REQUEST FOR APPLICATIONS (RFA)

MSCRF Validation Program

INTRODUCTION:

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

FUNDING OBJECTIVES AND PROGRAM OVERVIEW

The Maryland Stem Cell Research Fund (MSCRF) Validation Program was created to foster the transition of promising stem cell technologies having significant commercial potential from universities and research labs where they were discovered, to the commercial sector, where they can be developed into products and services that meet identified market needs. The Validation Program is designed to promote the commercialization of stem cell-based technologies for unmet medical needs. This is achieved through validation, market assessment, and facilitating the licensing of technologies to a commercial entity.

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. With a strategic goal to enhance collaboration between academic institutions and businesses in Maryland, the program provides an opportunity to access supplementary funding ("Second-tier Funding") for advancing technology development, particularly in cases where there is potential for collaboration between an academic institution and a commercial entity.

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

ELIGIBILITY INFORMATION

To be eligible for the Validation Program, the applicant's PI must be a faculty member at a Maryland-based university or research institute (not a Federal Lab). Applications must advance the validation of technology:

a) that addresses an unmet medical need; and

b) that has been disclosed to the applicant's Technology Transfer Office (TTO), and for which there is at least one pending patent application or an issued patent that is owned by a university/research institute in Maryland, either solely or jointly with a third party; and

c) for which the underlying intellectual property is not currently optioned or licensed to a commercial entity; and

d) for which there is proof-of-concept data, but additional validation for commercial feasibility is required.

The applicant may collaborate on the research project proposed in the Application for the Validation Program ("Research Project") with any Maryland-based institution, including any federal laboratory in Maryland. In the event of a federal laboratory collaboration, a portion of the funds could be allocated to a federal laboratory for carrying out studies outlined in the Research Project, but the applicant must discuss the nature of collaboration with MSCRF team in advance to ensure that the program requirements are satisfactorily met.

Each Application for the Validation Program shall have only one (1) Principal Investigator (PI), but may have multiple Co-PIs, Investigators and/or collaborators. 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 $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

Under this RFA, the total primary budget may not exceed $250,000 per award for a maximum of 2 years duration.

Within the primary budget, Applicants can request up to$10,000 of the Validation grant budget to pay for patent expenses related to the technology, which are incurred by a qualifying university Technology Transfer Office (TTO) during the term of the award.

Within the primary budget, Applicants can request up to $10,000 may be requested for technical, commercialization, and regulatory assistance toward approval of a cell therapy product.
Funded Research Projects must be completed within **24 months** of the date of execution of the award. **Applicants should not expect approval of any no-cost extensions and should plan accordingly.**

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

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

Because the nature and scope of the proposed Research Project 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 a number or reasons, including but not limited to potential reductions in State appropriations or funding otherwise available to MSCRF.

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

Second-tier Funding: If the Technology Transfer Office (TTO) is in discussions with a potential commercial entity to further advance the Project/Technology and/or the underlying intellectual property towards commercialization through a collaboration, service, IP option, or IP licensing agreement, the award amount may be increased up to a maximum of $350,000 (referred to as "Second-tier Funding"). Second-tier Funding is designated for research activities within the State of Maryland, to be conducted at a business located in Maryland. The second-tier funding must be used exclusively at the Maryland-based commercial entity for the research work as outlined in the Application.

Applicant is required to furnish a letter of support/letter agreement, confirming the commercial entity's interest in advancing and commercializing the technology through the licensing of the technology and associated intellectual property. Furthermore, Applicant must submit a comprehensive research proposal, inclusive of milestones and budget allocations, detailing the activities intended to be carried out with the Second-tier Funding. The Second -tier funding will be disbursed upon signing of a legally enforceable agreement between the Grantee and its collaborator on the Project, which must be signed no later than 4 months from the effective date of the Award.

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

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 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 and uploaded in a PDF format using the instructions in the portal. 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, the commercialization potential of a technology, and the value of the proposed research project ("Research Project") in advancing the technology toward commercialization.

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 Research Project period of performance
- The total amount of funding requested, broken down into direct and indirect costs
- Total amount of Second-Tier Funding requested (if eligible)
- Whether the research is translational or basic
- 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)
- 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.

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

1. **Technology Description, Status, and Intellectual Property – Limited to seven (7) pages.**
   - Provide a detailed description of the Technology. The description should focus on how the Technology is unique/novel in its approach to solve an important problem relative to other approaches in the scientific literature and other products.
   - Describe the status of the Technology's development – summarize the studies completed and the conclusions derived (to support how unique your technology/idea is; can be previously published data).

- Provide the proof-of -concept data demonstrating the Technology is likely to work as predicted.
- Summarize the intellectual property secured for the Technology including the scope of the pending application(s) and/or issued patents, their title, filing date, and jurisdictions where such patent rights are sought. Also, summarize strategies for strengthening the Technology's intellectual property portfolio, including a brief summary of the intellectual property landscape (e.g., the results of a patent search including a description of the closest prior art) should also be included. Applicants should collaborate with TTO to gather this information.

