

North and Central Texas Clinical and Translational Science Initiative Pilot Grant Award Program

The University of Texas Southwestern Medical Center

Department of Clinical Sciences

Spring 2009 Application Cycle

Executive Summary: The Department of Clinical Sciences is pleased to announce the Spring 2009 application cycle for the North and Central Texas Clinical and Translational Science Initiative (NCTCTSI) Pilot Grant Award Program. This program is intended to provide support for innovative clinical and translational research projects from investigators participating in the NCTCTSI. This program is funded in part by the NIH UL1 RR014982. The purpose of this program is to engender preliminary data for extramural grant submission. Proposals will be reviewed by a rigorous peer-review process conducted by a committee of experienced researchers from all NCTCTSI participating institutions. The program will track the success of the pilot award recipients to facilitate extramural funding.

The NCTCTSI consortium consists of the following schools:

- The University of Texas Southwestern Medical Center at Dallas
- Children's Medical Center at Dallas
- Texas A&M Health Science Center Baylor College of Dentistry
- Texas Tech School of Pharmacy
- The University of North Texas Health Sciences Center/Texas College of Osteopathic Medicine
- The University of Texas at Austin School of Nursing
- The University of Texas School of Public Health Dallas Regional Campus
- The University of Texas at Dallas Erik Jonsson School of Engineering and Computer Science
- The University of Texas at Dallas School of Behavioral and Brain Sciences
- The Veteran's Administration North Texas Health Care System

The pilot grant award program will give preference to early-career investigators, such as fellows and junior faculty members (< 7 years since faculty appointment) to encourage novel research proposals by promising individuals in the stages of their careers where pilot awards may be most effective. However, the program is not limited to early-career investigators, and anyone who meets the eligibility criteria (see below) may apply.

Projects this mechanism will support: The Pilot Grant Awards Program is intended to support hypothesis-driven research using a broad variety of designs and methods including, but not limited to the following subjects: mechanisms of human disease, clinical trials, diagnostic methodologies, novel therapeutics, epidemiology, outcomes, health services research, and population science. **The awards may support translational research that combines basic biomedical and clinical science as long as there is a direct connection to human biology or disease. For instance, an application that studies the behavior of human tumor cells in an immunodeficient mouse will be acceptable if the purpose is to develop a unique assessment tool or a therapy that can be applied to humans harboring the tumor. It will not be acceptable if the purpose is to analyze physiological mechanism that may be very important to understand the biology of cancer cells, but does not have direct relevance to diagnosis or treatment of that particular tumor.** Pilot Grant Awards that support underserved populations and/or underrepresented fields of investigation are encouraged.

Eligibility: Applicants must be full-time trainees (graduate students, post-doctoral fellows) or faculty members with a primary appointment at any of the NCTCTSI Institutions, as well as conduct their research at any of the NCTCTSI Institutions. Applicants must have a doctoral degree (e.g. Pharm.D, Ph.D., M.D.) or its equivalent. There will be three categories of eligible applicants: 1) early-career investigators who are in the process of becoming independent (e.g. Instructors or Assistant Professors); 2) senior investigators (Associate or Full Professors) who are pursuing a research idea that represents a substantial departure from the investigator's established or ongoing line of research and 3) fellows and other trainees whose proposal is clearly designed to foster the skills and experience needed to pursue a research career at the end of their training. The applicant is responsible for completion of the work and submission of the necessary reports. Individuals who are being recruited from other institutions are also eligible provided that at the time the funding becomes effective they are members of the faculty of a NCTCTSI member institution. Investigators currently holding a K award or in a T or K award program are particularly encouraged to apply.

