

# Clinical and Translational Pilot Grants Program

Request for Proposals and Preliminary Application Instructions – 2026

\*\*\*Submission of this preliminary application is a requirement and the first step toward the submission of a Full Application.

# **Goals and Background**

The mission of the Delaware CTR ACCEL Program is to accelerate clinical and translational research that addresses health outcomes of Delawareans. The CTR Pilot Projects Program annually solicits applications for funding of projects related to clinical and translational (C&T) research. C&T Pilot grants may be either <u>Regular</u> <u>*C&T Pilots*</u> or <u>*Community Engagement C&T Pilots*</u>. Regular C&T Pilots will provide funds for a 1-year period; Community Engagement C&T Pilots will provide funds for a 2-year period. A budget of up to \$80,000 direct costs may be requested. Both types of Pilots are intended to allow a research team to develop a more substantial basis for independent external support from the NIH.

# Deadlines

Interested applicants are required to submit a <u>*Preliminary Application*</u>, due **Monday, Jan 20, 2025 by 5:00 PM**. Based on a scientific review of the Preliminary Applications, a subset of applicants will be invited to submit a <u>*Full Application*</u>, due <u>*Monday, May 12, 2025 by 5:00 PM*</u>. PIs are strongly encouraged to complete both submission processes well in advance of their deadlines, as the submission windows will close at 5 pm sharp and <u>*no exceptions will be made*</u>. Partial or incomplete applications will not be reviewed.

Before a proposal can be submitted, the <u>proposal PI must register as an ACCEL user and have a valid ORCID</u> <u>account linked to ACCEL.</u> If an ORCID is not linked to the investigator profile and their full profile is not populated, updated and attested to, then this preliminary application will be <u>administratively</u> withdrawn. Proposals must be submitted by the PI. Proposals submitted under another user's ACCEL account will not be accepted.

# Eligibility

Grants are given to support clinical or translational work that will addresses health outcomes of Delawareans and facilitate the growth or expansion of the PI's work toward an impactful and independent line of research that will be competitive for external support from the NIH.

PIs must be from one of the ACCEL partner institutions, i.e., University of Delaware, Nemours, Christiana Care, and Delaware State University. Multiple PI (MPI) applications are allowed, as long as all PIs are from ACCEL partner institutions. PIs of Community Engagement C&T Pilot proposals must include a community member (not from a partner institution) as a member of the research team.

PIs must hold a faculty appointment or equivalent at the time the award commences. These are individuals









who can independently apply for Federal or non-Federal investigator-initiated peer-reviewed Research Project Grants (RPGs). Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible PIs.

PIs may not concurrently have research funding from other IDeA Program award mechanisms (e.g., INBRE, COBRE, CTR). If the proposal includes subcontracts, please consult with your institutional PI prior to submitting. Subcontracts to institutions located in non-IDeA states are not allowed. However, services provided in non-IDeA states can be purchased on a fee-for-service basis. Pilots may not overlap with ongoing funded projects.

### Credentialing

Investigators who will be working in hospitals may need to obtain credentials and are encouraged to begin that process well in advance of the start date of the grant, as the process can take several months.

# **Consultation with ACCEL Cores**

Use of one or more of the ACCEL Cores is encouraged before submission and/or during the project award period. A brief description of some of the ACCEL Core resources is provided below. More detailed information about each of the cores can be found on the <u>ACCEL website</u>.

### ACCEL Biostatistics, Epidemiology & Research Design (BERD) Core

Applicants are encouraged to consult with the BERD Core to review their study design, methods, and statistical approaches prior to submission: <u>https://dash.de-ctr.org/consult/submit/berd</u>. The BERD Core also has established mechanisms to obtain access to Medicaid and Medicare claims data as well as to the National COVID19 Cohort Collaborative (N3C) registry (<u>https://covid.cd2h.org/N3C</u>) for investigators with relevant research aims. Requests for BERD Core assistance prior to submission of a Full Application should be made no later than April 14, 2025. Contact <u>Dr. Claudine Jurkovitz</u> for more information.

# ACCEL Professional Development (PD) Core

\*\*Pilot proposals led by investigators who have not previously been the PI of a funded NIH K or R series grant **must** identify a research mentor. A research mentor must be identified, and his/her biographical sketch must be included as part of the preliminary application packet as well as a letter of support, detailing the mentoring support provided A mentoring compact will also need to be signed and included in the documents required at the final submission in May (if selected). Investigators are strongly encouraged to contact the PD Core beginning at this Preliminary Application Stage to begin working with the Core to maximize assistance.

The PD Core also offers a **Flight School** to help investigators prepare to submit a pilot grant to ACCEL. At the first Flight School session (Spring 2025), submission requirements are reviewed and research ideas for each pilot proposal are discussed. Additional resources needed by investigators are identified. At the second session (Spring 2025), specific aims are reviewed and discussed, and the other components of the proposal are reviewed. Contact <u>mentoring@de-ctr.org</u> for more information about sign up and dates for Flight School.

