



CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

MENTORED CAREER DEVELOPMENT (KL2) AWARDS REQUEST FOR APPLICATIONS

Announcement Date: 6.22.2023

LOI Due: 7.14.2023

BACKGROUND

A major goal of the **University of Massachusetts Center for Clinical and Translational Science** (UMCCTS) is to develop and support the next generation of leaders in clinical and translational research. Success in today's complex and competitive environment requires training that is truly transdisciplinary in nature, encompassing the full translational science spectrum, from discovery, through pre-clinical development and first-in-human studies, to implementation science and population-based studies with additional continuous feedback to basic science research.

Training of investigators who will make a career of innovative, transdisciplinary clinical research in support of translational science is a top UMCCTS priority, and the UMCCTS Mentored Career Development (KL2) Program is designed to address this need. The KL2 Training Program will combine coursework, seminars, and mentored research.

In this funding cycle, ***up to three awards will be made, depending on the receipt of meritorious applications and the availability of funds.***

At least one of the awards will specifically focus on enhancing faculty diversity and thus will be available for funding meritorious applications from eligible scholars who are from underrepresented racial/ethnic groups, have a disability, or are from disadvantaged backgrounds. While the focus of the KL2 program is on translational science, an award may be made to a basic science scholar.

DEFINITIONS OF CLINICAL AND TRANSLATIONAL RESEARCH and TRANSLATIONAL SCIENCE

The NIH defines ***Translational Science*** as:

- The field that generates innovations that overcome longstanding bottlenecks and roadblocks to accelerate progress along the translational research pipeline. These include scientific, operational, financial and administrative innovations that transform the way that research is done.

The NIH defines ***Translational Research*** as:

- The process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease.

The NIH defines ***Clinical Research*** as:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. ***Excluded*** from this definition are *in vitro* studies that utilize

human tissues that cannot be linked to a living individual.

- Epidemiological and behavioral studies.
- Outcomes research and health services research.

The NIH defines *Basic Science Research* as:

- Research that aims to gain a better understanding of fundamental aspects of phenomena or observable facts through experimental laboratory investigations.

ELIGIBILITY FOR THE MENTORED CAREER DEVELOPMENT PROGRAM

- Research or health professional doctoral degree (e.g., MD, DO, PhD, ScD, DVM, PharmD).
- University of Massachusetts (any campus) faculty appointment (Instructor or preferably Assistant Professor) **prior to award start**. For the Diversity K program, the faculty appointment must be at UMass Chan in Worcester. (This includes faculty from Baystate and Lahey regional campuses with appointments at UMass Chan.)
- Commitment to a career as an independent investigator in clinical and translational research.
- Talent and aptitude for scholarship and critical thinking; prior productive research experience highly desirable.
- Personal commitment to and departmental support of a minimum of 75% protected time for 2 years. However, certain clinical specialties, such as surgery, can have less than 75%, but no less than 50%, protected time if sufficiently justified and approved by KL2 program leadership.
- There is no post-completion time limitation from post-doctoral or fellowship training to be eligible to apply as long as the applicant states a compelling need for the mentored career development plan that is required as part of the application.
- Applicants cannot have previously been the principal investigator on an R01, R21, R34, or equivalent award, Program Project grant, or a Co-PI on a Program Project grant.
- Applicants may not simultaneously submit or have pending an application for any other PHS mentored career development award (e.g., K07, K08, K22, K23) that duplicates any of the provisions of KL2 program; however, **KL2 awardees will be expected to apply for individual mentored external K awards (or R-level grants) during their two-year tenure as KL2 scholars**; if successful, funding for the scholar would transition from the KL2 program to the new individual K award.
- Candidates should assemble a strong mentoring team made up of at least 3 to 4 individuals – a **primary mentor** with clinical or translational research and training experience and a commitment to help develop the candidate's research career, a **junior faculty member** with relevant expertise as a mentor in training, an **experienced investigator** with specific methodological and/or complementary expertise that will promote career development, and if needed a member of the UMCCTS Biostatistics, Epidemiology, and Research Design (BERD - <https://www.umassmed.edu/ccts/resources/berd/>) core.
- At least the three core mentors noted above must be University of Massachusetts faculty members, with at least one having an affiliation to the UMass Chan Morningside Graduate School of Biomedical Sciences (GSBS).
- Applicants must be US citizens, non-citizen nationals, or permanent residents.
- Applicants and mentors must be members of the UMCCTS. Applications for free membership can be completed by accessing the UMCCTS website and completing the online membership form at: <https://umassmed.edu/ccts/about/membership/>
- Individuals from underrepresented racial/ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are particularly encouraged to apply. Please see the recent Notice of NIH's Interest in Diversity for more information: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>.

