DELAWARE-CTR ACCEL
ACCELERATING CLINICAL TO TRANSLATIONAL RESEARCH

Clinical and Translational Research Shovel-Ready Pilot Grants Program 2019

Application Instructions Spring 2019

Goals and Background

Many investigators submit proposals and receive good scores but yet are not funded due to today's competitive climate. To aid such investigators transition their good proposals into fundable ones, the ACCEL program has created this Shovel-Ready Grant Program (SHoRe Grants). These awards are for investigators who already have submitted research grant applications (NIH, PCORI, VA, NSF, etc.) and have received summary statements, but need funds to collect additional data to strengthen their resubmission and address reviewer concerns.

The SHoRe RFP solicits applications for projects that will be completed within six months and must result in a resubmitted research grant application.

The technical scope of the research plan should be related to clinical and translational research (see Rubio et al., 2010). Areas of high importance to the DE-CTR ACCEL program include

Rehabilitation	Big Data
Cancer	Obesity
Cardiovascular Diseases	Women's Health and Infant Mortality
Stroke	Community engaged research

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. 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. Summary statement from previous research grant.
F. Research Strategy (see below—using NIH continuation forms—download here)
G. 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.
H. References (using NIH continuation forms—download here)
I. NIH Human subjects (download here) and planned enrollment forms (here), if applicable

J. Vertebrate animals justification and protection (download here), if applicable
K. A letter of Support from the PI's Department Head/Chair
L. 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)

The proposal need not be routed through the institutional research offices for institutional signatures (unless required—check with institutional research office), but upon submission may be forwarded to the PI's appropriate institutional office for budget and effort verification.

Pre-Submission Assistance and Feedback

Applicants are encouraged to have the ACCEL *Biostatistics, Epidemiology & Research Design (BERD) Core* provide assistance with and/or review their statistical and methodological approach prior to submission:

BERD Core

The BERD team will review and provide comments on the Request for Assistance information submitted at 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. Note that the average turn-around time is 18 days.

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/).

Applicants are also encouraged to engage with our *Community Engagement and Outreach (CEO) Core as part of the pre-submission process.*

Community Engagement and Outreach (CEO) Core

Experts from the CEO Core will review and provide feedback on Section B, which includes a statement of the relevance of the proposed research to public health. This statement is a critical component of NIH and DE-CTR ACCEL sponsored research and will be a part of the evaluation process. The statement of relevance should use plain language that can be understood by a general, lay audience. The CEO core can be contacted at https://www.de-ctr.org/redcap/surveys/?s=PF7989REXL for assistance with framing the relevance and potential impact of projects and for connection to community partners where appropriate.

Research Strategy

The Research Strategy part of the proposal (section **F** above) should be organized in four sections to describe the (1) Specific Aims of the work, (2) Significance, (3) Innovation, and (4) Approach. Together, these four sections should be a maximum of four pages in length. The focus of the proposal should be on what will be done in the six month time period to address the reviewers' comments and strengthen the original proposal to improve the score.

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 SHoRe project submission. However, if applicable, such approval is required before the selected projects are sent to the NIH for federal approval on **June 24**. If a project is selected for funding by the ACCEL External Advisory Committee but does not have IRB/IACUC approval by **June 24**, 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 SHoRe 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 SHoRe projects may not concurrently have research funding from other IDeA Program award mechanisms (e.g. INBRE, COBRE, CTR).

SHoRe project funding 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 **May 1, 2019**. 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., Epidemiology/Biostatistics and Community Engagement—see Pre-Submission section above) must be done at least two weeks before the submission date.

Budget

Up to $20,000 (direct costs) may be requested. A typical SHoRe grant will support clinical research coordinators, postdoctoral fellows, or graduate students, as well as appropriate amounts for supplies, travel, etc. PI salary is discouraged as faculty release time for this work is expected to be provided as an institutional commitment; the anticipated effort should be indicated in the budget. A budget period of up six months may be requested. Investigators should plan for funding to begin on or soon after **August 15, 2019**.

Evaluation

Each ACCEL SHoRe 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 (especially as it pertains to the type of research being proposed in relation to established Cores). They will then be given an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, as well is 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. An addition score based on Community Engagement will be provided by our CEO Core to determine if projects are addressing the health outcomes of Delawareans. 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.

Contacts

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

Thomas S. Buchanan, PhD, *ACCEL Pilot Project leader*
Robert Akins, PhD, *ACCEL Professional Development Core (PD-Core) leader*
Claudine T. Jurkovitz, MD, MPH, ACCEL *Biostatistics, Epidemiology & Research Design* Core (BERD Core) leader
Heather Bittner Fagan, MD, MPH, *ACCEL Community Engagement & Outreach (CEO) Core leader*

Checkboxes to appear on web application

- ☐ Letter from Department Head/Chair is included **(required)**
- ☐ Mentors' letter is included **(required for "new" investigators)**
- ☐ Consultation with Biostatistics Epidemiology and Research Design Core (recommended)
- ☐ Consultation with Community Engagement Core (recommended)
- ☐ Discussion with OSP/Research office personnel regarding appropriateness of budget (optional)
- ☐ This proposal emerged from an ACCEL Research Planning Retreat
- ☐ This work involves human subjects
- ☐ This work involves vertebrate animals

Timeline for 2019 DE-CTR ACCEL ShoRe Proposals

25-Feb	Call for ShoRe Project Proposals issued
17-Apr	Pre-Submission Assistance and Feedback from BERD Core Deadline
1-May	**Proposals due**

1-Jun	Reviews completed, send to ACCEL Executive Committee
15-Jun	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.
24-Jun	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
15-Aug	SHoRe 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 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? Does the proposed approach address the concerns of the original reviewers?

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 is its chance of being developed into a full NIH proposal with a high likelihood of success.

CTR 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 the project is not clinical and 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	*Strengths*
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	*Weaknesses*

An addition score based on Community Engagement will be provided by our CEO Core to determine if projects are addressing the health outcomes of Delawareans.