REQUEST FOR APPLICATIONS (RFA)

MSCRF Commercialization Program

INTRODUCTION

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

FUNDING OBJECTIVES AND PROGRAM OVERVIEW

The Maryland Stem Cell Research Fund (MSCRF) Commercialization Program was created to support translational activities necessary to advance technologies with significant commercial potential to a clinical-stage or to market, whether such technologies are therapeutic, diagnostic, enabling/supportive of human stem cells, or technologies involving human stem cell derivatives (including extracellular vesicles and secretome). Specifically, it is the intent of the Commercialization Program to foster the commercialization of such technologies.

The Commercialization Grant Program offers two funding levels based on the maturity of the technology and the proposed development activities:

Level 1 – Early Stage: Supports early-stage product development activities aimed at establishing product feasibility and addressing critical technical or commercial uncertainties.

Level 2 – Advanced Stage: Supports technologies with validated proof-of-concept, with funding aimed at achieving significant product development, regulatory, manufacturing, or market-entry milestones.

Applicants must select **only one funding level** that best aligns with the technology's stage of development and proposed activities. Both funding levels are open to eligible technologies, including therapeutics, diagnostics, research tools, devices, and other qualifying products. Applicants may not apply to both funding levels for the same proposed project.

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

ELIGIBILITY INFORMATION

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

1. The company must have secured the underlying Intellectual Property (IP) in the company directed to the technology proposed in the application for the Commercialization Program. The company must provide a copy of the IP transfer agreement documenting that the company has secured such IP rights from the owner of the IP. If the Company is in negotiations with the IP owner for the transfer of such IP to the company at the time of application submission, the company must provide written evidence along with a copy of the IP agreement draft that is being negotiated but, in any case, the company must provide a copy of such IP agreement within 90 days of receiving notification of the MSCRF award, and in any case before the disbursement of any grant funds.
2. Alternatively, the company must own the IP related to the technology proposed in the application or hold rights to use the IP—either through acquisition or an assignment—from a third party.
3. The technology must have credible preliminary supporting data for Level 1 or at a minimum validated proof-of-concept data for Level 2, appropriate to the proposed product and stage of development.
4. The Research Project must advance the technology toward further product development, clinical development, or product launch, as appropriate to the selected funding level and type of technology.

Level 1 – Early Stage: Stage-Specific Eligibility and Application Requirements

In addition to the general eligibility requirements above, applicants seeking Level 1 Early-Stage funding must meet the following stage-specific criteria:

• A company can apply for level 1 funding when the proposed product, indication, or application is at an early feasibility stage.
• The applicant must provide credible initial data supporting the underlying technology or proposed product concept and identify one or more well-defined feasibility questions that must be resolved before further development.
• The proposed project should focus on early proof-of-concept or de-risking work with measurable milestones, as appropriate to the technology. Examples include additional in vitro or early in vivo testing, target validation, lead or prototype optimization, initial process development/manufacturability studies, and preliminary regulatory-enabling work.
• The applicant must provide an initial plan or concept for commercial feasibility, identifying the likely customers or end users, potential market need, intended product utility or value proposition, and initial competitive landscape. Customer discovery or relevant stakeholder feedback should be described where available.
• The applicant must identify an anticipated regulatory pathway, including the likely regulatory classification and relevant regulatory considerations, to the extent applicable and reasonably known at this stage.

Level 2 – Advanced Stage: Stage-Specific Eligibility and Application Requirements

In addition to the general eligibility requirements above, applicants seeking Level 2 funding must meet the following stage-specific criteria:
• The applicant must provide substantial, validated data supporting the underlying technology or product.

