

Clinical and Translational Pilot Grants Program

Application Instructions

Goals and Background

The Clinical and Translational Pilot Grants Program solicits applications. Pilot Grants provide funds for a one-year period that will allow a research team to develop a more substantial basis for independent external support from the NIH. Meritorious projects may be renewed for a second year.

The technical scope of the research plan should be related to clinical and translational research (see [Rubio et al., 2010](#)). In addition to the traditional priority areas of Cancer, Cardiovascular Disease, Stroke, Big Data, Obesity, Women's Health and Infant Mortality, and Community Engaged Research and along with focus areas identified through our Community Research Needs Assessment in Social Determinants of Health, Health Disparities/Equity and Substance Use and/or Opioid Epidemic, ACCEL has recently identified three additional areas of high importance:

**Rehabilitation
Preventive Care
Behavioral and Mental Health**

Other areas of clinical and translational research will be considered Use of one or more of the research cores at the ACCEL institutions is encouraged, but not mandatory. Information about these cores can be found on the ACCEL website (www.de-ctr.org).

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. The proposal need not be routed through the institutional research offices for institutional signatures (unless required), but upon submission may be forwarded to the PI's appropriate institutional office for budget and effort verification. Proposals should be submitted at <https://www.de-ctr.org/dash/apps/proposal/pilot/> using PHS 398 forms. Instructions can be found [here](#). Each proposal should include the following sections:

- A. NIH face page ([download here](#))
- B. NIH Page 2&3: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel ([download here](#))
- C. Budget using NIH forms Page 4, including budget justification on Page 5 (download [here](#) and [here](#))
- D. Biographical Sketch(es) of PI and Key Personnel including the primary mentor (if needed), other members of the mentoring team (if needed), and collaborators who would play a significant role in accomplishing the goals of the proposal (use this new [form](#))

- E. Research Strategy (see below—using NIH continuation forms—[download here](#))
- F. Success from Prior Awards: PIs who have led a project supported by CTR, INBRE, COBRE or DHSA grants should include a short section (1 page maximum) outlining the progress on that prior work, including their success in leveraging that research into independent external support and explaining why further support is necessary. If this is a renewal request for a second year of funding, a one-page progress report is required. Use NIH continuation forms—[download here](#).
- G. NIH Human subjects ([download here](#)) and planned enrollment forms ([here](#)), if applicable
- H. Vertebrate animals justification and protection ([download here](#)), if applicable
- I. A letter of Support from the PI's Department Head/Chair
- J. If the project is led by a new investigator (see NIH definition [here](#)), the application must include a letter of support from the primary mentor detailing previous experience, the candidate's potential, the existing mentoring or working relationship (if any), and specifics as to how the mentor will interact with the candidate during the funding period (see mentoring agreement [here](#))
- K. Resubmissions may include an introduction (one page maximum) that summarizes substantial changes to the application and/or responds to issues and criticisms raised in a prior review. Use NIH continuation forms—[download here](#).
- L. Community engagement [form](#), if applicable

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/>. Be sure to indicate that the request is linked to a Clinical and Translational Pilot Grant submission.

Also, the BERD core has established mechanisms to obtain access to Medicaid and Medicare claims data. Please contact Claudine Jurkovitz (cjurkovitz@christianacare.org) for more information.

Proposals led by new investigators (see NIH definition [here](#)) will be required to work with our *Professional Development Core (PD-Core)* to submit detailed mentoring plans (from the mentors) and Individual Development Plans (from the PIs) prior to receiving funds. The Mentoring Plan and IDP are not required as part of the original submission process but applicants are encouraged to use the tools to help in planning the submission (see <https://www.de-ctr.org/dash/apps/medcore/>).

The PD Core offers a Flight School to help investigators get ready to submit a Pilot grant to the Delaware CTR ACCEL.

- a) At the first session (January 17, 12:00-1:00), submission requirements are reviewed and research ideas for each pilot proposal are discussed. Additional resources needed by investigators are identified.
- b) At the second session (February 20, 11:30-1:30), specific aims are reviewed and discussed, and the other components of the proposal are reviewed. The draft specific aims are due to Erin.Riegel@nemours.org by noon on 2/13/2020.

You can attend in person or connect via phone/computer. Contact Erin.Riegel@nemours.org for directions or access information.

Applicants are strongly recommended to engage with our *Community Engagement and Outreach (CEO) Core* as part of the [pre-submission process](#) for assistance with framing the relevance and potential

impact of projects and for connection to community partners where appropriate. In addition, applicants for community engaged projects must complete or show competence in ACE curriculum within 6 months of start date.

Research Strategy

The Research Strategy part of the proposal (section E above) 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. Information about the ACCEL Cores can be found on the ACCEL website.

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.

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, Christiana Care Health System, 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.

Leaders 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 (RPG). 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).

Pilot projects may not overlap with ongoing funded projects.

