KL2 Mentoring and Project Oversight

Each awardee will have at least two mentors — a research mentor, who serves as a guide for their research project, and an academic/career mentor, who provides career/academic oversight and professional advice. The KL2 program director will assign the academic/career mentors. Mentors are accomplished investigators in clinical and translational research with a history of success in training new investigators and fostering their success as independent researchers.

Eligibility

We encourage applicants from all health disciplines who meet the following criteria:

- Must be a U.S. citizen or permanent resident by the application deadline (those with visa status are not eligible to apply)
- Junior faculty in the UTL, MCL or NTLR line
- Must hold a research or health-professional doctoral degree
- Must be able to commit 75 percent of professional effort to the program (surgeons may commit as little as 50 percent time).
- Must ensure the remaining funding (25%) will come from a non-federal source
- Must not be or have been a principal investigator on an NIH R01, or a project leader on a sub-project of a Program Project (P01), Center (P50, P60, U54), mentored career development grant (K23, K08, K01, etc.)
- Must not have a current application for another mentored K award (e.g. K23, KO8) submitted or under review
- Must be pursuing a career path and proposed program in human/translational research

Terms and Conditions

Data Safety and Monitoring of Clinical Trials

- In accordance with the NIH’s policy on data and safety monitoring of clinical trials NIH Grants Policy Statement (Part 11, Chapter 4 http://grants.nih.gov/grants/policy/nihgps.pdf), the grantee must submit a data and safety monitoring plan for review and approval.

Prior Approval of Delayed Onset Research Involving Human Subjects and Live Vertebrate Animal Subjects:

- Prior to the start of the KL2 award period, all scholars that conduct research with animal and/or
human subjects’ research are required to obtain prior approval from the National Institutes of Health. Prior approval must be submitted 30 days prior to proposed implementation of the research project.

- **Human Subject Projects Documentation Required:**
  - Provide the IRB-approved research protocol (e-protocol application is not considered a research protocol)
  - IRB-approved informed consent, verbal consent transcript, assent and parental permissions documents, or documentation of IRB waiver, if applicable
  - Summary of request and line item budget for the specific aspects of the proposed study that will be supported by NCATS funds
  - Summary of parent study, if applicable
  - NIH Biosketches for Study Principal Investigator (PI), KL2 Scholar, and each Key Personnel involved in the proposed study
  - Institutional letter attesting to Human Subjects Protection Training (i.e., CITI Training Record) completed by the KL2 Scholar, Research Mentor and study Key Personnel

- **Animal Projects Documentation Required:**
  - Complete the NCATS Prior Approval Live Vertebrate Animals Form (form to be provided)
  - Provide research/scientific protocol
  - Provide APLAC/IACUC approval letter
  - NIH Biosketch for KL2 Scholar and Research Mentor

**Non-Human or Animal Subjects Research Projects**
- If the KL2 research project does not require IRB or APLAC approval, submission to the IRB to request a Non-Human Subjects Determination is required. To learn more, see here: [https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers](https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers).

- In order to begin the KL2 research project, scholars will need to provide the following documentation:
  - Determination Letter from the IRB
  - Research/Scientific Protocol
  - NIH Biosketch for KL2 Scholars and Research Mentor

**ClinicalTrials.gov**
- If applicable, the clinical trial must be registered on ClinicalTrials.gov.

**KL2 Application Requirements**
- **Candidate Personal Statement** (education, career experience, short- and long-term goals, reasons for applying to the KL2 program and how it will further professional objectives). Limit your response to 800 words.

- **Research Plan** (Limit the total of the following subsections, excluding references, to 1,600 words):
o Structured Abstract (title, background, research question, study design, methods, outcome measures, potential implications of work and innovation)

o Overall Research Question(s) and Specific Aims

o Background / Significance

o Preliminary Data (if relevant) and feasibility assessment: If the project is in the early stages of development, describe any strategy to assess feasibility, and address the management of any high-risk aspects of the proposed work.

o Approach / Methods (including key measurements, primary outcome measures and analytic plan)

o Nature of Originality / Innovation

o Potential Implications / Contribution of Work

o Research Timeline, with key progress benchmarks

o References (not included in the word count)

• Current Curriculum Vitae

• Research Mentor’s NIH Biosketch

• Signed Letter of Support from the department chair or division chief guaranteeing 75-percent protected time to pursue the educational and research goals of the KL2 program. The divisional/departmental letter of support must specifically attest that the trainee is able to accept KL2 funds toward the entire 75% of their research effort and that they do not hold any concomitant federal support.

• Current and Pending Funding Support information from all sources (external and internal)

• OrcID (Open Researcher and Contributor Identification) is a unique digital identifier meant to connect researchers with their science contributions over time and across changes of name, location and institutional affiliation. There is no cost to register. This ID will be linked to our eRA Commons profile. https://orcid.org

Please Note: Prior to the start of the KL2 award period, all scholars that conduct research with animal and/or human subjects research are required to obtain prior approval from the National Institutes of Health.

Contact

Please send questions on the above guidelines and application process to researchoffice_training@stanford.edu