

## REQUEST FOR APPLICATIONS (RFA)

# MSCRF Launch 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 primary aim of this Program is to provide support to researchers in the early stages of their academic careers in the field of stem cell research. Additionally, it serves the objective of assisting established researchers who wish to gain experience in the stem cell field, recognizing that this is a pivotal step in advancing their research objectives. 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.

This Launch Request for Applications is soliciting applications from faculty members in Maryland who aspire to contribute to the field of stem cell research and regenerative medicine, driving innovative research for improving patient outcomes. The RFA is for research grants on new and innovative hypotheses, approaches, mechanisms, or models. Although some preliminary or some proof-of-concept data supporting the application is preferred, it is not required. Grants awarded under this RFA will fund both basic and translational research involving human stem cells.

### **Important note: Revised and improved RFAs.**

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

### ELIGIBILITY INFORMATION

The following requirements must be met to apply for grant funding through this Program:

- a) The Applicant PI is a researcher who has either: (i) begun a tenure-track position (or equivalent academic position) no more than five years prior to the application submission deadline or; (ii) a faculty member at any career stage who is a newcomer to the field of human stem cell research, lacking prior grants or publications in the area, yet possesses established expertise and a proven track record in another field, and is seeking to contribute to the field of stem cell research.

- b) The Applicant PI may not have been previously funded by any of the MSCRF programs. The project for which the Applicant PI has submitted the launch application (“Research Project”) must not be funded by any other funding source. However, an Applicant PI may receive complementary funding from another source to cover other work that is related to the same overall Research Project.
- c) All MSCRF-funded personnel must conduct research directed to the Research Project in Maryland and remain employed or retained by an eligible Maryland-based organization while conducting such work. This employment or retainer may be permanent, temporary, full-time, or part-time.

Applicants from Maryland-based public and private, not-for-profit research organizations of all types (not including Federal research labs) are eligible for this Award (e.g., universities, colleges, research institutes, and medical centers). The Applicant PI may collaborate on the Research Project with any Maryland-based institution, including any federal lab. In the event of Federal Lab collaboration, the applicant must discuss the nature of collaboration with the MSCRF team in advance to ensure that the program requirements are satisfactorily met.

Applicant PI can submit a Revised Application for a Research Project that underwent a previous review by the MD Stem Cell Research Commission (“Commission”) but was not awarded funding. These Revised Proposals must include the previous MSCRF submission's Application Number, along with a concise point-by-point response to the prior scientific review, limited to three (3) pages.

Each Application for a Launch Program grant shall have only one 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.

Individuals from under-represented minorities and individuals with disabilities are encouraged to apply.

#### **ELIGIBLE RESEARCH AND CELL TYPES:**

All research funded by the MSCRF **must** involve human stem cells. Animal cells may be used to supplement studies with human stem cells. Basic and translational Research Projects are all eligible for funding. The MD Stem Cell Act defines eligible human stem cells as follows: human cell that has the ability to: (1) divide indefinitely; (2) give rise to many other types of specialized cells; and (3) give rise to new stem cells with identical potential. The full text of the Stem Cell Act is available on the MSCRF Web site (see [www.MSCRF.org](http://www.MSCRF.org)).

#### **OTHER ELIGIBILITY CRITERIA**

Awardees will receive MSCRF funds only after providing documentation to TEDCO confirming that the research to be conducted with MSCRF funds has been approved or exempted by the relevant Institutional Review Board (“IRB”) and, if applicable, Institutional Animal Care and Use Committee (“IACUC”). Awardees conducting research that involves human embryonic stem cells (“hESC”) must provide documentation of approval by a Stem Cell Research Oversight Committee before MSCRF funds shall be released.

## AWARD INFORMATION

### AVAILABLE FUNDS

The MSCRF is currently budgeted to commit up to \$20.5 million, in aggregate, in FY2024 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 costs proposed may not exceed \$350,000 per award for a maximum of 2 years duration. This will INCLUDE indirect costs, not to exceed 15% of direct costs. Maximum amount per Award is \$350,000.

