RFA # 17607 NYS Grants Gateway # DOH01-PART3-2019

New York State Department of Health and the New York State Spinal Cord Injury Research Board Request for Applications

Projects to Accelerate Research Translation (PART) and Innovative, Developmental or Exploratory Activities (IDEA) in Spinal Cord Injury (Round 3)

KEY DATES:

RELEASE DATE: 2/21/2018

APPLICANT CONFERENCE REGISTRATION DUE: 3/2/2018

APPLICANT CONFERENCE: 3/6/2018 at 10:30 AM

By Webinar (WebEx) at:

1-844-633-8697 or 1-518-549-0500

Meeting ID # 649 012 837

LETTER OF INTENT DUE (Strongly encouraged): 2/28/2018

CONFLICT OF INTEREST DUE (Optional): 2/28/2018

QUESTIONS DUE: 3/13/2018

QUESTIONS, ANSWERS AND

UPDATES POSTED: 3/19/2018

APPLICATIONS DUE: 4/18/2018 by 4:00 PM

DOH CONTACT NAME AND ADDRESS:

Charles J. Burns
Extramural Grants Administration
New York State Department of Health
Wadsworth Center
Empire State Plaza, Room C345
PO Box 509, Albany, NY 12201-0509
(518) 474-7002 (phone)
scirb@health.ny.gov

Staff will be available at the phone number and email address above to answer questions about the RFA during regular business hours and up to 4PM on the application due date.

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I. Introduction

A. Background

Approximately 1,000 New York residents suffer a traumatic spinal cord injury (SCI) each year, joining the estimated six million people in the United States who are living with paralysis and other effects of SCI. The personal and economic costs to these persons, their families and to society are immense. Since 1998, the New York State Spinal Cord Injury Research Board (SCIRB) advises the New York State Department of Health (NYSDOH), Spinal Cord Injury Research Program (Program) regarding research focused on cures for SCI and SCI-induced paralysis.

The SCIRB's mission and goal is to:

- 1. Seek major advances toward a cure and not simply incremental research gains or incremental improvements for SCI patients
- 2. Support research that tests novel hypotheses and/or advances innovative research approaches that could move the field of SCI research significantly toward discovering a cure for SCI.

The SCIRB's mission is to stimulate high-quality, innovative SCI research that will help promote treatment and cure for SCI, including methods for reversing paralysis or restoring function caused by injury, or for minimizing or preventing damage occurring during acute phases of injury. To achieve this mission, the Program offers a portfolio of competitive research awards to support the New York State scientists and their collaborators from a variety of biomedical disciplines in initiating and pursuing such efforts. Information about the Program and SCIRB can be found at: http://www.wadsworth.org/extramural/spinalcord.htm.

B. Purpose of the Funds

The SCIRB wishes to stimulate the growth of SCI research and to accelerate the pace with which basic (preclinical) findings are translated into clinical benefits for spinal cord-injured persons. In addition, SCIRB wishes to fill fundamental gaps in knowledge that are barriers to scientific advances in SCI research. The goal is to expend \$8.5 million for SCI research every State fiscal year.

The SCIRB welcomes basic, translational and clinical neurological research applications on topics bearing on its mission. Although the SCIRB has not formally developed a list of research priorities, projects targeting tissue regeneration, repair, or restoration of function through biomedical and bioengineering research are of strongest interest.

C. Available Funds

Projects will be supported by State funds. Approximately \$5.0 million in total funding is available to support 5-14 awards. The amount of funds awarded will be contingent upon the quality of applications submitted. In determining final awards, the Department reserves the right to allocate funds between the two funding mechanisms offered within this RFA as it deems appropriate. Eligible institutions are invited to submit applications for the following funding mechanisms:

1. Projects to Achieve Research Translation (PART)

- Contract term will be up to three years; and
- Annual direct costs are capped at \$275,000 plus Facilities and Administrative costs up to

2. Innovative, Developmental or Exploratory Activities (IDEA)

- Contract term will be up to two years; and
- Annual direct costs are capped at \$150,000 plus Facilities and Administrative costs up to 20% total modified indirect costs

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.

