DELAWARE-CTR ACCEL
ACCELERATING CLINICAL TO TRANSLATIONAL RESEARCH

Clinical and Translational Research
OrBiTS Program 2018b

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 last 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/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) with 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 new form)
E. OrBiTS 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.

Pre-Submission Assistance and Feedback

Applicants are encouraged to engage with our *Community Engagement and Outreach (CEO) Core as part of the pre-submission process*. Those who do not 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 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. 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.

OrBiTS 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. Together, these should be four 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, Hence, 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 one investigator from one of the ACCEL partner institutions: the University of Delaware, Nemours, Christiana Care Health System, Delaware State University, and the Medical University of South Carolina (MUSC). They must be multi-investigator proposals with at least three faculty-level investigators (above the post-doc level) at ACCEL institutions. 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 as team leader.

Leaders of these awards 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.

Timeline

Proposals should be submitted electronically using the ACCEL website office 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.

Budget

Funding for this mechanism will be from approximately $20,000 to $150,000 per project and must provide resources for multiple investigators. Please outline in the budget justification section a timeline for the spending of the requested funds. A competitive renewal may be considered if it can be demonstrated that the work is especially meritorious

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.

Contacts

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

Thomas S. Buchanan, PhD, *ACCEL Pilot Project leader*
Heather Bittner Fagan, MD, MPH, *ACCEL Community Engagement and Outreach (CEO) Core leader*

Checkboxes to appear on web application

- ☐ Letter from Department Head/Chair and each team member is included **(required)**
- ☐ Consultation with Epi/Biostats Core (if appropriate)
- ☐ 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 (should be "no" as no specific research projects should be proposed)
- ☐ This work involves vertebrate animals (should be "no" as no specific research projects should be proposed)

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 there at least three investigators that will benefit from this work? Are the investigators well qualified to perform this work and lead future NIH-funded projects? If the PI has had previous funding, was there adequate success?

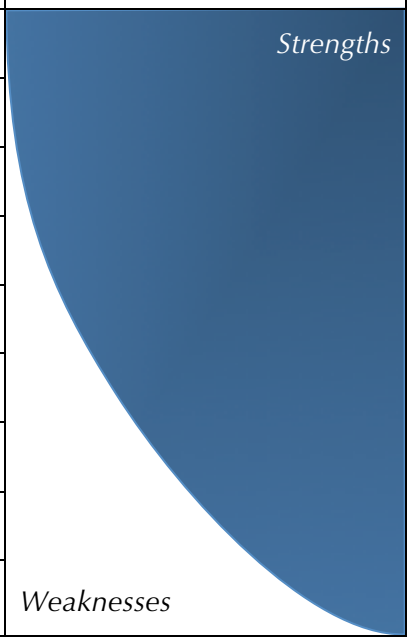
Innovation—Is the proposed research plan novel and innovative, advancing the field?

Approach—Are the methods sound and likely to be successful? Are there unique barriers to success that will be overcome through these awards? Will the funding will be transformative? Is the sustainability plan reasonable?

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 helping in the development of 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 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	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	