Duke Clinical & Translational Science Institute

Duke-NCCU Clinical & Translational Science (CTS) Grants Pilot Request for Applications (RFA)

Mandatory Letter of Intent Deadline: February 28, 2023
Application Deadline: April 3, 2023
Funding Period: September 1, 2023 – April 30, 2024

I. Key Dates:

Information Sessions	January 19, 2023, 11:00 am – 12:00 pm. Register here. February 8, 2023, 2:00 pm – 3:00 pm. Register here.
Mandatory Letter of Intent Deadline	February 28, 2023
Mandatory Consultations with Duke CTSI*	January 16 – March 10, 2023
Full Application Deadline	April 3, 2023
Anticipated Funding Decisions	June 30, 2023
Funding Period †	September 1, 2023 – April 30, 2024

*All applicants are *required* to consult with the Pilot Program Team prior to submitting a full proposal to ensure optimal responsiveness to the RFA.
†Awards are contingent upon availability of funds.

II. Purpose and Background

The Duke Clinical & Translational Science Institute (CTSI) is the academic home of the National Institutes of Health Clinical and Translational Science Award (CTSA) at Duke University and North Carolina Central University (NCCU).

As defined by the National Center for Advancing Translational Sciences (NCATS), translation is the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. Advances in translational science are the focus of this RFA. The CTS Grants program is intended to support Clinical and Translational Science (CTS), the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational *process.* Whereas *translational research* focuses on the specific case of a target or disease, ***translational science*** **focuses on the general case that can be applied to research on any target or disease.**

A key tenet of translational science is to understand common causes of inefficiency and failure in translational research projects (e.g., incorrect predictions of the toxicity or efficacy of new drugs, lack of data interoperability, ineffective clinical trial recruitment). Many of these causes are the same across targets, diseases, and therapeutic areas; therefore, **advances in translational science will increase the efficiency and effectiveness of translational research to enhance health, lengthen life, and reduce the burdens of illness and disability.** Like any other science, translational science seeks to elucidate general

operative principles to transform translation from an empirical, phenomenological process into a predictive science. The application of scientific and operational innovation and strategies to improve the efficiency and effectiveness of all research is at the heart of developing, demonstrating, and disseminating the science of translation. See specific examples of Translational Research (TR) vs Translational Science (TS) projects.

Endemic health inequities were exacerbated by the COVID-19 pandemic, and therefore, there's an urgent and imperative need to ensure that 1) the clinical research enterprise and local communities become equity-minded, and 2) clinical science benefits are disseminated equitably. Effective engagement of non-academic partners such as community members, clinicians, patients, industry, and policymakers is critical to improving health and achieving health equity. Community engagement fosters communication and trust, improves assessment efforts, and contributes to the sustainability of health initiatives.

Only projects that develop methodologies and/or generalizable solutions that address common challenges and roadblocks across the translational spectrum will be funded. **The Duke-NCCU CTSA has a strong focus on healthy equity; projects that seek to elucidate mechanisms and solutions to overcome translational roadblocks to achieving health equity are strongly encouraged**. Proposals should demonstrate community engagement to facilitate the exchange of knowledge with those who will implement findings.

Translational **research** projects, i.e. projects focused on crossing a particular step of the translational process for a particular target or disease, are not allowed. However, the proposed research may use a specific use case to test a CTS hypothesis, as long as the CTS relevance of the work is clearly described and generalizable across other domains of translational science.

Examples of some CTSA Pilot Projects that may be Supported Include:

1. Projects that Overcome Roadblocks in Studies of Health
    - Quality Improvement (QI) Research: Research designed to improve and /or streamline clinical and translational research processes. This includes a broad range of topics focused on investigation and intervention on 1) institutional research infrastructure (e.g. IRB, IACUC, Grants and Contracts, Office of Regulatory Affairs); 2) investigator and staff perceived roadblocks to the efficient conduct of research; and/or 3) community and institutional partners perceptions of roadblocks in conducting research with Duke and NCCU investigators. Projects designed to improve and streamline partnered research between Duke, NCCU, and community partners are highly encouraged.
    - Mechanisms: Identify new, generalizable determinants of health and resilience (molecular, physiological, behavioral, social, and other) across the life course and in various contexts.
    - Layered Determinants: Develop or demonstrate new integrative and generalizable methods to study the molecular, physiological or metabolic, behavioral, social, and other factors to health and resilience.
    - Interventions: Develop new methods to promote sustained health and resilience that can be generalized across different areas/disciplines.
    - Transdisciplinary Science: Identify new approaches for integrating molecular or physiological discoveries with implementation science to accelerate translation.
    - Patient engagement: Research on patient recruitment, and retention. Research involving

