

Innovation & Commercialization Award

REQUEST FOR APPLICATIONS

Issue Date: May 2, 2022

Application Due Date: September 16, 2022

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 the development of new technology and its commercialization. These technologies should help fulfill the CTSC mission of developing novel approaches to translational research and to promote and support the bench-to-bedside-to-community goal of the NIH.

The purpose of this RFA is to support innovative, high-risk/high-reward pilot projects to develop biomedical technology and move it towards successful commercialization. These projects are intended to provide the preliminary data, models or prototypes, and/or initial corporate relationships that are typically needed to pursue competitive NIH funding (e.g., through an SBIR/STTR mechanism) or other viable pathway to commercial development. To support this initiative, we will award several grants ranging from \$5,000-\$25,000 to be spent between December 1, 2022 through November 30, 2023.

One avenue for appropriate submissions is the UNM CTSC Biodesign Initiative, which brings together biomedical researchers, clinicians, engineers, and other specialists to develop commercially viable medical devices that will positively impact the lives of people living with diseases and health conditions. During facilitated brainstorming sessions, participants devise solutions to existing problems and barriers in current clinical practice. Successful teams are encouraged to submit a proposal for a CTSC Innovation & Commercialization award, which provides access and financial support to use CTSC's translational technologies and clinical facilities. Biodesign Initiative projects are not required to involve human participants at an early stage. The Biodesign Initiative program and its pilot funding is supplied through a separate mechanism than this call. To propose and discuss participation in the Biodesign program area contact: Dr. Eric Prossnitz (EProssnitz@salud.unm.edu).

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. Translational Science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. NIH is committed to increasing awareness and understanding of translational science through the development, demonstration, and dissemination of educational and training resources to stakeholder communities. The [translational science spectrum](#) represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. Stages include Basic Research, Pre-Clinical Research, Clinical Research, Clinical Implementation and Public Health.

The spectrum is not linear or unidirectional; each stage builds upon and informs the others. At all stages of the spectrum, NIH develops new approaches, demonstrates their usefulness and disseminates the findings. Patient involvement is a critical feature of all stages in translation. **Basic research performed on human samples linked to identifiers and/or outcomes counts as translational research. Purely non-human animal research does not qualify for as translational research for funding under this program.**

Certain commercialization projects do not necessarily involve human participants at the earliest stages. Investigators with questions about the appropriateness of a proposed project for this award are encouraged to discuss any concerns or questions with Dr. Corey Ford (CFord@salud.unm.edu) early in the planning stages.

Definitions

- 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.

Application Deadline, Notice of Awards and Funding Cycle

Application Release Date: May 2, 2022

IRB Submission Deadline: July 22, 2022

Application Deadline: September 16, 2022 5:00 pm

IRB Approval Deadline for NIH Review: September 16, 2022

Notice of Intent to Fund/Decline: October 10, 2022

Earliest Notice of Award: November 11, 2022

Funding Cycle: December 1, 2022 through November 30, 2023

Eligibility and Project Requirements

- Principal Investigators for these pilot awards *must* have a primary appointment as UNM HSC faculty. Any non-HSC investigator is not eligible to be Principal Investigator for this award. Projects with co-Principal Investigators, at least one of whom is a member of the UNM HSC faculty, may be eligible for consideration.
- **New requirement: CTSC GCP training certificate to be included in pilot application.** CTSC adheres to the NIH requirement that all investigators and research personnel complete the required Good Clinical Practice (GCP) training when conducting NIH-funded projects and/or NIH-related projects (NOT-OD-148; <https://grants.nih.gov/grants/guide/notice-files/not-od-16-148.html>). The CTSC GCP training course is recognized by the TransCelerate GCP Mutual Recognition Program, which certifies that this course meets the ICH E6 R2 minimum requirements. Please contact Regis Lacher (RLacher@salud.unm.edu) or [visit the CTSC website](#) to register for this training. It is recommended that the investigators and research team plan ahead for this training and visit the [website for the training schedule](#).
- 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.
- Eligible projects will cover a wide range of novel devices or drugs, strategies for commercialization of translational technologies, novel approaches to clinical investigations, and development of novel methodologies for translation of science to communities. However, in all cases we are looking for products that will ultimately be commercializable and lead to better health care.
- Collaborative proposals should consider corporate partnerships that have demonstrated working success, due to the short timeframe of these proposals.
- 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, all submitted publications, and any grant applications or sponsored research agreements (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, 2023) 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 Research Resources and 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 submitting any peer-reviewed journal articles resulting from research funded by this award to PubMed Central, the NIH digital archive of biomedical and life sciences journal literature. This will generate not only a PubMed number but a PMCID number, as well. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-160.html>.

Evaluation Criteria

Successful projects will exemplify the CTSC mission of developing clinical and translational research. 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, alternative approaches, demonstration of feasible and generalizable translational research solutions, team science, and interdisciplinary collaboration*).
5. Investigator (*including team composition and an evaluation of the status and outcomes of prior projects by key personnel*)
6. Environment
7. Probability that this project will lead to extramural funding, licensing, and/or commercialization.

8. Utilization of CTSC resources or initial proposal development through CTSC Biodesign program.

Additional review considerations will include:

9. Alignment with CTSC programmatic goals
10. Integration of special populations (if applicable)
11. “Go/No Go” Milestones (suggested by the investigator and/or established by the review committee)
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: 15%
- Significance: 15%
- Approach, Environment, and Investigator: 30%
- Plan for and likelihood of extramural funding, licensing, or other path to commercialization: 30%
- Utilization of CTSC Resources or initial proposal development through CTSC Biodesign program: 10%.

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 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 research. 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
- postdoctoral salaries
- non-HSC staff salaries
- graduate student support (stipends, tuition, etc.)
- administrative or office supply costs (office supplies, paper, ink, telephone, etc.)
- meals or hospitality (i.e., no food, beverages, or alcohol)
- travel (per diem, hotel, rental car, mileage, flights, 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 22, 2022 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 16, 2022 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.

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

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; 505-272-0195) with any questions about this RFA or the application process.