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. Developing 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 AND PROGRAM OVERVIEW

The Maryland Stem Cell Research Fund (MSCRF) Commercialization Program was created to support translational activities necessary to advance technologies with significant commercial potential to a clinical-stage or to market, whether such technologies are a potential stem cell-based -therapeutic, diagnostic, or tool to market-. Specifically, it is the intent of the Commercialization Program to foster the commercialization of such technologies being developed by Maryland-based companies.

It is also the intent of the Program to foster collaborations between the private and public sectors. With the strategic goal to enhance collaboration between research institutions and businesses in Maryland, the program provides an opportunity to access supplementary funding ("Second-tier Funding") for advancing technology development in cases where there is potential for collaboration between n research institution and a commercial entity. To access the Second-tier Funding, the applicant must establish a collaborative relationship with a Maryland-based research institution through which specific research activities integral to the research project will be conducted in the research institution.

Important note: Revised and improved RFAs.

Funding applications have been modified to include revised and/or new submission fields. Please peruse the recently revised RFAs to be appropriately informed of the changes to prevent delays in the application submission process.

ELIGIBILITY INFORMATION

To be eligible for funding through the Commercialization Program, the applicant must meet specific criteria:

1. A startup company based in Maryland that must have secured the underlying Intellectual Property (IP) in the company directed to the technology proposed in the application for the Commercialization Program. The company must provide a copy of the IP transfer agreement documenting that the company has secured such IP rights from the owner of the IP. If the Company is in negotiations with the IP owner for the transfer of such IP to the company at the time of application submission, the company must provide written evidence along with a copy of the IP agreement draft that is being negotiated but, in any case, the company must provide a copy

of such IP agreement within 90 days of receiving notification of the MSCRF award, and in any case before the disbursement of any grant funds.

2. Alternatively, an established company based in Maryland may qualify if it is working on a regenerative medicine technology for which it owns the IP either through an acquisition of a third party that owns the IP or through exclusive rights to license such rights from a third party.
3. The technology to be commercialized must have initial proof-of-concept data that demonstrates the validation and commercial feasibility of the technology for further research and development.
4. The research proposal included in the application ("Research Project") must advance the technology toward clinical development/product launch.

The company (Applicant) must be based in Maryland. MSCRF reserves the right to require additional documentation for its presence and for its intention to remain in Maryland.

Each Application for the Commercialization Program shall have only one (1) Principal Investigator (PI), but may have multiple Co-PIs, Investigators, and/or collaborators. Applicant PIs may participate as Investigators or collaborators in any number of MSCRF-funded Projects in the same funding cycle.

Any one candidate may apply to the MSCRF as the PI for only one new Award in any given cycle. Individuals from under-represented minorities and individuals with disabilities are encouraged to apply.

Applicants who have received prior MSCRF funding may apply in a subsequent funding cycle on a similar or different topic, under the same or a different MSCRF funding mechanism.

AWARD INFORMATION

AVAILABLE FUNDS

The MSCRF is currently budgeted to commit up to $20.5 million, in aggregate, in FY 2024 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

Commercialization awards are capped at $400,000 unless the applicant proposes (and demonstrates a commitment to) a collaboration with a research institution in Maryland. Under those terms, an additional $100,000 (defined below as 'Second-tier Funding') may be requested for a total award of $500,000.

Commercialization projects, including all subcontracts, must be completed within 12 months of the date of the award.

Project funding will be subject to the successful completion of several Research Project milestones. Applicants should be aware that Research Project funding could be terminated at any point during the Research Project if early data suggests that the technology will not be sufficient for the intended commercial application or if the Research 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 Research Projects may be funded at or below the requested/proposed amount, for one or more reasons, including potential reductions in State appropriations or funding otherwise available to MSCRF.

Second-tier Funding: If the Applicant is engaged in negotiations with a research institution for the purpose of entering into a collaboration to further advance the development of the technology, an additional $100,000 (Second-tier Funding) may be available to the Applicant for a total award of $500,000.

For this purpose, the Applicant is required to furnish written documentation between the Applicant and the research institution confirming both parties' commitment to enter into a collaboration to conduct research activities outlined in the Application as part of the Research Project. Furthermore, the Applicant must submit in the Application a comprehensive research proposal, inclusive of milestones and

allocations, detailing the activities intended to be carried out with the Second-tier Funding. The Second-tier Funding will be disbursed, only if the successful Applicant has executed an MSCRF grant agreement and upon the execution of a collaboration agreement or a service agreement between the applicant and the research institution. defining the specific research activities to be conducted by each as a part of the Research Project.

Up to 10% of Commercialization awards may be used by the Applicant for overhead costs, including paying 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 expenses are not allowed.

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

Commercialization awards will be made in the form of a grant.

