INSTITUTE FOR INTEGRATION OF MEDICINE & SCIENCE, CLINICAL AND TRANSLATIONAL SCIENCE AWARD, MILITARY HEALTH INSTITUTE, TEXAS BIOMEDICAL RESEARCH INSTITUTE, UNIVERSITY OF TEXAS AT SAN ANTONIO

REQUEST FOR APPLICATIONS – PILOT PROJECTS

Deadlines: April 8, 2016 (Letter of Intent) & April 28, 2016 (Full Proposal)

Overview

The Institute for Integration of Medicine & Science (IIMS), the Military Health Institute (MHI), Texas Biomedical Research Institute (TBRI), and The University of Texas at San Antonio (UTSA) are soliciting proposals for pilot project awards. The primary goal of these programs is to support early-stage collaborative translational and clinical studies that will lead to increased interdisciplinary, institutional, and community-based research likely to compete successfully for national grant support and ultimately to improve human health. The programs are supported by the Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH), as well as by various institutional funds.

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 [UTSA], University of Texas School of Public Health–San Antonio and Brownsville Regional Campuses, University of Texas College of Pharmacy). Faculty are encouraged to collaborate with individuals from CTSA partner organizations. Previous pilot project award recipients may apply again, but the new application must be a distinct project or a substantial departure, not a simple extension of the previously funded project. Pilot awards target, in particular, junior faculty with potential for career development. However, senior faculty are eligible if the project is a novel departure from currently funded programs.

MHI Program

Applicants must hold faculty-level appointments at UTHSCSA.

TBRI Program

Applicants to the TBRI program must be collaborating investigators, with the PI being a TBRI 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.
Submission, terms, and conditions

An individual may submit no more than one project as a Principal Investigator, plus one as a Co-Investigator.

A required letter of intent (LOI) must be submitted by Friday, April 8, 2016 at 5:00 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 (Click here for LOI template). 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 then proceed to full proposal preparation). The deadline for receipt of the full application is Thursday, April 28, 2016 at 5:00 pm. Both the LOI and the full proposal should be submitted electronically as explained on the form. Pilot application forms can be found here. If you have any questions, please contact Cindy Russel (russel@uthscsa.edu) at 210-562-4010.

Awards will be made for a one-year project period starting on or about August 1, 2016. Progress reports will be requested 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 and 36 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. 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 maximum budget for these one-year awards is $50,000, although proposals with smaller budgets will be considered and reviewed under the same criteria. Facilities and Administrative (F&A, indirect cost) expenses will not be reimbursed. Funds may not be used to support the salary of the PI or faculty-level collaborators. 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 $10,000, including computer hardware); PI or Co-PI travel to relevant scientific meetings (maximum $1,500); consumable laboratory supplies; animal purchase and per diem; IIMS, TBRI, UTSA, or other core facility fees; 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 that will make use of an IIMS Clinical Research Unit (CRU), a budget for these expenses must be developed in advance and submitted with the application (contact Deborah Mote – 567-4612, mote@uthscsa.edu). Tuition is not an allowed budget item. Account management will be centralized within IIMS-CTSA, MHI, TBRI, or UTSA 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. Font size should 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 included) is limited to 4 single-spaced pages. The organization of the proposal should be as follows:

- Link to application form (here)
- **Budget and Budget justifications** (p. 3 and 4, plus CRU budget, if applicable – see above)
- Biographical sketch for PI (maximum 5 pages; for NIH template, format, and sample see [http://grants.nih.gov/grants/funding/424/index.htm#biosketch](http://grants.nih.gov/grants/funding/424/index.htm#biosketch))
- 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** (maximum 1 page – use continuation page)
- **Additional information** regarding the project (maximum 1 page) to include:
  - Past IIMS funding (TTR and/or pilot project awards) and list of grants obtained or applied for resulting from IIMS support
  - Pending or planned scientifically related applications to other pilot 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 (**this is a required element**)
  - Collaborative, interdisciplinary, or community engagement features, if applicable
  - Description of how the pilot project will interact with existing programs of the IIMS-CTSA, TBRI, MHI, UTSA, or other CTSA partners, as appropriate.
- **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 go through a two-tiered system of review. The first phase, or scientific review, will be performed by Scientific Review Committees, 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
- Contribution to career development of clinical / translational scientists, if applicable
- Extent of meaningful interdisciplinary collaboration and / or community engagement
- Likelihood of future NIH or other competitive external funding
• Use and leveraging of IIMS-CTSA, TBRI, UTSA, or partner resources (for example, core facilities, biobanking)
• Potential for ultimately improving health outcomes
• Protection of human subjects and experimental animals

