

# **ACCEL Shovel-Ready** Grants Program

## Request for Proposals and Application Instructions

## **Goals and Background**

In today's highly competitive climate, many investigators submit strong proposals and receive good scores, yet are not funded. To help such investigators transition their good proposals into fundable ones, the ACCEL Program has created the Shovel-Ready (ShoRe) Grants Program. ShoRe grants are for Principal Investigators (PIs) who already have submitted a research grant application (NIH, PCORI, VA, NSF, etc.) and have received reviews but need funds to collect additional data to strengthen their resubmission and address reviewers' concerns. ShoRe grants must be related to clinical and translational research.

## **Deadline**

Completed applications are accepted on a rolling basis. The ACCEL Program will continue to fund projects until all funds have been awarded for the award year timeframe. Award years run July 1 through June 30 of the following year. Please make sure to complete all requirements of an application. Partial applications will not be accepted.

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; proposals submitted under another user's ACCEL account will not be accepted.

#### Award Information

ShoRe projects must be completed within six months and must result in a resubmitted research grant application. Projects must consist of clinical or translational research (see definition by <a href="Rubio et al., 2010">Rubio et al., 2010</a>). 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 ShoRe proposal that was not selected for funding) and Renewal (previously awarded ShoRe project that requires further support) applications are accepted. Revisions (modifications/expansions of a proposal already in submission) are not allowed. The number of awards is contingent on the ACCEL budget and NIH appropriations.

#### **Timeline**

A budget period of up to six months may be requested. Projects are expected to be completed within this timeframe and, as such, proposals should focus just on the aim(s) that can be accomplished in six months. There is no automatic carryover or no cost extensions. Extensions must be approved by the ACCEL Executive Committee and will only be granted in extenuating circumstances.









#### Budget

Up to \$30,000 (direct costs) may be requested for ShoRe projects. A typical ShoRe 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 <u>anticipated effort should be indicated in the budget</u>. 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 additional data collection or analyses to strengthen the resubmission of a large-scale research grant. The total budget for the originally submitted proposal must be at least \$200,000 (for a regular ShoRe budget of \$30,000) or at least \$100,000 (for a half-scale ShoRe budget of \$15,000). Smaller-scale projects are not supported through this mechanism. Reviews of the original application must have already been received and are to be included in the ShoRe application materials.

PIs must be from one of the ACCEL partner institutions (i.e., University of Delaware, Nemours, Christiana Care, Delaware State University). PIs must have already submitted a research grant application (NIH, PCORI, VA, NSF, etc.) and received reviews, but need funds to collect additional data to strengthen their resubmission and address reviewers' concerns. Multiple PI (MPI) applications are allowed, as long as all PIs are from ACCEL partner institutions.

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). ShoRe project funding may not overlap with ongoing funded projects.

## 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.

#### **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: <a href="https://dash.de-ctr.org/consult/submit/berd">https://dash.de-ctr.org/consult/submit/berd</a>. 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 (<a href="https://covid.cd2h.org/N3C">https://covid.cd2h.org/N3C</a>) for investigators with relevant research aims. Requests for BERD Core assistance prior to submission should be made with enough time for BERD to provide a comprehensive review. Contact <a href="Claudine Jurkovitz">Claudine Jurkovitz</a> for more information.

## ACCEL Professional Development (PD) Core

Proposals led by junior investigators are encouraged to take advantage of the career development programs offered. The Junior Investigators Network (JIN) provides weekly sessions that include topics like career development and research proposal writing that can be attended via phone or computer. The PD Core can consult on Specific Aims and (if time permits) assemble a mock study section for review prior to submission. Please contact the PDC Mentoring Team (mentoring@de-ctr.org) for more information.

## ACCEL Community Engagement and Outreach (CEO) Core

Applicants are recommended to engage with the CEO Core prior to submission. The CEO Core helps PIs realize the potential community impact of their work and facilitates connections to community partners where appropriate. Contact <u>Lee Pachter</u> for more information.

## **Application Submission Information**

Whether or not internal routing is required prior to submission is determined by each institution. PIs are strongly encouraged to 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:

ChristianaCare: Al Bacon

Delaware State University: Sangeeta Gupta

Nemours: Ranita Chakrabarti

University of Delaware: Robyne Nizer

Upon submission, the application may be forwarded to the appropriate institutional office for budget and effort verification.

#### **Submission Components**

The proposal is to be similar in format and style to that of an NIH R03 proposal, except in terms of the length of the *Research Strategy* section. The *Specific Aims* page (limited to 1 page) and *Research Strategy* section (limited to 4 pages), must be no longer than 5 pages combined (see below for details). Proposals should be submitted through the DE-CTR ACCEL <u>Dashboard</u> using <u>PHS 398 fillable forms</u>. For more information, *please read the detailed step-by-step ACCEL Dashboard ShoRe Submission Instructions*, which are appended to this document. All applications will be administratively reviewed to ensure all submission components are present in the application package. Applications found to be non-compliant with any of the submission instructions will be administratively withdrawn prior to scientific review and will be considered ineligible for funding.

