

RFA # 1602230252
NYS Grants Gateway # DOH01-STEM5-2016

**New York State Department of Health
and the
Empire State Stem Cell Board
Request for Applications**

Investigator Initiated Research Projects (IIRP) and
Innovative, Developmental or Exploratory Activities (IDEA)
in Stem Cell Research (Rd 5)

RELEASE DATE: 4/12/2016

LETTER OF INTENT DUE (Strongly Encouraged): 5/20/2016

Applicant Conference Registration Due: 5/13/2016

APPLICANT CONFERENCE: 5/16/2016 at 10:00 AM
By telephone conference call at:
1-866-776-3553 or 1-844-633-8697
Meeting ID # 646 374 211

QUESTIONS DUE: 5/19/2016

QUESTIONS, ANSWERS AND UPDATES POSTED: 5/25/2016

APPLICATIONS DUE: 6/23/2016 by 6:00 PM

DOH CONTACT NAME AND ADDRESS:

Charles J. Burns
Extramural Grants Administration
New York State Department of Health
Wadsworth Center
E-mail: nystem@health.ny.gov
(518) 474-7002 (phone)

TABLE OF CONTENTS

| | | |
|-------------|---|-----------|
| I. | INTRODUCTION | 1 |
| II. | WHO MAY APPLY? | 1 |
| III. | PROJECT NARRATIVE/WORKPLAN OUTCOMES | 2 |
| | A. Investigator Initiated Research Project (IIRP) | 2 |
| | B. Innovative, Developmental or Exploratory Activities (IDEA) | 2 |
| IV. | ADMINISTRATIVE REQUIREMENTS | 3 |
| | A. Issuing Agency | 3 |
| | B. Question and Answer Phase | 3 |
| | C. Letter of Intent | 4 |
| | D. Applicant Conference | 4 |
| | E. How to File an Application | 4 |
| | F. Department of Health Reserved Rights | 5 |
| | G. Term of Contract | 6 |
| | H. Payment and Reporting Requirements | 7 |
| | I. Minority & Woman-Owned Business Enterprise Requirements | 8 |
| | J. Limits on Administrative Expenses and Executive Compensation | 9 |
| | K. Vendor Identification Number | 10 |
| | L. Vendor Responsibility Questionnaire | 10 |
| | M. Vendor Prequalification for Not-for-Profits | 10 |
| | N. General Specifications | 12 |
| V. | APPLICATION REVIEW AND AWARD PROCESS | 13 |
| | A. Application Acceptance | 13 |
| | B. Freedom of Information Law | 13 |
| | C. Review and Scoring | 13 |
| | D. Application Penalties and Summary Statements | 14 |
| | E. Review Criteria | 15 |
| | F. Empire State Stem Cell Board Funding Committee Review | 16 |
| | G. Award Decisions and Pre-Funding Requirements | 16 |
| | H. Award Announcements | 17 |
| VI. | ATTACHMENTS | 17 |

I. Introduction

The Empire State Stem Cell Board (ESSCB) is authorized to provide funding for basic, applied, translational and other research designed to advance scientific discoveries in fields related to stem cell biology. In conjunction with NYSTEM (the New York State Stem Cell Science Program), the ESSCB makes funding recommendations for creative and innovative biomedical research projects to be supported by the Empire State Stem Cell Trust Fund. Information about the ESSCB and NYSTEM can be found at <http://stemcell.ny.gov>.

The ESSCB wishes to stimulate and support basic, applied (mechanistic, technological), pre-clinical and clinical scientific investigations on any aspect of stem cell biology that will lead to a better understanding of the unique properties of stem cells and allow their utilization to treat disease. The ESSCB is interested in supporting established and early career stage investigators from applicant organizations. Investigators can include those new to the field of stem cell research and those in disciplines that have not historically focused on stem cell research. Although collaborations are not required, they are strongly encouraged. Research studies that promote translation of stem cell science to therapeutic applications are encouraged.

All awards will be financed by the Empire State Stem Cell Trust Fund. The number of awards and total funds awarded per application will be contingent on the quality and content of applications received as well as the scale and scope of the proposed projects. Approximately \$35 million is available to support approximately 50 awards from this RFA. In determining final awards, the Department reserves the right to allocate funds between the two funding mechanisms in this RFA as it deems appropriate.

Eligible organizations are invited to submit applications for the following funding mechanisms:

1. Investigator Initiated Research Project (IIRP)

- Contract term will be up to three years; and
- Annual **direct costs** are capped at \$300,000.

2. Innovative, Developmental or Exploratory Activities (IDEA)

- Contract term will be up to two years; and
- Annual **direct costs** are capped at \$150,000 with a maximum of \$275,000 in direct costs to be spent over the two-year period.

II. Who May Apply?

The applicant must be a not-for-profit organization or governmental organization in New York State. Awarded organizations will be expected to monitor the use of funds, maintain individual accounts and fulfill other fiscal management criteria. Subcontracting and collaborating organizations may include public, not-for-profit and for-profit entities within or outside of New York State.

The eligible Principal Investigator (PI) is designated by the application organization, has the skills, knowledge, and resources necessary to carry out the proposed Workplan, and is not a postdoctoral fellow or other dependent research staff. At the time of application and award

acceptance, the PI must not be restricted from receiving Public Health Service (PHS) funding or debarred by the United States Food and Drug Administration (FDA) or any other federal or New York State government entity.

Eligible organizations are not limited as to the number of applications submitted in response to this RFA. **However, each eligible PI is limited to one application for each funding mechanism (IIRP and IDEA, see Section III for definitions of the mechanisms). If more than one application per funding mechanism is received from an eligible PI, all applications from the PI for that funding mechanism will be disqualified.**

Submission of an application certifies that the applicant organization and the PI meet the eligibility criteria stated here.

III. Project Narrative/Workplan Outcomes

A. Investigator Initiated Research Project (IIRP)

The Investigator Initiated Research Project mechanism is designed to:

- investigate a well-developed problem or research hypothesis; or
- develop technologies or resources that are essential to overcome existing barriers to progress toward therapeutic applications.
- An application for this mechanism should include robust preliminary data

B. Innovative, Developmental or Exploratory Activities (IDEA)

The IDEA mechanism is designed to:

- open a new area of investigation; or
- test a novel or innovative hypothesis; or
- produce viable data for preparation of a full-scale research application; or
- apply or develop state-of-the-art technologies, tools or resources for stem cell research.
- An application for this mechanism should be highly speculative, exploratory, or high-risk and have the potential for high scientific payoff (with or without pilot data). IDEA awards are not intended to fund smaller components of larger Investigator Initiated Research Projects, or for compression of a larger project into a smaller time frame. However, it is the intent of the ESSCB that successful IDEA projects will be eligible to apply for future IIRP awards.

Applicants may subcontract components of the scope of work. For those applicants that propose subcontracting, it is necessary to identify subcontracting agencies during the application process. Applicants that plan to subcontract are expected to state in the application the specific components of the scope of work to be performed through subcontracts. Applicants should note that the lead organization (contractor) will have overall responsibility for all contract activities, including those performed by subcontractors, and will be the primary contact for the DOH. All subcontractors must be approved by the Department of Health.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the New York State Department of Health (Department), NYSTEM program. The Department is responsible for the requirements specified herein and for the evaluation of all applications.

B. Question and Answer Phase

All substantive questions must be submitted in writing to:

Charles J. Burns
Extramural Grants Administration
nystem@health.ny.gov

To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. Written questions for each part of the application will be accepted until the dates posted on the cover of this RFA. This includes Minority and Women Owned Business Enterprise (MWBE) questions and questions pertaining to the MWBE forms.

Questions of a technical nature may be addressed in writing or via telephone by calling Charles J. Burns at (518) 474-7002. **Questions are of a technical nature if they are limited to how to prepare the application (e.g., formatting) rather than relating to the substance of the application.**

Some helpful links for questions of a technical nature are below. Questions regarding specific opportunities or applications should be directed to the DOH contact listed on the cover of this RFA.

- www.grantsreform.ny.gov/grantees
- Grants Reform Videos (includes a document vault tutorial and an application tutorial) on YouTube: <http://www.youtube.com/channel/UCYnWskVc7B3ajjOVfOHL6UA>
- Agate Technical Support Help Desk
Phone: 1-800-820-1890
Hours: Monday thru Friday 8am to 8pm
Email: helpdesk@agatesoftware.com
(Technical questions)
- Grants Team Email: Grantsreform@budget.ny.gov
(Application Completion, Policy, and Registration questions)
- www.grantsgateway.ny.gov

Prospective applicants should note that all clarifications and exceptions, including those relating to the terms and conditions of the contract, are to be raised prior to the submission of an application.

This RFA has been posted on the NYS Grants Gateway website at: and the Department of Health's public website at <http://www.health.ny.gov/funding>. Questions and answers, as well as any updates and/or modifications, will also be posted on these websites. All such updates will be posted by the date identified on the cover sheet of this RFA.

C. Letter of Intent

The prospective applicant institution is **strongly encouraged** to complete and submit a Letter of Intent (**see RFA Attachment 1**) for each application anticipated. This form will assist in the development of review panels in a timely manner. The Letter of Intent form can be found in the Grants Gateway in the Pre-Submission Uploads section of the online application. The file name should include applicant organization and PI names. The completed Letter of Intent should be e-mailed to nystem@health.ny.gov. A copy of the Letter of Intent should also be submitted/uploaded in the Grants Gateway in the Pre-Submission Uploads section of the online application. Please ensure that the RFA number, organization name and PI name are noted in the e-mail subject line. Submit the Letter of Intent via both formats by the date posted on the cover of the RFA.

Submission of a Letter of Intent is not a requirement or obligation upon the applicant to submit an application in response to this RFA. Applications may be submitted without first having submitted a Letter of Intent.

D. Applicant Conference

An applicant conference will be held to give potential applicants the opportunity to receive an overview of the RFA and ask specific questions. The conference will be held via telephone conference call only on the date and time posted on the cover sheet of this RFA. The Department requests that potential applicants register for this conference by calling (518) 474-7002 to ensure a sufficient number of conference phone lines. The deadline for reservations is posted on the cover page of this RFA. Failure to attend the applicant conference will not preclude the submission of an application.

E. How to File an Application

Applications must be submitted online via the Grants Gateway by the date and time posted on the cover of this RFA. Tutorials (training videos) for use of the Grants Gateway are available at the following web address (and upon user log in): <http://grantsreform.ny.gov/Grantees>.

To apply, log in to the Grants Gateway and click on the View Opportunities button under View Available Opportunities. To get started, in the Search Criteria, enter the Grant Opportunity name listed on the cover page and select the Department of Health as the Funding Agency and hit the Search button. Click on the name of the Grant Opportunity from the search results grid and then click on the APPLY FOR GRANT OPPORTUNITY button located left of the Main page of the Grant Opportunity.

In order to access the online application and other required documents such as the attachments you **MUST** be registered and logged into the NYS Grants Gateway system in the user role of either a "Grantee" or a "Grantee Contract Signatory".

The following table provides a snapshot of which roles are allowed to Initiate, Complete and Submit the Grant Application(s) in the Grants Gateway.

| Role | Create and Maintain User Roles | Initiate Application | Complete Application | Submit Application | Only View the Application |
|------------------------------|--------------------------------|----------------------|----------------------|--------------------|---------------------------|
| Delegated Admin | X | | | | |
| Grantee | | X | X | | |
| Grantee Contract Signatory | | X | X | X | |
| Grantee Payment Signatory | | X | X | | |
| Grantee System Administrator | | X | X | X | |
| Grantee View Only | | | | | X |

For further information on how to apply, please access the Grantee Quick Start Guide under the Pre-Submission Upload Properties for this opportunity.

Reference materials and videos are available for Grantees applying to funding opportunities on the NYS Grants Gateway. Please visit the Grants Reform website at the following web address: <http://grantsreform.ny.gov/Grantees> and select the “Grantee Quick Start Guide” from the menu. There is also a more detailed “Grantee User Guide” available on this page as well.

Once the application is complete, prospective grantees should submit their applications, **at a minimum**, one (1) hour prior to the submission deadline. The system will perform an application error check and all identified issues must be resolved before the application is successfully submitted. Failure to leave adequate time to address issues identified during this process may jeopardize an applicant’s ability to submit their application. The Grants Gateway will notify applicants of successful submission via a pop-up message.

Late applications will not be accepted. **Applications will not be accepted via fax, e-mail, hard copy or hand delivery.**

F. Department of Health Reserved Rights

The Department of Health reserves the right to:

1. Reject any or all applications received in response to this RFA.
2. Withdraw the RFA at any time, at the Department’s sole discretion.
3. Make an award under the RFA in whole or in part.
4. Disqualify any applicant whose conduct and/or proposal fails to conform to the requirements of the RFA.

5. Seek clarifications and revisions of applications.
6. Use application information obtained through site visits, management interviews and the state's investigation of an applicant's qualifications, experience, ability or financial standing, and any material or information submitted by the applicant in response to the agency's request for clarifying information in the course of evaluation and/or selection under the RFA.
7. Prior to application opening, amend the RFA specifications to correct errors or oversights, or to supply additional information, as it becomes available.
8. Prior to application opening, direct applicants to submit proposal modifications addressing subsequent RFA amendments.
9. Change any of the scheduled dates.
10. Waive any requirements that are not material.
11. Award more than one contract resulting from this RFA.
12. Conduct contract negotiations with the next responsible applicant, should the Department be unsuccessful in negotiating with the selected applicant.
13. Utilize any and all ideas submitted with the applications received.
14. Unless otherwise specified in the RFA, every offer is firm and not revocable for a period of 60 days from the bid opening.
15. Waive or modify minor irregularities in applications received after prior notification to the applicant.
16. Require clarification at any time during the procurement process and/or require correction of arithmetic or other apparent errors for the purpose of assuring a full and complete understanding of an offerer's application and/or to determine an offerer's compliance with the requirements of the RFA.
17. Negotiate with successful applicants within the scope of the RFA in the best interests of the State.
18. Eliminate any mandatory, non-material specifications that cannot be complied with by all applicants.
19. Award grants based on geographic or regional considerations to serve the best interests of the State.

G. Term of Contract

Any contract(s) resulting from this RFA will be effective only upon approval by the New York State Office of the State Comptroller.

It is expected that contracts resulting from this RFA will begin on July 1, 2017 for a term of up to three years for IIRP awards and up to two years for IDEA awards. Contracts will not be renewable.

Continued funding throughout this period is contingent upon availability of funding and state budget appropriations. The Department also reserves the right to revise the award amount as necessary due to changes in the availability of funding.

H. Payment and Reporting Requirements

1. No advances will be allowed for contracts resulting from this procurement.
2. The grant contractor will be required to submit quarterly invoices and required reports of expenditures through the Grants Gateway (in the future) to the State's designated payment office:

New York State Department of Health
Wadsworth Center
Extramural Grants Administration
Empire State Plaza, Room C345
PO Box 509
Albany, NY 12201-0509

Grant contractors must provide complete and accurate billing invoices to the Department's designated payment office in order to receive payment. Billing invoices submitted to the Department must contain all information and supporting documentation required by the Contract, the Department and the Office of the State Comptroller (OSC). Payment for invoices submitted by the CONTRACTOR shall only be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with OSC's procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at OSC's website at: <http://www.osc.state.ny.us/epay/index.htm>, by email at: epayments@osc.state.ny.us or by telephone at 855-233-8363. CONTRACTOR acknowledges that it will not receive payment on any claims for reimbursement submitted under this contract if it does not comply with OSC's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper as set forth above.

Payment of such claims for reimbursement by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law.

Payment terms will be:

- The contractor will be reimbursed for actual expenses incurred as allowed in the Contract Budget and Workplan.
- All claims for payment submitted by the contractor pursuant to this agreement shall be submitted to the State no later than 30 days after the end of the quarter for which reimbursement is being claimed.

- Quarterly claims for payment will not be paid until all required progress reports for that period are submitted and deemed acceptable by NYSTEM staff.
 - The final claim for payment will be paid following the acceptance and approval of the final progress report.
 - In no event shall the amount received by the contractor exceed the amount approved by the State.
3. The grant contractor will be required to submit through the Grants Gateway (in the future) the following periodic reports:
- Written progress reports in accordance with the forms and formats provided by NYSTEM, no later than 30 days after the end of each reporting period.
 - A final cumulative progress report in accordance with the forms and formats provided by NYSTEM, no later than 60 days after the end of the contract term.
 - A grantee-wide Intellectual Property Report in accordance with the forms and formats provided by NYSTEM, each January 31st and July 31st of the contract term.

All payment and reporting requirements will be detailed in Attachment D of the final NYS Master Grant Contract.

I. Minority & Woman-Owned Business Enterprise Requirements

Pursuant to New York State Executive Law Article 15-A, the New York State Department of Health (“DOH”) recognizes its obligation to promote opportunities for maximum feasible participation of certified minority- and women-owned business enterprises and the employment of minority group members and women in the performance of DOH contracts.

In 2006, the State of New York commissioned a disparity study to evaluate whether minority and women-owned business enterprises had a full and fair opportunity to participate in state contracting. The findings of the study were published on April 29, 2010, under the title "The State of Minority and Women-Owned Business Enterprises: Evidence from New York" (“Disparity Study”). The report found evidence of statistically significant disparities between the level of participation of minority- and women-owned business enterprises in state procurement contracting versus the number of minority- and women-owned business enterprises that were ready, willing and able to participate in state procurements. As a result of these findings, the Disparity Study made recommendations concerning the implementation and operation of the statewide certified minority- and women-owned business enterprises program. The recommendations from the Disparity Study culminated in the enactment and the implementation of New York State Executive Law Article 15-A, which requires, among other things, that DOH establish goals for maximum feasible participation of New York State Certified minority- and women-owned business enterprises (“MWBE”) and the

employment of minority groups members and women in the performance of New York State contracts.

Business Participation Opportunities for MWBEs

For purposes of this solicitation, the New York State Department of Health hereby establishes a goal of **30%** on any subcontracted labor or services, equipment, materials, or any combined purchase of the foregoing greater than \$25,000 under a contract awarded from this solicitation. The goal on the eligible portion of this contract will be **15%** for Minority-Owned Business Enterprises (“MBE”) participation and **15%** for Women-Owned Business Enterprises (“WBE”) participation (based on the current availability of qualified MBEs and WBEs and outreach efforts to certified MWBE firms). A contractor (“Contractor”) on the subject contract (“Contract”) must document good faith efforts to provide meaningful participation by MWBEs as subcontractors or suppliers in the performance of the Contract and Contractor agrees that DOH may withhold payment pending receipt of the required MWBE documentation. For guidance on how DOH will determine “good faith efforts,” refer to 5 NYCRR §142.8.

The directory of New York State Certified MWBEs can be viewed at: <https://ny.newnycontracts.com>. The directory is found in the upper right hand side of the webpage under “Search for Certified Firms” and accessed by clicking on the link entitled “MWBE Directory”. Engaging with firms found in the directory with like product(s) and/or service(s) is strongly encouraged and all communication efforts and responses should be well documented.

By submitting an application, a grantee agrees to complete an MWBE Utilization plan as directed in **Attachment 9** of this RFA. DOH will review the submitted MWBE Utilization Plan. If the plan is not accepted, DOH may issue a notice of deficiency. If a notice of deficiency is issued, Grantee agrees that it shall respond to the notice of deficiency within seven (7) business days of receipt. DOH may disqualify a Grantee as being non-responsive under the following circumstances:

- a) If a Grantee fails to submit a MWBE Utilization Plan;
- b) If a Grantee fails to submit a written remedy to a notice of deficiency;
- c) If a Grantee fails to submit a request for waiver (if applicable); or
- d) If DOH determines that the Grantee has failed to document good-faith efforts to meet the established DOH MWBE participation goals for the procurement.

In addition, successful awardees will be required to certify they have an acceptable Equal Employment Opportunity policy statement.

J. Limits on Administrative Expenses and Executive Compensation

On July 1, 2013, limitations on administrative expenses and executive compensation contained within Governor Cuomo’s Executive Order #38 and related regulations published by the Department (Part 1002 to 10 NYCRR – Limits on Administrative Expenses and Executive Compensation) went into effect. Applicants agree that all state funds dispersed under this procurement will, if applicable to them, be bound by the terms, conditions, obligations and regulations promulgated by the Department. To provide assistance with compliance regarding Executive Order #38 and the related

regulations, please refer to the Executive Order #38 website at:
<http://executiveorder38.ny.gov>.

K. Vendor Identification Number

Effective January 1, 2012, in order to do business with New York State, you must have a vendor identification number. As part of the Statewide Financial System (SFS), the Office of the State Comptroller's Bureau of State Expenditures has created a centralized vendor repository called the New York State Vendor File. In the event of an award and in order to initiate a contract with the New York State Department of Health, vendors must be registered in the New York State Vendor File and have a valid New York State Vendor ID.

If already enrolled in the Vendor File, please include the Vendor Identification number on the application cover sheet. If not enrolled, to request assignment of a Vendor Identification number, please submit a New York State Office of the State Comptroller Substitute Form W-9, which can be found on-line at:
http://www.osc.state.ny.us/vendor_management/issues_guidance.htm.

Additional information concerning the New York State Vendor File can be obtained on-line at: http://www.osc.state.ny.us/vendor_management/index.htm, by contacting the SFS Help Desk at 855-233-8363 or by emailing at helpdesk@sfs.ny.gov.

L. Vendor Responsibility Questionnaire

The New York State Department of Health recommends that vendors file the required Vendor Responsibility Questionnaire online via the New York State VendRep System. To enroll in and use the New York State VendRep System, see the VendRep System Instructions available at http://www.osc.state.ny.us/vendrep/vendor_index.htm or go directly to the VendRep system online at <https://portal.osc.state.ny.us>.

Vendors must provide their New York State Vendor Identification Number when enrolling. To request assignment of a Vendor ID or for VendRep System assistance, contact the Office of the State Comptroller's Help Desk at 866-370-4672 or 518-408-4672 or by email at ciohelpdesk@osc.state.ny.us.

Vendors opting to complete and submit a paper questionnaire can obtain the appropriate questionnaire from the VendRep website at:
http://www.osc.state.ny.us/vendrep/forms_vendor.htm or may contact the Office of the State Comptroller's Help Desk for a copy of the paper form.

Applicants should complete and submit the Vendor Responsibility Attestation (**see RFA Attachment 8**).

M. Vendor Prequalification for Not-for-Profits

All not-for-profit vendors subject to prequalification are required to prequalify prior to grant application and execution of contracts.

Pursuant to the New York State Division of Budget Bulletin H-1032, dated June 7, 2013, New York State has instituted key reform initiatives to the grant contract process which

requires not-for-profits to register in the Grants Gateway and complete the Vendor Prequalification process in order for applications to be evaluated. Information on these initiatives can be found on the [Grants Reform Website](#).

Applications received from not-for-profit applicants that have not Registered and are not Prequalified in the Grants Gateway on the application due date listed on the cover of this RFA cannot be evaluated. Such applications will be disqualified from further consideration.

Below is a summary of the steps that must be completed to meet registration and prequalification requirements. The [Vendor Prequalification Manual](#) on the Grants Reform Website details the requirements and an [online tutorial](#) are available to walk users through the process.

1) Register for the Grants Gateway

- On the Grants Reform Website, download a copy of the [Registration Form for Administrator](#). A signed, notarized original form must be sent to the Division of Budget at the address provided in the instructions. You will be provided with a Username and Password allowing you to access the Grants Gateway.

If you have previously registered and do not know your Username, please email grantsreform@budget.ny.gov. If you do not know your Password, please click the [Forgot Password](#) link from the main log in page and follow the prompts.

2) Complete your Prequalification Application

- Log in to the [Grants Gateway](#). **If this is your first time logging in**, you will be prompted to change your password at the bottom of your Profile page. Enter a new password and click SAVE.
- Click the *Organization(s)* link at the top of the page and complete the required fields including selecting the State agency you have the most grants with. This page should be completed in its entirety before you SAVE. A *Document Vault* link will become available near the top of the page. Click this link to access the main Document Vault page.
- Answer the questions in the *Required Forms* and upload *Required Documents*. This constitutes your Prequalification Application. Optional Documents are not required unless specified in this Request for Application.
- Specific questions about the prequalification process should be referred to your agency representative or to the Grants Reform Team at grantsreform@budget.ny.gov.

3) Submit Your Prequalification Application

- After completing your Prequalification Application, click the **Submit Document Vault Link** located below the Required Documents section to submit your Prequalification Application for State agency review. Once submitted the status of the Document Vault will change to *In Review*.

- If your Prequalification reviewer has questions or requests changes you will receive email notification from the Gateway system.
- Once your Prequalification Application has been approved, you will receive a Gateway notification that you are now prequalified to do business with New York State.

Vendors are strongly encouraged to begin the process as soon as possible in order to participate in this opportunity.

N. General Specifications

1. By submitting the "Application Form" each applicant attests to its express authority to sign on behalf of the applicant.
2. Contractors will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.
3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer Phase (Section IV.B.) must be clearly noted in a cover letter attached to the application.
4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.
5. Provisions Upon Default
 - a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.
 - b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
 - c. If, in the judgment of the Department, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive equitable compensation for such services as shall, in the judgment of the State Comptroller, have been satisfactorily performed by the Contractor up to the date

of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

V. Application Review and Award Process

A. Application Acceptance

Applications will first be examined against mandatory Pass/Fail requirements by program staff (**see RFA Attachment 2**). Applications that do not meet the mandatory requirements will not be considered for review, and the applicant organization and PI will be notified.

B. Freedom of Information Law

All applications may be disclosed or used by DOH to the extent permitted by law. DOH may disclose an application to any person for the purpose of assisting in evaluating the application or for any other lawful purpose. All applications will become State agency records, which will be available to the public in accordance with the Freedom of Information Law. **Any portion of the application that an applicant believes constitutes proprietary information entitled to confidential handling, as an exception to the Freedom of Information Law, must be clearly and specifically designated in the application.** If DOH agrees with the proprietary claim, the designated portion of the application will be withheld from public disclosure. Blanket assertions of proprietary material will not be accepted, and failure to specifically designate proprietary material may be deemed a waiver of any right to confidential handling of such material.

C. Review and Scoring

The Department contracts with an independent peer review organization to develop and coordinate the review and scoring of applications. Each eligible application will be evaluated by an Independent Peer Review Panel (the Review Panel) assigned by the Peer Review Contractor. The Review Panel members will be selected from among non-New York State experts in the fields appropriate to the nature of the applications received.

Applications will be reviewed based on the criteria specified in Section V.E. The Review Panel will use an established combination of processes to evaluate each application:

1. pre-meeting review with adjectival scoring (see table below)
2. on-line conferral among assigned reviewers
3. triage based on adjectival scores of assigned reviewers for the criterion identified in Section V.E.
4. panel meeting discussion via teleconference, videoconference or in-person (review method chosen at the discretion of the Department) with numerical scoring (see table below).

Applications that are not triaged prior to panel meeting discussion will receive numerical scores from each participating panel member for each evaluation criterion using an

integer scale that equates to adjectival scores, where 1 equates to highest merit and 9 equates to lowest merit. The numerical score given each criterion will be multiplied by that criterion’s weight. Each panel member’s weighted scores for each criterion will be added together to give their individual total score. Review Panel members’ individual total scores will be added together and divided by the number of Review Panel members who scored the application to give an overall panel score for the application. The numerical scores correspond to adjectival scores as follows:

| Numerical Score | Adjectival Score |
|------------------------|-------------------------|
| 1 | Exceptional |
| 2 | Outstanding |
| 3 | Excellent |
| 4 | Very Good |
| 5 | Good |
| 6 | Satisfactory |
| 7 | Fair |
| 8 | Marginal |
| 9 | Poor |

Applications that are triaged (receive an adjectival score of Excellent or worse from each assigned reviewer for the criterion identified in Section V.E.) will not receive scores.

The Review Panel will comment on the responsiveness of the application to the funding mechanism as described in Sections I and III above. The Review Panel will identify potential overlap with other resources/projects. Additionally, the Review Panel will comment on the application with regard to the Contract Policy Statements and Conditions (NYS Master Grant Contract Attachment A-1 Part B). The Review Panel may recommend administrative review and resolution prior to contract execution. In addition, award recommendations made by the ESSCB Funding Committee may be contingent upon the applicant’s acceptance of required revisions.

The primary reviewer will prepare a written overall evaluation of each assigned application that is discussed by the Review Panel. Each assigned reviewer will provide a written critique of the application based on the established evaluation criteria.

D. Application Penalties and Summary Statements

It is the applicant’s responsibility to ensure that all materials to be included in the application have been properly prepared and submitted. ALL APPLICATIONS SHOULD CONFORM TO THE FORMAT/CONTENT PRESCRIBED IN RFA **ATTACHMENT 2**. The Peer Review Contractor will assess a penalty of 0.1 point for any application that scores 1.0 through 2.9 and deviates from the instructions (**see Checklist, RFA Attachment 2**).

The Peer Review Contractor will calculate final scores and compile a Summary Statement for each application for the Funding Committee of the ESSCB. The Summary Statements will document the evaluation and serve as the primary basis for the panel recommendation for the applications.

E. Review Criteria

Three evaluation criteria are considered by the Review Panel:

SIGNIFICANCE AND IMPACT (40%) – *triage criterion*

- Does the research project address an important problem or critical barrier to progress in a defined field of stem cell research?
- Is the proposed work a refinement, an improvement or a new application of concepts, methodologies, instrumentation or clinical practice in stem cell science?
- Does the application challenge paradigms of current research or clinical practice?
- Is the project likely to have a sustained impact on the field?
- Is stem cell related scientific knowledge, technical capability or clinical practice likely to be improved by the proposed project? **and/or**
- Is the project likely to have potential therapeutic significance?

APPROACH AND FEASIBILITY (40%)

- Are the overall strategy, proposed methods and analyses well-reasoned and the most appropriate to accomplish the specific aims of the project within the award period?
- Are the uses of human subjects, vertebrate animals and human pluripotent stem cells appropriate to the overall goals of the project?
- If the project is in an early stage of development, speculative or exploratory (as may be the case with IDEA proposals, for example), will the proposed work establish feasibility if successful?
- Are potential problems discussed and alternative strategies provided?
- Are the knowledge, skills, research tools, experience, and time commitments of the research team appropriate to complete the proposed work?
 - For Early Stage Investigators, do they have appropriate training and experience to lead the project?
 - For established investigators, have they demonstrated a track record of achievements advancing their field?
 - Are other team members appropriate for their roles in the project?
- Does the overall environment contribute to the likelihood of success? Are the scientific resources, equipment and organizational support available to investigators adequate for the proposed work? Are there unique features of the project environment that strengthen the application, such as access to research samples or subject populations?

BUDGET (20%)

- Are the items for each budget line explained?
- Are budget line items adequately justified as necessary for completion of the project?
- Are the budgeted amounts reasonable, cost effective and appropriate to accomplish the research aims?
- Are there specific excessive or unnecessary budget items?

- Does the budget reflect understanding of the human, material and financial resources needed, and the timeframes in which they are needed, for successful completion of the project within the contract term?

F. Empire State Stem Cell Board Funding Committee Review

The ESSCB Funding Committee will consider applications that receive a final score (after penalties are assessed) of 1.0 through 2.9. The ESSCB Funding Committee will not consider applications that received a final score of 3.0 to 9.0 or those that were triaged.

The ESSCB Funding Committee will consider the application strengths and weaknesses, and administrative recommendations. When making funding recommendations, the ESSCB Funding Committee will consider responsiveness to the mission of the ESSCB, responsiveness to the RFA, programmatic balance, availability of funds, and compliance with Public Health Law Article 2, Title 5-A, §265. The ESSCB Funding Committee is not obligated to recommend funding for any application. Scoring ties will be resolved on the basis of the above and with consideration of the score for Significance and Impact among those applications involved in the tie.

The ESSCB Funding Committee will vote on each application that scores 2.9 or better until available funds are exhausted and in compliance with ESSCB bylaws as well as applicable laws and regulations. If an application for which there are available funds is not recommended for funding, the ESSCB Funding Committee will fully justify in writing why the application was not approved.

The ESSCB Funding Committee may elect, at its discretion, to continue making recommendations for possible funding of proposals beyond what is available for the funding mechanism and the RFA. These applications will be given the status “Approved but not funded.” “Approved but not funded” applications may be funded should additional funds become available.

The ESSCB Funding Committee will make recommendations for funding to the Commissioner of Health.

G. Award Decisions and Pre-Funding Requirements

Prior to contract execution, program administrators will require resolution/submission/confirmation of the following items, as relevant to each application:

- Revisions to Workplan, project duration or budget
- Overlap
- Areas of possible concern with regard to Program Specific Clauses (NYS Master Grant Contract Attachment A-1 Part B)
- MWBE Utilization Plans
- Research protocol approvals
- Approved Facilities and Administrative Cost Rate

Once an award has been made, applicants may request a debriefing of their application. Please note the debriefing will be limited only to the strengths and weaknesses of the subject application and will not include any discussion of other applications. Requests

must be received no later than ten (10) business days from date of award or non-award announcement.

If changes in funding amounts are necessary for this initiative or if additional funding becomes available, funding will be modified and awarded in the same manner as outlined in the award process described above.

In the event unsuccessful applicants wish to protest the award(s) resulting from this RFA, applicants should follow the protest procedures established by the Office of the State Comptroller (OSC). These procedures can be found on the OSC website at <http://www.osc.state.ny.us/agencies/guide/MyWebHelp>.

H. Award Announcements

NYSTEM makes public in press releases and reports, the project title, the PI(s), the name of the organization, total projects costs and duration. The project abstract and progress report abstracts may also be edited and made public.

VI. Attachments

Please note that attachments can be accessed in the “Pre-Submission Uploads” section of an online application. In order to access the online application and other required documents such as the attachments, prospective applicants must be registered and logged into the NYS Grants Gateway in the user role of either a “Grantee” or a “Grantee Contract Signatory”.

Attachment 1: Letter of Intent

Attachment 2: Application Checklist and Instructions

Attachment 3: Application Forms 1-6

Attachment 4: Application Form 1-S

Attachment 5: Application Form 7

Attachment 6: Application Form 7-S

Attachment 7: Application Forms 8-15

Attachment 8: Vendor Responsibility Attestation

Attachment 9: Minority & Women-Owned Business Enterprise Requirement Forms

These attachments are located/included in the Pre Submission Uploads section of the Grants Gateway on line application.