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 a number of reasons, including potential reductions in State appropriations or funding otherwise available to MSCRF.

The Applicant PI shall assume responsibility for the planning, directing and execution of their Research Project. MSCRF-funded Launch Research Grants will be subject to the terms and conditions set forth in detail in the Grant Agreement entered between Applicant and MSCRF.

Under this RFA, MSCRF Grant Award funds may be used for the following direct costs, commensurate with the time dedicated solely to the Research Project:

- Salary and fringe benefits for the Applicant PI and essential personnel
- Equipment
- Supplies
- Consultant costs
- Contract services
- Collaboration expenses
- Travel and conference expenses
- Publications and miscellaneous costs

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.

Purchase of equipment and supplies, publication costs, conference expenses, contract manufacturing and services and other non-personnel costs may be incurred outside the State of Maryland, in accordance with customary practices of researchers.

Certain pre-Award costs are allowable. Applicants may, at their own risk, and without MSCRF's prior approval, incur obligations and expenditures to cover costs up to ninety (90) days before the effective

date of resulting Grant Agreement, if such costs are necessary to conduct the Research Project and would be allowable under the Grant, if awarded.

The incurring of pre-Award costs in anticipation of Award of a Launch Research Grant imposes no obligation on the MSCRF either to make an Award, or to increase the amount of the approved budget if an Award is made for less than the amount anticipated. Awardees should be aware that pre-Award costs result in essentially “borrowing” against potential future support, and that such borrowing must not impair Awardees’ ability to accomplish their Research Project objectives in the approved time frame or in any way adversely affect the conduct of their Research Projects.

Once a Grant has been awarded, up to ten (10) percent of funds can be reallocated between budget categories without prior MSCRF approval (e.g., from salaries to supplies). However, reallocations in excess of ten (10) percent must be approved in advance and in writing by MSCRF.

### **INTELLECTUAL PROPERTY**

Invention disclosures and intellectual property developed by the Applicant PI under this Program will be owned by, and the responsibility of, the Applicant, in accordance with standard U.S. intellectual property law on inventorship and ownership and the Applicant’s institutional guidelines.

Applicant PI and the Applicant shall determine whether to apply for patents or other intellectual property protections on discoveries or inventions developed with MSCRF funding under the Grant. In the event that an Applicant decides to apply for such intellectual property protections, the Applicant shall be responsible for all fees and expenses involved.

### **SHARING RESEARCH RESULTS AND NEW CELL LINES**

Applicant PI and the Applicant are required to share, with qualified researchers, their research results, any cell lines and other materials developed with MSCRF funding. Cell lines therefore must be derived from the tissues of individuals who provided consent to such sharing. Applicant PI and the Applicant may require that the recipient researcher(s) pay reasonable compensation for such new cell lines or materials. Applicant PI and the Applicant may include in the Grant Budget and use MSCRF funds to pay for reasonable expenses associated with sharing arrangements. Applicant PI and the Applicant shall determine whether and to what extent to cover such sharing of new cell lines and materials with intellectual property and contractual protections (i.e., Confidentiality Agreements, Material Transfer Agreements, Data-Sharing Agreements, License Agreements, Supply Agreements, etc.).

### **PUBLISHING**

Applicant PIs must commit to making the results of their MSCRF-funded research readily available to others, through publications (preferably), public presentations, or other accessible means.

## **APPLICATION AND SUBMISSION INFORMATION**

### **CONTENT & FORMAT OF APPLICATION**

#### **DEI Registration**

Pursuant to its enabling legislation, TEDCO is required to foster inclusive and diverse entrepreneurship and innovation throughout Maryland. Accordingly, TEDCO is now collecting race, gender, and ethnicity

data, to better understand the communities that are accessing MSCRF resources/funding. This data will not be accessible to MSCRF/TEDCO program/fund managers and will only be provided to them in an aggregated (anonymous) form. The data will not be used for funding consideration.

