

Linking Clinical Trials to Drug Discovery and Repurposing Award

REQUEST FOR APPLICATIONS

Issue Date: June 6, 2023

Application Due Date: September 8, 2023

Introduction

The Clinical and Translational Science Center (CTSC) of the University of New Mexico (UNM) Health Sciences Center (HSC) is soliciting applications from all HSC faculty members—senior as well as junior investigators—for pilot projects that will exemplify the CTSC mission of developing clinical and translational science, to promote and support the “bench to bedside to community and practice and back” goal of the National Institutes of Health. To support this initiative, we will award several grants ranging from **\$10,000-\$40,000** to be spent between December 1, 2023, through November 30, 2024. Of note, this is an increase in the \$ amount of award that has been supported historically. And allowable costs now include the potential for allocation of 5% FTE for clinical faculty salary with departmental match.

The purpose of this RFA is to support pilot projects that utilize the CTSC infrastructure to **produce preliminary data for competitive NIH grant proposals** in clinical and translational research as well as translational science. Translational Science goals must be of high methodological quality and must demonstrate feasible and generalizable solutions to translational science problems. All awards are dependent upon the availability of CTSA funds.

As part of our CTSC award, the NIH has identified the need to speed the movement of clinical science findings into the everyday practice of health care delivery. An additional goal is to promote the integration of special and underserved populations in translational science across the human lifespan.

Transitioning to a New Framework for All CTSC Pilot Awards

Incredible advances in basic science and technology have dramatically increased our understanding of human diseases. However, the National Center for Advancing Translational Sciences (NCATS), which oversees the Clinical and Translational Science Award program, has long recognized the slow translation of this explosion of knowledge into new diagnostic and treatment paradigms that benefit people¹. To address the barriers, future centers funded by NCATS (CTSA awards) will REQUIRE a shift in focus from Translational Research to Translational Science (defined below). With this pilot funding cycle, the UNM CTSC begins transitioning our focus toward funding Translational Science projects.

Importantly, the pilot RFAs offered with this cycle will still review and accept projects that follow the previous guidelines. That means Translational Research Projects are still acceptable. At the same time, we are encouraging applicants to think about Translational Science goals. This is a significant change. We encourage you to move in this direction by adding translational science aim(s) to your proposal. The review committee will give

extra weight to translational science goals and approaches, as it reviews the overall application for the upcoming cycle (Sept 8, 2023).

After this upcoming cycle, the next cycle of pilot awards in 2024 will REQUIRE a focus on Translational Science, as defined by NCATS. Pilot projects with the sole emphasis on Translational Research will not be funded.

This RFA contains references and links (below) to resources to help investigators understand how to adapt to this new framework and we will be providing educational opportunities, consultation, and support to help you make the transition.

Shifting Focus to Translational Science

To begin the process of alignment with NCATS future requirements, the UNM pilot program encourages Translational Research pilot applications with or without a Translational Science component for the September 8, 2023, submission deadline. NCATS defines Translational Science as *“the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.”* *The goal of Translational Science is to develop generalizable principles to accelerate translational research”* thereby turning “science into health.”

Projects are intended to: (1) explore innovative new leads or new directions; (2) stimulate team approaches that incorporate less traditional researchers and (3) provide initial support to establish proof of concept. Projects must be feasible within the proposed timeframe, have high methodological and scientific quality, and answer important scientific questions.

Projects with a Translational Science focus are encouraged and will be scored favorably during the internal review process for the next cycle (September 8, 2023, submissions).

NCATS Definitions:

- **Translation:** The process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.
- **Translational Research:** The endeavor to traverse a particular step of the translational process for a particular target or disease.
- **Translational Science:** The field of investigation focused on advancing the scientific and operational principles underlying each step of the translational process.
- **Learn more about Translational Science:**
<https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.13055>
<https://ncats.nih.gov/training-education/translational-science-principles>
[A New Resource from NCATS: The NCATS Translational Science Principles | clic \(clic-ctsa.org\)](#)
- NIH Definition of [Clinical Research](#): Research with human subjects that is:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. It includes:

- (a) mechanisms of human disease
- (b) therapeutic interventions
- (c) clinical trials
- (d) development of new technologies

Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.