patient preferences including focus groups and surveys--including topics such as best practices for return of results, direct-to-patient enrollment, and informed consent.
- Data sharing practices and policies: Research on roadblocks, accessibility among institutions, data use agreements, best practices on posting HIPAA-compliant de-identified datasets, best practices on linking multiple datasets and registries using direct or indirect patient identifiers.
- Projects designed to understand and improve the communities' trust in the clinical research enterprise and our institutions' trustworthiness.

2. Projects that Overcome Roadblocks in Studies of Health Equity
    - Mechanisms: Identify new, generalizable mechanisms (e.g., social, environmental, other) for health inequities.
    - Measures: Develop and utilize novel and generalizable measures of social and environmental determinants of health inequity (e.g., structural and environmental racism).
    - Data: Develop and test novel and generalizable approaches that enhance the use and integration of sources of data (e.g., from non-healthcare societal sectors, wearables) to study health equity.
    - Secondary Data Analysis: Duke has substantial data on the research enterprise including OnCore, IRB, and EHR. Example research questions could examine trends in the recruitment of diverse samples; characteristics of studies that effectively recruit diverse samples; and analysis of the use of inclusive and culturally sensitive language in consent forms.
    - Populations: Develop new approaches for engaging disparity populations in research.
    - Transdisciplinary Team Science: Address health equity problems through new transdisciplinary scientific methods (e.g., social and/or environmental scientists, clinical researchers, policy scholars, and others).
    - Settings and Partners: Develop new methods to effectively implement health equity in real-world contexts.
    - Research on Duke-NCCU as a Learning Health System: Example research include studies of approaches to increase clinician-research collaboration and partnerships; research on processes to improve clinical research practices within the context of health care settings; research designed to understand and intervene on barriers to recruiting individuals from marginalized communities in healthcare settings.

III. Eligibility

1. Application is open to investigators from Duke University and North Carolina Central University (NCCU)
2. Applicants at each institution must have a principal investigator status per the specific institution's written policy (Duke policy; NCCU policy). For questions regarding eligibility, contact Eman Ghanem @ ctsifunding@duke.edu.
3. Duke and NCCU interinstitutional collaborations are **strongly encouraged**, with the understanding that both PIs will share equal responsibility for the conduct and direction of the project.
4. More than one proposal may be submitted per NCCU or Duke faculty member acting as PI, but the faculty member is eligible to receive only one award as PI during a given funding cycle.

IV. Funding

1. The program will award up to eight (8) awards of $25,000 to $50,000 each in direct cost only.
2. **Note for Duke Investigators:** This award does not need to be routed through the Office of Research

Administration (ORA). However, we strongly recommend that you include your grants team in the preparation of this proposal budget.

3. Requests for no-cost extension will not be approved.

V. A Multi-step Application Procedure

A. Submission of a (up to 3 pages) Letter of Intent (LOI)
B. Consultation with Duke Pilot Program Team is ***required to move to the full proposal step***
C. Submission of Full Proposal

A. Submission of Letter of Intent

Applicants should submit a Letter of Intent through the MyResearchProposal@Duke system (MRP) by **11:59 pm on February 28, 2023**. The Letter of Intent comprises three 1-page sections, each of which are uploaded through the appropriate link on the submission page. Pilot Program Team will advise applicants on how to best present the translational science problem to be addressed and the general methodological approach **prior to Letter of Intent** submission. To request a consult, click here.

1. Outline of the proposed work in the form of a standard NIH-style Specific Aims page (*1-page limit, single spacing, font no smaller than Arial 11, and 1-inch margins*).
2. Description of the research team, highlighting the skills and experience that speak to the feasibility of the proposed work *(1-page limit, single spacing, font no smaller than Arial 11, and 1-inch margins*).
3. Outline of how the work will increase understanding of a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research, and If applicable, the CTS relevance of any Clinical and Translational Research (CTR) use case must be made clear. Provide a minimum of **2 examples** of how the research question generalizes to multiple health or health equity conditions or fields of study (*1-page limit, single spacing, font no smaller than Arial 11, and 1-inch margins*).

