RFA #20544 / SFS #TRANS62025

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

Translational Research Projects in Spinal Cord Injury (Round 6)

Addendum #1

The following Attachments have been replaced. CORRECTED Attachments must be downloaded at the link below:

https://grantsmanagement.ny.gov/doh-trans6-updated-files

1) **TRANS6 - Attachment 9 - Budget Years 1-5** has been replaced by the following document:

   TRANS6 - Attachment 9 - Budget Years 1-5 ***Replacement 1.6.25***. This document is **required** and the completed excel spreadsheet must be emailed to SCIRB@health.ny.gov for your application to be considered complete.

2) **TRANS6 - Attachment 10 - Subcontracting Budget(s)** has been replaced by the following document:

   TRANS6 - Attachment 10 - Subcontracting Budget(s) ***Replacement 1.6.25.*** This is an **optional** document and if necessary, the completed excel spreadsheet must be emailed to SCIRB@health.ny.gov for your application to be considered complete.

RFA #20544 / SFS #TRANS62025

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 6)

KEY DATES:

Release Date:	**11/27/2024**
Letter of Interest Due:	**12/11/20245**
Conflict of Interest Due:	**12/11/2024**
Applicant Conference Registration Deadline:	**12/16/2024**
Applicant Conference:	**12/17/2024**
Questions Due:	**12/24/2024**
Questions, Answers and Updates Posted (on or about):	**12/31/2024**
Applications Due:	**1/22/2025 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, (518) 474-7002, 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 the Spinal Cord Injury Research Trust Fund (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 known as Applicant Contributed Funds) to support the project beyond the available funding for this RFA. (see RFA Attachment 1 – Application Checklist and Instructions for further details).

II. Who May Apply

The applicant must be a not-for-profit organization or governmental organization in New York State.

The eligible Principal Investigator (PI) is designated by the applicant organization, has the skills, knowledge, and resources necessary to carry out the proposed work plan, and is not a postdoctoral fellow or other dependent research staff.

An eligible applicant 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, an eligible PI may be named on only one (1) application in response to this RFA, regardless of the organization under which the application is submitted. If a PI is named on more than one (1) application, all applications from that PI will be disqualified and will not be forwarded to peer review.

All eligible applicant organizations must meet the following mandatory eligibility requirements:

- Eligible Applicants must be prequalified in the New York State Statewide Financial System (SFS), if not exempt, on the date and time Applications in response to this Request for Applications (RFA) are due as specified in the "Key Dates" set forth on the Cover Page of this RFA.
- The applicant must be a not-for-profit organization or governmental organization in New York State
- The eligible PI is not a postdoctoral fellow or other dependent research staff and 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
- Completed attachments submitted to DOH are what was supplied by DOH through this RFA
- Attachment 15 - Translational Plan Narrative Sections a-e does not exceed the 25-page limit by ½ page or more
- The Year 1 Budget has been completely copied into SFS from Attachment 9 – Budget Years 1-5 and the attachment has been **emailed** to DOH
- The Work Plan has been completely copied into SFS from Attachment 14 – Translational Plan Summary and the attachment has been uploaded to the correct Bid Factor

Submission of an application certifies that the applicant organization and the PI meet the eligibility criteria stated here. If recommended for funding, an awarded organization will be expected to monitor the use of funds, maintain individual accounts, and fulfill other fiscal management criteria.

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 andtherapies 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. – Review & Award Process and V.G. – Spinal Cord Injury Research Board Review).

An Applicant may subcontract components of the Work Plan to be performed by Applicant pursuant to the terms of its Application. If known, the Applicant is expected to state in their Application the specific components to be performed through subcontracts well as the names of the subcontractors. Grantees will need to name subcontractors prior to reimbursement. Applicants should note that the lead organization (that is, the successful Applicant, as 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 and subcontracts will be required to be approved by the Department of Health.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the New York State Department of Health (hereinafter referred to as NYSDOH, or the Department), Wadsworth Center, Extramural Grants Administration. The Department is responsible for the requirements specified herein and for the evaluation of all Applications. *See,* Section V.C. (Review and Award Process).

B. Question and Answer Phase

All substantive questions by Applicants with respect to any aspect of the RFA must be submitted in writing to David Googins, NYSDOH, Wadsworth Center, Extramural Grants Administration, at the following email address: scirb@health.ny.gov. This includes Minority and Woman Owned Business Enterprise (MWBE) Requirements questions and related forms. *See,* Section IV.K. (Minority & Woman-Owned Business Enterprise Requirements). Questions of a technical nature related to formatting or other minor details related to preparation of an Application may also be addressed in writing to the email address noted above. 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.

