2023 NUCATS INSTITUTE TRANSLATIONAL SCIENCE PILOT AWARDS
REQUEST FOR LETTERS OF INTENT & APPLICATIONS
Letter of Intent Deadline: Friday, May 12, 2023
Full Submission Deadline: Monday, June 26, 2023
Maximum Funding Level: $30,000

INTRODUCTION
The Northwestern University Clinical and Translational Sciences (NUCATS) Institute announces this Request for Letters of Intent and Applications for the 2023 NUCATS Translational Science Pilot Awards.

NUCATS Translational Science Pilot Awards Funding Mechanism
Maximum Funding Level: $30,000; Expected Funding Period: 10-11 months
Earliest Anticipated Funding Start Date: July 31, 2023

The NUCATS Translational Science Pilot Awards program is seeking proposals for highly innovative, multi-disciplinary pilot projects that will advance Translational Science (TS, defined with examples below) and are aligned with one of two priority areas: Clinical and Translational Research (CTR) or Dissemination and Implementation (D&I). This funding mechanism combines, replaces, and builds on the two prior NUCATS pilot funding mechanisms: Clinical and Translational Pilot Awards and Dissemination and Implementation Pilot Awards.

Proposals may request funding for CTR, D&I, or hybrid effectiveness-implementation studies that encompass both CTR and D&I.

CTR (and hybrid effectiveness-implementation) proposals should involve innovative approaches to traverse critical steps in the pathway from development to efficacy to effectiveness testing of a drug, device, data science innovation, and/or behavioral intervention specific for a particular health condition.

D&I (and hybrid effectiveness-implementation) proposals should involve innovative approaches to accelerating translation of clinically effective interventions into evidence-based programs, practices, or policies in the hospital, clinic, or community setting with the aim of equitably enhancing public health. D&I (and hybrid effectiveness-implementation) proposals are highly encouraged to include relevant stakeholders (e.g., community members, clinicians, policymakers, public health practice partners) and to demonstrate that the proposal is a collaborative effort between the researcher/research team and the major community/practice partner(s). NUCATS' Center for Community Health offers guidance and support for partnership development. To learn more or to request support identifying partners, click here.

CTR, D&I, and hybrid effectiveness-implementation proposals should support generalizable lessons about TS as described in the examples below. Proposals are highly encouraged to conduct necessary preliminary research to establish plans/feasibility for subsequent federal research grant applications. In addition to other budget items, proposals may request funds for biostatistics or informatics support, D&I consultation, Clinical Research Ethics and Equity Consultation support, or other NUCATS resources.

Definition and Examples of Translational Science (TS)
“Translation is defined by the NIH National Center for Advancing Translational Sciences (NCATS) as the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes… Translational Science (TS) seeks to elucidate general operative principles to transform translation…into a predictive science. The application of scientific and operational innovation and strategies to improve the efficiency and effectiveness of all research is at the heart of developing, demonstrating, and disseminating the science of translation. An example – for illustration only – may help clarify the distinction

\(^1\)All funding must be spent within this time period or by June 30th of the awarded project period, whichever comes first. No-cost extensions are not permitted.
between CTR and TS. An investigator who wishes to test whether a particular drug improves outcomes in diabetes will need to recruit sufficient underserved participants; this is a CTR problem and will be addressed from the standpoint of effectiveness for the drug’s effects and the diabetes community, using established recruitment methods. By contrast, an investigator who wishes to understand the fundamental underlying barriers to recruitment for clinical trials generally, and test an intervention directed at those hypothesized causes and mechanisms, is engaging in TS. To test the hypothesis, the TS investigator may choose a use case that may in fact be the same as that used by the CTR researcher — in this example a drug for diabetes — but a TS question to be answered is...whether the TS innovation accomplishes full recruitment of the desired underserved population more effectively and efficiently.” (Source: National Center for Advancing Translational Sciences, NCATS)

Proposals for this NUCATS Translational Science Pilot Award funding mechanism should include one or more TS aims in the context of a project including other CTR and/or D&I aims. NUCATS will review proposals based on the following assumptions: (a) TS cannot be done in isolation from CTR or D&I, (b) TS need not be the entire focus of a NUCATS TS Pilot Award proposal, and (c) actively disseminating results of CTR and/or D&I aims to speed their study or application in a different health condition than the topic of the original study may be considered a TS aim if such efforts will promote generalizable knowledge about the CTR or dissemination/implementation process.

**Important Considerations for Submitting/Contact Principal Investigators (PIs)**

The NUCATS pilot awards are funded by our CTSA award from the NIH National Center for Advancing Translational Sciences (NCATS). 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.

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.

**PRINCIPAL INVESTIGATOR ELIGIBILITY**

Eligibility for these funding mechanisms is limited to Northwestern University faculty who 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). Faculty applicants must be engaged in research and be eligible to apply for follow-on external grant funding as a PI or MPI.

