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NUCATS Clinical and Translational Sciences Institute

Mentored Research Career Development Program in Clinical and Translational Science (K12, formerly KL2) Request for Applications: Information Session

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Introduction to the NUCATS K12 Program

K12 Program – Introduction

- Important focus of NUCATS
- Objective
  - To support research training of investigators needed to drive future innovation and effective clinical and translational research

K12 Program – Introduction

- Accomplishing this objective through K12 awards
  - Robust mentoring teams to assess educational needs of individual K12 awardees (Scholars) through the award period
  - Personalized career development opportunities, including coursework, peer mentoring, career guidance, (next) grant development support
  - Networking with Scholars from other CTSAs

K12 Program – Introduction

- Accomplishing this objective through K12 awards
  - K12 Advisory Committee oversees each Scholar's research training activities
    - Includes members from diverse backgrounds and areas of expertise
    - Supports development and monitoring of each Scholar's Individual Career Advancement Plan
    - Identifies novel opportunities and approaches to career development, personalized to each Scholar

K12 Program – Overview

- Accept applications from early-stage investigators pursuing a clinical or translational science research career and wishing to receive additional mentored research experience
- Provides support for up to two years; applications should cover a training period of two years
- Research career development activities over the two years must be detailed in addition to the mentored research project
- It is expected that Scholars will have made significant progress toward the submission of an individual K award application or an R01 or equivalent grant by the end of the first year of K12 funding.
- *This program occupies a unique "pre-K" niche in career development opportunities.*

K12 Program – Provisions of the Award *(RFA for details)*

- Salary support to protect 75% of a Scholar's full-time professional effort for training and clinical or translational research activities
- Up to $35,000 per year to support
  - Tuition and fees related to career development
  - Research expenses (to supplement those provided by Mentor)
  - Scholar travel
  - Statistical services
- Research Design Analysis Methods Program (RAMP) Mentor Support: additional 1-2 mentors with expertise personalized, according to the Scholar's needs

NIH Research Training Opportunities

researchtraining.nih.gov/

K12 Program – Eligibility

- *NU, NUCATS, and the K12 program are committed to supporting individuals early in their career trajectory and to creating, sustaining, and nurturing a diverse and inclusive campus community.*
- *Scholars from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems.*
- *Individuals belonging to groups that have been traditionally underrepresented in biomedical, clinical, behavioral, and social sciences (e.g., certain racial, ethnic, and gender minorities and individuals from disadvantaged backgrounds and individuals with disabilities) are strongly encouraged to apply to this program.*

K12 Program – Eligibility

- Include a clinical or translational project that involves human participants, human specimens, or human data, with the goal of improving the health of individuals or the public
  - Among lab-based scientists, applicants who seek a career path of translational work involving humans are particularly encouraged.
- Hold a research or health-professional doctoral degree or its equivalent, including but not limited to MD, DO, and Ph.D
  - Candidates from Northwestern University, including those from outside the Feinberg School of Medicine, are encouraged to apply.
- Have a full-time faculty appointment at the time of being awarded
- At the time of the application, be either a postdoctoral fellow, Instructor, or in the first 5 years of your first faculty appointment as Assistant Professor or Research Assistant Professor
  - Individuals who at the time of the application have been Assistant Professors/Research Assistant Professors for more than 5 years and those who are Assoc. Professors or Research Assoc. Professors are not eligible to apply.

K12 Program – Eligibility

- Be a U.S. citizen or permanent resident
- Commit 75% effort (or as low as 50% for procedure intensive specialists)
- Have mentors with sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of the K12
- Not be or have been a PI on an NIH R01-funded project or a project leader on a funded sub-project of a program project (P01) or center (P50) grant
- Not be or have been a PI on a PHS or non-PHS peer-reviewed research grant that is over $100,000 direct costs per year
- Former or current PIs of NIH Small Grants (R03), Exploratory/Developmental Grants (R21), or SBIR/STTR (R43, R44) grants are eligible

K12 Program – Eligibility

- At the time of their appointments, K12 Scholars must not have pending (or awarded) an application for any other PHS mentored career development award (e.g., K07, K08, K22, K23) that duplicates any of the provisions of the K component

Therefore,

- To be eligible to submit a K12 application in 2025, applicants may not submit an individual K application for the February 12, 2025 or March 12, 2025 deadlines.

