UNIVERSITY OF MINNESOTA

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Office of Discovery and Translation (ODAT)
2019 Targeted Request for Applications
Therapeutic Development

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.

This Request for Applications (RFA) is intended to identify and fund early-stage projects in which the primary goal is to develop a new pharmaceutical or biologic technology. The objective of funding is to establish the scientific and technical merit, translational feasibility, and commercial potential of the therapeutic in development.

Responsive applications must include the following elements:

- Purpose must be to develop a novel therapeutic (i.e., small molecule or biologic)
- Project must be at the stage of therapeutic definition or testing (lead identification and optimization, in vitro or in vivo proof of concept testing, preclinical development)
- Proposed work must be focused on advancing a research discovery toward the development of a commercializable therapeutic.
- Projects must have a high expectation for successful completion of milestones in the initial one-year funding period.

Projects will be evaluated primarily based on readiness of the project to advance to the next stage of translation from the proposed activity, strength of the investigative team and any partners and potential for commercialization, defined as having the potential to lead to the formation of a start-up company or license agreement with an established commercial entity.

Project Funding

Awards will be up to $50,000 in 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 will be transferred as a single milestone payment 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.

Projects successfully meeting project milestones, and that demonstrate continued advancement towards commercialization, may be eligible to apply for additional funding through other ODAT funding programs to further advance research and development efforts. The purpose of additional funding is to advance the project toward creation of a commercial entity or licensing agreement.

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.

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.
- An applicant may apply for only one award on which he/she would be a PI. There is no limitation to the number of projects on which a faculty member would participate as a co-investigator or collaborator.
- Projects with technology already licensed to a commercial entity will not be considered for funding

Application Process

Key Dates

LOI submissions due date	December 12, 2019 (5:00 p.m.)
Invitations to submit full proposals issued	On or before January 17, 2020
Full proposal due date	February 20, 2020 (5:00 p.m.)
Review period	March 2020
Awards announced	April 2020
Anticipated award start date	May 1, 2020

**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 Jodi Fenlon-Rebuffoni (fenl0003@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.

Mandatory letters of intent (LOIs) are due on December 12, 2019 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. What is the specific unmet healthcare need and why are current treatments inadequate?
5. Brief description of the future therapeutic in development and how it will address the unmet need.
6. Brief summary of the project based on its current status.
7. Brief high-level overview of specific work to be supported with ODAT funding (up to $50,000 direct for one year)
8. Whether the project has been disclosed to the UMN Technology Commercialization office and status of the intellectual property (if applicable).

LOIs must be submitted through the following link:
https://redcap.ahc.umn.edu/surveys/?s=KRYH74RMHF
*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.

LOIs will be screened for eligibility and reviewed by the ODAT Program Committee. Applicants will be notified of the review decision no later than January 17, 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 (if applicable)
7. Technology marketing and licensing (if applicable)
8. Strategic partnerships
9. Team roles and responsibilities
10. Project timeline
11. Budget overview
12. Biosketches
13. 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 whose proposals receive the highest scores 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 therapeutic meet a specific need that does not have an adequate solution on the market?
2. *Impact:* Does the proposed therapeutic 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)?

Funding Period Expectations

Grantees will agree to periodic check-ins with ODAT 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 product development will be tracked following the conclusion of funding.

Program Contact Information

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