A programmatic review will then be performed by the IIMS-CTSA, MHI, TBRI, and UTSA leadership teams for program relevance and potential public health impact, taking advantage of input from institutional and community partners. Funding decisions will be based on scientific merit, as well as programmatic considerations, such as breadth and depth of the overall pilot study portfolio, interactions among partners, community involvement, and balance among program areas and disciplines.

Special emphasis areas

**IIMS-CTSA**

Since the intent of this pilot project solicitation is to support a broad range of clinical and translational research activities, the topics for proposals are unrestricted. However, in keeping with priorities developed in the UTHSCSA CTSA application, several areas are highlighted for their special relevance to IIMS programmatic goals. Proposals responsive to the following specific IIMS/CTSA interests are especially encouraged:

• **Community Engagement** – Proposals for community-based research initiatives, including those involving Practice-Based Research Networks, health outcomes research, epidemiology, and public health research are strongly encouraged. Projects that address the focus areas and goals identified in the 2014 Bexar County Community Health Improvement Plan (CHIP, see especially p. 13 and following of the report – CHIP) will receive special consideration.

• **Comparative Effectiveness Research (CER)** – IIMS has a special interest in CER proposals that have the potential to inform health care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options using drugs, medical devices, diagnostic tests, surgeries, or means for delivering health care.

• **Biomedical Informatics** – IIMS is especially interested in projects that will develop and/or utilize databases that cross the three major domains of clinical research, clinical medicine, and population health. Projects might study approaches to the integration of data across CTSA partners or apply informatics methods to health status analysis of defined cohorts. Research on the development of novel systems for enhancing communication and data sharing among researchers in various settings (e.g., academic, healthcare, public health, community, mobile health systems) are of interest.

• **Drug Development** – Evolving NIH priorities encourage proposals representing collaborative translational science studies that test novel translational research hypotheses/concepts, examine cell or animal model systems related to human studies, elucidate disease pathways, and develop/validate biomarkers, novel drug targets, new agents, new devices/tools, or therapeutic technologies (e.g., drug and gene delivery systems).

• **Research Ethics and Regulatory Science** – Proposals addressing ethical and regulatory issues related to the conduct of clinical and translational research are encouraged. Among our interests are justice, culturally appropriate data collection, informed consent processes, and means for limiting risks to human subjects.

**MHI**

Projects must have the potential for health benefit to active military service members, veterans, and/or their families.
TBRI

A primary intent of the TBRI pilot project component is to promote collaborative interdisciplinary research between TBRI 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.

UTSA

A primary intent of the UTSA pilot 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. A broad range of proposal topics, including but not limited to those listed above, will be considered for funding.

Funding expectations

It is anticipated that up to $800,000 will be available to fund proposals received in response to this solicitation, depending to some extent on currently pending sources of support. The approximate number of awards for the various program components is generally expected to be as follows:

- IIMS-CTSA translational program – 8 projects
- IIMS-CTSA/MHI – 3 projects
- IIMS-CTSA/TBRI collaborative program – 3 projects
- IIMS-CTSA/UTSA collaborative program – 2 projects

Responsibilities of the Principal Investigator

The principal investigator of funded projects is required to:

- Abide by NIH rules and regulations
- Abide by IIMS-CTSA/MHI/TBRI/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 pilot 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-HSC investigator
- Submit complete and timely progress reports
- Acknowledge support from IIMS, MHI, TBRI, and/or UTSA grants and institute/center funds in all publications and reports generated with pilot project resources (details to be provided at the time of funding)