

2021 CALL FOR APPLICATIONS

KL2 MENTORED CLINICAL RESEARCH SCHOLAR AWARDS

Application Deadline: January 29th, 2021 at 5:00 PM EST

Apply [Here](#)

The Clinical Research Scholars Program is seeking applications for the 2021 KL2 Mentored Clinical Research Scholar Awards. The awards support the career development of individuals dedicated to a career in clinical investigation and who aspire to develop into future leaders in clinical research. Support is provided for three years. The Institute for Clinical and Translational Research/ Clinical and Translational Science Awards (ICTR/CTSA) provides support for the two initial years, based upon satisfactory progress, and the applicant's home division/department or UMB School provides support for the final year.

Purpose

The purpose of the KL2 is to provide support for clinical and translational research training and career development of persons in relevant disciplines and professions from the six professional schools on the UMB campus (Dentistry, Law, Medicine, Nursing, Pharmacy, and Social Work).

Research areas may include: patient-oriented research, epidemiology and behavioral studies, outcomes research and health services research. Epidemiologic and natural history studies, patient-oriented research, and clinical trials, are all possible types of research supported through this award. We support a spectrum of scientific disciplines (medicine, dentistry, nursing, social work, public health/ policy, pharmacology, statistics, psychology) that are employed by health professionals using a variety of study methodologies. Clinical research is a complex endeavor that is ideally performed by a multidisciplinary team using an integrated team approach. A multidisciplinary approach brings experts from diverse disciplines (for example, clinician, clinical researcher, clinical trialist, statistician, medicinal chemist, and pharmacologist) to address collectively a common complex problem. There is a well-recognized shortage of well-trained physicians and other health professionals performing clinical research in a rigorous, highly collaborative, team-oriented environment.

Fundamental elements of the award include: structured, core didactic coursework; training in the design, conduct, and analysis of clinical research in team settings (protocol development, preparation of IRB applications, clinical research/trial management, patient accrual, data collection, analysis and manuscript writing); conduct of a research project under the supervision of mentors and; engagement in related career development activities and seminars that include introduction to innovative methodologic approaches to translational science and regular grant-in-progress presentations.

SUBMISSION DUE DATE: January 29th, 2021 at 5 PM EST

START DATE: July 1st, 2021

Eligibility

The Johns Hopkins-University of Maryland Baltimore Clinical Research Scholars Program applicants must meet each of the following criteria:



- Research or health-professional doctoral degree or equivalent, including but not limited to MD, MBBS, DO, DDS, PhD, PharmD, JD, PsyD, DPH; Epidemiologists, behavioral scientists and nurses with clinically relevant doctoral degrees are eligible as well.
- A full-time junior faculty up to Assistant Professor for less than 5 years, at the University of Maryland Schools of Medicine, Nursing, Pharmacy, Dentistry, Social Work, or Law by the date of receipt of the award. Postdoctoral clinical fellows with a pending faculty appointment are eligible to apply. **The faculty appointment cannot be dependent upon receipt of the KL2 award.**
- At least 75% protected time available for research and training for three years. With justification, this can be reduced to 50% for those that are in surgery or surgical subspecialties. Justification will require documentation that more than a 25% clinical commitment is required in order to avoid loss of competence or credentialing in special clinical skills and approval by NCATS before appointment.
- A commitment to a career focused on clinical investigation.
- A commitment to additional training including a core didactic curriculum and either:
 - MS in an area of clinical research (e.g. Public Health, Informatics, Clinical Epidemiology, Clinical Investigation, Biostatistics, Innovation and Entrepreneurship, or Health Science) if not redundant https://www.umaryland.edu/media/umb/ictr/web-template-style-assets/UMB_MS_Certificate_Programs_update.pdf
 - Or certificate in an area of clinical research for applicants with a previous relevant MS degree.
- Identification of and support from at least one, but ideally an interdisciplinary team of UMB and potentially JHU active faculty mentor(s), established and successful in clinical investigation.
- US citizenship, permanent resident, or non-citizen national status (persons born in outlying possessions of the United States) at the time the application is submitted. Individuals on temporary or student visas are not eligible. Proof of residency may be required.
- Have NOT served as Principal Investigator on an NIH R01, sub-project of P-series program project award or U-series research grant or been recipient of any NIH K-series award (this does not include NIH Small Grants (R03) or Exploratory/Developmental (R21) grants or their equivalents).
- Must NOT have an active NIH K-series award application pending. Specifically, this means that K23 applicants may not simultaneously apply for the KL2. Will be expected to submit an independent career development by year 2.
- For additional research projects, the effort not directly committed to the K award (commonly up to 25%), KL2 award recipients may devote effort, with *compensation*, from Federal or non-Federal research projects as principal investigator, or in another role (e.g., co-Investigator), as long the specific aims of the other supporting grant(s) differ from those of the K award.

