



Request for Applications TRANSCEND Pilot Projects Grant

Letter of Intent due: **August 8, 2025**

Selected full initial applications due: **October 10, 2025**

Final submission to NIH: **March 6, 2026**

Anticipated award start date: **July 1, 2026**

Overview

The Translational Science Engaging North Dakota (TRANSCEND) Health Research Core is soliciting applications for **Pilot Projects**. The goal of TRANSCEND is to train investigators in clinical and translational (C&T) research to develop innovative means of combating and preventing disease in North Dakota. TRANSCEND's Health Research (HR) Core seeks 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 researchers to pursue novel hypotheses. We anticipate supporting 4-5 new Pilot Project awards at an amount of \$75,000 total costs (direct + indirect) for one year with an anticipated start date of July 1, 2026. Applications should focus on clinical and translational research. Preclinical studies will be considered *only* if there is a clear path 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. Investigators with a Principal Investigator (PI) role from other NIH IDeA funding mechanisms are not eligible for a PI role on TRANSCEND awards. Previous TRANSCEND Pilot Project awardees are not eligible to apply for a second Pilot Project award.

Prior consultation with the TRANSCEND 1) Navigator, 2) Professional Development Core, 3) Health Research Core, 4) Research Design, Compliance, and Data Management Core, and 5) Community Engagement and Outreach Core is required for proposal 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.

Priority research areas applications include the following topics:

Rural Communities, esp.:

- Health effects of environmental contaminants/exposures
- Healthcare access (e.g., screening)

New Americans, esp.:

- Housing access
- Harm reduction programs
- Healthcare access

Older Adults, esp.:

- Chronic disease
- Abuse
- Wandering & missing elders
- Aging in Place (i.e., aging in one's own community)

Youth & Young Adults, esp.:

- Electronic cigarette/THC use
- Suicide/Mental health
- Illicit drug use

Military Veterans, esp.:

- Healthcare access
- Addiction
- Suicide/Mental health
- Health effects of battlefield contaminants

General Population, e.g.:

- Suicide/Mental health
- Addiction medicine training
- Prenatal care issues
- IV illicit drug use (i.e., Hepatitis C/HIV transmission concerns)
- Barriers to effective healthcare treatment
- Cancers prevalent in ND (e.g., lung, colorectal, thyroid, chronic lymphocytic leukemia)

*Proposals applicable to the research priorities above will be given priority consideration for funding. Proposals in other research areas that are clearly relevant to North Dakota and its populations also will be considered. **It is incumbent on the applicant to demonstrate the importance of the problem selected to North Dakota.** Note that proposals that do not involve individual patients/persons (i.e., purely laboratory-based investigations that do not involve identifiable patient samples and/or purely data analysis applications that involve anonymous participants) are not eligible.*

Personnel 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.

Research personnel 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 a teammate but has not been able to identify one, the Navigator will assist in identifying one from among the collaborating

academic institutions and hospital networks participating in TRANSCEND. The PI must also meet eligibility requirements for NIH funding. 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 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 submission to the External Advisory Committee.*

Criteria for Evaluation of Pilot Projects Applications Include:

- Relevance to the research priorities and TRANSCEND mission;
- Potential for the research personnel to coalesce around a relevant topic;
- Strength of the investigative personnel and any collaborators;
- Strength of significance, innovation, approach, and environment.

General Terms and Conditions of Health Research Core Awards:

- 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 required 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 (if needed) is July 25, 2025.
- Letters of Intent (1 page maximum) are due August 8, 2025.
- Letters of Intent acceptance will be determined the week of August 11, 2025.
- Teams whose Letters of Intent are accepted must meet with all Cores by September 12, 2025.
- Full initial applications (all components except IRB/IBC/IACUC approvals) will be due October 10, 2025.
- Selected applicants following initial review will be notified to move forward by December 1, 2025.
- IRB/IBC/IACUC applications must be submitted by January 30, 2026.
- Applications must be routed through institutional SPAs by January 30, 2026.
- Applications will be submitted to for EAC review by February 13, 2026.
- Final submission of completed grant to NIH is due by March 6, 2026.
- Awards are expected to be announced by June 30, 2026.
- Expected award period will be July 1, 2026-June 30, 2027.

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:

- Explain briefly the nature or focus of the research that will be proposed, the relevance to North Dakota populations, and, if applicable, how it fits the research priorities identified by TRANSCEND
- Include a description of both the PI and any collaborator(s) roles in the proposed research
- 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
- Be sent to the email above as a PDF attachment by **5 PM on August 8, 2025**

Step 2 – Evaluation

Similarly to the full proposal, LOIs will be evaluated based on relevance to the research priorities and the TRANSCEND mission, potential for the research personnel to coalesce around a relevant topic, strength of the investigative personnel 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 August 11, 2025 if you are invited to prepare and submit a full application.

Step 3 – Prepare and Submit the Initial 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>

Please Complete the Following for the Initial Application:

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 and Co-Is (<https://grants.nih.gov/grants/forms/biosketch.htm>)
7. Other Support documents for PI and Co-Is (<https://grants.nih.gov/grants-process/write-application/forms-directory/other-support-format-page>)
8. Research Plan (single spacing, 11 pt. or greater font)
 - a. Response to review if resubmission (0.5 page)
 - b. Specific Aims (1 page)
 - c. Research Strategy (maximum 3 pages)
 - i. Significance (~0.5 page)
 - ii. Innovation (~0.5 page)
 - iii. Approach (~2 pages)
 1. 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).
 - d. Bibliography and References Cited (use Continuation Format Page)
 - e. Vertebrate Animals Section (if applicable)
9. Consortium/Contractual Arrangements (if applicable)
10. Letters of Support
 - a. from Department Head and/or Clinical Unit Chief, consortium participants, Senior/Key Personnel, and Other Significant Contributors included in application
11. Resource Sharing Plans(s) (if applicable)
12. Authentication of Key Biological and/or Chemical Resources (if applicable)
13. PHS 398 Checklist

In addition, please observe the following:

All applicants proposing studies involving human subjects or vertebrate animals must obtain IRB, IBC, and/or IACUC approval prior to submitting their *final* applications to NIH 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 involves human subjects, 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 working with human subjects
- Create Inclusion Data Record (IDR) and enter inclusion data in Inclusion Management System (IMS)

If the proposed project involves clinical trials, 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 conducting the trial

If the proposed project involves animals, 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 working with animals

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)

General questions about TRANSCEND's goals and opportunities can be directed to Gary G Schwartz, TRANSCEND Project Director (Gary.Schwartz@und.edu)