In addition, pilot proposals led by junior investigators or those without prior NIH experience are encouraged to take advantage of career development programs offered. The Junior Investigators Network provides weekly sessions on career development and research proposal writing that can be attended via phone or computer. Contact <u>mentoring@de-ctr.org</u> for more information.







### ACCEL Community Engagement and Outreach (CEO) Core

The CDC defines community engagement as "...the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people." See the CDC's complete description of <u>community engagement</u> for more details. ACCEL Community Engagement C&T Pilot proposals should include a plan for substantive collaboration and partnership with individuals or groups who are expected to be impacted by the research for the purpose of including their perspectives at multiple stages of the project. In addition, PIs conducting Community Engaged <u>curriculum</u> within 6 months of the pilot project start date.

To facilitate community engagement, *all applicants* are strongly encouraged to involve the CEO Core prior to submission. The CEO Core helps PIs realize the potential community impact of their work and can aid in making connections to community partners when appropriate. While it is expected that PIs of proposals for Community Engagement C&T Pilots will contact the CEO Core, applicants submitting Regular (non-community engaged) C&T Pilot proposals should also consider a CEO consultation, since all proposals need to address community engagement in the Full Application. Requests for CEO Core assistance should be submitted no later than April 1, 2025. Contact <u>Dr. Lee Pachter</u> for more information.

# **Application Submission Information**

Whether or not internal routing is required prior to submission of the preliminary or full application is determined by each institution. PIs should work with their institutional ACCEL administrator to assure that all required documents are completed correctly and submitted on time with the application. The following ACCEL research officers should be consulted prior to submission:

Christiana Care: <u>Brud Bacon</u> Delaware State University: <u>Sangeeta Gupta</u> Nemours: <u>Ranita Chakrabarti</u> University of Delaware: <u>Robyne Nizer</u>

Upon submission of the Full Application to the Delaware CTR ACCEL, it may be forwarded to the appropriate institutional office for budget and effort verification.

# **Preliminary Application Submission Components**

Preliminary Applications will consist of a structured proposal summary (1 page) that outlines succinctly the specific aims, significance, and approach planned for the pilot project. All key personnel must also be identified and biographical sketches for all are to be included. *Further details and step-by-step instructions to submit a Preliminary Application can be found at the end of this document*.

New (never before submitted), Resubmission (previously submitted pilot proposal that was not selected for funding) and Renewal (previously awarded pilot project with promise that requires further support) applications are accepted. However, for a Renewal application to be considered for funding, the PI must demonstrate a significant and impactful degree of progress over the previous funding period as well as a clear need for additional funds to continue the work. Revisions (modifications/expansions of a proposal already in submission) are not allowed. The number of awards is contingent on the ACCEL budget, NIH appropriations, and the submission of a sufficient number of meritorious applications. A PI may submit only 1 Preliminary Application.

A 1-page <u>Plan for Enhancing Diverse Perspectives (PEDP) is also required</u>. Examples can be found <u>here</u> and are provided below in the instructions.

### Preliminary Application Review

Preliminary Applications will be reviewed by members of the Delaware CTR ACCEL Program leadership.

Reviews use a modified version of the NIH R-type grant application scoring system, in which scores are given for *individual review criteria* as well as *overall impact*. Scores for each may range from 1 (Exceptional) to 9 (Poor). A score of 5 is considered an average score. The preliminary review will include an evaluation of the proposal based on the <u>new NIH review criteria</u> of *Importance of Research*, *Rigor and Feasibility*, and *Expertise and Resources* (including the primary mentor, if appropriate). The *overall impact score* will weigh each of the individual review criteria, with emphasis given to the feasibility, potential for development into a NIH proposal, and ACCEL priorities.

Preliminary Applications will be rank ordered by *overall impact score* and the top applications will be invited to submit a Full Application.

All pilots must involve research that falls on the translational spectrum (see definition <u>here</u>) and a majority of pilots funded by ACCEL will be clinical research. In addition, ACCEL prioritizes:

- Projects addressing medically underserved populations
- Projects addressing conditions disproportionately affecting Delawareans
- Projects led by junior PIs, defined as any of the following:
  - PIs of junior rank (assistant professor or equivalent)
  - PIs with no prior NIH funding as a PI (not including trainee funding; e.g., NIH F awardees)
  - PIs with no prior NIH R01 funding, or equivalent, as a PI
- PIs with no prior ACCEL funding (not including prior Mentored Research Development Awardees)
- Projects that are interdisciplinary and/or span multiple regions of the translational spectrum
- At least two Community Engagement C&T Pilots will be recommended for funding, if possible.
- All ACCEL partner institutions will be represented in the pilots recommended for funding, if possible.

