Translational and Clinical Pilot Project Award

REQUEST FOR APPLICATIONS
Issue Date: September 12, 2018
Application Due Date: January 19, 2019

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 research, to promote and support the “bench to bedside to community and practice and back” goal of the National Institutes of Health.

Clinical research involves human participants and includes epidemiological and behavioral studies; outcome and health services research; and patient-oriented research, such as the study of disease pathology and mechanisms, development and testing of therapeutic interventions or technologies, and clinical trials (NIH, 2013b). The NIH definition of translational research includes two broad areas: the translation of basic science and preclinical discoveries into human subject research and the subsequent translation of clinical trial results, research findings, and knowledge into practice in clinical and community settings (NIH 2013). Translational research exists along a dynamic continuum that is sometimes referred to as "bench-to-bedside" and "bedside-to-community" (Blumberg et al., 2012; ITHS, 2013; Khoury et al., 2007). This continuum includes four emphases: T1 research includes the process of applying basic science discoveries (T0 research) to humans in proof of concept studies or Phase 1 clinical trials designed to result in new methods of diagnosis, treatment, and prevention; T2 research is the translation of results from T1 studies to patients using controlled studies designed to lead to effective care (Phase 2 and Phase 3 clinical trials); T3 research translates findings from controlled studies of patients to practice studies that examine the delivery of recommended and timely care to the right patient (Phase 4 clinical trials and outcomes research); and T4 research moves from translation to practice to the translation to communities in population-level outcomes research that results in true benefit to society. 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 funding under this program.

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 (T1, T2, T3, and T4) research. Projects must be of high methodological quality and must demonstrate feasible and generalizable solutions to translational research 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 research findings into the everyday practice of health care delivery. To support this initiative, we will award several grants ranging from $10,000-$25,000 to be spent between April 1, 2019 through March 31, 2020.
Please note: All funds not spent by the end date of the Pilot Project Award (March 31, 2020) 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.

Application Deadline, Notice of Awards and Funding Cycle

Application Release Date: September 12, 2018
IRB Submission Deadline: November 16, 2018
Application Deadline: January 18, 2019 5:00 pm
IRB Approval Deadline for NIH Review: January 18, 2019
Notice of Intent to Fund/Decline: February 11, 2019
Notice of Awards: March 15, 2019
Funding Cycle: April 1, 2019 through March 31, 2020

Eligibility and Project Requirements

- Principal Investigators for these pilot awards must be members of the 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. Successful projects will exemplify the CTSC mission of developing clinical and translational research.
- 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.

Evaluation Criteria

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 the integration of special populations, approaches to articulated research barriers, and demonstration of feasible and generalizable translational research 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. “Go/No Go" Milestones (suggested by the investigator)
11. Budgetary Considerations
12. Regulatory Approvals
13. 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%.

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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-160.html).

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](mailto: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 costs (e.g., office supplies, telephone, etc.)
- meals or hospitality (i.e., no food, beverages, or alcohol)
- travel
- monetary incentives to clinics or providers
- other items typically supported by indirect costs

**What to Submit**

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

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.

1. IRB Approval - IRB approval letter for the proposed pilot
2. Summary – Summary paragraph of the proposed pilot
3. Protocol - Complete IRB approved pilot protocol
4. Consent, Assent, Parental Permission, Waiver of Consent – IRB approved consent documents
5. Inclusion - Inclusion Plans for Women, Minorities, and Children
6. Enrollment - Targeted Enrollment Table
7. Biosketch - The NIH Biosketch for the pilot project investigators
8. HSEdu - Certification that the pilot team has education in protection of human subjects
9. Safety - Data and Safety Monitoring Plan (DSMP)
10. IND, IDE - Documentation that an IND or IDE has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived, if a clinical trial is proposed
11. Product Info - Product information such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed
**IRB Guidelines**

NIH requires prior approval of all pilot human subjects research. All pilot submissions must have IRB Protocol approved at the time of submission. A pilot cannot use an existing IRB protocol approval. Please note all pilot IRB protocol titles must match the title of the CTSA pilot application. All applicants will be required to submit proof of IRB Approval or proof of non-human subjects research at time of Pilot Application Deadline. Applications without IRB submission prior to November 16, 2018 will be administratively disqualified. Applications must have IRB approval no later than January 18, 2019. Projects that do not have full IRB approval by this date will not be considered for funding. IRB modifications to the approved pilot protocol are not permitted after submission of pilot to NIH for 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, required to submit an IRB application, are strongly encouraged to meet with the CTSA’s Regulatory Affairs Manager, Sherry Sazesh (SSazesh@salud.unm.edu; 505-272-9542) for consultation and planning purposes.

**How to Apply**

1. Log on to the CTSC Funding Opportunities website, the application works best in Google Chrome Accessible from this webpage: http://hsc.unm.edu/research/ctsc/pilot-funding/current-opportunities/index.html
2. Click on the “Apply for Pilot Funding” Link
3. Log In with your HSC Net Id and Password (same as your HSC workstation)
4. Once you are logged in, click on the Start New Pilot Application Button
5. Application Sections that need to be completed as well as uploading the above documents:
   a. **General Information**
      i. Title of Pilot Project
      ii. RFA
   b. **Summary/Abstract**
      i. A Paragraph Summary of your pilot project
   c. **Key Personnel/Biosketches**
      i. Add Key Personnel
      ii. Upload Biosketch documents – Use the downloadable template provided on the webpage
   d. **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.
   e. **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.
f. Additional Information
   i. Research Plan – Upload Document – 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)
   ii. Letters of Support(Suggested/Optional) – Upload document
   iii. Describe Plan to Obtain Extramural Funding
   iv. Describe how project meets the definition of Translational Research
   v. Explain how proposal may be Generalizable

   g. Milestones – Two standard milestones are tracked, Funds Spent and Patient Enrollment. Please add two to three more milestones that can be used to track progress over the pilot award year. The CTSC Sage team will review milestones quarterly for progress. Milestones should be quantifiable and realistic. Failure to reach stated milestones may result in reduction of award.

6. 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.

7. 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.