

ADDENDUM# 1

RFA# 18482 / Grants Gateway# DOH01-TRANS4-2022

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

Translational Research Projects (TRP) in Spinal Cord Injury (Round 4)

Correction to the method of upload for the RFA's optional "Online Workplan Continuation" Form

It was brought to the Department's attention that there is no option in the NYS Grants Gateway to upload the optional "Online Workplan Continuation"

Please note RFA Attachment 2 page 15 has been modified to:

If text limits restrict you from entering complete Objective Descriptions, Task Descriptions, and/or Performance Measure Narratives, use Attachment 12, "Online Workplan Continuation Form" (found in the Pre-Submission Uploads section) to complete the Description and/or Narrative. Indicate in the applicable text box that the Description or Narrative is continued in the "Online Workplan Continuation Form." Only use one "Online Workplan Continuation Form" for the application. Include the complete, not just the language that wouldn't fit, Descriptions and Narratives for Objectives being entered on the "Online Workplan Continuation Form". Once this form is completed for all Objectives, it can be uploaded through the Grants Gateway in ~~Program Specific Question #7~~ in the **Grantee Document Folder**, then click the [SAVE] button.

RFA # 18482
NYS Grants Gateway # DOH01-TRANS4-2022

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

Translational Research Projects (TRP) in Spinal Cord Injury (Round 4)

KEY DATES:

Release Date:	10/13/21
Letter of Intent Due (Strongly Encouraged):	10/27/21
Conflict of Interest Due (Optional):	10/27/21
Applicant Conference Registration Deadline:	11/1/21
Applicant Conference:	11/02/21 at 10:30 AM EST By WebEx at: 1-844-633-8697 or 1-518-549-0500 Meeting ID # 161 036 0727
Questions Due:	11/08/21
Questions, Answers and Updates Posted (on or about):	11/15/21
Applications Due:	12/09/21 by 4:00 PM
NYSDOH Contact Name & Address:	David Googins Extramural Grants Administration New York State Department of Health Wadsworth Center Empire State Plaza, Room C345 Albany, NY 12237-0012 (518) 474-7002 (phone) scirb@health.ny.gov

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I. Introduction

A. Background

Approximately 1,100 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), Extramural Grants Administration (EGA) 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 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: <https://www.wadsworth.org/extramural/spinalcord>.

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.

This Request for Applications (RFA) offers researchers the opportunity to advance well-proven hypotheses and early translational research findings into mid/late-stage translational and/or pre-clinical research that has a clear and feasible translational path to clinical application. The RFA also offers the opportunity to validate and optimize or iteratively refine devices, tools and technologies to treat or cure SCI paralysis in ways that significantly improve current capabilities.

C. Available Funds

Projects will be supported by State funds. Approximately \$8 million will be available under this RFA to support up to two (2) awards. The amount of funds awarded will be contingent upon the quality of applications submitted. The contract term will be up to five years. Annual direct costs are capped at \$1,000,000. Additionally, funds will be available to support Facilities and Administrative (F&A) costs up to 20 percent of modified total direct costs. It is expected

that the size of each award will vary depending on the stage of development toward clinical application.

While not required, applicant and sub-applicant organizations are encouraged to contribute additional cash (in-kind funds) to support the project (see RFA **Attachment 2** for further details).

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 provided that each application is scientifically distinct. However, the eligible PI may submit only one application in response to this RFA, regardless of the organization under which (s)he submits the applications. If an eligible PI submits more than one application, all applications from that PI 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 and is not debarred by the United States Food and Drug Administration (FDA) or any other federal or New York State government entity
- 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 has not submitted more than one application
- The applicant is pre-qualified in the NYS Grants Gateway, on the application due date, if not exempt.

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

III. Project Narrative/Work Plan Outcomes

The application is expected to include robust data developed by the participating investigators that demonstrate proof-of-principle in an appropriate pre-clinical model. Translational Research Projects (TRP) are designed to build on a proven hypothesis and previously completed early translational work. The application is likely to capitalize on collaborative

approaches between research institutions, businesses and regulatory consultants or agencies, and to result in the development and commercialization of products, technology, tools, treatments and therapies for SCI. Proposed projects should be cohesive and sharply focused and address an important problem. Applications that include or lead to the conduct of Phase I and Phase II clinical and device trials are encouraged.

Applications must identify a specific clinical application and include a detailed **Translational Plan** from the starting point for the application to the envisioned patient health outcome. **The Translational Plan must explicitly state how results are to be obtained within the period of the award that will achieve a significant measurable advance that will inform and enable the next steps toward clinical application.** For the purposes of this RFA, the term “clinical application” is defined as the ability to utilize the resulting outcome(s) of the research project to improve SCI patient health in a medical setting by curing SCI paralysis or preventing paralysis following acute injury or trauma.

