Clinical & Translational Science Institute
of Southeast Wisconsin

2023 NIH CTSI Mentored Research Career Development Program Award

Program Overview and Requirements

The Clinical and Translational Science of Southeast WI (CTSI) invites applications for the Mentored Career Development Awards to support the research efforts and career development of junior faculty dedicated to clinical and translational research towards becoming independent investigators. The overall goal of the Program is to provide education and training opportunities that will support the career development for individuals in disciplines and professions across the translational spectrum (e.g., medicine, dentistry, engineering, pharmacy, population sciences, public health, etc.).

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 funded by the Program. The department chair must agree and provide a statement in the application documenting that this 75% of time will be protected for research and training for a period of 2 years. Scholars will receive up to $25,000 to support their scholarly activities each appointment year, and up to $2,500/year for research-related travel. Once appointed, scholars must propose a budget for how funds will be utilized; the budget is approved by the CTSI Executive Committee.

The candidate must name a primary sponsor/mentor, who, together with the applicant is responsible for the planning, directions, and execution of the program. 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 clinical and translational research that maximizes the use of relevant research, educational resources, and qualified faculty as mentors in clinical and translational research.

Scholars Program Goals

The objective of the CTSI Mentored Career Development Program 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 interests who will provide appropriate guidance in developing individualized curricula and career plans progress towards leaders in interdisciplinary C&TR.

CTSI is committed to increase 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 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:
- o Quarterly check-ins with Program Director
- o Submission of semiannual reports and final reports
- o Development and semiannual review of an individualized Career Development Plan
- o Participation in the CTSI Clinical Research Scholars program
- o Response to post-award tracking survey up to 15 years after program completion
- o Completion of pre/post program assessment survey
- o Engagement in multidisciplinary team-based research
- o Participation in a Team Science course during award period
- o Preparation and submission of manuscripts and grant proposals

Key Dates

Two awards are available for this RFA.

Application Release Date: May 30, 2022
*Funding proposal submission to institutional grant office: July 4, 2022
> (This date applies to MCW applicants' eBridge submission, other institutions - please follow your respective timelines/procedures)

Application Submission Deadline: July 11, 2022
Notification of application status: August 19, 2022
IRB Submission Deadline: August 29, 2022
IRB Approval Deadline: October 28, 2022
NCATS Prior Approval: December 28, 2022
Anticipated start date: January 2, 2023 *(date subject to change)*

**MCW Faculty (other faculty please follow your institutions' procedures): A Funding Proposal must be initiated in MCW eBridge system at least 5 days prior to the application due date. This is required by MCW for applications for funding through the NIH. The Funding Proposal will also need to be linked with an IRB protocol; therefore, it is required to start an IRB submission ahead of the application submission. The IRB submission is not due until 10 days *after* receiving the Recommendation for Funding, although it is encouraged to prepare the IRB materials during the review period in order to meet the submission deadline if recommended for funding.
> *MCW Funding Proposal Guidelines*:
> - General Proposal Information:
>   - o Type of Organization – select *Federal Pass-through*
> - Sponsor Information:
>   - o Sponsor/Pass-Through – select *Clinical & Translational Science Institute*
>   - o Prime Grantor – select *NIH Advancing Translational Sciences*
> - Funding mechanism: *UL1*
> - Project Location and Affiliations: please select *Clinical & Translational Science Institute* to be affiliated with this project

Funding for the KL2 Mentored Research Career Development Award program is provided by the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS). This research project will be a sub-award of the NIH-funded CTSI KL2 parent award.

* CTSI is supported by the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS). As such, "NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects." (https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm). Please be sure to reach out to your respective IRB Reliance office if needed.

*CTSI is required to submit documentation based on IRB approval for each applicable KL2 project that has been recommended for funding. NCATS requires IRB approval and all related documentation at least 30 days before the project start date. To accommodate this timeline, IRB must be submitted 10 days following the notice of recommendation for funding.

Eligibility Criteria

Full-time junior faculty from the Medical College of Wisconsin, University of Wisconsin-Milwaukee, Marquette University, and Milwaukee School of Engineering, with a professional doctoral degree or its equivalent (e.g., MD, PhD, DDS), US citizenship or permanent residency, and a documented commitment to clinical and translational research are eligible. *Adjunct and part-time faculty are not eligible to apply.* 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.

Application Format

The application must address the following areas. A template with the required sections can be downloaded here.

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), the goal(s) of the proposed project, hypothesis, and rationale. 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 CTSI Mentored Career Development Program will help you achieve your future goals in C&TR. Include a description of all 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 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 in order 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 KL2 sub-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 advance 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, 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, 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. **References**
    Include citations for all sources. (no page limit)

6. **Biographical sketch (NIH format) – applicant.**
   Please use the General Biographical Sketch Format Page** from the SF424 (R&R) Application and Electronic Submission Information page on the NIH website (updated by NIH 10/2021). (<5 pages)
   ***Biosketches submitted in an older format may result in the application being considered incomplete*

7. **Statements by mentor 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.

   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.

8. **Institutional commitment to applicant's research career development** (required)
   If recommended for funding, provide Letter(s) of Support from your Department Chair and Division Chief (if relevant) indicating acceptance of the terms of this award. Provide internal research support service center agreement, 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.