• The applicant must have a defined product-development strategy and propose work that meaningfully advances the product toward IND/IDE-enabling studies, regulatory-development milestones, or comparable commercialization milestones appropriate to the technology.
• The proposed scope should include advanced development work, as appropriate, such as further preclinical studies, pharmacology, toxicology, biodistribution, product characterization, process scale-up, manufacturing readiness, quality-related work, or regulatory-development activities.
• The applicant should have commercialization and market analysis addressing the target market, `customer segments, product differentiation, competitive landscape, and, as appropriate, market size, anticipated pricing/reimbursement, and sales or revenue opportunity.
• The applicant should preferably have some evidence of potential market, such as customer or key-opinion-leader feedback, industry engagement, letters of interest, pilot opportunities, or relevant market research, and discuss any remaining gaps.
• The applicant should describe a regulatory strategy, including anticipated pathway, major regulatory milestones, and development needs, where applicable to the product.

To summarize, Level 1 supports initial feasibility studies, product optimization, early in vivo studies where appropriate, and the resolution of critical uncertainties.

Level 2 supports advanced preclinical or comparable product-development studies, regulatory or manufacturing readiness, and milestones that position the product for subsequent clinical, commercial, or financing activities.

For both levels, applicants must identify the requested funding level and support their selection with the existing data, proposed activities, and anticipated milestones.

The company (Applicant) intending to apply to the Commercialization Program are encouraged to consult with MSCRF prior submitting their application. This discussion will help ensure eligibility and alignment with the most suitable funding program.

Applicant must ensure that all the research activities pertaining to the Research Project are performed in Maryland. Any effort for which salary from MSCRF is claimed must be expended in Maryland. MSCRF reserves the right to request additional documentation to establish that the Research Project will be performed in Maryland.

In the event any portion of the Research Project is contracted to a Maryland-based entity, such as with a contract service provider (e.g., CRO, CDMO), Applicant must discuss the nature of such activity with the MSCRF team in advance to ensure that the program requirements are satisfactorily met. Failure to do so may merit the application ineligible for funding.

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

Any one candidate may apply to the MSCRF as the PI for only one new Award in any given cycle. Individuals from under-represented minorities and individuals with disabilities are encouraged to apply. Applicants who have received prior MSCRF funding may apply in a subsequent funding cycle on a similar or different Research Project 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

Commercialization awards are capped at $400,000 unless Applicant proposes (and demonstrates a commitment to) a collaboration with a research institution in Maryland. Level 1 – Early Commercialization/Feasibility awards are capped at $250,000; Level 2 – Advanced Commercialization/Development awards are capped at $400,000. For either funding level, an additional $100,000 in Second-tier Funding (defined below) may be requested for an eligible collaboration with a Maryland research institution, increasing the respective maximum total awards to $350,000 (Level 1) and $500,000 (Level 2).

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

Project funding will be subject to the successful completion of several Research Project milestones. Applicants should be aware that Research Project funding could be terminated at any point during the Research Project if early data suggests that the technology will not be sufficient for the intended commercial application or if the Research Project is not reasonably progressing as originally proposed.

Because the nature and scope of the proposed research will vary from Application to Application, the size and duration of Awards may also vary. Approved Research Projects may be funded at or below the requested/proposed amount, for one or more reasons, including potential reductions in State appropriations or funding otherwise available to MSCRF.

Second-tier Funding: For either Level 1 or Level 2, an additional $100,000 may be available if the Applicant collaborates with a Maryland-based research institution to advance the technology. Maximum total awards are $350,000 for Level 1 and $500,000 for Level 2. The entire Second-tier Funding amount must be used exclusively at the collaborating research institution for the work outlined in the Application.

For this purpose, the Applicant is required to furnish written documentation between Applicant and the research institution confirming both parties' commitment to enter into a collaboration to conduct research activities outlined in the Application as part of the Research Project. Furthermore, Applicant must submit in the Application a comprehensive research proposal, inclusive of milestones and allocations, detailing the activities intended to be carried out with the Second-tier Funding. The Second-tier Funding will be disbursed, only if the successful Applicant has executed an MSCRF grant agreement and upon the execution of a collaboration agreement or a service agreement between the applicant and the research institution defining the specific research activities to be conducted by each as a part of the Research Project. Such executed collaboration or service agreement must be provided to MSCRF no later than four (4) months from the effective date of the MSCRF grant agreement.

