REQUEST FOR APPLICATIONS (RFA)

MSCRF Manufacturing Assistance Program

INTRODUCTION

Cell-based technologies offer 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 of 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. It is also the intent of the Program to foster collaborations between various schools, departments, and institutions within academic research organizations, and between public and private sectors.

Grants awarded under this RFA will fund projects involving human stem cells, stem cell derivatives (including extracellular vesicles and secretome), or other technologies enabling or supportive of human stem cells.

ELIGIBILITY INFORMATION

The Manufacturing Assistance Program is open to companies or organizations located in Maryland. Companies/Organizations that meet the eligibility requirements, and have the skills, experience, resources and support necessary to carry out the proposed research ("Research Project") may apply for a Manufacturing Assistance Grant.

Program awardees must conduct all MSCRF-funded work pertaining to the Research Project in the State of Maryland. MSCRF reserves the right to request additional documentation for its presence and for its intention to remain in Maryland.

The Manufacturing Assistance Program is for stem cell companies or organizations 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 Research 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 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.

Companies/Organizations owned by women, underrepresented minorities and individuals with disabilities are encouraged to participate in this program.

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.

ELIGIBLE RESEARCH AND CELL TYPES:

Only applications with a Research Project that include clearly defined and achievable milestones will be considered for review.

All research funded by the MSCRF must involve human stem cells or their derivatives. All types of human stem cells, as defined in the Stem Cell Act, are eligible without preference. The Stem Cell Act defines eligible human stem cells as follows: A human cell that has the ability to: (1) divide indefinitely; (2) give rise to many other types of specialized cells; and (3) give rise to new stem cells with identical potential. The full text of the Stem Cell Act is available on the MSCRF Web site (see www.MSCRF.org).

AWARD INFORMATION

AVAILABLE FUNDS

The MSCRF is currently budgeted to commit up to $16.05 million, in aggregate, in FY 2027 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 company/organization.

Research Project funding will be subject to the successful completion of a number of proposed Research Project milestones. The Manufacturing Assistance Program is a reimbursable grant, and as such, proposed milestones should be tied to specific timelines with justifiable use of budgeted funds. Payments will be disbursed at the completion of each milestone upon proof of proposed expenditures (e.g., receipts). 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 applications may be funded at or below the requested/proposed amount, for a number of reasons, including potential reductions in State appropriations or funding otherwise available to MSCRF.

Manufacturing Assistance awards will be made in the form of 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 Research 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.

APPLICATION INFORMATION

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.

CONTENT & FORMAT OF APPLICATION

All Sections of the application must be submitted through the MSCRF submission site. The document must be formatted using point size 12 Arial font with margins no smaller than one-half (0.5) inch on all sides and uploaded in a PDF format using the instructions in the portal. The applications not meeting the minimum requirements will be rejected without further consideration and the Applicant will be so notified. Information or documents submitted after the Application Submission Deadline will not be accepted, included, or considered in the review of the application.

APPLICATION COMPONENTS

The intent of the application is to provide enough information so a panel of reviewers can effectively evaluate the scientific merit of the Research Project, the product/process outlined in the Research Project, its manufacturing, and the business plan of the Organization/Company pertaining to the product/process included in the Research Project. Application must include the following information:

Section I. Title of the Research Project

Section II. Web form Questions: Applicant must respond to the following questions:

- New application or resubmission and the prior application number (s) for prior MSCRF applications
- Proposed period of performance for the Research Project
- The total amount of funding requested, broken down into direct and indirect costs.
- IP status- whether there is a pending or issued patent application (s) directed to the Research Project
- Type of stem cell type that will be used for Research Project
- List the disease indication and disease category for the Research Project
- List Keywords for the Research Project (100 characters limit)
- Short non-confidential summary of the Research Project. If awarded, this information becomes public. Do not include any confidential or proprietary information. (1800 characters limit)

- Public Health Impact Statement: 2-3 sentences on public health impact. If the Research Project outcome will inform the development of a product that serves medically underserved communities or a rare disease, please also specify. (500 characters limit)
- 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. (1800 characters limit)
- Impact on Biotechnology in Maryland. 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. (1800 characters limit)
- PI Areas of scientific expertise (100 characters limit)
- PI Primary research focus (500 characters limit)
- Areas of potential collaboration that the PI is seeking (500 characters limit)
- Indicate the PI's previous experience as an MSCRF applicant and provide the application number if previously funded.
- Enter the URL address of your laboratory/company website.

