory Committee (CCRAC). All applications for the Children's Medical Center Fellow Research Scholar Award will be reviewed by CCRAC and the top scoring applicants will be asked to present their research proposal before the committee. The committee will then determine which Fellow(s) will be funded. The highest scoring recipient of the Fellow Research Scholar Award will be noted as a W. W. Caruth Scholar.

Eligibility

Applicants applying for the Fellow Research Scholar Award must be a Fellow in good standing at the time the award would commence and clearly bound for an academic career. The quality of the research and the environment in which the research is being conducted should represent a clear step towards an independent research career. Projects that are seen as mere extensions of the fellow's mentor, without establishing a pathway towards independence for the Fellow, will not be given a high priority.

Fellows must be members in good standing of the Children's Health House Staff and must have at least one year of fellowship remaining.

NOTE: Graduating fellows should apply for the Early Career Research Award and not the Fellow Research Scholar Award.

Applicants must meet the following eligibility requirements:

- Applicants must have sufficient protected research time (at least 75%) during the award period to complete the proposed project. Fellows who are currently in a clinical training year may apply provided that they will have at least 75% protected research time at the start date of the award period. Applicants from other institutions may apply provided they will commence

fellowship at Children's Health prior to the funding start date

- Fellows in the final year of fellowship are encouraged to apply for the Early Career Research Award. Fellows in the penultimate year of fellowship may apply, provided that they provide a letter from their division head or department chair attesting to continued support for the applicant after completion of the fellowship.

Children's Medical Center Fellow Research Scholar Award Amount:

The Fellow Research Scholar Award is designed primarily as *seed money* for basic science, clinical, or translational research studies.

It is anticipated that the award will aid the Fellow in obtaining preliminary data for other extramural funding in the future, such as a K08, K23, or another mentored career award.

Recipients of this award are eligible for two years of funding at a maximum level of $35,000 per year. At the end of year one, the recipients must demonstrate adequate progress before the second year of funding will be granted (see Reporting section).

Applicants with a two-year fellowship period will only be eligible for one-year of funding that must be used during the academic year of their appointment.

Awardees will also be eligible for an extra (i.e., non-budgeted) $1,000 for travel related expenses. Travel must be related to the project and must be approved by the Medical Director of Research.

Criteria for Funding

The main criteria for funding will be likelihood of success of the applicant at achieving external funding and developing a productive academic research career following the completion of this award. This will be evaluated based on 1) the applicant's trajectory, 2) the scientific quality of the project, 3) the applicant's career development plan, and 4) suitability of the environments selected for the Fellow's research.

The review process is intended to identify the most promising Fellows, in addition to 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.

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 (IRB) of the sponsoring institution (usually UT Southwestern), will be required before funding is disbursed. *Note*: pending protocol approval is acceptable, but IRB approval must be obtained within ninety (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 from one to two years, contingent on adequate progress and renewal of funding.

Deadlines and Review Schedule

Applications will be reviewed on the following schedule:

- Letters of Intent (LOI) and Curriculum Vitae (CV) are due by **January 19, 2026.**
- LOIs will be reviewed by members of CCRAC and, potentially, ad hoc reviewers and from these, no more than 10 will be invited to proceed with the application process. Applicant will be notified by **February 9, 2026**.
- Each selected applicant will be asked to prepare a video describing their research project. Videos can be no longer than 7 minutes and can include any modality (PowerPoint, animation, movies, etc.) though all content must be included in the video (i.e., the reviewers will not be expected to review material referenced or cited but not present in the video). Video presentations should have the following basic format (times indicated are estimates): Background and Significance (1-2 minutes); Statement of Hypothesis and Specific Aims (1-2 minutes); Study Design and Methods (2-3 minutes); Anticipated Outcomes, Potential Pitfalls (2-3 minutes). Videos will be due on **March 2, 2026.**
- Videos will be reviewed by members of CCRAC and, potentially, ad hoc reviewers and from these, no more than 4 will be invited to proceed with the application process. Applicant will be notified by **April 3, 2026**.
- Full applications from the 4 selected applicants will be due on **May 4, 2026.**
- The 4 finalists will be asked to present their research proposals to members of CCRAC in **June 2026.** (specific date to be determined)
- Funding start date will be **July 1, 2026.**

Address for Submission

Submit the following materials and files in PDF format electronically through the REDCap link below:

https://redcap.link/2026CCRAC

1) LOI and CV
2) Full Application (if selected as a finalist)

Submit video files (if invited) to Jeffrey Kahn, PhD, M.D. (Jeffrey.Kahn@utsouthwestern.edu) , Medical Director for Research, and copy CCRAC@childrens.com.

