REQUEST FOR APPLICATIONS (RFA)

MSCRF Commercialization 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) Commercialization Program was created to foster the transition of promising technologies having significant commercial potential from universities, 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 Commercialization Program to foster the commercialization of such technologies through technology validation, market assessment, and the creation of university start-up companies in Maryland. A "University Start-up" is a company reliant on a technology licensed from a university for commencement of its operations.

ELIGIBILITY INFORMATION

Applicants for Commercialization Program must be a Start-up meeting the following criteria in order to be eligible for funding from the Program:

- The new start-up has licensed technology from a university or a research institute; if the technology has not yet been licensed, a fully executed license agreement will be required within 90 days of notification of the MSCRF award. (A copy of the license agreement will be required to receive any funds).
- An established company working on a new stem cell product or new stem cell technology that they developed or licensed in.

The company must be located in Maryland.

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, awards of up to $400,000, may be made directly to a start-up company.

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.

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.

OVERVIEW AND PROGRAM DESCRIPTION

Commercialization: Early-stage Development

"Early-stage Development" includes corporate product development in preparation for a product launch or the advancement of a product technology to achieve a commercial milestone that significantly increases the company's value and better positions the company for follow-on investment.

Commercialization awards are capped at $400,000. Commercialization projects, including all subcontracts, must be completed within 12 months of the date of the award.

All Commercialization applicants who are selected to move on to the full review committee will be required to present to the MSCRF Review Committee. See "Review Process" section for details.

Up to 10% of Commercialization awards may be used by Start-up Companies for overhead costs, provided that not more than 50% of such overhead costs (i.e., 5% of the award amount) may be used to pay the university for patent or licensing costs. Any domestic travel expenses must be detailed and justified and included as part of the 10% overhead portion of the budget. International travel is not allowed.

The execution of any subcontracts and joint arrangements included as part of an application are ultimately the responsibility of the Principal Investigator (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.
Commercialization awards will be made in the form a **grant**.

CONTENT & FORMAT OF APPLICATION

All Sections of the Application must be submitted through the TEDCO on-line 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).

APPLICATION COMPONENTS

The intent of the application is to provide enough information so a group of reviewers can sufficiently evaluate the commercialization and business potential of a technology start-up. The final document is limited to maximum of 15 pages including all sections (not including the pitch deck). Sections C-F are limited to 5 pages.

A. **Company pitch deck** - Not to exceed 10 slides.

B. **Cover page -** Header/Applicant Information. Application must include:

- Title of the Project
- The name and address of the company
- The name of a principal investigator who will be responsible for the project
- The total amount of funding requested
- Short (300 words) abstract

Applications must include all the following sections and address *EACH* of the criteria bulleted under the sections in either the pitch deck or the relevant sections (use the sections below to expand on, or refer to, the information provided in the pitch deck):

C. **Market Assessment, Technology Description, and Status of Product Development**

- A 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 commercial problem relative to other approaches in the scientific literature and other commercial products Describe the key differentiator of the company or technology and the proposed innovation's benefits to the customer.
- Describe the market and addressable market for the technology.
- Describe how these products will solve a problem in the market and the overall importance of solving that problem.
- Outline the competition and the applicant's competitive advantages over competing products and services.
- Describe potential commercial products or services that could be based on the technology.
- Describe how the market opportunity been validated. Describe your customers and the value that these products will bring to customers.
- Describe the status of the Technology's development
- Include any preliminary, pre-clinical, mechanism of action data or other data suggesting that the Technology is likely to work as predicted.

D. **Intellectual Property**

- Describe the intellectual property secured for the Technology and strategies for strengthening the Technology's intellectual property portfolio
- A brief summary of the intellectual property landscape (e.g., the results of a patent search) should also be included.

E. **Commercialization Pathway and Risk Assessment**

- Provide a detailed overview of the overall steps/milestones needed to commercialize the Technology (beyond the MSCRF funding) including timeline and cost to achieve each milestone.
- Describe your commercialization approach. Identify potential commercial partners and the level of interest those partners have in the technology, if any.
- Describe the key technical challenges and risks in bringing the innovation to market. 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 those risks, i.e., what would be done if the proposed commercialization approach was not successful.

F. **Project Description, Milestones, and Detailed Budget/Justification**

- Include a summary of the proposed MSCRF project and milestones and a clear timeline. Indicate which milestones will be completed by the applicant's mid-term presentation (6 months into the project).
- Describe how each of the milestones leads to clear development of technology and how it brings the product closer to the commercial market. 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.
- A 250-word Bioethics statement describing the ethical issues relevant to the proposed research and how these issues will be addressed, including, but not limited to, a discussion of the ethical issues related to the cell type(s) and cell line(s) to be used; animal welfare (i.e., IACUC); IRB review and related concerns regarding human subjects, if applicable.

G. Executive Summary - An executive summary of the Start-up Company's business plan must be submitted. This executive summary may include:

- A clear outline of the management team expected to execute the commercialization strategy and move the company forward (beyond MSCRF funding).
- A description of the key players, and the plan to build and attract talent to the management team.
- An outline of what specific role the inventor will play in the company moving forward.
- A detailed description of the market opportunity, including a segmentation analysis, and a description of the company's marketing strategy.
- An overview of the fundraising strategy.
- A description of the Company operations including marketing strategy, product development, manufacturing, and other operations should be provided.

Any changes to the approved budget (greater than 10%) must be submitted in writing to the 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. If submitted, domestic travel must be included as an Indirect Cost.

The project budget should be formatted in tabular form and justified, and each line item should be classified into one of the following categories: Personnel – Salaries, Personnel – Fringe Benefits, Equipment, Materials & Supplies, Other Direct Costs, and Indirect Costs, which should be indicated in the budget.

H. Appendix - Upload in the same file as the main application

In addition, applications must include the following supplemental materials. These pages are counted as part of the maximum 15 pages total:

a. A current signed letter from the University's technology transfer office (if licensed) indicating their approval of the project, certifying the Technology's disclosure reference number and the status of the intellectual property described in Section 'D.' of the Initial Application (including its license status for Commercialization projects).
b. Recommendation/collaboration letters.
c. Supporting materials. Do not include information that should be in the main proposal.

The Appendix may not be used to circumvent the length limitations of the application. Applications that are incomplete, do not meet the format and/or content requirements, exceed specified length limits, are non-responsive to this RFA or are from ineligible applicants will not be reviewed.

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 includes a bioethics section (maximum 250 words) as well as other information.

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, which is limited to five pages, as described above.

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 Commercialization Program awards will be initially reviewed by the MSCRF staff 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 15 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 at 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 commercial opportunity based on the subject Technology.

Other criteria that will be considered: For all applicants who have received prior funding, the reviewers will consider the outcomes of the prior awards, and the PI's ability to meet the stated timelines and execute on the plan. Moreover, the applicant's ability to meet the program requirements on a timely basis, including the milestones, mid-term reporting and final reporting (including accounting and budget submissions) will also be considered when reviewing applications.

- **Significance:** Does this Project address an important problem? Is it 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 Commercialization 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?

- **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. The Commission will then review the ranked Applications and will make the final funding decisions.

Companies Selected for Review: All Commercialization applicants who score high enough preliminary score will move on to the full committee review and will be required to present at the MSCRF Review Meetings.

- The PI and the CEO (if not the same person) listed on the Commercialization Application must plan to present on the stated review dates. Other team members may attend; however, the PI and CEO 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 Commercialization company applicant will be allotted a 20-minute timed presentation, followed by 20 minutes for Q&A. The following information must be included in the presentation:

    - What is the Problem?
    - What is the Solution?
        - Technology Outline
        - Intellectual Property
    - Target Market?
        - Segmentation Analysis
        - Target Customer Profile
    - Product Development Process
        - Timeline and Costs
        - Risks and Mitigation Plan
        - Competition
    - Go-To-Market Strategy?
        - Partnering? Production? Marketing? Distribution?
        - Sales?
    - Finances
        - Revenue and Cost Projections
        - Financing Needed for the MSCRF Project?
        - Follow-on Financing for the Next Steps, Beyond MSCRF?
    - Management Team
        - Advisors? Board of Directors?

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 Programmatic 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 PI 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.

Award payments for Commercialization projects will be made as follows: 25% following execution of the agreement, 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

Commercialization 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 Reports**, which must provide an overview of all activities undertaking 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, jobs created, follow-on-funds raised during the project, 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.
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.