To the degree possible, each question submitted by a potential Applicant pursuant to the terms of this RFA should cite the RFA section and paragraph to which it refers. Written questions will be accepted until the date posted on the Cover Page of this RFA.

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.

- On-Demand Statewide Financial System Training Videos: On-demand training focused on using the new grants management features in SFS is available by logging in to the SFS Vendor Portal and clicking the SFS Coach icon available on the homepage. Additional questions? Contact the SFS Help Desk listed below:

- Statewide Financial System Technical Support Help Desk

Phone: 1-877-737-4185 toll-free / 518-457-7737
Hours: Monday thru Friday 8am to 8pm
Email: helpdesk@sfs.ny.gov

- Grants Management Team Email: grantsreform@its.ny.gov
  Phone: 518-474-5595
  Hours: Monday thru Friday 8am to 4pm
  (Registration questions)

Prospective Applicants must submit all requests for clarifications of, or exceptions or changes to, the terms, conditions or provisions of this RFA or the Master Contract for Grants during the Question and Answer Phase, which will end on the "Questions Due" date specified on the Cover Page of this RFA. An Applicant must clearly indicate the clarification, exception or change in the RFA or the Master Contract for Grants the Applicant is requesting. All questions, answers, and requests for clarification, exception or change will be published by the Department at SFS Public Portal Homepage to ensure equal access and knowledge by all prospective Applicants, on or about the date specified on the Cover Page of this RFA.

This RFA has been posted on the NYS Statewide Financial System website at: SFS Public Portal Homepage and additionally, via a link provided on the Department's public website at: https://www.health.ny.gov/funding/.

Questions and answers, as well as any updates, addendums to, and/or other modifications of this RFA, will be posted on these websites. All such questions and answers, updates, addendums to, and other modifications to this RFA will be posted by the date identified on the Cover Page of this RFA under "Key Dates".

All Questions must be received by the date and time specified on the Cover Page of this RFA, under "Key Dates", opposite the heading "Questions Due".

All questions submitted by email should state the RFA Title and Number set forth on the Cover Page (RFA #20544, Translational Research Projects (TRP) in Spinal Cord Injury (Round 6)) in the subject line of the email.

C. Letter of Intent

Prospective Applicants are strongly encouraged to complete and submit a letter of intent (refer to Attachment # 2). The peer review panel's supplemental (ad hoc) members will be identified based on the Letters of Intent. Prospective Applicants who submit a Letter of Intent by the date specified on the Cover Page of this RFA may receive email notifications when updates to and modifications of this RFA are posted, including responses to written questions. Letters of Intent should be submitted via the Statewide Financial System as an attachment to the applicable question of the online Application. A copy should also be emailed to scirb@health.ny.gov. Please ensure that the RFA number and title (RFA 20544, Translational Research Projects (TRP) in Spinal Cord Injury (Round 6)) is noted in the subject line and Letters of Intent are submitted by the date posted on the Cover Page of the RFA.

Submission of a Letter of Intent is not a requirement of this RFA, nor does the submission of a Letter of Intentt by a prospective Applicant impose any obligation upon the Applicant to submit an Application in response to this RFA. To be clear, an Application may be submitted without first having submitted a Letter of Intent.

D. Applicant Conference

An Applicant Conference WILL be held for this project. This conference will be via webinar (WebEx) on the date and time posted on the Cover Page of this RFA. The Department requests that potential Applicants register for this conference by completing the survey found here: https://meetny-gov.webex.com/weblink/register/r50ba921bd1b814bbdb0555365c38776b

The Registration Deadline for the Applicant Conference is posted on the Cover Page of this RFA. The failure of any potential Applicant to attend the Applicant Conference will not preclude the submission of an Application by that Applicant.

E. How to file an Application

Applications must be submitted online via the Statewide Financial System by the date and time posted on the Cover Page of this RFA under the heading "Key Dates".