All Sections of the Application must be submitted through the [TEDCO online submission system](#). The document must be formatted using point size 12 Arial font, with margins no smaller than one-half (0.5) inch on all sides. Uploaded file must be limited to 80 megabytes (MB).

The Application must include the following Sections:

**A. Cover page. Limited to one (1) page, and must include the following information:**

- a. Title of the Research Project.
- b. The name of the Applicant PI and University/research lab that is applying for funding.
- c. The total amount of funding requested broken down into direct and indirect costs.
- d. Short (300 words) non-confidential summary of the Research Project. If awarded, this information becomes public. Do not include any confidential or proprietary information.
- e. 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.

**B. Research Project Summary - Limited to one (1) page**

Research Project Summary describing the proposed research and its potential contribution toward the goals of the MSCRF and this RFA, as set forth in this document.

**C. Research Plan - Limited to six (6) pages, including all tables, figures and charts**

A description of the Research Strategy and Design, Data in support of the Proposal, Significance, Specific Aims, Rationale, Approach and Innovation.

**D. 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.

**E. Translational Potential and/or Plan - Limited to one half (1/2) page**

An explanation of (i) the relationship between the proposed research and the etiology, prevention, diagnosis, or treatment of human diseases or conditions; (ii) how clinical practice and treatment of human diseases or conditions will be advanced by the proposed research; (iii) how the proposed research may contribute to new medical therapies or test new therapies in human patients; and/or (iv) how the proposed research will translate prior research results into new medical therapies or test new therapies in human patients, and the projected timeline for accomplishing such clinical application(s).

**F. Data Sharing and Management Strategy - Limited to one half (1/2) 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.

**G. Resubmissions - Limited to three (3) 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.

**H. Bioethics**

A description of 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; and Stem Cell Research Oversight Committee review (required of all Projects that involve human embryonic stem cells). If new cell line(s) will be created, the Application must explain how the biological materials used to create them will be obtained and how subjects will be consented. Applicants should refer to existing human stem cell research ethics guidelines and the Maryland Stem Cell Research Act.

**I. Key Project Personnel - A table format, not included in the page count.**

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. Typically, these individuals have doctoral or other professional degrees, although individuals at the master's or baccalaureate level should be included if their involvement meets the definition of key personnel. "Effort of zero person months" and "as needed" are not acceptable levels of involvement for key personnel.

**J. Budget and Budget Justification - A table format, not included in the page count.**

A detailed yearly budget and budget justification, including salaries that are within the current NIH salary range and commensurate with the time allotted to the proposed research. This budget will be used if the Application is funded. Make certain that it is complete and accurate. Applicants should request only the funds needed to complete the proposed Project. Requests for less than the maximum allowable amount will not be considered as a weakness. In the event of collaboration with a federal laboratory in Maryland, MSCRF funds can only be allocated towards the performance of research activities directed to the Research Project in the collaborator's federal laboratory.

**K. Appendix - Limited to twenty-five (25) supplemental pages (Upload in the same file as the Application)**

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.

**The Appendix shall include (in this order):**

**(1) Literature in Support of the Application – Limited to Three (3) pages**

A list of scientific literature in support of the Proposal, including Author, Title, Journal, Volume, Publication Date, and Page Numbers.

**(2) Biosketches - Limited to four (4) pages each for the PI/Co-PI and two (2) pages each for key personnel**

Biosketches, and up to five (5) relevant publications, for key personnel, collaborators, and pertinent others. Include online publicly accessible links. Manuscripts in preparation, manuscripts submitted but not yet accepted and those currently in revision cannot be included.

**(3) Letter(s) of Collaboration, if applicable - Limited to five (5) total pages; one (1) page per collaborator**

**For Applications that involve Collaboration(s):** A Letter of collaboration from each collaborator (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.

