CTSA Clinical & Translational Science Awards

Minnesota Partnership for Biotechnology and Medical Genomics | University of Minnesota | Mayo Clinic

2014-2015 Request for Proposals
Translational Product Development Fund (TPDF)
Details and Instructions for Faculty

Awards Description and Criteria:

The Mayo Clinic Center for Clinical and Translational Science (CCaTS), and the University of Minnesota Clinical and Translational Science Institute (CTSI), in conjunction with the Minnesota Partnership for Biotechnology and Medical Genomics (MNP), have established the Translational Product Development (TPDF) funding program. The vision of this program is to impact the lives of Minnesota citizens through translating research discoveries into new therapies and treatment approaches for patients.

The goal of the TPDF is to provide support to University of Minnesota and/or Mayo Clinic investigators to advance projects with commercialization potential, defined as having the potential to lead to the formation of a start-up company or license agreement with an established commercial entity. This distinguishes the TPDF from the parent Partnership program, which prioritizes projects based on potential to advance the understanding or evaluate the natural history/mechanism, prevention, diagnosis or treatment of a disease.

Projects will be evaluated primarily on the basis of potential for commercialization, readiness of the technology to advance to the next stage of translation from the proposed activity, and strength of the investigative team and any partners. All funded projects will have clearly established milestones, and milestone progression will be monitored in collaboration with a CTSI/CCaTS Project Development Team.

- Responsive applications may include, but are not limited to the following:
  - Small molecule lead identification and optimization
  - Proof-of-concept testing of a novel therapeutic or device
  - Development and testing of a medical device prototype
  - Development of an IT-based service or platform for medical education or practice management
- Investigators may choose to partner with other laboratories or engage the services of commercial entities as appropriate.
- UMN or Mayo PIs may apply individually for funds. *Joint projects between the Mayo Clinic and the University of Minnesota are particularly encouraged.*
- Projects must have a high expectation for successful completion of milestones in one to two years depending on Tier of funding (see below).
- The investigator(s) must be willing to work with a selected Project Development Team to assist

and facilitate progress toward achieving project milestones.

- *Proposed work must be focused on advancing a research discovery toward the development of a commercializable product (required).*

Project Funding

There are two levels of possible funding:

Tier 1 Funding: Objective is to establish the scientific and technical merit, feasibility, and commercial potential of the proposed research and development efforts, and to determine the translational feasibility of the technology. Typical awards will be up to $50,000 total direct costs. Only a small portion of the funds can be spent on personnel.

Funding for Tier 1 projects will be transferred as a single milestone payment with the expectation that the Project Development Team will work with the grantee(s) to ensure adherence to the stated work plan. Deviation from the stated work plan without prior approval may result in a revocation of project funding.

Tier 2 Funding: Objective is to advance the research and development efforts achieved in Tier 1. Tier 2 awards are intended for projects that have advanced past the feasibility assessment as described in Tier 1, and are intended to advance a project toward creation of a commercial entity or licensing agreement. Projects that were awarded Tier 1 funding will be eligible for Tier 2 funding.

Projects positioned for Tier 2 funding may apply directly into Tier 2 only upon approval by program administration. Typical awards will be up to $200,000 total direct costs per year for one to two years. Only a small portion of the funds can be spent on personnel.

Funding for Tier 2 projects is milestone-based; continued funding within the grant period is contingent upon successful completion of the stated work plan and alignment with program goals as determined by the TPDF Operations Committee. Milestone payment structure is determined by the grantee(s) and program administration based on logical points of review for each project.

Eligibility

All full-time UMN faculty (all campuses) and Mayo Clinic Associate Consultant to Consultant investigators from the Rochester campus are invited to apply; because this program is supported by funds from the state of Minnesota, Arizona and Florida based investigators are not eligible. Joint projects between the two institutions are strongly encouraged but not required. Projects must meet the following requirements:

- Purpose must be to develop a novel therapeutic compound (i.e., drug, small molecule or biologic), device, diagnostic or IT product
- Project must be at the stage of product definition (feasibility, validation, prototype development, optimization or proof of concept)
- New technology must address an unmet medical or healthcare need
- Priority given to projects with potential novel IP
- Projects already licensed to a commercial entity will not be considered for funding

Eligible project types include but are not limited to:

- Drug or biologic: Lead identification and optimization, in vitro and in vivo proof of concept testing, preclinical development

- Device: Prototype development and optimization, bench testing, animal model or cadaver testing, pilot studies in humans
- Diagnostic: Testing of biomarker candidate sensitivity and specificity, development of clinical assays, validation in human samples
- Health IT: Development and validation of mobile apps, software, algorithms and database technologies

Application Process
**Please note that both the Letter of Intent and Full Proposal will be submitted using an online form by accessing the links identified below. If you have questions about this process, please contact Jodi Fenlon Rebuffoni (fenl0003@umn.edu).*

Step 1 – LOI submission

Mandatory letters of intent (LOIs) are due on December 19, 2014 (Cycle 1) and May 1, 2015 (Cycle 2) at 5 p.m. and must be submitted in an online form (see link below). The information required in the LOI includes:

1. Project title
2. PI(s) name(s) and contact information
3. Co-investigator(s) name(s)
4. Is this a University of Minnesota/Mayo Clinic collaboration?
5. What is the unmet medical or healthcare need being addressed?
6. What is the current standard of care, including available drugs, devices and diagnostics?
7. Why is the development of a new technology necessary?
8. Specifically, what population will benefit from this new technology?
9. Brief description of the technology and specific work to be supported by this funding

Letters of intent must be submitted through the following link:
https://redcap.ahc.umn.edu/surveys/?s=GjRbZZ5iLv

**You may save and return to complete your submissions at any time using the code provided when the "Save and Return Later" option is selected. To return to the form re-click the link identified above.*

