TRANSFORM KL2 Mentored Career Development Award
Information and Application Procedures and Forms

APPLICATION DUE DATE:
MONDAY, JANUARY 10, 2025 BY 5 PM
EARLIEST ANTICIPATED AWARD START DATE*:
JUNE 1, 2025

*By applying, you are confirming that you are able to start by this earliest date. Please discuss with your department/division and let us know if there are any issues with your start date being as early as June 1, 2025

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).

The Irving Institute for Clinical and Translational Research is pleased to announce a request for applications for the KL2 Mentored Career Development Award at Columbia University Irving Medical Center.

Current KL2 program directors
Dr. Daichi Shimbo (ds2231@cumc.columbia.edu)
Dr. Jeanine Genkinger (jg3081@cumc.columbia.edu)

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 including research assistant salary, tuition expenses, and travel (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 the Master of Science in Patient Oriented Research (MS/POR) degree program may be eligible for additional scholarships, which will be decided at the time of MS/POR application review.

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 or non-tenure 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 (Assistant Professor) by the time of the award (June 1); *the intent for the applicant to be Assistant Professor at the time of the award must be clearly indicated in the letter of support from the applicant's department chair and may not be conditional on receipt of the KL2 award*.

- 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 with a professorial appointment throughout the two years of funding, 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 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 KL2 awardee performance. Extensions beyond 2 years are possible but rare. *Please note that as a 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 as well as the allowed duration of the subsequent NIH K award and the specific NIH institute should be consulted for clarification.*
- **In fiscal year 2025, all KL2 scholars will be awarded one year of support as our current grant ends on May 30, 2026. At that time, the KL2 award is being phased out and replaced with a K12 by NCATS. The Irving Institute will transition to the K12 on June 1, 2026, pending our successful receipt of the grant proposal submitted in May 2025. While we do not anticipate substantial changes to the support and structure provided by this award after the transition, scholars transitioning to the K12 for their second year of support may experience delays in funding availability, may be asked to submit additional paperwork, and may have different training requirements in year two as required by NIH/NCATS guidance for the new mechanism.**
- The KL2 program places special emphasis on interdisciplinary team science research, which must be reflected in the research, training, and "team mentorship" plans. By "team mentorship," we mean that each applicant must identify at least **two KL2 mentors each from different disciplines** (preferably from different departments and/or schools) to supervise his/her research progress during the period of the award. Additional mentors as well as consultants may also be named, as needed and appropriate. A proposed schedule of meeting times and purpose of each meeting between the scholar and his/her mentors must be provided.

V. KL2 Award Requirements and Expectations

- To receive the KL2 Award, scholars and their mentors must sign a "KL2 Compact" indicating their agreement to all KL2 Award requirements and expectations.

1. All KL2 scholars must **complete** a 2-year research Master's degree (the MS in Patient Oriented Research – MS/POR), which includes the Columbia Summer Research Institute, unless the scholar has already completed comparable advanced training in research methods. These latter scholars must request a waiver from the program directors (Drs. Daichi Shimbo and Jeanine Genkinger) **prior to the submission of the application.** Please contact the program staff at ctsa_edu@cumc.columbia.edu to request a waiver. The program directors will review the prior training or degree's program content to make a waiver determination. Applicants who need to complete a MS/POR degree, will be required to apply **separately** to and, if accepted, complete the MS/POR degree offered at the Mailman School of Public Health (MSPH).

   - Additional information regarding the MS-POR program can be found at: https://www.mailman.columbia.edu/people/current-students/academics/degree-requirements/ms-programs/patient-oriented-research.
   - For details on applying to the MS/POR program, please see the MSPH application web site: https://www.mailman.columbia.edu/become-student/apply/process.