To access the MyResearchProposal@Duke:

1. Visit http://bit.ly/myresearchproposal
2. Click "Create New Account" or login if you already have an account. **Submissions must be made under the Principal Investigator's name.**
3. Enter Access Code 'CTSI', select "*Duke-NCCU Clinical & Translational Science (CTS) Grants LOI 2023-2024*" and follow the instructions.
4. A step-by-step user's guide for applying via the MyResearchProposal software is available here - Please review this document.

For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or 919-668-4774.

After evaluation by, and consultation with, the Pilot Program Team, applicants will be informed within 2 weeks whether or not they are invited to submit a full proposal.

B. Consultation with Duke-NCCU Pilot Program Team

To ensure that the proposed work is as responsive as possible to the goals of the CTS Pilot Program, applicants will meet with Pilot Program Team to discuss their project. After the LOI is submitted, applicants will receive a confirmation email containing a link to schedule a consultation with the Pilot Program Team.

This consultation is ***mandatory***. Representatives from relevant areas such as Health Equity Study Design Studios may be invited by the program staff to attend this consultation.

C. Submission of Full Proposal

Full applications are also submitted using the MRP system. Applications are due by **11:59 p.m. on April 3, 2023**. Applicants will be notified by email by June 30, 2023 whether their application has been selected for funding. Proposal sections are either uploaded as pdf files or provided as text entry (see Appendix I). The application sections are:

1) **Scientific Abstract:** Summary of the proposal (*1500-character limit, ~250 words*).
2) **Impact Statement:** Briefly describe the likelihood for your project to exert a sustained, powerful influence on the field of translational science (*300-character limit, ~50 words*).
3) **Research Plan:** The Research Plan should include Specific Aims, Significance, Innovation, and Approach. Include, where applicable, clear evidence of how the proposal meets the review criteria and how the project will be generalizable. (*PDF, 5-page limit, including tables and figures, single line spacing, font no smaller than Arial 11, and 1-inch margins*). *Cited references do not count towards the 5-page limit.*)
4) **Cited References:** (*PDF, no page limit*)
5) **Plan for Future Funding:** Describe, in as much detail as possible, how the data generated during the pilot project will support subsequent application(s) for external funding support (*PDF, 1-page limit, single line spacing, font no smaller than Arial 11, and 1-inch margins*).
6) **Timeline:** Outline the proposed activities for the funding period, including timeline and milestones (up to 8 months). It is important that the proposed work can be completed prior to April 30, 2024, *as no-cost extensions are not permitted.* Therefore, the timeline should address plans for spending grant funds within the funding period. Include specific factors (e.g., submitted/approved IACUC/IRB protocols, established study cohort, etc.) that speak to the feasibility of commencing the study on the 9/1/2023 start date, and completing the proposed work within the 8-month funding period. (*PDF, 2-page limit, including graphics, single line spacing, font no smaller than Arial 11, and 1-inch margins*).
7) **Discussion of the health equity ramifications of the proposed work**. One of the goals of the CTSA Program is to "*Create, provide, and disseminate innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all*." Discuss the proposed work's potential to contribute to health equity solutions. (PDF, *1-page limit, single line spacing, font no smaller than Arial 11, and 1-inch margins*).

   Note: Two recent publications discussing diversity, equity, and inclusion (DEI) in clinical and translational research are useful references when preparing this section:
   a. Boulware *et al* (2022) Diversity, equity and inclusion actions from the NCATS Clinical and Translational Science awarded programs. *Nature Medicine.* DOI: https://doi.org/10.1038/s41591-022-01863-7
   b. Castillo and Harris (2021) Directing Research Toward Health Equity: a Health Equity Research Impact Assessment. *J Gen Intern Med*. DOI: https://doi.org/10.1007/s11606-021-06789-3
8) **Budget and Budget Justification:**
   a) Use PHS 398 Form Pages 4 and 5 (combined into a single PDF with no page limit). **Note for Duke Investigators**: This award does not need to be routed through ORA. See Section VII "Budget Guidelines" below.
   b) The total project budget must be between $25,000 and $50,000, direct costs only.

c) Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. For projects involving more than one institution, institution-specific budgets and budget justifications must be included, and combined into a single PDF (*no page limit, single line spacing, font no smaller than Arial 11, and 1-inch margins*).

