

Duke CTSI Multidisciplinary Vision Program (MVP) Award

REQUEST FOR APPLICATIONS

Mandatory 'Letter of Intent to Submit' Deadline: 11:59 p.m. ET, October 22, 2020

Application Deadline: 11:59 p.m. ET, November 19, 2020

Funding Period: May 1, 2021 – April 30, 2022

The Duke Clinical and Translational Science Institute's (Duke CTSI) mission is to accelerate scientific discoveries to improve health and health equity for patients and communities. Duke CTSI facilitates translational research by providing funding, promoting investigator collaboration, encouraging innovation, providing project management assistance, and providing access to resources/services in a collaborative and service-oriented fashion.

Translational research includes:

- Studies that **address mechanisms contributing to human health and health equity**, regardless of whether the context of the discovery is the laboratory, individuals, or communities.
- Studies that **contribute to improvements in health or health equity by** addressing barriers to clinical care or access to care in community or population settings.
- Research that contributes to **improved health outcomes or health equity through changes in clinical practice or health policy**.

Proposals from teams of investigators from different disciplines are encouraged. Collaborations that bring together ideas, theories, methods and approaches from disparate scientific disciplines are particularly encouraged.

I. Purpose and Background

The Duke CTSI Multidisciplinary Vision Program (MVP) Award provides funding to support novel translational research focused on improving health and healthy equity. We anticipate awarding up to 3 grants, with grants not exceeding \$110,000 per award. Award amounts vary based upon amount requested and budget evaluation by the Program Leadership Committee. Please note that the funding period is from 05/01/2021- 04/30/2022 and that funds must be expended by 04/30/2022.

Duke CTSI supports translational research endeavors under the following domains:

- **Methods/Processes:** Scientific study of, and innovation in, the individual steps of the translational process, and its integration into an efficient system of translation from discovery to community.
- **Collaboration/Engagement:** Research in the structures, rationales, operations, purposes, outcomes, and metrics of engagement with stakeholders at each step of the translational process to elucidate principles and practices that make translation maximally efficient, focused, and relevant.
- **Informatics:** Development, demonstration, and dissemination of informatics and Information Technology (IT) innovations that accelerate both the science and operations of clinical translation.
- **Integration Across the Lifespan:** Development of scientific insights, and operational processes that will ensure that translational advances are realized in all populations, including children, pregnant and lactating women, the elderly, and other special populations, with particular emphasis on life stage transitions.
- **Workforce Development:** Innovations in the substance and culture of translational science workforce development, to create and sustain a robust, supported workforce with the skills, knowledge, and institutional environment necessary for continuous improvement in translational research and science.

II. Specific Objectives and Scope

The Duke CTSI aims to improve health and health equity of individuals and our communities by promoting research that identifies fundamental mechanisms of health and disease for all individuals, and by translating what is learned into effective interventions that are equitably implemented by practitioners, health systems, policy makers, and other stakeholders within our own communities and beyond. This RFA aims to support short-term projects that will establish a foundation for further long-term translational research, for example, new collaborations, resources, processes, or technologies.

Projects funded with these awards should:

- Be clearly generalizable beyond the specific example or use case addressed in the application;
- Have outcomes that are clearly defined and measurable and that support clear decisions (go/no-go) with regards to next steps; and
- Where appropriate, include partners and stakeholders in addition to academic investigators (e.g. industry, patient advocates, community members, citizen scientists).