TRAINING PROGRAM

Training for KL2 scholars must have **4 key components** tailored to individual goals: **1)** a transdisciplinary mentoring team and an intensive mentored research experience targeted to independence; **2)** coursework targeted to provide either advanced understanding of analytical methods (for more advanced entering scholars) or a degree (PhD for select MDs, MSCI for clinically-oriented scholars who do not already have an MPH or equivalent degree); **3)** KL2 required elements including: “Projects-in-Progress Seminar Series” (PiPSS); a specially-designed Translational Science Lecture Series; a writing skills development course; a scientific journal internship; and an annual research retreat; and **4)** enrichment activities (e.g., research seminars, workshops on a variety of topics, rotations focused on gaining experience in all stages of drug development from discovery through early-stage clinical trials) available through UMass Chan or other UMass institutions, collaborating programs and centers (e.g., MassBiologics, UMCCTS Small Molecule Screening Core). Scholars will pursue career development full-time, pursuing their independent research projects designed to launch their career, while developing the skills needed to compete for independent funding.

Year 1: Suggested coursework (if not already completed) includes training in: translational science, research study design (including clinical trial design and implementation); epidemiology; informatics for data storage/analyses; critical interpretation of literature and data; statistics; scientific integrity and the responsible conduct of research; human subjects training; regulatory; presentation of research; mentoring; team and leadership skills; individualized coursework relevant to project; and tutorials or mini-rotations with potential mentors in addition to coursework. Participants will be urged to give strong consideration to completing the Master’s in Clinical Investigation, if appropriate.

Years 1-2: Mentored research project; Submission of intramural and extramural grant applications to develop additional sources of funding.

THE KL2 PROGRAM PROVIDES

- Two years of 75% salary support for trainees up to \$100,000. The applicant’s home department is responsible for any remaining gap between \$100,000 and 75% of the salary of the scholar, as well as the remaining 25% of the scholar’s salary, for each of the two years. An additional year of support may be available with special permission of the KL2 Review Committee. NIH rules prohibit KL2 scholars from receiving salary support from other federal grants and contracts (except as noted at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-157.html>; see also <https://nexus.od.nih.gov/all/2017/10/11/clarifying-percentage-effort-and-support-for-career-development-k-awardees/>); however, other intramural and non-federal extramural grant sources may be used for this purpose.
- Course tuition. Planned courses should be budgeted in the proposal.
- \$25,000 per year for research supplies.
- \$2,500 per year for travel.
- Indirect costs will not be supported.
- Salary support for the mentors will not be supported.

THE DEPARTMENT/PROGRAM IS EXPECTED TO PROVIDE

- Assurance of full salary support for the duration of the training period. This includes support for any remaining gap between \$100,000 and 75% of the salary of the scholar, as well as the remaining 25% of the scholar’s salary. The remaining 25% of effort can be divided among other research, clinical, and teaching activities. As noted previously, NIH rules prohibit KL2 scholars from receiving salary support from other federal grants and contracts (except as noted

at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-157.html>; see also <https://nexus.od.nih.gov/all/2017/10/11/clarifying-percent-effort-and-support-for-career-development-k-awardees/>); however, other intramural and non-federal extramural grant sources may be used for this purpose.

- A minimum of \$25,000 for research supplies to be made available in the 1st year of funding.
- Tenure track appointment for KL2 recipients with primary appointment in a basic science department or selected clinical departments, following successful completion of the program.

Interested applicants are invited to attend an informational meeting to be held via Zoom on Tuesday, July 11, 2023 from 3:00-3:30 pm EDT at

<https://umassmed.zoom.us/j/93965736455?pwd=cjVteHV1cmtvQjMwcGF6ZEI1dG44dz09>

This meeting will clarify expectations for the program and answer questions.

APPLICATION PROCEDURE

STAGE 1: LETTER OF INTENT: All candidates must submit a letter of intent (LOI) and supporting materials as a single .pdf document. LOIs are due on **Friday, July 14, 2023 at 5:00pm EDT**.

Completed LOIs should be emailed to ccts@umassmed.edu.

- **Applicant Cover Letter:** Summarize applicant's prior training, research experience, career goals, and rationale for choice of mentor.
- **Letter of Intent:** maximum of 2 single-spaced pages outlining the proposed training period and training goals and plan (maximum of 0.5 page); research project rationale, specific aims, and experimental design. References are not required, but if included are not considered part of the two (2) page limit.
- **Applicant's Biosketch:** NIH format, maximum of 5 pages.
- **Department or Program Chair's Letter of Support** outlining the Department's commitment to mentoring the candidate as an independent researcher. The signed letter should provide assurance that the candidate will not have any administrative or other commitments that exceed 25% effort (50% for select clinical specialties) and will not spend any more than 25% of his/her time in activities other than research. The letter should also provide assurance that the Department will provide the expected supports, as listed above.
- **Demographic data** (Please note that NIH requires that we ask for this information):
 - Gender
 - a. Male
 - b. Female
 - c. Would rather not answer
 - Ethnicity
 - a. Hispanic or Latino
 - b. Non-Hispanic
 - c. Would rather not answer
 - Racial category
 - a. American Indian or Alaska Native
 - b. Asian
 - c. Native Hawaiian or other Pacific Islander
 - d. Black or African American
 - e. White
 - f. More than one race
 - g. Would rather not answer
 - Do you have a disability? (Refer to <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>, Section B.)
 - a. Yes
 - b. No

- Do you come from a disadvantaged background? (Refer to <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>), Section C.)
 - a. Yes
 - b. No

Letters of Intent will be peer-reviewed on a rolling basis. The most promising candidates will be selected to submit a full application and will be notified on August 4, 2023.