Up to 10% of Commercialization awards may be used by the Applicant for overhead costs, including paying the university for patent or licensing costs. Any domestic travel expenses must be detailed, justified, and capped at $5000. International travel expenses are not allowed.

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

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

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

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 based on the scientific merit and the commercialization/business potential of the technology. 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:

- Name of the Company Applicant
- Date of Incorporation
- Principal Address:
- Funding level requested: Level 1 – Early Stage or Level 2 – Advanced Stage; briefly justify the selection based on existing evidence and proposed milestones.
- 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)
- IP status- whether there is a pending or issued patent application (s) directed to the Research Project
- Status of relevant IP ownership: Exclusive option or license agreement, Assignment or Owned by the Company Applicant.
- 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.
- 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: where available, applicants must use the provided template to complete each of the subsections below to ensure adherence to page limits and prevent disqualification. Applicants at both funding levels must complete the same application components and observe the same page limits. The level of scientific, market, regulatory, manufacturing, and financial detail should reflect the selected funding level. Applicants should explicitly identify studies and milestones appropriate to their technology type.

1. **Technology Description, Status of Research/ Product Development, and Market assessment – Limited to ten (10) pages.**
   - A description of the associated technology should be provided. The description should focus on 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 the key differentiator of the company or technology and the proposed innovation's benefits to the customer.
   - Describe the development status of the technology – provide the key data and summarize the research/product development studies completed to date, the conclusion derived and the rationale for the Research Project as the necessary next step for the advancement/derisking of Technology towards commercialization.
   - Include a summary of any pertinent preliminary, pre-clinical, mechanism of action data or other supporting data suggesting the Technology is likely to work as predicted.
   - Level 1: emphasize credible preliminary evidence, key feasibility questions, and data required to de-risk the product. Level 2: emphasize robust validated proof-of-concept, advanced supporting studies, and readiness for the next major development milestone.
   - Describe the potential market and addressable market for the technology.
   - Describe how these products will solve a problem in the market and the overall importance of solving that problem.

- Outline the competition and the Applicant's competitive advantages over competing products and services.
- Describe potential commercial products or services that could be based on the technology.
- Describe how the market opportunity has been validated. Describe your customers and the value that these products will bring to customers.
- Level 1: identify the product, intended users/customers, preliminary market need (including customer discovery or stakeholder input where available), value proposition, and competitors.
- Level 2: provide a developed market assessment, market size and segmentation, evidence of customer or commercial validation, and a realistic competitive and market-entry strategy. Address pricing, reimbursement, and revenue where applicable.

2. **Intellectual Property – Limited to two (2) pages.**
   - Describe the intellectual property secured for the Technology and strategies for strengthening the Technology's intellectual property portfolio.
   - A brief summary of the intellectual property landscape (e.g., the results of a patent search) should also be included and plans to secure competitive advantage
   - For both levels, describe ownership, license or exclusive-option status, relevant agreements and the planned IP protection strategy consistent with the eligibility requirements.

3. **Research Project Description and Milestones – Limited to six (6) pages.**
   - Include a summary of the Research Project and milestones tied to a clear timeline. Indicate which milestones will be completed by the Applicant's mid-term presentation (6 months into the project).
   - Describe how each of the milestones leads to clear development of technology and how it brings the product closer to the commercial market. Milestones must be quantifiable and measurable so it will be obvious when/if they have been successfully met.
   - For Level 1, milestones should resolve critical feasibility uncertainties, include measurable go/no-go decision points, and support the next product-development decision. For Level 2, milestones should deliver a substantive advanced product-development, regulatory, manufacturing, clinical, or commercial step, as appropriate to the technology. For both levels, describe risks, alternative approaches, and mitigation plans.

