REQUEST FOR APPLICATIONS (RFA)

MSCRF Validation Program

INTRODUCTION:

Stem cell research offers extraordinary promise for new medical therapies and a better understanding of debilitating human diseases, injuries and conditions. The development of new medical strategies for the prevention, diagnosis, treatment and cure of human diseases, injuries and conditions through human stem cell research is a high priority for the State of Maryland.

FUNDING OBJECTIVES

The Maryland Stem Cell Research Fund (MSCRF) Validation Program was created to foster the transition of promising stem cell technologies having significant commercial potential from universities and research labs where they were discovered, to the commercial sector, where they can be developed into products and services that meet identified market needs. Specifically, it is the intent of the Validation Program to foster the commercialization of such technologies through technology validation, market assessment, and towards the creation of university start-up companies in Maryland. It is also the intent of the Program to foster collaborations between various schools, departments, and institutions within research organizations in the State.

ELIGIBILITY INFORMATION

To be eligible for the Validation Program, the applicant must be a faculty member at a Maryland-based university or research institute (not a Federal Lab). Applications must be directed to the validation of a technology or group of technologies: (i) owned by a university or a research institute; (ii) disclosed to a technology transfer office (TTO); (iii) for which there exists appropriate intellectual property protection; and (iv) the technology is not licensed to any entity.

AWARD INFORMATION

AVAILABLE FUNDS

The MSCRF is currently budgeted to commit up to $20.5 million, in aggregate, in FY 2023 to fund Grants under all of its RFAs. The number of Grants awarded will depend upon the quality, size and mix of Applications received.

AWARD SIZE, DURATION & TERMS

Subject to meeting the Program requirements, an award not to exceed $250,000 may be made for a project. Funded Projects must be completed within **24 months** of the date of execution of the award. **Applicants should not expect approvals of any no-cost extensions and should plan accordingly.**

The Program will allow universities to include facilities and administrative charges (i.e., indirect charges) of up to 15% of the primary budget of $230,000.

Up to an additional $10,000 of the Validation grant budget may be allocated by a qualifying university Tech Transfer Office (TTO) to pay for patent expenses related to the technology, which are incurred during the term of the award.

Up to an additional $10,000 may be requested for technical, commercialization, and regulatory assistance toward approval of a cell therapy product. Therefore, the **total maximum amount per award, including the patent costs and additional technical/regulatory assistance, is $250,000**.

Note that the optional additional budget line-item funds requested and approved toward patent costs and/or technical/regulatory assistance will need to be documented by the applicant and verified by MSCRF during the mid-term report.

Because the nature and scope of the proposed research will vary from Application to Application, the size and duration of Awards may also vary. Approved Projects may be funded at or below the requested/proposed amount, for a number or reasons, including potential reductions in State appropriations or funding otherwise available to MSCRF.

Project funding will be subject to the successful completion of a number of proposed project milestones. Applicants should be aware that project funding could be terminated at any point during the project if early project data suggests that the technology will not be sufficient for the intended commercial application or if the project is not reasonably progressing as originally proposed.

OVERVIEW AND PROGRAM DESCRIPTION:

Validation program builds on preliminary data demonstrating the utility of a technology for a specific commercial application. This is not new research. The technology must have appropriate intellectual property protection secured by the applicant institution.

A final report will be the deliverable for this component of the Validation Program.

BEYOND VALIDATION PROGRAM FUNDING

The goal of the MSCRF Programs is to move technologies from the successful validation stage to the commercial sector via a license to a (a) University Start-up company located in Maryland or (b) another company outside of the state. To this end, investigators who have successfully achieved specified Validation Program project milestones and submitted their final report are encouraged to work toward the creation of a start-up company and to have that company apply for funding for Early-stage Development by submitting a Commercialization Program Application.

Validation Program Awards will be made in the form of a grant.

CONTENT & FORMAT OF APPLICATION

All Sections of the Application must be submitted through the TEDCO online submission system. The document must be formatted using point size 12 Arial font, with margins no smaller than one-half (0.5) inch on all sides. Uploaded file must be limited to 80 megabytes (MB).

University applicants must obtain approval from their research/grants administration office before submitting an application. Please attach letter or evidence of such approval along with the uploaded application.

APPLICATION COMPONENTS

The intent of the application is to provide enough information so a group of reviewers can sufficiently evaluate the commercialization potential of a technology and the value of the proposed project in advancing the technology toward commercialization.

Validation Program applications must include all of the following sections and address *EACH* of the criteria bulleted under the sections (Sections B through E should be limited to 10 pages):

A. Cover page. The applicant must include:

- The name of the Applicant/PI and University/Research Lab that is applying for funding and owns the Technology.
- The total amount of funding requested including indirect costs.
- Title of the Project.
- Short (300 words) abstract.

