REQUEST FOR APPLICATIONS (RFA)

MSCRF Manufacturing Assistance Program

INTRODUCTION

Cell-based technologies 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. As treatments and cures advance to the clinic, manufacturing for cell therapies remains a key challenge in this growing industry.

FUNDING OBJECTIVES

The Maryland Stem Cell Research Fund (MSCRF) Manufacturing Assistance Program was created to provide initial resources to enable companies to advance GMP production of cell therapy products in the State of Maryland. This program will accelerate the timely and cost-effective manufacturing of cell-based products that meet identified market needs and will support and retain an advanced manufacturing workforce in Maryland.

ELIGIBILITY INFORMATION

The Manufacturing Assistance Program is open to companies located in Maryland. Organizations that meet the in-state eligibility requirements, and have the skills, experience, resources and support necessary to carry out the proposed research may apply for a Manufacturing Assistance Grant.
Program awardees must conduct all MSCRF-funded work in the State of Maryland.

The Manufacturing Assistance Program is for Maryland-based stem cell companies to build or acquire modular manufacturing facilities, prefabricated clean rooms, closed systems, or similar manufacturing platforms to enable GMP production of cell therapy products in Maryland.

All projects shall require, at a minimum, a 1:1 match of non-state money, with up to 24 months from the effective date of the award to make the funded manufacturing platform operational.

Each application for an award funded by the MSCRF shall have only one (1) PI, but may have multiple Co-PIs, Investigators and/or collaborators. PIs may participate as collaborators in any number of MSCRF-funded projects in the same funding cycle. However, they may apply to the MSCRF as the lead PI for only one new award in any given cycle.

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, funds of **up to $1,000,000** may be made under this Program directly to the Maryland-based company.

Project funding will be subject to the successful completion of a number of proposed project milestones. Proposed milestones should be tied to specific timelines and with justifiable use of budgeted funds. Applicants should be aware that project funding could be terminated at any point during the project if early manufacturing milestones suggest that the technology will not reasonably progress as originally proposed.

Because the nature and scope of the proposed manufacturing plan and product will vary between applications, the size and duration of awards may also vary, but may not exceed 24 months in duration. 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.

Manufacturing Assistance awards will be made in the form a **grant**. All projects shall require, at a minimum, a 1:1 match of non-state money, with up to 24 months from the effective date of the award to make the funded manufacturing platform operational.

The awards are capped at $1,000,000. The project, including all subcontracts, must be completed within 24 months of the date of the award. The execution of any subcontracts and joint arrangements included as part of an application are ultimately the responsibility of the awardee. 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.

The physical location of the manufacturing facility must be in the State of Maryland. If not provided in the application, the location must be reported to, and approved by, the MSCRF within 30 days of notification of award.

CONTENT & FORMAT OF APPLICATION

All sections of the application must be submitted through the TEDCO online submission system. The document must be formatted using 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 product, manufacturing, and business plan. The final document is limited to maximum of 15 pages including all sections (not including the pitch deck).

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

C. **Executive Summary –** Provide an executive summary. This executive summary may include:

- A clear outline of the management team expected to execute the manufacturing strategy and move the product forward (beyond MSCRF funding).
- A description of the key players, including external consultants.
- A description of the company operations including location and facilities, marketing strategy, product development, and other operations should be provided.
- A detailed description of the market opportunity, including a segmentation analysis.
- An overview of the fundraising strategy.

D. **Technology Description, Project Description and Milestones**

- Describe the technology/product to be manufactured. The description should include 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 current status of technology/product development (include any data suggesting that the technology is likely to work as predicted).
- Briefly describe of the intellectual property secured for the technology and strategies for strengthening the technology's intellectual property portfolio.
- Briefly describe addressable market, competition and competitive advantages.
- Describe the manufacturing plan including a description of system/components being acquired for manufacturing the cell therapy product. Address metrics such as performance, productivity, efficiency, acquisition costs, labor costs, time to market and data collection. Provide baselines/industry standards as applicable.
- Include a summary of the proposed MSCRF project tied to quantifiable milestones and a clear timeline. Indicate which milestones will be completed by the project's mid-term timepoint.
- Describe how the milestones leads to clear development of the technology and how it brings the product closer to the commercial market.
- Describe the commercialization approach.
- 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 will be done if the proposed manufacturing and commercialization approach is not successful.

- **Post-award Operational Plan:** describe the manufacturing plan following award completion. This section should address the amount of time the platform will be operational, type of product/s and its intended use (i.e., clinical trials, product offerings, etc.), follow-on investment, scale up/out, IND/BLA status (if applicable), and potential collaborations. Supplemental material to demonstrate product demand post-award, such as letters of intent from potential customers, plans for clinical trials, as well as the financial plan to support its operation should be included as applicable.

E. **Key Project Personnel** – If not already provided in other sections or pitch deck, please provide list of the names, affiliate organizations, and roles of all key personnel who contribute to the development or execution of the project in a substantive way.

