

Duke CTSI Special Populations Pilot Agreements REQUEST FOR 2018-2019 APPLICATIONS

Mandatory Letter of Intent/Proposal Concept Deadline: 11:59 p.m., September 17, 2018

Full Proposal Application (by invitation only) Deadline: 11:59 p.m., December 4, 2018

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 accelerates translational research, by resourcing discovery to preclinical research and human trials, through to implementation into practice. 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 research that promotes health equity for groups who have traditionally been under-represented in health research or excluded altogether.

The Duke CTSI Special Populations Pilot Agreement provides funding up to \$25,000 (direct costs only) to support novel clinical and translational research in its many forms. Projects must show strong potential to inform subsequent grant applications to the NIH or other funding agencies.

Submissions must focus on one of the following populations: pediatric populations, adolescents and young adults, older adults; people with disabilities and/or rare disorders, and/or populations which have been underserved or underrepresented in clinical research (e.g., African Americans, Native Americans, Latinos, rural populations or populations with low socioeconomic status). For example, Duke CTSI Special Populations is interested in the following types of research projects:

- Projects that address health disparities in one or more of the populations listed above.
- Projects that develop and test strategies to increase our understanding of or research capacity to examine health outcomes across the lifespan. Projects may include, but are not limited to, planned follow up of special populations of interest, use of data registries, and linkages across existing datasets or data collection sources to follow individuals longitudinally, or use of specialized statistical methods to address challenges.
- Projects to implement or expand a registry(ies) that enroll subjects from the populations listed above.
- Pilot strategies for recruiting participants or using data through existing datasets or data warehouses (e.g., the Carolina Data Research Networks) to advance integration of special populations in health research.
- Testing and evaluation of tools or existing resources designed for recruiting and retaining under-represented or other populations of interest.
- Projects which demonstrate or pilot test research methods and strategies designed to increase participation of under-represented populations in health research. Projects may include, but are not limited to, use or testing methods and strategies to facilitate research with special populations including use of mobile and web-based tools; strategies that explicitly address barriers to research participation; or was development and testing of novel tools, materials, tailored messaging, etc. to improve diverse recruitment or research participation.
- Developing, testing, and disseminating interventions to achieve health and healthcare equity in one or more of the populations listed above.

- Research that applies or accelerates discovery into testing in clinical or population settings.
- Development and/or evaluation of the evidence base that changes practice to improve outcomes among special populations. For example, following the successes of the Pediatric Trials Network, PK/PD studies testing dosing and efficacy of commonly used medications with older populations may inform practice (and potential policy/label changes).
- Research that impacts how practice improves health policy, health outcomes, and the health of populations.

Proposals from early stage and new investigators,¹ and proposals with collaborations across Duke Departments or Schools (e.g., School of Nursing, School of Medicine, Aging Center, Pediatrics, Cancer Center, Public Policy, School of Engineering, etc.) are highly encouraged.

II. Key Dates

- Mandatory Letter of Intent (LOI): **September 17, 2018**
- **Invited** Application Submission Deadline: **December 4, 2018**
- Selection of Awardees: **January 2019**
- **Notice of Awards: February 2019**
- **Funding Period:** The budget period is for 12 months beginning March 1, 2019 – February 28, 2020

III. Eligibility

- Proposals must be submitted by Duke regular rank faculty and comply with the Duke University Policy on PI Status in the Duke Faculty Handbook. Researchers 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 during a given funding cycle.
- Submission of **Mandatory** Letter of Intent (LOI).
- Upon conclusion of LOI reviews, **selected** applicants will be **invited** to submit a Full Proposal.

IV. Funding

Each 12-month award will consist of up to \$25,000 (direct costs only) with an expected start date of March 1, 2019. Requests for no-cost extensions (carryovers) will not be considered. Funded projects are eligible to re-apply for renewal in subsequent years and, if selected, receive funding for up to two cycles. The primary source of funding is from Duke's National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award UL1TR002553.

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

¹ Per NIH definitions. An **Early Stage Investigator** (ESI) is a new **investigator** who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant.

