Clinical and Translational Pilot Grants Program

Application Instructions

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 Grants Program solicits applications for projects related to clinical and translational research (see Rubio et al., 2010). Pilot Grants provide funds for a 1 (Regular Pilots) or 2 (Community Engagement Pilots) year period that will allow a research team to develop a more substantial basis for independent external support from the NIH. Use of one or more of the research cores at the ACCEL institutions is encouraged.

Deadlines

- **January 15, 2021, 5 PM EST:**   **Letter of Intent** submission (Submit Here) A brief letter of intent form must be completed electronically for each proposal.
- **March 15, 2021, 5 PM EST:**   **Proposal** submission (Submit Here)

Note: Before a letter of intent or a proposal can be submitted, the proposal PI must register as an ACCEL user and have an ORCID account.

Submission

The proposal format (11 point, Arial) is similar to that for an NIH R03 proposal, except in terms of the length of the research description section. You are strongly encouraged to work with your institutional Research Administrator to assure all required documents are submitted with your application. Please check with your institutional research office and/or CTR Site PI to determine whether internal routing is required prior to submission. Upon submission, the application may be forwarded to the PI's appropriate institutional office for budget and effort verification. Proposals should be submitted here using PHS 398 forms. Instructions can be found here. Each proposal should include the following sections:

A. NIH Title page (NIH Form Page 1)
B. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (NIH Page 2&3)
C. Budget (NIH 398 Form Page 4, plus detailed budget justification)
D. Biographical Sketch(es) of PI and Key Personnel (NIH format)
E. Research Strategy (NIH continuation forms)
F. Success from Prior IDeA Awards (NIH continuation forms)
G. If Human Subjects (see video tour for form completion)
    a. PHS Human Subjects and Clinical Trials Information (PHS Form)
    b. Study Record (Study Record forms)
H. If Vertebrate Animals, justification and protection (checklist, NIH continuation forms)
I. Letter of Support from the PI's Department Head/Chair
J. If a NIH New Investigator

        a.   Individual Development Plans ([IDP](#))
        b.   Mentoring Plan ([form](#))
   K.   Community Engagement Survey or, if a Community Engagement pilot project, Community Engagement Research Plan (both, [here](#))

Pre-Submission Assistance and Feedback

Applicants are encouraged to consult with the **ACCEL *Biostatistics, Epidemiology & Research Design (BERD) Core*** to review their statistical and methodological approach prior to submission: https://www.de-ctr.org/dash/apps/biostat/. Requests for BERD Core assistance should be submitted no later than March 1st, 2021. Also, the BERD Core 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). Contact [Claudine Jurkovitz](#) for more information.

Proposals led by new investigators (see NIH definition [here](#)) will be required to work with our ***Professional Development Core (PDC)*** to submit detailed mentoring plans (from the mentors) and Individual Development Plans (from the PIs) with the submission. Applicants are encouraged to use available tools to help plan the submission (see https://www.de-ctr.org/dash/apps/medcore/).

The PDC offers a **Flight School** to help investigators get ready to submit a pilot grant to the Delaware CTR ACCEL. At the first session (January), submission requirements are reviewed and research ideas for each pilot proposal are discussed. Additional resources needed by investigators are identified. At the second session (February), specific aims are reviewed and discussed, and the other components of the proposal are reviewed. Contact [Erin Riegel](#) for more information.

Applicants are strongly encouraged to involve our ***Community Engagement and Outreach (CEO) Core*** for assistance with framing the relevance and impact of projects and for connection to community partners where appropriate: https://www.de-ctr.org/redcap/surveys/?s=PF7989REXL. Requests for CEO Core assistance should be submitted no later than March 1st, 2021. In addition, applicants submitting a Community Engagement Pilot proposal must complete or show competence in the ACCEL Community Engaged [curriculum](#) within 6 months of the pilot project start date. Contact [Heather Bittner Fagan](#) for more information.

Research Strategy

The Research Strategy should describe the (1) Specific Aims of the work, (2) Significance, (3) Innovation, and (4) Approach. *Together*, these should be **four pages** in length. Within the Approach section, a statistical analysis subsection is required. If applicable, within the Approach section applicants should also discuss the potential for community engagement.

IRB/IACUC Approval

Human subjects Institutional Review Board (IRB) or vertebrate animal IACUC approval is not required at the time of pilot project submission. However, if applicable, such approval is required before the selected pilot projects are sent to the NIH for federal approval on May 15. If a project is selected for funding by the ACCEL External Advisory Committee but does not have IRB/IACUC approval by May 15, funding of the proposal may be deferred. Therefore, *applicants are **strongly encouraged** to submit IRB/IACUC documents for approval at the time of the pilot submission.*

Credentialing

Investigators who will be doing work at hospitals may need to obtain credentials. Such investigators are encouraged to begin that process well in advance of the start date of the grant as the process can take several months.

