

CLINICAL TRANSLATIONAL SCIENCE (CTS) PROJECTS – REQUEST FOR APPLICATIONS

Institute for Integration of Medicine & Science / Clinical & Translational Science Award,
Texas Biomedical Research Institute, University of Texas at San Antonio, the University of Texas
College of Pharmacy

Deadlines: Dec 10, 2021 (Letter of Intent) & January 10, 2021 (Full Proposal)

Overview

The Institute for Integration of Medicine & Science (IIMS), Texas Biomedical Research Institute (Texas Biomed), and The University of Texas at San Antonio (UTSA), the University of Texas College of Pharmacy are soliciting proposals for Clinical Translational Science (CTS) project awards.

As defined by the National Center for Advanced Translational Sciences (NCATS), CTS is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. Whereas clinical translational research (CTR) focuses on the specific case of a target or disease, CTS is focused on the general case that applies to any target or disease; advances in CTS are the focus of this RFA. A key tenet of CTS is to understand common causes of inefficiency and failure in translational research projects (e.g., incorrect predictions of the toxicity or efficacy of new drugs, lack of data interoperability, ineffective clinical trial recruitment). Many of these causes are the same across targets, diseases, and therapeutic areas; therefore, advances in CTS will increase the efficiency and effectiveness of CTR to enhance health, lengthen life, and reduce the burdens of illness and disability. Like any other science, CTS seeks to elucidate general operative principles to transform translation from an empirical, phenomenological process into a predictive science. Further details on CTS are described by Austin (*Clinical Translational Science* 2021;14:1629–1647).

An example – for illustration only – may help clarify the distinction between CTR and CTS. An investigator who wishes to test whether a particular drug improves outcomes in diabetes will need to recruit sufficient underserved participants; this is a CTR problem and will be addressed from the standpoint of effectiveness for the drug's effects and the diabetes community, using established recruitment methods. By contrast, an investigator who wishes to understand the fundamental underlying barriers to recruitment for clinical trials generally, and test an intervention directed at those hypothesized causes and mechanisms, is engaging in CTS. To test the hypothesis, the CTS investigator may choose a use case that may in fact be the same as that used by the CTR researcher – in this example a drug for diabetes – but the question to be answered is primarily whether the CTS innovation accomplishes full recruitment of the desired underserved population more effectively and efficiently.

The purpose of this RFA is to support CTS projects that address major roadblocks in clinical translational science. *Table 1* summarizes many of these roadblocks and

Table 1: Major Rate-Limiting Translational Problems in CTS (Adapted from Austin, 2021)

Access
Adherence
Understanding of translation and translational science
Data interoperability and transparency
Registries and natural history studies
Clinical diagnostic and outcome criteria
Patient/Community engagement
Clinical trial participant recruitment and diversity
Clinical trial networks
Electronic health records for research
Shortening the time of intervention adoption

the successful project will address one of them. Project(s) selected may be considered for inclusion in the 2022 UT Health San Antonio Clinical Translational Science Award application to the National Center for Advancing Translational Sciences.

Amount and Term: Requests for funds of \$125,000 - \$150,000 will be considered for a 2-year project period, with the possibility of a 3rd year extension. Funds are available to fund up to 2 projects. Funding of these projects is contingent upon the award of the 2022 CTSA application. Funds may not directly support any clinical trial beyond phase IIB with the exception of Phase III clinical trials for treatment of rare diseases. Projects that do not meet these clinical trial limitations will not be reviewed. This program is supported by the Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH), as well as by various institutional funds. Funding of these awards is contingent upon award of the 2022 CTSA application. **Applicants must adhere fully to the guidelines and formats stipulated in this RFA, as non-complying applications may be administratively inactivated.**

Eligibility

IIMS-CTSA Program

Applicants must hold faculty-level appointments at the University of Texas Health Science Center at San Antonio (UTHSCSA) or one of its CTSA partner institutions (San Antonio Metropolitan Health District, San Antonio Military Health System, South Texas Veterans Health Care System, Texas Biomedical Research Institute, University Health System, University of Texas San Antonio, University of Texas School of Public Health (San Antonio Regional Campus), University of Texas College of Pharmacy). Faculty are encouraged to collaborate with individuals from CTSA partner organizations.

Texas Biomed Program

Applicants to the Texas Biomed program must be collaborating investigators, with the PI being a Texas Biomed faculty member and the Co-Investigator a UTHSCSA faculty member.

UTSA Program

Applicants to the UTSA program must be collaborating investigators, with the PI being a UTSA faculty member and the Co-Investigator a UTHSCSA faculty member. The UTSA PI must be full-time, tenure track or tenured faculty at UTSA, in residence at the time of application.

UT Program

Applicants to the UT program must be collaborating investigators, with the PI being a UT faculty member at the College of Pharmacy and the Co-Investigator a UTHSCSA faculty member. The UT PI must be full-time, tenure track or tenured faculty, in residence at the time of application.

Submission, terms, and conditions

An individual may submit **no more than one project as Principal Investigator** but may also serve as a **Co-Investigator** on one other project.

All applications (both letters of intent and full proposals) must be **submitted through the Survey Monkey Apply** platform (<https://apply-uthscsa.smapply.io/>) under the Primary Investigator's account. The funding opportunity at that site is listed as: **2022 IIMS/CTSA CTS Projects**

A required letter of intent (LOI) must be submitted by December 10, 2021 at 11:59 pm and should include the title of the project, principal investigator (PI), a very brief summary of the project and a list of 3 to 4 potential reviewers from UTHSCSA or CTSA partner institutions, but not from the same department or research group as the PI. Note that the LOI is required for planning purposes but will not serve as a screening tool for proposal submission (i.e., all PIs submitting the LOI should proceed to full proposal preparation). The deadline for receipt of the full application is **January 10, 2021 at 11:59 pm**. If you have any questions, please contact Cindy Castilleja (castillejac@uthscsa.edu) at 210-744-6446.

Awards will be made for a 2-year project period starting on or about **June 1, 2023**. Progress reports will be required six months (brief) and 12 months after the initiation of funding. In addition, a follow-up survey of related grants and publications will be solicited at 24, 36, and 48 months. Recipients who fail to submit timely and meaningful progress reports will be deemed ineligible for future funding cycles. For projects involving the use of human subjects or vertebrate animals, no expenditures will be permitted until IIMS is provided with a copy of the official letter of approval by the appropriate Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), respectively. Investigators are encouraged to submit IRB and IACUC protocols early in order to avoid significant delays in project initiation. In addition, CTSA-supported projects comprising either human or vertebrate animal research must be pre-approved by the NCATS. Excessive delays in meeting these regulatory requirements may result in withdrawal of the award. Applicants must also be up to date on compliance with institutional research training and conflict of interest disclosure policies.

Budget and financial policies

The budget for these awards is **\$125,000-\$150,000/year for 2 years with a possible 3rd year extension**. Facilities and Administrative (F&A, indirect cost) expenses will not be reimbursed. No more than 10% effort of the PI or faculty-level collaborators are allowed. Although the PI (and Co-PI/Co-I, if applicable) should be listed in the personnel section of the summary page, there is no minimum effort requirement. Salary (plus associated fringe benefits) may be requested for non-faculty support staff, including post-docs. Other allowable expenses include: equipment essential for the project (maximum \$25,000, including computer hardware); PI or Co-PI domestic travel to relevant scientific meetings (maximum \$2,500); consumable laboratory supplies; core facility fees at IIMS, Texas Biomed, UTSA, UT or other sites; consultation fees (maximum \$5,000); computer time; software; publication / presentation expenses; costs related to human subject enrollment and management (listed as "Patient Care Costs" on budget page); and other expenditures that can be justified as being essential for the completion of the project. Note that for projects making use of an IIMS Clinical Research Unit (CRU), a budget for these expenses **must be developed in advance** and submitted with the full application. For a quote, complete the [Study Data Collection Form](#) and contact Lisa Fleming – flemingl1@uthscsa.edu. Tuition expense is not an allowed budget item. Account management will be centralized within IIMS-CTSA, Texas Biomed, UTSA or UT with expenditures and encumbrances for UTHSCSA projects being committed as they are incurred. For projects supported at other CTSA partner institutions, funds will be disbursed at appropriate intervals, based on the receipt of invoices for budgeted expenditures.

Application requirements and format

Applications should be prepared using the templates provided and uploaded as a single .pdf document. Font size can be no smaller than 11 point, preferably Arial or Times New Roman. The font size for figures, figure legends, charts, and tables may be smaller, but must be clearly legible. Margins all-around should be at least 0.5". Pages should be numbered sequentially. The length of the Research Plan (narrative with illustrations and tables included) is limited to 4 single-spaced pages. The organization of the proposal should be as follows:

- [SurveyMonkey Apply website](#) funding opportunity - **2022 IIMS/CTSA CTS Projects**
- Link to additional application forms ([here](#))

- The CTS project budget is included in the application and does not need to be attached separately
- Project summary (level appropriate for scientific peers in the field)
- Additional information regarding the project (included in the application and does not need to be attached separately) to include as appropriate:
 - Past IIMS funding and list of grants obtained or applied for resulting from IIMS support
 - Pending or planned scientifically related applications to other CTS project programs (e.g., Pepper Center, School of Medicine, SNPRC), including a summary of potential overlap
 - Career development potential, if applicable
 - Prospects and specific plans for outside funding
 - Collaborative, interdisciplinary, or community engagement features, if applicable
 - Description of how the CTS project will interact with existing programs of the IIMS-CTSA, Texas Biomed, UTSA, or other CTSA partners, as appropriate.