4. **Commercialization Pathway and Risk Assessment – Limited to eight (8) pages.**
   - Provide a detailed overview of the overall steps/milestones needed to commercialize the Technology (during and beyond the MSCRF funding) including timeline and cost to achieve each milestone. Level 1: identify a preliminary regulatory pathway and important regulatory/manufacturing considerations where applicable. Level 2: describe a defined regulatory strategy and major milestones, with appropriate manufacturing feasibility, scale-up, quality-control or CMC considerations where relevant.
   - Describe financing needs and plans to secure follow-on resources after MSCRF support. For Level 1, a preliminary financing strategy is sufficient; for Level 2, describe financing and partnership plans linked to specific next-stage development milestones.
   - Company Funding History –All applicants must disclose total company funding secured since incorporation, including equity investments, convertible notes or other convertible instruments, grants, loans, and other financial support. Provide amounts and dates by funding source, identify funds received to date, describe available financial resources and current financial status, and identify anticipated future financing needs. Companies with no prior financing should state this explicitly; prior fundraising is not an eligibility requirement.

- Describe the key technical challenges and risks in bringing the innovation to market. The major risks of failure (beyond the Research Project, e.g., technology risk, market risk, etc.) should also be described along with the Applicant's plans to manage those risks, i.e., what would be done if the proposed commercialization approach was not successful.

5. **Personnel and Resources – Limited to Two (2) pages.**
   - Management Team: Describe the key members of the company's management and technical teams, their relevant expertise, and their roles and responsibilities.
   - Talent Acquisition and Team Development: Describe plans to recruit additional personnel, attract key talent, and strengthen the management team's capabilities.
   - Inventor's Role (if applicable): For companies spun out of Maryland research institutions, describe the inventor's current and anticipated role in the company, including their involvement in technology development, management, or commercialization. If the company does not anticipate a role for the inventor, provide a rationale explaining why their continued involvement is not considered necessary.
   - Facilities and Resources: Describe the facilities, equipment, infrastructure, and other resources available to conduct the proposed work, including access to specialized facilities, organizational support, and collaborative arrangements, and explain how these resources will contribute to the project's successful execution and advancement toward commercialization.

6. **Executive Summary – Limited to Two (2) pages.** Company's executive summary must be submitted. The level of detail and supporting evidence should be commensurate with the company's stage of development, with preliminary plans acceptable for Level 1 and more developed strategies expected for Level 2. This executive summary must include:
   - Company Overview: Brief description of the company, its mission, and stage of development.
   - Unmet Need: Problem or market need being addressed by the company.
   - Technology/Product: Overview of the proposed technology or product and its current development status.
   - Value Proposition: Unique benefits and competitive advantages of the technology or product.
   - Customer Discovery and Market Validation: Target customers, potential market, and activities undertaken or planned to assess customer needs and market demand.
   - Commercialization Strategy: Proposed business model, pathway to market, and regulatory considerations, as applicable.
   - Intellectual Property: IP protection status, and plans to secure competitive advantage
   - Management Team: Key personnel and relevant scientific, technical, and business expertise.
   - Financial Overview: Funding raised to date (Funding History), current financial status, and anticipated funding needs.
   - Proposed Project and Milestones: Objectives, key deliverables, and how MSCRF funding will advance the technology toward commercialization.

7. **Resubmissions – Limited to two (2) pages**. In the event that an Applicant's proposal for Commercialization Grant Program is initially rejected, and the Applicant chooses to reapply for funding, the Applicant must submit a written response to the reviewers' comments including how those comments were addressed in the resubmitted application. The Response to Reviewer's Comments must not exceed two (2) pages.

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 submitted using the provided template. 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 10% of Commercialization awards 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. 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 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 Commercialization 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 provided in the template.

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/MSCRF'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. Limit 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 Technology's disclosure reference number 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.

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.

- 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 Commercialization Program awards will be initially reviewed by the MSCRF staff to ensure that they meet the minimum requirements, as specified in this RFA (the "Compliance Review"). Applications not meeting the minimum requirements will be rejected without further consideration and the applicant will be so notified. A complete submission (all sections) cannot exceed the page limit as included for each section or it will be rejected without consideration.

