REQUEST FOR APPLICATIONS (RFA):
PILOT TRANSLATIONAL AND CLINICAL STUDIES PROGRAM GRANTS ADMINISTERED BY THE CTSI
Revised Jan 2015

1. NATURE AND PURPOSE OF THIS RFA

The Clinical and Translational Sciences Institute (CTSI) with funding from the Office of the Vice President for Research and Graduate Studies will provide funds for pilot research projects conceived and designed by clinicians and translational researchers at Michigan State University and its partners. Success of this program will be judged by the rate at which these grants produce new extramural funding for clinical and translational research or create new MSU intellectual property.

Translational science has many definitions, but the fundamental concept is the practical application of a new discovery, technology, or methodology within the general realm of life sciences. More specifically, this has been targeted to the development of new therapies or diagnostics for human diseases and morbidities. This development spans the discovery phase, initial testing, human trials, deployment, and finally to widespread dissemination and efficacy validation. A project needs to fit somewhere along this trajectory to be considered translational. Suitable projects might encompass drugs, devices, assay development for disease detection, or procedures that enhance treatment efficacy or subject well-being within a population at risk.

For additional reading on the implementation of translational research, refer to the NIH-NCATS Request for Information - IOM Summary, “Enhancing the Clinical and Translational Sciences Awards Program (page 7) and the citation for the definitions for translational research.

2. CRITERIA FOR FUNDING

In order to be considered for funding:

- The research is clinical and/or translational as defined above.
- Preference will be given to projects already submitted for extramural funding, or where tangible evidence is provided to link the proposed research to a future award approval.
- Projects that include studies of important populations, such as the young, the elderly, medically underserved and/or underrepresented will be especially responsive to this program.

3. GRANT APPLICATION SUBMISSION AND DECISIONS

To provide both flexibility and agility to funding decisions, online grant applications will be accepted at any time during the year.

However, an initial letter of intent (preapplication) must be submitted prior to acceptance of a full application. The letter of intent – two-page limit (please use this template) should describe the goals of the proposed project, with an emphasis on its potential to produce external funding or intellectual property. It is also imperative that the letter describe how the proposed project will meet the funding criteria described above. Only one LOI submission can be under review from the same Principal Investigator. A decision to encourage or disallow submission of a full application will be provided within one month of submission of the letter of intent.

To ensure that funding decisions occur in as short a time as possible, full applications will be processed each month. It is anticipated that the review and decision process will take approximately two months. If an external review (for example, NIH summary statement) is provided with the full proposal submission, the decision time will be less.

online submission site
4. ELIGIBILITY

All faculty members employed by Michigan State University, in any department, at any level are eligible to submit applications for this RFA. Community-based investigators must apply in collaboration with MSU employed faculty.

5. REQUIREMENTS

The principal investigator must agree to provide 5-10% in-kind effort to the project for the period of funding and to prepare an application for external funding to be submitted during or after project completion. The Principal Investigator's effort can not be supported in the proposed budget.

6. FUNDING

Up to $25,000 may be requested for a period not to exceed one year. Projects with larger budgets will be considered if the additional funds are required for project success. At this level of funding, the proposals should be focused on near-term deliverable experiments that fit into an overall strategy, rather than the funding of long-term projects. Funds may be used for any legitimate research purpose, such as research assistants, equipment, supplies, laboratory testing, or data management and analysis. Use of MSU core facilities for laboratory work is encouraged. PI salary support, travel costs to scientific meetings, and indirect costs will not be supported.

7. FORMAT AND ELEMENTS OF THE PROJECT GRANT APPLICATION

Online submissions only. The letter of intent and full application can only be uploaded as one file in an Adobe Acrobat (pdf) format via the CTSI grant site.

Required elements of the full application are listed below. The body of the application (sections a-g) is limited to 7 pages in length. Biosketches, figures, tables, and references are not included in this limit.

a) Summary (limited to 250 words);
b) Background
c) Translational significance
d) Specific aims
e) Research plan
f) Specific plans for obtaining future external funding
g) Intellectual property potential
h) Budget and Justification - Note: Awards will be made in General Fund dollars, thus fringe benefit costs need not be included in the budget, with the exception of support for Graduate Assistants. If you include GA’s, you must cover fringe benefit & tuition cost in your budget. Budgets should be broken down into three categories:
   1) Salary for key personnel: segregate regular employees, student & temp labor
   2) Supplies and services:
   3) Equipment (individual items costing over $5000).
i) Append biosketches for principal investigator(s) and all key personnel using the NIH-format
j) If applicable, append external review

8. CLINICAL RESEARCH

If your application is a clinical research project involving patient care, use of external facilities, or services/tests, the following additional elements will be required for review:

- Study schedule of events - a table representing what processes/procedures are required at what study visits
- Informed consent form
- Signed quotes from service/test providers

Please note that if your project is being done at a site external of MSU, an agreement/subcontract will need to be in place between MSU and the institution before the project can begin. Depending upon the external entity/affiliate, there could be additional requirements to obtain permission to conduct research at these organizations. These can include separate approval processes, additional requirements for training,
credentialing, budgeting, and documentation. When contemplating adding an external entity's/affiliate's site to your research, you must contact them to determine if there will be additional research requirements.

If your project is approved for funding and the IRB has also given approval, Office of Sponsored Programs/Business-CONNECT will create and finalize this agreement. If the research is being done at an external entity, as part of this process you will need to complete the MSU Research Impact & Cost Quote form for each department involved with the research - this can serve as your cost quote as well as your Impact Statement as required by any outside IRBs

9. REVIEW

The CTSI Pilot Translational and Clinical Studies Program Advisory Committee will perform an initial review of all submitted grant applications to ensure their close alignment with the overall strategic goals of the MSU-CTSI, with the aim of funding those projects judged to provide maximal balance and impact to the overall MSU research portfolio. Committee members involved in the project or those who have academic appointments in the same unit as an applicant will not participate in the review to avoid potential conflicts of interest. If an external review is provided with the full proposal submission, the review will be completed by the Advisory Committee. For applications without an external review, the Advisory Committee will then recruit 2-3 appropriate individuals from inside and/or outside the MSU system to evaluate the scientific merit of the proposals (via written critique). Reviewers will score the proposal (via e-mail communications) on a 1–5 scale employing the same criteria used in NIH peer review. The written critiques serve as feedback for the applicants, with reviewers’ names removed. The Advisory Committee will make a final decision on funding according to the criteria and principles discussed above. Unapproved applicants may resubmit after a 3-month waiting period.