Section III. Attachments: Ensure strict adherence to the page limits. Incompliance with the application requirements will result in disqualification.

1. **Technology Description, Project Description, and Milestones - Limited to twelve (12) pages.**
   - Describe the technology, its scientific basis, and the product to be manufactured. The description should include how the technology is unique/novel in its approach to solving 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). Summarize the research/product development studies completed to date, the conclusion derived and the rationale for the Research Project as the necessary step for the advancement of the technology towards commercialization.
   - Include a summary of any pertinent data suggesting the technology is likely to work as predicted.
   - Briefly describe 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 and budget attributable to achieving each milestone. Indicate which milestones will be completed by the project's mid-term timepoint.
   - Describe how the milestones lead 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.

2. **Executive Summary - Limited to two (2) pages.** Provide an executive summary. This executive summary must 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.

3. **Resubmission - Limited to two (2) pages.** If an applicant PI's proposal is initially rejected, and the applicant PI chooses to reapply for the Program funding, the Applicant PI must submit a written response to the reviewers' comments including how those comments were addressed in the resubmitted application. Please include an introduction to the revised Application, including the Application Number of the previous MSCRF submission, and a point-by-point response to the prior scientific review.

4. **Key Research Project Personnel - Limited to two (2) pages.** If not already provided in other sections please provide a list of the names, affiliate organizations, and roles of all key personnel who contribute to the development or execution of the Research Project in a substantive way.

5. **Bioethics**: A detailed bioethics section describing the ethical issues relevant to the proposed Research Project and how these issues will be addressed, including:
   - Cell lines and ISCRO review
     - Does the proposed project use adult, embryonic, iPS or other human stem cell lines?
     - If human embryonic stem cells are involved, has the Proposal been approved by an ESCRO/SCRO Committee?
     - If an existing stem cell line is to be used, what are the justifications for that line?
     - From where will they be obtained (e.g., commercial source, laboratory and under what protocol or with what institutional approval)?
     - If new lines are to be created, what measures will be taken to comply with the Stem Cell Act, as well as existing stem cell research bioethics guidelines?
     - If human donors are involved, have they been properly consented?
     - Has an ISCRO reviewed and approved the proposed research?

   - Human subjects and IRB review
     - Will human subjects be enrolled in the proposed research?
     - If human subjects are involved, what protections will be in place to ensure their rights and welfare?
     - Has IRB approval or exemption been obtained for the proposed research, or will it be?

- Nonhuman animals and IACUC review
  - Will nonhuman animals be used in the proposed research?
  - If so, what type/model will be used, sex, and what is the justification?
  - How many? What is the justification for the number to be used?
  - Has IACUC approval been received, or will it be?
  - What measures will be taken to comply with IACUC guidelines?

6. **Supporting Literature - Limited to three (3) pages.** Provide a list of scientific Literature in support of the Research Project.

7. **Biosketches**: Do not exceed five (5) pages for the PI and two (2) pages each for other key Research Project personnel. NIH biosketch format is permitted as long as it meets the above page requirements.

8. **Other Support**: List Other Support for the PI, including both current and pending support as described in the instructions.

9. **Statement of Work (SoW) - Limited to one (1) page.** Applicants must use the provided template to prepare a Statement of Work that defines the project's period of performance, overall objective and scope, and the specific aims or tasks, key activities/milestones, target completion date, and measurable success criteria for each milestone. Such information is required only for each significant developmental milestone rather than for every aim listed in the application. Milestones and deliverables should be concise, measurable, and consistent with the proposed project timeline and budget.

10. **Budget & Budget Justification:** A detailed budget of the costs required to conduct the project should be provided in the general format provided in the application portal. In preparing the budget section, please correlate the detailed budget to a specific and quantifiable set of milestones. **The Manufacturing Assistance Program is a reimbursable grant, and as such, proposed milestones should be tied to specific timelines with justifiable use of budgeted funds.** Payments will be disbursed at the completion of each milestone upon proof of proposed expenditures (e.g., receipts). It is recommended that milestones be equally spaced such that installments can be disbursed upon verification of completion of each set of milestones. Applicants should request only the funds needed to complete the Research 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. MSCRF funds must not be used to cover personnel costs of Investigators who are located and/or conduct the work outside the State of Maryland.