## IRB/IACUC Approval

Human subjects Institutional Review Board (IRB) or vertebrate animal Institutional Animal Care and Use Committee (IACUC) approval is not required at the time of ShoRe application submission. However, if applicable, final documentation of such approval <u>is required by the Just-In-Time deadline</u> (see below). Therefore, <u>funding recommendations by the ACCEL External Advisory Committee are contingent upon timely IRB/IACUC approval</u>.

#### **Review Criteria**

Reviewers of ShoRe 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 range from 1 (Exceptional) to 9 (Poor). A score of 5 is considered a good score. The review criteria will include an evaluation of the proposal based on the *individual review criteria* of *Responsiveness to prior critiques, Significance, Investigators,* and *Approach,* addressing how this ShoRe grant will make your resubmission of the primary funding mechanism stronger and in a better position for funding. The *overall impact score* will weigh each of the individual review criteria, with emphasis given to the feasibility, potential for future funding with the resubmission, and ACCEL priorities. 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 ShoRe grants, the overall impact score indicates the reviewer's assessment of the likelihood for the project to (a) exert a sustained, powerful influence on the research field(s) involved and (b) be successfully funded upon resubmission to the original funding agency.

Proposals are also given an ACCEL priority score, based on how the PI and the scope of work match the priorities of the ACCEL Program. In addition to the requirements that all ShoRe grants involve research that falls on the translational spectrum (see definition <a href="here">here</a>) and that a majority of ShoRes include clinical research, ACCEL priorities include the following:

- Projects led by junior PIs (assistant professor rank or not yet having been PI of a NIH K- or R-series award or equivalent)
- Projects whose team members are inter-institutional
- Projects that are interdisciplinary and/or span different regions of the translational spectrum
- Projects addressing conditions disproportionately affecting Delawareans

Based on Overall Impact scores and factoring in ACCEL priorities, the ACCEL Executive Committee determines which grants to recommend for funding. Final recommendations must be approved by the ACCEL External Advisory Committee before recommendations are forwarded to NIH for approval. NIH approval is required before an award can be made.

**ACCEL ShoRe Award Timeline**- The ShoRe timeline is now rolling so there is no submission deadline date. This will better align with receipt of summary statements.

Day 1 Application submission

~30 days later Potential awardees notified

~30 days later Just-In-Time deadline (IRB/IACUC approval, human subjects certifications due)

~30 days later Just-In-Time deadline (IRB/IACUC approval, human subjects certifications due)
~60 days later Anticipated project start date after receipt of approval from NIH/EAC

## **Expectations**

It is expected that a ShoRe award will result in a new or resubmitted grant application by the PI. Awardees are also required to attend and present their work at ACCEL conferences (Annual Community Research Exchange, Annual Advisory Meeting, and Annual PCBRN Meeting) and 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 interim progress reports and a NIH annual progress report each February. For junior PIs, active participation in professional development activities is strongly recommended. Awardees must keep ACCEL profiles up to date (at least twice per year) and respond to ACCEL surveys. PIs are responsible for reporting outcomes at award end, up to three years post award end, and as requested during the life of the Delaware ACCEL CTR Program.

#### Contacts

For questions about the ShoRe Grants Program submission and review process, please contact:

<u>Megan Wenner</u>, PhD, ACCEL Pilot Projects Program Director

<u>Karen Hough</u>, ACCEL Program Administrator

For specific questions related to core resources, please contact the appropriate core director:

Robert Akins, PhD, ACCEL Professional Development Core – (mentoring@de-ctr.org)

Claudine T. Jurkovitz, MD, MPH, ACCEL Biostatistics, Epidemiology & Research Design Core

Lee M. Pachter, DO, ACCEL Community Engagement & Outreach Core

## **ACCEL Dashboard**

## **ShoRe Submission Instructions**

Proposals are to be submitted through the DE-CTR ACCEL <u>Dashboard</u>. Select the correct mechanism from the list of funding opportunities and follow the prompts to complete all sections and upload documents. Note that before a proposal can be submitted, <u>the proposal PI must register as an ACCEL user and have a valid ORCID account linked to ACCEL.</u> Also, an investigator's FULL profile needs to be updated and confirmed in the dashboard by submission of the ShoRe project. Proposals must be submitted by the PI; proposals submitted under another user's ACCEL account will not be accepted.