2. **Application of Technology as a Product/Market Assessment, Commercial Relevance, and Competition – Limited to two (2) pages.**
   - Describe potential products or services that could be based on the Technology.
   - Describe how these products will solve a problem in the market and describe the overall importance of solving that problem.
   - Include a description of the value that these products will bring to customers – cost savings, time savings, convenience, improved outcomes, etc.
   - Outline a general description of the applicant's competitive advantages over competing products and services.

3. **Commercialization Strategy and Risk Assessment – Limited to two (2) pages.**
   - Provide a detailed overview of the strategy, overall steps/milestones needed to commercialize the Technology (during and **beyond** the MSCRF funding) including how long it will take and how much it will cost to achieve each milestone.
   - Describe the best approach and rationale for commercialization, whether through licensing to an established company or licensing to a newly formed spin-off for the Technology. Include details on the level of interest expressed by potential commercial collaborator(s) in the Technology (if available, provide supporting letters from commercial collaborator and/or investors). Applicants should collaborate with the Technology Transfer Office (TTO) to gather this information. To be eligible for Second-Tier Funding, the applicant must obtain a letter from the TTO confirming ongoing discussions with a commercial partner regarding the commercialization of the Technology (to be included in the Appendix)
   - Describe the major risks of failure (beyond the proposed Research Project, e.g., Technology risk, market risk, etc.), along with the applicant's plans to manage that risk, i.e., what would be done if the proposed commercialization approach was not successful.

4. **Research Project Description, Design, and Milestones – Limited to five (5) pages.**
   - Include a detailed summary of the Research Project and the anticipated milestones and a clear timeline (**remember, this is not Discovery – this is validating your findings for commercial feasibility**). Indicate which milestones will be completed by the applicant's mid-term presentation and throughout.
   - A description of the objectives of the Research Project, research strategy and design, initial Proof-of-concept data in support of the Research Project (Significance, Specific Aims, Rationale, and Approach).
   - Describe how each of the milestones leads to a clear demonstration or further validation of the technology for the proposed commercial purpose and/or significantly advances the Technology along the commercialization pathway. Milestones must be quantifiable and measurable so it will be clear whether or not they have been successfully met.

5. **Resources and Environment - Limited to one (1) page.**
   A description of the facilities in which the work will be conducted and how the scientific environment will contribute to the probability of success, especially such things as independent space, department support and institutional support, collaborative arrangements involving on-site resources.

6. **Data Sharing and Management Strategy – Limited to one (1) page.** Facilitating the sharing of data and insights resulting from MSCRF-funded projects is pivotal for propelling stem cell research and expediting patient treatments. MSCRF mandates awardees to create and implement a comprehensive Data Sharing and Management Strategy encompassing data handling, preservation, and accessible dissemination to the wider scientific community. Moreover, MSCRF enforces adherence to FAIR data principles and necessitates data sharing via recognized repositories like specialized NIH-supported repositories, generalist repositories, cloud platforms, and institutional repositories.

7. **Resubmissions - Limited to two (2) pages.** In the event that an Applicant PI's proposal is initially rejected, and the Applicant PI chooses to reapply for 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.

8. **Second-tier Funding – Limited to four (4) pages.** If applicable, provide a description of each milestone and budget for the research/work to be performed with this additional funding.

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 and Budget Justification:** A detailed budget of the costs required to conduct the project should be provided in the general template format available on the online submission portal. A justification for all of the project costs should be provided. If Second-tiered funding is requested, provide a description of each milestone and budget for the research/work to be performed with this additional funding in a separate table using the provided form. Provide a list of the names, affiliate organizations, and roles of all key personnel, in addition to the Applicant PI, who will contribute to the scientific development or execution of the Research Project in a substantive way and devote measurable effort (in person months) to the Research Project, whether or not salaries are requested. "Effort of zero person months" and "as needed" are not acceptable levels of involvement for key personnel.

    Up to 15% of Validation award may be used for indirect costs. Expenses for domestic travel are capped at $5000. International travel is not an allowable expense. All expenses directed to the Research Project should adhere to the specific line items listed in the proposal.
    Applicants are advised that requested salaries should not exceed fifty percent (50%) of the total project budget. Budgets should be planned accordingly.

    Any budget changes or reallocation of funds between budget categories over 10% of the overall budget must be approved by MSCRF **prior to** reallocation. In the event of remaining unspent funds

from one installment, a carryover request must be submitted to MSCRF for approval to carry the funds to the next installment with a justification of why the funds were not used and how they will be used in the next installment.