2) Epidemiological and behavioral studies

3) Outcomes research and health services research

- NIH Definition of [Clinical Trial](#): A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- NIH Definition of [Human Subjects Research](#): According to 45 CFR 46 Link to Non-U.S. Government Site - Click for Disclaimer, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- NIH Definition of [special populations](#): Groups who have traditionally been underrepresented in health research or excluded altogether For example, pediatric populations, older adults, people with disabilities and/or rare disorders, underrepresented racial/ethnic and/or sexual and gender minorities, rural populations or populations with low socio-economic status.

NCATS wants development of methods, resources, scaffolds, procedures that will facilitate translational science. Thus, potential topics in **Translational Science** include¹:

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| • Understanding of translation and translational science | Single/harmonized IRBs |
| • Target qualification* | Clinical trial operational efficiency |
| | Clinical trial networks |

¹ Austin, CP, **Opportunities and challenges in translational science**, Clin Transl Sci. 2021;14:1629–1647

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| <ul style="list-style-type: none"> • De-risking undruggable Targets/untreatable diseases* • Predictive efficacy • Predictive toxicology • New therapeutic modalities; repurposing* • Biomarker qualification • Data interoperability and transparency* • Registries and natural history studies* • Clinical diagnostic and outcome criteria • Patient/community engagement • Clinical trial participant recruitment and Diversity* | <ul style="list-style-type: none"> Adaptive clinical trial designs Electronic Health Records for research Shortening time of intervention adoption* Access and adherence Pharmacoepidemiologic studies and comparative effectiveness trials* Integration of project management Incentives/credit for team science Incentives/credit for health improvements Education/Training (scientific and cultural) Collaborative structures, agreements, IP management |
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Major rate-limiting translational problems that are the focus of Translational Science. *Identified in the Drug Development Map (18, Supplemental Figure SB) as being particularly prone to failure, delay in progression, and/or high cost and therefore high priority for innovation. IP, intellectual property; IRB, institutional review board

Application Deadline, Notice of Awards and Funding Cycle

Application Release Date: June 6, 2023

IRB Submission Deadline: July 24, 2023

Application Deadline: September 8, 2023, 5:00 pm

IRB Approval Deadline for NIH Review: September 18, 2023

Notice of Intent to Fund/Decline: October 9, 2023

Earliest Notice of Award: November 15, 2023

Funding Cycle: December 1, 2023, through November 30, 2024

Eligibility and Project Requirements

- Principal Investigators for these pilot awards *must* have a primary appointment as UNM HSC faculty (junior or senior investigators). Any other investigator who cannot submit the grants emanating from this pilot award through the UNM HSC is not eligible to receive this award.
- All investigators selected to receive funding and their team members are encouraged to complete the CTSC GCP Training Course within 6 months of receiving award.
- All investigators selected to receive funding will be expected to submit progress reports on go/no-go milestones monthly to ensure continued funding.
- All investigators selected to receive funding will be expected to submit a Final Progress Report at the end of the funded project and an additional report one year later, detailing progress to date, expenditures, and all submitted publications and grant applications (pending or funded) relating to the pilot project.
- Should investigators receive NIH funding during the Pilot period of performance, the investigator must ensure there is no budgetary overlap.
- Funds may not be used to provide interim support for active projects or to extend previously conducted work.

Please note: All funds not spent by the end date of the Pilot Project Award (November 30, 2024) will be returned to the CTSC and NIH. No extensions will be granted. Applicants are eligible for no more than a total of two CTSC pilot awards, after which they need to demonstrate that they have received a score for an extramural grant submission before they will be considered for another CTSC pilot award.

