

Duke CTSI Special Populations Pilot REQUEST FOR 2020-2021 APPLICATIONS

Mandatory Letter of Intent/Proposal Concept Deadline: 11:59 p.m., January 6, 2020

Full Proposal Application (by invitation only) Deadline: 11:59 p.m., March 17, 2020

The Duke Clinical and Translational Science Institute (Duke CTSI) is the academic home of the National Institutes of Health's Clinical and Translational Science Awards (CTSA) funding program. The Duke CTSI facilitates translational research to move discoveries from the laboratory to human trials to real-world settings. Duke CTSI accelerates translational research not only by providing funding, but also by promoting investigator collaboration, encouraging innovation, providing project management assistance, and providing access to resources/services in a collaborative and service-oriented fashion.

I. Purpose

The purpose of the Special Populations Pilot program is to facilitate novel clinical and translational research that promotes health equity for groups who have traditionally been under-represented in health research or excluded altogether. Projects must have strong potential to inform subsequent grant applications for external funding. Pilot awards will be up to \$25,000 (direct costs only); applications that include a strong community stakeholder-academic partnered approach will be eligible for an additional \$10,000 (see **Community-Engaged Approaches** below).

Submissions must focus on one of the following populations: pediatric populations, adolescents, or young adults; older adults; people with disabilities and/or rare disorders; and/or populations that have been underserved or under-represented in clinical research (e.g., African Americans, Native Americans, Latinos, rural populations, or populations with low socioeconomic status).

Proposals from early stage and new investigators and proposals with collaborations across Duke Departments or Schools are highly encouraged.

Community-Engaged Approaches: CTSI's [Community Engaged Research Initiative \(CERI\)](#) is collaborating with the [Special Populations Core](#) on this RFA to provide an additional \$10,000 for a total of \$35,000 in pilot funding **for a team that includes a strong community stakeholder-academic partnered approach**. The stakeholder-academic partnership can consist of either a new partnership that will establish and build relationships between a Duke researcher and a stakeholder partner co-applicant (e.g., organization, coalition) or expand the work of an existing stakeholder-academic partnership. Examples of projects with community-engaged approaches include but are not limited to:

- Pilot testing community-based social support interventions to improve symptom management in young adults.
- Testing the feasibility and acceptability of a community health worker intervention to improve early detection of a chronic disease in rural communities.
- Developing cross-sectoral partnerships to improve the efficacy of interventions promoting aging in place.
- Exploring social determinants of a specific health outcome using secondary data.

Please note that inclusion of community-academic partnered approach **will not impact** whether applicants are invited to submit full proposals or ultimately receive funding.

II. Key Dates

- Mandatory Letter of Intent (LOI): **January 6, 2020**
- Invitation to Submit Full Application: no later than **January 24, 2020**
- Invited Application Submission Deadline: **March 17, 2020**
- Selection of Awardees: **May 2020**
- Notice of Awards: no later than **June 1, 2020**
- Funding Period: **July 1, 2020 – June 30, 2021**

III. Eligibility

- Proposals must be submitted by Duke investigators with PI status per [Duke's written policy](#). Investigators holding an adjunct appointment are not eligible.
- Non-Duke faculty may be named as co-investigators with appropriate justification for the collaboration.
- More than one proposal may be submitted per faculty member acting as PI, but the faculty member is only eligible to receive one award as PI from this funding mechanism during a given funding cycle.
- Applicants are required to submit a mandatory letter of intent (LOI).
- Upon conclusion of LOI review, selected applicants will be invited to submit a Full Proposal. All investigators invited to submit a full proposal are required to attend a consultation meeting with the Special Populations team and CERI (if applicable).

IV. Funding

Each 12-month award will consist of up to \$25,000 (direct costs only) with a start date of July 1, 2020. Proposals with a community-engaged approach will be eligible to receive an additional \$10,000 for a maximum total of \$35,000. **Requests for no-cost extensions (NCEs/carryovers) will not be considered.** Funded projects are eligible to reapply for renewal in subsequent years and, if selected, receive funding for up to two cycles. The primary source of funding is from the National Center for Advancing Translational Science's (NCATS) Clinical and Translational Science Award UL1TR002553 to Duke University.

