Innovation & Commercialization Award

REQUEST FOR APPLICATIONS
Issue Date: June 5, 2020
Application Due Date: September 25, 2020

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, 2020 through November 30, 2021.

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. Mark Burge (MBurge@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: June 5, 2020
IRB Submission Deadline: July 31, 2020
Application Deadline: September 25, 2020 5:00 pm
IRB Approval Deadline for NIH Review: September 25, 2020
Notice of Intent to Fund/Decline: October 19, 2020
Earliest Notice of Award: November 20, 2020
Funding Cycle: December 1, 2020 through November 30, 2021

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
- All investigators selected to receive funding will be expected to complete the CTSC Good Clinical Practice 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.

Please note: *All funds not spent by the end date of the Pilot Project Award* (November 30, 2021) *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. Meeting with the CTSC Research Concierge, (HSC-CTSCResearchConcierge@salud.unm.edu), for consultation and planning purposes in the effective use of CTSC Core services utilization for your research proposal is required.

Responsible budgeting is critical for the 12 month project. Your proposed budget will be reviewed and potentially revised based on Peer Review 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 (formerly Clinical Research Unit [CRU]): 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: Offers HSC researchers ready access to appropriate expertise in study design, biostatistics, and basic data management through individual consultations with biostatistics faculty.
- 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.
- Animal Imaging (Brain and Behavioral Health Institute): Specialize in neuroimaging of animal models with various neurological and psychiatric disorders.
- 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

Non-Human Subjects/Exempt Human Subjects Research:

CTSA is required to obtain prior approval of all pilot projects from NIH prior to funding. All pilot submissions will be required to submit proof of IRB Approval with exemption determination or IRB determination of non-human subjects research at time of Pilot Application Deadline. Amendments or a sub-study/ancillary study to an existing IRB-approved parent protocol are not allowed. Each pilot must have its own standalone IRB. Please note CTSA pilot application title must match IRB protocol title and the Principal Investigator of the pilot application must match the Principal Investigator on the IRB letter. Applications must have IRB determination no later than September 25, 2020. Projects that do not have IRB determination by this date will not be considered for funding.

Human Subjects Research – Minimal or Greater than Minimal Risk:

CTSA is required to obtain prior approval of all pilot projects from NIH prior to funding. All pilot submissions involving human subjects must have IRB Protocol approved at the time of submission. All projects involving human subjects are strongly encouraged to meet with the CTSA's Regulatory Affairs Specialist, Rebecca Brito (RBrito@salud.unm.edu; 505-272-9542) for consultation and planning purposes.

Amendments or a sub-study/ancillary study to an existing IRB-approved parent protocol are not allowed. Each pilot must have its own standalone IRB. Please note CTSA pilot application title must match IRB protocol title and the Principal Investigator of the pilot application must match the Principal Investigator on the IRB letter. Applications without IRB submission prior to July 31, 2020 will be administratively disqualified. Applications must have IRB approval no later than September 25, 2020. Projects that do not have IRB approval by this date will not be considered for funding. ***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 required prior to enrollment of the first participant. To have an account created, contact the UNM CT.gov administrator, Rebecca Brito (RBrito@salud.unm.edu).

How to Apply

1. Log on to the CTSC Funding Opportunities website, the application works best in Google Chrome or Firefox, Accessible from this webpage: http://hsc.unm.edu/research/ctsc/pilot-funding/current-opportunities/index.html
2. If you are accessing the application off campus, you must have VPN access (Cisco AnyConnect)
3. Click on the “Apply for Pilot Funding” Link
4. Log In with your HSC Net Id and Password (same as your HSC workstation)
5. Once you are logged in, click on the Start New Pilot Application Button
6. Complete all application sections – a. through f.
7. Upload the required documents where advised – listed in the “What to Upload” section below
   - **a. General Information**
     - i. Title of Pilot Project
     - ii. RFA
     - iii. Animal Research Determination
     - iv. Human Subjects Research Determination
     - v. Clinical Trial Determination
     - vi. Upload all Human Subjects Research Files
     - vii. Enter Planned Enrollment
   - **b. Key Personnel/Biosketches**
     - i. Add Key Personnel
     - ii. Upload Biosketch documents – Use the downloadable template provided on the webpage