Examples of projects that would be supported under this program include, but are not limited to:

1. Research focusing on evaluation of how the determinants of health disparities (i.e., environmental, social, biological/genetic, psychosocial, and economic) are associated with disparities in healthcare quality, health systems delivery, and access to care in health disparity populations.
2. Research related to community health improvement: disease prevention; health system improvement; policy; development of novel approaches (vaccine, diagnostics, therapeutics — including drug repurposing); medical device development; and precision medicine.
3. Preclinical and clinical research aimed at novel approaches, including, but not limited to: vaccine development; diagnostics; therapeutics including drug development, drug repurposing, and medical devices; and precision medicine.
4. Projects utilizing high throughput screening of small molecule libraries at NC Central University (NCCU).
5. Research leveraging existing databases and registries at Duke or outside (e.g., MURDOCK, Baseline study, Dyads study, Clinical Research Data Mart, etc.), to target gaps or other priority areas in lifespan health so as to inform health maintenance strategies and disease transition at the individual and population levels across the lifespan (neonates and children, adolescents, individuals vulnerable to disease, older adults) in underrepresented and underserved groups.
6. Implementation science approaches to bridge research to practice for diverse populations to advance health equity: novel and innovative approaches to identifying, understanding, and developing strategies for overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions, tools, policies, and guidelines (e.g. new health system and community-based models of care).
7. Data Science and Informatics tools applied to health systems, community surveillance, and community health.
8. New research models in pandemic environments (e.g. remote clinical trials).
9. Community engaged models of research including bidirectional communication and mutual benefits; transparency and co-creating models to accelerate science; models that span the translational research spectrum; community and patient engagement models to enhance data science, informatics, and surveillance, to engage the community and patients as partners throughout the research process, as leaders/experts and participants; and models which incorporate a clear health equity lens.
10. Collaborative *in silico* drug screening efforts.
11. Innovative utilization of wearable/mobile devices for translational science.

12. Evaluating different methods of engaging communities in research, including recruiting individuals from understudied populations into clinical or translational research studies.
13. The use of telemedicine approaches in research.
14. Adapting technology and methodology shown to be successful in other domains to address challenges in clinical and translational research.
15. Innovative approaches to translational science education and training.
16. Innovative clinical trial designs.
17. Innovative informatics and IT solutions to translational science problems.
18. Innovative approaches to the collection and utilization of direct patient reported outcomes.
19. Novel strategies for working with other health care agencies [e.g. the Health Resources and Services Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS)].
20. If infrastructure building projects are being proposed, proposals must also include what potential research projects will result from the added infrastructure. Proposals must provide strong justification for why the infrastructure is needed and clearly outline the translational impact of and sustainability plans for the proposed infrastructure.

Examples of projects that would not be supported under this RFA include, but are not limited to:

1. Incremental improvement or enhancement of an established approach.
2. Translational research projects focused on a specific disease that does not have broader implications for translational science
3. Clinical trials that are beyond Phase IIb
4. Proposals that do not have a hypothesis driven research focus that addresses a disease or population health issue
5. Proposals that focus *solely* on Infrastructure building for translational research*
6. Any other examples from Leadership of projects we do not want to support?

Teams are encouraged to identify areas in the application where **students or trainees** may be engaged as part of the research team.

* See #20 in Section II above

III. Key Dates

- Letter of 'Intent to Submit' (Mandatory): October 22, 2020
- Application Submission Deadline: November 19, 2020
- Final Selection: January/February, 2021
- Project Planning Run-In Period: February, 2021 through April 30, 2021
- Funding Period: May 1, 2021 through April 30, 2022

IV. Eligibility

- Applicants must have principal investigator status per Duke's [written policy](#).
- Researchers holding an adjunct appointment are **not** eligible to apply.
- Non-Duke faculty may be named as co-investigators if they have a separate aim that will be funded by their local CTSA or other funding sources.
- More than one proposal may be submitted per faculty member acting as PI, but the faculty member is only eligible to receive one award from this funding mechanism per funding cycle.

V. Funding

The Duke CTSI Multidisciplinary Vision Program (MVP) Award will not exceed \$110,000 (direct costs only) per award to support the translation of projects. Award amounts **vary** based upon amount requested and budget evaluation of the Program Leadership Committee. Applicants should propose a budget that appropriately resources the study. The expected project start date will be **May 1, 2021 and ending on April 30, 2022. Funds must be expended by April 30, 2022.** The Duke CTSI Multidisciplinary Vision Program (MVP) Awards are not meant as bridge funding or as supplementary funding for existing projects. **Requests for no-cost extensions (carryovers) will not be approved.**

Note: This award is supported with existing CTSA grant funds and does **not** need to be routed through the Duke Office of Research Administration (ORA) for approval.

