Clinical and Translational Pilot Grants Program
Request for Proposals and
Preliminary Application Instructions - 2024

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 Regular C&T Pilots or Community Engagement C&T Pilots. 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. Both kinds are intended to allow a research team to develop a more substantial basis for independent external support from the NIH.

Special Note for 2023-24
The Delaware CTR ACCEL Program is in its final year of funding. Although a renewal application has been submitted, there is currently no guarantee of additional funding. Thus, 2024 Clinical & Translational Pilot Award funding is contingent upon successful renewal of the ACCEL Program by NIH.

Deadlines
Interested applicants are required to submit a Preliminary Application, due Friday, March 31, 2023 by 5:00 PM. Based on a scientific review of the Preliminary Applications, a subset of applicants will be invited to submit a Full Application, due Friday, July 7, 2023 by 5:00 PM. 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 no exceptions will be made. Partial or incomplete applications will not be reviewed.

Before a proposal can be submitted, the proposal PI must register as an ACCEL user and have a valid ORCID account linked to ACCEL. Proposals must be submitted by the PI (or their ACCEL designee). Proposals submitted under another user’s ACCEL account will not be accepted.

Award Information
All pilot awards must consist of clinical or translational research (see definition of translational research by Rubio et al., 2010). In addition, more than half of all pilot proposals awarded by ACCEL must be clinical, i.e., involving human subjects. Further, because community engagement is a priority of the Delaware CTR ACCEL Program, all applications (i.e., including Regular C&T Pilot applications) must outline a plan for outreach, involvement, and/or dissemination of their research findings to a relevant community. See the CDC’s definition of community engagement for more details.

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 (see Pre-Submission Assistance and Feedback section). More detailed information about each of the cores can be found on the ACCEL website.


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.

**Timeline**
A budget period of up to 12 months (Regular C&T Pilots) or up to 24 months (Community Engagement C&T Pilots) may be requested. Pilots may be granted a no-cost extension of 6 additional months, if adequately justified.

**Budget**
Up to $80,000 direct costs may be requested for pilot projects. A typical pilot grant will support clinical research coordinators, postdoctoral fellows, or graduate students, as well as appropriate amounts for supplies, travel, etc. PIs are discouraged from requesting salary for this work, instead providing it as an institutional commitment. Whether salary is charged to the grant or not, the anticipated effort must be indicated in the budget. For UD investigators, a minimum of 1% cost share is required. Budgets must follow all NIH budget guidelines for allowability of costs.

**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 should strongly consider including 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.

**Pre-Submission Assistance and Feedback**

**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: [https://dash.de-ctr.org/consult/submit/berd](https://dash.de-ctr.org/consult/submit/berd). 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 ([https://covid.cd2h.org/N3C](https://covid.cd2h.org/N3C)) for investigators with relevant
requests for BERD Core assistance prior to submission of a Full Application should be made no later than June 23, 2023. Contact Dr. Claudine Jurkovitz for more information.

**ACCEL Professional Development (PD) Core**

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 Dr. Rob Akins for more information.

In addition, *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* and work with the PD Core to develop and submit a detailed individual development plan (IDP, written by the PI) and mentoring plan (MP, written by the mentor) as part of the Full Application. The IDP and MP do not need to be completed at the time the Preliminary Application is submitted, but the research mentor must be identified, and his/her biographical sketch should be included as part of the application packet.

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 (May), submission requirements are reviewed and research ideas for each pilot proposal are discussed. Additional resources needed by investigators are identified. At the second session (June), specific aims are reviewed and discussed, and the other components of the proposal are reviewed. Contact Dr. Rob Akins for more information about sign up and dates for Flight School.

**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 community engagement 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 Engagement C&T Pilots must complete or show competence in the ACCEL Community Engaged curriculum 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 June 14, 2023. Contact Dr. Lee Pachter 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: Mia Papas
- Delaware State University: Dayna Littleton
- Nemours: Ranita Chakrabarti
- University of Delaware: Robyne Nizer

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.

**Full Application Submission Components**

The full proposal is similar in format and style to that of an NIH R03 proposal, with a few exceptions. The Specific Aims page must be no longer than 1 page and the Research Strategy section (with Significance, Innovation, Approach, and Community Engagement subsections) must be no longer than 4 pages. Further details and step-by-step instructions to submit a Full Application will be provided at the time notification is sent to those who are invited to submit.

**Review Criteria**

**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 **individual review criteria** of Significance, Investigators (including the primary mentor, if appropriate), and Approach. 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.

**Full Application Review**

**Scientific Merit Scoring:** Reviewers of the Full Applications are selected based on their relevant research expertise. Reviews use 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 individual review criteria are Significance, Investigators(s), Innovation, Approach, Community Engagement, and Environment. The **overall impact score** reflects a reviewer’s overall evaluation of all aspects of the project (not the numerical average of the individual criterion scores). For pilot grants, the **overall impact score** indicates the reviewer’s assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved as well as it’s chance of being developed into a full NIH proposal with a high likelihood of success. Full Applications will be rank ordered by **overall impact score**.

