Translational Science and Clinical Pilot Project Award
Request for Applications

Required Pilot Pre-Proposal Due: January 8, 2024
Invited Full Application Due: March 1, 2024

Introduction

The Clinical and Translational Science Center (CTSC) at the University of New Mexico (UNM) Health Sciences Center (HSC) seeks to develop and implement innovative solutions that will improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities.

CTSC is soliciting **Pilot Pre-Proposals** from all HSC faculty members interested in applying for pilot funding. Submission of full proposals will be by invitation only after review of pre-proposals. By January 19, 2024, those who make it to the next round will be invited to submit a full research proposal. Instructions on how to prepare a full research proposal (elements listed below) will be provided by email with the invitation to participate. Full proposals will be due by noon on **March 1, 2024.** Pilot Pre-Proposals are limited to 2 pages and should include the following.

- The pre-proposal should include a title, a description of objectives/aims, the most innovative and novel aspects of your proposed research, a description of how the project can be completed in 12 months, and must directly address how the project meets the definition of Translational Science.
- A brief budget overview. Investigators should meet with CTSC Research Concierge at HSC-CTSCResearchConcierge@salud.unm.edu to develop a budget for CTSC services.

Additional documents (not included in the 2-page limit):

- Bio sketch for the PI, and a letter of support from your Department Chair/Dean noting your qualifications, availability of protected time, and the potential impact of your work.

It is anticipated that approximately 4 full pilot applications will be selected for funding in the current cycle.

Pilot applications for this announcement will exemplify the CTSC's 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 grants ranging from **$10,000-$40,000** to be spent between June 1, 2024, through May 31, 2025. Allowable costs include the potential for 5% FTE allocation 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 science. Translational Science goals must be highly methodological and 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

With this pilot funding cycle, the UNM CTSC transitions our focus to funding Translational Science projects. 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 people[1]. To address the barriers, future centers funded by NCATS (CTSA awards) require a shift in focus from Translational Research to Translational Science (defined below). **As such**, **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 offer educational opportunities, consultation, and support to help you make the transition.

Translational Science

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.

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)
- UNM HSC CTSC Translational Science Panel Video

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*** include[1]:

- Understanding of translation and translational science
- Target qualification*
- 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*

Single/harmonized IRBs
Clinical trial operational efficiency
Clinical trial networks
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

Major rate-limiting translational problems 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: November 13, 2023
Pilot Pre-proposal to CTSC: January 8, 2024
CTSC invitation to submit full application: January 19, 2024
Full Application Deadline: March 1, 2024, by 12 noon
IRB Submission Deadline: March 1, 2024
Notice of Intent to Fund/Decline: April 5, 2024
IRB Approval Deadline for NIH Review: April 15, 2024
Notice of Award: May 17, 2024
Funding Cycle: June 1, 2024, through May 31, 2025

Eligibility and Project Requirements

- **Investigators must submit a Pilot Pre-proposal. Only invited investigators**

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

are allowed to submit final proposals for pilot funding. Email the Pilot Pre-proposal to Christy Anderson, CHAnderson@salud.unm.edu

- 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 the 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 with human subjects selected to receive funding will be expected to submit a monthly recruitment/enrollment report.
- 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* (May 31, 2025) *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

- Awardees are expected to publish their findings in scholarly peer-reviewed journals and present their research at professional meetings.
- All publications, grants, and presentations resulting from research funded by the 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 PMCID 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, demonstration of feasible and generalizable translational science solutions, team science and interdisciplinary collaboration, feasibility of recruitment if human subjects).*
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
15. Aim(s) with strong Translational Science objectives.

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%

Guidance for Studies Enrolling Human Participants

If your project requires recruitment of human participants, please include the following information as part of the Approach section of the application. The review committee will be specifically looking for these details.

- What is the available population for recruitment?

- Is your target enrollment number feasible in the one-year time limit of the pilot award? Is that number based on a power analysis?
- Who will do the recruiting (investigator/PI, coordinator, other team member(s), PCI or CERC)?
- If you plan to use the PCI or CERC, have staff from those services reviewed the project?
- Do you have sufficient protected time for this study separate from other duties?
- Do you have prior experience from other studies recruiting this population?
- When will you enroll your first participant and what percentage of your population is likely to meet the inclusion/exclusion criteria?

Note: The SAGE committee will review every pilot with human participants ***at 2-month intervals*** to assess enrollment progress. Concerns will be directly communicated to PI's by phone and email. Corrective actions may be suggested or taken including, assistance and training. Warnings may be issued that pilot funding may be pulled and the study discontinued, unless the PI provides a good rationale that lagging enrollment will catch up with projections.

Budget Guidelines

Utilization of CTSC 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. This consultation step is required for planning purposes and to ensure effective use of CTSC Core services utilization for your research proposal.

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 the 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. 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 community engagement and outreach, study coordination and project implementation, qualitative interviewing, focus group facilitation Community Engagement Studios, 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 by March 1, 2024, will be administratively disqualified. This deadline provides HRPO with efficient time to review all submissions prior to submission to NIH. Projects will need IRB approval by April 15, 2024.

- 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.

All projects involving human subjects are strongly encouraged to meet with the CTSA's Regulatory Affairs Specialist, Samiha Mateen (SMateen@salud.unm.edu) for consultation and planning purposes.

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. To have an account created, contact the UNM CT.gov administrator, Samiha Mateen (SMateen@salud.unm.edu).

How to Apply

Investigators interested in applying to this RFA **must first submit Pilot Pre-Proposal**. The Sage Committee will review Pilot Pre-Proposal for project feasibility and

responsiveness to Translational Science. Following the review CTSC will invite investigators to submit a full proposal for funding.

Once invited to apply, Pilot Project Award applications are submitted 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 12:00 noon 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 email Christy Anderson, CHAnderson@salud.unm.edu, with any questions about this RFA or the application process.