**(4) Collaborative Plan, if applicable - Limited to two (2) pages**

**For Applications that involve Collaboration(s):** A detailed description of the nature and terms of the collaboration, and a management plan explaining such issues as how the Applicant PI and collaborator(s) will communicate and handle confidential information, use milestones to determine resource allocation and Research Project direction, share data and resources, prepare required reports and handle geographic separation, if applicable.

**(5) Other Current and Pending Support**

The project number(s), title(s) and funding source(s) of all currently supported research, and a short paragraph summarizing each Project.

**(6) Letter of approval**

University Applicant PIs must obtain approval from their research/grants administration office before submitting an application. Please attach a letter or evidence of such approval along with the uploaded application

**Web form Information**

**In addition, Applicants must complete the web form information in the online system as early as possible to avoid unexpected delays.** This information includes:

- Short Abstract (maximum 300 words). If awarded, this information becomes public. Do not include any confidential or proprietary information.
- A bioethics section (maximum 250 words)

- Impact on biotechnology in Maryland statement (maximum 250 words): Briefly describe the potential of this application to impact the biotechnology sector in the state of Maryland. Some examples may include IP that may be licensed or lead to commercialization, existing or proposed collaborations, creation of new jobs, and workforce development.
- Translation potential and plan

**University Applicant PIs must obtain approval from their research/grants administration office before submitting an application. Please attach a letter or evidence of such approval along with the uploaded application.**

#### **SOURCE FOR APPLICATION INFORMATION**

Application information will be available electronically on the MSCRF Web site (see [www.mscref.org](http://www.mscref.org)).

#### **SUBMISSION DEADLINES & REVIEW DATES**

- **Application submission deadline:** January 22, 2024, by 5:00 p.m. EST.
- **Peer review date(s) and presentation by the applicant:** 1<sup>st</sup> week of April 2024
- **Commission review date(s) and announcement of awards:** May 2024

#### **METHODS OF SUBMISSION**

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

### **REVIEW INFORMATION**

#### **AWARD DECISION CRITERIA**

A Scientific Peer Review Committee will review all Applications and rank them based on scientific merit. Similar to the NIH, a scoring system of 1-9 will be used to rate the overall impact/priority of the proposed 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 make final funding decisions.

The purpose of the Application is to provide enough information so a group of reviewers can sufficiently evaluate the scientific merit and the value of the Research Project. In the application, please address the following categories:

- **Scientific Rationale, Innovation, and Significance:** Is the Research Project likely to have a major scientific impact and make a substantial contribution toward accomplishing the goals of the MSCRF program? Does this Research Project address an important scientific problem relevant to human stem cells? Is the Research Project original or innovative; does it challenge existing paradigms, address a critical barrier to progress, or develop/employ new concepts, approaches, and methodologies? What is the relationship between the proposed research and etiology, prevention,

diagnosis, or treatment of human diseases or conditions? If the aims of the Application are achieved, how will scientific knowledge or clinical practice and treatment of human diseases or conditions be advanced? What effect will these studies have on the concepts, methods, technologies, treatments, services, and/or preventative interventions that drive stem cell biology?