VI. Proposal Preparation

A. Mandatory Letter of 'Intent to Submit' (LOI) :

- a. Applicants must submit an LOI with a one-page preliminary proposal. Please submit the LOI via MyResearchProposal (see [Section VIII LOI and Application Procedure](#) below). The LOI must list the specific aims, collaborators, anticipated budget, and translational relevance of the project.
- b. The Duke CTSI Project Office will review the LOI and arrange a consultation meeting, if necessary, with the listed PI and appropriate consultants based on the specific project needs to provide feedback prior to application submission.

VII. Review Process and Evaluation Criteria

LOI and Application Submission: A Review Committee comprised of researchers, clinicians, and experts in translation will perform a detailed review of the applications and select the finalists. Reviewers will consider each of the review criteria below in the determination of overall scientific merit. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field. The Review Committee will consider the following criteria when reviewing and scoring applications:

- Overall Impact: Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the translational research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).
- Significance – The novelty, uniqueness, and impact of the opportunity presented by the proposal; opportunities that provide generalizable solutions to translational research problems are highly encouraged.
- Innovation – Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? If the project succeeds, will the proposed innovation transform some domain of translational science?
- Approach – The overall strategy, methods and analyses used are well-reasoned and suitable to complete value recognition studies and proposed specific aims.
- Feasibility – Project scope of work is appropriate for the timeframe and level of funding.
- Investigator(s) and/or Collaboration – Investigator and/or Collaboration of investigators provide complementary skills and expertise.
- Translation – Translational potential of the opportunity as it pertains to proposed area of research. Is the translational pipeline clearly articulated, and has successful translation been defined for the

proposed project? Have the investigators described how success and impact can be evaluated and measured? Additionally, in assessing translational potential, Reviewers will specifically ascertain if the following points have been addressed or articulated: 1) what is the clinical/population health impact of the proposed work?; 2) what are the translational research findings of the proposed work?; and 3) what is the potential for scalability and sustainability of the findings of the proposed work?

- Environment – Will the scientific environment in which the work will be done contribute to the probability of success?
- Students/Trainees engagement plan if engaged as part of the research team.
- Level of stakeholder engagement

Additional review criteria: As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score:

- Study Timeline: Specific to applications proposing clinical trials- Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards

Project Planning Run-In Period: The project selected for funding will undergo a run-in period of up to 90 days to ensure that all requisite preliminary work, including IRB, animal use, and other institutional and NCATS approvals are obtained before initiating funding.

VIII. LOI and Application Procedure

Duke CTSI uses the MyResearchProposal online application portal to submit LOIs and applications.

- Click [here](#) to access MyResearchProposal and log in or choose “Create New User” to apply. 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 [here](#).
- Enter Access Code ‘CTSI’ then select the “**LOI - Duke CTSI Multidisciplinary Vision Program (MVP) Award**” and follow the funding opportunity instructions. Duke CTSI Multidisciplinary Vision Program (MVP) Award.
- For any questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or call 919-668-4774.

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

- Project Title, Brief Description, and Amount Requested
- Co-Investigators: Name, rank, department, and area of expertise
- General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, ongoing sources of funding, intellectual property, relevant citations)

Proposal sections (except sections **A, B, C, F, G, & H**) will be uploaded as individual PDF files. The application sections are:

- A. **Project Narrative:** Describe the relevance of this research to public health in, at most, three sentences.