Note: This award is internally funded and does not need to be routed through the Duke Office of Research Administration (ORA).

V. Consultation and Proposal Preparation Assistance

1. Full proposal applicants are required to arrange a consultation with the Special Populations Core prior to submission by contacting specialpopulations@duke.edu. Those applying for the community-engaged supplement will also be required to meet with the CERI team. Applicants may also contact these groups with questions via specialpopulations@duke.edu or CeRi@dm.duke.edu.
2. Duke CTSI strongly recommends involving a biostatistician early in the application development process and including biostatistics support in the budget where necessary to ensure success. The online application form will ask for the name of the biostatistician who consulted on the proposal. Duke investigators who do not know whether their affiliated department/center/institute has an existing collaborative agreement with the Duke CTSA Methods Core can be connected with an appropriate biostatistician, quantitative, or qualitative methodologist through the Duke CTSI [Methods Core](#) by submitting a [Core Resource Request form](#). Once a request is submitted, Duke investigators will be referred to the appropriate collaborative group if an appropriate collaboration model exists. If the Duke

investigator submitting the request does not belong to a group that has an established collaboration model affiliated with the Core, or additional methodology expertise is needed, the Core leadership will attempt to identify methodologists with appropriate expertise and collaborative interest/availability. Identifying the appropriate methodologist can be a time-consuming process because the network is large across Duke and the methodologists may have limited availability. Therefore, the Core may not be able to accommodate requests with tight deadlines, especially if there is not an established collaboration to support the work. **In all cases, a request for collaboration should identify a Duke funding source for the effort that will be needed and must be submitted at least 6 weeks prior to a deadline.** Because the Core receives multiple requests, this can take much longer for many projects, so we ask that investigators contact the Core as soon as possible.

VI. Selection Process and Review Criteria

A Review Committee comprised of researchers, clinicians, and experts will perform a detailed review of the applications and select the finalists. The Review Committee will consider the following criteria when reviewing and scoring applications:

- **Significance** – Project addresses an important problem or barrier to research progress in improving health among Special Populations (see Section [I. Purpose](#)). Project has a strong scientific premise, well-considered and clearly defined aims, and potential to advance research and understanding of health outcomes among Special Populations.
- **Investigator(s)** - Investigator's qualifications to conduct proposed research, investigator's prior productivity (relative to career stage), and potential for future funding. We encourage applications from early stage investigators and investigators from groups typically under-represented in scientific research. Additionally, investigative teams involving collaborations from two or more Departments/Schools or disciplines are encouraged.
- **Approach** –The overall strategy, methods, and analyses are well-reasoned and appropriate to accomplish the specific aims of the project. Aims and approach are both scientifically sound and feasible for the timeframe and level of funding requested.
- **Innovation** – Application design/research plan includes innovative elements, as appropriate, that enhance its sensitivity, potential for information, or potential to advance scientific knowledge or clinical practice relevant to advancing Special Populations research.
- **Overall Impact** - Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to enable and advance future research that is in line with CTSI mission and may have a powerful influence on the relevant research field(s), and in consideration of the review criteria described above. Applicants are encouraged to identify dissemination strategies and plans for future follow on proposals and aims that build on the pilot project results. Opportunities that provide generalizable solutions to translational research problems are highly encouraged.
- **Community-Engaged Approach** – CERI representatives will evaluate whether the proposal includes a meaningful community-academic partnership. Please note that inclusion of community-academic partnered approach **will not impact** whether applicants are invited to submit full proposals or ultimately receive funding.

VII. Application Procedures

Applications must be submitted online through the [MyResearchProposal](#) portal.

- To apply, visit <http://bit.ly/myresearchproposal> and click on “Create New User” (or log in if you already have an account). Proposals must be submitted under the Principal Investigator’s name.
- A step-by-step user’s guide for applying via the MyResearchProposal software is available - Please review this [document](#).
- Enter Access Code ‘**SPCPOP**’ then select: LOI - Duke CTSI Special Populations Pilot Agreement”.
- For any questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or call 919-668-4774.
- Please note that applicants invited to submit full applications will receive an email notification when the full application is accessible. Unsolicited full proposals submitted will **not** be reviewed.