CONTENT & FORMAT OF APPLICATION

DEI Registration

Pursuant to its enabling legislation, TEDCO is required to foster inclusive and diverse entrepreneurship and innovation throughout Maryland. Accordingly, TEDCO is now collecting race, gender, and ethnicity data, to better understand the communities that are accessing MSCRF resources/funding. This data will not be accessible to MSCRF/TEDCO program/fund managers and will only be provided to them in an aggregated (anonymous) form. The data will not be used for funding consideration.

All Sections of the Application must be submitted through the MSCRF 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 files must be limited to 80 megabytes (MB). Applications not meeting the minimum requirements will be rejected without further consideration and the Applicant will be so notified.

APPLICATION COMPONENTS

The intent of the application is to provide enough information so a group of reviewers can sufficiently evaluate based on the scientific merit and the commercialization/business potential of the technology.

The final document, including all sections and appendices, is limited to a maximum of 26 pages (or a maximum of 30 pages if applying for Second-tier Funding). Sections B-H are limited to 15 pages.

A. **Cover page. One (1) page limit**. Application must include the following information:

- Title of the Research Project
- The name and address of the company
- The name of a Principal Investigator who will be responsible for the project
- The contact information of the CFO of the company
- The total amount of funding requested, broken down into direct and indirect costs
- Total amount of Second-Tier Funding requested (if eligible), broken down into direct and indirect costs.
- Short (300 words) non-confidential summary of the Research Project. If awarded, this information becomes public. Do not include any confidential or proprietary information.
- Impact Statement: 2-3 sentences on public health impact. If the project outcome will inform the development of a product that serves medically underserved communities or a rare disease, please also specify.

Applications must include all the following sections and address *EACH* of the criteria bulleted under the sections in the relevant sections.

B. **Technology Description, and Status of Research/ Product Development and Intellectual Property and Market assessment**

- 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 development status of the technology– summarize the research/product development studies completed to date, the conclusion derived and the rationale for the Research Project as the necessary next step for the advancement of Technology towards commercialization.
- Include a summary of any pertinent preliminary, pre-clinical, mechanism of action data or other supporting data suggesting the Technology is likely to work as predicted.
- 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 has been validated. Describe your customers and the value that these products will bring to customers.

C. **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.

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 timeline and cost to achieve each milestone.
- Summarize the capital raised through private equity, venture capital, grants, or other mechanisms and the financial needs with the plan to raise such capital for further development of the technology beyond MSCRF funding.
- Describe your commercialization approach. Identify potential commercial partners, and strategic partners including, but not limited to, investors and the level of interest those potential funders 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 Research 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.

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

- Include a summary of the Research Project and milestones tied to 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/if they have been successfully 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.
- Second-tier Funding: If applicable, up to an additional 4 pages (not to be counted toward the 15-page limit of the application) may be included to provide a description of each milestone and budget for the research/work to be performed with this additional funding.

F. Bioethics

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 Company's business plan must be submitted. This executive summary must 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 if it is spin-off company from a research institution in Maryland
- 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.

H. **Resubmissions** - **One (1) page limit**. In the event that an Applicant's proposal is initially rejected, and the Applicant chooses to reapply for 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 must not exceed one (1) page.

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 and supplies, Other Direct Costs, and Indirect Costs, which should be indicated in the budget.

I. **Appendix - Upload in the same file as the main application. Additional 10 pages**

In addition, applications must include the following supplemental materials. These pages are counted as part of the maximum 26 pages (or a maximum of 30 pages if applying for Second-tier Funding) 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. Biosketches of the PI and, if different, CEO, limited to 2 pages each.
d. Supporting materials. Do not include information that should be in the main proposal.
e. If applying for Second-tier Funding, documentation such as a copy of the Letter Agreement or Collaboration Agreement between the Applicant and the research institution in Maryland confirming the collaboration between the parties for the performance of the Research Project.

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 must include:

- Short (300 words) non-confidential summary of the Research Project. If awarded, this information becomes public. Do not include any confidential or proprietary information.

- 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.

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 22, 2024, by 5:00 p.m. EST
- **Presentation by the Applicant:** 1st week of April 2024
- **Commission Review and Announcement of Awards:** May 2024

Late submissions will not be considered, and the application will be withdrawn. Any sections or page that exceeds in words or length the limit stated in the RFA will not be reviewed. Do not use the appendix to circumvent any page limits either. Any such information provided will not be reviewed.

METHODS OF SUBMISSION

Applicant PIs are encouraged to register in the TEDCO online submission system at least one month before the Application Submission Deadline. Grant Applications must be submitted through the MSCRF online submission system by January 22, 2024, no later than 5:00 p.m. Late submissions will not be considered.

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 26 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 application and the applicant's ability to address *each criterion listed in the section*. Consideration will be based on how completely the applicant has provided the information requested for the section and how convincingly the applicant has made a case for the

commercial opportunity based on the subject technology**.** 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.

