

2024 NUCATS Translational Science Pilot Awards Funding Opportunity Announcement

The Northwestern University Clinical and Translational Sciences (NUCATS) Institute announces this Request for Applications (RFA) for the **2024 NUCATS Translational Science Pilot Awards**. The NUCATS pilot awards are contingent upon the funding of an NIH National Center for Advancing Translational Sciences (NCATS) UM1 grant which is currently pending review.

NUCATS Focus

NUCATS studies Translational Science: how to accelerate moving transformative scientific discoveries from the lab to patients and communities. Consultative resources and expertise to accomplish this are also provided to researchers. We aim to **cultivate inclusive excellence**, **catalyze innovation**, and **infuse implementation science** methods across the translational research continuum as a leader in Translational Science.

Intention of the NUCATS Translational Science Pilot Awards

The NUCATS Translational Science Pilot Awards program seeks proposals for highly innovative, multidisciplinary pilot projects that will advance Translational Science. For the definition as well as scientific and operational principles of Translational Science, please see <u>Faupel-Badger JM et al. Clin Transl Sci. 2022.</u> Information on what qualifies as a Translational Science proposal is in "Proposal Eligibility" below in this document.

This Pilot is intended for faculty to develop data supporting subsequent applications for independent external funding and not for trainee career development.

Deadlines and Award Timeline

RFA Issued	Wednesday, January 31, 2024
Optional Consultations ¹	Available upon request
Proposal Submission Deadline	April 19, 2024
Protocol Submission to the IRB or IACUC	April 19, 2024
Deadline ²	
Notice of Award	May 31, 2024
NCATS Prior Approval Documents Due ²	June 14, 2024
Earliest Anticipated Funding Start Date	July 1, 2024
Funding Period	All funding must be spent within 11 months (by June 30,
	2025) of the awarded project period. No-cost extensions are
	not permitted.

¹Applicants are encouraged (but not required) to request a consultation through NUCATS resources prior to submission, if relevant (see Proposal Eligibility section). The request form is available on the <u>NUCATS website</u>.

²Our funding agency requires additional documentation prior to the release of funds for research involving human subjects or vertebrate animals. Protocols must be submitted to the IRB or IACUC by April 19, 2024. Applicants will be required to cite our grant in your IRB or IACUC documentation and related publications, and we will need to forward your IRB or IACUC approval, protocol, and consent form to the NIH for review and approval prior to the commencement of the project. This process typically takes 30–90 days, depending on the complexity of the proposal and the IRB's determination of risk level. Funds may not be used for clinical trials beyond phase IIA. Funded projects that involve greater than minimal risk and/or are classified as clinical trials will be required to submit additional documentation as part of the prior approval process.



PI Eligibility

Eligibility is limited to Northwestern University faculty.

- Faculty applicants must be engaged in research and be eligible to apply for follow-on external grant funding as a PI or MPI.
- Faculty applicants may or may not also hold appointments in one of the NUCATS Institute's clinical affiliate institutions (Northwestern Memorial HealthCare, Ann & Robert H. Lurie Children's Hospital of Chicago, or Shirley Ryan AbilityLab).

Priority for funding will be given to PIs (or submitting/contact MPIs) who have not yet received an NIH R01-equivalent award.

Northwestern University Feinberg School of Medicine residents, clinical fellows, and postdoctoral fellows are <u>not</u> eligible to apply as a PI or MPI.

- Such trainees are eligible to have a limited role on a proposal as a co-investigator.
- A fellow may be eligible to apply if a letter stating that a faculty appointment is imminent is provided by their department chair or division chief and uploaded with the full application. In this case, the imminent faculty appointment must become effective during the funding period.

Proposal Eligibility

Our funding agency (NCATS) requires that pilot projects <u>focus</u> on Translational Science (TS) – understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translation of scientific advances into improving health for all.

An application could be eligible as a TS project if it:

- Includes an aim studying an innovative approach to traverse a critical step in the pathway from development to trials assessing efficacy to effectiveness testing of a drug, device, data science innovation, and/or behavioral intervention specific for a particular health condition AND leads to generalization of learnings to additional health conditions.
- Uses a dissemination and implementation science approach in at least one aim to accelerate translation
 of interventions already proven clinically effective into evidence-based programs, practices, or policies in
 hospital, clinic, or community settings with the aim of equitably enhancing public health. Such proposals
 must include relevant community partners (e.g., community members, clinicians, policymakers, public
 health practitioners) and demonstrate that the proposal is a collaborative effort between the research
 team and the major community/practice partner(s). NUCATS's Center for Community Health offers
 guidance and support for partnership development. To learn more or to request support identifying
 partners, click here.
- Proposes a hybrid effectiveness-implementation study, thereby including an aim assessing implementation as well as assessing effectiveness of an intervention. To request a dissemination and implementation science consultation <u>click here</u>.