**Mentorship Scoring:** PIs who have not previously been the PI of a funded NIH K or R series grant must identify a research mentor and include an Individual Development Plan (IDP) and a Mentorship Plan (MP) with their Full Application. After the Preliminary Application is reviewed but before the Full Application is due, these PIs will work with the ACCEL Professional Development (PD) Core to develop their unique IDP and MP. See details provided in the ACCEL PD Core section above. Reviews of these applications will include an additional individual review criterion for the **Training Plan**, and this criterion will be factored into the **overall impact score**.

**Community Engagement Scoring:** Regular Clinical & Translational Pilots must include, at a minimum, a plan to disseminate their research findings to a relevant community. Applications lacking a dissemination plan will be considered incomplete and will be administratively withdrawn without review. Further, Community Engagement C&T Pilots must include a detailed community engagement plan and will be scored on the quality of this plan as well as the anticipated impact of the proposal on the community. Community engagement plans and anticipated community impact will be scored as either ‘Outstanding’, ‘Satisfactory’, or ‘Not Satisfactory’.

**ACCEL Priorities**

In addition to reviewing each with regard to scientific merit and potential impact, all Full Applications will also be given an ACCEL priority score, based on how the PI and the scope of work match the priorities of the ACCEL
Program. All pilots must involve research that falls on the translational spectrum (see definition here) 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.

Based on overall impact scores and factoring in ACCEL priorities (and community engagement scores, for Community Engagement Pilots), the ACCEL Executive Committee determines which grants to recommend for funding. Final recommendations must be approved by the ACCEL External Advisory Committee before forwarding to NIH for approval. NIH approval is required before an award can be made.

**ACCEL Pilot Award Submission Timeline**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 31, 2023 by 5:00 pm</td>
<td>Preliminary Application submission deadline</td>
</tr>
<tr>
<td>April 28, 2023</td>
<td>Invitations for Full Applications sent</td>
</tr>
<tr>
<td>July 7, 2023 by 5:00 pm</td>
<td>Full Application submission deadline</td>
</tr>
<tr>
<td>Aug 20, 2023</td>
<td>Potential awardees notified</td>
</tr>
<tr>
<td>October 20, 2023</td>
<td>Just-In-Time deadline (IRB/IACUC approval, human subjects certs due)</td>
</tr>
<tr>
<td>November 15, 2023</td>
<td>Proposals sent to NIH for approval</td>
</tr>
<tr>
<td>January 1, 2024</td>
<td>Anticipated project start date</td>
</tr>
</tbody>
</table>

**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. They are required to cite the ACCEL grant (NIH U54 GM104941) on all related publications and to submit quarterly interim progress reports and a 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 profiles up to date (at least twice per year) and respond to ACCEL surveys. If applicable, clinical trial registration and timely reporting of results at ClinicalTrials.gov is required. ACCEL 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: [Susanne M. Morton, PT, PhD](mailto:susanne.morton@accel.udel.edu); ACCEL Pilot Projects Program Director

For specific questions related to ACCEL Core resources, please contact the appropriate Core Director: [Robert Akins, PhD](mailto:robert.akin@accel.udel.edu); Professional Development Core Director  
[Claudine T. Jurkovitz, MD, MPH](mailto:claudine.jurkovitz@accel.udel.edu); Biostatistics, Epidemiology & Research Design Core Director  
[Lee M. Pachter, DO](mailto:lee.pachter@accel.udel.edu); Community Engagement & Outreach Core Director
Delaware CTR ACCEL

2024 C&T Pilot Grant Submission Instructions

PRELIMINARY APPLICATION SUBMISSION INSTRUCTIONS

Preliminary Applications will be submitted through the Delaware CTR ACCEL Dashboard. Select the correct mechanism from the list of funding opportunities: “Clinical & Translational Research Pilot Grants Program”, click the button, “Submit a Preliminary Application” 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. Proposals must be submitted by the PI (or their ACCEL designee); 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 (8½” x 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**

- **Title of proposed research**  In the text box, provide a descriptive, yet succinct, title for the project.

**Investigator Status**

- **Career stage**  Select from the options to indicate whether the project PI is an early-stage investigator, mid-career 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.

- **Prior NIH funding status**  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.

**Type of Research**

- **Human subjects**  Indicate whether the proposal involves human subjects.

- **Vertebrate animals**  Indicate whether the proposal involves vertebrate animals.

- **Type of pilot application**  Indicate whether the proposal is a Regular Pilot or a Community Engagement Pilot application.

**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. 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.

Add New Team Member  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.

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

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

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
Structured proposal summary  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.

References  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.

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