Funds Available: The number of projects funded will be based on the scientific quality and the funds available. Three levels of support are envisioned: (1) a large number of awards at the level of \$10,000 - \$30,000; (2) a smaller number of awards at the level of \$30,000 - \$75,000; and (3) one or two awards at the level of \$75,000 - \$125,000. Applicants can apply for any award level, but they should give due consideration to the specific financial needs of the project and the fact that – given the limited number of large awards – the competition for large awards will be intense. Applications for awards at the \$75,000 - \$125,000 level that provide evidence of considerable interdisciplinary collaboration will be given priority.

Criteria for Funding: The main criteria for funding will be the scientific quality, innovation, and sustainability through future extramural funding. The Pilot Grant Award Committee will consider each study proposal and its budget in comparison to the others on a cost benefit basis.

Applications by trainees will also be judged based on the trajectory of the trainee and the quality and suitability of the research training environment. The environment is a major criterion for determining funding for trainee applicants. Therefore, it is important that such applicants and their mentors provide convincing evidence that the environment has been selected appropriately to ensure a high likelihood of success for mentored investigators.

While funding requests at all levels will be considered, preference will be given to those projects likely to produce the greatest benefit at the lowest relative cost. Applicants may submit multiple applications, but only one may be funded per cycle. Applications that are not successfully funded may be resubmitted. Applicants who previously received a pilot grant award may apply for additional new pilot awards providing that previous pilot grant award(s) from this source were completed successfully, or remain in good standing. In addition, sustained attempts to obtain extramural funding should include copies of reviews of extramural proposals if available.

Organization and Submission of Applications

Letter of Intent: An email containing the name of the principal investigator, academic rank, one paragraph (250 words) project summary, and a list of all faculty participants and/or sponsors in the study should be submitted to NCTCTSPilotAward@utsouthwestern.edu by Wednesday, April 1, 2009 by 5:00 p.m. CST. A letter of intent is **REQUIRED** in order to submit an application.

All letters of intent will undergo a summary administrative review. Investigators may be contacted if questions about the eligibility of the investigator or the proposed research arise during this review. However, the letter of intent may not contain sufficient information to establish eligibility and thus the unquestioned acceptance of the letter does not imply that the full application will be eligible for review.

Application: Applications should be e-mailed to NCTCTSPilotAward@utsouthwestern.edu by, April 15, 2009 by 5:00 p.m. CST. * **Only electronic submissions will be accepted, and all attachments must be in pdf format. Failure to adhere to the application instructions and guidelines, including page limitations and formatting, will result in the rejection of the application.** Emails should include the following attachments:

1. **NCTCTSI Pilot Award Application Form** – The applications is available at <http://www.utsouthwestern.edu/clinicalsciences> (click on the “[Pilot Grant Award Program](#)” link at the bottom of the Quick Link Menu on the right). If forms fields are not visible, click the “highlight fields” button in the purple toolbar. Complete all fields as instructed and attach the following documents by following the instructions in the yellow speech bubble at the top-right of the application form.
2. **Pilot Budget Form** – Budget forms are also available via the link above.
3. **Research Plan**
 - **Hypothesis and Specific Aims (One Page, begin numbering at page 8)**
 - **Background and Rationale (One page, page 9):** provide sufficient and properly cited source documentation of previous research related to the proposed topic of study. Define precisely why the proposed work is innovative; how it challenges current concepts or paradigms that would make extramural funding unlikely in the absence of preliminary data; how it fosters collaborations that would otherwise not take place; or how it establishes the feasibility of an idea in order to support a future grant application.
 - **Study Design and Methods (Four pages max., beginning on page 10):** include a description of how the experimental approach relates to the aims, and a discussion of how the data will be interpreted. This section must include an outline of potential experimental problems and the solutions devised to overcome them, clinical significance, and a time-table for the performance of the studies. The research design and methods section should focus on the details of the study design, including patient populations and inclusion/exclusion criteria (where appropriate), methods of data collection and analysis, and must include a statistical analysis plan. Collaboration with a biostatistician regarding the study design and analysis is encouraged for most investigators. The description of the research plan should provide a clear understanding of how the investigator will approach the testing of the hypotheses, sufficient detail in the execution of the experiments, and a discussion of how the data will be interpreted, specifying alternative experimental and/or analytical provisions when pertinent.
 - **Literature cited (Three pages max., beginning on a new page)**
Formatting: single spaced, ½” margin, arial 11 font with applicant’s name in header on right-hand margin and paginated in the bottom-right corner. Submit as a pdf file.
4. **Biosketch Forms** – Biosketch forms are also available via the link above. Biosketches should be completed for the applicant PI and all individuals listed on page 2 of the application. Beginning with PI and proceeding alphabetically by last name, numerate the pages continuing from the research plan (should begin on page 12-17).
5. **Letter of support (if applicant is a trainee)** - For applications submitted by non-faculty trainees, attach a letter from the applicant’s primary research mentor in pdf format:
 - 1) Describing the trainee’s potential as an investigator
 - 2) Explaining the ability of the trainee to carry out the work as proposed
 - 3) Describing the environment
 - 4) Explaining how the study will contribute to the applicant’s professional goals
 - 5) Stating he/she has evaluated and approved the submission of the research proposal
 - 6) Stating he/she will provide scientific oversight throughout the duration of the project and will be responsible for the conduct of the study
 - 7) Assuring access to resources needed to conduct the research*The letter must include all seven points. Please follow the order and include numeration as listed above. Items 1 – 4 must provide a thorough explanation or description.*
6. **Letter of resubmission** – If this application is a resubmission from a prior application cycle, attach a letter responding to reviewer comments of the prior application(s).

Note: Neither the letter of support nor the letter of resubmission is required to be paginated.

Applicants should note that, in previous cycles, the most common reasons for applications to be rejected without review or to receive a poor score if reviewed are: 1. the work contained in the proposal has no direct relevance to humans; 2. a senior investigator does not provide a convincing argument that the proposed research is a departure from his/her previous line of work; 3. a trainee does not provide the required information to assure the reviewers that the work is part of a well designed plan to prepare him/her for a career in research; and 4. the budget and the timeline of the studies is unrealistic and incommensurate with a pilot study.

Duration of Funding: The project time frame will be one year. A no cost extension of unspent funds beyond year one may be permitted providing there is sufficient justification. Requests for no cost extension should be submitted as a letter from the PI at least one month prior to the grant expiration date. Investigators may reapply for additional funding at the end of the year, but the reapplication will be considered only if progress reports have been completed, and there are strong reasons why additional funding is required. All reapplications will be reviewed competitively.

Deadlines and Review Schedule: The deadlines for the first round of applications are as follows:

Letter of Intent Due	Application Due
Wednesday, April 1, 2009 by 5:00 p.m. CST	Wednesday, April 15, 2009 by 5:00 p.m. CST

Pre-Funding Requirements: Once a project is selected for funding, the awardees must submit a letter of support (**2 pages maximum**) from their department chair or division chief documenting that the PI has their time protected and their salary supported to conduct the proposed research, and a commitment to return unspent funds if the project is determined to be unfeasible.

Rolling Review Provision: For applications that narrowly miss the cutoff for funding and where the committee finds that relatively minor changes in the proposal are needed to enable an otherwise outstanding project, the committee may recommend that the applicant amend and resubmit the application within 30 days of the receipt of their review. The project will be reconsidered for funding at this time.

Tracking and Reporting: A weekly schedule has been established that requires funded applicants to give an oral presentation of their project before their peers and a panel of experienced clinical researchers. Funded applicants are also required to attend 50% of their peers' presentations.

Reporting requirements for funded applicants include but are not limited to: an interim progress report (at six months), and a final progress report (at the completion of the pilot project). At minimum, progress reports should specify: (1) the title of the application and the funding organization for all submitted extramural grants based on work funded by the pilot award; 2) peer-reviewed publications resulting from the pilot award; and 3) formal presentations and abstracts resulting from the pilot award.

