

**2016 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 the initial one-year funding period.
- 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 stages 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. Use of funding for salary support will be limited to key personnel required to execute activities described in the work plan.

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: Projects successfully meeting Tier 1 milestones will be eligible to apply for Tier 2 funding, contingent on availability of program funding. Objective is to advance the research and development efforts achieved in Tier 1. Tier 2 awards are intended for projects that have moved past the feasibility assessment as described in Tier 1. The purpose of Tier 2 funding is to advance a project toward creation of a commercial entity or licensing agreement.

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. Typical awards will be up to \$200,000 total direct costs per year for one to two years. Use of funding for salary support will be limited to key personnel required to execute activities described in the work plan.

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 February 10 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. What specific population will benefit from this new technology?
8. Brief description of the technology
9. Summary of specific work to be supported with Tier 1 funding

Letters of intent must be submitted through the following link:

<https://redcap.ahc.umn.edu/surveys/?s=KWDL9D8XC>

**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)

Details about the full proposal content and submission process will be provided to those individuals invited to submit proposals. In brief, the following information will be required in full proposals:

1. Executive summary
2. Project background
3. Unmet medical need
4. Proposed product or solution
5. Expected benefit and how the new product or solution will enhance or replace the current standard of care
6. Project plan and timeline
7. Intellectual property status
8. Strategic partnerships
9. Milestone and budget summary
10. Project team roles and responsibilities
11. Biosketches

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. Full 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.

2016 Review and Award Dates	
LOI submissions due date	February 10, 2016 (5:00 p.m.)
Invitations to submit full proposals issued	On or before March 7, 2016
Full proposal due date	April 6, 2016 (5:00 p.m.)
Review period	April-June
Awards announced	June 2016
Anticipated award start date	September 1, 2016

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)?

Projects selected for awards in previous funding cycles have the following common strengths and characteristics:

1. A clear and viable path to commercialization is identified in the application, and is verified by technology transfer personnel.
2. Proposals outlined a feasible strategy and methodology to advance technology development, with logical aims identified for follow-on (Tier 2) funding.
3. The proposed technologies meet specific healthcare needs that do not have adequate solutions on the market.
4. The funded technologies advance the state-of-the-art in their field of practice and have the potential to improve outcomes, reduce complications of care or improve quality of life.
5. The work will be completed in a scientific environment in which there is a high probability of success, including adequate scientific, technical and clinical representation on the investigative team.

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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