![Northwestern University NUCATS Clinical and Translational Sciences Institute]

Date: October 1, 2024

To: Northwestern University (NU) Chairs, Chiefs, Center and Institute Directors, Training Grant Directors, and Faculty

From: Leena Sharma, MD, Chang-Lee Professor of Medicine and Preventive Medicine, NU Feinberg School of Medicine, *MPI, NUCATS Mentored Research Career Development Program*

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

Northwestern University Clinical and Translational Sciences Institute (NUCATS) is pleased to announce a Request for Applications for the *Mentored Career Development Program in Clinical and Translational Science (K12).*

We are committed to supporting individuals early in their career trajectory and to creating and nurturing scholarly community. Scholars from heterogeneous scientific disciplines and a range of personal experiences are strongly encouraged to apply.

Key dates and deadlines:
- **K12 Information Sessions**:
  - **Tuesday, November 5, 2024 from 12:00 pm – 1:00 pm**. If you wish to attend, please register for this session **here.**

- **Letter of Intent Due**: **February 14, 2025** (*previously February 3, 2025*).
  - If you miss the letter of intent due date, please contact Morgan Barrowman at morgan.barrowman@northwestern.edu as soon as possible in order for your application to proceed to review.

- **Applications Due:** March 3, 2025

- **Funds Available:** August 1, 2025

Please refer to the RFA beginning on the next page or the **NUCATS Mentored Research Career Development Program website** *for a program description, eligibility, and application instructions.*

Mentored Research Career Development Award

Program Information and Proposal Instructions for 2024-2025

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I. Introduction

The **Mentored Research Career Development Program in Clinical and Translational Science** is an important focus of NUCATS.

The overarching goal of this program is to train and nurture clinical and translational scientists to be resilient leaders of high-functioning, interdisciplinary teams, leaders who are well positioned to tackle translational roadblocks and procure external funding, and who employ implementation science principles and partner with affected/interested groups and end-users.

In order to accomplish this objective, the program provides robust mentoring teams to assess the educational needs of individual K12 Scholars and provide optimal, personalized training and career development resources. The program supports Scholars across disparate areas of expertise and investigation.

II. Overview

The NUCATS Mentored Research Career Development Program accepts applications from early-stage faculty members who are pursuing a clinical or translational research career and wish to receive additional mentored research experience. The award is open to individuals with doctoral level degrees, including but not limited to PhD, MD, or DO degrees, who seek to pursue additional training in clinical and translational research or science. Scholars are accepted from a wide array of specialties, departments, schools, and partner institutions across Northwestern University.

The program provides support for up to **two years** and submitted applications should cover a training period of two years. The two-year training must include both mentored research and plans for other research career development activities. During the period of the award, individuals who are funded by this mechanism will receive assistance in applying for other research career development awards or other independent grants. It is expected that appointed 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.

Early-career investigators in the program (Scholars) will participate in an integrated didactic and mentored research program overseen by the [K12 Advisory Committee](). The AC includes members from broad backgrounds and with varied expertise. Activities of the AC include support for development and monitoring of each Scholar's Individual Career Advancement Plan and the identification of novel opportunities and approaches to career development, personalized to each Scholar. The AC includes several experienced investigators and mentors and is chaired by Drs. Leena Sharma and Betina Yanez.

III. Eligibility

Northwestern University, NUCATS, and the NUCATS Mentored Research Career Development Program are committed to supporting individuals early in their career trajectory. Scholars from broad backgrounds with different perspectives, creativity, and individual enterprise to address complex scientific problems.are strongly encouraged to apply to this program.

Applicants must meet the following criteria:

- Include a clinical or translational project that involves human participants, human specimens, or human data, with the ultimate 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 PhD. 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; this must be documented in the letter of support from the Department Chair.
- At the time of the application, be either a postdoctoral fellow, Instructor, or in the first five years of their 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 Associate Professors or Research Associate Professors are not eligible to apply.
- Be a U.S. citizen or permanent resident.
- Commit 75% effort to the K12 program (or as low as 50% for surgeons or other procedure intensive specialists requiring 50% direct patient care time to maintain skills. Please inquire at morgan.barrowman@northwestern.edu for additional information if proposing effort lower than 75%.)
- Have mentors with sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs. The use of mentoring teams including co-mentors to achieve the goals of the program is strongly encouraged.
- 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.
- To be eligible to submit an application in 2025, applicants may not submit an application for an individual PHS mentored career development (K) award (e.g., K01, K07, K08, K22, K23, or any other individual K mechanism) for the February 12, 2025 or March 12, 2025 NIH deadlines.
- At the time of their appointments, Scholars must not have pending (or awarded) an application for any other PHS mentored career development (K) award (e.g., K01, K07, K08, K22, K23, or any other individual K mechanism) that duplicates any of the provisions of the K component.
- Appointed Scholars are encouraged, and will be strongly mentored, to apply for individual mentored career development (K) awards (e.g. K01, K07, K08, K22, K23) and/or independent research awards (R01, R21); if successful, Scholars may be required to reduce effort on the mentored career award to a minimum of six-person months and hold concurrent support from their mentored career award and a competing PHS research grant on which they are the PD/PI or component lead. Another option may be to terminate the mentored award appointment depending on Program requirements (See NOT-OD-08-065).

IV. Provisions of the Award

The NUCATS Mentored Career Development award provides a number of tangible resources to support the career development of early-stage faculty who are fully committed to a career in clinical or translational research. Some of these provisions include:

- **% Effort:** The K12 protects 75% of a Scholar's full-time professional effort for training and clinical or translational research activities. This is based on the entire amount of time worked in a typical week. The remaining 25% effort can be divided among other clinical, administrative, and teaching responsibilities.

- **Salary & Fringe**: Sources of salary support for the 75% effort include funds of up to $120,000 per year. The Department must cover the difference, if any, between the available $120,000 and 75% of the Scholar's salary & fringe. Fringe is *not* included in the $120,000 per year. Please refer to [Section XI](#) for additional information about NIH policy on receiving concurrent support.
- **Other Direct Costs:** The budget should include funds to support Scholar research projects and career development activities:
  - **Scholar Research and Development Support:** Up to $16,000 is available to cover research-related expenses such as supplies, equipment, and technical personnel, statistical support, and research personnel support. Mentor support may be included, up to $10,000 per year, for associated laboratory or other research-related expenses.
  - **Tuition**: Up to $2,750 may be applied to support coursework in the Master of Science in Clinical Investigation (MSCI) program or other associated Feinberg School of Medicine graduate programs. Scholars will be encouraged to participate in courses to supplement their current knowledge and expertise in clinical and translational research as part of their Individual Career Advancement Plan process and in consultation with their mentoring teams and the K12 Advisory Committee.
  - **Travel:** Up to $1,500 per year is provided to Scholars to attend the annual Association of Clinical and Translational Science (ACTS) Conference or an alternative conference. Travel costs will include Scholar registration, airfare, hotel, and associated transportation (to and from airport, tolls, parking), meals, and incidentals. Domestic travel to additional conferences beyond what is supported by the $1,500 may be budgeted within the research and development support (see Other Direct Costs, above). Foreign travel may not be charged on this award.
- **Research Design Analysis Methods Program (RAMP) Mentor Support**: One or two RAMP mentors are assigned to each Scholar to provide individualized, hands-on, and educational mentorship throughout the two-year award in areas including biostatistics, epidemiology, bioinformatics, qualitative research methods, and/or health services research. RAMP mentor selection is personalized, according to the Scholar's needs. RAMP mentor effort is provided by the program and does not need to be accounted for in the individual budget of each Scholar.
- **Commitment by Scholar's Department:** The Department agrees to release the funded Scholar for the following activities, which are included in the Scholar's 75% (or as low as 50% for procedure intensive specialists) effort:
  - Orientation Bootcamp at the beginning of the Scholar's appointment period
  - Periodic progress meetings
  - Monthly peer-mentoring seminar series, Succeeding with Your K Award, held the third Monday of each month from 12 – 1:00 PM CST
  - Monthly RAMP mentor meetings
  - Responsible Conduct of Research (RCR) Training in cases where the RCR requirement has not already been met within the past 3 years

V. Reporting and Evaluation

- **Reporting Requirements:** Scholars and their mentors are required to provide semi-annual updates on the Scholar's research and career development progress as well as complete annual reports for the Research Performance Progress Report (RPPR) submitted to NCATS. Scholars also agree to complete annual RPPR requests for 15 years after completion of their award period.
- **Linking and Citing the K12 Award:** Scholars must link their publications to their award in PubMed and cite the award on their publications. Instructions will be provided upon appointment to the award.