Reference materials and videos are available for Grantees applying to funding opportunities on the NYS Statewide Financial System. Please visit the Statewide Financial System website at the following web address: SFS Public Portal Homepage and click the "Search for Grant Opportunities" tile. There is also a more detailed "Statewide Financial System: Vendor User Guide" available in the documents section under Training & Guidance; For Grant Applicants located in SFS Coach. Training webinars are also provided by the Grants Management Team. Dates and times for webinar instruction can be located at the following web address: Live Webinars | Grants Management (ny.gov)

To submit an Application an Applicant must:

1. Log into the Statewide Financial System Vendor Portal .
2. Click the Grant Management Tile. Next, Click the Bid Event Search tile.
3. Enter the applicable search criteria in the Search Criteria Fields. Locate an opportunity; search by Funding Agency (DOH01) or enter the Grant Opportunity name into the Search by Grant Opportunity field: Translational Research Projects (TRP) in Spinal Cord Injury (Round 6)**.** You can also filter search by Status such as "available" which filters to include only the bid events that are published and open for potential bid response.
4. Click on "Search" button to initiate the search.
5. Click on Event ID link to initiate a bid response.
6. Please review the Grantee User Manual found in SFS Coach for additional steps on how to respond to various types of Bid Events.

Once the Application is complete, a prospective Applicant is **strongly encouraged** to submit their Application at least **48 hours prior to the** Application's due date and time specified on the Cover Page of this RFA. 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, SFS, and Grants Management staff are available to answer an Applicant's technical questions and provide technical assistance prior to the Application due date and time. Contact information for the Grants Management Staff and SFS is available under Section IV.B. (Question and Answer Phase) of this RFA.

PLEASE NOTE: Although NYSDOH and the Grants Managment staff will do their best to address concerns that are identified less than 48 hours prior to the due date and time for the submission of an Application, there is no guarantee that they will be resolved in time for the Application to be submitted on time and, therefore, considered for funding.

During the Application process, please pay particular attention to the following:

- Not-for-profit Applicants must be prequalified, if not exempt, on the date and time Applications in response to this Request for Applications (RFA) are due as specified in the "Key Dates" set forth on the Cover Page of this RFA. Be sure to maintain prequalification status between funding opportunities. **NOTE:** Three of a not-for-profit's essential financial documents - the IRS990, its Financial Statement, and its 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 role of "Bid Response Submitter" can submit an Application on behalf of an Applicant.
- Prior to submission, the Statewide Financial System will automatically initiate a global error checking process to protect against an incomplete Application. An Applicant may need to attend to certain parts of the Application prior to being able to submit the Application successfully. An Applicant must be sure to allow time after pressing the submit button to clean up any global errors that may arise. (Vendor User Guide).
- Applicants 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 (20 MB) when uploading documents. Applicants should ensure that any attachments uploaded with their application are not "protected" or "pass-worded" documents.

The Applicant's Delegated Administrator is able to assign, modify, remove roles for the applicant in SFS. Please see SFS Vendor Portal Access Reference Guide, SFS_Vendor_Portal_Access_Reference_Guide.pdf (ny.gov), for additional information on roles. **Bid Response Initiator** and **Bid Response Submitter** are the **necessary roles for applying to a Bid Event in SFS**. If you are a not-for-profit you will also need Prequalification Processor for Prequalification purposes.

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.

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

LATE APPLICATIONS WILL NOT BE ACCEPTED.

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 Application fails to conform to the requirements of the RFA.

5. Seek clarifications and revisions of Applications, in the Department's sole discretion.

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 Department'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. Negotiate with successful Applicants within the scope of the RFA in the best interests of the State.

13. Conduct contract negotiations with the next responsible Applicant, should the Department be unsuccessful in negotiating with the selected Applicant.

14. Utilize any and all ideas submitted with the Applications received, at the Department's sole discretion.

15. Unless otherwise specified in the RFA, every offer in an Applicant's Application is firm and not revocable for a period of 60 days from the Application opening.

16. Waive or modify minor irregularities in Applications received after prior notification to the

Applicant.

17. 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 Applicant's Application and/or to determine an Applicant's compliance with the requirements of the RFA.

18. Eliminate any term of this RFA that can be complied with by none of the 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: *10/1/2025 – 9/30/2030*

Continued funding throughout this period of up to 5 years is contingent upon availability of funding and state budget appropriations and the Grantee's continued satisfactory performance of its obligations under the Contract. 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 at https://grantsmanagement.ny.gov/system/files/documents/2023/12/january-2024-contract-for-grants.pdf

H. Payment & Reporting Requirements of Grant Awardees

1. No advances will be allowed for contracts resulting from this procurement.

2. The Grantee will be required to submit invoices and required reports of expenditures based upon the terms for payment set forth in Attachment A-1 to its Grant Contract to the State's designated payment office (below) or, if requested by the Department, through the Statewide Financial System:

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

A Grantee must provide complete and accurate billing invoices in order to receive payment of the grant funding provided for under the terms of its Grant Contract. 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 Grantee shall only be rendered electronically unless payment by paper check is expressly

authorized by the Commissioner of Health, 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. Each Grantee acknowledges that it will not receive payment on any claims for reimbursement submitted under its Grant 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 claims for reimbursement by the State (Department) 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 the Master Contract for Grants 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 Grantee 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 Statewide Financial System:

    - 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: Payment and Reporting", of the final STATE OF NEW YORK MASTER CONTRACT FOR GRANTS.