B. Technology Description, Status, and Intellectual Property.

- A detailed description of the associated Technology should be provided. The description should focus on how the Technology is unique/novel in its approach to solve an important problem relative to other approaches in the scientific literature and other products.
- Describe the status of the Technology's development – describe the studies completed and the conclusions derived (to support how unique your technology/idea is; can be previously published data).
- Any preliminary data or other results supporting that the Technology is likely to work as predicted should be included.
- Describe the intellectual property secured for the Technology and strategies for strengthening the Technology's intellectual property portfolio, including a brief summary of the intellectual property landscape (e.g., the results of a patent search including a description of the closest prior art) should also be included.

C. Application of Technology as a Product/Market Assessment.

- Describe potential products or services that could be based on the technology.
- Describe how these products will solve a problem in the market and describe the overall importance of solving that problem.
- Include a description of the value that these products will bring to customers – cost savings, time savings, convenience, improved outcomes, etc.
- Outline a general description of the applicant's competitive advantages over competing products and services.

D. Commercialization Pathway and Risk Assessment.

- Provide a detailed overview of the overall steps/milestones needed to commercialize the Technology (during and **beyond** the MSCRF funding) including how long it will take and how much it will cost to achieve each milestone.
- Describe the general approach and rationale for commercialization – licensing or start-up. In either case, identify potential commercial partners and the level of interest those partners have in the technology, if any (**it is recommended to provide support letters**).
- The major risks of failure (beyond the proposed MSCRF project, e.g., technology risk, market risk, etc.) should also be described along with the applicant's plans to manage that risk, i.e., what would be done if the proposed commercialization approach was not successful.

E. Project Description, Milestones, and Detailed Budget/Justification.

- Include a detailed summary of the proposed MSCRF project and the anticipated milestones and a clear timeline (**remember, this is not discovery – this is validating your findings and the market**). Indicate which milestones will be completed by the applicant's mid-term presentation (about 9 months into the project) and throughout.
- A description of the Research Strategy and Design, Data in support of the Proposal (preliminary data if applicable), Significance, Specific Aims, Rationale, Approach and Innovation.
- Describe how each of the milestones leads to a clear demonstration or validation of the technology for the proposed commercial purpose and/or significantly advances the technology along the commercialization pathway. Milestones must be quantifiable and measurable so it will be obvious when they have been successfully, or unsuccessfully, met.
- A detailed budget of the costs required to conduct the project should be provided in the general format provided below.
- A justification for all of the project costs should be provided. Any changes to the approved budget (greater than +\- 10%) must be submitted in writing to MSCRF for approval prior to the completion date.
- International travel is not an eligible expense. Domestic travel will be closely scrutinized and must be justified as critical to the project.

The Validation program budget should be formatted in tabular form, and each line item should be classified into one of the following categories: Personnel – Salaries, Personnel- Fringe benefits, Equipment, Materials & Supplies, Contracts, Other Direct Costs, and Indirect Costs, which should be indicated in the budget. For the optional additional line-items of patent costs or technical/commercialization/regulatory assistance, further classifications may be provided.

F. Appendix - Additional 12 pages limit (upload in the same file as the application)

In addition, applications must include the following supplemental materials. These pages are counted as part of the maximum 22 pages total:

a. A signed letter from the University's technology transfer office indicating their approval of the project, certifying the Technology's disclosure reference number and the status of the intellectual property described in Section 'B.' of the Initial Application.
b. Recommendation/collaboration letters supporting and justifying the project and aims endpoints.
c. Biosketches of the team, limited to 2 pages each.
d. Supporting materials. Do not include information that should be in the 10-page limit of the proposal. References can be included here.

Web form Information

In addition, applicants must complete all the web form information in the online system as early as possible to avoid unexpected delays. This information include:

- A bioethics section (maximum 250 words)
- Impact on biotechnology in Maryland statement (maximum 250 words)
    - Briefly describe the potential of this application to impact the biotechnology sector in the state of Maryland. Some examples may include IP that may be licensed or lead to commercialization, existing or proposed collaborations, creation of new jobs, and workforce development.

Resubmissions

Response to Reviewer's Comments. In the event that an applicant's proposal is initially rejected and the applicant chooses to reapply for Program funding, the applicant must submit a written response to the reviewers' comments including how those comments were addressed in the resubmitted application. The Response to Reviewer's Comments may not exceed one (1) page and is not counted as part of the page count for the resubmitted application.

Include an *updated* letter from the Qualifying University's technology transfer office indicating any current activity or updates to tech transfer activities.