STAGE 2: FULL PROPOSAL: Candidates who are invited to submit a full application must submit all components of the proposal (listed below) as a single .pdf document by **Wednesday, October 4, 2023 at 5:00pm EDT**. Full proposals should be emailed to ccts@umassmed.edu.

Please follow the NIH format and page guidelines for K Awards (for example, the omnibus K23 - <https://grants.nih.gov/grants/guide/pa-files/PA-19-119.html>).

The full NIH-style proposal consists of (include all of the following):

- **Abstract** of the Project (1 page)
- **Specific Aims** (1 page)
- **Candidate and Training Information:** (12 pages for all sections combined)
 - Candidate’s background, career goals and objectives
 - Career development/training activities during award period
 - Project research strategy
- **References** Section (no page limit)
- **Training** in the Responsible Conduct of Research (1 page)
- Description of **Institutional Environment** (1 page)
- **Biographical Sketch** (maximum of 5 pages)
- **Departmental and Mentor Resources Supporting the Application.** This includes a **Departmental Support Letter** attesting to the department’s commitment to providing the expected supports listed above, and **statements by mentors, co-mentors, consultants, and contributors**. Includes the Departmental / Mentor’s resources to support the applicant, a statement of support for the applicant’s training plan (support letter can elaborate on training plan if appropriate) a description of the level of mentoring time for the applicant, a description of the full mentoring team and how they will be coordinated, and how the proposed project fits with the mentor’s ongoing program of research and laboratory/research resources. Specific source(s) of available grant or institutional support for the proposed project should be discussed (7 pages max).
- **Primary Mentor’s NIH Biosketch:** including list of current /former trainees and funding sources.
- **Letters of Reference:** Two letters of reference (maximum) that attest to the candidate’s commitment to and suitability for development as an independent researcher. The reference letters should come from individuals not involved with the project who can speak to the applicant’s past research training, experience, and productivity. Do not send more than two letters of reference.
- **Budget:** NIH PHS 398 Form (pages 4 and 5) which includes budget justification. Salary portion of the budget must reflect 75% of scholar’s current salary (or, if known, salary as of the planned project start date), not to exceed \$100,000, and applicable fringe.
- **Appendices:** not allowed.

Awardees will be required to submit “Just-in-Time” information, as follows, PRIOR to making an award.

- **Current Other Support.** Use the sample format provided on the “Other Support Format Page” in the PHS 398 Fillable Forms. For all Key Personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.

- **Certifications.**
 - If Human Subjects are involved, please provide the assurance type and number and the Certification date of IRB Review and Approval. *Pending or out-of-date approvals are not acceptable.*
 - If Vertebrate Animals are involved, please provide the assurance number, verification of IACUC approval with date, and any IACUC imposed changes. *Pending or out-of-date approvals are not acceptable.*
- **Human Subjects Education.** For grants involving Human Subjects, provide certification that each person identified under Key Personnel involved in human subjects research has completed an educational program in the protection of human subjects.
- If the project will include **human subjects research studies**, these must conform to the NIH policies on the inclusion of women, minorities, and children in study populations. Details of such studies, including a description of the population and the rationale for inclusion/ exclusion of women and minorities, must be provided to the KL2 program office before any awardees undertake such studies.
- **Financial Conflict of Interest Form.**
- Your data for inclusion in the UMCCTS **All Personnel Report:** PHS 2590 Form (page 7).

TIMELINE

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| Announcement Date | Thursday, June 22, 2023 |
| Information Session | Tuesday, July 11, 2023 |
| Letters of Intent Due | Friday, July 14, 2023 |
| LOI Finalists Notified | Friday, August 4, 2023 |
| Full Proposals Due | Wednesday, October 4, 2023 at 5:00pm EDT |
| Earliest Project Start Date | Wednesday, November 1, 2023 |

QUESTIONS?

For the KL2 program or proposal, email:

Dr. Catarina Kiefe (catarina.kiefe@umassmed.edu) - or -
 Dr. Milagros C. Rosal (milagros.rosal@umassmed.edu).

For grant preparation or submission, email:

Dr. Jan Nissly (jan.nissly@umassmed.edu).

Complete information is available on the UMCCTS website at:
<http://www.umassmed.edu/ccts/education/KL2-training-program/>.