Applications proposing only laboratory experiments that lack an aim addressing TS are not eligible.

Preliminary research necessary to establish plans/feasibility for subsequent federal research grant applications can be proposed. Describing plans for a subsequent federal research grant application is encouraged.

For descriptions of application and budget requirements, instructions on submittal via Competitions, information on review criteria, and other important considerations, please see:

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Application Requirements

In the order they are outlined below, applications must compile all requirements into a single PDF and use the following filename convention:

[Submitting/Contact PI's Last Name]-[Submitting/Contact PI's First Name]-NUCATSPilot-2024.pdf (e.g., DAquila-Richard-NUCATSPilot-2024.pdf).

Incomplete proposal submissions will not be considered by the NUCATS TS Pilot Awards Scientific Review Panel.

- Cover Sheet: Complete the required cover sheet. (https://www.nucats.northwestern.edu/docs/nucats-pilot-coversheet.docx)
- Scientific Research Strategy: In 2,000 words or fewer, applicants should address the project's significance, aims and associated hypotheses, analysis plan, impact, deliverables, lack of alternate funding, and plans for future funding. The 2,000-word limit does not include figures or references, although applicants are encouraged to limit the cumulative space for figures and/or references to no more than 2 pages.
 - Applicants are strongly encouraged to provide <u>detailed</u> feasibility and analysis plans.
 - Following NIH guidelines, applications must address how sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.
 - When describing plans for future funding, include as much <u>specific detail</u> as possible (e.g., intended mechanism and/or targeted RFA).
- Budget: NIH-style budget (including, when applicable, (a) specific line-item estimates from the applicable NU research cores and/or resources or (b) separate budget expenses/amounts for the academic and community MPIs; https://www.nucats.northwestern.edu/docs/nucats-pilot-budget.docx).
 - Note: If the proposed project has secured support for expenses in excess of the maximum budget cap allowed in this request for proposals, the applicant must clearly document guaranteed complementary funding.
- Budget Justification: NIH-style budget justification describing all proposed expenses in detail.
- Biosketch(es): NIH-style biosketches for all key personnel (principal investigator, co-investigators, other significant contributors).
- o **Other Support**: NIH-style other support document for all key personnel (principal investigator, coinvestigators, other significant contributors).
- o **Other Documents**: Formal, detailed cost estimate from a research core, such as the Northwestern Medicine Enterprise Data Warehouse (NMEDW), if utilized.

Additional requirements for applicants who do not have prior or current NIH funding:

- 1-paragraph statement from the applicant's faculty mentor indicating they reviewed the proposal, their support for the proposed pilot project, and their willingness to mentor the applicant throughout the project period.
- o Faculty mentor's NIH-style biosketch.

Applicants who do not have prior or current NIH funding are required to ask a Feinberg-based faculty mentor to (a) review the full pilot application prior to submission and (b) provide a 1-paragraph statement in the full application indicating their support for the proposed pilot project and willingness to mentor the applicant throughout the project period, if funded. Moreover, applicants are encouraged to choose a mentor early and to name this faculty mentor in their application. Applicants may request up to 2% effort for the mentor in the application (applying NIH salary cap at time of pilot submission) or use other effort already designated for this specific mentoring responsibility.

Applicants with prior or current NIH funding may choose to engage a faculty mentor as described above but are not required to do so.