MSCRF funds may not be used to cover personnel costs of Investigators who are located and/or conduct the work outside the State of Maryland, regardless of whether such out-of-State Investigators are employed or retained by a Maryland-based or non-Maryland based organization. Applicants are permitted to include out-of-State Investigators and/or collaborators under the Launch Research Grant if they demonstrate that no MSCRF funds will be used to support work or personnel costs for the out-of-State Investigators.

11. **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?

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

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

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

15. **Appendix: Collaborator/Recommendation Letters. Limited to one (1) page per Collaborator**. The PI should include Letters of Collaboration, if applicable. A Letter of collaboration from each collaborator on university, institute, or company letterhead (i) agreeing to the proposed collaborative research; (ii) briefly outlining the nature of the collaboration; and (iii) agreeing that, if MSCRF funding is awarded, they shall share research results with each other and comply with the

progress reporting duties under the MSCRF Grant Agreement, conditioned upon TEDCO's duty to maintain the confidentiality of the reported information to the extent reasonably permitted by Title 10, Subtitle 6 of the State Government Article of the Annotated Code of Maryland. Such letters must be co-signed by the collaborators and responsible officials at the collaborator's affiliate institutions.

16. **Appendix: Technology Transfer Office Letter. Limited to two (2) pages.** Provide a current signed letter from the University's technology transfer office (if licensed) indicating their approval of the project, certifying the IP directed to the Technology is secured and the status of the intellectual property that the PI has described in the application (including its license status for Commercialization projects). Indicate any current activity or updates to tech transfer activities. Provide on university, institute, or company letterhead.

17. **Appendix: Second Tier Funding Documentation.** If applying for Second-Tier Funding, provide documentation, such as a copy of the Letter Agreement or Collaboration Agreement between the PI and the research institution in Maryland confirming the collaboration between the parties for the performance of the Research Project.

18. **Appendix: 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.

19. **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 Validation 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 the page limit as included for each section or it will be rejected without consideration.

REVIEW PROCESS:

Following the Eligibility and Compliance Review, all Applications will be assigned by the MSCRF Scientific Review Officer (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 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 for funding.

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 opportunity based on the subject Technology.**

Other criteria that will be considered by the reviewers are the novelty of the Technology and the approach to solving a problem (meeting a market need), the strength of the Technology's competitive advantage (intellectual property position), the likelihood that the Technology will be licensed for commercialization, the market/commercialization opportunity represented by the project, and the team's ability to carry out the project.

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

- **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? Is there a summary of the Proof-of- Concept data? 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 (life-saving, 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?

- **Research 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 Research Project address an important scientific problem relevant to human stem cells? What is the relationship between the proposed project and the etiology, prevention, diagnosis or treatment of human diseases or conditions? If the aims of the Application are achieved, how will this move you closer to commercial or clinical practice and treatment of human diseases or conditions?
- **Approach:** Is there adequate Proof-of- Concept data to support the Research Project? Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well-reasoned and appropriate to the aims of the Research Project? Is relevant literature appropriately referenced? Are anticipated results discussed and justified? Does the applicant acknowledge potential problem areas and consider alternative tactics? Are the experiments as designed likely to significantly advance the technology?
- **Translation Potential and Plan**: Does the Application include strong commercial or clinical components? Is there a clear plan for translating results to the commercial market? Will the Research Project lead to new medical therapies or test new therapies in patients?

SCORING

A Scientific Peer Review Committee will review all Applications. Similar to 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.

Applicants Selected for Review: All Validation 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 Peer Review Meetings. Importantly, requests for virtual attendance will not be considered.

- The PI listed on the Validation Application must plan to present on the stated review dates. Other team members may attend; however, the PI must attend.
- All presentations will be scheduled as part of 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 close as a few days before the review day, so PIs will need to remain flexible during this process. **Applicants should plan for and secure the week of April 4, 2027, for the in-person presentation.**
- The Validation applicant will be required to submit his/her presentation deck to MSCRF at least 48 hours in advance of the peer review meeting.
- Applicant will have **15 minutes to present, followed by a timed Q&A session**.
    - 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, Milestones
    - Detailed Budget/Justification
        - Cost Projections
        - Financing Needed for the MSCRF Project
        - Follow-on Financing for the Next Steps, Beyond MSCRF
    - Translation Potential and Plan
        - Timeline and Costs
        - Risks and Mitigation Plan
    - 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 Peer Review Committee Meeting, applications will receive a final score based on an average of all the overall scores provided by the Committee Members.

Applications will be ranked by average final score and submitted to the MD Stem Cell Research Commission ("Commission") for review and final approval.

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

AWARD ADMINISTRATION INFORMATION

NOTIFICATION

The Applicant 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) will receive the first disbursement of funds and 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.

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

The disbursement of the Second-tier Funding award will occur upon the successful execution of the intellectual property (IP) option or licensing agreement between the PI's institution and the commercial collaborator. In all cases, any unused funds must be returned to MSCRF.

POST AWARD REPORTING

Validation Program awardees must submit the following reports to the 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 the remaining award 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.

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