The Translational Plan will establish quantifiable milestones and key decision points, outlining the critical path to accomplish the goals within the contract term. Milestones provide a clear delineation of the criteria used to identify completed activities, but also provide for contingency plans to address anticipated impediments that could require a revision to the timeline. The attainment of milestones will be monitored through progress reporting and may result in go/no-go decision points throughout the contract term. If the proposed project is expected to lead to the conduct of Phase I or Phase II clinical trials during the contract term, the Translational Plan must set forth a plan for patient monitoring and follow up that extends beyond the term of the contract.

Because **Good Laboratory Practice (GLP)**, **Good Clinical Practice (GCP)**, **Good Clinical Laboratory Practice (GCLP)** and **Good Manufacturing Practice (GMP)** will be necessary for development of clinical therapies and devices, it is expected that the experimental design and implementation will be carried out in accordance with these standards consistent with the requirements of the Food and Drug Administration (FDA).

The PI will have a record of effective scientific leadership and provide the vision, strategy, direction and fiscal accountability to the overall project. Research teams are not required to have prior collaborative experience but must be able to demonstrate an integrated, practical approach that will result in the effective progression toward application in the clinic. Prior success working with relevant for-profit and regulatory entities is desirable among research team members. The roles and relevant expertise of each investigator, collaborator, contributor and consultant should be made clearly evident as essential to the success of the project.

The application may not include any scientific, budgetary or commitment overlap with other awards that will be active beyond the anticipated start date of the TRP awards. If overlap with SCIRB awards is present, the TRP application will not be funded (**also see RFA Sections V.C. and V.G.**).

Applicants may subcontract components of the scope of work. For those applicants that propose subcontracting, it is preferable 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 NYSDOH. All subcontractors

should be approved by the Department of Health.

Prior to beginning the application process, potential applicants are strongly encouraged to complete the Self-Assessment Checklist (RFA Attachment 11). The self-assessment is a tool to help potential applicants evaluate if the proposed project is “ready” for funding from this RFA. The Self-Assessment Checklist can be found in the Pre-Submission Uploads section of the online application.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the New York State Department of Health (NYSDOH), 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 via email to:

David Googins
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 David Googins 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 NYSDOH contact listed on the cover of this RFA.

- <https://grantsmanagement.ny.gov/resources-grant-applicants>
- Grants Gateway Videos: <https://grantsmanagement.ny.gov/videos-grant-applicants>
- Grants Gateway Team Email: grantsgateway@its.ny.gov
Phone: 518-474-5595
Hours: Monday thru Friday 8am to 4pm
(Application Completion, Policy, Prequalification and Registration questions)

- Agate Technical Support Help Desk
Phone: 1-800-820-1890
Hours: Monday thru Friday 8am to 8pm
Email: helpdesk@agatesoftware.com
(After hours support w/user names and lockouts)

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: <https://www.health.ny.gov/funding/>. Questions and answers, as well as any updates and/or modifications, will 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

Prospective applicants are **strongly encouraged** to complete and submit a letter of intent (**RFA Attachment 1**). The Letter of Intent form will be used to develop the review panel in a timely manner. Prospective applicants may also use the letter of intent to receive notification when updates/modifications are posted; including responses to written questions. Letters of intent should be submitted via the Grants Gateway under 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. A copy must also be emailed to scirb@health.ny.gov. The Letter of Intent should be submitted by the date posted on the cover of the RFA. Please ensure that the RFA number is noted in the subject line.

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 for this project. 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. 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> on the dates 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. Reference materials and videos are available for Grantees applying to funding opportunities on the NYS Grants Gateway. Please visit the Grants Management website at the following web address: <https://grantsmanagement.ny.gov/> and select the “Apply for a Grant” from the Apply & Manage menu. There is also a more detailed “Grants Gateway: Vendor User Guide” available in the documents section under Training & Guidance; For Grant Applicants 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://grantsmanagement.ny.gov/live-webinars>.

To apply for this opportunity:

1. Log into the [Grants Gateway](#) as either a “Grantee” or “Grantee Contract Signatory”.
2. On the Grants Gateway home page, click the “View Opportunities” button”.
3. Use the search fields to locate an opportunity; search by State agency (NYSDOH) or enter the Grant Opportunity name “Translational Research Projects (TRP) in Spinal Cord Injury”
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 **strongly encouraged** 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 NYSDOH 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.