Letter of Intent (LOI) and Concept Proposal (Mandatory)

Applicants will enter general project information via the web-based form:

Letter of Intent

1. Project Name (Principal Investigator and Project Name)
2. Principal Investigator (Name, Department/School, Area of expertise relevant to proposal)
3. Co-Investigator(s) (Name, Department/School, Area of expertise relevant to proposal)
4. Anticipated Budget Request (up to \$25K, or up to \$35K for community-engaged projects)
5. Area of Impact (Age Group, Special Population engaged)
6. Community-engaged approach (Are you including a community-engaged approach? If so, provide the name of the community partner/organization and a brief description of the partnership.)

Concept proposal

- A. Abstract/Specific aims (500 word limit)
- B. Summary of proposed research plan (pdf upload, up to 2 pages not including references, 1-inch margins, Arial 11 font, and single spaced):
 - a. Approach (e.g., participants, recruitment and data collection procedures, outcomes and measures, analytic plan)
 - b. Innovations
 - c. Anticipated feasibility (e.g., timeline, challenges, solutions, etc.)
 - d. Expected significance and impact, especially from a translational science perspective
- C. Draft budget and brief justification (High level info, e.g., 10% FTE PI salary support, 90% supplies and equipment usage fee) (1 page)

Invited Applications for Full Proposals

Invited applicants will submit their full proposals through [MyResearchProposal](#). Proposal sections (except the Abstract) will be uploaded as individual PDFs. The application sections are:

1. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI (500 word maximum).

2. **Research Plan:** The Research Plan should follow the standard NIH format and address the following: *Specific Aims, Significance, Innovation, and Approach* (including timeline and future plans). Include where applicable clear evidence of how the proposal meets the review criteria. (5-page limit, including tables and figures, excluding references; single line spacing, font no smaller than Arial 11, 1-inch margins)
3. **DRAFT Budget with Budget Justification:** Using [PHS 398 Form Pages 4 and 5](#) (combined into a single PDF with no page limit). Initial submissions are approximate and do not need institutional approval. Finalists invited to submit full proposals will be required to submit a detailed NIH budget and updated budget justification. This award is internally funded and does not need to be routed through Duke ORA; Duke CTSI will route final budgets to departments for review and approval.
4. **Human and/or Animal Subjects Protections:** Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission but will be required prior to funding. Briefly describe any human and/or animal subject issues. If human subjects are involved, provide a description of their involvement and characteristics, study procedures, materials used in the research, potential risks to subjects, the process for recruitment and informed consent, and protection against risks. Provide assurance that the project will be reviewed and approved by the Duke IRB and comply with HIPAA. If vertebrate animals are to be used, provide a description of the proposed use of the animals in the work outlined and procedures for ensuring that discomfort, distress, pain and injury will be limited. Projects involving animal subjects must be reviewed and approved by a Duke IACUC (no page limit).
5. **Investigators** - [NIH Biosketches](#) for key members of the research team (as a single PDF).

Budget Guidelines

Please note the following during budget preparation:

1. The budget period is July 1, 2020 through June 30, 2021. No indirect or overhead costs are awarded; the awardees receive direct costs only.
2. As part of federal requirements, Duke has an obligation to report effort correctly on sponsored projects. The investigators must include and commit sufficient effort to accurately reflect the needs of the project
3. Grant funds **may** be budgeted for:
 - salary support for the PI or faculty collaborators
 - research support personnel
 - tuition and fees if not covered by other funding mechanisms
 - travel necessary to perform the research
 - small equipment, research supplies and core lab costs, or
 - other purposes deemed necessary for the successful execution of the proposed project
4. Grant funds may **not** be budgeted for:
 - general consumable supplies
 - foreign components, as defined in the [NIH Grants Policy Statement](#)
 - effort for post-doctoral trainees or fellows already supported by training grant equivalents
 - capital equipment
 - office supplies or communication costs, including printing and postage
 - meals or travel, including to conferences, except as required to collect data
 - professional education or training