9. **Detailed budget and budget justification.**
   Recipients should budget for:
   - Salary support is limited to $120,000 (cost-share is required if 75% FTE exceeds this amount)
   - Research-related costs of up to $25,000 per year (e.g., tuition and fees related to research development; supplies, equipment and technical personnel; statistical services)
   - 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 or 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). The CTSI will support up to $150,000 (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. Applicants are allowed to budget for indirect/F&A costs at a percentage of up to 8%, pursuant to NIH guidelines Departments may be asked to leverage funds for their selected scholar.

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.

10. 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. The mentor(s) may also submit letters of reference, but these are considered independent of the three required. All letters of reference should be submitted by the scientists directly through the REDCap portal. A custom link will be sent after their contact information has been entered in the Application portal.

How to Prepare Your Application, Submission Process

Items (1 – 9) are to be submitted electronically together to the CTSI as a single PDF file or Word Document (.doc or .docx) through the Mentored Career Development Award Program Application form. 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 through the REDCap application portal using a custom link that will be emailed to each recommender.

Important Notes:
- For the Letters of Recommendation email to be sent, you must "Save" the application in REDCap. Upon saving, the recipient will receive a link to complete their letter of recommendation. It is recommended for applicants to begin the REDCap application well in advance of the application due date and verify the individuals received the email requesting the Letter of Recommendation.
- Submitted Applications from MCW investigators do require prior Grants and Contracts review via eBridge (see page 2, "*MCW Faculty"). Non-MCW investigators should notify their respective grants office of their application before it is submitted.

Other Application and Funding Criteria: (NIH/NCATS)

NCATS Prior Approval for Studies Involving Human Subjects or Animals
- If recommended for funding, CTSI will request documentation for NCATS Prior Approval in accordance with federal requirements. The following conditions must subsequently be met:
  - ✓ NCATS requires IRB/IACUC approval at the time of submission for Prior Approval
  - ✓ NCATS requires receipt of documents at least 30 days before the project start date; therefore, CTSI requires that all documentation be provided and the NCATS survey be completed no later than 45 days prior to the anticipated project start.
  - ✓ PIs will utilize the REDCap repository to upload the required NCATS documents.
- To accommodate this time restriction, CTSI requires that all IRB applications be submitted to each respective IRB within 8 business days of receiving notice of the recommendation for funding. If the complete IRB application has not been submitted within this time frame the recommendation for funding may be rescinded.

Restriction of Clinical Activity Beyond the end of Phase IIa:

- o *In accordance with section 479(b) of the Public Health Service Act (as amended by the Consolidated Appropriations Act, 2012, Public Law 112-74 and by the 21st Century Cures Act, 2016, Public Law 114-255), unless specifically authorized via Revised Notice of Award, with attendant specific Terms of Award, no clinical trial activity beyond phase IIB using fiscal year 2020 funds may be supported by this grant through the pilot project. However, all phases of clinical trials may utilize infrastructure and resources provided through the CTSA (NCATS).*

Stem Cells – information required

- o *No funds in this award may be used for any research involving human embryonic stem cells (hESCs) until the grantee has submitted to NIH information on the specific, approved hESC line(s) that will be used from the NIH Human Embryonic Stem Cell Registry: NIH Human Embryonic Stem Cell Registry . While the Registry will include lines pending review; only those hESCs listed on the Registry as eligible for NIH funding may be used in this award.*

- o *The grantee may use only those hESCs that appear on the NIH Human Embryonic Stem Cell Registry as eligible for NIH funding and in accord with any restrictions placed on the use of those lines. For more information, view the NIH Guidelines on Human Stem Cell Research .*

Human/Animal Subjects Restriction

- o *It is understood that no clinical research scholar or mentor will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate.*
- o *If any scholar undertakes a project which includes human subject research studies, these must conform to the NIH policies on the inclusion of women, minorities, and children in study populations.*

Human Subjects Education Certification Requirement

- • *This award reflects the NCATS' acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, Required Education in the Protection of Human Research Participants.*

- • *Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Documentation of required certifications must be provided before submitting for NCATS Prior Approval.*

- • *Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.*

Restriction: Data Safety and Monitoring of Clinical Trials

- o *The scholar must ensure that each clinical trial has an approved DSM plan or Data and Safety Monitoring Board, as appropriate, before any scholar participates in or resources are used to support the clinical trial. This plan must be approved and documentation submitted to CTSI before the project can be submitted for NCATS Prior Approval. All investigators must comply with the approved DSM plan for the applicable clinical trial. The NIH policies for DSM can be found at the following websites:*

  - o http://grants.nih.gov/grants/guide/notice-files/not98-084.html
  - o http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

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

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

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

Research Plan

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

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

- o   Are the qualifications of the mentor(s) in the area of the proposed patient-oriented research appropriate?
- o   Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- o   Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- o   Is the mentor's description of the elements of the research career development activities, including formal course work adequate?

- o Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- o Is there evidence of previous research productivity and peer-reviewed support focusing on patient-oriented research?
- o Is active/pending support for the proposed research project appropriate and adequate?
- o Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

Environment & Institutional Commitment to the Candidate
- o 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?
- o Is the institutional commitment to the career development of the candidate appropriately strong?
- o Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- o Is the environment for scientific and professional development of the candidate of high quality?
- o Is there assurance that the institution intends the candidate to be an integral part of its research program?

Additional Review Criteria (Unscored)
- o Protections for Human Subjects
- o Inclusion of Women, Minorities, and Individuals across the Lifespan

Additional Review Considerations
- o Training in Responsible Conduct of Research
- o 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