2. For KL2 scholars excused by the program directors from taking the MS/POR due to having previously completed comparable advanced training, the following are course requirements:

   - Successful completion of POR Career Development Colloquium (P8103)*
   - Successful completion of Team science: Building Interdisciplinary Research Models (89260)*
   - Successful completion of Responsible Conduct of Research & Related Policy Issues: Responsible Conduct of Research and Related Policy Issues (G4010) or Protection, Participation, and Prevention: Research Ethics and Public (P9630)
   - Successful completion of Funding and Grantsmanship for Research and Career Development Activities (M9780)*
   - And successful completion of a <u>minimum</u> of four course electives relevant to the KL2 scholar's research.

     *If you have already taken these courses, please let the KL2 program staff know and note this in the application.

- **For all KL2 scholars, the following are additionally required:**
  - **Weekly:**
    - Attend POR Career Development Colloquium sessions
  - **Monthly:**
    - Attendance at monthly KL2 scholars meetings – presentation of research progress required at 2-3 meetings per year
  - **Annually:**
    - Participation in at least one additional seminar or workshop (e.g. precision medicine; interdisciplinary and team science training; design, innovation, and entrepreneurship; data sciences; statistical genetics/genomics, other) <u>per year</u>
    - Meeting with KL2 program directors to review progress toward fulfilling award requirements
    - Submission of written Individual Development Plan (IDP) and accompanying progress reports and evaluations at least **twice** annually
    - Completion of team science leadership competency assessment
  - **During funded period:**
    - Execution of clinical and translational research aims
    - Participation in Columbia's symposium on rigor and responsibility

- o Participation in **at least one** Association for Clinical and Translational Science (ACTS) meeting (either in-person in Washington, DC or virtually, if there is no in-person option) throughout the duration of the award
- o Participation in a Writing Accountability Group during the first summer after appointment (cross-institutional effort) if not participating in CSRI and in the second year after appointment if participating in CSRI
- o Participation in one externship opportunity during the funding period (possible externship opportunities are listed below)
- o Periodic updates on KL2 scholar's academic career accomplishments and feedback on the program and mentorship, both during the program and throughout the scholar's career
- o Attendance of the KL2 scholar and his/her mentors at periodic progress report meetings
- o Completion of any requested NIH required documentation (e.g. progress reports, appointment and termination forms, career updates, adherence to the NIH Public Access Policy, etc.)
- o Management of KL2 funds for the costs of research expenses, tuition, and travel.
- o Scholar's submission of application(s) for independent research funding (as a PI) to NIH or other agency (which should occur by the end of the first year of support, and certainly no later than the middle of the second year of support)

Description of Possible Externships

Please note that for those KL2 scholars interested in community-based participatory research (CBPR), the CBPR externship (described below) is required.

- **Accelerate,** one of two Irving Institute CTSA Program hub optional functions, is focused on life sciences commercialization. This includes our disease agnostic Translational Therapeutics (TRx) accelerator and collaborations with our partners in the Cancer Center's Accelerating Cancer Therapeutics (Cancer Therapeutics) and Biomedical Engineering's BioMedX device accelerator. Starting in 2019, these accelerators combined their educational efforts to form an integrated life science lab-to-market boot camp that is available to KL2 scholars as an externship. The boot camp is organized by faculty and entrepreneurship experts from the Columbia Technology Ventures Office (CTV), the Irving Institute, the Cancer Center, and Biomedical Engineering in collaboration with the Business and Engineering Schools. Twelve sessions cover key aspects of drug and device therapeutic development and commercialization including: identifying clinical unmet need; patent and licensing; business models and financing; and hands-on pitch training. Boot camp attendees also include faculty-led teams that have applied to the accelerator pilot award programs, business MBAs, and engineering graduate scholars that register for credit. In this externship, scholars work with Innovation Teams comprised of a project manager (PhD-level fellows training with CTV), industry consultants, a licensing officer, directors of relevant Columbia cores, and scientific advisors for hands-on exposure to the drug and device development process. During the boot camp, teams apply concepts covered during the lectures and prepare weekly presentations for breakout interactive sessions and then a full proposal that incorporate all course topics. A subset of teams are invited to pitch before of a panel of industry and venture capital judges, and KL2 scholars have an opportunity to participate in the pitch day. This rotation allows scholars to participate in teams, which include faculty leads and business mentors, that develop a scientific and commercialization strategy for a translational project with potential impact on market and on patient care.
- **Columbia's Health Tech Assembly** (**HTA**) aims to foster an environment of collaboration between clinicians, engineers, and entrepreneurs across Columbia. It is co-directed by a team of three graduate students, one each from the medical, engineering and business schools, with guidance from a faculty advisor, Dr. Adler Perotte, a faculty 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 how to turn those ideas into successful products and companies. HTA provides logistical support, space, and access to young investigators at Columbia. KL2 scholars who sign up for this externship are required to attend three or more HTA sessions to learn about the process of collaboration and engagement with venture capitalists.