Presentations and Publications

- CTSC or using CTSC resources should cite the CTSC as a contributing source of support and indicate the CTSC's citation as follows: "This project was supported by the National Center for Advancing Translational Sciences for the National Institutes of Health through Grant Number UL1TR001449, The University of New Mexico Clinical and Translational Science Center."
- Investigators are responsible for linking any journal articles resulting from research funded by this award to the grant in MyNCBI (UL1TR001449, Nancy Pandhi/Matthew Campen), and for submitting the publication for a PMID number to comply with NIH's Open Access policy (different than an automatically assigned PMID) <https://publicaccess.nih.gov/>

Evaluation Criteria

Successful projects will exemplify the CTSC mission of developing clinical and translational science. Applications should be well written, precise, and succinct. Applications will be subject to both scientific and programmatic review and will receive scientific review by the CTSC Review Committee. The following criteria will be used in evaluating these proposals:

1. Overall Impact
2. Significance
3. Innovation
4. Approach (should include evaluation of approaches to *articulated research barriers*, and demonstration of feasible and *generalizable translational science solutions, team science and interdisciplinary collaboration*).
5. Investigator (including an evaluation of the status of prior pilot funding awards and the outcomes from those studies)
6. Environment
7. Probability that this project will lead to extramural funding
8. Utilization of CTSC resources

Additional review considerations will include:

9. Alignment with CTSC programmatic goals
10. Integration of special populations
11. "Go/No Go" Milestones (suggested by the investigator)
12. Budgetary Considerations
13. Regulatory Approvals
14. Letters of Support and Commitment

Scoring: To emphasize the importance of extramural grant submission and attainment deriving from these pilot awards, each of the first 8 items above will be scored on a 1-9

scale (where 1 is best), and composite scores will then be weighted so that the final overall impact score is determined as follows:

- Innovation: 10%
- Significance: 10%
- Approach, Environment, and Investigator: 30%
- Plan for and probability of extramural funding: 30%
- Utilization of CTSC Resources: 20%.

Budget and Core Usage Guidelines

Utilization of Core services is strongly encouraged and will be a review consideration. It is important that you schedule a meeting with the CTSC Research Concierge at HSC-CTSCResearchConcierge@salud.unm.edu and Center for Molecular Discovery Core Director Tione Buranda (TBuranda@salud.unm.edu). This consultation step is required for planning purposes and to ensure effective use of CTSC Core services utilization for your research proposal. To initiate the budget and core utilization process, fill out the DR3N consultation form [at this link](#) prior to the submission of the pilot project.

Responsible budgeting is critical for the 12-month project and it is common to overestimate what you can accomplish in that limited time frame. Your proposed budget will be reviewed and potentially revised based on Peer Review and Core management feedback. If successfully funded, reallocation of the budget is strongly discouraged. However, consideration will be made for reallocation of funds within CTSC Cores if justified. Prior approval is necessary.

CTSC resources included in the budget will be covered using a non-refundable voucher program. These funds may not be reallocated to other expenses after the grant has been awarded. ***Rationale for not using CTSC Core services needs to be specifically justified.*** Details of services offered by each Core can be found at each of the following links:

- **Participant Clinical Interactions (PCI)**: Offers clinical research support staff, recruitment assistance, clinic space, bionutrition, as well as consultation on protocol development and implementation.
- **Biomedical Informatics**: Offers clinical data warehouse mining, “honest broker” services for access to data from multiple sources, and web-based electronic data capture and survey tools via REDCap.
- **Biostatistics**: The CTSC Biostatistics, Epidemiology and Research Design Support (BERD) Core is designed to provide HSC investigators with expert early consultation and service on all aspects of study design, biostatistics, and basic data management for effective clinical and translational studies. The Core provides easily accessible consultation and services, user-friendly courses for researchers at all levels, and novel tools and methods intended to solve problems and address barriers to the conduct of clinical and translational science. Please note that this service does NOT include data collection, data entry, and similar services that are the responsibility of your team.
- **Community Engagement and Research (CERC)**: provides grant application development, community engagement and outreach, study coordination and

project implementation, qualitative interviewing and focus group facilitation, data management, and qualitative analysis for investigators