APPLICATION REVIEW PROCESS

Following the Compliance Review, all Applications will be assigned by the MSCRF SRO to a number of reviewers for review and preliminary scoring. All Applications, receiving average scores above a threshold determined by the Program will be brought to the full MSCRF Review Committee.

The MSCRF Review Committee will consist of representatives of the research, business and investor community and are all from outside of the state of Maryland. Each applicant will receive a copy of the reviewer comments and scores at the end of the process, whether the applicant is approved or declined.

REVIEW CRITERIA

Applicants will be reviewed against the criteria for their selected funding level. Both levels apply the same standards for scientific rigor, bioethics, regulatory compliance, and research integrity, but the expected maturity of preliminary data, market validation, regulatory and manufacturing planning, and financing strategy differs by level. Reviewers will evaluate the proposed activities in the context of the product type and development stage.

For Level 1 Applications:

A. Technology Description, Scientific Merit, and Intellectual Property

- Is the proposed technology innovative and relevant to human stem cell research, regenerative medicine, or related enabling technologies within the MSCRF Commercialization Program?
- Does the applicant provide credible preliminary data supporting the scientific rationale and potential feasibility of the technology or proposed product? Is relevant literature appropriately referenced?
- Does the technology address an important unmet clinical or commercial need, and is its potential advantage over existing approaches adequately explained?
- Has the applicant identified and secured the relevant intellectual property rights in accordance with the Commercialization RFA, and is there a reasonable strategy to protect or strengthen the IP portfolio? Is there a summary of the intellectual property landscape (e.g., the results of a patent search)?

B. Feasibility Studies, Project Approach, and Milestones

- Are the proposed studies appropriately designed to address one or more critical technical or product-development uncertainties?
- Are the scientific approach, experimental methods, and proposed analyses appropriate and scientifically justified?
- Are the proposed milestones specific, measurable, achievable within the award period, and directly linked to establishing feasibility or reducing development risk?
- Does the applicant identify potential technical challenges, alternative approaches, and appropriate go/no-go decision points?
- Will successful completion generate meaningful data to support further product development, investment, or advancement toward Level 2 funding?

C. Preliminary Market Assessment and Commercial Potential

- Has the applicant identified a potential product or commercial application, including its intended customers, end users, or beneficiaries?
- Is there preliminary evidence of a market need, such as customer discovery, clinical stakeholder feedback, or other relevant market research?
- Has the applicant identified existing or emerging competing technologies and explained the potential value or differentiation of its product?

D. Regulatory Considerations and Development Pathway

- Has the applicant identified the likely regulatory classification and anticipated regulatory pathway, where applicable and reasonably known at this stage?
- Are the key regulatory, manufacturing, or product-development challenges recognized?
- Are the proposed studies aligned with the information or evidence likely to be needed for subsequent development?

E. Company Capabilities, Resources, and Budget

- Does the applicant company have the scientific and technical expertise, personnel, collaborators, and facilities necessary to execute the proposed studies?
- Are gaps in business or product-development capabilities recognized, with reasonable plans to address them?

- Is the proposed budget reasonable, adequately justified, and appropriate for the scope of the feasibility studies?
- Does the applicant present a credible strategy for obtaining subsequent funding or resources needed to advance the technology after the MSCRF award?

F. Overall Significance and Expected Impact

- Will successful completion materially reduce a critical technical or commercial risk?
- Will the project provide a sound basis for deciding whether the technology merits further investment and product development?
- Does the project have the potential to advance commercially relevant human stem cell technology and contribute to Maryland's biotechnology ecosystem?

Level 1 review emphasis: Reviewers place greatest emphasis on the scientific rationale, quality of preliminary evidence, significance of the feasibility questions, appropriateness of the experimental approach, and potential value of the resulting data. Applicants should not be expected to demonstrate completed IND-enabling studies, extensive commercial validation, established revenues, or advanced fundraising.