The UMB ICTR is committed to increasing the participation of women and individuals from ethnic or racial groups underrepresented in the biomedical and behavioral sciences. Such groups include American Indian or Alaska native, Asian, Black or African-American, Hispanic or Latino, and Native Hawaiian or Other Pacific Islander. Applications from women and minority candidates are encouraged. In addition, accommodations will be made to assist any individuals with disabilities so those persons who are qualified applicants can complete the program.



Sources of Support

Funding for the KL2 Scholars Program will come from the John Hopkins and UMB CTSA partnership funded by the NIH National Center for Advancing Translational Science (NCATS).

Scholar Support

- Scholars will receive up to \$110,000 plus fringe in salary support proportional to effort committed to program activities (required 75%) for up to 2 years (ongoing support is contingent upon the Scholar making adequate progress in the program and completing program requirements).
- Tuition fees for full time faculty at UMB undergoing a master's degree will be supported by UMB. Funds to help with research costs to cover related activities such as (supplies, computers/software, biostatistics services, personnel, and other project infrastructure) will also be provided upon approval to each UMB KL2 Scholar.
- Funds will be provided to help cover annual travel to attend the **required** annual Association of Clinical and Translational Science (ACTS) meeting and other National CTSA career development meetings as well as other relevant scientific meetings and research training opportunities.

Award Stipulations

The KL2 Scholar Program is a **three-year** commitment. The first two years are supported by the KL2, while the third year salary support, with at least 75% protected time for research, is provided by the nominating division/department or school. Surgical or Surgical sub specialty trainees, if receiving prior justification for 50% research effort, can continue on their prior effort into the 3rd year. Much of year one is devoted to didactic studies. Year two is devoted to the research project, any remaining academic requirements, and submission of K or other appropriate career development award. Year three is a continuation of research efforts, additional grant writing and , if needed, K or other career development award resubmission.

- Scholars are required (unless redundant) to complete structured, didactic coursework, leading to an advanced degree. Scholars are expected to maintain good academic standard, a minimum semester GPA of 3.0.
- Potential MS or Certificate programs: https://www.umaryland.edu/media/umb/ictr/web-template-style-assets/UMB_MS_Certificate_Programs_update.pdf
- Scholars are expected to submit a K23 Mentored Patient-Oriented Research Career Development Award or equivalent NIH K award application by the end of the second year
- Annual participation in the Association for Clinical and Translational Science Annual meeting is required
- Participation in **required** program activities over the three-year period of combined support – including monthly Grants-in-Progress meetings and CATALiST Seminar Series.
- Demonstration of ongoing participation in mentors' multidisciplinary clinical research team(s).
- Scholars are required to submit biannual progress reports to the ICTR and annual progress reports to the NIH
- Extensions of support or leaves of absence are possible only under exceptional circumstances



- Scholars are expected to update the program on publications, grants and awards during and after appointment

KL2 Mentor(s) Expectations

- Proposed mentors will be expected to:
 - Meet with the KL2 scholar mentee at least every 2 weeks to supervise the development and implementation of the scholar's project,
 - Provide feedback, and guide the scholar's career development,
 - Submit biannual mentor reports,
 - Attend the Scholar's annual Grant in Progress presentation, and to
 - **Participate in Mentor Skills Development Workshop(s).**

KL2 SCHOLAR APPLICATION PROCESS

Applications and ALL required documents must be submitted electronically no later than January 29th, 2021 at 5 pm. The electronic application link can be found [Here](#). You will need to log in using your UMB username and password. Please note that some items (transcripts, test score reports) may take weeks to be sent by other institutions.

Concurrent application should be submitted to the UMB Graduate School for either MS Degree or Certificate Program https://www.umb.edu/media/umb/icttr/web-template-style-assets/UMB_MS_Certificate_Programs_update.pdf (please see more information on item 4.a). A completed application must include:

1. Cover letter

2. **Personal statement** (2-3 pages) detailing accomplishments to date plus career goals and plans. This statement should specifically address:

- a. Background information relevant to the applicant's interest in clinical/translational research; we encourage projects that have a clear translational component.
- b. Long-term career goals
- c. How the KL2 award would advance these goals
- d. Need for additional training to achieve goals and which specific MS or Certificate program applicant chooses to pursue if awarded KL2 award.
- e. Interactions to date with potential mentors within the sponsoring clinical division or department including any prior or ongoing research experience and/or plans for identifying and selecting a mentor/preceptor for the program's research requirement.

3. **Research Plan** (2-5 pages) describing ongoing or proposed clinical/translational research project. Please include Project Title. Research Plan may include:

- a. *Introduction*- required for resubmissions only. One page to respond to prior critiques and describe changes in revised application.



- b. *Specific Aims* - objectives of your research project, what you want to accomplish; should be driven by the hypothesis you set out to test; make sure they are highly focused.
- c. *Background/Significance* - how your research is innovative/is from a fresh point of view/develops or improves technology; justify with background information about the field.
- d. *Preliminary Data* - may consist of your or others' publications, unpublished data from your own laboratory or from others; make sure it is clear which data are yours and which others reported.
- e. *Research Design/Methods* - describe the design and procedures in detail; provide rationale.
- f. *Literature Cited* (will not count toward page limit) - Refer to the literature thoroughly and thoughtfully but not to excess. The publications you cite need not be exhaustive but should include those most relevant to your proposed research.