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 the Letter of Intent

The Letter of Intent must contain the name of the Principal Investigator (PI), title of the study, a one-paragraph abstract (250 words) description of the study, and a list of all faculty participants and sponsors in the study. All faculty mentors should be listed in the Letter of Intent. The file name for the Letter of Intent should be Last Name_First Name_LOI_Fellow_CCRAC_2026. Submissions must include a CV.

Requirements for the Video Presentation

For those applicants who are invited to submit a video, please include a face page (file name: Last

name_First name_CCRAC_Fellow_Video_2026) with the following information and send to the email addresses listed above along with the submission of the video or link:

- Name of Principal Investigator
- Title of Study
- Abstract (maximum 250 words)
- Year of fellowship as of July 1, 2026
- Status of IRB application (e.g., submitted, under review, approved), if applicable
- Duration of fellowship (years)
- Duration of study (years) (maximum is 2 years)
- **If an applicant is in their final year of fellowship training as of July 2026 and they are requesting 2 years of funding, a letter of support from the Division Director or Department Chair assuring support for the duration of the study is required with the final submission of the video. Video applications lacking this attestation will <u>NOT</u> be reviewed.**

The video describing the research project can be no longer than 7 minutes and can include any modality (PowerPoint, animation, movies, etc.) though all content must be included in the video (i.e. the reviewers will not be expected to review material referenced or cited but not present in the video). Videos or a link to the video (on a platform such as YouTube) should be sent to the addresses and by the date specified above. Please see suggested format of the video presentation described above.

Organization of the Full Application

- **APPLICATIONS MUST BE SUBMITTED IN PDF FORMAT**
- **FILE NAMES SHOULD BE: Last name_First name_Full_Fellow_CCRAC_2026**

Formatting shall be single-spaced with 12-point Arial (or other equivalent Sans-serif font) and ½ inch margins. Page limits for each section are provided below.

Completed Application Cover Sheet (see attachment A) One page: Cover letter.

Please include the appropriate Cover Letter which corresponds to the specific grant award (i.e., Fellow Research Scholar Award).

The cover letter should be written by the applicant's faculty sponsor familiar with the applicant's career path (the Program or Division Director or the trainee's research mentor may act as sponsors) and should 1) describe the trainee's potential as an investigator and 2) the ability of the trainee to carry out the work as proposed. The cover letter will be considered part of the application and will be used by the reviewers to assess whether the application is consistent with the eligibility criteria.

Page 1. Project Title and Credits
Principal Investigator, Mentor(s), Department(s), Address and contact information, e-mail, phone and fax. Note: Mentored investigators should list the names and titles of the mentoring team, including the biostatisticians (if applicable); IRB or IACUC status of proposed study. A pending status is acceptable, but the award will not be granted until approval is obtained.

Page 2. Abstract (maximum 250 words).

Page 3. Lay abstract (maximum 300 words written in language understandable by an educated, but non-medical reader).

Pages 4-10. NIH-style bio sketch of applicant and, of the research mentor and appropriate

mentoring team members. Skip unused pages in assigning page numbers.

Page 11. Budget Summary: Please provide budget justification with explicit detail regarding how cost estimates were developed. If requesting research coordinator support, please use an additional page to detail the amount and scope of the work you are requesting to be done by a research coordinator. Note: salary support for the PI is not permitted by this grant program.

Please note: All procedures that occur at Children's Health will be priced according to the Children's Health Research Fee Schedule. If the project involves any procedures that will occur at Children's Health, the investigators must contact Research Finance (research.finance@childrens.com) at least 10 business days prior to submission of the full 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**.