F. **Budget & Budget Justification**

In preparing the budget section, please correlate the detailed budget to a specific and quantifiable set of milestones. It is recommended that milestones be equally spaced such that installments can be disbursed upon verification of completion of each set of milestones.

- A detailed budget of the costs required to conduct the project should be provided with justification. The project budget should be formatted in tabular form and justified, and each line item should be classified into categories such as: Personnel – Salaries, Personnel – Fringe Benefits, Equipment, Materials & Supplies, Other Direct Costs, and Indirect Costs. Applicants should request only the funds needed to complete the proposed project. Requests for less than the maximum allowable amount will not be considered as a weakness. Applicants must provide matching funds details in the budget.

- Any changes to the approved budget (greater than 10%) must be submitted in writing to the MSCRF for approval prior to the completion date.

G. **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 manufactured, and IRB approval and related concerns regarding human subjects, if applicable.

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

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

a. References
b. Recommendation/collaboration/contractor letters.
c. Other 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. This information may include bioethics section as well as impact on biotechnology in Maryland.

Applicants who are selected to move on to the full review committee may be required to present in person to the MSCRF Review Committee.

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
MD Stem Cell Research Commission (Commission) Review Date(s): May 2023
Earliest Anticipated Start Date: June 2023

METHODS OF SUBMISSION

Grant Application: Organizations are encouraged to register in the TEDCO online submission system early before the application submission deadline to avoid any technical issues with the submission process. Note that additional information is required in the online submission portal and that late submissions will not be accepted. 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 the Manufacturing Assistance Program 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.

APPLICATION REVIEW PROCESS

Following the Compliance Review, all applications will be assigned by the MSCRF Scientific Review Officer to several reviewers for review and preliminary scoring. All applications receiving average scores above a threshold as determined by the Program will be brought to the full MSCRF Review Committee.

The MSCRF may bring applicants who scored below the Program 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 communities 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. 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 manufacturing opportunity of 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 of the project**
- **Technology and status of development**
- **Manufacturing metrics such as:**

  - **Performance**: Measures of the characteristics of the entire system, its components, or the execution of a manufacturing task. Types of performance metrics include accuracy, capabilities, completeness, ergonomics, generalizability, quality, reconfigurability, success/error rate, and usability.

  - **Productivity**: The rate at which a manufacturing process is occurring, expressed in units (e.g., items, articles, batches) per time interval (e.g., minute, hour, day). Types of productivity metrics include defect rate, first time yield, and throughput rate.
  - **Efficiency**: The amount of time required to perform a manufacturing task, or the percentage of time spent in set-up, calibration, transition, production, etc., compared to total cycle time of a manufacturing process. Units for these metrics should be time intervals (e.g., minutes, hours, days). Types of efficiency metrics include performance time, set-up time, and touch time.
  - **Acquisition**: Cost for initial acquisition of the proposed system. Types of acquisition cost metrics include capital cost and implementation cost.
  - **Cost**: Costs, labor, and/or time measures associated with continued operation of the manufacturing process using the proposed system. Types of cost metrics include involved labor, operational cost, process cost, safety, training time, and return on investment.
  - **Timeline:** Estimated time for manufacturing facility/arrangement to be functional and any anticipated scale up or tech transfer.
  - **Data collection:** If applicable, description of any real-time data collection and analysis.

- **Bioethics**

SCORING

The Scientific Peer Review Committee will review all applications and rank them based on scientific merit. Similar to the NIH, a scoring system of 1-9 will be used to rate the overall impact/priority of the proposed project. 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.

Applicants Selected for Review: All applicants achieving a high enough preliminary score may move on to the full committee review and may be required to present in person at the MSCRF Review Meetings. If so required,

- The PI and the CEO (if not the same person) listed on the Manufacturing Assistance application must 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 little as a week before the review day, so PIs will need to remain flexible during this process.

- The applicant will be allotted a 15-minute timed presentation, followed by up to 20 minutes for Q&A. 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 midterm and final project reports (as described below) are due. In all cases, any unused funds must be returned to TEDCO serving in its capacity as the administrator of the Program.

POST AWARD REPORTING

To ensure each set of milestones is met, MSCRF staff may require an onsite visit prior to releasing an installment. At a minimum, the applicant must demonstrate that the proposed milestones were successfully met via a 'Request for Disbursement' form included as an exhibit to the Grant Agreement. Manufacturing Assistance Program awardees must submit the following reports to MSCRF:

a. **Midterm Progress Report**: At the midterm, the applicant must present their progress either in person, if an onsite meeting is requested by MSCRF, or virtually via a video conferencing platform. The progress report is 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 manufacturing plan and budget.

b. **Final Report**: The final report must provide an overview of all activities that were undertaken during the course of the funded project; a description of the results of the project; the impact on manufacturing; the success with achieving the proposed milestones; jobs created; follow-on-funds raised during the project; and full accounting of all expenditures charged to the award.

The final report must be submitted together with the financial statement and a formal close-out letter as a packet through the online application portal.