

**Office of Discovery and Translation
Junior Investigator Translational Grant Funding Opportunity
Fall 2012**

PURPOSE

The purpose of this funding opportunity is to support and facilitate the highest quality early stage translational research. This round of ODAT pilot funding will be restricted to Junior Investigators (Assistant Professor in rank) conducting *early stage translational research, which is defined as research focused on transitioning a basic science discovery to the clinical setting*. The overarching goal is an endpoint where definitive progress has been made toward positively impacting human health in Minnesota and the nation. This funding opportunity differs from traditional internal award programs by virtue of the fact that the funded investigators are required to enter into a partnership with ODAT. This partnership is characterized by the inclusion of a Project Development Team (PDT) that will provide project mapping and translational research expertise to facilitate the achievement of specific metrics and endpoints.

SUBMISSION, REVIEW AND AWARD TIMELINE

September 17, 2012 (5:00 pm): Full applications due
September 18 – October 31, 2012: Proposal review process
November 2012: Awards announced
December 2012: Funding initiated

ELIGIBILITY

1. U.S. citizens, permanent residents and non-permanent residents are eligible.
2. The principal investigator (PI) must be junior faculty (Assistant Professor in rank) at the University of Minnesota at the time of grant submission. Eligibility includes affiliated faculty at the VA, HCMC, Regions Hospital, and the Children's Hospitals of Minnesota. Faculty members holding adjunct appointments are ineligible.
3. The PI must hold a doctorate degree (MD, PhD, DVM, DO, DDS, PharmD).
4. Applications can be submitted by a PI with no previous NIH funding, pending NIH funding, or an active NIH award. However, the current application cannot overlap with the aims in a funded grant.
5. An application can originate from a single PI, or a PI and one or more co-investigators (co-I).
6. If the application has a PI and co-I, they can be from different colleges, a single college, or the same department within a college. *Applications are particularly encouraged from research teams comprising clinicians and basic scientists.*
7. Applicants must identify a senior investigator (Associate or Full Professor) as a co-I.

8. Junior investigators who have previously submitted a proposal to this grant program that was not selected for funding are eligible to submit a revised application.

RESEARCH FOCUS

1. Application must be focused on T1 human research, which tests findings derived from basic research for clinical applicability, and yields knowledge about human disease origin and progression and the potential for prevention and/or treatment.
2. Project should be at the stage of producing data that will be critical to the development or translation to the clinic of a new therapy, intervention, diagnostic, or treatment strategy.
3. Strong rationale should exist based on the applicant's research activity or published data to justify the proposal.

APPLICATION

1. FOR RESUBMISSIONS: point-by-point response to reviewers' comments (one-half page limit).
2. Cover letter (one page) describing:
 - a. The unresolved problem being addressed and its relevance to human health and/or disease
 - b. What product (e.g. drug, device diagnostic, treatment strategy, etc.) or service could result from the proposed work
 - c. The credentials of the PI and the investigative team (if there is one)
 - d. The degree to which the team has worked together in the past
 - e. Whether the proposed work is unfunded, or either partially or entirely supported by internal or external grants
 - f. The proximity of the proposed work to integration into human studies or a clinical application
 - g. Why the money is needed
3. Two-page application including Background, Project Goals, and Experimental Plan with appropriate milestones. A third page can be used for references and preliminary data (not required). NIH style formatting guidelines should be used.
4. NIH biosketch (4 page limit) that includes active and pending internal and external funding (including direct costs per current year) for the PI and each co-I.
5. Budget (one page) requesting NIH style items. Up to \$50,000 in direct costs for one year can be requested. Salary support for the PI and co-I(s) is not allowed. No indirect costs are allowed.
6. Letters of support (up to three).
7. If IRB or IACUC approval are required and have not yet been obtained, please indicate the status of, and the plans for obtaining approval (separate page). Funds will not be released without the necessary approvals.
8. **The complete application should be emailed as a single PDF by September 17, 2012 at 5:00 pm to: ctsiodat@umn.edu.**

REVIEW PROCESS

1. Applications will be initially screened to confirm eligibility based on the criteria listed above.
2. A review team will then evaluate eligible applications based on several considerations, including:

- a. Does the proposal address an important problem and, if successfully completed, will the results have or potentially lead to a definable impact on human health?
 - b. What is the potential for the proposed work lead to advancement of a basic science discovery toward the development of a specific product (e.g. drug, device, diagnostic, treatment strategy, etc.) or service? (see POST-AWARD EXPECTATIONS)
 - c. Is the proposal innovative?
 - d. Is the project focused and achievable in one year?
 - e. Does the individual PI or the investigative team have the necessary expertise to conduct the study?
3. Applicants whose proposals receive the highest scores in the initial review for both scientific merit and translational potential will then be granted an interview with a review team to explain and defend their proposals and receive critical input.
 4. Applications selected for funding will be strongly encouraged to make appropriate revisions on their experimental plans reflecting feedback from the interview.

FUNDING PERIOD EXPECTATIONS

1. A project development team (PDT) will be assigned to each funded application to assist and facilitate conduct of the study and progress toward achieving specific metrics. The members of the PDT will be selected based on their expertise and capability to provide constructive input on the project. An initial meeting between the PDT and grantee will be held at the time the grant is funded.
2. Grantees will agree to quarterly meetings with the PDT following initiation of the award. The purpose will be to monitor progress on the project, and make any mid-course corrections that reflect unexpected results or the need to modify the experimental design. A final report will be due 1 month following completion of the study.
3. No-cost extensions will not be allowed.

POST-AWARD EXPECTATIONS

Upon completion of the project, it is expected that significant progress will have been made toward future human testing or clinical application.

Examples of successful outcomes include:

1. Submission of a new federal or national grant application for further development of a new technology.
2. Movement of the project into the Center for Translational Medicine for further pre-clinical development.
3. Movement of the project into the Institute for Therapeutic Development and Discovery for further pre-clinical development.
4. Movement of the project into Molecular and Cellular Therapeutics for further pre-clinical development and scale-up.
5. Partnership with the Office for Technology Commercialization for filing of invention disclosures and/or patents, and/or development of external industry collaborations.

TYPES OF ELIGIBLE PROJECTS

1. Studies in cell-based systems with relevance to human health and disease.

2. Use of established animal models of human disease or development of new animal models of human disease (e.g., cancer, autoimmunity, cardiovascular, neurologic, microbial infections).
3. Genomic, pharmacogenomic, metabolomic and proteomic studies.
4. Structural/imaging studies.
5. Development of human tissue/organ culture systems for safety and efficacy studies of drugs and vaccines.

TYPES OF INELIGIBLE PROJECTS

1. Studies with no relevance or application to human health or disease.
2. Phase 1, 2 or 3 clinical trials.
3. Drug, device and treatment protocol development.
4. Observational or survey studies.
5. Studies with no laboratory component.

QUESTIONS

Questions may be directed to:

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