V. Special Populations Core – Pilot Application Process

Application Steps	Dates
Applicants will log in or register for an account in MyResearchProposal to access the Special Populations Core Pilot Funding Application.	
<ul style="list-style-type: none"> • Letter of Intent (LOI)/Concept Proposal <ul style="list-style-type: none"> • Applicants must submit a LOI with a preliminary proposal. Please submit LOI via MyResearchProposal (see LOI and Application Procedure below). 	9/17/2018
<ul style="list-style-type: none"> • Invitations for Full Proposal <ul style="list-style-type: none"> • The Duke CTSI Project Office and Special Populations Core Team will review the LOIs for scientific soundness and relevance to the aims of the Special Populations Core and CTSA. • Applicants with LOIs selected in the preliminary review will be notified no later than 10/15/18 and invited to submit full proposals. 	Applicants notified nlt 10/15/2018
<ul style="list-style-type: none"> • Full Proposal Application Submission (invited) <ul style="list-style-type: none"> • Invited applicants will prepare and submit a full proposal with required sections. • Applicants are encouraged to consult with the CTSI Project Office and Special Populations Core Team during full proposal preparation. 	12/04/2018
<ul style="list-style-type: none"> • Select Process and Review Criteria <ul style="list-style-type: none"> • A Review Committee comprised of researchers, clinicians, and experts will perform a detailed review of the applications and select the finalists. The review process and criteria are adapted from NIH peer-review procedures. Awardees will be notified via email (through MyResearchProposal). 	TBD
Funding Award Period: 12 months	Start date: 3/01/2019

VI. Consultation and Proposal Preparation Assistance

1. Full proposal applicants are encouraged to arrange a consultation with the Duke CTSI Projects Office and/or the Special Populations Core Team to gather feedback prior to application submission. Applicants may also contact these groups with questions via Duke CTSI Project Office at ctsiconsultstudio@duke.edu or specialpopulations@duke.edu.
2. Duke CTSI recommends a consultation with the [Duke CTSI Community Engagement Core](#) to identify opportunities to include stakeholder engagement in the project, if appropriate. For example, depending on the special population targeted in the proposal, consultation may be arranged with the Aging Center, CHDI, REACH Equity program, or others.
3. Applicants are strongly recommended to involve a biostatistician early in the application development process and to include biostatistical 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. For investigators without access to a biostatistician, biostatistical support can be obtained through the [Duke CTSI Biostatistics Core](#) by submitting a Core Resource Request [form](#). The core provides an initial 1-hour consultation upon request at no cost.

VII. 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 ([adapted from NIH review criteria](#)):

- **Significance** –Project addresses an important problem or barrier to research progress in improving health among special populations (see [I. Purpose section](#)). Project has a strong scientific premise, with well-considered and clearly defined aims, with potential to advance research and understanding of health outcomes among special populations.
- **Investigator** - Investigator’s qualifications to conduct proposed research, investigator’s prior productivity (relative to career stage), potential for future funding. We encourage applications from early stage investigators and investigators from groups typically under-represented in scientific research. In addition, 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.

VIII. Application Procedures

Applications must be submitted online, through MyResearchProposal.

- To apply visit <http://bit.ly/myresearchproposal>, 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.

Note: 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(s) of expertise relevant to proposal)

3. Co-Investigator(s) (Name(s), Department/School affiliations, Area(s) of expertise relevant to proposal)
4. Anticipated Budget Request (up to \$25K)
5. Area of Impact (Age Group, Population [Underserved/underrepresented groups, Rare disease/disability, Other])

Concept proposal

- A. Abstract/Specific aims (500 word limit)
- B. Summary of proposed research plan (pdf upload, up to 2 pages not including references, 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, and 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

Applicants receiving invitations to submit full proposals via email will be granted access to submit Invited Proposal Applications (in Myresearchproposal).

1. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI (4,000 characters maximum including letters, spaces, punctuation, special characters, etc.).
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 (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, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. 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 the 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 March 1, 2019 through February 28, 2020. 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
 - 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 on 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.

IX. 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 and NCATS. The Duke CTSI will request required documents from the PI and submit a regulatory package to NCATS for review and approval prior to the funding start date. If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project's start date. 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 one on one meetings with Duke CTSI Special Populations, and to submit brief written progress reports at six (6) month and twelve (12) months. Duke

CTSI Special Populations 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.

- Duke's CTSA grant UL1TR002553 notice of grant award included both federal funding and our institutional commitment. The institutional funds used in our CTSA pilot funding programs take on the identity of federal funds in this award mechanism and therefore should be treated as such with regards to IRB, IACUC, and tech transfer office reporting. NCATS approval is required prior to initiating research involving 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 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 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.