- **Human Subjects and Live Vertebrate Animals Approval:** The program is required to comply with the NCATS policy regarding research involving human subjects and live vertebrate animals. Scholar projects involving human subjects or live vertebrate animals are required to secure approval from NCATS before funds can be released and project work can begin. Please refer to [Section XI](#) for guidance on the approval process.
    i. Materials are NOT required for the application, but Finalists will be sent detailed instructions and are encouraged to begin preparing at that stage.
    ii. Scholars selected for the award must submit a modification to the IRB/IACUC to have the grant # added. To avoid delays due to lack of IRB/IACUC approvals, Scholars are encouraged to begin the process to secure approvals as soon as possible upon notification as Finalist.
    iii. Please be aware that the NCATS prior approval process takes a minimum of 30 days <u>once a request is submitted to NCATS.</u>
    iv. **Research funds cannot be released until NCATS approval has been obtained.** Scholars <u>are</u> able to receive salary support.

VI.   Selection Criteria

The evaluation of each application will be holistic, considering everything the applicant brings.

The following criteria will be scored, using the 9-point NIH scoring system. Please refer to the evaluation criteria below and take into account how these criteria are assessed by reviewers (See [Appendix-1](#)) while preparing the proposal:

- Candidate
- Career Development Plan; Career Goals & Objectives; Mentor(s) Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-mentor(s), Consultant(s), Collaborator(s)
- Institutional Commitment to the Candidate and Environment

VII.   Proposal Instructions Overview

Feinberg School of Medicine and other Northwestern University investigators should work with their Department or Division Research Administrator to submit this internal award. This submission does not need to go through the Office for Sponsored Research.

Lurie Children's investigators should work with the [Office of Sponsored Programs](#) to submit their application. Investigators must complete internal routing and address budget questions to the Lurie Office of Sponsored Programs [(staff listing)](#).

Shirley Ryan AbilityLab investigators should work with the SRAlab Office of Research Administration (ORA) to submit their application. Investigators must complete internal routing and address budget questions to their assigned research administrator in ORA.

<u>Elements of the application process include:</u>

- **Letter of Intent, Due Friday, February 14, 2025, by 11:59 PM – completed through REDCap form**
    o The [K12 Applicant & Proposal Information Form](#) serves as the letter of intent
    o Requires data on the applicant (Department, primary mentor, etc.) as well as a project summary/abstract

- **Full Application, Due Monday, March 3, 2025, by 11:59 PM - completed in [NU Competitions](#).** (Note: Applicants should log in using NU NetID) Full applications must include:
    1. Biosketches
        a. Applicant Biosketch

        b. Primary Mentor(s) Biosketches
2. Proposal – 9 total pages
        a. Candidate's Background – 1 page
        b. Career Goals and Objectives – 1 page
        c. Career Development Plan/Career Goals & Objectives/ Mentor(s) Plan to Provide Mentoring – 2 pages
        d. Specific Aims – 1 page
        e. Research Strategy – 4 pages
3. Letters of Support
        a. Joint letter from Department Chair & Division Chief (Required)
        b. Primary mentor (Required)
        c. Co-mentors (Required), consultants (as appropriate), and contributors (as appropriate)
4. Budget & Budget Justification outlining the use of award funds for a period of two years.

- **Updates to the Letter of Intent, Due Monday, March 3, 2025, by 11:59 PM**
  - If any information in your letter of intent changes between February 14 and March 3, you must update your letter of intent information by the full application deadline. If you need to make revisions, please contact morgan.barrowman@northwestern.edu for the link and code to access your LOI.

VIII.   Detailed Proposal Instructions

Feinberg School of Medicine and other Northwestern University investigators should work with their Department or Division Research Administrator to submit this internal award. This submission does not need to go through the Office for Sponsored Research.

Lurie Children's investigators should work with the Office of Sponsored Programs to submit their application. Investigators must complete internal routing and address budget questions to the Lurie Office of Sponsored Programs (staff listing).

Shirley Ryan AbilityLab investigator should work with the SRAlab Office of Research Administration (ORA) to submit their application. Investigators must complete internal routing and address budget questions to their assigned research administrator in ORA.