c. **Requested Services**
   i. Select CTSC Services – Sort Services by selecting the specific department or by searching in the search box provided. Select services by dragging and dropping the service below the teal box – you will then be able to edit the Quantity of each selected item.
d. **Budget Summary**
   i. Review selected CTSC services
   ii. Add Non CTSC Services
   iii. Add Non-CTSC Personnel Salaries
   iv. Add Shared Facility Services
   v. Provide Budget Justification
e. **Additional Information**
   i. Upload Summary
   ii. Upload Research Plan – 5 page limit (use the downloadable template at the top of the pilot application web page)
      1. specific aims
      2. background and significance
      3. preliminary studies
      4. research design and methods
      5. bibliography and references cited (not included in the 5 page limit)
   iii. Upload Letters of Support(Suggested/Optional)
   iv. Describe Plan to Obtain Extramural Funding
   v. Describe how project meets the definition of Translational Research
   vi. Describe how this project engages underrepresented of excluded groups
   vii. Explain how proposal may be Generalizable
f. **Go/No Go Milestones**
   i. Two standard milestones are tracked, Funds Spent and Patient Enrollment. Please add two to three more Go/No Go milestones that can be used to track progress over the pilot award year. The CTSC Sage team will review milestones monthly for progress. Milestones should be quantifiable and realistic. Failure to reach stated milestones may result in reduction of award.

What to Upload

Emphasis on concise communication of the relevant information will help to demonstrate effective proposal writing and communication skills, and the likelihood of success in developing the full, competitive proposals to follow these pilots. Uploaded documents must adhere to the following formatting specifications:

- 11-point Arial font
- Single-spaced
- ¾” margins on all sides
- 8 ½” x 11” (i.e., standard size) paper
- Number all pages
- Headers identifying the Principal Investigator
- Footers identifying the document and page number (IRB-approval, consent, Biosketch, etc.)

Attach the following documents as individual PDF files using the following naming convention: **UNM_PILastNameFirstInitial_ProtocolShortTitle_Document_YYYYMMDD.pdf** (e.g. UNM_AndersonC_PediatricAsthma_Biosketch_20170821.pdf) Templates for some of these forms can be found within the CTSC Camino Pilot Application once a new pilot project has been initiated.

The following document is required for All Pilot Project Submissions:

1. **Human Subjects Research Study Document** – download inside application database

The following documents are required, along with the one above, if the pilot is Minimal Risk Human Subjects Research or has an Exemption determination:

2. **Summary -** Provide a brief (< 500 words) summary of the specific aspects of the proposed study that will be supported and include a line item budget for each aspect (list supplies, services, and personnel costs)
3. **Research Plan -** Research Plan – 5 page limit
    1. specific aims
    2. background and significance
    3. preliminary studies
    4. research design and methods
    5. bibliography and references cited (not included in the 5 page limit)
4. **Letters of Support**
5. **IRB Approval Letter -** If Human Subjects research
6. **IRB Exemption Determination** – if exempt from federal regulations
7. **Biosketch** – For the investigator, co-investigators and key personnel
8. **Human Subjects Training** - Certification that the PI, Co-I and key Personnel have education in protection of human subjects
9. **Protocol** - IRB approved pilot protocol
10. **Consent, Assent, Parental Permission, Waiver of Consent** – IRB approved consent documents
11. **Inclusion of Individuals Across the Lifespan -** Individuals of all ages are expected to be included in clinical research unless there are scientific or ethical reasons not to include them.
12. **Inclusion of Women and Minorities -** Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design.
13. **Recruitment and Retention Plan -** Describe both planned recruitment activities as well as proposed engagement strategies for retention.
14. **Study Timeline -** Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates
15. **Protection of Human Subjects –** Use Template in Application

The following documents are required, along with 1-15 above, if the pilot is Greater than Minimal Risk Human Subjects Research OR Meets NIH Definition of a Clinical Trial:

16. **Data and Safety Monitoring Plan** (DSMP) - The overall framework for safety monitoring and what information will be monitored
17. **Overall Structure of the Study Team -** Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers
18. **Statistical Design and Power -** Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use
19. **Dissemination Plan -** Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met
20. **IND, IDE** - Documentation that an Investigational New Drug (IND) or Investigational Device Exemption(IDE) has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived
21. **Product Info** - Product information such as the clinical investigator brochure, package insert, or description of the device

Once you have reviewed the application for completeness, submit it to the CTSC for Review by clicking the Submit button at the bottom of the page.
The CTSC will offer a basic administrative review to those who have their applications submitted at least one week in advance of the due date. Please contact Christina Anderson (ChAnderson@salud.unm.edu) to let her know you would like your pilot reviewed.

On your Camino Home Page, you will be able to see the status of your Pilot Application

a. Draft
b. Submitted
c. Under Review
d. Administratively Denied
e. Pilot Funding Denied
f. Pilot Funding Awarded

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 Christina Anderson (ChAnderson@salud.unm.edu; 505-272-0195) with any questions about this RFA or the application process.