**INSTITUTE FOR INTEGRATION OF MEDICINE AND SCIENCE
CLINICAL AND TRANSLATIONAL SCIENCE AWARD**

REQUEST FOR APPLICATIONS – PILOT PROJECTS

Overview

The Institute for Integration of Medicine and Science (IIMS) is soliciting proposals for pilot project awards. The primary goal of this program 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. This program is supported by the Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH), as well as by institutional funds and a grant from the AT&T Foundation.

Eligibility

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 (Christus Santa Rosa Children's Hospital, San Antonio Metropolitan Health District, San Antonio Military Medical Center, South Texas Veterans Health Care System, Southwest Foundation for Biomedical Research, University Health System, University of Texas San Antonio, University of Texas Pan American, University of Texas Brownsville, University of Texas School of Public Health – San Antonio Regional Campus, University of Texas College of Pharmacy – San Antonio Program).

Submission, terms, and conditions

The deadline for application receipt is **Monday, February 2, 2009.** Proposals should be submitted electronically in pdf format attached to an email message to Ms. Cindy Russel (russel@uthscsa.edu), with a copy to Dr. Robert Clark (clarkra@uthscsa.edu). Awards will be made for a one-year project period. Progress reports will be requested six months (brief) and 12 months after the initiation of funding. Under unusual circumstances, a no-cost extension of no more than 3 months may be granted upon specific request, accompanied by a progress report and justification for the extension. For projects involving the use of human subjects or 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. Applicants must also be up to date on compliance with institutional 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 (e.g. $10-25,000) 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 Principal Investigator (PI) or faculty-level collaborators. In order to minimize the impact of cost-sharing for departmental / institutional salary support for the PI, the listed effort on the grant budget may be kept at a modest level (e.g. 5 to 10% or 0.6 to 1.2 calendar months). Salary (plus associated fringe benefits) may be requested for non-faculty support staff. Other allowable expenses include: equipment essential for the project (maximum $10,000, including computer hardware); PI travel to relevant scientific meetings (maximum $1,500); consumable laboratory supplies; animal purchase and per diem; IIMS or other core facility fees; consultation fees; computer time; software; publication / presentation expenses; costs related to patient and normal 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. Account management will be centralized within IIMS, 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 from IIMS at appropriate intervals, based on the receipt of invoices for budgeted expenditures.

Application requirements and format

Applications should be prepared using the templates provided (adapted from PHS Form 398). 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 five single-spaced pages. The organization of the proposal should be as follows:

- Cover page (p. 1)
- Project summary and key personnel (p. 2)
- Budget (p. 3)
- Budget justifications (p. 4; maximum 1 page)
- Biographical sketch for PI (maximum 4 pages; for NIH template, format, and sample see http://grants1.nih.gov/grants/funding/phs398/phs398.html)
- Biographical sketches for other key personnel (maximum 4 pages each)
- Research plan (maximum 5 pages; use continuation page template)
  - Hypothesis and specific aims
  - Background and significance
  - Preliminary data
  - Work proposed (including statistical analysis, pitfalls, alternatives)

- Literature citations (maximum 1 page)
- Additional information regarding the project (maximum 2 pages)
    - Career development potential
    - Prospects and specific plans for outside funding
    - Collaborative, interdisciplinary, or community engagement features
    - Relevance to areas of special IIMS/CTSA interest (see below)
    - Summary of human subjects use and status of IRB protocol, if applicable
    - Summary of vertebrate animal use and status of IACUC protocol, if applicable
- Letters of support (optional)

Review process, criteria, and special emphasis areas

The IIMS will carry out a two-tiered system of review similar to that used by the NIH, with protocols first reviewed for scientific merit and then considered for programmatic relevance. The initial review will be conducted by a Scientific Review Committee, including appropriate content experts and representatives from the CTSA key function groups involved in pilot projects. Scientific merit will be scored (using the NIH scale of 1 to 5) 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 resources
- Potential for ultimately improving health outcomes
- Protection of human subjects and experimental animals

The second phase, or programmatic review, will be performed by the IIMS Leadership Group, taking advantage of input from CTSA 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.

Although the intent of this pilot project solicitation is to support a broad range of clinical and translational research activities, in keeping with priorities developed in the UTHSCSA CTSA proposal, several areas are highlighted for their special relevance to

IIMS programmatic goals. Proposals responsive to the following specific IIMS/CTSA interests are especially encouraged:

- Novel Clinical and Translational Methodologies – IIMS is interested in methodological research that spans the continuum from laboratory-based investigations through health services research and type 2 translational studies. Proposals should address a recognized roadblock to clinical or translational research and exhibit promise for advancing research across traditional disciplinary boundaries.
- Research Ethics – Proposals addressing ethical issues related to the conduct of clinical and translational research are strongly encouraged. Among the interests are such issues as justice, approaches to culturally appropriate data collection, and means for limiting risks to subjects in both type 1 and type 2 translational research.
- Regulatory Knowledge and Support – IIMS has an interest in proposals to conduct research on regulatory issues related to both human subjects research (e.g. the informed consent process) and research on animals (e.g. means for reducing numbers or adverse impacts).
- 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 dealing with the demographics and prevalent health problems in our region are of particular interest. Examples include factors related to culture, ethnicity, socioeconomic status, health access, and health disparities, as well as such clinical disorders as obesity, diabetes, infectious diseases, cancer, cardiovascular disease, trauma, and mental health disorders.
- Biomedical Informatics – Funds from our AT&T Foundation award are reserved in part for supporting pilot and demonstration projects in the area of biomedical informatics. IIMS is especially interested in projects that will aid in the development of our Enterprise Data Warehouse, which is envisioned as a system that crosses the three major domains of clinical research, clinical medicine, and population health. Projects might study approaches to the integration of data from one or more CTSA partners – e.g. San Antonio Metropolitan Health District, University Health System, or UT Medicine. Other projects of interest might apply informatics methods to health status analysis of a defined clinical cohort or beneficiary population. 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) would also be of substantial interest.

Funding expectations

It is anticipated that approximately $300,000 to $350,000 will be available to fund proposals received in response to this solicitation, depending to some extent on currently pending sources of IIMS support.