All applications will first be administratively reviewed to ensure all submission components are present in the application package. <u>Applications not fully compliant with any of the submission instructions will be administratively withdrawn prior to scientific review and will be considered ineligible for funding.</u> Therefore, it is imperative that applicants read and adhere to all of the submission instructions described here.

The documents to be uploaded should be created using PHS 398 fillable forms. Documents must be written with Arial 11 pt font. Pages are to be standard letter size ( $8\frac{1}{2}$ " x 11") with at least one-half inch margins. Documents should be converted to PDF for submission.

#### **Project Information Page.**

- 1. <u>Project Title</u> Enter the title of the project in the text box provided.
- 2. <u>Project Abstract</u> Enter the project abstract, using language that would be understandable to a broad scientific audience. Explain the overall aim(s) of the work and the expected impact to be made in the field when the work is completed.
- 3. <u>Project Lay Description</u> Enter a description of the project using language that would be understandable to the lay community.
- 4. Interdisciplinary or Multidisciplinary Project? Check Yes or No

#### **Investigator Status Page.**

Click "Yes" or "No" to indicate whether you are or are not a junior investigator. <u>The ACCEL CTR defines</u> <u>junior investigators as those investigators who have not yet reached the rank of associate</u> <u>professor or equivalent or have not previously been PI of a NIH K- or R-series award or equivalent.</u>

#### **Budget Page.**

Indicate the requested amount of budgetary support in the text box provided. ShoRe budgets are capped at \$30,000 for regular applications (for projects that the total budget of the originally submitted proposal was at least \$200,000) or \$15,000 for half-scale applications (total budget for the originally submitted proposal at least \$100,000). Smaller-scale projects are not supported through this mechanism.

#### **Team Members Page.**

1. Is this a Multi PI (MPI) project? Check Yes or No. If YES, use the button on the far right "Add New PI". Biosketches are to be attached in this section when the MPI is added. 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.

- 2. PI Your name will be automatically populated and assigned the role of PI.
- 3. <u>Additional Team Members</u> Add additional team members as needed. For each additional team member, select from the list of appropriate roles. All team members listed here should also be listed on the Project Summary Page (see below) and vice-versa. A biosketch for community or clinical partners is optional; a biosketch for all other types of team members is required. Do not upload the PI's biosketch here; that will be done in a later section. See details below for information on how to complete Biographical Sketches.

#### **ORCID Setup Page.**

If you have not yet setup your ORCID account and linked it to ACCEL, you will be instructed to do so here.

#### Files Page.

- 1. <u>Human Subjects</u> Click "Yes" or "No" in response to the question, "Does this project involve human subjects?" If you select "Yes", you will be required to submit the Human Subjects Forms (see below).
  - a. If your project involves human subjects, click "Yes" or "No" in response to the question, "Based on your answers in Section 1.4 (Clinical Trials Questionnaire) on the PHS Human Subjects and Clinical Trials Information Form, does this study meet the definition of a Clinical Trial (i.e. all answers to 1.4.a-1.4.d on the questionnaire are "Yes")?
    - i. If your project is a clinical trial, provide your <u>ClinicalTrials.gov</u> Identifier (e.g., NCT87654321) for the project, if known.
- 2. <u>Vertebrate Animals</u> Click "Yes" or "No" in response to the question, "Does this project involve vertebrate animals?" If you select "Yes", you will be required to submit the Vertebrate Animals Forms (see below).
- 3. Supporting Files

Upload all the completed project forms in the appropriate locations. Recall that forms should be created using PHS 398 fillable forms. Documents must be written with Arial 11 pt font. Pages are to be standard letter size  $(8\frac{1}{2}" \times 11")$  with at least one-half inch margins. Documents should be converted to PDF format for submission.

• Face Page – required
Upload the completed Title Page / Face Page (Form Page 1).

#### • Project Summary Page – required

Upload the completed Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells Page (<a href="Form Page">Form Page</a> 2). The <a href="Project/Performance Site Format Page">Project/Performance Site Format Page</a> may be appended to this and submitted as a single PDF if additional space is needed.

• **Detailed Budget** – required

Upload the completed Detailed Budget for Initial Budget Period Page (Form Page 4).

• **Budget Justification** – required

A detailed budget justification must be provided. There is no specific form, but the NIH required format must be followed. A link to the University of Delaware's template is here.

• Biographical Sketch(es) – required

Upload completed new <u>Biographical Sketch Format Pages</u>, not to exceed 5 pages per person, for each of the following personnel:

- o PI required
- Other Key Personnel *if applicable* Biosketches must be provided for every person identified on the Project Summary Page

(Form Page 2) and will be uploaded on the Team Members page of the application submission site.

Detailed instructions for the biosketch format may be found <u>here</u> and a sample format biosketch may be found <u>here</u>.