I. Procurement Requirements

1. General Requirements

The Grantee may procure various goods and services in connection with the grant-funded project ranging from routinely purchased goods or services to those that involve substantive programmatic work. The procurement of such goods or services, however, must be conducted in an equitable and competitive manner to promote equal treatment, efficiency, and economy in grant-funded activities.

Any Grantee that is a State entity (i.e., a State agency or political subdivision of the State) must follow the same policies and procedures it uses for procurements from its general funds. All other Grantees (private companies, not-for-profit-organizations, etc.) must have a sufficient and documented procurement process that maintains records to detail the history of procurements associated with any awarded grant project. These records shall include, but are not limited to, rationale for the method of procurement (e.g., micro-purchase, small purchases, sealed bids, request for proposals, noncompetitive/sole source), the selection of a contract type, contractor selection and/or rejection, and the basis of a contract price.

The Grantee's documented procurement process must conform with any applicable federal, State and local laws and regulations. As part of the required procurement procedures, a Grantee must maintain written standards of conduct covering conflict of interest and governing the actions of its employees engaged in the selection, award, and administration of contracts. The standards of conduct must provide for disciplinary actions to be applied for violations by officers, employees or agents of the Grantee. Such standards shall provide, at a minimum, that no employee, officer, or agent of the Grantee will participate in the selection, award, or administration of a contract supported by grant funds if a conflict of interest, real or actual, is involved. Such conflicts may arise when:

- The employee, officer, or agent, or
- Any member of such individual's immediate family, or
- Such individual's partner, or
- Any organization which employs, or is about to employ the selected contractor, has a financial or other interest in or receives or stands to receive a tangible personal benefit from a firm being considered for a contract.

The standards of conduct shall also cover organizational conflicts of interest. Organizational conflicts of interest arise where an entity is or appears to be unable to conduct an impartial procurement action due to relationships with a parent company, affiliate, or subsidiary organization.

2. Bid Protest Procedures

Any contractor, subcontractor, or aggrieved party has the right to protest actions before or after the award of a contract utilizing grant funds. The Grantee alone will be responsible, in accordance with good administrative practice and sound business judgement, for the settlement of all contractual and administrative issues arising out of procurement contract solicitations and awards.

Grantees shall have written protest procedures, which may be analagous to those set forth in Part 24 of Title 2 of the New York Codes, Rules and Regulatons, in order for effective due process to be achieved. A Grantee's specific protest procedures shall be outlined in all bid requests, request for proposals, request for applications, etc. issued by or on behalf of the Grantee concerning any grant-funded projects. In summary, Grantees are responsible for handling all contract activity protests. Except in matters of direct State or possibly Federal concern (in cases involving federally funded grants), the Department of Health will not substitute its judgement for that of the Grantee.

3. Procurement Contract Language

Any contract concerning a grant-funded project must be a written agreement between the Grantee a the third party providing specific goods and/or services. Whether with a contractor, subcontractor, consultant or vendor, the contract must as appropriate state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, subcontractor consultant or vendor, including the above procurement requirements; and any other terms and conditions of the grant and the master grant contract.

J. Assurances of No Conflicts of Interest and/or Other Detrimental Effects

The Grantee as well as any subgrantees, contractors, subcontractors or consultants engaged by the Grantee to provide goods or services in connection with the grant-funded project shall attest that their performance of any contracted services does not and will not create a conflict of interest with nor position the Grantee to breach any other contract it currently has in force with the State of New York.

The Grantee as well as any subgrantees, contractors, subcontractors or consultants engaged by the Grantee to provide goods or services in connection with the grant-funded project shall disclose any existing or contemplated relationship with any other person or entity, including relationships with any member, shareholder of 5% or more, parent, subsidiary, or affiliate organization, which would constitute an actual or potential conflict of interest or appearance of impropriety, relating to other clients/customers/agents of the Grantee, subgrantees, contractors, subcontractors, consultants or former officers and employees of the State and its affiliates, in connection with the providing of goods or rendering of services related to the grant-funded project. The Grantee shall have procedures in place for alerting the State of any such actual or potential conflicts as well as procedures to resolve the same.

K. Minority & Woman-Owned Business Enterprise Requirements

Pursuant to New York State Executive Law Article 15-A, the Department recognizes its obligation to promote opportunities for maximum feasible participation of New York State-certified minority- and women-owned business enterprises (M/WBEs) 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 (“M/WBE”) 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 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 total amount of the Budget provided for the Work Plan in the Grant Contract entered into pursuant to this RFA.

The goal on the Eligible Expenditures portion of a Grant Contract awarded pursuant to this RFA 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 M/WBE firms). A Grantee awarded a Grant Contract pursuant to this RFA must document good faith efforts to provide meaningful participation by M/WBEs as subcontractors or suppliers in the performance of the Grant Contract and Grantee will agree under the terms of its Grant Contract that NYSDOH may withhold payment pending receipt of the required M/WBE documentation required by the Department or the OSC. For guidance on how NYSDOH will determine "good faith efforts," refer to 5 NYCRR §142.8.

The directory of New York State Certified M/WBEs 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 a Grantee to evidence its good faith efforts to encourage M/WBE participation in the performance of its obligations under its Grant Contract.

By submitting an Application, each Applicant and potential Grantee agrees to complete an M/WBE Utilization plan as directed in **Attachment 22** of this RFA. NYSDOH will review the M/WBE Utilization Plan submitted be each Grantee. If a Grantee's M/WBE Utilization 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 M/WBE 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 M/WBE participation goals for the procurement.

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

L. 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 of a grant to a successful Applicant pursuant to the terms of this RFA and in order to initiate a Grant Contract with the New York State Department of Health, a Grantee 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, the Applicant should include the Vendor Identification number in your organization information. If not enrolled, to request assignment of a Vendor Identification number, an Applicant should 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.

M. Vendor Responsibility Questionnaire

The Department strongly encourages each Applicant to 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.

An Applicant 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 23**) of the RFA. The Attestation is located under the SFS Attachments Section and once completed should be uploaded to the applicable PSQ/Bid Factor.

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 response to the applicable PSQ/Bid Factor.

N. Vendor Prequalification for Not-for-Profits

Each not-for-profit Applicant subject to prequalification is required to prequalify prior to having the ability to submit an Application in the NYS Statewide Financial System.

Pursuant to the New York State Division of Budget Bulletin H-1032, dated July 16, 2014, and revised on December 9, 2023, the new Prequalification Policy will be effective as of January 16, 2024. The updated policy requires that not-for-profit organizations register and prequalify in the SFS using the updated Prequalification Application. The updated Prequalification Application and New York State Prequalification Manual for Grantees can be found on the Grants Management website at: https://grantsmanagement.ny.gov/get-prequalified.

An Application cannot be submitted/received from a not-for-profit Applicant that (a) has not Registered in the NYS Statewide Financial System or (b) has not Prequalified in the Statewide Financial System by the Application's due date specified on the Cover Page of this RFA.

Below is a summary of the steps that must be completed to meet registration and prequalification requirements. The Vendor User Manual within the Statewide Financial System Website details the requirements and job aid walks users through the process.

1) Register for the Statewide Financial System

- Applicants will first need to create an account in SFS. Applicants that need to create an account should do so at the following link: https://www.osc.ny.gov/state-vendors/portal/enroll-vendor-self-service-portal. Any questions related to SFS accounts should be sent to the SFS Help Desk (HelpDesk@sfs.ny.gov).

If you have previously registered and do not know your Username, please email helpdesk@sfs.ny.gov. If you do not know your Password, please click the "I Forgot My Password" link from the main log-in page and follow the prompts.

2) Complete your Prequalification Application

- Log in to the Statewide Financial System.

- Applicants will first need to create an account in SFS. Applicants that need to create an account should do so at the following link: https://www.osc.ny.gov/state-vendors/portal/enroll-vendor-self-service-portal. Any questions related to SFS accounts should be sent to the SFS Help Desk (HelpDesk@sfs.ny.gov).

- Instructions for SFS Prequalification can be found on Page 20 of the SFS Grantee User Manual entitled, "! Grantee Processing in SFS". This user manual is accessible to organizations with an SFS account under the SFS Coach Tile/Button in the SFS Vendor Portal. Select "Handbook: User Manual with Screenshots" from the Training Type drop down to locate the manual. If you have any problems accessing the manual please contact HelpDesk@sfs.ny.gov. Please see the section entitled, "Enter and Submit a Prequalification Application", located on page 20 of the SFS Grantee User Manual, for complete instructions on how to complete and submit an SFS Prequalification in the NYS Statewide Financial System.

- Specific questions about the prequalification process should be referred to your primary New York State agency representative (vendor.responsibility@health.ny.gov) or to the Grants Management Team at grantsreform@its.ny.gov.

3) Add a signatory or "Grant Contract Approver" to your account

- In order to have your designated signatory (known in SFS as Grant Contract Approver) sign a contract and have their name appear on the contract agreement you have to add the Grant Contract Approver's name to your SFS Vendor Profile. The Delegated Administrator for your organization can add the Signatory's Name by following the instructions found on page 17-20 of the SFS Grantee User Manual entitled, "! Grantee Processing in SFS". This user manual is accessible to organizations with an SFS account under the SFS Coach Tile/Button in the SFS Vendor Portal. Select "Handbook: User Manual with Screenshots" from the Training Type drop down to locate the manual. If you have any problems accessing the manual please contact HelpDesk@sfs.ny.gov.

All potential Applicants are strongly encouraged to begin Statewide Financial System Registration and Prequalification process as soon as possible in order to participate in this opportunity.

O. General Specifications

1. By submitting the "Application Form" each Applicant attests to its express authority to sign on behalf of the Applicant.

2. Grantees 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 any Contract awarded pursuant to this RFA 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 terms and conditions contained in this RFA, including the terms and conditions of the Master Contract for Grants. Any exceptions the Applicant would like considered by the Department relating to the terms and conditions of this RFA and/or Master Contract for Grants must have been raised during the Question and Answer Phase of this RFA (See, Section IV.B.).

4. An Applicant may be disqualified from receiving an award 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, in the State of New York or otherwise.

5. Provisions Upon Default

a. If an Applicant is awarded a grant pursuant to this RFA, the services to be performed by the successful Applicant pursuant to the terms of the Grant Contract entered into with the Department 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 Grantee, 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 Grantee.

c. If, in the judgement of the Department, the Grantee 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 Grantee. In such case the Grantee shall receive equitable compensation for such services as shall, in the judgement of the State Comptroller, have been satisfactorily performed by the Grantee up to the date of the termination of the Contract, which such compensation shall not exceed the total cost incurred for the work which the Grantee 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 Statewide Financial System: Vendor User Guide for assistance in applying for this procurement through the NYS Statewide Financial System. This guide is available by logging into the Statewide Financial System and searching under SFS Coach.

Please respond to each of the sections described in **Attachment 1 – Application Checklist and Instructions** when completing the Statewide Financial System 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 your agency and its services. Your answers should be specific, succinct, and responsive to the statements and questions as outlined. Please be aware that the value assigned to each section described below indicates the relative weight that will be given to each section of your Application when scoring your Application.

ALL APPLICATIONS SHOULD CONFORM TO THE FORMAT/CONTENT PRESCRIBED in **Attachment 1 – Application Checklist and Instructions**. PENALTIES WILL BE APPLIED TO APPLICATIONS WHICH DEVIATE FROM THE PRESCRIBED FORMAT.

It is each Applicant's responsibility to ensure that all materials included in its Application have been properly prepared and submitted.

Applications must be submitted via the Statewide Financial System by the Application deadline date and time specified on the Cover Page of this RFA.

IMPORTANT: Any material added to a Bid Factor "Add Comments" box in SFS will not be reviewed as part of a submitted application. Please use the "Response" box for narrative responses unless otherwise instructed within this RFA. However, please continue to provide any requested attachments as specified within this RFA.

- Program Specific Questions(PSQ)/Bid Factors

RFA Attachments will be available in SFS under the **"Attachments Section**" of the Statewide Financial System online Application/Bid Event.

All required attachments and any optional attachments must be emailed to DOH at scirb@health.ny.gov prior to application submission in SFS. If the total combined file size of attachments is greater than 20MB, then the files must be submitted in a ZIP file. The subject for this email must be "TRANS6 – PI Name - Institution". DOH recommends that applicants turn on the delivery receipt notification for their protection.

Once the Application is complete, a prospective Applicant is strongly encouraged to submit their Application at least 48 hours prior to the Application's due date and time specified on the Cover Page of this RFA. 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, SFS, and Grants Management staff are available to answer an Applicant's technical questions and provide technical assistance prior to the Application due date and time. Contact information for the Grants Management Staff and SFS is available under Section IV.B. (Question and Answer Phase) of this RFA.