- **Investigators and Collaboration(s):** Does the proposed research involve collaboration(s) among scientists and/or clinicians from for-profit and not-for-profit institutions, companies, and organizations? If so, is there a demonstrated commitment from each institution? Is there a management plan that addresses how the Applicant and collaborator(s) will communicate, handle confidential information, use milestones to determine resource allocation and Research Project re-direction, share data and resources, prepare required reports, and handle geographic separation, if applicable? Are the Investigators appropriately trained and well-suited to carry out the Research Project? Is the proposed Research Project appropriate to the experience level of the PI and other Investigators? Does the research team bring complementary and integrated expertise to the Research Project? If the PI's work was previously funded by other funding sources, in whole or in part, the following additional factors will be evaluated: Did the PI make significant scientific progress towards the goals of the previously funded research? Were results of the previously funded project reported in scientific publications and/or presented at conferences? Did the previously funded research result in new collaborations, inventions, or resources?
- **Approach:** Is there enough support from the literature/or preliminary data to support the rationale of 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? Does the Applicant acknowledge potential problem areas and consider alternative tactics? Are the experiments as designed likely to significantly impact the field?
- **Resources and Environment:** Does the scientific environment in which the work will be conducted contribute to the probability of success? Do the proposed studies benefit from any unique features of the scientific environment or subject population? Do these studies employ useful collaborative arrangements involving on-site resources or personnel? Is the institutional support adequate?
- **Translation Potential and Plan and Impact on Biotechnology in Maryland:** Does the Application include strong interactions between basic, translational, and/or clinical components?? Will the Research Project lead to new medical therapies or test new therapies in patients? Will the research help explain the course of any human disease(s) or condition(s)? Will it identify new biomarkers or other methods for preventing or diagnosing disease(s) or condition(s)? Will it identify new targets for treatment? Will it develop new treatment strategies, products, or tools? What is the potential impact of the proposed research on the advancement of biotechnology in Maryland's academic, business, and/or non-profit sector(s)? Will this Research Project help create new biotechnology jobs, grow companies, and/or program opportunities in Maryland?
- **Bioethics:** Does the proposed research use adult, embryonic, iPS or other human stem cell lines? If an existing line is to be used, what are the justifications for that line? If new lines are to be created, what measures will be taken to comply with the Stem Cell Act as well as existing stem cell research bioethics guidelines? If human donors are involved, have they been properly consented? If human

subjects are involved, what protections will be in place to ensure their rights and welfare? If animal subjects are to be used, what measures are taken to comply with IACUC guidelines?

- **Budget and Budget Justification:** Is the requested period of support appropriate for the scope of the Research Project? Is the effort listed for all personnel appropriate for the proposed work? Is each budget category realistic and justified in terms of the aims and methodology? If equipment is requested, is it justified, cost-effective, and budgeted appropriately?

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 Applicant PIs.

### POST AWARD REPORTING

#### A. Annual Progress Reports

The Applicant PIs must file Annual Progress Reports describing the research conducted, and the interim and/or final results of that research, at the end of each funding year. The Annual Progress Reports must include a summary of any new patent filings or status update of any existing intellectual property arising out of the Research Project, as may be applicable. Financial reporting relevant to the MSCRF-funded Research Project shall be specified in the Grant Agreement executed between TEDCO and the Applicant. Progress Reports must be submitted to the MSCRF electronically through the TEDCO on-line submission system, no later than thirty (30) days after the end of the annual period covered in the report.

The MSCRF will review all Annual Reports to evaluate the progress that has been made relative to the plans, timetables, milestones, and budget proposed in the respective Applications before funding for the subsequent year is approved.

#### B. Annual Symposium Presentations

The Commission may conduct an in-State Annual Symposium to report to the scientific community and the public on the progress of the MSCRF program. All Applicant 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.

#### C. Final Report

Within forty-five (45) days after the end of the overall Grant period, Applicant PIs must file their Final Reports, describing the research conducted and the results of this research. This Final Report shall include explanations and justifications for any proposed studies that were substantially changed or not completed. The Final Report must include a summary of any new patent filings or status update of any existing intellectual property arising out of the Research Project, as may be applicable. The Final Report

must also describe the impact, significance, translational potential and/or clinical applicability of the research results, as well as a full accounting of all expenditures charged to the award in a tabular format signed by the financial officer, and a formal closeout letter prepared and signed by the Office of Research Administration (ORA). The details concerning the format, content and length of the Annual Progress Report shall be specified in the Grant Agreement executed between TEDCO and the Applicant.

#### **COMPLIANCE**

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

#### **AGENCY CONTACTS**

Inquiries about this RFA must be submitted by email to: [mscrfinfo@tedcomd.com](mailto:mscrfinfo@tedcomd.com)