



CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE
OF SOUTHEAST WISCONSIN

2024 CTSI Child Health Mentored Research Career Development Award

Program Overview and Requirements

The Clinical and Translational Science Institute of Southeast WI (CTSI) and the Children's Research Institute (CRI) invites applications for the Child Health Mentored Research Career Development Awards (KL2) to support the research efforts and career development of junior faculty dedicated to clinical and translational research towards becoming independent investigators focused on the health and well-being of children. The overall goal of the program is to provide education and training opportunities that will support individuals in disciplines and professions (e.g., medicine, dentistry, nursing, engineering, pharmacy, population sciences, public health, etc.) across the translational spectrum (T0-T4).

The program offers well-structured career development pathways that lead to the exploration of novel approaches in patient-centered diagnostic, therapeutics, epidemiological, behavioral, health services, and outcomes research. Curriculum design for each scholar is a joint undertaking involving the scholar, mentors, and the Program Director, and is based on an assessment of the unique needs and articulated learning goals and objectives of the scholar, and a performance and evaluation plan.

Scholars will be expected to focus on their own mentored research project and the development of a major grant proposal. Awardees will have opportunities to attend national meetings that can enhance their career and provide networking opportunities, and to participate on institutional research-related committees, such as IRBs or other scientific review committees.

In addition, scholars will be provided 75% protected time (**see page 3*). The department chair must agree and provide a statement in the application documenting that this time will be protected for research and training for a period of two years. This award supports up to \$175,000 (direct costs) annually, to cover:

- Salary support (limited to \$120,000 – NIH salary cap, not including fringe benefits; cost-share is required if 75%* FTE exceeds this amount)
- Research-related costs (e.g., tuition and fees related to research development; supplies, equipment and technical personnel; statistical services; fringe benefits)
- Travel funds of up to \$2,500 per scholar per year (e.g., scientific meetings, training workshops)

The candidate must name a primary sponsor/mentor, who, together with the applicant is responsible for the overall career development and research plan, direction, and execution. The mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training independent investigators in clinical and translational research. The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award. Candidates may also nominate co-mentors, as appropriate to the goals of the program. The candidate and mentor must describe a career development program with an emphasis on pediatric clinical and translational research that maximizes the use of relevant research, educational resources, and qualified faculty as mentors in clinical and translational research.

The candidate's research program should be aligned with the mission of Children's Wisconsin Research Institute. This includes improving the way we prevent, diagnose or treat childhood diseases, or enhancing childhood health and well-being, including management strategies for living with chronic disease.

Scholars Program Goals

The objective of the Child Health Mentored Research Career Development Award is to accelerate career progression of scientists dedicated to clinical and translational research (C&TR). As such, scholars are allowed requisite time to work with experienced mentors in their areas of interest who will provide appropriate guidance in developing individualized curricula and career plans to progress towards leaders in interdisciplinary C&TR.

CTSI is committed to increasing the participation of individuals currently underrepresented in clinical and translational sciences/research. This includes underrepresented racial/ethnic, social, cultural, economic, or educational backgrounds that may have inhibited their ability to pursue careers in C&TR. Ideal candidates may have completed a significant amount of formal research training and require protected time to develop a C&TR project that will lead to an external grant proposal by the end of the first year.

Awarded KL2 scholars are expected to be engaged in the following activities during and after the 2-year award period:

During -

- Completion of pre-program assessment survey
- Quarterly check-ins with Program Director
- Submission of semiannual reports and final reports
- Development and semiannual review of an individualized Career Development Plan
- Participation in the CTSI Clinical Research Scholars program
- Participation in Children's Specialty Practice Unit (SPU) as defined by the SPU leader
- Participation in a Team Science course during award period

During/After -

- Preparation and submission of manuscripts and grant proposals
- Engagement in multidisciplinary team-based research as appropriate

After -

- Completion of post-program assessment survey
- Response to post-award tracking survey up to 15 years after program completion

Key Dates

One award is available for this RFA annually.