APPLICATION AND SUBMISSION INFORMATION

Application information will be available electronically on the MSCRF Web site (see www.mscrf.org).

SUBMISSION DEADLINES & REVIEW DATES

Application Submission Deadline: January 19, 2023, by 5:00 p.m.
Peer Review Date(s): March 2023
Commission Review Date(s): May 2023
Earliest Anticipated Start Date: June 2023

METHODS OF SUBMISSION

Grant Application

Principal Investigators must register in the TEDCO online submission system at least one month before the Application Submission Deadline. Grant Applications must be submitted through the TEDCO online submission system by January 19, 2023, no later than 5:00 p.m.

REVIEW INFORMATION

REVIEW PROCESS:

All applications for Validation Program awards will be initially reviewed to ensure that they meet the minimum requirements, as specified in this RFA (the "Compliance Review"). Applications not meeting the minimum requirements will be rejected without further consideration and the applicant will be so notified.

A complete submission (all sections) cannot exceed a total of 22 pages or it will be rejected without consideration.

Application Review Process

Following the Compliance Review, all Applications will be assigned by the MSCRF SRO to a number of reviewers for review and preliminary scoring. All Applications, receiving average scores above a threshold determined by the Program will be brought to the full MSCRF Review Committee.

The MSCRF may bring Applications scoring below the threshold to the Review Meeting under special circumstances, which shall be determined as the sole discretion of the Program. All Applications will be ranked according to their final scores and the top scoring applications will be recommended to the Commission, which will have the final authority to approve funding.

The MSCRF Review Committee will consist of representatives of the research, business and investor community and are all from outside of the state of Maryland. Each applicant will receive a copy of the reviewer comments and scores at the end of the process, whether the applicant is approved or declined.

REVIEW CRITERIA:

Applicants will be evaluated on each section of their proposal and the applicant's ability to address each criterion listed in the section. **Consideration will be based on how completely the applicant has provided information requested for the section and how convincingly the applicant has made a case for the opportunity based on the subject Technology.**

Other criteria that will be considered by the reviewers are: the novelty of the Technology and the approach to solving a problem (meeting a market need), the strength of the Technology's competitive advantage (intellectual property position), the likelihood that a University Start-up will be created based on the Technology, the market/commercialization opportunity represented by the project, and the team's ability to carry out the project. Be sure to address the following areas:

- **Significance:** Does this Project address an important scientific problem, relevant to human stem cells? What is the relationship between the proposed project and the etiology, prevention, diagnosis or treatment of human diseases or conditions? If the aims of the Application are achieved, how will this move you closer to commercial or clinical practice and treatment of human diseases or conditions?

- **Approach:** Is there adequate preliminary data to support the Validation Project? Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well-reasoned and appropriate to the aims of the Project? Is relevant literature appropriately referenced? Are anticipated results discussed and justified? Does the Applicant acknowledge potential problem areas and consider alternative tactics? Are the experiments as designed likely to significantly advance the technology?

- **Translation Potential and Plan**: Does the Application include strong interactions to commercial or clinical components? Is there a clear plan for translating results to the commercial market? Will the Project lead to new medical therapies or test new therapies in patients?

- **Bioethics:** Does the proposed project use adult, embryonic, iPS or other human stem cell lines? If an existing line is to be used, what are the justifications for that line? If human donors are involved, have they been properly consented? If human subjects are involved, what protections will be in place to ensure their rights and welfare? If animal subjects are to be used, what measures are taken to comply with IACUC guidelines?

SCORING:

The Scientific Peer Review Committee will review all Applications and rank them based on scientific merit. Similar to the NIH scoring system of 1-9 will be used to rate the overall impact/priority of the proposed research. In this system, "1" indicates the highest impact/priority and "9" indicates the lowest impact/priority.

Applicants Selected for Review: All Validation applicants who score high enough preliminary score will move on to the full committee review and will be required to present **in person** at the MSCRF Review Meetings.

- The PI listed on the Validation Application must plan to present on the stated review dates. Other team members may attend; however, the PI must attend.

- All presentations will be scheduled as part of standing MSCRF review days listed below. Due to the number of applications on any given review day, presentation times will be assigned by MSCRF.
- The PI will need to hold the review day open until the time is assigned. This may be confirmed as close as a week before the review day, so PI's will need to remain flexible during this process.
- The Validation applicant will be allotted a 10-minute timed presentation, followed by up to 20 minutes for Q&A. We **recommended no more than 10 slides**. Following are the required slides for the presentation:

    - Title slide
    - What is the Problem, Significance?
    - What is the Solution, Approach?
        - Technology Outline
        - Intellectual Property
    - Target Market?
        - Segmentation Analysis
        - Competition
    - Project Description, Milestones
    - Detailed Budget/Justification?
        - Cost Projections
        - Financing Needed for the MSCRF Project?
        - Follow-on Financing for the Next Steps, Beyond MSCRF?
    - Translation Potential and Plan
        - Timeline and Costs
        - Risks and Mitigation Plan
    - Team
        - Current team?
        - Partners?
        - Advisors?

After presentation of the preliminary scores and discussion of applications at the MSCRF Review Committee Meeting, applications will receive a final score based on an average of all the overall scores provided by the MSCRF Review Committee Members.

Applications will be ranked by average final score and submitted to the Commission for review and final approval.

The Commission reserves the right to pursue collaborative funding arrangements with third parties and, in such an event, the further right to share the application materials and/or the review summaries with those potential co-funders upon the execution of a Confidentiality Agreement restricting their further disclosure.

AWARD ADMINISTRATION INFORMATION

NOTIFICATION

The PI's affiliate organization will be notified electronically when the Application is received. A formal notification, in the form of a Notice of Award ("NOA"), signed by the MSCRF Executive Director, will be sent via email to successful Applicants.

CLOSING AND AWARD PAYMENTS:

Once the proper approval for a project has been obtained, Applicants will be asked to execute an agreement and **the Principal Investigator will be asked to immediately start working on the Project**. The agreement will detail the conditions of the award and it will include an agreed upon number of mid-term and final milestones for each project and the dates that Mid-term and final project reports (as described below) are due.

All PIs are expected to present in person for the mid-term review. (Details will be sent approximately one month prior to the mid-term of the project, based on the date of the executed agreement.) All PIs should know the start date (the signed agreement date) of their MSCRF Project, as well as the end date.

Award payments for Validation projects will be made as follows: 25% following execution of the grant agreement and compliance documents (i.e., IRB, IACUC, SCRO), 50% upon submission and approval of a Mid-term Report and the successful completion of approved milestones, and 25% upon submission and approval of a Final Report.

In all cases, any unused funds must be returned to TEDCO serving in its capacity as the administrator of the Program.

POST AWARD REPORTING

Validation Program awardees must submit the following reports to the MSCRF Program including:

a. **Award Manager Meeting** – each applicant is required to meet with the MSCRF Award Manager at least once, prior to the mid-term. This is to assist each awardee in understanding and meeting expectations for the program. This is also an opportunity for the awardee to share feedback, discuss ideas and ask for additional assistance.
b. **Mid-Project Reports**, (PowerPoint presentation to MSCRF) which must include a description of project activities and results to date, the progress toward meeting mid-term milestones, an accounting of expenditures charged to the award, and details on the proposed Commercialization Plan and budget;
c. **Final Report -** Within forty-five (45) days after the end of the overall Grant period, PIs must file their Final Reports, describing the research conducted and the results of this research. This Final Report shall include:
    i. **Project report**, which must provide an overview of all activities undertaken during the course of the funded project, a description of the results of the project, the impact on commercialization, the success with achieving the proposed milestones, a full accounting of all expenditures charged to the award in a tabular format signed by the financial officer, and a formal closeout letter prepared and signed by the ORA office.
    ii. **Commercialization Planning** Includes conducting a commercial opportunity and risk assessment for a Technology and developing and drafting a detailed commercialization and go-to-market plan (**a specific deliverable for the Validation Program**) that includes a plan for the specific steps required to complete the development of a product, its manufacture, regulatory approvals, and its execution. The Commercialization Plan should include:

- A clear market assessment and marketing strategy;
- The team, and their biographical information;
- A viable revenue model; and
- A strategy for financing the plan.

MSCRF recognizes the challenges associated with developing a commercialization strategy for an early-stage technology and understands that any such strategy is likely to change during the course of development of a commercial product. Nevertheless, as a commercialization program, the goal of MSCRF is to ensure that there is at least one viable pathway toward commercialization for a technology and that such a pathway has been carefully considered and can be clearly described by the applicant.

The execution of any subcontracts and joint arrangements included as part of an application are ultimately the responsibility of the PI. Each entity involved in the proposed project set forth in the submitted application is expected to meet the timelines and milestones, as submitted by the PI, who will be held accountable as part of the mid-term and final report review.

d. **Symposium presentation** - The MSCRF may conduct an in-State Annual Symposium to report to the scientific community and the public the progress of the MSCRF program. All PIs must present, orally or in poster format, their on-going or completed MSCRF-funded research at each Annual Symposium, during and immediately following their Grant period.

AGENCY CONTACTS

Questions about this RFA must be submitted by email to: mscrfinfo@tedco.md. Telephone inquiries will not be accepted.