Eligibility

Each proposal must be submitted by one investigator from one of the ACCEL partner institutions (i.e., University of Delaware, Nemours, ChristianaCare, Delaware State University and the Medical University of South Carolina). Proposals that include investigators from multiple partner institutions are especially encouraged and are given priority. Note: multiple PI applications are not allowed and only a single PI will be recognized.

PIs of pilot projects must hold a faculty appointment or equivalent at the time the pilot 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 to lead pilot projects. The Project lead for pilot projects may not concurrently have research funding from other IDeA Program award mechanisms (e.g. INBRE, COBRE). If the pilot 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.

Budget

Up to $80,000 (direct costs) may be requested. Investigators should plan for funding to begin on July 1, 2021. Two types of awards will be made: Regular Pilots and Community Engagement (CE) Pilots. The budget for Regular Pilots is up to $80,000 for one year. The budget for CE Pilots is up to $40,000/year for two years. CE Pilots are those that focus on a problem involving Community Engagement. We have learned that these projects generally take longer to complete, hence the extra time. 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* should be indicated in the budget. PIs should work with their institutional ACCEL research officer prior to submission:

> **ChristianaCare:** Mia Papas
> **Delaware State University:** Sangeeta Gupta
> **Medical University of South Carolina:** Carrie Hackett
> **Nemours:** Denise AxSmith
> **University of Delaware:** Laura Holmes

Evaluation

The letter of intent will be used only to assemble a scientific review panel with the requisite expertise. All proposals will be evaluated based on scientific merit as done by NIH study sections. Proposals will be given five scores based on significance, investigators, innovation, approach, and environment, and an overall impact score to reflect the assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, as well its chance of being developed into a full NIH proposal with a high likelihood of success. Scores are on a 1 (exceptional) through 9 (poor) scale, following the standard NIH guidelines for reviews of individual (R-type) research grants.

In addition to the scientific review (priority scores), proposals will also be evaluated based on how the investigator and the scope of work fit within the mission of the ACCEL Program. The BERD Core will also assess applications with respect to research design elements and the CEO Core will assess Community Engagement Pilot proposals to determine the potential for a successful community engaged project that addresses health outcomes of Delawareans. The ACCEL Executive Committee makes recommendations for funding based on both scientific merit (priority scores) and the ACCEL mission. Funding decisions must be approved by the External Advisory Committee and the NIH.

Preference will be given as follows:
- Proposals involving multiple partner institutions are prioritized over single institutions.
- Projects generated from ACCEL sponsored research planning retreats will be given priority.
- While all projects must be translational, at least half of the projects that will be funded must be clinical in nature (i.e., although not a requirement, clinical projects are especially welcome).

Expectations

Awardees are required to attend the annual ACCEL Research Conference and to present their work at the annual (national or regional) NIH IDeA Conference. They are required to cite the ACCEL grant (NIH U54 GM104941) on all publications and to submit quarterly progress reports. Also, for NIH-defined new investigators, active participation in the mentoring process is required for both mentors and mentees, which includes completion of mentor reports. Awardees must keep ACCEL profiles up to date (at least twice per year) and respond to ACCEL surveys. They will be responsible for reporting on any outcomes at the end of the award and up to three years post award end.

Contacts

For questions about the Pilot Grant Program and review process contact:

Susanne Morton, PT, PhD, *ACCEL Pilot Project Core Director*
Robert Akins, PhD, *ACCEL Professional Development Core (PDC) Director*
Claudine T. Jurkovitz, MD, MPH, *ACCEL Biostatistics, Epidemiology & Research Design (BERD) Core Director*
Heather Bittner Fagan, MD, MPH, *ACCEL Community Engagement & Outreach (CEO) Core Director*

Key Dates

- **December 4, 2020**   Call for Pilot Project Proposals issued
- **December 15, 2020**   Flight School #1
- **January 15, 2021**   Letter of intent due by 5 PM EST
- **February 8, 11, or 12, 2021 (must email to secure a date/slot)**   Flight School #2 (Aims draft due 1 week in advance)
- **March 1, 2021**   Deadline to submit requests for pre-submission assistance and feedback from BERD and/or CEO Cores
- **March 15, 2021**   Proposal due by 5 PM EST
- **April 15, 2021**   Reviews completed, send to ACCEL Executive Committee
- **May 15, 2021**   ACCEL Executive Committee recommendation forwarded to EAC and PDC (JIT info requested at this time)
- **May 20, 2021**   EAC decision made. Institutional IRB/IACUC approval due. Projects sent to NIH for approval. Approved projects should work with the PD and/or CEO Cores to ensure mentoring and/or community engagement plans are approved prior to commencement.

- **July 1, 2021** Pilot projects commence