



CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

MENTORED CAREER DEVELOPMENT (KL2) AWARD REQUEST FOR PROPOSALS

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 spectrum of translational research from discovery through pre-clinical development and first-in-human studies to implementation science with additional continuous feedback to basic science research.

Training of investigators who will make a career of innovative clinical and translational research 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,

- One award, sponsored by UMassMemorial Health Care, will focus on mentored research in health systems improvement that capitalizes on our Data Lake and associated analytics, along with expertise in systems engineering, implementation science, and health outcomes.
- Two awards will focus on enhancing faculty racial/ethnic diversity and thus will be available for funding meritorious applications from eligible scholars from racial/ethnic underrepresented minority groups. While the focus of the KL2 program is on translational research, one of the two positions may be awarded to a basic science scholar.

DEFINITIONS OF CLINICAL AND TRANSLATIONAL RESEARCH

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 **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 **Basic Science Research** as:

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

ELIGIBILITY FOR THE MENTORED CAREER DEVELOPMENT PROGRAM

- Research or health professional doctoral degree (MD, DO, PhD, ScD, DVM, PharmD).
- 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 2-3 years. Additional years of support will only be granted with special permission of the KL2 Review Committee. 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.
- Post-doctoral fellow applicants are in most cases not eligible to enter the program any earlier than their second year of post-doctoral fellowship. However, exceptional candidates with less than two years of post-doctoral training may receive special permission to apply. To apply for a waiver, please send the applicant's CV and letter from the applicant's Department or Program Chair justifying the request for a waiver to ccts@umassmed.edu no later than 5:00 PM on January 2nd, 2019.
- Cannot have previously been the principal investigator on an R01, R21, R34, or 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. KL2 awardees are encouraged to apply for individual mentored K awards; 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 three individuals – a **primary mentor** with translational research experience and a commitment to help develop the candidate's research career, a **junior faculty member** with relevant expertise as a mentor in training, and an **experienced investigator** with specific methodological and/or complementary expertise that will promote career development as appropriate. Basic science applicants are not required to have a translational researcher as their primary mentor.
- Faculty members with a Graduate School of Biomedical Sciences (GSBS) affiliation are eligible to be a mentor for KL2 scholars.
- Applicants must be US citizens, non-citizen nationals, or permanent residents.
- Mentors must be members of the UMCCTS. Membership applications can be completed by accessing the UMCCTS website and completing the online membership form at: <https://umassmed.edu/ccts/about/membership/>
- Individuals from underrepresented groups, individuals with disabilities, and individuals from disadvantaged backgrounds are particularly encouraged to apply.

TRAINING PROGRAM

Training for KL2 scholars has **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 postdoctoral scholars who do not already have an MPH degree); **3) KL2** required elements including: “Projects-in-Progress” (PIP) seminar series; a specially- designed Translational Science Lecture Series; a writing skills development course; a scientific journal internship; and an annual research retreat; **4) enrichment activities** (e.g., research seminars, workshops, rotations focused on gaining experience in all stages of drug development from discovery through early stage clinical trials) available through UMMS 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 research study design; 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; 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 1-3: Mentored research project; Submission of intramural and extramural grant applications to develop additional sources of funding.

THE KL2 PROGRAM PROVIDES

- A minimum of two years of 75% salary support for trainees up to \$120,000. The applicant’s home department is responsible for any remaining gap between \$120,000 and 75% of the salary of the scholar, as well as the remaining 25% of the scholar’s salary. NIH rules prohibit KL2 scholars from receiving salary support from other federal grants and contracts (except in the final two years of K funding, as noted at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-065.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.
- Course tuition for UMMS courses. Non-UMMS 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 \$120,000 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. NIH rules prohibit KL2 scholars from receiving salary support from other federal grants and contracts (except in the final two years of K funding, as noted at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-065.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 recipient following completion of the program.

APPLICATION PROCEDURE

STAGE 1: LETTER OF INTENT: All candidates must submit a letter of intent and supporting materials as a single .doc or .pdf document by Friday, February 15th, 2019, 5:00 PM via email to CCTS@umassmed.edu

Interested applicants are invited to attend an informational meeting on:

January 16th, 2019, 12-1PM

Med School Building S3-825 (Vascular Surgery Conference Room)

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

- **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 0.5 page); research project rationale, specific aims, and experimental design. References are not required, but if included are not considered part of the 2 page limit.
- **Applicant's NIH Biosketch** (5 page format).
- **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 requisite funds for salary support and research supplies for the candidate.
- **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? (http://grants.nih.gov/training/faq_diversity.htm)
 - a) Yes
 - b) No
 - Do you come from an economically disadvantaged background? (http://grants.nih.gov/training/faq_diversity.htm)
 - a) Yes
 - b) No

Letters of intent will be peer-reviewed. The most promising candidates will be selected to submit a full application and will be notified by March 1st, 2019.

STAGE 2: FULL PROPOSAL: Candidates who are invited to submit a full application must submit the following as a single Word or PDF document by 5PM on April 15th, 2019. Please follow the NIH format and page guidelines for K Awards (for example, the omnibus K23 - <http://grants1.nih.gov/grants/guide/pa-files/PA-11-194.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 (5 pages)
- Departmental and Mentor resources supporting the application. This includes a Departmental Support Letter (can also be mentor's letter), and **statements by 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 curriculum vitae, including list of current and former trainees; funding sources.**
- **Letters of reference:** Two letters of reference that attest to the candidate's commitment to and suitability for development as an independent researcher. Past research training, experience, and productivity should be highlighted. Do not send more than two letters of reference.
- Budget (NIH PHS 398 form pages 4 & 5 which includes budget justification)

Appendices are not allowed.

Awardees will be required to submit “Just-in-Time” information 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 (if changed from the initial submission) 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 (if changed from the initial submission), 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 subject 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.**
- Data for the UMCCTS All Personnel Report (PHS 2590 form page 7).

TIMELINE

Announcement for Letters of Intent	Friday, November 30, 2018
Letters of Intent Due	Friday, February 15, 2019
LOI Finalists Notified	Friday, March 1, 2019
Full Proposals Due	Monday, April 15, 2019
Project Start Date	May 2019

QUESTIONS

Questions regarding the KL2 program or the proposal should be addressed to the KL2 Program Leaders, Dr. John Keaney (john.keaney@umassmed.edu), Dr. Jeroan Allison (jeroan.allison@umassmed.edu), Dr. Milagros C. Rosal (milagros.rosal@umassmed.edu), or Dr. Javier Irazoqui (javier.irazoqui@umassmed.edu).

Questions regarding grant preparation or submission should be addressed to Nate Hafer, (nathaniel.hafer@umassmed.edu)

Complete information is also available on the UMCCTS website at:

<http://www.umassmed.edu/ccts/education/KL2-training-program/>