Attachments –

- CRU budget, if applicable – (see above)
- *Biographical* sketch for PI (maximum 5 pages; for NIH template see <https://grants.nih.gov/grants/forms/biosketch.htm>)
- Biographical sketches for other key personnel (maximum 5 pages each)
- Research plan (maximum 4 pages)
 - Hypothesis and specific aims
 - Background and significance
 - Preliminary data
 - Work proposed (including statistical analysis, power calculations, pitfalls, alternatives)
- Literature citations (be selective, but no page limit – use continuation page)
- Letters of support (brief) from core directors or Research Imaging Institute are required (if applicable)
- Letters of collaboration (optional)
- Appendices are **not** allowed
- A UTHSCSA Certificate of Proposal (COP) is **not** required

Review process and criteria

Applications will undergo a two-tiered system of review. The first phase, or scientific review, will be performed by the CTS Project Study Section, including appropriate content experts and representatives from CTSA resources and services and other CTSA partner organizations. Scientific merit will be scored by these reviewers based on the following criteria:

- Significance
- Novelty / innovation
- Strength of the study protocol, including:
 - Design
 - Feasibility
 - Preliminary data (to the extent available)
 - Integration with ongoing research
 - Quality of the investigative team
- Likelihood of future NIH or other competitive external funding
- Contribution to career development of the PI or other team members, if applicable
- Extent of meaningful interdisciplinary collaboration and / or community engagement
- Use and leveraging of IIMS-CTSA, Texas Biomed, UTSA, or partner resources (for example, core facilities, biobanking)
- Potential for ultimately improving health outcomes
- Protection of human subjects

A programmatic review will then be performed by the IIMS-CTSA, Texas Biomed, UTSA and UT leadership teams for program relevance and potential public health impact, taking advantage of input from institutional and community partners. The purpose of this RFA is to support CTS projects that address major roadblocks in clinical translational science that are generalizable to the discipline of CTS and of local and national significance. Note that we are particularly interested in CTS projects that address health disparities. Please see the Overview section for a review of CTS and a list of major rate-limiting translational problems in CTS. Funding decisions will be based on scientific merit, as well as programmatic considerations, such as breadth and depth of the overall CTS study portfolio, interactions among partners, community involvement, and balance among program areas and disciplines.

Special emphasis areas

IIMS-CTSA

A primary intent of the IIMS-CTSA CTS projects is to address health disparities.

Texas Biomed

A primary intent of the Texas Biomed CTS project component is to promote collaborative interdisciplinary research between Texas Biomed and UTHSCSA faculty scientists, especially projects that bring basic scientists together with clinical/translational investigators. A broad range of proposal topics, including but not limited to those listed above, will be considered for funding. Priority will be given to studies that are focused on infectious diseases or related inflammatory diseases and fit in the three programmatic areas of Texas Biomed (Host-Pathogen Interactions, Population Health, and Disease Intervention and Prevention).

UTSA

A primary intent of the UTSA CTS project component is to promote collaborative interdisciplinary research between UTSA and UTHSCSA faculty scientists, especially projects that bring basic scientists together with clinical/translational investigators.

Responsibilities of the Principal Investigator

The principal investigators of funded projects are required to:

- Abide by NIH rules and regulations
- Abide by IIMS-CTSA/Texas Biomed/UTSA, and/or CTSA partner policies and procedures
- Provide demographic information in a timely fashion, as required before expenditures can be authorized
- At the time of funding provide a complete list of other support, including other CTS project mechanisms, along with explanations of any potential scientific or budgetary overlap
- Provide a waiver of Facilities and Administrative (F&A) fees or Indirect Costs from your institution if you are a non-UTHSCSA investigator
- Submit complete and timely progress reports
- Acknowledge support from IIMS, Texas Biomed, and/or UTSA grants and institute/center funds in all publications and reports generated with CTS project resources (details to be provided at the time of funding)