Utility of the K12 Process

- If the K12 application is not successful, K12 application review critiques can be used to enhance an individual NIH K application in time for the next individual K deadlines – June 12, October 12

2024 – 2025 RFA Timeline

Action Items	Timeline
Release RFA	October 1, 2024
K12 Info Session	November 5, 2024
Letter of Intent due	February 3, 2025
Updates to Letter of Intent due	March 3, 2025
Full applications due	March 3, 2025
Application materials assigned to reviewers	Early March 2025
Reviews due	Early April 2025
Review panel convenes	Mid/Late April 2025
Finalists' interviews	Early May 2025
Scholar selection	May 2025
Notification of decisions with critiques	May 2025

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Developing a Successful K12 Application

Writing a successful proposal takes time

- Development of project starts well in advance of writing proposal
  - Start with a literature search and progress to discussions with others
  - Project development is not done through sitting in a room by yourself
- During time set aside for proposal preparation, be ready for iterative process
  - Protected time for writing and rewriting is key
  - In addition to internal review, consider external review
- A K proposal is as much about career development as it is about the science
  - The two are inextricably connected
  - All elements of the proposal should be integrated

Biosketches

- Opportunity to highlight
  - commitment to research and research training and to academic pursuits
  - prior experience in the field
  - familiarity with proposed tools
  - mentoring experience of mentors and mentor’s relationship with applicant
  - presence of right collaborators

Specific Aims

1 page

- Single most important page in grant
  - Tells “What are you going to do”
  - All other sections are foreshadowed in it
  - Spend a long time on it but don’t box yourself in because of Aims
  - As research strategy evolves, come back and edit the Aims
  - Multiple screens facilitate simultaneous review of Aims and other sections to ensure consistency and integration

Specific Aims

1 page

- Start with “Broad Goals”
  - Big picture that addresses Significance in general
- Proceed to your entry into problem and defend with rigor of prior research
  - More focused way to address Significance
- Briefly tell Reviewers your overarching hypothesis and what you will do
  - This gets at Approach
- Follow with precise Aims
  - To define, elucidate, identify
  - Specific hypotheses, declarative statements with directionality
- Avoid descriptive Aims if possible and Aims that are dependent on each other

Proposal

8 pages

- Reviewing prior successful applications is helpful but make yours unique
- Avoid generalizations that could apply to any young investigator
- Make Reviewers believe you
  - Integrate with other sections of application
  - Tangible specifics (easiest when activities ongoing)
- Think like a Reviewer
- Be clear: In thinking, hypothesis generation and writing
- Use formatting to underscore your clarity

Candidate's Background

1 page

- Tell your story and make it unique
  - What made you interested in a research career?
  - Why this specific area?
  - Brief highlights of prior academic productivity
  - If changing research direction, explain why
  - Provide specifics about accomplishments with a specific eye to showcase commitment to research career development and passion for scientific area

Career Goals and Objectives

1 page

- Outline your short and long-term goals
  - What is preventing you from writing your individual K or R grant?
  - What competencies, skills do you need to advance to independence?
  - Map the career development skills to the gaps you need filled and to current project
  - Let the reviewers envision that there are multiple follow up studies that you can lead following this submission
- Make use of Tables, Charts and Timelines to make it easier on Reviewers

Career Development Plan/Career Goals & Objectives/ Mentor(s) Plan to Provide Mentoring

2 pages

- Name the Mentor/Mentoring team
  - Teams accelerate advancement of research and career development
  - Describe exactly what each person will do to contribute to your advancement
- List training activities and relate to training goals, project and to mentors
- Consider including a table of milestones, benchmarks, or a timeline of accomplishing career development objectives

Research Strategy

4 pages

- Consider 1 page for Significance and Innovation, 3 pages for Approach
- Significance: set stage, drill down, focus, make clear what needs to be done next
- Innovation: another opportunity, beyond Aims, to highlight innovative aspects
- Approach
  - Preliminary data if available could be integrated into Approach sections
  - Critical, individualistic, but also once Aims are set, the grant writes itself
  - Explain forks in the road
  - Provide clear explanation about how Approach will test the stated hypotheses