• **Community-based participatory research (CBPR).** Our Community Engagement Core Resource **(CECR)** administers the annual CBPR Scholars and Awards Program, which is a two-part program that offers structured training and practical experience in CBPR. Participants begin their training with the "Introduction to CBPR" course, which provides an overview of the fundamental concepts and components of CBPR methodology and acquaints participants with strategies for developing academic-community partnerships. Working in academic-community partnered pairs, participants co-develop a pilot research proposal that they submit to the Irving Institute for CBPR pilot project funding consideration.

• In collaboration with Ms. Schultz (Director of Entrepreneurship Programs at Columbia's Engineering School), the annual **National Science Foundation (NSF) NYCRIN I-Corps Short "Start Me Up Bootcamp"** is available as a KL2 externship. The short experiential course begins with an in-person two-day kickoff workshop where teams learn about the Business Model Canvas, a hypothesis-testing methodology, and customer discovery interviews to explore if there's a viable market fit for their product or idea. At the end teams present their findings based on customer interviews and learn about next steps with NSF I-Corps during an in-person closing session. Upon completion, teams are eligible to apply for the NSF I-Corps Teams program.

• **Customized externships tailored to each scholar's career development.** Working with individual scholars, we have developed customized externships tailored to the scholar's interests, values, and career development (identified from the IDP). Criteria for these externships include:

> (1) the training is based on experiential rather than didactic learning; and
> (2) the training is new and cannot be accomplished in mentors' laboratories; and
> (3) duration of the externship is at least three days. All customized externships need prior approval from the program directors.
>
> **If you would like to propose a customized externship, please include a summary of your proposed externship in the application. 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?**

VI. Application

Applications are due by **5 PM on January 10, 2025.** The Application must include the following:

- Curriculum Vitae
- Candidate's current NIH biosketch (*https://grants.nih.gov/grants/forms/biosketch.htm*)
- A research personal statement (maximum 1 page)
- An abstract of the plan for the proposed study (maximum 250 words)
- A proposed training plan (maximum 5 pages) including rationale for research training, description of the mentors and mentorship team including mentor-scholar meeting schedule, integration of training components including required and elective coursework (see above), and potential externships.
- Each applicant must also submit three letters of reference (2 from the primary mentors and 1 from the Department Chair). Please note that a Division Chief may co-sign a letter with the Department Chair. Applicant may upload or letters can be emailed directly to ctsa_edu@cumc.columbia.edu
- Research proposal (maximum 5 pages)*: 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, approach (overall design, statistical approach, and human subjects issues).
- Academic Transcripts: Graduate and/or medical school transcripts. Please note for purposes of this application, unofficial copies are acceptable, but when applying to the Master's Degree program, you will need official transcripts from each school.
- Budget proposal: Short, approximate budget showing how you anticipate using your $16,500 in research funds each year. You will have an opportunity to update this if awarded.

Applicants must also apply to the MS/POR program at the MSPH to be considered for the KL2 program (see above URL) unless they have received a waiver. Full-time attendance during the Columbia Summer Research Institute, which is part of the MS/POR program is required. *Applications to the MS-POR program are due **April 1, 2024** (date subject to change, so please check the MSPH website). Applicants do not need to separately apply to* the Columbia Summer Research Institute (which can be taken without entering the MS/POR program).