- computers or audiovisual equipment
- cell phones
- manuscript preparation and submission, or
- indirect costs

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to government regulations and Duke requirements. Duke CTSI reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal. The general criteria for determining allowable direct costs on federally-sponsored projects is set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance). The [Duke General Accounting Procedure \(GAP\) 200.320](#) is a resource to determine whether or not a particular cost item would be considered an allowable direct cost for budgeting and/or charging on a federally sponsored project.

VIII. Terms of the Award

A. Approvals Required Prior to Funding Start Date

- Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke IRB. If the research includes animals, the appropriate IACUC animal research forms must be approved before the project's start date. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to Duke CTSI prior to funds being released. Human subjects or animal research must be reviewed in accordance with the university's general assurances and HIPAA. In addition, if the research involves human subjects, all personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period.
- Research involving live vertebrate animals and/or human subjects may require approval by the National Center for Advancing Translational Sciences (NCATS) prior to receiving funds. The Duke CTSI will request required documents from the PIs and submit an approval package for each institution to NCATS for review and approval.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Investigators agree to provide quarterly project updates via meetings with Duke CTSI Special Populations Core and/or the assigned Duke CTSI Project Leader. Investigators will submit brief written progress reports at six and twelve months.
- Duke CTSI Special Populations Core may terminate and reallocate residual funds for any team failing to submit required written reports in a timely manner. Proposed aims of funded projects may be changed, added or deleted during the funding period pending Investigator and Duke CTSI Special Populations Leadership Committee review and agreement. Funding amount may be modified pending Investigator and Duke CTSI Program Leadership Committee agreement. **Projects must complete in the 12-month period; no-cost extensions will not be granted.**
- Investigators will be assigned a Duke CTSI Project Leader. The project leader will work with investigators to manage projects, report progress relative to planned milestones, and serve as a resource to identify and fulfill unmet project needs via the Duke CTSI and other key resources.

- The institutional funds used in our CTSA pilot funding programs may take on the identity of federal funds in this award mechanism and therefore may require to be treated as such with regards to IRB, IACUC, and tech transfer office reporting. NCATS approval is required prior to initiating research involving live vertebrate animals and/or human subjects, and inventions resulting from pilot awards must be reported in iEdison and include UL1TR002553 as the source of federal funding.
- All publications that are the direct result of CTSA funding must reference: *“Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR002553. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”* Publications must also be registered in PubMed Central.
- Any awardee who leaves his or her position should contact Duke CTSI Special Populations Core to discuss future plans for the project.

C. Post-Award Reporting

The Duke CTSI tracks significant events (“translational units”) required to translate a scientific discovery from laboratory, clinical or population studies into clinical or population-based applications to improve health by reducing disease incidence, morbidity and mortality. The Duke CTSI will contact investigators annually for five years post-award to determine if any translational units have been achieved as a result of this award. Examples include:

- Abstracts/presentations, manuscripts, published guidelines
- Follow-on funding (e.g., grants, SBIR/STTR, angel and venture capital investment)
- Milestones achieved in animal models, manufacturing and toxicity campaigns
- Regulatory meetings and filings (e.g., 510K, IDE, IND, BLA, NDA)
- Initiation of appropriate clinical studies
- Improved diagnosis or treatment of disease
- Implementation in clinical practice and community
- Translation of models to other geographical areas
- Translation of models to other therapeutic areas
- Clinical outcomes in practice and communities
- Agreements with partners and strategic collaborators to translate more broadly
- Commercialization (e.g. new intellectual property, patent applications, license, commercial partnerships)
- Direct-to-consumer interactions (e.g. apps)

When requested, all awardees will be expected to provide updates of publications and other translational units that originated from the award.

Awardees and applicants are expected to serve as reviewers for future Duke CTSI funding opportunities.

CONTACT INFORMATION

For additional information on this funding opportunity, please contact specialpopulations@duke.edu.