- B. **Translational Impact Statement:** Describe how the proposed collaborative project, if successful, will have impact on the field of translational science, or human health, or will result in an intermediate outcome linked to health impact (250 word maximum, equivalent to 1,500 characters including letters, spaces, punctuation, special characters, etc.)
- C. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI (500 word maximum, equivalent to 3,000 characters including letters, spaces, punctuation, special characters, etc.)
- D. **Specific Aims:** 1-page limit, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, with at least 0.5-inch margins.
- E. **Research Plan:** The Research Plan should follow the standard NIH format with the following mandatory sections (5-page limit, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, with at least 0.5-inch margins). Include where applicable clear evidence of how the proposal meets the review criteria.
 - a. Significance & Background
 - b. Innovation
 - c. Approach, Methods, and Analysis (include hypotheses, design, procedures, sample recruitment, methods/measures, potential pitfalls and alternatives, benchmarks for success, facilities/environment plan, and data management and analysis plan)
 - d. Timeline & table of quarterly milestones to be achieved
- F. **Translation Plan:** The applicant must clearly delineate the strategy and plan for successful translation, and define what translation means in the context of the proposed project. Furthermore, applicants should clearly articulate the following for the proposed research: 1) its clinical/population health impact; 2) expected translational research findings; and 3) its scalability and sustainability: applicants must clearly outline how the project is/will be translated – into the clinic/population & the sustainability plan for the translation of the proposed work. Applicants must choose **a total of up to 5** Indicators of the [Translational Science Benefits Model \(TSBM\)](#) 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; also see Appendix A].
- G. **Stakeholder 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)
- H. **Student Engagement Plan:** The applicant must outline the roles and responsibilities of the mentor, mentoring activities, research areas of engagement, etc. if students are part of the research team.
- I. **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. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. This **does not need to be routed through (ORA)**; Duke CTSI will route approved budgets to departments for review and approval.
- J. **Human and/or Animal Subjects:** 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, include the following: (1) description of procedures, (2) justification, (3) minimization of pain and distress, (4) euthanasia. Projects involving animal subjects must be reviewed and approved by the Duke IACUC (no page limit)

- K. **NIH Biosketches** for key members of the research team (as a single PDF) - [click here for details](#).
- L. One copy of a relevant publication (no page limit; Optional)
- M. Letters of Support (optional)

IX. Budget Guidelines

Please note the following during budget preparation:

- A. The budget period is for 12 months beginning May 1, 2021 through April 30, 2022. No F&A, indirect or overhead costs are awarded; the awardees receive direct costs only.
- B. 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 effort on the project.
- C. Grant funds **may** be budgeted for
 - Salary support for the PI or faculty collaborators
 - Research support personnel
 - Use of Duke's core services
 - Student stipend and tuition and fees **if not** covered by other funding mechanisms. **NOTE: 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.**
 - Travel necessary to perform the research
 - Small equipment, research supplies and core lab costs (NOTE: Project specific research supplies are allowable, however supplies that are typically allocable across multiple projects or for lab-wide use are unallowable)
 - Other purposes deemed necessary for the successful execution of the proposed project
- D. Grant funds may not be budgeted for
 - General consumables (NOTE: Project specific general consumable supplies are allowable, however supplies that are typically allocable across multiple projects or for lab-wide use are unallowable.)
 - 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, (excludes project specific teleconference charges), including printing and postage
 - Meals or travel, including to conferences, except as required to collect data
 - Professional education or training
 - Computers or audiovisual equipment (unless essential and dedicated to the research project)
 - Cell phones
 - Manuscript preparation and submission
 - F&A; Indirect costs
- E. Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to government regulations and Duke's 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.

X. Terms of the Award

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 \(GAP\) 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.