Mentor (s)

Expectations

- Established investigators with ongoing funding and with track record of mentoring young investigators
- Mentor, sponsor & provide support
  - gaps in funding
  - analyst/coordinator time
  - supplies

Letter

- Provide details about
  - Candidate's potential
  - Mentor’s qualifications
  - Plan for candidate’s training
  - Nature of mentoring/commitment
  - Support mentor will provide
  - Breakdown of activities
  - Metrics for success
  - Plans for progression to independence

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K12 Application Scoring and Review Considerations

K12 Application – Holistic Review

The evaluation of each application will be holistic, taking into account everything the applicant brings.

In Candidate's Background, in addition to research background, include any other aspects of your background and lived experiences that have influenced your career development.

NUCATS K12 Scoring Guide

Review Criteria	Score (1-9)
Candidate	
Career Development Plan/Career Goals & Objectives/[Mentor(s)] Plan to Provide Mentoring	
Research Plan	
Mentor(s), Consultant(s), Collaborator(s)	
Environment and Institutional Commitment to the Candidate	
Overall Impact (synthesis, not an average of criterion scores)	

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
High	2	Outstanding	Extremely strong with negligible weaknesses
High	3	Excellent	Very strong with only some minor weaknesses
Moderate	4	Very Good	Strong but with numerous minor weaknesses
Moderate	5	Good	Strong but with at least one moderate weakness
Moderate	6	Satisfactory	Some strengths but also some moderate weakness
Low	7	Fair	Some strengths but with at least one major weakness
Low	8	Marginal	A few strengths and a few major weaknesses
Low	9	Poor	Very few strengths and numerous major weaknesses

K12 Application – Review Considerations, CANDIDATE

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate’s academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate’s commitment to meeting the program objectives to become an independent investigator in research?
- Do the reference letters address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

K12 Application – Review Considerations, CAREER DEVELOPMENT PLAN/CAREER GOALS AND OBJECTIVES

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate’s research and career development progress?

K12 Application – Review Considerations, MENTOR(S), CO-MENTOR(S), CONSULTANT(S), COLLABORATOR(S)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, and/or collaborator's previous experience in fostering the development of independent investigators?

K12 Application – Review Considerations, MENTOR(S), CO-MENTOR(S), CONSULTANT(S), COLLABORATOR(S) *(continued)*

- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

K12 Application – Review Considerations, ENVIRONMENT & INSTITUTIONAL COMMITMENT TO THE CANDIDATE

- Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?

FELLOWSHIPS & CAREER AWARDS

Overall Impact:
The likelihood that the proposed training (F) or career development (K) will enhance the candidate's potential for a productive, independent scientific research career in a health-related field.

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact
Consider the 5 criteria
(weighting based on reviewer's judgment):

Fs	Ks
• Applicant • Sponsor(s) • Research Training Plan • Training Potential • Institutional Environment & Commitment	• Candidate • Career Development Plan/Goals* • Research Plan • Mentor(s)** • Environment & Institutional Commitment

and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

*K05 and K24: Plan to Provide Mentoring
**K02: Consultants/Collaborators

e.g. Proposes training or career development of high value/benefit for the candidate who has high potential for developing into a productive, independent scientist. May have some or no weaknesses in the criteria.

e.g. Proposes training or career development of high or moderate value/benefit for the candidate who has high or moderate potential for further development, but weaknesses in the criteria reduce the overall impact to medium.

e.g. Proposes training or career development of moderate value/benefit for the candidate who shows moderate potential. May have some weaknesses in the criteria.

e.g. Proposes training or career development of moderate or low value/benefit for the candidate who has moderate or low potential for further development. Weaknesses in the criteria reduce the overall impact to low.

e.g. Proposes training or career development of low value/benefit for the candidate who shows low potential. May have some weaknesses in the criteria.

5 is a good, medium-impact application. The entire scale (1-9) should always be considered.

Reach out to us….

We can link you to resources and possible help to fill mentoring team gaps…reach out!

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Questions?