- **Friday, February 14, 2025 – Letter of Intent Due** (**By 11:59 pm**)
  - Complete the NUCATS Mentored Career Develop Program Applicant & Proposal Information Form (serves as the letter of intent). This form will capture applicant data and proposal information including the project summary/abstract.
    - Applicants may return to this form and save it to complete or adjust their responses at any time until March 3, 2025. Contact Morgan Barrowman for link and code to regain access to submitted form.
    - Use this link for guidance on NIH project summary/abstracts. Please note, you are **not** submitting a project narrative and you should only refer to the project summary/abstract information.
    - If any information in this form changes (e.g., mentoring team) between the Letter of Intent due date (February 14) and the Full Application due date (March 3), you must update the information in this form.

- **Monday, March 3, 2025– Full Application Due (By 11:59 pm)**
  - **Applications are completed through NU Competitions.**
    - NU Competitions is a platform that allows you to log in with your Northwestern NetID.
    - Technical support for submissions in NU Competitions can be reached at: competitions@northwestern.edu

- o **The Full Application consists of the following sections:**
  - ▪ **Project Title**
  - ▪ **Application Document** (combined .pdf document uploaded to the application). Must include:
    - • **Applicant's Biosketch**
    - • **Proposal** – 9 pages total
      - o Candidate's Background – 1 page
        - ▪ In addition to your research background, please include any other aspects of your background and lived experiences that have influenced your career development.
      - o Career Goals and Objectives – 1 page
      - o Career Development Plan – 2 pages
      - o Specific Aims – 1 page
      - o Research Strategy – 4 pages
        - ▪ In addition to proposed strategy/design, methodology, and analyses, include plans for the inclusion of individuals on the basis of sex, race, and ethnicity
        - ▪ Include information on any affected/interested group and community engagement. While this is not a review criterion, community engagement is supported by the award. For information on community-engaged research and resources, please visit the [Center for Community Health](#) website.
        - ▪ **References do not count toward page limitations.**
    - • **Primary Mentor Biosketch**
    - • **Letters of Support**: Letters should document the strengths and attributes of the applicant, the role of the mentor in the career development of the Scholar, and how the work proposed fits into the overall program funded by the mentor.
      - o Department Chair & Division Chief (Required. If you have a Division Chief, this can be a shared letter.)
      - o Primary Mentor (Required. If your primary mentor also serves as your Department Chair or Division Chief, they may submit one letter that clearly outlines the distinct roles they will serve and the type of support they will provide within each role.) Primary Mentor Letter should include the following sections:
        - ▪ Candidate's Potential
        - ▪ Information on mentor's research qualifications and previous mentoring experience
        - ▪ Plan for candidate's training and research career development
        - ▪ Nature of mentoring and commitment to the candidate's development
        - ▪ Source of anticipated support for the candidate's research project
        - ▪ Anticipated breakdown of professional responsibilities during the award period
        - ▪ Metrics determining successful progress
        - ▪ Plan for progression from the mentored stage to independent research investigator status
      - o Co-Mentors (Required), Consultants (as appropriate), and Contributors (as appropriate).

- **Budget**
  - **Read the** Budget Justification Information for instructions on completing the Budget & Budget Justification.
  - Complete the Budget Template (.**docx file**)**.** - *Please contact Morgan Barrowman for this template.*
    - .Xls will ultimately be submitted upon receiving the award, but the current platform for submitting proposals does not allow this format. We request a .docx rather than a .pdf to make it easier to help you with edits later on.
  - Upload the completed budget in NU Competitions.
- **Budget Justification**
  - Complete the Budget Justification Template (.**docx file**) - *Please contact Morgan Barrowman for this template.*
  - Upload the completed Budget Justification in NU Competitions.
- **Update K12 Applicant & Proposal Information before final proposal submission**
  - Applicants should review the information submitted in the NUCATS Mentored Career Development Award Applicant & Proposal Information form and make updates as needed.
  - Submit final version by 11:59 pm on Monday, March 3, 2025.

IX.   Important Dates

- Request for Applications released   October 1, 2024
- Information Session #1   November 5, 2024 (Register Here)
- Letter of Intent Due   February 14, 2025
- Full Application Due   March 3, 2025
- Review Panel Convenes   Early April 2025
- Interviews Finalists & Mentors   Mid April – Late April 2025
  - Finalists identified by the Review Panel will participate in an interview with selected ELC members. Finalists will respond to a series of questions concerning their past, present, and future research and life experiences to assist reviewers in obtaining a comprehensive view of the candidate.
- Notification of Decisions   Early May 2025
- Award Begins   August 1, 2025
- KL2 Orientation Bootcamp   June 2025

X.   Contacts for Application Support

- **Support with Preparing and Submitting your Application**
  - **Feinberg School of Medicine and other Northwestern University investigators** should work with their Department or Division Research Administrator to submit this internal award. This submission does not need to go through the Office for Sponsored Research.
  - **Lurie Children's investigators** should work with the Office of Sponsored Programs to submit their application. Investigators must complete internal routing and address budget questions to the Lurie Office of Sponsored Programs (staff listing).
  - **Shirley Ryan Ability Lab investigator** should work with the SRAlab Office of Research Administration (ORA) to submit their application. Investigators must complete internal routing and address budget questions to their assigned research administrator in ORA.

