Request for Applications TRANSCEND Pilot Projects Grant

Letter of Intent due September 6, 2024
Selected full initial applications due: November 8, 2024
Final submission to NIH: February 3, 2025
Anticipated award start date: April 1, 2025

Overview

The Translational Science Engaging North Dakota (TRANSCEND) Health Research Core is requesting applications for **Pilot Projects** Grant Awards. The goal of TRANSCEND is to train investigators in clinical and translational (C&T) research to develop unique and innovative means of combating disease in North Dakota. The mission of the Health Research (HR) Core is to stimulate the growth of expertise and engagement in C&T research through seed funding mechanisms. For general information about TRANSCEND, see https://med.und.edu/research/transcend/index.html.

The **Pilot Projects Grant** is intended to provide support to allow a research team to pursue a novel hypothesis. We anticipate supporting 4-5 new Pilot Projects awards at an amount of $75,000 total costs (direct + indirect) for one year with an anticipated start date of April 1, 2025. Applications should focus on clinical and translational research. Preclinical studies will only be considered if there is a clear plan to progress to clinical research. To determine whether or not your project is eligible for funding, see the resources on the HR Core's webpage, https://med.und.edu/research/transcend/health-research-core.html. The primary goal is to allow investigators to connect with all TRANSCEND Cores to generate competitive proposals for the TRANSCEND Developmental Projects Grant mechanism.

Eligibility Criteria

Faculty and clinicians at participating TRANSCEND institutions who have applied and been accepted into the TRANSCEND Portal network https://pathfinder.med.und.edu/ are eligible to apply. Investigators with a Principal Investigator (PI) role from other NIH IDeA funding mechanisms are not eligible for a PI role on TRANSCEND awards.

Prior consultation with the TRANSCEND 1) Navigator, 2) Professional Development Core, 3) Health Research Core, and 4) Research Design, Compliance, and Data Management Core is required for submission. Demonstration of available research percentage effort for the PIs/co-Is and associated personnel on the proposal must be provided. Evidence of available research effort and salary support must be provided in the form of a letter from the departmental chair or clinical service unit chief for each PI/co-I. All proposals must have completed internal approval at their respective institution.

Research areas applications can consider include the following topics:

- Any health concern relevant to North Dakota such as, but not limited to head and neck cancer, neurodegenerative diseases, behavioral problems, and environmental threats to health.

All proposals must include a discussion of the relevance of the proposal to the TRANSCEND mission and vulnerable populations in North Dakota: American Indian (rural and urban), rural, New American, Immigrant, and Foreign born (NFI) communities, and the lesbian, gay, bisexual, transgender, & queer + (LGBTQ+) community.

Team Requirements

Pilot Projects can be led either by an independent investigator or by a clinician fellow working with a research mentor. We define clinicians broadly as individuals involved in the treatment, care, or diagnosis of patients. This category includes physicians, therapists, nurses, clinical pharmacists, and speech pathologists, among others. All PIs and co-Is of Health Research Core projects must hold either a faculty appointment or equivalent position or a doctorate at one of the participating TRANSCEND institutions when the award begins. Any qualified clinician or non-clinician wishing to compete for these awards will be encouraged to work with the Administration Core to apply for an adjunct appointment at the relevant institution.

The teams may or may not require mentoring and collaborative support to initiate and carry out a research project with the express goal of maintaining a research effort. If a potential PI needs but has not been able to identify a relevant teammate, the Navigator will assist in identifying one from among the collaborating academic institutions and hospital networks participating in the TRANSCEND program. <u>The primary PI must also meet eligibility requirements for NIH funding.</u> Preparation of all pilot awards should involve extensive interaction pre-submission as well as post-award with the Navigator and Health Research Core, who will coordinate interactions with other cores to provide insight regarding research design, grant/publication preparation, and federal/non-federal funding mechanisms.

In accordance with NIH's guidelines for team roles and agreements, the PI will lead the project's scientific development or execution. The co-I will be involved with the PI in the project's scientific development or execution, but not quite at the level of a full PI. In your application's budget justification, you must detail the activities/contributions of the PI, co-I, and any other key personnel.