Pages 12-17 (6 pages**). Research Plan**

The research plan **must** include the following specific sections:

1. **Hypothesis (or Hypotheses) and Specific Aims**. (limited to 1 page)

2. **Career Development Plan**. Please include an outline of the mentoring environment, future goals and career path, and timeline for applying for extramural support.

3. **Background and Rationale**, providing sufficient and properly cited source documentation of previous research related to the proposed topic of study. (limited to 1 page).

4. **Study Design and Methods**, including a description of how the experimental approach relates to the aims, a discussion of how the data will be interpreted (including a detailed statistical analysis), an outline of the potential experimental problems and the solutions devised to overcome them, and a timetable for the performance of the studies.

The biostatistician, Rong Huang, MS, who is affiliated with Research Administration at Children's Health will be available to assist with methodological questions involving study design and analysis. Please contact Mr. Huang one month prior to the deadline. He can be reached at rong.huang@childrens.com.

Page 18. Justification: Please explain 1) the clinical significance; and 2) how these funds will enhance the likelihood of extramural funding and advance the applicant's career goals.

Page 19-20. **Letters of Support**. For Fellow Research Scholar Awards 2 letters of support are required:

1. A letter from applicant's **Scientific Mentor** indicating: 1) he/she has evaluated and approved

the final submission of the research proposal; 2) he/she will provide scientific oversight throughout the duration of the project and responsibility for the conduct of the study;
3) assurance of access to resources to conduct the research; and 4) how the study will contribute to the applicant's professional goals.

2. A letter from the applicant's **Division Chief or Fellowship Director** outlining how the proposed research will advance the career and training of the Fellow and providing an assurance that the Fellow will have the required protected time (≥ 75%) to conduct the proposed research. For Fellows who will be in their final year of fellowship at the time of the award, support for the applicant through the award period (i.e., as an Instructor or Assistance Professor) must be assured. The letter should describe the source for the applicant's salary support to conduct the study. The overall commitment by the Fellow to an academic career should be discussed.

Pages 21-30. Bibliography and Additional Materials pertinent to the grant (e.g., IRB approval, if available at the time of submission, additional letters from collaborators, etc.).

Presentation to the Research Advisory Committee (RAC)

The finalists will be invited to present their research proposal to panel of reviewers (using PowerPoint presentation). The presentations will each be 10 minutes with at least a 10-minute Q&A session. Following the presentation session, the committee will deliberate, and the funded investigator will be selected. Funding will begin on July 1, 2026.

Reporting

Investigators receiving awards will be required to submit a progress report every 12 months, and/or a final report at the completion of the 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 Health network to access the site).

Annual updates on publications and extramural funding resulting from a CCRAC award is required for 10 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 award period. The investigator(s) should indicate how the progress relates to the specific aims of the proposal, detailing any unexpected problems that prevented completion of the aims in the period designated by the original proposal. The PI must also submit a detailed financial statement of expenditures with the progress report. Failure to do so will result in the progress report being returned as incomplete. Subsequent distributions will be withheld until a complete progress report is received and approved. Plans and an updated budget for the second year of funding should also be included.

Final report: The PI must submit a maximum of three pages outlining the following: 1) 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 (see below), otherwise remaining funds must be transferred back to Children's Health within 30 days. Failure to provide a complete final progress report, including a detailed financial statement of expenditures, will disqualify the PI from future awards.

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.
- The NCE request is accompanied by the progress report.

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 or the Department of Pediatrics.
- A Request for Transfer of Funds letter on UT Southwestern letterhead and project budget must be drafted and submitted to Research Finance at 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 be acknowledged accordingly. The support should also be acknowledged 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

This is a career development award. Change of the Principal Investigator is not allowed. If the PI is unable to continue the research for any reason, the remaining funds must be returned to Children's Health within 30 days.

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 in terminated projects will revert to Children's Health within 30 days. CCRAC funds provided by the awards are not transferable to another project, individual, 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)

Children's Medical Center Fellow Research Scholar Award Application Cover Sheet

DATE:

APPLICANT:

DIVISION:

STUDY TITLE:

VELOS#:

IRB#:

MENTOR(S):

AMOUNT OF FUNDING REQUEST:

Year 1:

Year 2:

Total: