

Part I - Overview Information

Participating Organizations

The Maryland Stem Cell Research Commission and The Maryland Stem Cell Research Fund.

Title: Investigator-Initiated Research Grants for Basic & Translational Stem Cell Research In Support of Medical Therapies

Request For Applications (RFA) Number: RFA-MD-10-1

Key Dates

Release Date: September 30, 2009

Required Letter of Intent Receipt Deadline: COB November 12, 2009

Application Receipt Deadline: COB January 14, 2010

Peer Review Date(s): March 2010

Commission Decision Date(s): April 2010

Earliest Anticipated Start Date: June 2010

Introduction

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

There is currently a need for more investment in both basic and translational research to pursue the promise of stem cells. There is insufficient funding available at the Federal level for all types of basic and translational human stem cell research.

The Maryland Stem Cell Research Fund ("MSCRF") has been established by the Maryland General Assembly, under the Maryland Stem Cell Research Act of 2006 (the "Stem Cell Act"), to promote state-funded human stem cell research and medical treatments through grants to public and private entities in the state.

The Maryland Stem Cell Research Commission ("Commission") has established three funding mechanisms for the MSCRF: Investigator-Initiated Research Grants, Exploratory Research Grants, and Post-Doctoral Fellowship Research Grants. The Investigator-Initiated Research Grants are designed for investigators with preliminary data supporting the grant application. The Exploratory Research Grants are designed for investigators who are new to the stem cell field (young investigators and investigators from other fields), and for new hypotheses, approaches, mechanisms or models that may differ from current thinking in the stem cell field, without any preliminary data supporting the application. The Post-Doctoral Fellowship Research Grants are for exceptional pre-doctoral students and post-doctoral fellows who wish to conduct post-doctoral basic and/or translational research on human stem cells in the State of Maryland.

This Request for Applications, RFA-MD-10-1, is soliciting Applications for Investigator-Initiated Research Grants to be funded by the MSCRF.

The Commission is strongly encouraging collaboration between for-profits and not-for-profits. See additional information in the review criteria section of this RFA.

Maryland-based organizations of all types are eligible for Investigator-Initiated Research Grants. Such organizations include public and private, for-profit and non-profit, universities, colleges, research institutes, companies, medical centers and others.

Executive Summary

- **Purpose:** The purpose of this RFA is to promote collaborative state-funded human stem cell research and medical treatments for human diseases and conditions. The grants to be awarded under this RFA will fund basic and translational research on human stem cells of all types as defined in the Stem Cell Act.
- **Goals:** The goals of this program are to broaden and advance the knowledge of human stem cell biology and the development of clinical applications, for prevention, diagnosis and treatment of human diseases and conditions.
- **Topics:** No mandatory or illustrative topics are specified for this program. Under this initial RFA, the Commission is seeking the widest range of research topics that may contribute to achievement of the stated goals of the program.
- **Eligible Cell Types:** The research under this program must be conducted with human (not animal) cells. All types of human stem cells as defined in the Stem Cell Act are eligible.
- **Collaborations:** The research funded under this program is strongly encouraged to include collaborations among scientists in academic, for-profit or non-profit organizations, among clinicians, and between scientists and clinicians, who will explore together clinically relevant questions of basic research, as well as translational research.
- **Funding:** A single Application for an Investigator-Initiated Research Grant may request up to **\$1,000,000** of direct costs per project to be budgeted from **two to five years**. Each Investigator-Initiated Research Grant Application is to have only one Principal Investigator (“PI”), but may have multiple co-PIs.
- **Letter of Intent:** All prospective applicants are required to submit a Letter of Intent electronically, through the TEDCO Funds system (see www.tedcofunds.org), no later than November 12, 2009. One signed original of the Letter of Intent must also be submitted to TEDCO in paper form.
- **Length limit:** An Application may not exceed fifteen (15) pages, and the Appendix may not exceed an additional twenty-five (25) pages. Repeating non-funded applications from previous years may have an additional three (3) pages to respond to the reviewers’ comments.
- **Translation potential and/or plan:** All Applications must include an explanation of the translation potential and/or plan of the proposed research. Translation potential means the relevance and potential utility of the research (including basic research) for clinical applications. A translation plan means the anticipated process for accomplishing such clinical applications.
- **Bioethics plan:** All Applications must include a written bioethics plan for the proposed research that should include but not be limited to the ethical issues related to: cell type; cell line(s); animal welfare (i.e., IACUC); IRB review and related concerns regarding human subjects; and ESCRO/SCRO review; please refer to the Maryland Stem Cell Statute as well as relevant existing ethics guidelines (e.g., NIH, ISSCR, NAS).
- **Project Summaries:** All Applications must include two project summaries (one technical and one non-technical), summarizing the proposed research and explaining how the research will contribute to accomplishment of the goals of this RFA. These Project Summaries are not counted in the length limit for the Application or the Appendix, but are subject to a separate length limit of 3,000 characters each.
- **Submission process:** All Applications must be submitted electronically through the TEDCO Funds electronic submission system (see www.tedcofunds.org). In order to do so, the applicant organization and the PI must register in the TEDCO Funds database before submission. One signed original of the Application must also be submitted to TEDCO in paper form.
- **Annual reports:** Annual progress reports to the Commission and presentation, at an annual in-state symposium, of interim and final results of the basic or translational research funded by the MSCRF will be required of all awardees.
- **Sharing of cell lines:** New cell lines initially developed with funding under this RFA will be required to be shared with other qualified researchers. Reasonable compensation may be required. Applicants shall determine, in their discretion, whether and to what extent to cover such new cell lines with intellectual property and contractual

