

(REVISED SEPT 2009)

**REQUEST FOR APPLICATION
MEDICAL COLLEGE OF WISCONSIN
CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE
2009 CALL FOR RESEARCH PROPOSALS**

Title: Pilot and Collaborative Clinical and Translational Research Grants

Participating Organizations: Medical College of Wisconsin, Marquette University, Milwaukee School of Engineering, University of Wisconsin-Milwaukee, BloodCenter of Wisconsin, Children's Research Institute, and their affiliated Hospital systems: FMLH, CHHS, ZVAMC.

Key Dates:

Release/Posted: July 16, 2009

Letters of Intent Receipt: September 2009

Proposal Due to Grants and Contracts Office: October 22, 2009 (*Instructions below*)

Application Submission/Receipt: **October 29, 2009 (*Revised submission date*)**

PCCTRP Committee Review: December 7, 2009

CTSI Executive Committee Review: December 15, 2009

Anticipated Start Date: January 1, 2010

Summary: The fundamental goal of this RFA is to stimulate translational and clinical research in and across the institutions that comprise the CTSI of Southeastern Wisconsin. It seeks to encourage transdisciplinary collaboration between clinical and basic scientists, as well as social scientists, ethicists, engineers, and clinicians. To stimulate interdisciplinary collaborations in translational and clinical research, funds will be provided to: 1) support new and promising clinical and translational projects; 2) provide a mechanism for young investigators to focus efforts in clinical and translational research; 3) stimulate collaborative research between bench and clinical investigators within similar thematic areas; 4) foster interdisciplinary collaborations between and within constituent institutions of the CTSI and 5) support brain imaging research.

Overview:

The NIH Roadmap for Medical Research has launched a new program, the Clinical and Translational Science Award (CTSA), to completely re-engineer the clinical research enterprise. The following description from the NIH website is given as a summary of the goals of this program [<http://nihroadmap.nih.gov/clinicalresearch/overview-translational.asp>].

"The purpose of the CTSA Program is to assist institutions to forge a uniquely transformative, novel, and integrative academic home for Clinical and Translational Science that has the consolidated resources to: 1) captivate, advance, and nurture a cadre of well-trained multi- and inter-disciplinary investigators and research teams; 2) create an incubator for innovative research tools and information technologies; and 3) synergize multi-disciplinary and inter-disciplinary clinical and translational research and researchers to catalyze the application of new knowledge and techniques to clinical practice at the front lines of patient care."

“The members of the CTSA consortium are expected to serve as a magnet that concentrates basic, translational, and clinical investigators, community clinicians, clinical practices, networks, professional societies, and industry to facilitate the development of new professional interactions, programs, and research projects. It is anticipated that these new institutional arrangements, coupled with innovative advanced degree programs, will foster the nascent development of a new discipline of Clinical and Translational Science that will be much broader and deeper than the classical and separate domains of translational research and clinical investigation.”

This program will advocate, facilitate, and foster the continuum of research from bench to bedside, and from bedside to community practice. In this sense, translational research includes the process of applying scientific discoveries made from basic research into the treatment and prevention of human disease. It also includes the processes by which these clinical applications are systematically transferred into community practice. Achieving these broader scientific aims requires the collaboration of basic and clinical scientists with social scientists, ethicists, biostatisticians, engineers, organizational theorists, and innovators of information technology. A specific goal of such work is the bidirectional flow of information between the research setting and the community.

The overall goal of the CTSI of Southeastern Wisconsin is to capitalize on a strong foundation of basic science and community outreach programs within the academic institutions of southeastern Wisconsin and thereby bridge translational investigation to the bedside and into the community. This will produce a new, broadly-trained generation of clinical investigators on our campuses and in our community. **It is the goal of our CTSI to diminish the barriers between Institutions and disciplines, while encouraging novel approaches to solving complex medical problems facing clinicians.**

Objective: Funding from the CTSI is being directed to stimulate translational and clinical research in and across the institutions that comprise the CTSI of Southeastern Wisconsin. Such funding will provide the impetus for bringing basic and clinical scientists together, and train the next generation of translational and clinical scientists. More specifically, funds will be provided to: 1) support new and promising clinical and translational projects; 2) provide a mechanism for young investigators to focus on clinical and translational research; 3) support focused scientific areas of interest which will stimulate interaction of clinical and basic researchers; and 4) foster interdisciplinary collaborations between, and within, constituent groups of the CTSI. It is the intention of this effort to bring together clinical and basic scientists with social scientists, ethicists, biomedical engineers, physicists, chemists, information technologists and clinicians in all health care disciplines to address problems which impact health of all age groups in southeastern Wisconsin.