For Level 2 Applications:

A. Technology Description, Scientific Validation, and Intellectual Property

- Does the applicant provide substantial and convincing proof-of-concept data supporting the proposed technology, product, or therapeutic candidate?
- Are the supporting preclinical, functional, efficacy, mechanistic, or other relevant studies sufficiently robust to justify advancement beyond initial feasibility?
- Does the technology offer a compelling competitive advantage or potential improvement over existing products, treatments, or technologies?
- Has the applicant secured appropriate intellectual property rights, and is the IP portfolio and protection strategy sufficiently developed to support continued commercialization? Is there a summary of the intellectual property landscape (e.g., the results of a patent search)?

B. Advanced Product Development, Project Approach, and Milestones

- Does the proposed project represent a significant advancement beyond initial feasibility and address an important product-development or regulatory milestone?
- Are the proposed advanced studies, such as large-animal studies, pharmacology, toxicology, biodistribution, product characterization, manufacturing-readiness, or comparable development activities, scientifically justified and appropriate to the technology?
- Are the study designs, methods, analyses, and anticipated outcomes sufficiently rigorous to support the intended next phase of development?
- Are the milestones specific, measurable, achievable within the proposed timeline, and clearly connected to advancement toward IND-enabling studies, regulatory submissions, clinical development, or commercialization?
- Are major technical and product-development risks identified, with credible mitigation strategies?

C. Market Validation and Commercialization Strategy

- Does the applicant provide a well-developed analysis of the market opportunity, including the target market, customer segments, competitive landscape, and product differentiation?

- Is there credible evidence supporting market demand or customer adoption, such as customer or key-opinion-leader feedback, strategic industry engagement, letters of interest, pilot opportunities, or other market-validation activities?
- Does the applicant present a compelling value proposition and a realistic strategy for product positioning, market entry, partnerships, licensing, or distribution?
- Are anticipated pricing, reimbursement, or revenue opportunities reasonably addressed, where applicable?
- Does the proposed project meaningfully improve the commercial prospects and potential value of the technology?

D. Regulatory and Manufacturing Development Strategy

- Is there a clearly defined and scientifically appropriate regulatory strategy for the proposed product, where applicable?
- Has the applicant identified the major regulatory milestones and data requirements necessary for advancing toward clinical development or market entry?
- Are the proposed studies appropriately aligned with anticipated regulatory expectations and future development needs?
- Has the applicant adequately considered manufacturing feasibility, scalability, product consistency, quality control, or other relevant CMC-related requirements, as appropriate to the technology?
- Does the proposed project meaningfully advance regulatory or manufacturing readiness?

E. Company Capabilities, Financial Readiness, and Budget

- Does the company have access to the management, scientific, technical, regulatory, and commercialization expertise required to execute the proposed development plan?
- Are the personnel, facilities, contractors, and strategic collaborators adequately positioned to achieve the proposed milestones?
- Is the proposed budget appropriate and adequately justified for the advanced scope of work?
- Does the applicant provide a credible financial and fundraising strategy to support subsequent development, including follow-on financing, strategic partnerships, or other funding sources?
- Is the company reasonably positioned to leverage successful project outcomes to secure additional resources or accelerate product development?

F. Overall Significance and Expected Impact

- Will successful completion achieve a major milestone that significantly advances the technology toward clinical development, regulatory submission, commercialization, or market entry?
- Will the project strengthen the company's commercial position, competitive advantage, or attractiveness for follow-on financing or strategic partnerships?
- Does the proposed work have the potential to generate significant clinical, commercial, and economic impact, including contributions to Maryland's regenerative medicine and biotechnology ecosystem?

Level 2 review emphasis: Reviewers place greater emphasis on the robustness of existing proof-of-concept evidence, relevance of the proposed development milestones, regulatory and manufacturing readiness, strength of commercial validation, and likelihood that the award will lead to a substantive next-stage development or financing milestone.

