Application Instructions

Goals and Background

To overcome barriers that investigators face in successful translation of their work across the research continuum, we will fund proposals from researcher/investigator teams for *Overcoming Barriers to Translational Success* (OrBiTS) awards. These **two-year grants** will enable a team of at least three investigators to hire technical staff, procure specialized equipment, purchase data sets, or hire a specialized consultant so that they could generate strong clinical and translational research programs. The OrBiTS awards are not for specific research projects, but for infrastructure that will aid clinical and translational research. We anticipate that this type of support will provide considerable help in bringing basic scientists into the clinical and translational arena or facilitate translational researchers doing clinical trials, ultimately leading to procurement of large center-type grants.

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/overcoming-barriers-to-translational-success-orbits-awards/ 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) which should incorporate a timeline for spending.
D. Biographical Sketch(es) of PI and Key Personnel and collaborators who would play a significant role in accomplishing the goals of the proposal (use this Non Fellowship Biosketch form)

E. OrBiTS 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, or COBRE 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. Use NIH continuation forms—[download here](#).

G. A letter of Support from the PI's Department Head/Chair and each of the team members. If the project is an MPI structure, a letter of support for each PI is required.

Pre-Submission Assistance and Feedback

Applicants are encouraged to engage with our *Community Engagement and Outreach (CEO) Core.* Those who do not do so prior to submission will be required to engage with the CEO prior to award commencement.

> *Community Engagement and Outreach (CEO) Core*
>
> Experts from the CEO Core will review and provide feedback on Section B, which <u>includes a statement of the relevance of the proposed research to public health</u>. This statement is a critical component of NIH and DE-CTR ACCEL sponsored research. 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/consulting-services/ for assistance with framing the relevance and potential impact of projects and for connection to community partners where appropriate.

OrBiTS Aims and Research Strategy

The OrBiTS Strategy part of the proposal (section **E** above) should describe the (1) Specific Aims of the work, (2) Significance, (3) Innovation, and (4) Approach, (5) Community Engagement, and Evaluation of outcomes leading to Sustainability. Together, the aims and strategy should be five pages in length. Investigators are expected to highlight the unique barriers to success that will be overcome through these awards and how the funding will be transformative. Each project is expected to include a sustainability plan that addresses how the work will be supported and continued when the OrBiTS award expires.

IRB/IACUC Approval

These awards are for infrastructure that will aid research, not for specific research projects. Therefore, human subjects Institutional Review Board (IRB) or vertebrate animal IACUC approval should not be required for the work proposed.

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 an investigator from one of the ACCEL partner institutions: the University of Delaware, Nemours, ChristianaCare Health Services, Inc.

and Delaware State University. They must be multi-investigator proposals with at least three faculty-level investigators (above the post-doc level). Multiple PI (MPI) applications are allowed, as long as all PIs are from ACCEL partner institutions. PIs of Community Engagement OrBiTS proposals must include a community member (not from a partner institution) as a member of the research team. **Proposals that include investigators from multiple partner institutions are especially encouraged and are given priority.**

Leaders of these awards 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 (RPG). Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible to lead OrBiTS projects

Timeline
Proposals should be submitted electronically using the ACCEL website at www.de-ctr.org. Review of proposal is on a rolling basis and will continue until all available funds are allocated. Note that all investigators on the proposal must have user accounts on the ACCEL website prior to submission. If you do not currently have one, you can create one here.

Budget
Funding for this mechanism will range from $20,000 to $150,000 in Direct Costs and must provide resources for multiple investigators. Please outline in the budget justification section, a timeline for the spending of the requested funds. Additional details are provided below. A competitive renewal may be considered if it can be demonstrated that the work is especially meritorious.

Expectations
OrBitS 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. Awardees must keep ACCEL profiles up to date (at least twice per year) and respond to ACCEL surveys. ACCEL site PIs have direct oversight of all OrBiTS 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 OrBiTS Grants Program submission and review process, please contact: Megan Wenner, PhD; ACCEL Pilot Projects Program Director

For specific questions related to **ACCEL Core resources**, please contact the appropriate Core Director:
Robert Akins, PhD and copy Julianne Ross; Professional Development Core Director
Claudine T. Jurkovitz, MD, MPH; Biostatistics, Epidemiology & Research Design Core Director Lee M. Pachter, DO; Community Engagement & Outreach Core Director

Review Criteria

Scientific Merit Scoring: Reviewers of the OrBiTS applications are selected based on their relevant research expertise. 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 individual review criteria are Significance/Innovation, Investigator(s) and Environment, Approach, and Evaluation of Outcomes leading to Sustainability, along with Community Engagement. 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 OrBiTS 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. If necessary, OrBiTS applications will be rank ordered by overall impact score.