    Up to 10% of Manufacturing Assistance awards may be used for indirect costs. Expenses for domestic travel are capped at $5000. International travel is not an allowable expense.

    Applicants are advised that requested salaries should not exceed fifty percent (50%) of the total project budget. Budgets should be planned accordingly.

    All expenses directed to the Research Project should adhere to the specific line items listed in the proposal. Any budget changes or reallocation of funds between budget categories over 10% of the overall budget must be approved by MSCRF **prior to** reallocation.

11. **Appendix: Collaborator/Recommendation/Support Letters.** Limited to one (1) page per letter. The PI should include Letters of Collaboration/Recommendation, if applicable.

12. **Appendix: Other supporting materials**. This section may not be used to circumvent the length limitations of the Application. Do not include information that should be in the main proposal application. Compile all supporting documents into a single PDF file. Do not include information that should be in the main proposal.

13. **Photo:** Upload a headshot photo of the PI for publishing on the MSCRF website if awarded.

Notes:

- 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.

- University Applicant PIs must obtain approval from their research/grants administration office before submitting an application.

- Prior to submission, compile all documents into a single PDF file using the template provided in the applicant portal.

SUBMISSION INFORMATION

SUBMISSION DEADLINES & REVIEW DATES

- **Application Submission Deadline**: January 20, 2027, by 5:00 p.m. EST

- **Peer review date(s) and presentation by the Applicant:** Week of April 4, 2027

- **Commission Review and Announcement of Awards:** May 2027

METHODS OF SUBMISSION

The MSCRF online submission system is now open for application submissions. Applicant PIs are encouraged to submit their application at least one week before the Application Submission Deadline. The Grant Application must be submitted by **January 20, 2027, no later than 5:00 p.m. EST**. **Late submissions will not be considered.** Applicants are advised to submit well in advance of the deadline, as technical support cannot be guaranteed for issues encountered on the submission date.

REVIEW INFORMATION

ELIGIBILITY AND COMPLIANCE REVIEW:

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 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 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 listed under the application components and the applicant's ability to address each criterion listed in those sections. 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.

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.

To receive a high scientific priority score, Applicants are encouraged to address the following categories:

Significance of Manufacturing Assistance Project

- Does the proposed manufacturing assistance project hold significant potential for accelerating the timely and cost- effective manufacturing of cell-based products, meeting identified market needs, and supporting and retaining an advanced manufacturing workforce in Maryland?
- Is the project technology unique or novel in its approach to solving an important commercial problem relative to other approaches in the scientific literature and commercial marketplace?

Technology Description, Project Description, and Milestones

- Was the technology, its scientific basis, and the product to be manufactured properly described? The description should include how the technology is unique/novel in its approach to solving an important commercial/manufacturing problem relative to other approaches in the scientific literature and other commercial products.
- Was the current status of technology/product development appropriately discussed?
- Is the technology to be manufactured or acquired adequately described and justified with reference to an addressable market and potential competitors?
- Does the application include an adequate description of project-relevant intellectual property?
- Are the project milestones sufficiently detailed and reasonable?
- Are quantifiable and measurable milestone metrics included for monitoring and evaluating progress?
- Was the time discussed? The estimated time for the manufacturing facility/arrangement to be functional and any anticipated scale up or tech transfer?
- Does the application adequately describe key technical challenges and risks in bringing the innovation to market, including risks of failure beyond the proposed MSCRF project period, as well as plans for managing those risks?
- Does the applicant adequately anticipate and address potential challenges and difficulties in meeting the proposed project milestones?
- Does the application include an adequately detailed description of the market opportunity, including a segmentation analysis?

Manufacturing Metrics

- Does the proposal provide adequately detailed metrics, such as performance, productivity, efficiency, acquisition costs, labor costs, time to market, and data collection, relative to recognized industry baseline and standards?

PERFORMANCE:

- Were measures of the characteristics of the entire system, components, or the execution of a manufacturing task included?
- Were types of performance metrics, including accuracy, capabilities, completeness, ergonomics, generalizability, quality, reconfigurability, success/error rate, and usability discussed?