IMPORTANT: Applications must consist of both the SFS submission and email of required attachments sent to DOH. DOH must receive the email with required attachments by the Application due date and time specified on the Cover Page of this RFA. Emails received by DOH after the due date and time will be considered late submissions and applications will not be reviewed.

In the event an electronic submission cannot be read by the Department, the Department reserves the right to request a hard copy and/or electronic resubmission of any unreadable files. Offeror shall have 2 business days to respond to such requests and must certify the resubmission is identical to the original submission.

The Department discourages overly lengthy Bids. Therefore, marketing brochures, user manuals or other materials beyond that sufficient to present a complete Bid, are not desired and will not be reviewed or evaluated. Elaborate artwork or expensive paper is not necessary or desired. In order for the Department to evaluate bids fairly and completely, all Bids should follow the format described in this IFB and provide all requested information and no extraneous or additional information or material.

Audio and/or videotapes are not allowed. Any submitted audio or videotapes will be ignored by the evaluation teams.

Applicants must upload all attachments noted with ** to SFS in PDF Format in response to the relative Bid Factor. **All other required attachments and any optional attachment must be emailed to DOH as instructed above. Attachments with a # are optional.**

Attachment 1 - Checklist and Instructions (Informational only – Do Not Submit)

Attachment 2 - Letter of Intent - LOI[#] (Optional, to be submitted by email)
Attachment 3 - Applicant Face Page[**](Required, see bid factor H-TRANS-PSQ-Q3 in SFS)
Attachment 4 - Sub-Applicant Face Page[**,#] (Optional, see bid factor H-TRANS-PSQ-Q4 in SFS)
Attachment 5 - Staff, Collaborators, …[**] (Required, see bid factor H-TRANS-PSQ-Q5 in SFS)
Attachment 6 - Acronyms and Abbreviations[**] (Required, see bid factor H-TRANS-PSQ-Q6 in SFS)
Attachment 7 - Lay Abstract[**] (Required, see bid factor H-TRANS-PSQ-Q7 in SFS)
Attachment 8 - Scientific Abstract[**] (Required, see bid factor H-TRANS-PSQ-Q8 in SFS)
Attachment 9 - Budget Years 1-5 (Required, to be submitted by email)
Attachment 10 - Subcontracting Budget(s)[#] (Optional, to be submitted by email)
Attachment 11 - Introduction[**] (Required, see bid factor H-TRANS-PSQ-Q11 in SFS)
Attachment 12 - Biographical Sketch(es) [**] (Required, see bid factor H-TRANS-PSQ-Q12 in SFS)
Attachment 13 - Facilities and Resources[**] (Required, see bid factor H-TRANS-PSQ-Q13 in SFS)
Attachment 14 – Translational Plan Summary[**] (Required, see bid factor H-TRANS-PSQ-Q14 in SFS)
Attachment 15 – Translational Plan Narrative[**] (Required, see bid factor H-TRANS-PSQ-Q15 in SFS)
Attachment 16 - Human Subjects[**] (Required, see bid factor H-TRANS-PSQ-Q16 in SFS)
Attachment 17 - Vertebrate Animals[**] (Required, see bid factor H-TRANS-PSQ-Q17 in SFS)
Attachment 18 - Other Support (Required, to be submitted by email)
Attachment 19 - Conflict of Interest Form[#] (Optional, to be submitted by email with LOI)
Attachment 20 - Appendices Document[**,#] (Optional, see bid factor H- TRANS-PSQ-Q20 in SFS)
Attachment 21 – Self-Assessment Checklist (Informational Only – Do Not Submit)
Attachment 22 - Minority & Women-Owned Business Enterprise Requirement Forms[**](Required, see bid factor H- TRANS-PSQ-Q22 in SFS)
Attachment 23 - Vendor Responsibility Attestation[**](Required, see bid factor H- TRANS-PSQ-Q23 in SFS)

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, and will be available to the public in accordance with the New York State Freedom of Information Law (FOIL). **Any portion of an Application that an Applicant believes constitutes proprietary information entitled to confidential handling, as an exception to the general rule regarding the availability to the public of State agency records under the provisions of the Freedom of Information Law, must be clearly and specifically designated in the Application.** If NYSDOH agrees with the Applicant's claim regarding the proprietary nature of any portion of an Application, 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 1 – Application Checklist and Instructions**). Applications that do not meet the mandatory minimum eligibility (Pass/Fail) criteria as stated in Section II. Who May Apply of this RFA will be disqualified and no longer considered for funding, 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 (Peer Review Contractor) to develop and coordinate the review and scoring of applications. Each eligible application will be evaluated by an Independent Merit 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 in Attachment 3: Form 4 – Lay Abstract.