Delaware CTR ACCEL

OrBiTS Grant Submission INSTRUCTIONS

Applications will be submitted through the Delaware CTR ACCEL Dashboard. Select the correct mechanism from the list of funding opportunities, click the box "Submit Proposal", and follow the prompts to complete all sections and upload documents. **Note that before a proposal can be submitted, the proposal PI must register as an ACCEL user (you can do so here) 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.

The documents to be uploaded should be created using PHS398 Forms. Documents must be written with Arial 11 pt or larger font. Figure legends or tables may include smaller font but must remain easily legible when printed. Text boxes, footnotes, etc. may not be used to circumvent page/font limits. 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.

Instructions for the Delaware CTR ACCEL DASHBOARD OrBiTS Submission Website:

Project Information Page.

1. Project Title   Enter the title of the project in the text box provided.
2. Project Abstract   Enter the project abstract, using language that would be understandable to a broad scientific audience. Explain the overall aim(s) of the project and the expected impact to be made in the field when the work is completed.
3. Project Lay Description   Enter a description of the project using language that would be understandable to the lay community.
4. Project Discipline(s)   Select 'yes' or 'no' to indicate whether the project is interdisciplinary/multidisciplinary or not. If 'yes', then also identify the different disciplines involved in the project proposal.

Investigator Status Page.

1. Prior NIH funding status   Select 'yes' or 'no' to indicate whether you as the project PI are an ACCEL-defined new investigator. Use the ACCEL CTR definition of a new investigator: any investigator who has not previously been PI of a funded NIH K- or R-series award or equivalent extramural funding. For MPI applications, this question applies to the corresponding (submitting) MPI. Prior NIH funding status for the other MPI(s) will be obtained under the Team Members Page (see details below).
2. Career stage   Select from the options to indicate whether you as the project PI consider yourself an 'early- stage' investigator, 'mid-career' investigator, or 'senior' investigator. The ACCEL CTR generally 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. For Multiple PI (MPI) applications, this question applies to the corresponding (submitting) MPI.

Demographics Page.

 Select the most correct option for each of the questions about you as the project PI and your personal demographic information. You are permitted to choose 'Prefer not to respond' to any of these questions. Please note, your answers will not be seen by reviewers and do not influence the review of your proposal. Your answers are used solely in aggregate to help inform ACCEL leadership of the demographic makeup of our applicant pool over time. Questions pertain to identification of gender, race, ethnicity, and physical, mental, or emotional disability.

Disadvantaged Background Determination Page.

 Indicate if any of the disadvantaged background categories apply/applied to you personally as the project PI.
 Please select all that are applicable to you. You are permitted to select 'Do not wish to provide' to any of these questions. Please note, your answers will not be seen by reviewers and do not influence the review of your proposal. Your answers are used solely in aggregate to help inform ACCEL leadership of the demographic makeup of our applicant pool over time. If you are uncertain whether one of the categories applies to you, please click on the box in the upper right, "Disadvantaged Background Determination" to read some more detailed information.

Education Page.

 Please provide the requested information about your, the project PI's, educational background. Please note, your answers will not be seen by reviewers and do not influence the review of your proposal. Your answers are used solely in aggregate to help inform ACCEL leadership of the demographic makeup of our applicant pool over time. Questions pertain to your highest degree as well as any post-graduate clinical training you may have completed (if none, type "none" in the text box). If you do not know the exact graduation date, please make your best estimate.

Project Classification Pages.

1. Medically Underserved Populations Page Select 'yes' or 'no' to indicate whether the proposal addresses a medically underserved population in Delaware. If "yes", then indicate which population(s) apply.
2. Medically Underserved Areas Page Select 'yes' or 'no' to indicate whether the proposal addresses a medically underserved area/region in Delaware. If "yes", then indicate which area(s) apply.
3. Translational Spectrum Classification Page Select the one or multiple most appropriate region(s) of the translational spectrum addressed by the proposed project. If you are uncertain whether one of the categories applies to you, please click on the box in the upper right, "Translational Science Spectrum Classification" to read some more detailed information.
4. Health Conditions and Risk Factors Page Select 'yes' or 'no' to indicate if the proposed project addresses any of the health conditions, risks factors, or areas of healthcare focus listed. If "yes", then select all that apply below.

Mentoring Plan Page.

Not applicable.

IDP Page.

Not applicable.

CEO Page.

Select 'yes' or 'no' in response to the question, "Is this a community engagement project "

All Community Engagement projects 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.

> If "yes", then please also indicate which region of the community engagement spectrum best describes your proposal. Please click on the box in the upper right, "Community Engagement Spectrum" to read more detailed information on the definitions of these categories.

Budget Page.

Indicate the requested amount of budgetary support in the text box provided. OrBiTS budgets range from **$20,000 to $150,000 in Direct Costs and are up to 24 months in length.**

Team Members Page.