Appendices are not allowed in the Research Plan.

- 4. **Plans for Proposed Advanced Training** (1-2 pages). A description of the plans for advanced training must be included. Acceptance into an advanced didactic training program in clinical research (Public Health, Informatics, Clinical Epidemiology, Clinical Investigation, Biostatistics, Innovation and Entrepreneurship, or Health Science Master's at UMB) would suffice. An alternative plan for training outside of a degree program based on individual needs will be considered for applicants with prior relevant MS degrees.
 - a. **Applicant must submit a concurrent graduate school application [HERE](#).** For questions regarding Graduate School application please email gradapply@umaryland.edu.
- 5. **Curriculum vitae** including list of publications and current/prior grant support.
- 6. **Nomination letter** written by the primary mentor and the Division/Department Director (though separate letters are acceptable). The letter should address:
 - a. Career development plans for the candidate and how the award would facilitate these plans.
 - b. Candidate's promise for a successful academic career in clinical investigation and listing of any supporting past accomplishments.
 - c. Mentor's/division's commitment to the candidate's career development, including what commitment and/or plans there are for the nominee should a KL2 Award NOT be made.
 - d. Assurance of a third year of support and dedicated research time from the division/department – a specific commitment to salary support and at least 75% effort (or justified 50% for surgery and surgical sub specialties) for research to complement the two year KL2 award, including identifying the likely source of such support (During this third year, there is no salary/stipend, tuition, research or mentor funding from the KL2 Scholar Program).
 - e. Provisions (if any) made for faculty advancement, mentoring, space and other support.
 - f. **The nomination letter must specifically state, "I/We will guarantee a third year of salary and research funds support for Dr. X with (indicate source of support) and protect their time so that at least 75% time is available for the pursuit of research, education and training activities for three years."**



7. **Proposed mentor(s) NIH formatted biosketch** including research support. Applicants without a mentor should submit a letter explaining this and outlining potential identifiable mentors.
8. **Two letters of recommendation and reference forms** from faculty, past mentors/advisors who can assess the candidate's ability. These letters are in addition to the Nomination letter and should not be written by your primary mentor or Department/Division directors.
9. **Unofficial Transcripts** from *all* degree granting academic institutions.

Regulatory Requirement/Approval

IMPORTANT! NEW, ADDITIONAL NIH NCATS APPROVAL REQUIREMENTS

For the projects funded by the CTSA, KL2 funds cannot be released without NCATS review of the project, IRB Determination letter and/or IACUC letter, and CITI training documentation. NCATS may take up to four weeks to review and approve the project. NCATS prior-approval forms and supportive documents can be downloaded from these links.

Human Subjects: <https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/prior-approval-of-planned-research-involving-human-subjects/>

Vertebrate Animals: <https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/prior-approval-of-planned-research-involving-live-vertebrate-animals/>

Review and Selection Process

Our goal is to select candidates who, with proper career development and clinical and/or translational research training, have potential to become independently funded, successful and ethical clinical investigators. A committee of faculty from the UMB Schools including a Diversity Advocate, will review applications, interview candidates and select an awardee. Decisions will be based on the strength of the application materials submitted, the overall potential of the applicant and the track record of the mentor(s).

Written Review: March

Candidate Interviews: end of March

Official Award Notification: by mid-April

Contact Us

Applicants and/or nominating sponsors are encouraged to contact the KL2 Associate Director or Program Director or UMB ICTR Director and to discuss eligibility requirement, obtain guidance about any special circumstances or discuss other aspects of the KL2 award and its terms.

Graziela Kalil, PharmD

Assistant Professor

University of Maryland School of Medicine

Associate Director, CTSA TL1 Clinical Research Training Program and

Associate Director, CTSA KL2 and Internal KL2 Mentored Clinical Research Scholars Programs

Diversity Advocate, Institute for Clinical and Translational Research (ICTR)

gkalil@som.umaryland.edu

Rose M. Viscardi, M.D.

Professor of Pediatrics and Medicine,

Director, CTSA KL2 Mentored Clinical Research Scholars Programs

rviscard@som.umaryland.edu



Christy Chang, PhD

Associate Professor

Department of Medicine

Director, Internal KL2 Mentored Clinical Research Scholars Program

Director, CTSA KL2 Mentored Clinical Research Scholars Program (starting January 1, 2021)

University of Maryland, Baltimore School of Medicine

cchang@som.umaryland.edu

Stephen N. Davis, MBBS, FRCP, FACE, MACP

Theodore E. Woodward Professor of Medicine

Professor of Physiology

Chairman, Department of Medicine, University of Maryland School of Medicine

Director, Institute of Clinical and Translational Research

Vice President of Clinical Translational Science

University of Maryland Baltimore

Physician-in-Chief

University of Maryland Medical Center

410-328-2488

sdavis@som.umaryland.edu