Budget and Proposal Approval Requirements

Depending on the institutions involved in the project, institutional Sponsored Programs Administrations (SPAs) may have additional requirements for budget and proposal approval. The University of North Dakota and North Dakota State University SPAs require applications to be electronically routed through Novelution *prior to final submission to the Health Research Core.*

<u>**Criteria for Evaluation of Pilot Projects Applications Include:**</u>
- Relevance to the research priorities and vulnerable populations identified by TRANSCEND;
- Potential for the team to coalesce around a relevant topic;
- Strength of the investigative team and any collaborators;
- Strength of significance, innovation, approach, and environment.

<u>**General Terms and Conditions of Health Research Core Awards:**</u>
- TRANSCEND Health Research projects must have a single PI who will be responsible for the scientific direction and management of the project. The PI can be a non-US citizen on a visa.
- The PI for Health Research projects may not concurrently have research funding from other IDeA Program award mechanisms (e.g., INBRE, COBRE, and DaCCoTA).
- Funds may be used for consumable supplies, services, small laboratory hardware (nothing >$5,000), personnel costs (including salaries of PIs and co-Is up to 5%), and travel.
- All funded projects must participate in a mentored grant writing program through the Health Research and Professional Development Cores throughout the duration of the project period.

- All funded projects must have clearly established milestones, with milestone progression monitored by the Health Research Core and Administrative Core. These milestones include biannual progress reports for each progress year, one of which will be submitted to NIH, and a project completion survey at the end of the project period. Also at the end of the project period, Pilot Projects must submit a manuscript draft for internal and external review.
- Investigators who receive TRANSCEND support are <u>required</u> to provide an **oral presentation at the annual TRANSCEND symposium**, as well as a summary appropriate for non-researchers. A video recording of the presentation and summary will be maintained on the TRANSCEND website for dissemination to the public and communities of interest in North Dakota.
- Any publication arising from the work supported by TRANSCEND must cite the grant, 1P20GM155890-01.
- Term and budget adjustments: The TRANSCEND PIs reserve the right to make term and budget adjustments in accordance with the intent of the funding mechanism and NIH policies concerning scientific overlap of projects.
- Unanticipated new requirements: By accepting TRANSCEND funds, awardees agree to comply with any and all requirements not already mentioned that may be imposed on TRANSCEND by NIH or other institutional authority.

The Application Process and Deadline

The deadline for seeking assistance in finding a collaborator from the Navigator is August 30, 2024.
Letters of Intent (1 page maximum) are due September 6, 2024.
Letters of Intent acceptance will be determined the week of September 9, 2024.
Teams whose Letters of Intent are accepted must meet with the RDCD Core by October 11, 2024.
Full initial applications (all components except IRB/IBC/IACUC approvals) will be due November 8, 2024.
Selected applicants following initial review will be notified to move forward by December 2, 2024.
IRB/IBC/IACUC applications must be submitted by December 16, 2024.
Applications must be routed through institutional SPAs by December 16, 2024.
Applications will be submitted to for EAC review by January 2, 2025.
Final submission of completed grant is due by February 3, 2025.
Awards are expected to be announced by March 31, 2025.
Expected award period will be April 1, 2025-March 31, 2026.

Step 1 – Letter of Intent

Before submitting a Letter of Intent (LOI), prospective applicants must connect with the TRANSCEND Navigator, Jamie (Scholl) Bushman (Jamie.Scholl@USD.edu), and Health Research Core Coordinator, Savannah Macias-Daugherty (Savannah.M.Daugherty@UND.edu). LOIs should be sent as a PDF via email to Savannah Macias-Daugherty.