- *Application Release Date:* June 5, 2024
- *Letter of Intent Due:* June 24, 2024
- *Application Submission Deadline:* August 1, 2024
- *Recommended IRB Submission Deadline:* September 25, 2024
It is recommended that all applicants submit to the IRB by this date, as (if funded) you cannot begin human subjects research until you have IRB approval, which must be acquired no later than 90 days following the award start date.
- *Review of Applications:* October 1-16, 2024
- *Awardee Approved by CRI Operations Committee:* December 3, 2024
- *Notification of Application Status:* December 15, 2024
- *IRB Approval Deadline:* December 31, 2024
- *Anticipated Start Date:* January 1, 2025

Eligibility Criteria

Full-time early-stage investigators who hold primary appointments in Children's Wisconsin Research Institute and have a faculty appointment from the Medical College of Wisconsin, University of Wisconsin-Milwaukee, Marquette University, or Milwaukee School of Engineering, with a professional doctoral degree or its equivalent (e.g., MD, PhD, DDS), US citizenship or permanent residency, and an institutional commitment to the candidate's clinical and translational

research efforts are eligible. *Adjunct and part-time faculty are not eligible to apply since this award supports full-time research and clinical effort.* Ineligible individuals also include faculty who have had previous similar training awards, or who have served as Principal Investigator on any peer-reviewed research grants (NIH or other funding agencies) that are in excess of \$100,000/year direct costs, or who are project leaders on sub-projects of a program project or center grant.

Candidates must demonstrate active participation in a Children's Specialty Practice Unit (SPU). These include pediatric medical, surgical and diagnostic subspecialties; nursing, dental, and primary care.

Non-Competitive Letter of Intent

Non-competitive letters of intent are mandatory and are being requested to identify potential reviewers and confirm eligibility. Applicants must submit a letter of intent (1-page maximum) that briefly describes the proposed project scope of work and its goals, and how it specifically meets the eligibility criteria noted in this RFA.

Application

The application must address the following areas. A template with the required sections can be downloaded [here](#).

Body of the Application, #1-6 – not to exceed 14.5 pages.

1. Specific Aims

The Specific Aims page is an abbreviated version of the grant proposal. This section should include an introductory paragraph with what is known and current gaps in knowledge. Include an explanation of how your proposed research can address the gap(s), goal(s), hypothesis, and rationale of the proposed project. The Specific Aims should address the identified need and be related to the overall project goals without being highly dependent on one another.

(1 page)

2. Candidate

Provide a statement detailing your accomplishments to date, career goals and plans towards an independent academic career in clinical and translational research (C&TR). Provide background information relevant to your interest and experience in C&TR and indicate how the Child Health Mentored Research Career Development Award will help you achieve your future goals in C&TR. Include a description of your current professional activities/responsibilities in the institution and elsewhere and show how these will help ensure career progression to achieve independence as an investigator conducting C&TR.

Include a statement indicating your commitment to 75%* effort to the program and related career development activities.

(No more than 1 page)

- Exceptions to the effort commitment may be made for surgeons or procedure-intensive specialties (see below).

*Accommodation for Certain Clinical Specialties

To remain consistent with NIH guidelines (see links below for additional detail), it is acknowledged that individuals in medical specialties that require significant clinical activity to maintain specialty clinical competency skills may be unable to devote the required minimum of 9 person months of effort (i.e., 75% of full-time professional effort). The CKL2 award will allow certain clinical specialties (e.g., surgical and procedure-intensive specialties) to request less than the required 9 person months of effort for the

specific purpose of maintaining specialty clinical competency skills. Applicants may request a minimum of 6 person months (50%) of effort in the application. A clear justification for the reduced level of effort must be included.