Budget Requirements

Maximum Funding Level: \$30,000

- Examples of allowable expenses:
 - Salary expenses for Northwestern PI, MPI(s), and Co-I(s) (applying NIH salary cap at time of pilot submission)
 - Salary expenses for the lead PI's Northwestern faculty mentor (<u>up to 2% effort</u>, applying NIH salary cap at time of pilot submission)
 - Compensation for community partners to serve as MPI or Co-I on the proposal (highly encouraged for DIR or other proposals with community partners)
 - Consultation with Northwestern faculty/staff with quantitative and/or qualitative analysis expertise
 - o Computational Cluster Central Processing Unit (CPU) time to run specific analyses
 - Laboratory or hospital tests (e.g., complete blood count (CBC) tests)
 - Participant recruitment stipends
 - Regulatory support from NUCATS
 - Analysis of samples by a Northwestern University or affiliated research core facility (including research cores at the University of Chicago and University of Illinois at Chicago covered by the reciprocation agreement)
 - Design/printing of materials
 - Event expenses
- Examples of non-allowable expenses:
 - o Consultants, except as noted above
 - Student or temporary employee salary expenses
 - Subcontracts with or payments to other academic institutions or other public/private organizations (beyond clinical affiliate institutions identified above or research cores covered by the reciprocation agreement)
 - Technology development
 - Travel
 - Tuition expenses
- **Indirect Costs**: Indirect costs are not permitted and will not be funded. Applicants with primary appointments at a clinical affiliate institution should confirm the institution's acceptance of these terms prior to submission.
- **Trial Phase**: Pilot research funds may not be used for clinical trials beyond phase IIA. This is a strictly enforced limitation by our funding agency at the NIH.
- In addition to other budget items, proposals may request funds for <u>biostatistics</u>/research design or <u>informatics support</u>, <u>D&I consultation</u>, <u>Clinical Research Ethics and Equity Consultation support</u> (select CREEC on the request form), or other <u>NUCATS</u> resources.

Application Review Process

Proposals will be reviewed by a multidisciplinary standing review committee comprised of faculty with expertise in TS as well as community partners, all of whom will be required to complete training in equitable review practices.

REVIEW CRITERIA

Ideal proposals will clearly demonstrate the following elements:

- Strong potential to lead to meaningful impact on human health and more generalized study/acceleration
 of the process of translation, with specification of how the proposal will maintain a high likelihood of
 translation and/or population health impact for a specific condition as well as plans for broader impact on
 TS across other health conditions.
- A concept that is too preliminary to qualify for federal funding programs and for which supporting preliminary data would greatly enhance the likelihood of receiving a subsequent NIH-funded award.

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- Appropriate infrastructure to support the project (including plans to access NUCATS consultation services for support in areas such as D&I, community stakeholder engagement, biostatistics, and informatics)
- A feasible timeline to complete all proposed activities within the approved funding period (with the understanding that no-cost extensions are not permitted)
- Clear objectives, feasibility plan, analysis plan, timeline, anticipated results, and outcome measures.
- A plan to apply to NIH for follow-on funding upon completion of the pilot project with as much detail as
 possible; identifying a specific NIH FOA to which there will be a response by a specific submission date
 is <u>strongly</u> encouraged.

The NUCATS Pilot Scientific Review Panel will <u>prioritize proposals led by junior faculty</u> (Instructor and Assistant Professor ranks, regardless of track) who have not yet established a significant funding base (PI or MPI on an NIH R01-equivalent award). The lead principal investigator (PI) is the submitting/contact PI. Proposals led by junior faculty that include significant contributions from one or more senior faculty collaborators will be prioritized as well if the junior faculty member is not yet PI on an NIH grant and is planning future federal proposals. Applicants with well-established federal funding bases will not be prioritized for funding.

Important Considerations for Submitting/Contact Principal Investigators (PIs)

Please read the following statements carefully:

- 1) The NUCATS pilot awards are contingent upon the funding of an NIH National Center for Advancing Translational Sciences (NCATS) UM1 grant which is pending review.
- 2) Our funding agency does not permit no-cost extension requests for pilot awards. Therefore, applicants should be certain that all proposed activities will be completed during the maximum funding timeframe. Applicants are strongly encouraged to submit proposed projects to the appropriate IRB/IACUC for review by the application deadline on this RFA.
- 3) A key focus of NUCATS and more broadly the CTSA program is the reduction of disparities throughout the translational pipeline, as well as the promotion of a more diverse Translational Science workforce. Applicants are therefore strongly encouraged to submit proposals aiming for more equitable translation and/or with diverse, interdisciplinary teams.

CONFIDENTIALITY

Proposals are reviewed internally and are considered confidential information, not to be disclosed to anyone outside the review process.

QUESTIONS

Questions regarding the application process may be directed to NUCATS-Funding@northwestern.edu.

Questions regarding NUCATS Competitions may be directed to competitions@northwestern.edu.