Six Month Report: The six month report should be no more than two pages in length and contain: 1) a description of the progress made since initiation of funding; 2) how this progress relates to the specific aims of the proposal; 3) a list and brief explanation of any unexpected problems that may prevent completion of the aims in the period designated by the original proposal; and 4) a statement of plans for the subsequent 6 month period, and if appropriate a description of any alterations in the original plans. Failure to submit this report at the designated time may delay continued funding of the project.

Twelve Month Report: The twelve month report should be no more than three pages in length and contain: 1) the name, title, and institution of the principal investigator; 2) the findings of the study as they relate to the original aims; 3) plans for continuation of the work; and 4) publications (submitted or in draft) or grant applications emanating from the work (copies of the manuscripts and applications should be included).

Final Report: In cases of a no cost extension, a final report, which contains information similar to that requested for the twelve-month report, must be submitted at the completion of the extension period.

Letters of Intent, Applications, and Reports must be submitted electronically via email to:

NCTCTSPilotAward@utsouthwestern.edu

***Please do not submit questions concerning the pilot program to this email address. Instead, please email any questions to Julia.Richardson@utsouthwestern.edu.**

Terms of Award

Approved Uses of Funds:

Personnel - funds from this mechanism may be used for any of the following salary support: non-PI research personnel such as research nurse, technician, data entry personnel, consultants, etc. Personnel costs must also include the appropriate amount of fringes.

Supplies – funds may be used to offset costs for laboratory or research supplies.

Other expenses – funds may be used to offset costs for laboratory analyses, data collection including study subject payments, data analysis, statistical support *, support for community administration in Community-based Participatory Research, database design/support, Clinical and Translational Research Center (formerly GCRC), Clinical Trials Office, and Clinical Investigator Resource Core.

**For minimal statistical support (<2 hrs./mo.) - \$1,000; mid-level statistical support (2 – 4 hrs./mo.) - \$3,000; in-depth statistical support (>4 hrs./mo.) - \$5,000.*

Non-approved Uses of Funds: Funds may not be used for PI salary or indirect costs under any circumstances. Travel or equipment including computers should also not be included unless strongly justified in the budget justification section of the proposal.

Distribution of Funds: Applicants appointed to UTSW will have funds distributed into an account at UTSW. All other applicants from institutions other than UTSW will have funds made available through a subcontract between UTSW and applicant's institution.

Contingencies: For funded projects, continued funding will be contingent on successful progress and/or completion of the project. In addition, unspent funds will be returned to the pilot grant award administrator in the event that the project is determined to be unfeasible, is not completed for any other reasons, or the funds are no longer required for the project (for example, if external support is obtained for the same project).

Acknowledgment: All publications supported by this award should include the following statement: "This [project/grant/publication] was supported by Grant Number UL1RR024982, titled, "North and Central Texas Clinical and Translational Science Initiative" (Milton Packer, M.D., PI) from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH) and NIH Roadmap for Medical Research, and its contents are solely the responsibility of the authors and do not necessarily represent the official view of the NCRR or NIH. Information on NCRR is available at <http://www.ncrr.nih.gov/>. Information on Re-engineering the Clinical Research Enterprise can be obtained from <http://nihroadmap.nih.gov/clinicalresearch/overview-translational.asp>."

For publications supported through Baylor School of Dentistry, the publication should also contain the following statement: "This project was supported in part by The Baylor College of Dentistry and The Baylor Oral Health Foundation"

For publications supported by the Children's Medical Center Foundation, the publication should also include the following statement: "This project was supported in part by a grant from the Children's Medical Center Research Foundation"

Change of Principal Investigator: The Pilot Grant Award Committee must authorize any request for a change of principal investigator. Such a request must be submitted in writing to (Julia.Richardson@utsouthwestern.edu) and include the justification for the request, and biographical information on the new principal investigator.