Common Review Requirements (Both Levels)

- Bioethics and Regulatory Compliance: Reviewers assess whether appropriate ethical issues have been identified and addressed, including stem cell sourcing and use, donor consent, human subject protections, animal welfare, and applicable SCRO/ISCRO, IRB, and IACUC requirements. These standards should not be relaxed for Level 1 applicants.
- Prior MSCRF Funding and Performance: For applicants previously funded by MSCRF, reviewers consider achievement of prior milestones, appropriate use of funds, timely reporting, and the extent to which the proposed work represents meaningful additional advancement.
- Second-Tier Funding: Where requested, reviewers assess the scientific value of the proposed collaboration with a Maryland-based research institution, whether the additional work is integral to the project, and whether its milestones and budget are justified.
- Company Funding History: For Level 1, past financing is contextual and should not serve as a competitiveness threshold; companies may have raised no capital. For Level 2, reviewers place greater emphasis on financing readiness and the credibility of securing resources required for subsequent development. No minimum amount raised is required at either level.

SCORING

A Scientific Peer Review Committee will review all Applications and rank them. Like the NIH, a scoring system of 1-9 will be used to rate the overall impact/priority of the proposed research. In this system, "1" indicates the highest impact/priority, and "9" indicates the lowest impact/priority. The Commission will then review the ranked Applications and will make the final funding decisions.

Companies Selected for Review: All Commercialization applicants who receive a high enough preliminary score will move on to the full committee review and will be required to present in person at the MSCRF Review Meetings. It is important to note that requests for virtual participation will not be considered.

- The applicant PI and the CEO (if not the same person) listed on the Commercialization Application must plan to present on the stated review dates. Other team members may attend; however, the PI and CEO must attend.
- All presentations will be scheduled as part of standing MSCRF review days. Due to the number of applications on any given review day, presentation times will be assigned by MSCRF.
- The PI will need to hold the review day open until the time is assigned. This may be confirmed as close as a few days before the review day, so PIs will need to remain flexible during this process. **Applicant PI and CEO should plan for and secure the week of April 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:
    - Technology
        - Describe the technology and its commercial applications
        - Summary of the development status of the technology
        - Intellectual Property on the technology: scope and status
        - Describe the Research Project if it is narrower in scope compared to the Technology
    - What is the Problem that the technology/Research Project addresses?
    - What is the Solution, and how does your technology provide the solution?
    - Target Market for your technology

        - Segmentation Analysis
        - Target Customer Profile
        - Competitive analysis
    - Product Development Process
        - Timeline and Costs associated with the Research Project
        - Risks and Mitigation Plan for the Research Project/technology
    - Go-To-Market Strategy?
        - Partnering? Production? Marketing? Distribution?
        - Sales?
    - Finances
        - Revenue and Cost Projections
        - Financing Needed for the MSCRF Project?
        - Follow-on Financing for the Next Steps, Beyond MSCRF?
    - Management Team: Advisors? Board of Directors?
    - Second-tier Funding (if applicable):
        - Identify the research institution and the collaborator's name.
        - Scope of the research work under the Research Project that will be performed at the research institution along with the budget.

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 MSCRF Peer Review Committee Members.

Applications will be ranked by average final score and submitted for programmatic review, subsequent Commission review, and consideration for approval. The Commission reserves the right to pursue collaborative funding arrangements with third parties and, in such an event, the further right to share the application materials and/or the review summaries with those potential co-funders upon the execution of a Confidentiality Agreement restricting their further disclosure.

AWARD ADMINISTRATION INFORMATION

NOTIFICATION

The Applicant will be notified electronically when the Application is received. A formal notification in the form of a Notice of Award ("NOA"), signed by the MSCRF Executive Director, will be sent via email to successful Applicants.

CLOSING AND AWARD PAYMENTS

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

Furthermore, the applicant must furnish specific regulatory compliance documents listed below before commencing the Research Project. Once these compliance documents are received and approved by

MSCRF, the applicant's Principal Investigator (PI) 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 Commercialization projects will be made as follows: 25% following execution of the agreement, 50% upon submission and approval of a Mid-term Report and the successful completion of approved milestones, and 25% upon submission and approval of a Final Report. In all cases, any unused funds must be returned to MSCRF.

POST AWARD REPORTING

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

a. **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 should be submitted by email to: mscrfinfo@tedcomd.com