PRODUCTIVITY:

- If applicable, was the rate at which the manufacturing process is occurring, expressed in units (e.g., items, articles, batches) per time interval (e.g., minute, hour, day) laid out? Types of productivity metrics include defect rate, first time yield, and throughput rate.

EFFICIENCY:

- Were any efficiency metrics discussed? 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.

DATA COLLECTION:

- If applicable, was a description of any real-time data collection and analysis provided?

Post-award Operational Plan

- Are the manufacturing plans for the post-award period adequately detailed and reasonable?
- Does the application adequately describe the amount of time the platform will be operational, the product types of their intended uses (e.g., clinical trials, product offerings, etc.), plans for follow-on investment, scale up/out, IND/BLA status (if applicable), and potential collaborations?
- Is supplemental information provided 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, as applicable?
- Does the proposal adequately describe the management team expected to execute the manufacturing strategy and move the product forward beyond the MSCRF funding period?
- Is the fundraising strategy overview adequately detailed and reasonable?

Key Project Personnel

- Are the key project personnel, including external consultants, adequately qualified and experienced for planning and successful execution of the proposed project?
- Does the research team bring complementary and integrated expertise to the Research Project?

Collaboration Plan (if applicable)

- If the proposed research involves collaboration(s) among scientists and/or clinicians from for-profit and/or not-for-profit organizations, is there a demonstrated commitment from each entity and a realistic management plan that addresses all potential obstacle (i.e., how the Company and collaborator(s) will communicate milestones to handle confidential information, use milestones to

determine resource re-allocation and Project re-direction, share data and resources, prepare required reports and handle geographic separation, if applicable)?

Environment (Resources and Facilities)

- Does the application present adequate details about the organization's operations, location(s), facilities, marketing strategy, product development history?
- Does the scientific environment in which the work will be conducted contribute to the probability of success?
- Do the proposed studies benefit from any unique features of the scientific environment or subject population?
- Do these studies employ useful collaborative arrangements involving on-site resources and personnel?
- Is the institutional support adequate?

Executive Summary of Company's Business Plan

- Is there a description of the key players, and the plan to build and attract talent to the management team?
- Is there an outline of what specific role the faculty will play in the company moving forward?
- Is there a detailed description of the market opportunity, including a segmentation analysis, and a description of the company's marketing strategy?
- Is there an overview of the fundraising strategy?
- Is there a description of the Company operations which should be provided?

Budget/Justification

- Is the budget request detailed, justified, and commensurate with proposed project milestones?
- Does the application budget include details about adequate matching funds?
- Is the cost for initial acquisition of the proposed system adequate?
- Are the costs of labor, and/or time measures associated with continued operation of the manufacturing process using the proposed system appropriate?
- Are the indirect costs appropriate (up to 10% of funds may be used)?
- Were any acquisition metrics discussed? The cost for initial acquisition of the proposed system. Types of acquisition cost metrics include capital cost and implementation cost.
- Was the cost of labor, and/or time measures associated with continued operation of the manufacturing process using the proposed system discussed? Types of cost metrics include involved labor, operational cost, process cost, safety, training time, and return on investment.
- Is there any budgetary overlap with active or pending support?

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 new lines are to be created, what measures will be taken to comply with the Stem Cell Act, as well as existing stem cell research bioethics guidelines?
- 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 human embryonic stem cells are involved, has the Proposal been approved by an ESCRO/SCRO Committee?
- If animal subjects are to be used, what measures are taken to comply with IACUC guidelines?

Impact on Biotechnology in Maryland

- What is the potential impact of the proposed research on the advancement of biotechnology in Maryland's academic, business and/or non-profit sector(s)?
- Will this Project help create new biotechnology jobs and grow Companies and/or program opportunities in Maryland?

Prior Submissions/Awards

- If this was a resubmission, was a written response to the previous reviewers' comments provided, including how those comments were addressed in the resubmitted application?
- If the work was previously funded by the MSCRF, in whole or in part:
    - Did the Investigator make significant scientific progress towards the goals of the previously funded research?
    - Were results of the previously funded Project reported in scientific publications and/or presented at conferences?
    - Did the previously funded research result in new collaborations, inventions or Project-generated resources or subsequent funding from non-MSCRF sources?

SCORING

The Scientific Peer Review Committee will review all applications and rank them. 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 Peer Review Meetings. Importantly, requests for virtual attendance will not be considered.