All applicants selected as finalists after review will be asked to complete an interview with their proposed mentors and the KL2 Directors. You may be asked questions about your proposed research, training plan, roles of your mentors, the dynamics of your research team, your career goals, or any other information related to the KL2 application, mentored research project, and didactic training. This interview will be the final stage of the application before award decisions are made, so it is important that both mentors are in attendance with the applicant.

Once an applicant has been selected as a finalist, the applicant will need to submit National Center for Advancing Translational Sciences (NCATS) Prior Approval documents. Applicants cannot be funded and start the TRANSFORM KL2 Mentored Career Development program without NCATS Prior Approval.

VIII. Emphasis on Interdisciplinary Research

The CTSA award, which funds the TRANSFORM KL2 program, seeks to promote interdisciplinary research initiatives. Consequently, applications that reflect a strong interdisciplinary training and research approach 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.

IX. KL2 Team Mentorship

Each application must specify at least **two primary KL2 mentors** from different disciplines (who may be from different schools, departments, or divisions) to oversee the candidate's progress in patient-oriented research.

Additional mentors are allowed. 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. It is strongly recommended that both of the primary mentors are located at Columbia University. If one of the primary mentors is located outside of Columbia, then a strong rationale and feasible plan for mentors and project-related meetings needs to be provided. The KL2 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 KL2 program directors to discuss how to proceed. In some instances, the KL2 Committee may recommend that a more senior mentor or mentor from a specific discipline join the mentoring team. Because of the outstanding cadre of clinical/translational investigators at Columbia University and its affiliates, we do not expect any difficulty in identifying excellent mentors. Applicants may send specific questions on mentor selections via email to the program directors.

A specific schedule for meetings and content of the 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 investigators (i.e. 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 KL2 Committee at meetings 2 to 3 times per year. Finally, written feedback and evaluations are required periodically of both scholars and mentors.

X. Miscellaneous Issues

- If selected as a finalist, you must present a formal budget; remember that tuition costs come out of your research funds.
- Once selected as a finalist, your NCATS Prior Approval documents will be submitted to NCATS.
- If research, non-MS/POR degree course 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.
- Appendices are not permitted.
- We reserve the right to request additional information at any point during the review process.
- **MS/POR Ways to Pay Tuition:**
  1. Reduced Employee Tuition Rate: For those completing the MS-POR, a reduced employee tuition rate is available that will reduce your tuition by 35%. The Program does not cover non-credit courses; course, lab or other school-specific fees; textbooks; housing fees; or tuition charged for auditing courses.
  2. Tuition Exemption or Reduced Rate Tuition: After completing two consecutive years of service at Columbia, tuition exemption will cover the cost of one course per term (up to three per year) for those enrolled in graduate degree programs or one course per academic year for non-degree students.
  3. KL2 funding: $6,000 per year is earmarked for tuition from your KL2 funds. Additional funds from your TRE may be applied toward tuition if you do not need to utilize all of it for research expenses. Any funds beyond the $6,000 should be requested in advance and approved by KL2 program director, Dr. Daichi Shimbo, as well as TRANSFORM Program Manager, Harley Lynch.
  4. MS-POR Scholarships: In some cases, scholarship funding is available directly from the Mailman School of Public Health through the MS-POR program. After being accepted to the program, leadership will meet to determine scholarship availability.
  5. Irving Institute Scholarships: For those enrolled in the MS-POR with additional financial need after all of the above have been considered, some additional scholarship funding may be available through the Irving Institute.

* **Guidelines for the Research Proposal**
The research proposal should be organized as follows (modified from PHS SF424 instructions):

- Specific Aims (1 page). State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
- Research Strategy (4 pages)
    - Significance. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
    - Innovation. Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches, or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methods, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
    - Approach. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how data will be collected, analyzed, and interpreted. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. Describe any strategy to establish feasibility and address the management of any high risk aspects of the proposed work. Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in humans. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. Finally, describe your approach to rigor and reproducibility.

Human Subjects Section (no page limit). For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children.