9) **Protection of Human and/or Animal Subjects:** Although Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission, IRB/IACUC approval **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 and/or NCCU 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 and/or NCCU IACUC. (PDF, no page limit, single spacing, font no smaller than Arial 11, and 1-inch margins). **Note that no funds will be disbursed until required NCATS prior approval is received (*See Section VIII below*)**
10) **Translation Path:** This funding mechanism employs the Translational Science Benefits Model (TSBM) as a framework for planning, demonstrating, and communicating the impact of translational science. Applicants must choose a total of up to 5 Indicators of the TSBM that are germane to the proposal and specifically address how the proposed work will have an impact on the chosen TSBM Indicators [More details in the Application]. Using the TSBM, the applicant must identify primary impact indicators and clearly delineate the strategy and plan for successful translation and commercialization plan (if applicable); define what translation means in the context of the proposed project; and describe how translational success and impact can be evaluated and measured.
11) **Community Engagement Plan:** The applicant must clearly outline relevant stakeholders; strategies to engage with them; and delineate stakeholder-relevant outcomes (i.e., outcomes relevant to patients, consumers, families, practitioners, administrators, and/or policymakers).
12) **Biosketches:** NIH format, provide for team members at the PI, Co-PI, or any relevant co-investigators level only. (*Combined into a single PDF, no page limit).*
13) **Letter(s) of Support (optional)**: Letters of Support may be included if they outline work that will be done for the project by a consultant (not necessary for co-PIs, co-investigators or CTSI collaborators) or clearly state a commitment of resources required for the project's success. (*Combined into a single PDF, no page limit).*
14) **External Funding Agency Review (if applicable):** If the proposal references a prior review from an external funding agency (e.g., NIH), include the agency reviewer comments (*PDF, no page limit*). If the purpose of the pilot project is to respond to specific reviewer concerns, the relevant section of the review should be indicated by highlighting or other means.

VI. Full Proposal Review Criteria

It is the applicant's responsibility to present the proposal in a clear and logical fashion, to make a convincing case for the significance of the work, and to present the proposed methods in sufficient detail so that an adequate evaluation of the proposal can be made. The following review criteria will be considered during review of the full proposal:

1. Significance of the translational work to advance clinical & translational science methods and processes.
2. Novelty/Innovation of the proposal.
3. Relevance of the proposed study to translational science.
4. Multidisciplinary team in place that is integral to the conduct of the research.
5. Diversity, equity, and inclusion (DEI) relevance of proposed work.
6. Translation path and potential of the project to generate strategic partnerships, follow-on funding, or intellectual property to advance the proposed work.
7. Potential to broadly and equitably disseminate and sustain outcomes related to advancements in clinical and translational science.
8. Soundness of the proposed methods.
9. Feasibility of accomplishing the stated project goals within the project funding period.
10. Level of community engagement (if applicable).

VII. Budget Guidelines

1. The budget period is for 8 months beginning September 1, 2023 through April 30, 2024. No indirect or F&A 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 sufficient effort to accurately reflect their oversight and effort on the project (minimum of 2%).
3. Where the proposed work involves investigators from both Duke and NCCU, separate institution-specific budgets and budget justifications should be included. While an equitable distribution of funds between institutions is encouraged, the proposed work will determine the optimal distribution of effort and funds between team members and institutions, and unequal distribution of funds between institutions is acceptable if adequately justified.
4. **Grant funds may be budgeted for:**
    i. Salary support for the PI or faculty collaborators.
    ii. Research support personnel.
    iii. Student[1] stipend and tuition and fees if not covered by other funding mechanisms.
    iv. Travel necessary to perform the research.
    v. Project-specific research supplies[2] and core lab costs.
    vi. Subcontracts to NCCU are allowed.
    vii. Other purposes deemed necessary for the successful execution of the proposed project.
5. **Grant funds may not be budgeted for:**
    i. General consumables that are typically allocable across multiple projects or for lab-wide use.
    ii. Foreign components, as defined in the NIH Grants Policy Statement.
    iii. Effort for post-doctoral trainees or fellows on training grant equivalents.
    iv. General purpose equipment that are not limited to research, medical, scientific, or other technical activities. Examples include office equipment and furnishings or information technology equipment and systems.
    v. Capital equipment.
    vi. Office supplies including printing and postage or communication costs (excludes project specific

[1] Teams are encouraged to identify areas in the application where students or trainees may be engaged as part of the research team. The amount of tuition expenses allowed is commensurate with the level of student effort on the project.
[2] Supplies that are typically allocable across multiple projects or for lab-wide use are unallowable.

teleconference charges).
vii. Meals or travel, including to conferences, except as required to collect data.
viii. Professional education or training.
ix. Computers, audiovisual equipment, or cell phones.
x. Manuscript preparation and submission.
xi. Indirect costs (F&A or G&A).
xii. Subcontracts to institutions other than NCCU.

6. Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CTSA funds. 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.
7. 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

- We anticipate completing reviews and notifying successful applicants by June 30, 2023. The grant funding period commences 9/1/2023 and is strictly limited to 8 months. It is very important, therefore, that teams be ready to start their work as close to the 9/1/2023 start date as possible.
- Prior to receiving funds, research involving human subjects must have appropriate approvals from Duke or NCCU. Applicants are strongly encouraged to start preparing IRB paperwork as soon as they are invited to submit a full application.
- If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project's start date. Applicants are strongly encouraged to start preparing IACUC paperwork as soon as they are invited to submit a full application.
- 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.
- 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.
- The program is funded through a CTSA grant from the National Center for Advancing Translational Sciences (NCATS). NCATS reviews and approves all CTSI pilot grants using CTSA funding and involving human and animal subjects research prior to funds being released. If a funded application involves human or animal subjects research, CTSI will require additional documentation to send to NCATS. NCATS expects to complete their review within 30 days. Projects determined to be "minimal risk" may commence two weeks after prior-approval documents are submitted to NCATS.

B. Project Execution

- Duke-NCCU CTSA staff will work closely with funded projects throughout the grant period to monitor progress and provide assistance. In the period between notification of application success and commencement of the funding period, Pilot Program staff will work with awardees to assist with

regulatory documentation and to liaise with other areas to ensure that required services will be available to the research team. Pilot Program staff will work closely with investigators, meeting regularly to discuss progress, troubleshoot unforeseen obstacles, and plan future research and funding directions.

- A Duke CTSI Project Leader will be assigned to each funded project. The Duke and NCCU investigators are required to interact regularly with the Project Leader, who will work with the investigators to manage projects, report progress relative to planned milestones, and serve as a resource to identify and fulfill unmet project needs via CTSI and other key resources.
- Quarterly progress reports and a final progress report will be required. CTSI expects the project PI to report over the funding period the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.
- The funding program requires annual reporting on project progress for 7 years post end of the funding cycle.

If an awardee leaves their position, they should contact CTSI **prior** to departure to discuss next steps.

IX. Contact Information

For additional information on this funding opportunity, please contact the Program Officer, Dr. Eman Ghanem at (CTSIfunding@duke.edu).

Appendix I

Application Sections Uploaded as **PDF Files**

Application Section	Page Limit	Format
Research Plan	5 pages	*Single line spacing, font no smaller than Arial 11, and 1-inch margins*
Cited References	NA	*Single line spacing, font no smaller than Arial 11, and 1-inch margins*
Plan for Future Funding	1 page	*Single line spacing, font no smaller than Arial 11, and 1-inch margins*
Timeline	2 pages	*Single line spacing, font no smaller than Arial 11, and 1-inch margins*
Biosketches	NA	NIH format, combine into a single pdf
Health Equity Research Plan and Health Equity Ramifications	1 page	*Single line spacing, font no smaller than Arial 11, and 1-inch margins*
Budget and Budget Justification	NA	PHS 398 Form Pages 4 and 5 and budget justification combined into a single pdf, s*ingle line spacing, font no smaller than Arial 11, and 1-inch margins*
Equity in Research Plan and Health Equity Ramifications	1 page	*Single line spacing, font no smaller than Arial 11, and 1-inch margins*
Protection of Human and/or Animal Subjects		
Publications (optional)	NA	Combine into a single pdf
Letters of Support (optional)	NA	Combine into a single pdf
External Funding Agency Review (if applicable)	NA	NA

Application Sections Completed as Text Entry

Application Section	Word and/or Character Limit
Project Description	2,000 characters, ~ 300 words
Scientific Abstract	1,500 characters, ~250 words
Impact Statement	300 characters, ~50 words
Community Engagement Plan	1,500 characters, ~250 words
Students/Trainees Engagement	3,000 characters, ~500 words