Applications will be reviewed based on the criteria specified in Section V.F. – Review Criteria. 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. Triage based on adjectival scores of assigned reviewers for one criterion (see Section V.F. Review Criteria below)
4. Panel meeting discussion via teleconference, videoconference or in-person (review method chosen at the discretion of the Department) with numerical scoring (see table below).

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 that are not triaged prior to panel meeting discussion will receive numerical scores from

each participating panel member for each evaluation criterion using an integer scale that equates to adjectival scores, where 1 equates to highest merit and 9 equates to lowest merit. The numerical score given to each criterion will be multiplied by that criterion's weight to arrive at a weighted score. 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

Applications that are triaged (receive an adjectival score of Good or worse from each assigned reviewer for the criterion identified in Section V.E) will receive only the adjectival scores of the assigned reviewers. No integers or weighting will be applied, and the application will not be further reviewed for compliance penalties. Triage will only be utilized when the total number of applications being review is greater than or equal to 25.

The Review Panel will comment on the responsiveness of the application to the funding mechanism as described in RFA Section III – Project Narrative/Work Plan Outcomes 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. – Letter of Intent) by the deadline stated on the cover of this RFA. Applicants may use RFA Attachment 13 to identify perceived conflicts with up to three (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 1 – Application Checklist and Instructions. The Peer Review Contractor will assess a penalty of 0.1 point for any application that is not triaged, scores between 1.0 and 4.9, and deviates from the instructions.

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.

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/or 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.

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.

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

Applicants will be deemed to fall into one of three categories: 1) not approved, 2) not funded due to limited resources, and 3) approved and funded. Not funded Applications may be awarded should additional funds become available.

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 work plan, project duration or budget
- Overlap
- Areas of possible concern with regard to Contract Policy Statements and Conditions (NYS Master Grant Contract Attachment A-2, Program Specific Terms and Conditions
- Approved Facilities and Administrative Cost Rate

Once awards have been made pursuant to the terms of this RFA, an Applicant may request a debriefing of their own Application (whether their Application was funded or not funded). The debriefing will be limited only to the strengths and weaknesses of the Application submitted by the Applicant requesting a debriefing and will not include any discussion of ANY OTHER Applications. Requests for a debriefing must be received by the Department's Extramural Grants Administration no later than fifteen (15) Calendar days from date of the award or non-award announcement to the Applicant requesting a debriefing.

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 6 RFA).

Unsuccessful Applicants who wish to protest the award(s) resulting from this RFA on legal and/or factual grounds, should follow the protest procedures established by the Office of the State Comptroller (OSC). These procedures can be found on the OSC website at https://www.osc.state.ny.us/state-agencies/gfo/chapter-xi/xi17-protest-procedures (Section XI. 17.)

VI. Attachments

- Please note that ALL Attachments to this RFA are accessed under the **"Attachments Section"** of the Statewide Financial System online Application/Bid Event and are not included in the RFA

document. In order to access the online Application/Bid Event and other required documents such as the Attachments, a prospective Applicant must be registered and logged into the NYS Statewide Financial System. Attachments that are requested to be uploaded as part of an Application/Bid Event response will be requested in individual corresponding Bid Factors (See Section V.A., "Program Specific Questions(PSQ)/Bid Factors"). Attachments with a # are optional.

Attachment 1 - Checklist and Instructions
Attachment 2 - Letter of Intent#
Attachment 3 - Applicant Face Page
Attachment 4 - Sub-Applicant Face Page#
Attachment 5 - Staff, Collaborators, Consultants, and Contributors
Attachment 6 - Acronyms and Abbreviations
Attachment 7 - Lay Abstract
Attachment 8 - Scientific Abstract
Attachment 9 - Budget Years 1-5
Attachment 10 - Subcontracting Budget(s)#
Attachment 11 - Introduction
Attachment 12 - Biographical Sketch(es)
Attachment 13 - Facilities and Resources
Attachment 14 – Translational Plan Summary
Attachment 15 – Translational Plan Narrative
Attachment 16 - Human Subjects
Attachment 17 - Vertebrate Animals
Attachment 18 - Other Support
Attachment 19 - Conflict of Interest Form#
Attachment 20 - Appendices Document (See Attachment 1 - Checklist and instructions)#
Attachment 21 – Self-Assessment Checklist
Attachment 22 - Minority & Women-Owned Business Enterprise Requirement Forms
Attachment 23 - Vendor Responsibility Attestation