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. Additional information on developmental stages of projects supported through this program can be found here: https://www.ctsi.umn.edu/sites/ctsi.umn.edu/files/odat-technology-development-classification-stages.pdf.

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 or 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.
- Applications are accepted for single institution (UMN or Mayo) projects as well as for collaborative UMN-Mayo projects.
- 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

Funding is awarded in two stages. Only projects receiving Tier 1 funding are eligible to apply for Tier 2 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 Program 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.

*Note: For Tier 1 and Tier 2 projects requiring regulatory approvals (e.g. IACUC, IRB, FDA), it is expected that all regulatory documents will be submitted to the appropriate regulatory authority within one month of award notification. Delays in regulatory approvals may result in revocation of project funding.*

### 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 welcome, but not required.

A faculty member may apply for only one grant per cycle on which he/she would be a PI. There is no limitation to the number of grants on which a faculty member would participate as a co-investigator or collaborator. Typically, new awards are not made to investigators who are leading another project currently funded through the TPDF program.

A proposal may be resubmitted one time, but must include a description of the changes made from a prior application as part of the 5-page full proposal application.

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) or product testing
• New technology must address an unmet medical or healthcare need
• Proposed work must be focused on technology development towards a commercializable product
• Priority given to projects with novel technology that has been disclosed to the UMN Technology Commercialization office or Mayo Clinic Ventures.
• Projects with technology already licensed to a commercial entity will not be considered for funding
• For collaborative UMN-Mayo projects, a substantial contribution must be made by each institution

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 with human samples
• Health IT: Development and validation of mobile apps, software, algorithms and database technologies

Application Process

Key Dates

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<th>2020 Review and Award Dates</th>
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<td>LOI submissions due date</td>
<td>February 5, 2020 (5:00 p.m.)</td>
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<td>Invitations to submit full proposals issued</td>
<td>On or before March 2, 2020</td>
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<td>(Mayo applicants) Submission ready proposal due to OSPA for budget development</td>
<td>March 20, 2020 (5:00 p.m.)</td>
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<tr>
<td>Full proposal due date</td>
<td>April 1, 2020 (5:00 p.m.)</td>
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<td>Review period</td>
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<td>Anticipated award start date</td>
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**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 Brittni Peterson (bmpete@umn.edu).**

Step 1 – Letter of Intent (LOI) submission

Mandatory LOIs are due on **February 5, 2020 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 specific unmet healthcare need and why are current treatments inadequate?
6. Brief description of the future product in development and how it will address the unmet need.
7. Brief summary of the project based on its current status.
8. Summary of specific work to be supported with Tier 1 funding (up to $50,000 direct for one year)
9. For collaborative projects between Mayo and UMN, briefly explain the contributions made by each institution.
10. Whether the technology has been disclosed to the UMN Technology Commercialization office or Mayo Clinic Ventures, status of the intellectual property, and intentions to commercialize the technology

LOIs must be submitted through the following link: https://redcap.ahc.umn.edu/surveys/?s=YJKL8APKXW

*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.

LOI Review Process

LOIs will be reviewed for eligibility (see Eligibility section above) the TPDF Program Committee. Applicants will be notified of the review decision no later than March 2, 2020.

Step 2 – Proposal submission (by invitation only)

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. Proposed product or solution
3. Project background
4. Work plan
5. Collaborations and other support
6. Intellectual property
7. Technology marketing and licensing
8. Strategic partnerships
9. Team roles and responsibilities
10. Project timeline
11. Budget overview
12. Biosketches
13. Letters of collaboration

Proposal Review Process

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.

Proposal 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 technology being developed have the potential to significantly improve outcomes, reduce complications of care or improve quality of life for patients facing serious medical problems? Is there a meaningful need for funding and impact of the award on commercial potential?
3. **Feasibility:** Are the overall strategy, methodology, and analysis well-reasoned and appropriate to accomplish the goals of the project?
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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