This year, a portion of available funds has been set aside to support translational brain imaging research. Multi-disciplinary and multi-institutional proposals which utilize brain imaging technology are particularly encouraged.

Eligibility:

To ensure the results of scientific research will be used to directly benefit human health, proposals in all disciplines relevant to biomedical investigation will be considered for funding. A criterion for funding of any proposal is the potential to directly translate into improved preventative health, diagnostics, therapeutics, or health outcomes of our population.

- Principal Investigators must have a full time faculty appointment at Medical College of Wisconsin.

- A principal investigator may only have one active AHW research or education award. A principal investigator may submit a new application, if the existing AHW funded project will expire prior to the start of the new award period.
- Each principal investigator may submit only one application.
- For budgetary purposes, a single MCW faculty member and his/her sponsoring group must be designated as the primary awardee.
 - a) Co-Principal Investigators may be identified at any CTSI-member Institution, but the budget resides with the primary awardee.
 - b) Faculty salaries are permitted with a maximum of 15% effort under the current NIH salary cap.
 - c) No “indirect costs” may be charged for any CTSI funding under this RFA
- If a previously submitted proposal has not received funding, a revised application may be submitted only once and must include a detailed response to concerns raised in the review of the original application.
- Principal Investigators may receive awards for successive proposals but not concurrent or overlapping proposals.
- The funds for these proposals are not intended to be used as “bridge funding” for lapsed grants from any extramural source, but must be discrete, new projects.
- All personnel must be identified prior to the start date to replace any “to be named” positions proposed in the application.
- CTSI funds distributed through this RFA cannot be used for procurement of laboratory or clinical equipment.
- CTSI funds may not be used to supplant funds or resources that are available from other sources. Use of the CTSI funds to supplement other financial resources is permitted with clear justification. Matching funding and opportunities to leverage the CTSI funds to obtain other sources of financial support are specifically encouraged.
- Investigators are encouraged to submit their IRB applications as soon as they submit their proposals to the CTSI, to minimize the wait for IRB approval once an award has been made. Alternatively investigators may wait until an award has been made, and then submit an IRB application – but this approach ensures a minimum eight-week delay before research activity may begin.

*Please note: This funding is through the Advancing a Healthier Wisconsin (AHW) endowment. Award recipients are subject to comply with AHW and MCW fund policies and guidelines. Additional information on the AHW endowment can be found at <http://www.mcw.edu/healthierwisconsin>.

Types of funding for Pilot Studies:

- Small pilot projects that explore the multidisciplinary translational and/or clinical potential of a novel and promising mechanistic finding or basic discovery. These projects might include two collaborating investigators, one basic and one clinical, either junior and/or established investigators. These projects may arise from of any CTSI-partner Institutions. Projects will be supported up to a total of \$50,000, and must have a duration of less than two years.
- Translational opportunity grants would support exploration of novel discoveries for clinical testing of new devices and compounds with the hope that these studies will attract industrial partners. Funding for these grants will be up to a total of \$50,000, and must have a duration of less than two years.

- Small pilot projects for trainees will be funded to obtain preliminary data for use in applications to support multidisciplinary clinical and translational research. These include the research projects of CTSI translational tract graduate students. The amount of support will be no more than a total of \$30,000 for a period not to exceed two years.
- Brain Imaging projects will be funded up to a total of \$50,000 per project for a duration of no greater than two years. These projects should address research which specifically utilizes brain imaging as a key enabling technology. These collaborative projects could include areas of interest such as presurgical brain mapping, neurorehabilitation, connectivity and neural network models, addiction, cerebral perfusion, behavioral development and learning, emotion and affective disorders, and memory. For this RFA, funds for at least two such meritorious projects have been set aside in support of the successful 2009 CTSI-sponsored symposium: Utilization of Brain Imaging in Translational Research.

Application procedure and proposal format:

A letter of intent must precede the submission of the application. This letter should be sent to the CTSI Office and include: Title, PI, Key Personnel, and a brief description of the project as it relates to the mission of the CTSI (not to exceed two pages).

