



TRANSFORM KL2 Mentored Career Development Program for Junior Faculty, Columbia University

INFORMATION AND APPLICATION PROCEDURES AND FORMS

PHASE I APPLICATION DUE DATE:

SEPTEMBER 29, 2017

PHASE II SELECTED APPLICANTS ANNOUNCED:

NOVEMBER 1, 2017

PHASE II APPLICATION DUE DATE:

DECEMBER 1, 2017

ANTICIPATED AWARD START DATE:

JUNE 1, 2018

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 travel, supplies, research assistant salary, and tuition expenses (up to \$20,000 per year). The remainder of the salary and fringe is provided by the awardee's home department; additional salary support must come from non-Federal funds. 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, 2020; and
 - the department will provide financial support for the remaining salary and fringe amounts using non-Federal funds. 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. (After 2-3 years as a TRANSFORM KL2 Scholar, individuals are still eligible for K awards from the NIH in most cases. Note that 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 POR required and elective courses 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.
- 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 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 (\$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. Please indicate your preference in the application. Options include:

- **Applications in Public Health**, in partnership with the **New York City Department of Health and Mental Hygiene**. We will collaborate with the NYC DOHMH to create additional interdisciplinary externships with a focus on public health for our trainees. Specifically, faculty and project leaders at the NYC DOHMH will identify their projects that are suitable for pre-doctoral trainees on a yearly basis, through a process similar to how internship opportunities are identified and collated within the existing Health Research Training Program (H RTP) at the NYC DOHMH. Previous projects have included topics such as "Evaluation of Cardiovascular Interventions in New York City" and "Using Health Information Technology to Improve Population Health".
- **Entrepreneurship Boot Camp**, in partnership with the **Columbia-Coulter Program**. We are teaming with the Columbia-Coulter Translational Research Partnership, an interdisciplinary, cross-school program aimed at catalyzing biomedical innovation by providing mentoring,



project management, and funding to clinician-engineer teams. The program is led by the Department of Biomedical Engineering at Columbia's School of Engineering, in collaboration with the Departments of Surgery, Orthopedic Surgery and Radiology at CUMC, and Columbia Technology Ventures, the university's technology transfer office. Teams (which must include an engineer and a practicing clinician) identify an important clinical health problem and a potential technological solution. Throughout the spring semester, applicant teams participate in a "boot camp" course aimed at helping them delve into two fundamental questions: 1) Does their envisioned technology address a true unmet clinical need? 2) Does a business opportunity exist? The course also simultaneously supports their preparation of a full proposal and pitch for project funding, based on commercialization potential and clinical impact. Select teams advance to a final stage of the competition, working closely with business, technical, legal, and regulatory experts to define commercially-relevant hypotheses and design a work plan, budget, and timeline for research to support technical and business proofs-of-concept.

- **Quality Improvement in the Hospital Setting**, in partnership with the **New York Presbyterian Hospital (NYP)**. We will collaborate with the Value Institute at NYP, a recently created Institute focused on data-driven quality improvement initiatives, to provide externship opportunities for quality improvement and implementation science for our trainees. Recent NYP projects led by Dr. Karina Davidson's group include "Implementation of an ED Dashboard to Improve Patient Flow" and "A Systematic Review of Interventions to Improve Patient Satisfaction Surveys". The trainees will work under the guidance of Dr. Davidson and will also collaborate closely with NYP leadership and staff, to conduct specific QI projects and evaluations that will result in deliverables including reports to NYP leadership, publications/presentations, and potential subsequent grant applications.
- **Enhancing Partnerships and Productivity with Industry**, in partnership with **Merck, Regeneron, and Janssen**. We have developed specific opportunities to provide our trainees with exposure to drug development and industry research, through engaging with industry partners that have worked closely with Columbia University investigators. Specifically, working with Dr. Daniel Bloomfield, VP of Clinical Research and Cardiovascular Therapeutic Area Head at Merck Research Laboratories, we will create a day-visit program to Merck for our trainees to gain insight into aspects of drug development including discovery, validation, clinical development, medical affairs, and marketing. We are also coordinating a similar day-visit program with Regeneron, a leading biopharmaceutical company located in nearby Westchester County, NY. We will also work with Janssen Pharmaceutical Companies, through Dr. Hussein Manji, Global Head of Neuroscience Therapeutic Area, and Dr. Dashyant Dhanak, Global Head of Discovery Sciences, to create joint a program to collaborate for research and education. Through a joint steering committee, this program will allow Janssen scientists to participate in our training activities, serving as guest lecturers as well as mentors and supervisors for our trainees.
- **Biomedical Entrepreneurship**, in partnership with **Columbia Health Tech Assembly (HTA)** (<http://www.healthtechassembly.com/>): The mission of HTA is to foster an environment of collaboration between clinicians, engineers, and entrepreneurs across the 2 Columbia campuses. It is co-directed by a team of three graduate students: one from the medical school, one from the engineering school, and one from the business school, with guidance from a faculty advisor, Dr. Adler Perotte, a physician who completed a postdoctoral fellowship and Master's degree in Biomedical Informatics. HTA runs monthly sessions where nascent ideas can be evaluated for their real-world applicability (clinicians and scientists), feasibility (engineers), and market potential (business leaders and entrepreneurs). HTA spurs the development and



refinement of new ideas and provides guidance on concrete steps towards turning those ideas into successful products and companies. We have partnered with HTA to provide logistical support, space, and access to young investigators on the CUMC campus. Our trainees will be required to attend 3 or more HTA sessions and/or case competitions to learn about the process of interdisciplinary collaboration and engagement with venture capitalists.

- **Translational Drug Development**, partnering with the **Translational Drug Development module**, headed by Serge Cremers, PhD: We will offer 3-month rotations in multidisciplinary translational drug development teams to trainees with clinical and basic science backgrounds. These rotations will provide hands-on exposure to the drug development process through attending team meetings and learning about the laboratory methods for a specific project. This rotation is thus a unique opportunity to experience first-hand interdisciplinary Early Phase Drug Development within academia.

V. Phase I Application.

Phase I applications are due by **5pm on September 29, 2017**. The Phase I Application must include the candidate's current NIH biosketch (version D), a personal statement, an abstract, a proposed mentor meeting schedule, and a proposed training plan. Each applicant must also submit three letters of reference (2 from primary mentors and 1 from the Department Chair). See section VIII below for more on mentor selections.

Please note: 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 2018 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, 2018** (date subject to change, so please check the MSPH website).

The KL2 Selection Committee will announce candidates selected to participate in Phase II by November 1, 2017.

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 overall design, significance, 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 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. Melissa Begg (mdb3@columbia.edu) and 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 frequent (e.g., weekly) 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, the 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.

- There is no need to present a formal budget; just be sure that you will have enough funds to do what you have planned, and remember that **tuition costs come out of your annual fund** for travel, supplies, etc.
- If research, non-Master’s degree tuition, and other costs are expected to exceed the annual allotment of \$25,000, 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 2 separate phases:

1. The Phase I Application can be accessed [here](#). The recommendation form can be found [here](#). The application is due by **5pm on September 29, 2017**. Phase I includes the application form plus all supporting documents. ***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, 2018).*** 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 November 1, 2017.**

2. Applicants who are invited to compete in Phase II must submit the Phase II Application by **5pm on December 1, 2017**. The final instructions will be sent separately to invited applicants.

Questions? Contact Sarah Oldham at smo2127@cumc.columbia.edu or 212-304-5550.