- <https://grants.nih.gov/grants/guide/notice-files/NOT-AG-21-019.html>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-CA-21-054.html>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-HL-21-003.html>
- https://grants.nih.gov/grants/policy/nihgps/html5/section_12/12.3.6_level_of_effort.htm

3. Career Development and Mentoring Plan

Provide a description of your needs for career development, including activities and external enrichment experiences that may be beneficial to your success. The candidate and the mentor are jointly responsible for the preparation of the career development plan. *Include a timeline for your career development with intermediate and final goals.* The sponsor/mentor may form an advisory committee to assist with the development of the program of study or to monitor the candidate's progress through the career development program. Indicate any prior completion or recent acceptance into any advanced didactic programs in C&TR or equivalent education and/or training. For e.g., indicate prior education/training or plans to participate in courses such as: data management, epidemiology, study design, hypothesis development, drug development, conflict of interest, responsible authorship, policies for handling misconduct, lab and personnel management, etc., as well as the legal and ethical issues associated with research on human subjects.

Required Training in Responsible Conduct of Research: Include a description of a program to receive formal or informal instruction in scientific integrity or the responsible conduct of research. Applications without plans for instruction in the responsible conduct of research will be considered incomplete.

(1-2 pages)

4. Research Plan

Describe your planned research while in the program, providing a vision of your research program. The research plan should represent a 2-year research program. The research strategy should include background and significance, innovation, research design and methods/approach, sample size/power, plan for statistical analysis, pitfalls & alternative strategies, and a timeline. The candidate should consult with mentor(s) regarding the development of this section. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects.

(3 pages)

5. Human Subjects and/or Vertebrate Animals

Include Protection of Human Subjects (5-page maximum) and/or Vertebrate Animals (2-page maximum) documents. See NIH [Protection of Human Subjects](#) and [Vertebrate Animals](#) instructions for further information.

(See page limits above)

6. Alignment

Describe how your research project has the potential to improve the way we prevent, diagnose or treat childhood diseases, or enhance childhood health and well-being, including management strategies for living with chronic disease. Please also describe your active participation in a Children's Specialty Practice Unit (SPU).

(½ page)

Additional required Items not included in 14.5-page limit:

7. References

Include citations for all sources.

(No page limit)

8. Biographical Sketches (NIH format) of applicant and all mentors

Please use the General Biographical Sketch Format Page** from the [SF424 \(R&R\) Application and Electronic Submission Information](#) page on the NIH website (≤ 5 pages).

**Biosketches submitted in an older format may result in the application being considered incomplete.

9. Statements by Mentor(s), Advisors and Collaborators

Mentors: The application must include a statement from the mentor(s) indicating; a) research qualifications and previous experience as a research supervisor; 2) mentoring plan describing the nature of the supervision and mentoring that will occur during the proposed award period; and 3) plan for transitioning the candidate from the mentored phase of their careers to the independent investigator phase during the project period of the award. The mentor must agree to provide annual evaluations of the candidate's progress for the duration of the award. Similar information must be provided by any co-mentor. If more than one mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate.

(6-page limit)

Advisor(s), Consultant(s)/Collaborator(s): Signed statements must be provided by each consultant/collaborator confirming their participation in the project and describing their specific roles. Collaborators and consultants generally do not need to provide their biographical sketches. However, information should be provided that clearly documents expertise in the proposed area(s) of consulting/collaboration.

(6-page limit)

10. Institutional Commitment to Applicant's Research Career Development (required)

Provide Letter(s) of Support from your Department Chair and Division Chief and/or SPU leader jointly signed indicating acceptance of the terms of this award. The letter of support should address your role in the SPU, and the guarantee of protected time/resources for the research project.

- Provide letter of support from internal research support service center, if applicable.
- Applicants from UWM, Marquette, and MSOE must also submit a Letter of Intent from their institution indicating their acceptance of terms of the award.