PLEASE NOTE: Although NYSDOH 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 prequalified 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.68 of the Grants Gateway: Vendor 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 Administrator		X	X	X	
Grantee View Only					X

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 offeror's application and/or to determine an offeror'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 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 have the following time period: *10/1/2022 – 9/30/2027*.

Continued funding throughout this five-year period is contingent upon availability of funding and state budget appropriations. NYSDOH 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 invoices and required reports of expenditures to the State's designated payment office (below) or, if requested by the Department, through the Grants Gateway:

New York State Department of Health
Wadsworth Center
Extramural Grants Administration
Empire State Plaza, Room C345
Albany, NY 12237-0012

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 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 Work plan.

- 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 reports to the Department of Health at the address above or, if requested by the Department, through the Grants Gateway:

- Written progress reports in accordance with the forms and formats provided by the Extramural Grants Administration, 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 Extramural Grants Administration, 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 (“NYSDOH”) 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 NYSDOH 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 NYSDOH 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 NYSDOH may withhold payment pending receipt of the required MWBE documentation. For guidance on how NYSDOH 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 on this page under “NYS Directory of Certified Firms” and accessed by clicking on the link entitled “Search the 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 10** of this RFA. NYSDOH will review the submitted MWBE Utilization Plan. If the plan is not accepted, NYSDOH 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. NYSDOH 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 NYSDOH determines that the Grantee has failed to document good-faith efforts to meet the established NYSDOH 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: <https://www.osc.state.ny.us/files/vendors/2017-11/vendor-form-ac3237s-fe.pdf>

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. The Vendor Responsibility Questionnaire must be updated and certified every six (6) months. To enroll in and use the New York State VendRep System, see the VendRep System Instructions available at <https://www.osc.state.ny.us/state-vendors/vendrep/file-your-vendor-responsibility-questionnaire> or go directly to the VendRep system online at <https://www.osc.state.ny.us/state-vendors/vendrep/vendrep-system>.

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 itservicedesk@osc.ny.gov.

Applicants opting to complete online should complete and upload the Vendor Responsibility Attestation (**Attachment 9**) of the RFA. The Attestation is located under Pre-Submission uploads and once completed should be uploaded in the same section.

Applicants opting to complete and submit a paper questionnaire can obtain the appropriate questionnaire from the VendRep website, www.osc.state.ny.us/vendrep, and upload it with their Application in the Pre-Submission uploads section in place of the Attestation.

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 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 Management 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 Management 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 Management Website, download a copy of the [Registration Form for Administrator](#). A signed, notarized original form must be sent to the NYS Grants Management office at the address provided in the submission 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 [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 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.

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 included with 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

A. Application Format/Content

Please refer to the Grants Gateway: Vendor User Guide for assistance in applying for this procurement through the NYS Grants Gateway. This guide is available on the Grants Management website at: <https://grantsmanagement.ny.gov/vendor-user-manual>. Additional information for applicants is available at: <https://grantsmanagement.ny.gov/resources-grant-applicants>.

Also, you must use Internet Explorer (11 or higher) or Microsoft Edge to access the Grants Gateway. Using Chrome or Firefox causes errors in the Work Plan section of the application.

Please respond to each of the sections described below when completing the Grants Gateway online application. Your responses comprise your application. Please respond to all items within each section. When responding to the statements and questions, be mindful that application reviewers may not be familiar with the agency and its services. Therefore, answers should be specific, succinct and responsive to the statements and questions as outlined.

ALL APPLICATIONS SHOULD CONFORM TO THE FORMAT/CONTENT PRESCRIBED in Attachment 2 – Application Checklist and Instructions. PENALTIES WILL BE APPLIED TO 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.

B. Freedom of Information Law

All applications may be disclosed or used by NYSDOH to the extent permitted by law. NYSDOH 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 NYSDOH 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 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.

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 NYSDOH 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 a self-designated 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 reviewers will prepare a written overall evaluation of each assigned application that is to be discussed by the Review Panel. Additionally, secondary and tertiary reviewers will provide a written critique for each of their assigned applications 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
HIGH	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor ^a weaknesses
MEDIUM	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate ^b weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
LOW	7	Fair	Some strengths but with at least one major ^c weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

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

^b**Moderate weakness:** A weakness that lessens merit and/or the expected successful completion of the overall project

^c**Major 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.

At the conclusion of the Review Panel discussions, the primary reviewers of each application that is discussed will prepare a written overall evaluation, which is a synopsis of the panel discussion of the applications.