- The PI and the CEO (if not the same person) listed on the Manufacturing Assistance application must present in person 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 the 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. **Applicant PI should plan for and secure the week of April 4, 2027 for the in-person presentation. Virtual attendance will not be considered.**
- Company PI will be required to submit the presentation directed to the Research Project to MSCRF at least 48 hours in advance of the meeting.
- Each applicant will have **15 minutes to present, followed by a timed Q&A session**. The following information must be included in the presentation:
    - Title slide
    - What is the Problem, Significance?
    - What is the Solution, Approach?
        - Technology Outline
        - Intellectual Property - summary of the scope of the pending and issued claims, filing date and jurisdiction sought for intellectual property protection.

- Target Market?
  - Market Segmentation Analysis (Analysis of what group of consumers/patients your Technology/product will be targeted to)
  - Competition (competing products that are either in development and/or in market)
- Project Description, manufacturing plan, quantifiable milestones and a clear timeline Milestones
- Detailed Budget/Justification
  - Cost Projections
  - Financing Needed for the MSCRF Project
  - Follow-on Financing for the Next Steps, Beyond MSCRF
- Translation Potential and Commercialization approach
  - Timeline and Costs
  - Risks and Mitigation Plan
- Current team including Partners and Advisors
- Address any reviewers' critique provided on the application by MSCRF

- The applicant must thoughtfully address reviewers' comments in their presentation. Applicants are recommended to present no more than 10 slides.

After the 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

After receiving the Notice of Award (NOA), the Applicant will be required 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 that matches the award's title, and expiration date. In the event the title of the approved IACUC protocol is different, an official letter from an authorized IACUC representative must be furnished to indicate that the animal research to be conducted under the newly awarded MSCRF Research Project is covered under that IACUC protocol.
- Stem Cell Research Committee (SCRO) approval or exemption including the Applicant's name, project title that matches the award's title, and expiration date if the research involves embryonic stem cells. In the event the title of the SCRO approval/exemption is different, an official letter from an authorized SCRO representative must be furnished to indicate that the stem cell research to be conducted under the newly awarded MSCRF Research Project is covered under that SCRO approval/exemption.

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. **MSCRF Award Meeting** – Each awardee 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. The applicant can reach out to MSCRF staff at mscrfinfo@tedcomd.com email to schedule this meeting.

b. **Mid-Term Project Reports** – Each awardee is required to submit the mid-term project report ("Written Progress Report") on MSCRF portal, the link to which will be provided in advance of the submission date by MSCRF. The progress report must include a description of project activities and outcomes to date, progress toward meeting mid-term milestones, an accounting of expenditures charged to the award, and information on any deliverables, such as products, public presentations, publications, intellectual property, and follow-on funding. Additionally, each awardee must submit a PowerPoint presentation summarizing the Written Progress Report. After submitting the mid-term report and the PowerPoint presentation via the portal, MSCRF staff will schedule a meeting for the awardee to report on the progress made on the Research Project. The PI investigator must then meet with MSCRF staff to deliver a PowerPoint presentation summarizing the report's content and addressing any questions from the MSCRF team. This step is required prior to the approval of the report and the disbursement of funds.

c. **Final Reports -** Each awardee is required to submit the final report on MSCRF portal, the link to which will be provided in advance of the submission date by MSCRF. A final report 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 clinical outcome, the success with achieving the proposed milestones, jobs created/supported, information on any deliverables, such as products, public presentations, publications, intellectual property, follow-on funding table, and a full accounting of all expenditures charged to the award in a tabular format signed by the financial officer, as well as a formal closeout letter.

d. Symposium presentation - The MSCRF may conduct an in-State Annual Symposium or other related events 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 on-going or completed MSCRF-funded research at each Annual Symposium, during and immediately following their Grant period.

COMPLIANCE

A Principal Investigator not in compliance with the reporting obligations under the Manufacturing Assistance Research Grant shall not be eligible to apply for continued or subsequent MSCRF funding.

AGENCY CONTACTS

- Inquiries regarding this RFA or other programmatic matters should be submitted by email to: mscrfinfo@tedcomd.com

- Inquiries regarding technical assistance with the application and/or reporting portal should be submitted by email to: mscrfinfo@tedcomd.com