An eligible organization is not limited to the number of applications it can submit in response to this RFA. However, an eligible PI may be named on only one application per funding mechanism in response to this RFA, regardless of the organization under which the application is submitted. If a PI is named on more than one application for an IDEA award and/or more than one application for a PART award, all applications from that PI for that funding mechanism will be disqualified and will not be forwarded to peer review.

Eligibility to apply also includes the following mandatory items:

- The PI is not 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 (see Section II, pg. 2)
- The application does not propose support for a research center
- The application does not propose support for a Phase III clinical trial
- The application does not propose expansion of enrollment for an ongoing clinical trial
- The PI is not named on more than one application per funding mechanism

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

III. Project Narrative/Workplan Outcomes

Subcontracting agencies must be identified during the application process for those applicants that propose subcontracting. 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 should be approved by the Department of Health.

A. Projects to Accelerate Research Translation (PART) Award

The intent of the PART award is to foster the translation of results from basic (preclinical) research into the next research phase. PART awards are expected to contribute to rapid movement of findings to potential therapeutic applications or treatment strategies. The PART

mechanism is designed to investigate a well-developed problem or research hypothesis focusing on cures for SCI paralysis or the prevention of paralysis following trauma. Proposed projects should be cohesive and sharply focused. Translational aspects of the study may involve either animal or human studies. The research may be applied or may integrate fundamental and applied approaches. Applications that seek to apply knowledge gleaned from lower order mammals to appropriate non-human primate models are also eligible. The application will include at least one translational aim/goal, and should explicitly state how results will inform and enable the next research stage, (e.g., preclinical or clinical research).

Applications considered non-responsive to this RFA include those lacking a specific and attainable translational or clinical goal (i.e., completion of the workplan cannot lead to another basic research grant application).

B. Innovative, Developmental or Exploratory Activities (IDEA) Award

The intent of the IDEA award is to provide initial support for:

- preliminary testing of novel or high-risk hypotheses
- applying novel approaches and methods
- challenging existing paradigms or developing new paradigms
- considering an existing problem from a new perspective.

The IDEA mechanism provides researchers the opportunity to try new methods and approaches to investigate the problems associated with SCI. IDEA projects are self-contained research projects. They are not intended to: fund smaller components of larger research projects; solely for data collection; for incremental or correlative research aims; or for compression of a larger project into a smaller time frame. Responsive applications include the following projects:

- highly speculative, exploratory, or high-risk may not have pilot data, but have the
 potential for high scientific payoff
- application or development of state-of-the-art technologies, tools or resources for SCI research
- innovative or developmental focus on exceptionally promising topics and have some pilot data, but not yet sufficiently mature to compete successfully for funding for a fullscale study
- testing new hypotheses based on research grounded in a non-SCI research area

The SCIRB seeks to fund research projects in which there is a high likelihood that the results will yield the opportunity to apply for future funding from other sources.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the New York State Department of Health (Department), Wadsworth Center, Extramural Grants Administration. 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 or via email to:

Charles J. Burns, Extramural Grants Administration scirb@health.ny.gov

To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. Written questions will be accepted until the date 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 can 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 your 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.

- https://grantsreform.ny.gov
- Grants Gateway Videos (includes a document vault tutorial and an application tutorial) on YouTube: https://grantsreform.ny.gov/youtube

Grants Gateway Team Email: <u>grantsgateway@its.ny.gov</u>

Phone: 518-474-5595

Hours: Monday thru Friday 8am to 4:30pm

(Application Completion, Policy, and Registration questions)

Agate Technical Support Help Desk

Phone: 1-800-820-1890

Hours: Monday thru Friday 8am to 8pm Email: helpdesk@agatesoftware.com

(Technical questions)

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: https://grantsgateway.ny.gov/IntelliGrants_NYSGG/module/nysgg/goportal.aspx and a link provided on the Department'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 the Grants Gateway. All such updates will be posted by the date identified on the cover 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**). This form will be used to develop the review panel in a timely manner. Letters of Intent should be submitted via the Grants Gateway in the Pre-Submission Uploads section of the online application. Please note that you will receive an error message when uploading the letter into the application as other Pre-Submission uploads are not due until the application is submitted. The file name should include applicant organization and PI names. A copy must also be e-mailed to scirb@health.ny.gov. 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

Potential applicants are strongly encouraged to participate in the applicant conference to receive an overview of the RFA and ask specific questions. The conference will be held via webinar (WebEx) 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 emailing scirb@health.ny.gov. The Department will send a confirmation email with instructions for joining the conference to all registrants. The deadline for reservations is posted on the cover page of this RFA. Applicants unable to participate in the webinar will have the option to view the applicant conference slides at their convenience. The applicant conference slides will be posted with the Questions and Answers document on the NYS Grants Gateway website at: https://grantsgateway.ny.gov by the date posted on the cover 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. 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: https://grantsreform.ny.gov/Grantees and select the "Grantee Quick Start Guide Applications" from the menu on the left. There is also a more detailed "Grantee User Guide" available on this page as well. Training webinars are also provided by the Grants Gateway Team. Dates and times for webinar instruction can be located at the following web address: https://grantsreform.ny.gov/training-calendar.

To apply for this opportunity:

- 1. Log into the Grants Gateway as either a "Grantee" or "Grantee Contract Signatory".
- 2. Click on the "View Opportunities" button under "View Available Opportunities".
- 3. In the Search Criteria, enter the Grant Opportunity name "Projects to Accelerate Research Translation (PART) and Innovative, Developmental or Exploratory Activities (IDEA)" and select the Department of Health as the Funding Agency.
- 4. Click on "Search" button to initiate the search.
- 5. Click on the name of the Grant Opportunity from the search results grid and then select the "APPLY FOR GRANT OPPORTUNITY" button located bottom left of the Main page of the Grant Opportunity.

Once the application is complete, prospective grantees are <u>strongly encouraged</u> to submit their applications at least 48 hours prior to the due date and time. This will allow sufficient opportunity for the applicant to obtain assistance and take corrective action should there be a technical issue with the submission process. Failure to leave adequate time to address issues identified during this process may jeopardize an applicant's ability to submit their application. Both DOH and Grants Gateway staff are available to answer applicant's technical questions and provide technical assistance prior to the application due date and time. Contact information for the Grants Gateway Team is available under Section IV. B. of this RFA.

<u>PLEASE NOTE:</u> Although DOH and the Grants Gateway staff will do their best to address concerns that are identified less than 48 hours prior to the due date and time, there is no guarantee that they will be resolved in time for the application to be submitted and, therefore, considered for funding.

The Grants Gateway will always notify applicants of successful submission. If a prospective grantee does not get a successful submission message assigning their application a unique ID number, it has not successfully submitted an application. During the application process, please pay particular attention to the following:

- Not-for-profit applicants must be prequalified on the due date for this application submission.
 Be sure to maintain prequalification status between funding opportunities. Three of a not-for-profit's essential financial documents the IRS990, Financial Statement and Charities Bureau filing expire on an annual basis. If these documents are allowed to expire, the not-for-profit's prequalification status expires as well, and it will not be eligible for State grant funding until its documentation is updated and approved, and pregualified status is reinstated.
- Only individuals with the roles "Grantee Contract Signatory" or "Grantee System Administrator" can submit an application.
- Prior to submission, the system will automatically initiate a global error checking process to
 protect against incomplete applications. An applicant may need to attend to certain parts of
 the application prior to being able to submit the application successfully. Be sure to allow
 time after pressing the submit button to clean up any global errors that may arise. You can
 also run the global error check at any time in the application process. (see p.66 of the
 Grantee User Guide).
- Grantees should use numbers, letters and underscores when naming their uploaded files. There cannot be any special characters in the uploaded file name. Also be aware of the restriction on file size (10 MB) when uploading documents. Grantees should ensure that any attachments uploaded with their application are not "protected" or "pass-worded" documents.

The following table will provide 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		Х	V	Х	
Administrator		^	^	^	
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.

Applicants 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.

PLEASE NOTE: Waiting until the last several days to complete your application online can be dangerous, as you may have technical questions. Beginning the process of applying as soon as possible will produce the best results.

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

F. Department of Health's 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 Comptroller.

It is expected that contracts resulting from this RFA will begin on May 1, 2019 for a multi-year term of up to three years for PART 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. DOH also reserves the right to revise the award amount as necessary due to changes in the availability of funding.

A sample New York State Master Contract for Grants can be found in the Forms Menu once an application to this funding opportunity is started.

H. Payment & Reporting Requirements of Grant Awardees

- 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 to the State's designated payment office (below) or, in the future, through the Grants Gateway:

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 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 check 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 Spinal Cord Injury Research Program 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 the following progress reports to the Department of Health at the address above or, in the future, through the Grants Gateway:
 - Written progress reports in accordance with the forms and formats provided by the SCI Research Program, 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 the SCI Research Program, no later than 60 days after the end of the contract term.

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

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% as follows:

- 1) For Not-for Profit Applicants: Eligible Expenditures include any subcontracted labor or services, equipment, materials, or any combined purchase of the foregoing under a contract awarded from this solicitation.
- 2) For-Profit and Municipality Applicants: Eligible Expenditures include the value of the budget in total.

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 "". 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 11** 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 be sure the Vendor Identification number is included in your organization information. 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/forms.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 strongly encourages 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/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.

Applicants should complete and submit the Vendor Responsibility Attestation (see RFA Attachment 10).

M. Vendor Pregualification 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 July 16, 2014, 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 <u>and</u> 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 <u>Vendor Prequalification Manual</u> on the Grants Reform Website details the requirements and an <u>online tutorial</u> are available to walk users through the process.

1) Register for the Grants Gateway

On the Grants Reform Website, download a copy of the <u>Registration Form for Administrator</u>. 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 grantsgateway@its.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 <u>Grants Gateway</u>. 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 Gateway Team at grantsgateway@its.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.

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

N. General Specifications

- 1. By submitting the "Application Form" each applicant attests to its express authority to sign on behalf of the applicant.
- 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 judgement 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 judgement 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. Completing the Application, Review and Award Process

A. How to Apply

Please refer to the Quick Start Guide for assistance in applying for this procurement through the NYS Grants Gateway. This guide is available on the Grants Reform website at: https://grantsreform.ny.gov/grantees.

ALL APPLICATIONS SHOULD CONFORM TO THE FORMAT/CONTENT PRESCRIBED in Attachment 2 – Application Checklist and Instructions. POINTS WILL BE DEDUCTED FROM APPLICATIONS WHICH DEVIATE FROM THE PRESCRIBED FORMAT.

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared and submitted. Applications must be submitted via the Grants Gateway by the date and time posted on the cover of this RFA.

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 & Award Process

Applications will first be examined against mandatory Pass/Fail requirements by Extramural Grant Administration 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.

Applications with minor issues (missing information that is not essential to timely review and would not impact review scores) MAY be processed, at the discretion of the State, but all issues need to be resolved prior to time of award. An application with unresolved issues at the time award recommendations are made will be determined to be non-responsive and will be disqualified.

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. The Peer Review Contractor has established a standing Review Panel to which expertise is added to evaluate the merit of actual applications submitted in response to the RFA.

The Review Panel will be assigned based on the category of research being conducted. All applications must include the category of research being conducted as "Rehabilitation" (Rehabilitation) or "Cellular Regeneration & Therapeutics" (Cellular Regeneration). This information will be requested on Form 4 in Attachment 3.

Applications will be reviewed based on the criteria specified in Section V.F. Initially, a subcommittee of the applicable Review Panel consisting of three peer reviewers will consider each application. At least two members of each subcommittee, including the primary reviewer, shall consist of senior review scientists. For purposes of this RFA, a senior review scientist is a researcher who has been a primary investigator or co-primary investigator on more than one scientific research project, which has been previously funded in the field of spinal cord injury. The subcommittee of 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. panel meeting discussion via teleconference, videoconference or in-person (review method chosen at the discretion of the Department) with numerical scoring (see table below).

The primary reviewer of each panel will prepare a written evaluation of each assigned application that is to be discussed by the Review Panel. Additionally, each of the assigned reviewers of a particular subcommittee will provide a written critique of the application based on established evaluation criteria.

Thereafter, the entire Review Panel will meet via teleconference, videoconference or in person (review method chosen at the discretion of the Department) to discuss and score each of the applications. Each member of the Review Panel will provide a confidential numerical score for each application they are eligible to review.

Applications 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.

	Numerical Score	Adjectival Score	Guidance
	1	Exceptional	Exceptionally strong with essentially no weaknesses
HIGH	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minora weaknesses
	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate ^b weakness
MEDIUM	6	Satisfactory	Some strengths but also some moderate weaknesses
	7	Fair	Some strengths but with at least one major ^c weakness
LOW	8	Marginal	A few strengths and a few major weaknesses
LOW	9	Poor	Very few strengths and numerous major weaknesses

^aMinor weakness: An easily addressable weakness that does not substantially lessen merit and/or the expected successful completion of the overall project

bModerate weakness: A weakness that lessens merit and/or the expected successful completion of the overall project balance weakness: A weakness that severely limits merit and/or the expected successful completion of the overall project

The Review Panel will comment on the responsiveness of the application to the funding mechanism as described in Section III above. The Review Panel will identify potential overlap with other resources. 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. Award recommendations made by the SCIRB may be contingent upon the applicant's acceptance of reductions or required revisions.

The primary reviewer will prepare a written 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. Conflicts of Interest and Reviewer Exclusions

The SCIRB aims to conduct a review process that is rigorous and impartial. All participants in a review (including scientific reviewers, Department members and members of the SCIRB) are required to disclose financial interests and declare all conflicts that meet relevant SCIRB and State New York conflict of interest regulations.

In addition, the SCIRB understands that even strict policies may not account for every perceived conflict. Therefore, all applicants seeking funding may identify up to three individuals (excluding SCIRB members and employees) and/or for-profit organizations that such applicant believes could be biased whether for personal, professional, or competitive reasons (e.g., a company that is a direct competitor with respect to the applicant's proposed research or product). Individuals, and current employees, board members, and consultants (working on potentially competing research or product) of companies, identified by applicants pursuant to this screening mechanism will not be permitted to participate in the review of such applicant's application.

Applicants who wish to submit a Conflict of Interest Form, **must do so as part of the Letter of Intent (see Section IV.C.)** by the deadline stated on the cover of this RFA. Applicants may use RFA Attachment 9 to identify perceived conflicts with up to 3 individuals excluding SCIRB members and Department employees.

Please refer to RFA Attachment 9.

E. Application Format, 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 deviates from the instructions (see Application Checklist and Instructions, RFA Attachment 2).

The Peer Review Contractor will calculate final scores for the research project and compile a Summary Statement for each application for SCIRB. The Summary Statements will document the merit evaluation and serve as the primary basis for the panel recommendation for the applications.

F. Review Criteria

The following evaluation criteria will be considered by the Independent Scientific Merit Peer Review Panel:

1. PART Award

Research Plan (60%)

- The likelihood that the proposed research will have high impact in achieving a cure for SCI
- The originality of the research question(s) and the approach taken in its investigation through a research effort
- The importance of the research questions and their basis in the scientific literature
- The suitability of research design and methods to achieve the application's SCIrelated aims
- The likelihood of successful completion of the study based on the research design, methods, background and experience of the investigators, the research environment and the availability of time and resources
- The appropriate use of human subjects and vertebrate animals to accomplish the overall goals of the project

Translational/Clinical Potential (20%)

 The potential for the proposed work to contribute to therapeutic applications or treatment strategies and cures for SCI-induced paralysis or to prevent paralysis following acute injury

Budget (20%)

- The need for each budget item is explained
- o Each budget line is justified as necessary for completion of the project
- Budgeted amounts are reasonable, cost-effective and appropriate to accomplish the research aims
- There are no excessive or unnecessary budget items

Note: The entire Panel will review and comment on the Budget section. Numeric scores for the Budget criterion will be provided only by the assigned reviewers.

2. IDEA Award

Research Plan (60%)

- The extent to which basic concept and hypotheses are speculative, exploratory, or develop new paradigms
- The extent to which the project applies or develops state-of-the-art technologies, methods, tools or resources for SCI research, or addresses important under- or unexplored areas
- The innovative and developmental potential of the project, with a focus on exceptionally promising topics
- o The originality of the research question(s) and the approach taken in its investigation
- The importance of the research questions and their basis in the scientific literature
- The likelihood of successful completion of the study aims based on the research design, methods, background and experience of the investigators, the research environment and the availability of time and resources

Impact (20%)

- The extent to which the project, if successfully completed, would make an original and important contribution to treatments and cures for SCI-induced paralysis or to prevent paralysis following acute injury (high-risk/high-reward)
- o The likelihood the project will lead to further funding or be translated into practice

Budget (20%)

- The need for each budget item is explained
- Each budget line is justified as necessary for completion of the project
- Budgeted amounts are reasonable, cost-effective and appropriate to accomplish the research aims
- There are no excessive or unnecessary budget items

Note: The entire Panel will review and comment on the Budget section. Numeric scores for the Budget criterion will be provided only by the assigned reviewers.

G. Spinal Cord Injury Research Board Review

The SCIRB will discuss the strengths and weaknesses of all applications, administrative and budget recommendations as outlined in the reports of the Review Panel. When making funding recommendations, the SCIRB will consider Review Panel Scores and recommendations, responsiveness to the mission of the SCIRB and responsiveness to the RFA, programmatic balance and availability of funds. The SCIRB may vote in favor or against any application submitted for funding. Scoring ties will be resolved on the basis of the above and with consideration of the score for 'Research Plan' among those applications involved in the tie.

The SCIRB will vote on each application in compliance with SCIRB bylaws as well as applicable laws and regulations. If an application for which there are available funds is not recommended for funding, the SCIRB will fully justify in writing why the application was not approved.

The SCIRB 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 SCIRB will make recommendations for funding to the Commissioner of Health.

H. Award Decisions & Pre-Funding Requirements

Grant award contracts are entered into between New York State applicant organizations and the New York State Department of Health. Funding is contingent upon full execution of a contract between the applicant organization and the New York State Department of Health and approval by the Commissioner of Health, State Attorney General and State Comptroller.

Following the Commissioner's approval of awards, PIs and their applicant organizations will receive formal notification in writing.

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 Contract Policy Statements and Conditions (NYS Master Grant Contract Attachment A-1 Part B)
- Approved Facilities and Administrative Cost Rate

Once an award has been made, all applicants (whether their application was funded or not funded) 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 fifteen (15) business days from date of award or non-award announcement.

To request a debriefing, please send an email to <u>scirb@health.ny.gov</u>. In the subject line, please write: Debriefing request (PART & IDEA Rd 3 RFA).

In the event unsuccessful applicants wish to protest the award 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 (Section XI. 17.)

I. Award Announcements

SCIRB makes public in press releases and annual reports to the Governor and Legislature, 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 all attachments are accessed in the "Pre-Submission Uploads" section of an online application and are not included in the RFA. 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 1-5
Attachment 4: Application Form 1-S
Attachment 5: Application Form 6
Attachment 6: Application Form 6-S
Attachment 7: Application Forms 7-11
Attachment 8: Application Form 12
Conflict of Interest Form

Attachment 10: Vendor Responsibility Attestation

Attachment 11: Minority & Women-Owned Business Enterprise Requirement Forms