**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 LOI. Up to 2% effort may be requested 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.

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

Please note: Northwestern University Feinberg School of Medicine residents, clinical fellows, and postdoctoral fellows are not eligible to apply as a PI or co-PI. Such trainees are eligible to have a limited role on a proposal as
a co-investigator. These mechanisms are intended for faculty to develop data supporting subsequent applications for independent external funding, and not for trainee career or proposal development. A fellow may be eligible to apply if a letter, stating 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.

ALLOWABLE AND NON-ALLOWABLE EXPENSES (Maximum Funding Level: $30,000)
- **Examples of allowable expenses:**
  - Salary expenses for Northwestern PI, Co-PI(s), and Co-I(s) (applying NIH salary cap at time of pilot full application submission)
  - Salary expenses for the lead PI’s Northwestern faculty mentor (up to 2% effort, applying NIH salary cap at time of pilot full application submission)
  - Compensation for stakeholders/community partners to serve as Co-PI or Co-I on the proposal (highly encouraged for D&I or other proposals with community partners)
  - Consultation with Northwestern faculty/staff with quantitative and/or qualitative analysis expertise
  - Computational Cluster Central Processing Unit time to run specific analyses
  - Laboratory or hospital tests (e.g., complete blood count 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:**
  - 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.

APPLICATION PROCESS

**Phase 1: Letter of Intent**
- Eligible applicants should submit a Letter of Intent as a PDF electronically no later than **Friday, May 12, 2023**, using the form at the following link: [https://competitions.fsm.northwestern.edu/grants/2023PilotsLOI](https://competitions.fsm.northwestern.edu/grants/2023PilotsLOI).
- A complete Letter of Intent includes:
  - Submitting PI’s full name, email address, primary department, and current academic rank
  - Proposed project title (non-binding)
  - Proposed project team (if submitting PI is collaborating with academic and/or community partners, non-binding)
  - Draft proposed project aims, including at least one aim studying TS: testing how to accelerate/improve the process of translation at any point on the spectrum from basic science discovery through clinical trials evaluating efficacy to dissemination and implementation to enhance
population impact. TS aims can include active dissemination of results of CTR and/or D&I aims to speed their study or application in a different health condition than the topic of the pilot application, provided that such efforts will create generalizable knowledge about the CTR or dissemination process.

- Proposed project total budget amount, up to a maximum of $30,000 (a detailed budget is not required in Phase 1: Letter of Intent)
- Draft proposed project expected deliverables and dissemination plans
- Draft proposed project downstream funding target(s) (non-binding)

- Letters of Intent are limited to 2 pages. Citations are not required.
- Submitting PIs may be contacted and invited to discuss their LOI after submission. The purpose is to ensure alignment with the requirement for projects that, broadly defined, advance TS in the context of CTR or D&I.
- Applicants will be notified via email within 2 weeks of LOI submission of either an invitation to submit a full proposal or encouragement to submit a revised LOI in a future round.

Phase 2: Full Applications (Requires Invitation)

- Invited applicants should submit a complete application via Competitions no later than Monday, June 26, 2023. The new Competitions link will be provided to invitees.
- Applicants submitting D&I or hybrid effectiveness-implementation studies are encouraged (but not required) to request a consultation through the NUCATS D&I program prior to submission of a full application. For investigators submitting hybrid trials, the NUCATS D&I program can help to provide strategic guidance as to which priority area (CTR or D&I) to target. The request form is available on the NUCATS website.
- A full application includes:
  - 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 detailed feasibility and analysis plans.
    - When describing plans for future funding, include as much specific detail 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 co-PIs; 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).
  - Other Support: NIH-style other support document for all key personnel (principal investigator, co-investigators, other significant contributors).
  - 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.
    - Faculty mentor’s NIH-style biosketch.
2023 NUCATS Translational Science Pilot Awards

- **Other Documents**: Formal, detailed cost estimate from a research core, such as the Northwestern Medicine Enterprise Data Warehouse (NMEDW), if utilized.

**PROPOSAL FORMATTING & UPLOAD (Full Application Stage)**
The full application requirements listed above should be uploaded into NUCATS’ Competitions application system as a single, compiled PDF. The single PDF should follow the order outlined in the proposal requirements section. Please use the following filename convention for naming the PDF file: [Submitting/Contact PI’s Last Name]-[Submitting/Contact PI’s First Name]-NUCATSPilot-2023.pdf (e.g., DAquila-Richard-NUCATSPilot-2023.pdf). Incomplete proposal submissions will not be considered by the NUCATS Pilot Awards Scientific Review Panel.

**PRIOR APPROVAL REQUIREMENT**
Our funding agency requires additional documentation prior to the release of funds for research involving human subjects or vertebrate animals. 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.