# **ACCEL Pilot Award Submission Timeline**

<b>1/20/25</b> by 5:00 pm	Preliminary Application submission deadline * required to move forward into Full Submission application
2/10/25, 2025	Invitations for Full Applications sent
May 12, 2025 by 5:00 pm	Full Application submission deadline
Aug 11, 2025	Potential awardees notified
Sept 30, 2025	Just-In-Time due (IRB/IACUC approval, human subjects certs due, HSCT forms, fully compliant biographical sketches)
November 1425	Proposals sent to NIH for approval
January 1, 2026	Anticipated project start date

# **Expectations**

All pilot awardees are required to attend ACCEL conferences to present their work (Annual Community Research Exchange and Annual Advisory Meeting) and the annual (national or regional) NIH IDeA Conference. Awardees are required to present their project once during a Junior Investigators Network Touchbase session and at least once to communities of interest through CEO Core coordination. They are required to cite the ACCEL grant (NIH U54 GM104941) on all related publications and to submit quarterly interim progress reports and an NIH annual progress report. For mentored awardees, active participation in the mentoring process is required for both mentors and mentees, including completion of mentor reports. Awardees must keep ACCEL FULL profiles up to date (at least twice per year) and respond to ACCEL surveys. If applicable, clinical trial registration and timely reporting of IRB changes, Adverse Events (AEs) or results at ClinicalTrials.gov is required. ACCEL institutional site PIs have direct oversight of all pilot projects and awardees must share project outcomes and progress reports with their site PI. Awardees are responsible for reporting outcomes at award end, up to three years post award end, and as requested during the life of the Delaware CTR ACCEL Program.

# Contacts

For questions about the Pilot Grants Program submission and review process, please contact: <u>Megan</u> <u>Wenner, PhD</u>; ACCEL Pilot Projects Program Director

For specific questions related to ACCEL Core resources, please contact the appropriate Core Director: <u>Robert Akins, PhD</u> and <u>copy Julianne Ross</u>; Professional Development Core Director <u>Claudine T. Jurkovitz, MD, MPH</u>; Biostatistics, Epidemiology & Research Design Core Director <u>Lee M. Pachter, DO</u>; Community Engagement & Outreach Core Director

# **Delaware CTR ACCEL**

# **2026 C&T Pilot Grant Submission Instructions**

#### PRELIMINARY APPLICATION SUBMISSION INSTRUCTIONS

Preliminary Applications will be submitted through the Delaware CTR ACCEL <u>Dashboard</u>. Select the correct mechanism from the list of funding opportunities: "Clinical & Translational Research Pilot Grants Program", click the button, "Submit a <u>Preliminary Application</u>" and follow the prompts to complete all sections, upload documents, and submit the proposal. Note that before a proposal can be submitted, the proposal PI must register as an ACCEL user and have a valid ORCID account linked to ACCEL. If an ORCID is not linked to the investigator and their full profile is not populated, updated and attested to, then this preliminary application will be <u>administratively</u> withdrawn. Proposals must be submitted by the PI; proposals submitted under another user's ACCEL account will not be accepted.

The documents to be uploaded should be written with Arial 11 pt or larger font. Pages are to be standard letter size  $(8^{1/2}" \times 11")$  with at least one-half inch margins. Documents should be converted to PDF for submission. Any documents not following these requirements may be administratively withdrawn without review.

# Instructions for the Delaware CTR ACCEL Preliminary Application Submission:

#### **Project Details**

<u>Title of proposed research</u> In the text box, provide a descriptive, yet succinct, title for the project. Note: If your project includes human subjects, your title must match exactly your project title on your IRB and Human Subjects paperwork.

#### **Investigator Status**

<u>Career stage</u> Select from the options to indicate whether the project PI is an early-stage investigator, midcareer investigator, or senior investigator. The ACCEL CTR considers early-stage investigators to be at the assistant professor or equivalent ranking, mid-career investigators to be at the associate professor or equivalent ranking, and senior investigators to be at the full professor or equivalent ranking.

<u>Prior NIH funding status</u> Select 'yes' or 'no' to indicate whether the project PI is a new investigator. The ACCEL CTR considers a new investigator to be any investigator who has not previously been PI of a funded NIH K- or R-series award or equivalent extramural funding. *Any PI who is considered by ACCEL to be a new investigator must identify a primary research mentor who will contribute to the science of the project and the mentorship of the PI.* New investigators are <u>strongly encouraged</u> to reach out to the PD Core during these initial stages to maximize assistance.

#### **Type of Research**

Human subjects Indicate whether the proposal involves human subjects.

<u>Vertebrate animals</u> Indicate whether the proposal involves vertebrate animals.