protections (Confidentiality Agreements, Material Transfer Agreements, Data-Sharing Agreements, Licenses, Supply Agreements and the like).

- **Intellectual Property:** Any intellectual property developed under an Investigator-Initiated Research Grant funded by the MSCRF will be owned by the recipient investigator in accordance with standard U.S. intellectual property law on inventorship and ownership.
- **Eligible organizations:** Public and private, for-profit and non-profit organizations, universities, colleges, research institutes, companies, medical centers and others, based in the State of Maryland, are all eligible. Organizations based outside the State of Maryland are not eligible to apply. However, collaborations with non-Maryland based organizations or persons may be allowable so long as the applicant can demonstrate that none of the MSCRF funding will be used for personnel costs outside the State of Maryland.
- **Eligible individuals:** The PI (and other personnel) must conduct the MSCRF funded work in Maryland, and be employed or retained by an eligible Maryland-based organization while conducting such work. Such employment or retainer may be permanent or temporary, full-time or part-time. Individuals from underrepresented minorities and individuals with disabilities are encouraged to apply.
- Telecommunications for the hearing impaired is available at: TTY 443-539-0180.

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Part II - Full Text of Announcement

Section I. Funding Objectives

The objectives of this RFA are to broaden and advance the knowledge of human stem cell biology that will be relevant for eventual development of clinical Applications, and to enable, support and accelerate such clinical Applications for prevention, diagnosis and treatment of human diseases and conditions. Studies in human patients may be supported under this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the Investigator-Initiated Research Grant award mechanism. The PI will be solely responsible for planning, directing, and executing the proposed project.

The specific funding methods and procedures will be specified in the Grant Agreement entered into between an awardee and TEDCO for the administration of the grant.

2. Funds Available

The MSCRF intends to commit up to \$12.4 million, in aggregate, to fund Grants under all RFAs in FY 2010. The number of grants will depend upon the quality, size, and mix of Applications received. Because the nature and scope of the proposed research will vary from Application to Application, it is anticipated that the size and duration of awards will also vary.

3. Award Size and Duration

The total project period proposed in an Application for an Investigator-Initiated Research Grant under this RFP may not exceed Five (5) years. Although the size of award may vary with the scope of research proposed, the total direct costs proposed in an Application may not exceed \$1,000,000 per award.

4. Allowable Costs; Terms and Conditions

Under this RFA, MSCRF funds may be used for:

- Salary and fringe benefits for the PI and other essential personnel
- Equipment that is necessary for the proposed research
- Supplies
- Consultant costs
- Contract services
- Collaboration expenses
- Facilities and Administrative costs (indirect costs), not to exceed fifteen percent (15%) of direct costs
- Travel and conference expenses
- Publications and miscellaneous costs
- Facilities or renovations that are necessary for the proposed research.

Purchases of equipment and supplies, publications, conference expenses, contract manufacturing and other contract services, and other non-personnel costs may be incurred outside the State of Maryland, in accordance with customary practices of researchers. Overall, MSCRF-funded Investigator-Initiated Research Grants will be subject to terms and conditions, cost principles, and other considerations comparable to those described in the NIH Grants Policy Statement. (See <http://grants.nih.gov/grants/policy/policy.htm>). Such terms and conditions will be set forth in detail in the Grant Agreement entered into between an Investigator-Initiated Research Grant awardee and TEDCO for the administration of the Grant.

MSCRF funds also may not be used for patent and other intellectual property fees and expenses. Certain pre-award costs are allowable. An applicant may, at his/her own risk and without the Commission's prior approval, incur obligations and expenditures to cover costs up to ninety (90) days before the beginning date of the initial budget period of an Investigator-Initiated Research if such costs are necessary to conduct the project, and would be allowable under the grant, if awarded.

The incurring of pre-award costs in anticipation of award of an Investigator-Initiated Research Grant imposes no obligation on the Commission either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. The Commission expects the awardee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the awardee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project.

5. Award Decision Criteria

Applications will go first to the Scientific Peer Review Committee for evaluation of scientific merit, and then to the Commission for final decision. In determining whether to award an Investigator-Initiated Research Grant to an applicant, the Commission will consider the following factors and make the final decisions:

- A. How well the proposed research fulfills the overall objectives of this MSCRF program, as set forth in Section I.
- B. The scientific merit of the proposed basic or translational research, based upon the evaluation, rankings, and recommendations of the Peer Review Committee using the criteria set forth in Section II.5.B.;
- C. A high priority will be given to collaborative projects between for-profits and not-for-profits.

5.A. Overall Decision Criteria

Overall objectives of this MSCRF program: The goals of this program are to broaden and advance knowledge of human stem cell biology that will be relevant for eventual development of clinical applications, and to enable, support and accelerate such clinical applications for prevention, diagnosis and treatment of human diseases and conditions

Impact on Biotechnology in Maryland: Will the proposed research contribute to the development of biotechnology in Maryland? Will the proposed application help create new biotechnology jobs and/or program opportunities in Maryland?

5.B. Scientific Merit

The Peer Review Committee will review and evaluate the scientific merit of Applications received under this RFA. Such review and evaluation will include use of the following criteria to judge the likelihood that the proposed basic or translational research will make a substantial contribution toward accomplishment of the goals of the MSCRF funding, as set forth in Section I. An Application needs to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score.

Significance: Does this study address an important problem? What is the relationship between the proposed research and the 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 will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? What is the potential impact of the proposed research on the advancement of biotechnology in Maryland's academic, business, or non-profit sectors?

Translation potential and/or plan: Will the proposed research contribute to the feasibility of new medical treatment strategies? Will it translate any prior research results into new medical therapies or test any new therapies in human patients? Will the research help explain the course of any human diseases or conditions? Will it identify new biomarkers or other methods of identifying and diagnosing a disease or condition? Will it identify new targets for treatments to address? Will it develop new strategies, products or tools to diagnose or treat a disease or condition?

Ethics: Does the proposed research use cell lines that are adult/embryonic/iPS or other? If an existing line is to be used what are the justifications for that line. If new lines are to be created what measures are taken to comply with Maryland Statute and existing ethics guidelines (e.g., NIH, ISSCR, NAS or others)? If animal subjects are to be used in the research what measures are taken to comply with IACUC guidelines? If human subjects are involved, what protections will be in place to protect their rights and welfare?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice, address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area? Does the Application include strong collaborative interactions between basic and preclinical components and a clear plan for transfer of potential findings from basic to preclinical studies? What is the potential impact on the advancement of biotech or medical innovation in Maryland?

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Collaboration: Does the study address the plans to manage collaborations, including geographic separation, if any? How will the investigators manage key project decision points, e.g., use of milestones for determining resource re-allocation, project re-direction, etc.? Do the researchers present a plan for sharing data at grantee meetings, and is it consistent with the goals described above? Is there a proven commitment from each institution?

Environment: Does the scientific environment in the academic, for-profit or non-profit setting in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment in that academic, for-profit or non-profit setting, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Budget and Budget Justification: The budget submitted on-line via TEDCO Funds is the only one that will be reviewed, and is the one that will be used in the event that an Application receives a grant award. Please ensure that it is both complete and accurate. The rationality of the proposed budget and the requested period of support in relation to the proposed research will be assessed by the reviewers. Is the effort listed for the PI/co-PI appropriate for the work proposed? Is each budget category realistic and justified in terms of the aims and methods? The reviewers may recommend approval of the budget as submitted by the Applicant or may recommend budget cuts. **As resources are limited more than ever, you are not required to use the maximum permissible amount in the RFA, and a more conservative budget will not be considered as a weakness.**

6. Intellectual Property

Any intellectual property developed under an Investigator-Initiated Research Grant funded by the MSCRF will be owned by, and the responsibility of, the recipient investigator in accordance with standard U.S. intellectual property law on inventorship and ownership. Applicants shall determine, in their discretion, whether to apply for patents or other intellectual property on discoveries or inventions developed with MSCRF funding under an Investigator-Initiated Research Grant. In the event that an applicant decides to apply for such intellectual property, the applicant shall be responsible for all fees and expenses involved, and may not use MSCRF funds for such fees or expenses.

7. Reporting

7.A. Annual Progress Reports

Each Principal Investigator under an Investigator-Initiated Research Grant shall be responsible for filing an Annual Progress Report with respect to each year of the grant period, describing the research performed and the interim and final results of such research, under the Investigator-Initiated Research Grant. Each Principal Investigator shall also be responsible for submitting a brief letter requesting continuation of the Grant funding for each year of the grant period after the first year. The format, content and length of the Annual Progress Report and letter request shall be specified in the Grant Agreement executed between TEDCO and the awardee. Such Annual Progress Reports and letter requests shall be submitted to the Commission electronically through the TEDCO Funds system (www.tedcofunds.org) no later than thirty (30) days following the end of the annual period covered in the report. The Commission will review all Annual Reports and letter requests to evaluate the progress made relative to the plans, timetables and budgets which had been proposed in the respective Applications and had formed the basis for the Grants awarded.

7.B. Annual Symposium Presentation

The Commission plans to conduct an in-state Annual Symposium to report to the public on progress in the all Research Grants. Each Principal Investigator shall be responsible for presenting, at each Annual Symposium during and immediately following his/her grant period, a description of the research he/she is undertaking under the Grant, the translation potential and significance of that research, and the interim and final results obtained.

7.C. Final Reports

Each Principal Investigator under an Investigator-Initiated Research Grant shall be responsible for filing a Final Report, within forty-five (45) days after the end of the overall grant period, describing the research performed and the results of such research. In the event that any of the research that was proposed in the Application to be conducted was not conducted, was not completed, or was materially modified, the Final Report shall include an explanation and justification of such failure to conduct or complete such research, or of the material change(s) in the research. The Final Report shall also describe the translation potential and significance of the results obtained from the research conducted. Further aspects concerning the format, content and length of the Annual Progress Report shall be specified in the Grant Agreement executed between TEDCO and the awardee.

7.D. Compliance

A Principal Investigator who is not in compliance with the reporting obligations under an Investigator-Initiated Research Grant shall not be eligible to apply for further MSCRF funding.

8. Publications; Sharing of Research Results and New Cell Lines

Applicants are encouraged, but not required, to include in their Application for an Investigator-Initiated Research Grant a plan or commitment to publish the results of the research performed under the Grant (in addition to the required Annual Symposium presentation under Section II.7.B, and the required Annual Reports and Final Reports under Sections II.7.A and C). Applicants will be required to share with other qualified researchers any cell lines initially developed with funding under this RFA. Applicants may require the receiving researchers to pay reasonable compensation for such new cell lines. Applicants may include in the Grant budget, and use MSCRF funds to pay for, all reasonable expenses associated with sharing arrangements. Applicants shall determine, in their discretion, whether and to what extent to cover such sharing of new cell lines with intellectual property and contractual protections (Confidentiality Agreements, Material Transfer Agreements, Data-Sharing Agreements, License Agreements, Supply Agreements and the like).

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Organizations

To be eligible for an Investigator-Initiated Research Grant funded by the MSCRF, an organization must be based in Maryland. An organization is considered to be based in Maryland if its primary location of operations is in Maryland. Such organizations may include:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, medical centers, companies and laboratories and others.

A **one-time** registration is required for each applicant organization in the TEDCO Funds database (see www.tedcofunds.org). Such registration with TEDCO Funds requires registration of both the applicant organization and one or more contacts. It is required that applicants commence this registration process prior to the receipt date for the required Letter of Intent.

1.B. Eligible Individuals

Each Application for an Investigator-Initiated Research Grant funded by the MSCRF under this RFA shall have only one PI, but may have multiple Co-Principal Investigators (“co-PIs”) as well as collaborators. The PI for any Investigator-Initiated Research Grant must conduct the work in Maryland and be employed or retained by an eligible Maryland-based organization while conducting such work. Such employment or retainer may be permanent or temporary, full-time or part-time.

The PI must also register in the TEDCO Funds database (see www.tedcofunds.org). It is required that the prospective PI commence this registration process prior to the receipt date for the required Letter of Intent.

Any individual who meets such in-state eligibility requirement, and who has the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with his/her eligible organization to develop, or participate in, one or more Applications for an Investigator-Initiated Research Grant. An individual may only serve as the PI in one Application for an Investigator-Initiated Research Grant under this RFA, but may participate as an additional investigator or collaborator in any number of Applications under this RFA or other RFAs. Individuals from under-represented minorities and individuals with disabilities are encouraged to apply.

2. Eligible Cell Types and Research

The research under this program must be conducted with human (not animal) stem cells. Both basic and translational research (including clinical studies in human patients) are eligible on an equal basis. All types of human stem cells as defined in the Stem Cell Act are eligible on an equal basis without a preference among different cell types. The full text of the Stem Cell Act is available on the MSCRF website (www.MSCRF.org). The Act defines eligible human stem cells as follows:

“State-funded stem cell research” means stem cell research conducted using material obtained in accordance with section § 10-438 of the Stem Cell Act [see below] or “adult stem cells”.

“Stem cell” means a human cell that has the ability to: (1) divide indefinitely, (2) give rise to many other types of specialized cells, and (3) give rise to new stem cells with identical potential.

“Adult stem cell” means a cell that: (1) is derived from human tissue, and (2) is obtained after birth.

Material obtained in accordance with Section § 10-438 of the Stem Cell Act means human embryos (not oocytes) obtained by a licensed healthcare practitioner who treats individuals for infertility, and who provides information to such individuals to enable them to make an informed and voluntary choice, including a choice to donate such embryos for research.

3. Cost Sharing or Matching

This program does not require cost sharing.

4. Other Special Eligibility Criteria

Under an Investigator-Initiated Research Grant from the MSCRF, funding for personnel costs may only be expended for investigators who conduct the work in Maryland (including out-of-state investigators who move to Maryland to conduct the work in Maryland) and who are employed or retained by an eligible Maryland-based organization, as described in Section III.1.A above. MSCRF funds may not be used for personnel costs for investigators who are located and 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 in a MSCRF-funded research program if the applicant can demonstrate that no MSCRF funds will be used for personnel costs for those out-of-state investigators.

An applicant may not receive funding from another source for the same work for which MSCRF funds are awarded. However, an applicant may receive complementary funding from another source to cover other work that is related or is included in the same overall project.

An awardee is not eligible to receive MSCRF funds until he/she provides documentation to TEDCO confirming that the relevant proposed research to be conducted under the Investigator-Initiated Research Grant has been approved by the applicable Institutional Review Board (“IRB”) and/or Institutional Animal Care and Use Committee (“IACUC”).

Section IV. Application and Submission Information

1. Source for Application Information

Application information will be available electronically on the MSCRF website (see www.mscref.org).

Telecommunications for the hearing impaired: TTY 443-539-0180.

2. Submission Dates and Times

Required Letter of Intent Receipt Deadline: COB November 12, 2009

Application Receipt Deadline: COB January 14, 2010

Peer Review Date(s): March 2010

Commission Decision Date(s): April 2010

Earliest Anticipated Start Date: June 2010

3. Methods of Submission

The Letter of Intent must be submitted electronically to mscrefinfo@marylandtedco.org as well as to TEDCO at the following address:

Maryland TEDCO
MSCRF Letter of Intent
5565 Sterrett Place, Suite 214,
Columbia, MD 21044.

The Application must be submitted electronically using the TEDCO Funds system (see www.tedcofunds.org).

The electronic submission must be made no later than the specified date for receipt of the Applications. The originals in paper form Letter of Intent must be postmarked (by U.S. Post Office mail or nationally recognized courier) no later than November 12, 2009. Deliveries in person are not permitted, and will not be accepted. Any Letters of Intent or Applications submitted after the respective receipt dates, or postmarked more than one business day after the respective receipt dates, will not be reviewed.

4. Content and Form of Letter of Intent

Applicants are required to submit a Letter of Intent in order to be eligible to submit a grant application. The Letter of Intent is to be approximately one (1) page in length, and includes the following information:

- Descriptive title of proposed research
- Name, address, telephone number and email address of the PI
- Names of Co-PIs, if any, and other key personnel
- Participating organizations and sites of proposed research
- Type of grant sought, and RFA number
- Brief description (up to 2,000 characters) of the proposed research
- Indicate disease target
- Indicate cell type (hESC, ASC or iPS cell)
- Indicate whether the intended research is Basic or Translational

Indicate **expertise required from potential reviewer** - To facilitate the review of the application, please identify the areas and types of expertise needed to evaluate the proposal. Please include keywords that identify elements of the research proposal, such as disease focus, technical approaches, research fields and disciplines.

Applicants will not receive feedback on the Letters of Intent submitted. The Letters of Intent also will not be used by the application reviewers or considered in the evaluation of Applications. The sole purpose of the Letters of Intent is to enable the Commission to plan its workload and select the appropriate range and mix of expertise in the members of the Peer Review Committee, and to enable the Peer Review Committee to plan its review workload.

5. Content and Form of Application

5.A. Project Summaries

Applications are required to include two Project Summaries describing the proposed research and the potential contribution of the proposed research toward the goals of the MSCRF and this RFA, set forth in Section I. The Project Summaries shall not be included in the length limits for the application, but shall be subject to separate length limits. Each of the two Project Summaries shall be limited to 3,000 characters in length. One of the Project Summaries shall be technical in nature and directed to a scientific audience. The other Project Summary shall be non-technical in nature and directed to a lay audience.

5.B. Overall Content

The content and form of the Applications for an Investigator-Initiated Research Grant from the MSCRF shall be in accordance with the NIH PHS 398 instructions for preparing a research grant application (See <http://grants.nih.gov/grants/funding/phs398/phs398.html>), except for the content relating to the translation potential and/or plan, the impact on biotechnology in Maryland, and the ethics of the proposed research, which are described in this RFA and are not covered in the NIH PHS 398 instructions. In accordance with the PHS 398 instructions, each Grant Application will include, for example, the following sections: face page, project description, performance sites, key personnel, other significant contributors, budget (and budget justification), resources, and the Research Plan (specific aims, background and significance, preliminary studies/progress report, research design and methods, human subjects research, vertebrate animals, select agent research, literature cited, multiple PI leadership plan, resource sharing, and consultants), as well as an appendix, checklist, personal data and key personnel report.

In addition to the foregoing sections required in accordance with the PHS 398 instructions, all Applications for an MSCRF Investigator-Initiated Research Grant shall include sections on the translation potential and/or plan of the proposed research, the impact on biotechnology in Maryland, and the ethics of the proposed research. There is no specific length limit for each of the foregoing sections. Their lengths shall be at the applicant's discretion within the overall length limits for the application.