- **Qualification/Eligibility Questions**
  - Leena Sharma, MD, MPI, l-Sharma@northwestern.edu
  - Betina Yanez, PhD, MPI, betina.yanez@northwestern.edu
- **KL2 Application Process questions:**
  - Morgan Barrowman, CECD Senior Project Coordinator, morgan.barrowman@northwestern.edu
- **NU Competitions:** Technical Support: competitions@northwestern.edu

XI. **Useful Links**
- NIH Policy regarding Human subjects and/or Vertebrate Animals research prior approval: https://ncats.nih.gov/ctsa/funding/prior-approval-faq

- NIH Policy concerning concurrent support from a KL2 Award and a Research Grant: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-157.html

- NIH Biosketch Format: https://grants.nih.gov/grants/forms/biosketch.htm

- National Center for Advancing Translational Sciences (NCATS): https://ncats.nih.gov/

- Northwestern University Institutional Review Board: https://irb.northwestern.edu/

- NUCATS Website: https://www.nucats.northwestern.edu/

- NUCATS Mentored Career Development Award Website: https://www.nucats.northwestern.edu/education-and-career-development/career-development-awards/kl2/index.html

- Current K12 Scholars: https://www.nucats.northwestern.edu/training/nih-funding-opportunities/kl2/current-scholars.html

- Previous KL2 Scholars: https://www.nucats.northwestern.edu/training/nih-funding-opportunities/kl2/past-scholars.html

- NUCATS BERD/RAMP Core: https://www.nucats.northwestern.edu/research-resources/data-analytics-informatics/biostatistics-research-design.html

- NUCATS Center for Community Health: https://www.feinberg.northwestern.edu/sites/cch/

- Letter of Intent link (Applicant & Proposal Information): https://redcap.nubic.northwestern.edu/redcap/surveys/?s=3PAERHTNPE

- Budget Justification Information: *Please contact Morgan Barrowman for this document.*

- Budget Template: *Please contact Morgan Barrowman for this template.*

- Budget Justification template: *Please contact Morgan Barrowman for this template.*

- Application Frequently Asked Questions: https://www.nucats.northwestern.edu/training/nih-funding-opportunities/kl2/k12-application_faq1.pdf

- Lurie Children's Hospital Office of Sponsored Program: https://www.luriechildrens.org/en/research/management/sponsored-programs/

XII. Appendix 1 - Reviewer Criteria

Each application will be reviewed by three reviewers to score the following categories:
- CANDIDATE
- CAREER DEVELOPMENT PLAN/CAREER GOALS & OBJECTIVES:
- RESEARCH PLAN
- MENTOR(S), CO-MENTOR(S), CONSULTANT(S), COLLABORATOR(S)
- ENVIRONMENT AND INSTITUTIONAL COMMITMENT TO THE CANDIDATE
- OVERALL IMPACT

Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of the candidate's qualifications, scientific and technical merit of the proposed research, career development plan, mentor's qualifications and mentoring plan, environment and institutional commitment to the candidate, and give a separate score for each.

1. 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? How have lived experiences and disadvantages affected what the candidate has been able to accomplish? Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator?*

2. Career Development Plan/Career Goals & Objectives: *What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and to 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? What impact will the KL2 program have on the candidate's future trajectory?*

3. Research Plan: *Are the proposed research question, design, and methodology of significant scientific and technical merit? Is the prior research that serves as the key support for the proposed project rigorous? Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Is the research plan relevant to the candidate's research career objectives? Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?*

4. 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? 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?*

5. Environment and Institutional Commitment to the Candidate: *Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort (75%) will be devoted directly to the research and career development activities 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 independent investigator?*

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into in consideration of the following five scored review criteria. An application does not need to be strong in all categories to have a major impact. In assigning an overall impact score, reviewers will consider lived experiences that have influenced career development of the candidate.