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# Office of Discovery and Translation (ODAT)
# Committee for Pharmaceutical Development (CPD)
# Funding Program

## Overview

The Office of Discovery and Translation (ODAT) provides early-stage funding to support the translation of research discoveries into innovative products and services that positively impact human health.

The Committee for Pharmaceutical Development (CPD) Program funds projects in which the primary goal is to develop and commercialize a new therapeutic technology. The objective of funding is 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.

Responsive applications must include the following elements:

- Purpose must be to develop a novel therapeutic (i.e., small molecule or biologic) technology
- Project must be at the stage of product definition or testing (lead identification and optimization, in vitro or in vivo proof of concept testing, preclinical development, clinical phase 1)
- Proposed work must be focused on advancing a research discovery toward the development of a commercializable project
- New technology must address an unmet medical or healthcare need
- Technology must be disclosed to the UMN Technology Commercialization office
- Projects must have a high expectation for successful completion of milestones in the funding period

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 by ODAT.

## Project Funding

Award amounts are determined on a project by project basis and depend on what is needed to advance the technology toward creation of a commercial entity or licensing agreement. Use of funding salary support for faculty PIs is typically not allowed. Salary support for technical personnel must be limited to what is necessary to execute the proposed work plan.

Funding will be transferred in milestone payments with the expectation the grantee(s) adhere to the stated work plan. Deviation from the stated work plan without prior approval may result in a revocation of project funding. Milestone payment structure is determined by the grantee(s) and program administration based on logical points of review for each project. Continued funding within the grant period is contingent upon successful completion of the stated work plan and alignment with program goals as determined by ODAT.

*Please Note:*

- For 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.
- *The CPD program has a revenue sharing policy, wherein if the technology is eventually commercialized through a license agreement, 15% of all distributable proceeds from any therapeutic program receiving CPD funding will be allocated the CPD program to fund future CPD proposals with the remaining 85% of proceeds distributed in accordance with Regents policy.*

**Eligibility**

- U.S. citizens, permanent residents, and non-permanent residents are eligible.
- The principal investigator (PI) must have a full-time faculty appointment 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.
- Projects with technology already licensed to a commercial entity will not be considered for funding

**Application Process**

The application process is ongoing with submissions accepted at any time. Applicants will first submit a Letter of Intent (LOI) and may be invited to submit a Full Proposal.

***Please note that both the Letter of Intent and Full Proposal will be submitted using an online form by accessing the link identified below. If you have questions about this process or eligibility, please contact Brittni Peterson (bmpete@umn.edu).*

**Step 1 – Letter of Intent (LOI) submission**

*Submission of a brief letter of intent (LOI) is required.* The purpose of the LOI is to confirm applicant eligibility, ensure that the project fits with the purpose of this funding mechanism, and enable the identification of reviewers with applicable expertise.

The information required in the LOI includes:

- Project title
- PI(s) name(s) and contact information
- Co-investigator(s) name(s)
- What is the specific unmet healthcare need and why are current treatments inadequate?
- Brief description of the therapeutic in development and how it will address the unmet need.
- Brief summary of the project based on its current status.
- Brief high-level overview of specific work to be supported with CPD funding, estimate of total project costs and timeline.
- Whether the project has been disclosed to the UMN Technology Commercialization office, status of the intellectual property and whether a commercialization strategy has been identified.

**LOIs must be submitted through the following link:**
https://redcap.ahc.umn.edu/surveys/?s=38FEKFKRF8
**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.*

**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:

- Response questions raised during the LOI review
- Goal of CPD funding in the context of the overall technology development plan
- Executive summary
- Proposed product or solution
- Project background
- Work plan
- Collaborations and other support
- Intellectual property (if applicable)
- Technology marketing and licensing (if applicable)
- Strategic partnerships
- Team roles and responsibilities
- Project timeline
- Budget overview
- Biosketches
- Letters of collaboration

**Proposal Review Process**

1. Full proposals will undergo scientific review *and* an assessment of the commercial potential of the project. Full proposal review may include review by external experts operating under a confidentiality agreement.
2. Applicants may be asked to address issues raised in the proposal review.
3. Applicants selected for funding may be asked to make appropriate revisions to their work plan reflecting feedback from reviewers.

**Proposal Evaluation Considerations**

Proposals will be evaluated based on the following criteria:

1. *Medical/Healthcare need:* Does the proposed product meet a specific need that does not have an adequate solution on the market?
2. *Impact:* Does the proposed product 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 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.

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**

Grantees will agree to submit progress reports to ODAT following completion of each milestone. 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. ODAT will review progress and determine whether milestone payments are released. Advancement of the projects toward product development and commercialization will be tracked following the conclusion of funding.

**Program Contact Information**

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