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, NYSDOH staff members and members of the SCIRB) are required to disclose financial interests and declare all conflicts that meet relevant SCIRB and State of 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 Department 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 (**RFA Attachment 13**), **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 13** to identify perceived conflicts with up to 3 individuals excluding SCIRB members and Department employees. ***The Department will take this information into account when working with the peer review contractor to assemble review panels.***

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 Review Panel will score each application based on the following four criteria. The value assigned to each section is an indication of the respective weight that will be given when scoring an application. Scoring ties will be resolved on the basis of the above and with consideration of the score for "Feasibility and Translational/Clinical Potential" among those applications involved in the tie.

Evaluation Criteria:

Innovativeness and Approach (25%)

- To what extent will the project advance early translational findings into mid/late-stage translational and/or preclinical research or validate and optimize or iteratively refine devices, tools and technologies to treat or cure SCI paralysis in ways that significantly

- improve current capabilities or treatment methods?
- Are the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies and benchmarks for success presented? Do the strategy and timeline allow for management of particularly risky aspects of the approach?
- Does the research project design adequately address implementation using GMP, GLP, GCLP and GCP compliance standards as appropriate to support the overall Translational Plan?
- If the project involves human subjects and/or NIH-defined clinical research, are the plans for protection of human subjects from research risk and inclusion/exclusion criteria justified in terms of the scientific goals and research strategy proposed? Are potential ethical issues adequately addressed?
- If clinical or device trials (Phase I and/or Phase II) are planned during the contract term, is there documented institutional commitment from an appropriate official for patient monitoring and follow-up beyond the end of the contract term?

Feasibility and Translational/Clinical Potential (40%)

- To what extent are the proof-of-principle data convincing? Were the data developed by the participating investigators and by using an appropriate pre-clinical model?
- To what extent does the overall Translational Plan seek to shift current SCI clinical practice paradigms and/or identify specific ways in which clinical practice will be improved?
- Are the proposed milestones, key decision points and timelines appropriate to track progress toward specific clinical application? Are they reasonable?
- Will the proposed project result in the development and commercialization of products, treatments and therapies for SCI cures?
- Does the Translational Plan provide a clear and direct path to clinical application and the envisioned patient health outcome?
- Is there a high likelihood that the work plan for the contract term will be successfully completed within the proposed time frame?
- To what extent will the results obtained during the period of the award achieve a significant, measurable advance toward a specific clinical application to treat and cure SCI-induced paralysis or to prevent paralysis following acute injury?

Investigators and Environment (15%)

- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
- To what extent will the PI provide vision, strategy and overall project direction as well as provide scientific and fiscal accountability for the project?
- To what extent do the investigators have appropriate, complementary and integrated roles, training and expertise that are well-suited to the goals of the project and the overall Translational Plan?
- Do the leadership and organizational structure of the research team capitalize on collaborative relationships between research institutions, businesses and regulatory consultants or agencies? Is there a track record of prior success working with the relevant entities?
- Are the scientific resources, equipment and organizational support available to the

investigators adequate for the proposed project and do they contribute to the probability of success?

- Are adequate and appropriate data/resource sharing plans developed for the project?
- Are intellectual property agreements in place?
- To what extent was the applicant able to obtain additional funding and/or resources that would enhance the likelihood for successful implementation and/or commercialization of the resulting/intended device, tool, technology or treatment?

Budget (20%)

- Are the items for each budget line explained?
- Are the budget line items adequately justified as necessary for successful completion of the project?
- Are budgeted amounts reasonable, cost-effective and appropriate to accomplish the research aims/project goals?
- 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?

Note: The entire Review 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 “Feasibility and Translational/Clinical Potential” 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 due to limited resources.” “Approved but not funded due to limited resources” applications may be funded should additional funds become available.

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

H. Award Decisions and 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, applicants may request a debriefing of their application (whether their application was funded or not funded). Please note the debriefing will be limited only to the subject application and will not include any discussion of other applications. Requests must be received no later than fifteen (15) calendar days from date of award or non-award announcement.

To request a debriefing, please send an email to David Googins at scirb@health.ny.gov. In the subject line, please write: Debriefing Request (Translational Research Projects Rd 4 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 cost and duration. The project abstract and progress report abstracts may also be edited and made public.

VI. Attachments

Please note that certain attachments are accessed under the “Pre-Submission Uploads” section of an online application and are not included in the RFA document. 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”. These attachments are located/included in the Pre Submission Upload section of the Grants Gateway on line application.

- 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: Applications Forms 7-12
- Attachment 8: Application Form 13
- Attachment 9: Vendor Responsibility Attestation
- Attachment 10: Minority & Women-Owned Business Enterprise Requirement Forms
- Attachment 11: Self-Assessment Checklist
- Attachment 12: Online Work Plan Continuation Form
- Attachment 13: COI Form