UNIVERSITY of MARYLAND BALTIMORE
INSTITUTE FOR CLINICAL & TRANSLATIONAL RESEARCH

2022 CALL FOR APPLICATIONS

KL2 MENTORED CAREER DEVELOPMENT AWARDS

Application Deadline: January 28th, 2022 at 5:00 PM EST

University of Maryland Institute for Clinical & Translational Research is seeking applications for the 2022 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.

This request for applications is for up to 6 new scholars from University of Maryland Baltimore (UMB) and 1 new scholar from University of Maryland College Park (UMCP) (see **Source of Support**). Support, including salary, research funds, tuition fees and travel funds are provided for two years. Based upon satisfactory progress, the scholar's department will provide support for a third year. 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.

Contents

I. Purpose of KL2

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) and University of Maryland College Park. 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.

II. Application Due Date: **January 28th, 2022 at 5 PM EST**

Start Date: **July 1st, 2022**

III. Eligibility

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, or University of Maryland College Park 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 (if awarded CTSA Award). A commitment to a career focused on clinical investigation.
- A commitment to additional training including a core didactic curriculum and either:
    - o 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
    - o 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, UMCP, 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. KL2 Scholars will be expected to submit an independent career development grant proposal 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.

IV.   Diversity, Equity, and Inclusion

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.

V.   Types of Research Proposals Accepted

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.

VI.   Source of Support

This request for applications is for two types of awards: CTSA-funded KL2 award and Internally-funded KL2 awards (see Table below).

- Funding for the CTSA KL2 Scholar will come from the John Hopkins and UMB CTSA partnership funded by the NIH National Center for Advancing Translational Science (NCATS). Faculty from <u>all six UMBprofessional schools</u> are encouraged to apply.
- Fundin g for an Internal ICTR UMB KL2 Scholar will come from each of the five participating UMB Professional Schools (Dentistry, Medicine, Nursing, Pharmacy, and Social Work) for a total of 5 Internal ICTR UMB Scholars.
- Funding for one Internal ICTR UMCP scholar will come from University of Maryland College Park.

Award Type	Number of scholars selected	Participating Schools	Support for years 1-2	Support for year 3
CTSA	1	UMB Schools of Dentistry, Law, Medicine, Nursing, Pharmacy, and Social Work	NIH National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Awards (CTSA),	Applicant's home division/department
Internal UMB	1 per school (total 5)	UMB Schools of Dentistry, Medicine, Nursing, Pharmacy and Social Work	From each school's institutional funds	Applicant's home division/department
Internal UMCP	1	UMCP	School's institutional funds	Applicant's home division/department

VII.   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 and UMCP undergoing a master's degree will be supported by UMB/UMCP. 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 KL2 Scholar. It is expected that scholars complete their master or certificate program by the end of year 2.

- 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.

VIII.   Award Stipulations

The KL2 Scholar Program is a **three-year** commitment. The first two years are supported by the KL2, while the third year of salary support – with at least 75% protected time for research – is provided by the nominating division/department or school. Surgical or Surgical subspecialty 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 another 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 or an NIH R application by the end of the second year

- Annual participation in the Association for Clinical and Translational Science 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 CTSA funded scholars are required to submit 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.

IX.   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)**.

X.   Application Process

Only one application is necessary to apply to both CTSA and Internal KL2 award. Applications and ALL required documents must be submitted electronically **no later than January 28th, 2022 at 5 pm.**

- **UMB** applicants must use their UMID to log into the electronic application link found **Here** in the ***How to Apply*** section.

- **University of Maryland College Park (UMCP)** applicants must submit a request for an electronic application **Here**

Please note that some items (transcripts, test score reports) may take weeks to be sent by other institutions.

A letter of intent is not required. However, all faculty interested in this program should contact Dr. Graziela Kalil at gkalil@som.umaryland.edu while preparing their applications.

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:

   - Background information relevant to the applicant's interest in clinical/translational research; we encourage projects that have a clear translational component.

   - Long-term career goals.

   - How the KL2 award would advance these goals.

   - Need for additional training to achieve goals and which specific MS or Certificate program applicant chooses to pursue if awarded KL2 award.

   - 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. <u>Please include Project Title.</u> Research Plan may include:

   - *Introduction*- **required for resubmissions only**. For applicants who applied in previous rounds, one page to respond to prior critiques and describe changes in revised application.

   - *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.

   - *Background/Significance/Innovation* - justify your study with background information about the field, explain how your research is innovative/is from a fresh point of view/develops or improves technology;

   - *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.

   - *Research Design/Methods* - describe the design and procedures in sufficient details to demonstrate feasibility; provide rationale.

   - 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) is expected. An alternative plan for training

outside of a degree program based on individual needs will be considered for applicants with prior relevant MS degrees.

- Applicant must submit a concurrent graduate school application HERE. Concurrent application should be submitted to the UMB Graduate School for either a MS Degree or Certificate Program. For questions regarding Graduate School application please email gradapply@umaryland.edu.

5. **Curriculum vitae** including list of publications and current/prior grant support.

6. **Formatting Guidelines**

- Font size: Must be 11 points or larger. Smaller text in figures, graphs, diagrams, and charts is acceptable, if it is legible when the page is viewed at 100%. If you are converting to PDF, some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- Font types: Arial, Georgia, or Helvetica
- Type density: Must be no more than 15 characters per linear inch (including characters and spaces).
- Line spacing: Must be no more than six lines per vertical inch.
- Text color: black
- Name of the applicant (Last name, First name) should appear in the top right-hand corner of each page.
- Page numbers should appear on the bottom right-hand corner of each page.
- Paper Size and Margins
    Standard letter paper size (8 ½" x 11").
    Provide at least one-half inch margins (½") - top, bottom, left, and right - for all pages.

7. **Nomination letter**

- Written by the primary mentor and the Division/Department Director (though separate letters are acceptable). Nomination letter should be submitted **directly from nominators** to ICTR-navigator@umaryland.edu no later than January 28th, 2022 at 5 pm. The letter should address:

- Career development plans for the candidate and how the award would facilitate these plans.

- Candidate's promise for a successful academic career in clinical investigation and listing of any supporting past accomplishments.

- 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.

- 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 subspecialties) 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).

- Provisions (if any) made for faculty advancement, mentoring, space and other support.

- The nomination letter must specifically state,

  "I/We will guarantee a third year of salary and research funding 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."

8. **Proposed mentor(s) NIH formatted biosketch** including <u>current</u> research support. <u>Applicants without a mentor should submit a letter explaining this and outlining potential identifiable mentors.</u>

9. **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. Letters of recommendation should be submitted **directly from recommenders** to ICTR-navigator@umaryland.edu no later than January 28th, 2022 at 5 pm.

10. **Unofficial Transcripts** from *all* degree granting academic institutions.

XI. Regulatory Requirement/Approval

Projects cannot start or funding be released until all required regulatory documents (IRB Determination/Approval Letters, IACUC approval letters, etc.), training certificates (CITI, HIPAA, GCP), and biosketches/resumes of all study team members are provided.

XII. IMPORTANT! CTSA KL2 awardee has additional requirements.
The KL2 awardee designated for the NIH CTSA funding mechanism has additional document requirements in addition to those listed above. The burden of documents depends on the project type. The UMB ICTR will contact you regarding the additional required documents. After receipt of the required documents and approvals, the NIH NCATS may take up to 30 days to review and approve funding release for the project.

XIII. 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 and UMCP, including a Diversity Advocate, will review applications, interview candidates, and select awardees. 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 2022
Candidate Interviews: end of March 2022
Official Award Notification: by mid-April 2022

XIV. KL2 Information Sessions: Please check *ICTR website* for dates

XV. Contact ICTR

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.

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