Your letter of intent must:
- Be sent to the email above as a PDF attachment by **5 PM on September 6, 2024**
- Be no longer than one page, single spaced. Utilize 11 pt. or greater font. Provide at least one-half in margins (1/2") – top, bottom, left, and right – for all pages
- Explain briefly the nature or focus of the research that will be proposed and, if not obvious, how it fits the research priorities and populations identified by TRANSCEND
- Include a description of both the PI and collaborator(s) roles in the proposed research

Step 2 – Evaluation

Similarly to the full proposal, LOIs will be evaluated based on relevance to the research priorities and vulnerable populations identified by TRANSCEND, potential for the team to coalesce around a relevant topic, strength of the investigative team and any collaborators, and strength of significance, innovation, approach, and environment.

Based on evaluation of your LOI by the Health Research Core, you will be notified the week of September 9, 2024 if you are invited to prepare and submit a full application.

Step 3 – Prepare and Submit a Complete Application

Applications should be prepared in general accord with the NIH PHS 398 application guidelines.
Go to: https://grants.nih.gov/grants/funding/phs398/phs398.html
PDF Instructions for forms: https://grants.nih.gov/grants/funding/phs398/phs398.pdf

<u>**Please Complete the Following:**</u>
1. Form Page 1: Face Page
2. Form Page 2: Summary, Relevance, Project/Performance Sites
3. Form Page 2-continued: Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
4. Form Page 4: Detailed Budget for Initial Budget Period
5. Detailed Budget Justification
6. Biographical Sketches for PI, Co-I and Senior/Key Personnel
   (https://grants.nih.gov/grants/forms/biosketch.htm)
7. Research Plan (single spacing, 11 pt. or greater font)
   a. Response to review if resubmission (0.5 page)
   b. Specific Aims (1 page)
   c. Significance (0.5 page)
   d. Innovation (0.5 page)
   e. Research Strategy (maximum 6 pages)
      i. Rigor and transparency: As appropriate, a description of the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of project, and a description of the experimental design and methods proposed and how the investigator will achieve robust and unbiased results. If applicable, a brief description of the methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed project (see Notice NOT-OD-16-011 for details).
   f. Bibliography and References Cited (use Continuation Format Page)
   g. Vertebrate Animals Section (if applicable)
8. Consortium/Contractual Arrangements (if applicable)
9. Letters of Support
   a. from Department Head and/or Clinical Unit Chief, consortium participants, Senior/Key Personnel, and Other Significant Contributors included in application
10. Resource Sharing Plans(s) (if applicable)
11. Authentication of Key Biological and/or Chemical Resources (if applicable)
12. PHS 398 Checklist

In addition, please observe the following:

All applicants proposing studies involving human subjects or vertebrate animals must initiate the process of obtaining IRB or IACUC approval prior to submitting their applications and include letters verifying approval.

All proposals recommended by the TRANSCEND review panels will require approval by NIH prior to initiation. If the proposed study <u>involves human subjects</u>, the following documents will need to be submitted to Savannah Macias-Daugherty prior to application submission to NIH:

- Written protocol addressing the risks and protections for human subjects, in accordance with NIH's Instructions for Preparing the Human Subjects Section of the Research Plan
- Institutional Review Board (IRB) approval
- Human Subjects Training education courses through the Collaborative Institutional Training Initiative (CITI Program)
    - Certificates and completion reports must be included for PI and Key Personnel
- Create Inclusion Data Record (IDR) and enter inclusion data in Inclusion Management System (IMS)

If the proposed project <u>involves clinical trials</u>, in addition to above documents, the following documents must also be submitted to Savannah Macias-Daugherty before application submission to NIH:

- Specific plans for data and safety monitoring
- Good Clinical Practice (GCP) certification through the CITI Program
    - Certificates and completion reports must be included for PI and Key Personnel

If the proposed project <u>involves animals</u>, the following documents must be submitted to Savannah Macias-Daugherty before application submission to NIH:

- Animal Care and Use education courses through the CITI Program
    - Certificates and completion reports must be included for PI and Key Personnel

More information

Questions related to the **Pilot Projects Grant Awards** should be directed to Savannah Macias-Daugherty, Health Research Core Coordinator (Savannah.M.Daugherty@und.edu)