<u>Type of pilot application</u> Indicate whether the proposal is a Regular Pilot (12 months of funding) or a Community Engagement Pilot application (24 months of funding).

#### **Team Members**

The first PI's name and role will already be pre-populated in the table.

Multiple PIs Select 'yes' or 'no' to indicate whether the project involves multiple PIs (MPI). Selecting 'yes' will

trigger the button "Add New PI" to appear on the far right. Click "Add New PI" and provide the additional (second) PI's information and biosketch. Also provide the additional PI's career stage and prior NIH funding status (see descriptions above). If the additional PI is considered by the ACCEL CTR to be a new investigator, then that PI must identify a primary research mentor. Please note, for MPI applications, the PI completing the application in the Dashboard will be considered the contact PI to whom all correspondence will be addressed and will be the responsible party for reporting on the project's progress

<u>Add New Team Member</u> Click this button to add all other team members. Additional team members may include co-investigators (CI), consultant(s), and/or mentor(s), if applicable. Community / clinical partners should also be identified here, if appropriate.

<u>Biosketches</u> Biographical sketches are required <u>for most team members</u>. Upload biosketches (*limit, 5 pages per person*), formatted using the NIH <u>Biographical Sketch Format Pages</u> for each of the following personnel. Detailed instructions for the <u>current NIH biosketch format</u> may be found <u>here</u> and a sample format biosketch may be found <u>here</u>.

- PI required
- Other team members, including the primary mentor required, if applicable
- Community / clinical partner optional to include resume, CV, or biosketch, if applicable

\*\*Please note: If your project is determined to be recommended to the NIH for funding in the summer of 2025, the biosketch format and requirements listed above are <u>changing</u> as of May 25, 2025.

Please be prepared to generate a new biosketch using ScienCV for all team members for JIT collection. Because it is a new process, it may take additional time for investigators to complete. **It would be prudent** to begin generating an edited and compliant biosketch immediately after submitting to this Preliminary Application. There is also an **NIH Biosketch Supplement form** needed for each biosketch as well. Biosketch details should be specific to this project as they and the Letters of Support (Chair and Mentor) will be used to identify expertise and team strengths available for completion of the project. These items (LOSs and biosketches) are resources to support sufficient/not sufficient **reviewer ratings** for the investigator/facilities category consideration.

# **Project Topic(s)**

Indicate whether the topic of the proposal falls into any of the provided keyword categories. Select all that apply. If none apply, check 'Other'.

### **Supporting Files**

<u>Structured proposal summary</u> Upload the preliminary proposal. The structured proposal summary (*limit, 1 page*) outlines succinctly, *and using language that a scientist from outside your specific field could easily understand*, the specific aims, significance, and approach of the proposed pilot project. A single diagram or schematic may be included in the single page, if desired, to explain key aspects of the proposal, but note that text boxes, footnotes, etc. may not be used to circumvent page/font limits. The structured proposal summary should address the following:

- Identify the research question(s).
- Provide a rationale for the importance of the research question(s).
- Describe key background literature and identify the knowledge gap the proposal is intended to fill.
- State the specific aims and hypothesis(es) to be tested and/or the discovery(ies) to be made. Note that the aims must be proportional to the resources, timeline, and budget allotted for pilot awards.
- Broadly describe the research approach, in a concise and straightforward manner. Here, your writing should be streamlined so that reviewers outside of your specific field can easily grasp the information. Note that the Full Application, and not here, is where you will have the opportunity to thoroughly explain your plan, add more details and emphasis, and anticipate reviewers' questions.
- Describe the major expected outcomes and identify how any pitfalls will be handled.
- Describe the products expected to come from the project, if funded.

<u>References</u> Include a listing of the full citations (*no page limit*) for all references cited in the Structured Proposal Summary. In-text references should be provided either by author last name and date or by a superscript number. The references section should be appended to the single page proposal summary and uploaded together as a single PDF file. Hot links <u>are not acceptable</u> within the references.

Letter(s) of Support Required for mentor; may include for other key personnel.

<u>Plan for Enhancing Diverse Perspectives (PEDP)</u> Required. In this 1 page document, investigators must also include a Plan for Enhancing Diverse Perspectives (PEDP). <u>Examples</u> include: partnerships that enhance geographic and regional heterogeneity; teams composed of researchers at different career stages; participation of individuals from diverse backgrounds, such as those from underrepresented racial and ethnic groups, those with disabilities, and those from disadvantaged backgrounds, and women (click <u>here</u> for description); engagement from different types of institutions/organizations (e.g., research-intensive, undergraduate-focused, minority-serving community based). Use <u>Continuation Format Pages</u> for this document; 1 page limit.

\*\*\*Remember to adhere to page and formatting requirements and to upload all necessary documents. Applications that are incomplete or not in compliance with the formatting requirements will be administratively withdrawn without review. \*\*\*