(1-page limit)

11. Detailed Budget and Budget Justification.

This award supports up to \$175,000 (direct costs) annually. Recipients should budget for:

- Salary support is limited to \$120,000 (NIH salary cap, cost-share is required if 75%* FTE exceeds this amount)
- Research-related costs (e.g., tuition and fees related to research development; supplies, equipment and technical personnel; statistical services; fringe benefits)
- Travel funds of up to \$2,500 per scholar per year (e.g., scientific meetings, training workshops)

Provide the salary and fringe benefits requested and a detailed description with justification of all equipment, supplies and research personnel that will be used to help achieve the career development and research

objectives of this award. Please note that salary support for the mentors or administrative support personnel is not allowed. Funding cannot be used as “bridge funding” for lapsed grants from any extramural source and is intended to be used for new projects. Each recipient should budget salary support for 75%* protected time for research and training (subject to the current NIH salary cap). This award will support up to \$175,000 (direct costs) annually towards salaries, fringe benefits, research expenses, and travel for up to two years of supervised career development activities and mentored clinical and translational research.

[Budget Form](#): NIH PHS 398 budget Form 4, Form 5, and detailed budget justification

Complete Form 4 for the first year in the program and include a detailed budget justification form. Form 5 should include the cumulative numbers from each category of Form 4 for year one and include the total budgeted amount for each category for year two of the award. If there is a significant change in a category from the previous year this change should be justified in the box at the bottom of Form 5. A significant change is defined as increase or decrease $\geq 25\%$. The budget template can be found [here](#) and within the [application template](#).

12. Letters of Recommendation (3 required)

Three letters of reference should be submitted from well-established scientists addressing the above areas and any other evidence that the candidate has a high potential for becoming an independent investigator in patient-oriented research. Please note that mentors may not submit a letter of reference. All letters of reference should be submitted by the applicant within the REDCap application form.

How to Prepare Your Application, Submission Process

Items (1 – 10) are to be submitted electronically together to the CTSI as a single PDF file or Word Document (.doc or .docx) through the Child Health Mentored Research Career Development Award application form (a unique link will be sent to you following your submission of the LOI). The document should be formatted according to standard NIH submission guidelines, including font size no smaller than 11 pt. and at least .5” margins. All letters of reference will be submitted as individual attachments by the applicant within the REDCap application form.

To begin the application process, [click here for the Letter of Intent](#). Following the LOI submission, a unique link will be sent for you to fill out the application.

Award Review Criteria

Overall Impact

Reviewers will provide their assessment of the likelihood for the candidate to maintain a strong research program, taking into consideration the criteria below in determining the overall impact/priority score.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Candidate

- Does the candidate have the potential to develop as an independent and productive researcher focusing on patient-oriented research in child health?
- Is the candidate’s academic, clinical, and (if relevant) research record of high quality?
- Is there evidence of the candidate’s commitment to meeting the program objectives to become an independent investigator focusing on patient-oriented research?

- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan/Career Goals & Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the candidate's prior training and research experience appropriate for this award?
- Are the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives, appropriate?
- Are the content and duration of the proposed didactic research activities during the proposed award period clearly stated and appropriate?
- Are there adequate plans for evaluating the candidate's research and career development progress?

Research Plan

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives focusing on patient-oriented research in child health?
- Is there consideration given to pitfalls and alternative strategies?
- Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?
- If applicable, are there adequate plans for data and safety monitoring of clinical trials?

Mentor(s), Co-Mentor(s), Advisor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed patient-oriented research appropriate?
- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, advisor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of previous research productivity and peer-reviewed support focusing on patient-oriented research?
- Is active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 75%* of the candidate's effort will be devoted directly to the research and career development activities described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program?

Alignment

- Is the proposed research aligned with the research goals and mission of the SPU?

Additional Review Criteria (unscored)

- Human Subjects documentation
- Vertebrate animal documentation
- Training in Responsible Conduct of Research
- Budget and Period of Support

The scoring system uses a nine-point scale based on the rating scale used by the National Institutes of Health. The nine-point rating scale is anchored according to the following descriptions:

Range	Score	Descriptor	Characteristics
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weakness
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses