TRANSFORM KL2 Mentored Career Development Program
for Junior Faculty, Columbia University
INFORMATION AND APPLICATION PROCEDURES AND FORMS

PHASE I APPLICATION DUE DATE:
JANUARY 15, 2019
PHASE II SELECTED APPLICANTS ANNOUNCED:
FEBRUARY 28, 2019
PHASE II APPLICATION DUE DATE:
APRIL 1, 2019
ANTICIPATED AWARD START DATE:
JUNE 1, 2020

I. Background.
On September 29, 2006, Columbia University became one of the first twelve institutions to be awarded the new Clinical and Translational Science Award (CTSA) from the National Institutes of Health. Through the CTSA, the NIH has launched a national consortium that seeks to transform the conduct of clinical and translational research, ultimately enabling researchers to provide new and effective treatments more efficiently and quickly to patients. A key component of the CTSA at Columbia is the TRANSFORM KL2 Mentored Career Development program. The TRANSFORM KL2 award combines didactic training, mentoring, exposure to multidisciplinary research, and ongoing evaluation to prepare young investigators for careers in patient oriented research (POR).

II. Award Provisions.
With TRANSFORM KL2 support, junior investigators will participate in an integrated didactic and mentored research program, similar to an individual K23/Clinical Research Career Development Award. Awardees are required to devote at least 75% effort (or 50% effort for surgeons) towards their research. With a salary cap of $120,000, the award will provide funds to cover up to $90,000 of the individual's annual salary, and fringe on this amount, as well as funds for research expenses, travel, supplies, research assistant salary, and tuition expenses (up to $20,000 per year). The remainder of the salary, fringe, and any additional expenses is provided by the awardee's home department. Note that the amount of the award must remain consistent with NIH, University, and KL2 program policies, and therefore, may be subject to change. Individuals who enroll in a research Master's degree program and take at least 30 credits of coursework may be eligible for additional scholarships of up to $10,000 per year for a maximum of two years.

III. Eligibility Criteria.
- Applicant must be a U.S. citizen or permanent resident, and must hold a research or health-professional doctoral degree or its equivalent.
- Applicant must have a **professorial appointment** at Columbia University (tenure track or clinical track). It is acceptable to have a non-professorial title at the time of the application, so long as the applicant will be promoted to professorial rank by the time of the award (June 1); *this must be clearly indicated in the letter of support from the applicant's department chair*.

- Applicant must be able to devote a minimum of two years to the KL2 training program.
- Each applicant's department chair must provide a supporting letter guaranteeing that
    - if awarded, the scholar will devote a minimum of 75% effort (or as low as 50% for surgeons) to the KL2 research during the period of the award and that the individual will have no more than 25% time (or 50% for surgeons) committed to non-research (e.g., clinical) duties during the period of the award;
    - the individual is expected to be on faculty at least through May 31, 2022 and
    - the department will provide financial support for the remaining salary and fringe amounts. Note that the amount of the award must remain consistent with NIH policy, and therefore, may be subject to change.
- The applicant must not have been the recipient of any other K award from the NIH in the past or currently. In addition, the applicant may not have served, in the past or currently, as the PI of an R01, R29, or P50 grant award. Recipients of R03 or R21 awards, however, are eligible.

IV. Further Application and Award Details.

- Note that the typical duration of the KL2 award is 2 years, initially awarded as a one-year grant but renewable annually based on performance and renewal of the CTSA grant from NIH. Extensions beyond 2 years are possible but rare. *Please note that after 2-3 years as a TRANSFORM KL2 Scholar, individuals are still eligible for K awards from the NIH in most cases. Each NIH institute has its own policy on this issue and the institute should be consulted for clarification.*
- The KL2 program places special emphasis on multidisciplinary and interdisciplinary research (see section VII for definitions), which must be reflected in the research, training, and "team mentorship" plans. By "team mentorship," we mean that each applicant must identify **KL2 Mentors from at least two different disciplines** to supervise his/her research progress during the period of the award (see sections VII and VIII below for guidance). Additional consultants may also be named, as needed and appropriate. A proposed schedule of meeting times between the scholar and his/her mentors must be provided.
- If selected, each Phase II application must include a 5-page research proposal (page limits apply to sections A and B; instructions will be email to invited applicants only), developed in consultation with the applicant's mentors.
- **We will accept applications from individuals with doctoral-level degrees, whether or not they hold a Master's degree in patient oriented research or a related field**.
    - Those who enter the KL2 program without a research Master's degree will be required to apply **separately** to and, if accepted, complete the MS Program in Patient-Oriented Research (POR) offered through the Department of Biostatistics at the Mailman School of Public Health (MSPH). Additional information regarding the POR Master's program can be found online at: https://www.mailman.columbia.edu/people/current-students/academics/degree-requirements/ms-programs/patient-oriented-research.
    - For details on applying to the POR program, please see the MSPH application web site: https://www.mailman.columbia.edu/become-student/apply/process. Candidates who will enroll in the POR Master's program as part of their training should specify the elective courses they will choose, and how the required and elective courses in the POR will enhance their research and career plans.
    - Candidates who enter the program having already completed a patient oriented research Master's program (e.g., MS in Patient Oriented Research; MS in Clinical Research Methods; or MS in Epidemiology) will be expected to take 4-6 additional

courses related to their research interests and career development (to be described in the "plan for didactic training" as part of the application). These can be courses offered at Columbia or elsewhere and which are relevant to the applicant's research. Scholars will need to fill out a non-degree application to take courses. In all cases, applicants should describe how additional training will enhance their specific research program.

- o We also welcome applications from candidates who are currently enrolled in but have not yet completed a research Master's degree program.

- Successful completion of the 1-credit course entitled "Responsible conduct of research and related policy issues" (G4010), as well as the 2-credit course entitled "Building Interdisciplinary Research Methods" (BIRM; 89260) are required of all KL2 scholars.
- Active participation in and mandatory attendance (80% or better) at the weekly POR Career Development Colloquium is a program requirement, as well as completion of all assignments.
- Awardees will also be required to participate in at least one additional career development opportunity per year (e.g., leadership seminar, writing workshop) in addition to an externship.
- KL2 Scholars will be required to present oral progress reports 2-3 times per year and to submit a written report annually.
- Each scholar and his/her mentors must attend periodic progress report meetings, and must also provide upon request written updates on the scholar's academic career accomplishments and feedback on the program and mentorship, both during the program and throughout the scholar's career.
- Scholars must work with administrators in their home departments as well as CTSA administrators to ensure successful management of KL2 salary and funds for the costs of tuition, research expenses, travel, and supplies (up to $20,000 per year).
- All KL2 Scholars will be expected to apply for independent research funding from NIH or other agency by the end of the first year of support, and certainly no later than the middle of the second year of support.
- In order to receive a KL2 Award, scholars and their mentors must sign the "KL2 Compact" indicating their agreement to all KL2 Award requirements and expectations.

Scholars are also required to complete at least one externship. Options include:

- **Entrepreneurship Coursework.** The Columbia Biomedical Accelerator aims to catalyze the advancement of biomedical technologies by providing funding, education, resources and mentorship to interdisciplinary teams of clinicians, engineers, scientists and students working to develop solutions to clinical unmet needs, with the ultimate goal of bringing innovative research out of the lab to benefit society. Project support is expected to serve as a bridge to commercial investment, with awards granted to perform specific tasks needed to validate a commercial hypothesis (vs. a scientific hypothesis). For more information, please visit: www.columbia-coulter.org
- **Enhancing Partnerships and Productivity with Industry.** We have developed specific opportunities to provide our trainees with exposure to drug development and industry research, through engaging with industry partners (e.g. Regeneron, Merck, Janssen) that have worked closely with Columbia University investigators. We will create a day-visit program for our trainees to gain insight into aspects of drug development including discovery, validation, clinical development, medical affairs, and marketing.
- **Biomedical Entrepreneurship.** Our trainees will be required to attend 3 or more **Columbia Health Tech Assembly (HTA)** sessions and/or case competitions to learn about the process of

interdisciplinary collaboration and engagement with venture capitalists:
http://www.healthtechassembly.com/
- **Translational Therapeutics Boot Camp.** The **Translational Therapeutics (TRx) module** has developed a 6-week boot camp and additional seminar series to provide exposure to the drug development and commercialization process.
- **Other**. You have the option of proposing your own research externship. Please provide a detailed summary that addresses the following: Where and how often would you visit this externship location? Who would be supervising the externship? What are your goals for completing this externship? How would this externship enhance your current training?

V. Phase I Application.
Phase I applications are due by **5pm on January 15, 2019** The Phase I Application must include the candidate's current NIH biosketch (version D), a personal statement (maximum 1 page), an abstract of the research plan (200 words or fewer), and a proposed training plan including a mentor meeting schedule (maximum 5 pages). Each applicant must also submit three letters of reference (2 from primary mentors and 1 from the Department Chair. Please note that a Division Chief may co-sign a letter with the Department Chair.). See section VIII below for more on mentor selections.

*Applicants without a research Master's degree must concurrently apply to the POR Master's program at the Mailman School of Public Health to be considered for the KL2 program. Full-time attendance during the 2019 Columbia Summer Research Institute is required. Detailed requirements for the POR Master's program can be found online at https://www.mailman.columbia.edu/become-student/degrees/masters-programs/master-science/patient-oriented-research. Be sure to follow all of the school's instructions on applying, which can be found at: https://www.mailman.columbia.edu/become-student/apply. Applications to the POR Master's program are due **April 15, 2020** (date subject to change, so please check the MSPH website).*

> ### The KL2 Selection Committee will announce candidates selected to participate in Phase II by February 28, 2019.

VI. Phase II Application.
Applicants selected to Phase II must submit a 5-page research proposal. The research proposal should represent a well-developed scientific initiative in clinical or translational investigation. Because of page limitations, the proposal does not require the full detail of an NIH grant, but must be thorough enough to be evaluated in terms of significance, innovation, overall design, statistical approach, and human subjects issues (see the Phase II application instructions for specific KL2 instructions, modeled after NIH research grant instructions). The proposed research must meet the NIH definition of patient oriented research, so that the focus of the research can be translational, mechanistic, therapeutic, clinical trials-oriented, physiological, behavioral, or epidemiologic in nature.

Additionally, the applicant will need to fill out all required National Center for Advancing Translational Sciences (NCATS) Prior Approval documents.

VII. Emphasis on Multidisciplinary and Interdisciplinary Research.

The CTSA award, which funds the TRANSFORM KL2 program, seeks to promote multidisciplinary and interdisciplinary research initiatives. Consequently, applications that reflect a strong multidisciplinary or interdisciplinary flavor will be viewed very favorably. According to Patricia Rosenfield in her 1992 article in *Social Science and Medicine*, interdisciplinarity is "when researchers work jointly but from discipline-specific bases to address a common problem." In contrast with multidisciplinary research, interdisciplinary research suggests a more deeply integrated collaboration, and not simply working in parallel, to address a research question of interest.

VIII. KL2 Team Mentorship.

Each application must specify at least **two KL2 Mentors** from different disciplines (who may be from different schools, departments, or divisions) to oversee the candidate's progress in patient oriented research. As the ideal KL2 candidate will propose science that is interdisciplinary, the mentors should be chosen to reflect the disciplines needed to gain independence in the proposed research area. For example, a lab-based researcher and an endocrinologist might be chosen to supervise a project on early diabetes drug development. The KL2 Mentors should be chosen from the large pool of senior investigators at Columbia who have established reputations in clinical/translational research and mentorship. The primary mentor must be a member of any department at Columbia University. The KL2 Advisory Committee will review the credentials of the proposed mentors for appropriateness. Criteria used in their review will include scientific productivity, grant-funding record, and mentoring history. If the committee decides that a mentor is unsuitable, the applicant may be required to meet with CTSA program leaders to discuss how to proceed. In some instances, the KL2 Committee may recommend that a more senior mentor join the mentoring team, or propose additional mentors. Because of the outstanding cadre of clinical/translational investigators at CUMC and its affiliates, we do not expect any difficulty in identifying excellent mentors. Applicants may send specific questions on mentor selections via email to Dr. Daichi Shimbo (ds2231@cumc.columbia.edu).

A specific schedule for meetings between the scholar and mentors must be included in the application package. The strongest applications will specify frequency (e.g., weekly) and detailed team mentoring meetings in which all mentors meet simultaneously with the scholar. Meetings with other advisors/consultants are expected to take place less frequently. In addition, all KL2 Mentors must be available to report on the candidate's progress to the full KL2 Advisory Committee at meetings and symposia 2-3 times per year. Finally, written feedback and evaluations are required periodically of both scholars and mentors.

IX. Miscellaneous Issues.

- If selected as a Phase II candidate, you must present a formal budget; remember that **tuition costs come out of your annual fund** for travel, supplies, etc.
- Once selected as a Phase II finalist, your application will be submitted to NCATS for Prior Approval. Once NCATS has approved your application, you will be able to move forward through the application process. Please note that in order to submit NCATS Prior Approval documents, your research must be approved by the IRB.
- If research, non-Master's degree tuition, and other costs are expected to exceed the annual allotment of $20,000, a pledge of additional required funding from the candidate's mentors or department chair should be included in one of the letters of support.
- For guidance in choosing courses, it may be helpful to study the required and elective coursework for the MS in Patient Oriented Research (MS-POR):

https://www.mailman.columbia.edu/become-student/degrees/masters-programs/master-science/patient-oriented-research
- Appendices are not permitted.
- We reserve the right to request additional information at any point during the review process.

X. Application Procedures and Deadlines.
The application process is divided into 3 separate phases:
1. The Phase I Application and recommendation forms can be accessed at http://irvinginstitute.columbia.edu/education/research_train.html. The application is due by **5pm on January 15, 2019.** Phase I includes the application form plus all supporting documents and recommendations. ***Applicants who do not hold a research Master's degree must also submit a separate application to the Mailman School of Public Health's POR Master's program by the MSPH deadline (April 15, 2020).*** For more information on applying, please visit: https://www.mailman.columbia.edu/become-student/apply.

> **The KL2 Selection Committee will announce candidates selected for Phase II by February 28, 2019.**

2. Applicants who are invited to compete in Phase II must submit the Phase II by **9am on April 1, 2019**. The final instructions will be sent separately to invited applicants.

3. Phase II Finalists are <u>required</u> to complete NCATS Prior Approval documentation. Please note that your research proposal must have received IRB <u>approval</u> at the time of submission.

Questions? Contact Irving Institute Education Center at ctsa_edu@cumc.columbia.edu