\*\*PLEASE NOTE\*\* NIH will be moving to <u>SciENcv</u> (date to be determined) for Biosketch requirements. See <u>here</u> for instructions and how to prepare and start early!

## • **Prior IDeA award(s)** – required

Identification of all prior IDeA funding, and the successes from those funds, must be provided. Here, prior IDeA funding refers to any research support from a CTR, INBRE, COBRE or the DHSA program. This form should identify each prior funding mechanism and provide a brief description of the progress made on that prior work, especially any successes leveraging those funds to gain independent external support. If this is a renewal request, strong justification must be provided for additional funding. PIs who have not had prior IDeA support must still upload a page with a statement verifying that they have had no prior IDeA funding. Use Continuation Format Pages for this document; 1 page maximum.

## • Previous Reviews / Summary Statement – required

A copy of the full Summary Statement / reviewer comments from the previous grant that was reviewed but not funded, and for which the PI is requesting support in order to build an improved resubmission, must be included with the ShoRe application.

#### • Introduction to Resubmission – required

ShoRe applications must include an Introduction page that specifically responds to the comments in the Summary Statement / reviewer comments from the previous grant. It should summarize the planned changes to the application and/or responses to issues and criticisms raised in the prior review. Use <u>Continuation Format Pages</u> for this document; 1 page maximum.

#### • Specific Aims – required

List succinctly each of the specific objectives of the research proposed. State concisely the overall goals of the proposed research and summarize the expected impact that the results will have in the relevant research field. Use <u>Continuation Format Pages</u> for this document; 1 page maximum.

#### • Research Strategy – required

The Research Strategy should be organized into three sections entitled Significance, Innovation and Approach. Use <u>Continuation Format Pages</u> for this document; 4 pages maximum. Although each section does not have its own page limit, it is recommended that the Approach section be the most detailed. Within the Approach section, a statistical analysis subsection is required. The focus of the Research Strategy should be to describe and justify what will be done in the six-month award period to address reviewers' comments and strengthen the original proposal.

#### • References – required

All works cited in the application should be listed in a separate document entitled References. Use <u>Continuation Format Pages</u> for this document; no page limit. In-text references should be provided either by author last name or number in the body of the application and the References section should list each of these works and provide the complete citation. <u>Hot links are not allowed in the reference section.</u>

#### • Human Subjects Forms – if applicable

If the proposal involves the use of human subjects, upload the completed <u>PHS Human Subjects and Clinical Trials Information Form</u>, (download pdf and complete) with embedded Human Subject Study Record Form(s), as appropriate. Please note, depending on the type of human subjects research being

proposed, each Study Record form may require extensive and detailed information, therefore <u>PIs should allocate appropriate time to complete these forms</u>. Instructions for completing these forms may be found <u>here</u> (and must be uploaded no later than JIT documentation is secured.)

If your project involves human subjects, please also answer if this study is a Clinical Trial (Yes or No) based on your answers to the following questions:

- 1. Does the study involve human participants?
- 2. Are the participants prospectively assigned to an intervention?
- 3. Is the study designed to evaluate the effect of the intervention on the participants?
- 4. Is the effect being evaluate a health-related biomedical or behavioral outcome?

If you answer YES to all four of these questions, the study is a Clinical Trial.

### • **Vertebrate Animals Forms** – *if applicable*

If the proposal involves the use of vertebrate animals, please utilize the vertebrate animals use checklist and use <u>Continuation Format Pages</u> to upload a description of the procedures, justification, and minimization of pain and distress.

## • Letter(s) of Support – required

Letters of support should be on institutional letterhead and may not exceed 2 pages per letter.

- O PI's Department/Unit Head required This letter should provide an assessment of the PI's potential for a sustained, impactful influence in his/her relevant research field and to be recognized for such with future NIH funding; a description of how the PI's research fits within the clinical and translational mission of the DE-CTR ACCEL Program; and a description of the departmental and/or institutional support for the PI with regard to the specific proposal (e.g., protected research time, laboratory space, access to clinical populations, etc.).
- Others if applicable
   Other letters of support may be appropriate, to demonstrate the availability of specific resources and/or collaborators, mentors, and/or clinical/community partners for the project. If multiple letters of support are included, they can be appended to one another and submitted as a single PDF.

#### Sources Page.

Select all categories of events or processes that led to the proposed work, if any.

#### Tracking/EVAL Page.

Click "Yes" or "No" in response to a brief series of questions about your current or anticipated utilization of ACCEL Core resources.

#### **Summary Page.**

Check to be sure all sections have been completed and all documents have been appropriately uploaded. Make any file edits necessary. When complete, click the "Submit" button at the bottom of page.