Format of the proposal:

- Face page (Use standardized form provided)
- Abstract of the proposed research project (not to exceed 500 words)
- Budget and budget justification for supplies and personnel (Use form provided)
- Six pages (on standard NIH (PHS 398) format with 0.5 inch margins, utilizing 11 point arial font) on description of the proposed research project including specific aims, background, significance, preliminary data when warranted, and experimental design. A section should be included in which the investigator describes the translational aspects of the proposal. Literature citations should be listed at the end of the proposal but will not be included in the six page limit.
- Proposals should include descriptions of how CTSI infrastructure will provide regulatory support, specialized core laboratory support, assistance with data collection and analysis, or report preparation. (To find a description of available CTSI services, go to the “Translational Research Units” on the CTSI website at www.ctsi.mcw.edu.)
- Future directions and career plans (One page maximum)
- Biographical sketches of the PI and key personnel (limit 4 pages per individual). Follow the standard NIH biosketch format : (<http://grants.nih.gov/grants/funding/phs398/phs398.html>)
- Letters of support and collaboration

Multi-Institutional collaborations: If investigators are interested in forming new collaborative relationships, they are encouraged to contact the Translational Research Resources Offices (TRRO) found in “Research Resources & Infrastructure” on the CTSI website. The directors of the TRROs will assist with identifying potential trans-disciplinary and multi-institutional collaborators for these projects.

Submission process: Applications must be submitted electronically to the CTSI office for administrative approval by **October 29, 2009**. *Prior to this submission date, the application must be routed through eBridge to the MCW Grants and Contracts Office for appropriate*

signatures and approvals. Because the funding is from “Advancing a Healthier Wisconsin”, please select that option when prompted on Page C, 10.0; and Page I, 1.0. On Page C, 14.0, select “Clinical & Translational Science Institute” as the Institute affiliated with this project. You are also required to upload your complete proposal prior to submitting to your Division Official and/or Primary Department Official.

The complete grant file should be in MS Word format and sent as a single PDF file to: Sara Goetz, Administrative Coordinator, CTSI, ctsi@mcw.edu. 414-955-2537.

Review process: The Pilot and Collaborative Clinical and Translational Research Program (PCCTRP) Committee will review all applications along with appropriate *ad hoc* reviewers serving at the request of the committee. This committee is comprised of 11 members including the Director of the PCCTRP (Allen W. Cowley, Jr., PhD.), and a Co-Director (John Traxler, M.D., MSOE) plus 3 members from the MCW campus partner institutions, 2 members from MSOE, 2 members from UWM, and 2 members from Marquette University. The recommendations of the review panel will be made to the CTSI Executive Committee for approval. This process will ensure equitable representation of all of the partner institutions within the CTSI. *Conflict of Interest: Investigators that are in the same division or have worked or published together in the last three years, will not be allowed to review one another’s application and must recuse themselves from discussion.*

Examples of topics that could be developed that would involve multidisciplinary collaborations across the partner institutions:

- Demonstrate how interventions can be appropriately modified to improve clinical outcomes or sustain them in diverse practice settings.
- Determine the feasibility and utility of alternative methods to deliver interventions (e.g. telehealth) to improve delivery of interventions to underserved communities.
- Develop and/or apply a system composed of glucose monitors (or implantable sensors) integrated with a local computer to capture, store, and also transmit data (glucose levels, diet, exercise, etc.) to a central location where it could be automatically analyzed and flagged when glucose control is poor.
- Develop genetic markers of clinical diseases to predict what clinical events are likely for a particular patient even before there are early signs of disease.
- Develop a collaboration to characterize and assess substances in the synovial fluids of patients with osteoarthritis. New therapeutic approaches would be developed to modify clinical disease.
- Develop and/or test a new imaging modality for clinical diagnosis of disease or as a non-invasive correlate of functional outcome measurements.
- Develop and/or test new devices or procedures for the improvement of sensorimotor function after traumatic or degenerative neural disease.
- Develop targeted therapeutic approaches to the clinical symptoms of chronic disease by investigating central nervous system involvement in immunological, neurological, cancer or muscle disorders that contribute to the complaints of fatigue, pain, or nausea.
- Develop customized orthotics or artificial muscle using a combination of Rapid Prototyping, Finite Element Analysis, and clinical experimentation.

- The use of fMRI to study brain responses to different stages of addiction to drugs of abuse
- Correlate brain imaging to neurocognitive function during recovery from hypoxic CNS injury.