5.C. Length Limit and Format

Applications for Investigator-Initiated Research Grants under this RFA shall not exceed fifteen (15) pages, including tables and figures, and including all required sections other than the two Project Summaries and other than references. Accordingly, the fifteen-page limit includes the Research Plan (specific aims, background and significance, preliminary studies, research design and methods), the budget and budget justification, and the sections on translation potential and/or plan, impact on biotechnology in Maryland, and ethics. References and the two required Project Summaries shall be separate and in addition to this fifteen-page length limit. The two Project Summaries shall not exceed 3,000 characters each. One Appendix is permitted for each application. The Appendix shall be separate and in addition to the Application, the references and the Project Summaries. The Appendix shall not exceed an additional twenty-five (25) pages, including tables and figures. The font size, margins and other format elements of both the Application and the Appendix shall conform to the requirements set forth in the NIH PHS 398 instructions for preparing a research grant application. (See <http://grants.nih.gov/grants/funding/phs398/phs398.html>). Applications that exceed the length limits will not be reviewed.

5.D. Budget and Budget Justification

Each Application must contain a detailed budget, and justification for the budget. Salaries should be justified and within the NIH salary cap.

After grants are awarded, budget amounts with no specific limit may be reallocated within a budget category (e.g, salaries) without obtaining prior approval. Budget amounts may be reallocated between categories (e.g., from salaries to supplies) only up to a maximum of 10% without obtaining prior approval. Any reallocations between categories in excess of 10% must be approved in advance through TEDCO.

As resources are limited more than ever, you are not required to use the maximum permissible amount in the RFA and a more conservative budget will not be considered as a weakness.

5.E. Translation Potential and/or Plan

In this Section, the Application should explain the relationship between the proposed research and the etiology, prevention, diagnosis, or treatment of human diseases or conditions, explain how clinical practice and treatment of human diseases or conditions will be advanced by the proposed research, and explain how the proposed research may contribute to the feasibility of new medical treatment strategies or how it will translate prior research results into new medical therapies or will test new therapies in human patients. Examples of the foregoing (for illustrative purposes only) may include helping to explain the course of any human diseases or conditions, identifying new biomarkers or other methods of identifying and diagnosing a disease or condition, identifying new targets for treatments to address, or developing new strategies, products or tools to diagnose or treat a disease or condition, or testing new treatments in clinical trials in patients.

5.F. Impact on Biotechnology in Maryland

In this Section, the Application should describe how the proposed research may contribute to the development, expansion or improvement of biotechnology operations or capabilities in the State of Maryland. Examples (for illustrative purposes only) may include introduction of improved, streamlined or automated processes involving stem cells, expansion or improvement of stem cell production or storage, training of stem cell researchers, technicians and related personnel, and the like.

5.G. Ethics

In this section, the Application should describe the ethical issues, that may pertain to the proposed research, type of cell line to be used, whether new cell line(s) will be created and if so how they are to be obtained. Please explain how those ethical issues will be dealt with. In preparing this section, the applicant may consider the guidelines established by the NIH, the Maryland Stem Cell Research Act, the National Academy of Sciences and/or other relevant professional societies or bodies.

6. Application Processing

Upon receipt, Letters of Intent and Applications will be evaluated by the Commission for completeness, eligibility and responsiveness in meeting the format and content requirements specified in this RFA. Letters of Intent or Applications that are incomplete, ineligible or non-responsive will not be reviewed.

Section V. Award Administration Information

1. Award Notices

After the Commission has completed its decision-making and selected the Grants to be funded, a formal notification in the form of a Notice of Award (NoA) will be provided to each successful applicant. The NoA signed by the MSCRF Director will be the authorizing document for the Grants. The NoA will be generated via email notification from TEDCO after all administrative and programmatic issues have been resolved.

Selection of an Application for award is not an authorization to begin performance. Except as provided in Section II.4 above in regard to pre-award costs at the applicant's risk, no applicant may begin performance of an award until an MSCRF Grant Agreement has been signed by the awardee and TEDCO on behalf of the MSCRF and the Commission. A template for the MSCRF Grant Agreement will be available on the TEDCO website prior to the announcement of the Commission decisions on the Applications selected for MSCRF funding (see www.MSCRF.org). Any pre-award costs incurred before receipt of the NoA are at the applicant's risk, as provided in Section II.4, above

2. Agency Contacts

Questions about this RFA may only be addressed by email, through the following contact:

mscrinfo@marylandtedco.org.