- **Translational Technologies**
 - **Translational Technologies Laboratory**: Offers state-of-the-art equipment, technical assistance, consultation on protocol and assay development for any CTSC partner institution.
 - **Clinical Laboratory**: Develop and carry out research related sample analysis for bulk standard immunodiagnostic and chemical assays, as well as sample processing for any CTSC partner institution.
 - **Center for Molecular Discovery**: Expertise with multiplexed, high throughput flow cytometry for drug discovery.
 - **Human Imaging (Mind Research Network)**: Focus on human imaging providing MRI, MEG, and EEG services.
 - **UNM Human Imaging Core**: Focus on human imaging and providing MRI services.
 - **Preclinical Imaging Core (Brain and Behavioral Health Institute)**: The Preclinical Imaging Core at Domenici Hall houses a 7T MRI scanner (Bruker BioSpec 70/30USR) and a PET insert for preclinical and molecular in vivo and ex vivo imaging. The scanner is equipped with state-of-the-art multi-channel RF coils, allowing high-resolution in vivo or ex vivo imaging for application in life science, biomedical and preclinical research.
 - **KUSAIR (Keck-UNM Small Animal Imaging Facility)**: Provides high quality and customer specific functional imaging services on small animal research.

Costs *not* covered under these awards:

- faculty salaries unless clinical FTE buyout
 - clinical faculty may request up to 5% FTE with agreement and matching from the Chair of their Department. A letter of confirmation from the Chair is required.
- postdoctoral salaries
- non-HSC staff salaries
- graduate student support (stipends, tuition, etc.)
- administrative or office supply costs (office supplies, paper, ink, telephone, etc.)
- equipment >\$5,000 (items <\$5,000 are at the discretion of the committee and can be removed from the budget)
- computers, laptops, tablets
- monetary incentives to clinics or providers (e.g. recruitment bonus)
- other items typically supported by indirect costs (publication costs, printing/duplication costs)

IRB Guidelines

CTSA is required to obtain prior approval of all pilot projects from NIH prior to funding. Because of this, all pilot submissions will be required to submit one of the below IRB letters with their submission. Applications without IRB submission prior to July 24, 2023 will be administratively disqualified. This provides HRPO with efficient time to review all

submissions prior to the application deadline. Projects that do not have IRB determination by September 8, 2023 will not be considered for funding. IRB Letter with Determination of Non-Human Subjects Research

- IRB Letter with Approval of Exemption #1-9 Human Subjects Research
- IRB Letter with Approval of No More Than Minimal Risk Human Subjects Research
- IRB Letter with Approval of Greater than Minimal Risk Human Subjects Research

The following applies to each project.

- Each pilot submission must have its own standalone IRB protocol.
- Amendments or a sub-study/ancillary study to an existing IRB-approved parent protocol are not allowed.
- Pilot application title must match IRB protocol title and be reflected on the approval letter.
- Principal Investigator of the pilot application must match the Principal Investigator on the IRB protocol and be reflected on the approval letter.
- IRB modifications to the approved pilot protocol are not permitted after NIH approval. Every effort should be made to execute the protocol as approved by the IRB, Pilot Review Committee, and NIH.

Clinical Trial:

All studies meeting the NIH definition of a [Clinical Trial](#) must be registered on ClinicalTrials.gov and have an NCT number assigned to the study. Investigators should make sure the consent has the required language for Clinical Trial registration as it appears in the HRPO consent template. Investigators should register their protocol on CT.gov after receiving IRB approval. Registration is an NIH requirement prior to enrollment of the first participant.

How to Apply

Pilot Project Award submissions must be done electronically via the CTSC's Camino application. You must have an active HSC Net ID and Password (@salud). If you are accessing the application off HSC campus, you must obtain VPN access prior to logging into Camino. The Camino application works best with Google Chrome or Firefox. All instructions on how to apply for funding and the required templates to use are located on the [CTSC's Funding Website](#).

All applications are due **by 5:00 pm on the due date**, which can be found at the top of this RFA. Applications that are late or do not adhere to the above instructions may be administratively denied and not reviewed for funding. Please call or email Liz Torrez (METorrez@salud.unm.edu; 505-272-7588) with any questions about this RFA or the application process.