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

**DEADLINES**
- **Phase 1**: The deadline for submitting Letters of Intent is **Friday, May 12, 2023, by 5:00 p.m. CT**. Letters of Intent should be submitted to: [link to submission].
- **Phase 2**: Invited applicants should submit full applications no later than **Monday, June 26, 2023, by 5:00 p.m. CT**.
- All materials must be submitted by the submitting/contact PI using their Northwestern NetID and password.

**REVIEW CRITERIA**
Ideal proposals will clearly demonstrate the following elements:

- Innovation and novelty of proposed research
- A concept that is too preliminary to qualify for federal funding programs and supporting preliminary data would greatly enhance the likelihood of receiving a subsequent NIH-funded award
- A strong, diverse, multidisciplinary team (including a mentor, if required)
- 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)
- 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.
- Clear objectives, feasibility plan, analysis plan, timeline, anticipated results, and outcome measures
- A plan to present findings/outcomes of the pilot award as soon as possible after completion of the award
- 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 strongly encouraged.
- NUCATS also has special interest in, and may prioritize funding for, well-scored proposals that:
  - Align with the Chicago Department of Public Health’s Healthy Chicago 2025 goals
2023 NUCATS Translational Science Pilot Awards

- Address health disparities, improve health equity, and/or enhance inclusive excellence of the translational workforce
- The NUCATS Pilot Scientific Review Panel will prioritize proposals led by junior faculty (Instructor and Assistant Professor ranks, regardless of track) who have not yet established a significant funding base (PI or MPI on an NIH R-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. Potential applicants with well-established federal funding bases will not be prioritized for funding.

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

SUPPORTS PROVIDED TO PILOT AWARD RECIPIENTS
Recipients of NUCATS Translational Science Pilot Awards will receive a range of supports from NUCATS including (but not limited to): (a) announcement of the award on the NUCATS website and in the NUCATS newsletter; (b) linkage to NUCATS consultation cores, as needed, for methodological support in areas such as D&I, community engagement, biostatistics, and informatics; (c) resources to support compliance with NIH data sharing and clinical trial reporting policies; (d) linkage to NUCATS supports such as the grant repository to identify examples of funded grants that could support future grant writing; (e) resources to promote effective science communication strategies and techniques to support dissemination of research findings; and (f) invitations for select projects to disseminate results via channels such as NUCATS seminars, Pilot Symposium, and/or NUCATS podcast series.

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. Please direct questions specific to D&I proposals to cdis@northwestern.edu.

Additional Resource: DREAM TEAM RECOMMENDER TOOL

Applicants are encouraged to use the Dream Team Recommender (DTR) tool to search for possible collaborators. Use of this tool is entirely optional and has no impact on evaluation of an application. DTR is a web application that was deployed to facilitate the assembly of scientific teams. The DTR application is based on the Northwestern Scholars database and uses matching and ranking algorithms for individual faculty members to self-assemble teams or for research managers to staff research teams based on individual attributes (such as skills or areas of expertise) and prior networks (such as co-authorship).

DTR has been developed and built by the Science of Networks in Communities (SONIC) Research Group at Northwestern University as part of a research project funded by NIH. If you wish to participate in SONIC’s associated research study, you will have the option to do so by accepting the consent form. However, you may use DTR even if you decline to participate in the research study. The tool is available at https://dtr.soc.northwestern.edu/. Users should login using NetID credentials.
Is an InfoEd record required for the NUCATS pilot submission?
No. This is an internal, institutional funding competition. Awards to Lurie Children’s Hospital and Shirley Ryan AbilityLab faculty require a subcontract processed through the Northwestern University Office for Sponsored Research.

Are indirect costs permitted?
No. Indirect costs are not permitted.

Does a department/division representative need to sign the submitted budget or budget justification prior to submission?
No.

Who should submit the pilot application in the online Competitions interface?
The submitting/contact PI is required to submit the pilot application using their Northwestern NetID and password.

Are no-cost extension requests accepted when needed & appropriately justified?
No. The NUCATS pilot awards are funded by our CTSA award from the NIH National Center for Advancing Translational Sciences (NCATS). 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.

If required, when should the applicant submit the IRB or IACUC application associated with the proposed pilot project?
Applicants are strongly encouraged to submit proposed projects to the appropriate IRB/IACUC for review by the proposal deadline on this RFA.

What are the most frequent proposal errors or issues that I should double-check prior to submission?
- Proposals are submitted by someone other than the submitting/contact PI.
- Proposals include non-allowable expenses.
- Proposals do not provide detailed feasibility & analysis plans, including power calculations (when appropriate).
- Proposals intending to use a research Core Service (either a Northwestern core or a research core(s) at the University of Chicago and University of Illinois at Chicago covered by the reciprocation agreement) neglect to include a formal, detailed cost estimate from the relevant Core(s).

What is the typical funding rate for NUCATS Pilot Awards?
Although this rate varies by year, the typical funding rate is less than 20%. Competition for NUCATS pilot awards is robust, and applicants are encouraged to prepare thoughtful, innovative, and polished applications.