A. Approvals Required Prior to Funding Start Date

- Human subjects and animal research must be reviewed in accordance with the university's general assurances and HIPAA.
- Although IRB and IACUC approvals are not required to submit a proposal, prior to release of funds:
 - All research involving human subjects **must** have documentation of appropriate approvals from the Duke IRB and in some instances **may** require NCATS approval prior to release of funds.
 - All research involving human subjects **must** have **current** certification of training in the protection of human subjects for all personnel named on the budget page.
 - All research including live vertebrate animals **must** have documentation of appropriate approvals from the Duke IACUC **and require** approval by the National Center for Advancing Translational Sciences (NCATS).
- The Duke CTSI will request required NCATS documents from investigators and submit a regulatory package to NCATS for review and approval.
- **Please note NCATS approval takes a minimum of 30 days from time of submission.**
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Investigators agree to work in collaboration with Duke CTSI Pilots Operations to monitor progress and when necessary, provide assistance. Quarterly and final progress reports will be required and the team is expected to present the interim findings of the work at six months and final results at 12 months, if requested.
- During the project run-in period Investigators will meet with their assigned Duke CTSI Project Leader (PL) to review project plans and ensure projects are ready to start by May 1, 2021.
- The investigators are required to interact regularly with the assigned PL, 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 the Duke CTSI and other key resources.
- Proposed aims of funded projects may be changed, added or deleted during the funding period, pending Investigator and Duke CTSI Program Leadership Committee review and agreement. The investigator should work with the assigned CTSI project leader as soon as the Investigator is aware a project change needs to be implemented.
- Projects must complete in the prescribed time period; no-cost extensions will not be granted.
- Duke's CTSA grant program includes both federal funding and institutional support. 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, tech transfer office reporting and required NCATS approvals. 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 this 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](#). After your publication is accepted, [click here](#) for a guide to complying with the NIH Public Access Policy.
- Any awardee who leaves his or her position should contact Duke CTSI to discuss future plans for the project.

C. Post-Award Reporting

- The investigators are expected to report annually, for up to 5 years post-award, the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents. Duke CTSI may terminate and reallocate residual funds for any team failing to submit required written reports in a timely manner.
- 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 under the following categories ([Appendix A](#)).
 - CLINICAL & MEDICAL BENEFITS
 - COMMUNITY & PUBLIC HEALTH BENEFITS
 - ECONOMIC BENEFITS
 - POLICY & LEGISLATIVE BENEFITS
- When requested, all awardees will be expected to provide updates of publications and other translational units that originated from the award. Awardees that leave the institution within 5-years post award period will be expected to provide updated contact information for future communications.
- By accepting funding under this program, awardees and applicants are consenting to serve as reviewers for future Duke CTSI funding opportunities.

XI. Contact Information

For additional information on this funding opportunity, please contact the Duke CTSI Program Officer, Dr. Tarun Saxena, PhD at ctsifunding@duke.edu.

Appendix A: Metrics – Post-Award Reporting

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 under the following categories:

CLINICAL & MEDICAL BENEFITS	Examples of specific Translational Units include:
<ul style="list-style-type: none"> • Diagnostic Procedures • Investigative Procedures • Guidelines • Therapeutic Procedures • Biological Factors & Products • Biomedical Technology • Drugs • Equipment & Supplies • Software Technologies 	<ul style="list-style-type: none"> • 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
<p>COMMUNITY & PUBLIC HEALTH BENEFITS</p> <ul style="list-style-type: none"> • Community Health Services • Consumer Software • Health Education Resources • Health Care Accessibility • Health Care Delivery • Health Care Quality • Disease Prevention & Reduction • Life Expectancy & Quality of Life • Public Health Practices 	<ul style="list-style-type: none"> • Improved diagnosis or treatment of disease • Implementation in clinical practice or community • Translation of models to other geographical areas • Translation of models to other therapeutic areas • Clinical outcomes in practice and communities
<p>ECONOMIC BENEFITS</p> <ul style="list-style-type: none"> • License Agreements • Non-Profit or Commercial Entities • Patents • Cost Effectiveness • Cost Savings • Societal & Financial Cost of Illness 	<ul style="list-style-type: none"> • Clinical guideline or guidelines updated • Agreements with partners and strategic collaborators to translate more broadly • Commercialization (e.g. new intellectual property, patent applications, license, commercial partnerships, start-up company) • Direct-to-consumer interactions (e.g. apps)
<p>POLICY & LEGISLATIVE BENEFITS</p> <ul style="list-style-type: none"> • Committee Participation • Expert Testimony • Scientific Research Reports • Legislation • Policies • Standards 	