Letters of intent will be reviewed by a joint Mayo and University review panel. **Individuals invited to submit a full proposal will be notified approximately one month following receipt of LOIs.**

Step 2 – Proposal submission (by invitation)

Full proposals should include the following:

1. Proposal (maximum of 5 pages, including Executive Summary, Figures, and Tables, excluding References)
    a. Executive Summary (maximum of 1/2 page)
    Briefly describe the unmet medical or healthcare need being addressed, the significance and potential clinical impact of the proposed project, and the project objectives with measurable criteria for success.
    b. Background and Strategy
        i. Background and Significance

Describe the significance of the unmet need being addressed, the current standard of care, and the potential impact of the proposed project. Provide supporting evidence for the project objectives.

ii. *Work Plan*
Describe the proposed objectives, approach, expected outcome and specific, measurable criteria for success.

iii. *Timeline*
Provide a timeline for key project tasks and milestones.

iv. *Collaborations and Other Sources of Support*
List any collaborations and/or other sources of funding related to the proposed program.

c. Translation Plan

i. *Clinical Impact*
- Describe how the outcome of the proposed project could be applied to inform clinical decisions and/or improve care.
- Describe how this new therapy, diagnostic or treatment approach fits into the current treatment paradigm for the target disease setting.
- Discuss the expected improvement over current standard of care (e.g. more accurate diagnosis, improved efficacy, reduced toxicity, etc.).
- Provide an estimate for the number of patients that could be impacted through the development of this new therapy, diagnostic, or treatment approach.

ii. *Development Plan*
Describe the expected next steps after the successful completion of the proposed project milestones (e.g. patents, clinical trials, regulatory approvals).

iii. *Intellectual Property*
To the extent known, list existing intellectual property (e.g. patents, copyrights) related to the project with references and status (e.g. disclosure, patent application, out-licensed). Describe the potential of generating intellectual property after the successful completion of the project milestones. List any existing competing products or other research or development programs that may result in new similar technologies. As a reminder, all intellectual property contained in the proposal must be disclosed to the Office for Technology Commercialization or Mayo Clinic Ventures prior to submitting a full proposal.

iv. *Strategic Partnerships*
Provide a brief description of existing partnerships with organizations related to the project. Describe potential strategic partnerships that may be beneficial in the development of a resulting product.

d. References (not included in page limit)

2. Project Milestone and Budget Summary (Tier 1: $50,000 maximum in direct costs for up to 1 year; Tier 2: $200,000 maximum in direct costs per year for up to 2 years)
3. NIH BioSketch of Principal Investigator(s), Co-Principal Investigator(s) and Co-Investigator(s) (4 page maximum; use NIH Form “PHS 398/2590”) http://grants1.nih.gov/grants/funding/2590/biosketch.doc
4. Letters of Collaboration (if applicable)
5. Statewide-impact. Describe the potential impact of the project on the State of Minnesota (not to exceed 1/2 page).
6. Layperson Summary. Provide a summary of the project that could be understood by a lay audience (not to exceed 1/2 page).

General Instructions for Full Proposal

1. Page limit for Section 1 of the proposal (excluding references) is 5 pages, single-spaced, Ariel or Helvetica typeface, font size 11 or larger, fully contained in a single .PDF file.
2. A faculty member may apply for only one grant per cycle on which he/she would be the PI or co-PI. There is no limitation to the number of grants on which a faculty member would participate as a co-investigator or collaborator.
3. A proposal may be resubmitted once. A description of the changes made from a prior application should be included as part of the 5-page application.
4. Special instructions for University of Minnesota faculty: A Proposal Routing Form (PRF) is not required. However, your department may wish to approve your proposal prior to submission.
5. The deadlines for submission of full proposals are: **February 20 and July 8, 2015 (5:00 p.m.).**
6. Applications and attachments must be submitted electronically. The link to the full proposal submission form will be provided to those applicants invited to submit full proposals.

Review Process

LOIs will be screened for eligibility criteria by program administration. Full proposals will be invited for those LOIs the Operations Committee determines meet the program eligibility requirements. Proposals will undergo scientific review *and* an assessment of commercial feasibility. Projects will be evaluated primarily on the basis of potential for commercialization, readiness of the technology to advance to the next stage of translation from the proposed activity, and strength of the investigative team and any partners.

Review and Award Cycles		
	Cycle 1	**Cycle 2**
LOI submissions due (5:00 p.m.)	December 19, 2014	May 1, 2015
Full proposal due date (5:00 p.m.)	February 20, 2015	July 8, 2015 (updated 3/15)
Review	February-March	July-August
Awards announced	April 2015	September 2015
Earliest award start date	May 2015	October 2015

Evaluation Considerations

Proposals will be evaluated based on the following criteria:

1. *Medical/Healthcare need:* Does the technology meet a specific need that does not have an adequate solution on the market?
2. *Impact:* Does the problem being addressed provide answers to serious human medical problems with the potential to significantly improve outcomes, reduce complications of care or improve quality of life?
3. *Feasibility:* Are the overall strategy, methodology, and analysis well-reasoned and appropriate to accomplish the goals of the project? Is the proposed work focused on technology development rather than further research?
4. *Expertise:* Will the scientific environment in which the work will be done contribute to the probability of success? Does the PI or investigative team have the necessary expertise to

conduct the proposed work?

5. *Scientific quality:* Does the project have its origins in innovative, high-quality research conducted by the PI(s)?

Funding Period Expectations

1. A project development team (PDT) will be assigned to each funded application to assist and facilitate progress toward achieving specific milestones. 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 program administration and grantee will be held at the time the grant is funded.
2. Grantees will agree to periodic 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. Advancement of the projects toward commercialization will be tracked following the conclusion of funding.

Program Contact Information

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