- **Technology Description, Status, and Intellectual Property:** Is there a detailed description of the associated Technology? The description should focus on how the Technology is unique/novel in its approach to solving an important commercial/clinical problem relative to other approaches in the scientific literature and other products. Is there a description of the status of the Technology's development -– including the studies completed and the conclusions derived? Are there any preliminary data or other results suggesting that the Technology is likely to work as predicted? Is there a description of the intellectual property secured for the Technology and strategies for strengthening the Technology's intellectual property portfolio? Is there a summary of the intellectual property landscape (e.g., the results of a patent search)?

- **Application of Technology as a Product/Market Assessment:** Were potential commercial products or services that could be based on the technology clearly described? Is there a description of how these products or services will solve a problem in the market and is there a description of the overall importance of solving those problems? Is there a description of the value that these products will bring to customers (lifesaving, cost savings, time savings, convenience, improved outcomes, etc.)? Is there a description of how the products will make it to market and a brief summary of the size of the market opportunity that they represent? Is there an outline or a general description of the technological competitive advantages over competing products, companies, and services?

- **Project Description, Milestones, and Detailed Budget/Justification:** Is there a detailed summary of the proposed project and the anticipated milestones? 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? Are potential problem areas and alternative approaches addressed? Are the experiments as designed likely to significantly advance the technology? Is there a description of 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, and is it justified? Are the milestones quantifiable and measurable for determination of success? Is a detailed budget of the costs required to conduct the project provided?

- **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?

In addition to the criteria above, ensure the following areas are addressed:

- **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?

SCORING

A Scientific Peer Review Committee will review all Applications and rank them based on scientific merit. Like the NIH, a 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 receive a 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. It is important to note that requests for virtual participation will not be considered.

- The applicant 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. 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 PIs will need to remain flexible during this process. **Applicant PI and CEO should plan for and secure the week of April 1st for the in-person presentation.**
- Company PI will be required to submit the presentation directed to the Research Project to MSCRF at mscrfinfo@tedcomd.com one week in advance of the meeting.
- Applicants will be allotted a 20-minute timed presentation, followed by 20 minutes for Q&A. The following information must be included in the presentation:
    - Technology
        - Describe the technology and its commercial applications
        - Summary of the development status of the technology
        - Intellectual Property on the technology: scope and status
        - Describe the Research Project if it is narrower in scope compared to the Technology
    - What is the Problem that the technology/Research Project addresses?
    - What is the Solution, and how does your technology provide the solution?
    - Target Market for your technology
        - Segmentation Analysis
        - Target Customer Profile
        - Competitive analysis
    - Product Development Process
        - Timeline and Costs associated with the Research Project
        - Risks and Mitigation Plan for the Research Project/technology
    - 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?
    - Second-tier Funding (if applicable):
        - Identify the research institution and the collaborator's name
        - Scope of the research work under the Research Project that will be performed at the research institution along with the budget.

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

Applications will be ranked by average final score and submitted for programmatic review, subsequent Commission review, and consideration for 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 Applicant 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

After receiving the Notice of Award (NOA), the Applicant will be required to submit various pre-closing legal documents, as determined by the Commission's General Counsel from the Office of the Attorney General. Once all pre-closing documents are received, reviewed and approved, the applicants will be asked to sign a Grant Agreement. This agreement will outline the terms and conditions of the award and specify the number of mid-term and final milestones for each project, along with the due dates for mid-term and final project reports (as described below).

Furthermore, the applicant must furnish specific regulatory compliance documents listed below before commencing the Research Project. Once these compliance documents are received and approved by MSCRF, the applicant's Principal Investigator (PI) must promptly initiate work on the Research Project

Regulatory Compliance Documents list:

- Institutional Review Board (IRB) approval or exemption, including the Applicant's name, project title (matching the title of the Award), and expiration date.
- Institutional Animal Care and Use Committee (IACUC) approval if animal work is to be conducted, including the Applicant's name, project title, and expiration date.
- Stem Cell Research Committee (SCRO) approval or exemption including the Applicant's name, project title, and expiration date if the research involves embryonic stem cells.

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 MSCRF.

POST AWARD REPORTING

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

a. **Award Manager Meeting** – Each Awardee is required to meet with the MSCRF Award Manager at least once, prior to the mid-term. This is to assist the 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** - A 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** - Final Reports are required to deliver a comprehensive and detailed account, meeting MSCRF's satisfaction, of all activities undertaken during the course of the funded Research Project, a description of the results of the Research Project, updates on IP status including details on any new patent filings and/or issued patents, 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 CEO.
d. **Symposium presentation** - The MSCRF may conduct an in-State Annual Symposium to report to the scientific community and the public on the progress of the MSCRF program. All PIs must present, orally or in poster format, their ongoing or completed MSCRF-funded research at each Annual Symposium, during and immediately following their Grant period.

AGENCY CONTACTS

Inquiries about this RFA must be submitted by email to: mscrfinfo@tedcomd.com