1. <u>PI</u> Your name will be automatically populated and assigned the role of PI.
2. <u>Multiple PIs</u> Select 'yes' or 'no' to indicate whether the project involves multiple PIs (MPIs). Selecting 'yes' will trigger the button "Add New PI" to appear in the top right corner. 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). 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 and reporting responsibility assigned.
3. <u>Add New Team Member</u> Click this button to add all other team members. Additional team members may include co-investigators (CIs), consultants, mentors, and/or community / clinical partners, if appropriate.
4. <u>Biosketches</u> Biographical sketches are required for most team members: a biosketch is required for all PIs, co-investigators, collaborators, and mentors; a biosketch is optional for community or clinical partners. All co-investigators and collaborators should also be listed on the Project Summary Page (see below) and vice- versa. If a community / clinical partner has provided a biosketch, they should also be listed on the Project Summary Page. 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.
5. Click "Yes" or "No" in response to the question, "Is this the first time this group of team members has collaborated?"

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.

<u>Supporting Files</u>

Upload all the completed project forms in the appropriate locations. Recall that forms should be created using [PHS398 fillable forms](#). Documents must be written with Arial 11 pt font. Pages are to be standard letter size (8½" x 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 ([Form page 2](#)) The [Project/Performance Site Format Page](#) may be appended to this and submitted as a single PDF if additional space is needed.

Detailed Budget – *required*
Upload the completed Detailed Budget 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 the University of Delaware's template is [here.](#) A timeline for spending should be outlined in the budget justification.

Biographical Sketch(es) – *required*
Upload the completed Biographical Sketch, using the [Biographical Sketch Format Pages](#), not to exceed 5 pages per person, for each of the following personnel:
- PI – *required*
- Other Key Personnel – *if applicable*

Biosketches must be provided for every person identified on Form Page 2 and will be uploaded on the Team Members page of the application submission site.
Detailed instructions for completing a NIH biosketch may be found [here](#) and a sample biosketch may be found [here](#).

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.

OrBiTS Aims and Research Strategy – *required, <u>max 5 pages in total</u>*
The OrBiTS Strategy should include Specific Aims (1 page) and then be organized into four additional pages with sections entitled Significance, Innovation, Approach, Community Engagement, and Evaluation of Outcomes leading to sustainability. Use [Continuation Format Pages](#) for this and upload as one pdf document. Although each section does not have its own page limit, it is recommended that the Approach section be the most detailed. A general guideline (but not requirement) for the page length of each section is: Significance, ½-1 p; Innovation, ¼-½ p; Approach, 2-2½ p; Community Engagement, ⅛ p, and Evaluation of Outcomes leading to sustainability , ¼ p. Within the Approach section, a statistical analysis subsection is required. OrBiTS applications should include a detailed plan for community engagement consisting of: identification of the community(ies) to be impacted by the work; a description of the anticipated impact of the proposal on the community; identification of any community partners and their specific role(s) in the project, if appropriate; and a clear plan for disseminating the research findings to the community. Strong CE projects will identify outcomes that are valued by the target community and will involve community members at all stages of the research. <u>Regular OrBiTS applications need not include this level of detail, but must include, at a minimum, a description of the anticipated impact of the proposal on the target community and a plan to disseminate the research findings to the community.</u>

References – *required*
All works cited in the application should be listed in a separate document entitled References (no page limit). Use [Continuation Format Pages](#) for this document; no page limit. In-text references should be provided either by author last name and year or by number in the body of the application and the References section should provide a listing of the complete citation for each of these works. Hot links *<u>are not acceptable</u>* within the references.

Multiple PI (MPI) Leadership Plan – *if applicable*
If the proposal involves more than one PI, a leadership plan must be included that addresses: roles and responsibilities of each PI, fiscal and project management coordination, the process for making decisions on scientific direction and allocation of resources, data sharing and communication among investigators, publication and intellectual property (if needed) policies, and procedures for resolving conflicts. The plan must also identify which PI is the contact PI, to whom all correspondence will be addressed. Use [Continuation Format Pages](#) for this document; no page limit.

Human Subjects Forms –*not applicable*

Vertebrate Animals Forms –*not applicable*

Letter(s) of Support – *required*
Letters of support should be on institutional letterhead and may not exceed 2 pages per letter.

- ○ 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 Delaware 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.). <u>For MPI structured projects, a Department/Unit Head letter should be provided for each MPI.</u>

o Others – *if applicable*
Other letters of support may be appropriate, to demonstrate the availability of specific resources and/or collaborators/co-investigators, and/or clinical/community partners for the project. If multiple letters of support are included, they should 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.

Remember to adhere to page and formatting requirements and to upload all necessary documents.

Applications that are incomplete or not in compliance with the formatting requirements will be administratively withdrawn without review. *