Mentors: Proposals led by junior or “new” investigators (see NIH definition [here](#)) must identify a suitable mentor, and include the proposed mentor’s Letter of Support demonstrating his willingness to participate and support the applicant and project. Mentors with prior experience as PI on an NIH funded grant are preferred.

Timeline

Proposals should be submitted electronically using the ACCEL website office www.de-ctr.org by noon

on March 16, 2020. Note that all investigators on the proposal must have user accounts on the ACCEL website prior to submission. Contacting the other cores for support (i.e., BERD, CEO, PD—see Pre-Submission section above) must be done at least two weeks before the submission date.

Budget

Up to \$80,000 (direct costs) may be requested. Investigators should plan for funding to begin on July 1, 2020. Two types of awards will be made: Community Engagement (CE) Pilots and regular Pilots. The CE Pilots will be for up to \$40,000/year for two years and the regular Pilots will be up to \$80,000 for one year. CE Pilots are those that focus on a problem related to 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. While not required, 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 institutional ACCEL research officers prior to submission:

Christiana Care: [Mia Papas](#)

Delaware State University: [Sangeeta Gupta](#)

Medical University of South Carolina: [Carrie Hackett](#)

Nemours: [Denise AxSmith](#)

University of Delaware: [Tiffine CanneLongo](#)

Evaluation

Each ACCEL Pilot Project will be evaluated via a three-step process. In the first step, proposals will be evaluated based on scientific merit as is done in 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 as 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. Proposals will be given another score based on how the scope of work and investigator's status correspond to the priorities of the ACCEL program. Questions to be addressed include: Has the investigator received previous funding? If so, has it been well used? Is the research translational?

In the second step, the ACCEL Executive Committee will then determine which grants to recommend for funding based on the priority scores and the ACCEL mission. Additional scores will be provided by the CEO Core to determine if projects are addressing health outcomes of Delawareans and by BERD to assess experimental design. In the third step, final approval for funding will be made by the External Advisory Committee, albeit with NIH approval.

Preference will be given as follows:

- Proposals from multiple partner institutions are given priority over those from single institutions.
- 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).
- Projects generated from ACCEL sponsored research planning retreats will be given priority.

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 “new” investigators, active participation in the mentoring process is required for both mentors and mentees, which includes completion of mentor reports. Award recipients 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 award and up to three years post award end.

Contacts

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

[Jill Higginson](#), PhD, *ACCEL Pilot Project Director*

[Robert Akins](#), PhD, *ACCEL Professional Development Core (PD-Core) leader*

[Claudine T. Jurkowitz](#), MD, MPH, *ACCEL Biostatistics, Epidemiology & Research Design Core (BERD Core) leader*

[Heather Bittner Fagan](#), MD, MPH, *ACCEL Community Engagement & Outreach (CEO) Core leader*

Key Dates

- **January 8, 2020** Call for Pilot Project Proposals issued
- **January 17, 2020** Flight School #1
- **February 20, 2020** Pre-Submission Assistance and Feedback from BERD Core Deadline
- **February 20, 2020 Flight School #2** (Aims draft due by 2/13/20)
- **March 16, 2020** Proposals due
- **April 15, 2020** Reviews completed, send to ACCEL Executive Committee
- **May 15, 2020** ACCEL Executive Committee recommendation forwarded to EAC (JIT info requested at this time). Meet with the PD Core and complete the Mentoring Plan and Individual Development Plan.
- **May 20, 2020** EAC decision made. Institutional IRB/IACUC approval due. Projects sent to NIH for approval. Approved projects should work to ensure they have their mentoring plans and community engagement approval prior to project commencement
- **July 1, 2020** Pilot projects commence

Instructions for Scientific Reviewers

Scores should be given on a 1 (exceptional) through 9 (poor) scale, as depicted below. One score should be given for each of the following 7 categories:

Significance—Does the project address a significant clinical & translational research problem?

Investigators—Are the investigators well qualified to perform this work and lead future NIH-funded projects? Is the mentor suitable and committed? If the PI has had previous funding, was there adequate success?

Innovation—Is the proposed research plan novel and innovative, advancing the field?

Approach—Are the methods sound and likely to be successful?

Environment—Do the investigators have the resources necessary to perform this work and will it take advantage of established core resources?

Overall Impact—This takes into account all of the above 5 categories and should reflect the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, as well as its chance of being developed into a full NIH proposal with a high likelihood of success.

ACCEL mission—After scoring the overall impact, reviewers should provide an additional score to let the decision-makers know if the reviewer feels that the scope of the work and investigator’s status correspond to the priorities of the ACCEL program. For example, if a reviewer feels a project outside the scope of the ACCEL program or is not translational, a lower score should be given in this category and not in the other categories above. Also, if there are questions about eligibility or if a proposal should be disqualified, that should only be reflected here and will be dealt with by the CTR leadership.

Impact	Score	Descriptor	Strength/Weaknesses
High Impact	1	Exceptional	<p><i>Strengths</i></p> <p><i>Weaknesses</i></p>
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	