RFA # 1502050120 NYS Grants Gateway # DOH01-TRANS1-2015

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 1)

RELEASE DATE: 5/21/15

Applicant Conference Registration Due: 6/5/15

APPLICANT CONFERENCE: 6/8/15 at 10:30 AM

By telephone conference call at:

1-866-394-2346

Meeting ID # 9100872194

LETTER OF INTENT (strongly encouraged) DUE: 6/15/15

QUESTIONS DUE: 6/22/15

QUESTIONS, ANSWERS AND UPDATES POSTED: 6/29/15

APPLICATIONS DUE: 7/22/15 by 6:00 PM

DOH CONTACT NAME AND ADDRESS:

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

TABLE OF CONTENTS

l.	INTRODUCTION	. 1
	A. Background B. Purpose of the Funds C. Available Funds	. 1
II.	WHO MAY APPLY	. 1
III.	PROJECT NARRATIVE/WORKPLAN OUTCOMES	. 2
IV.	ADMINISTRATIVE REQUIREMENTS	. 3
	A. Issuing Agency B. Question and Answer Phase	. 4
	C. Letter of Intent D. Applicant Conference E. How to Complete and File an Application	. 5
	F. Department of Health Reserved Rights	. 6
	G. Term of Contract H. Payment and Reporting Requirements	. 7 . 8
	I. Minority & Woman-Owned Business Enterprise Requirements J. Limits on Administrative Expenses and Executive Compensation K. Vendor Identification Number L. Vendor Responsibility Questionnaire M. Vendor Prequalification for Not-for-Profits N. General Specifications	. 9 10 11 11
٧.	APPLICATION REVIEW AND AWARD PROCESS	14
	A. Application Acceptance B. Freedom of Information Law C. Review and Scoring D. Application Penalties and Summary Statements E. Review Criteria F. Spinal Cord Injury Research Board Review G. Award Decisions and Pre-Funding Requirements H. Award Announcements	14 15 16 17
VI.	ATTACHMENTS	18

I. Introduction

A. Background

Approximately 1,000 New York residents suffer a traumatic spinal cord injury (SCI) each year, joining the estimated six million people in the United States who are living with paralysis and other effects of SCI. The personal and economic costs to these persons, their families and to society are immense.

Since 1998, the New York State Spinal Cord Injury Research Board (SCIRB) has advised the New York State Department of Health (Department), Spinal Cord Injury Research Program (Program) regarding research focused on cures for SCI and SCI-induced paralysis. The SCIRB's mission is to stimulate high-quality, innovative SCI research that will help promote treatment and cure for SCI, including methods for reversing paralysis or restoring function caused by injury, or for minimizing or preventing damage occurring during acute phases of injury. To achieve this mission, the Program offers a program of competitive research awards to support the New York State scientists and their collaborators from a variety of biomedical disciplines in initiating and pursuing such efforts. Information about the Program and SCIRB can be found at: http://www.wadsworth.org/extramural/spinalcord.htm.

B. Purpose of the Funds

This 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 \$12 million is available to support these 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. 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 to support the project (see RFA Attachment 2 for further details).

II. Who May Apply

The applicant must be a not-for-profit 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 applicant organization and is an independent researcher who has the skills, knowledge, and resources necessary to carry out the proposed Workplan, and is not a postdoctoral fellow or other dependent research staff. At the time of application and award acceptance, the PI must not be restricted from receiving Public Health Service (PHS) funding or debarred by the United States Food and Drug Administration (FDA) or any other federal or New York State government entity.

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.

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

III. Project Narrative/Workplan Outcomes

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 DOH. All subcontractors should be approved by the Department of Health.

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 that propose support for research centers, Phase III clinical trials or expansion of enrollment to an ongoing clinical trial are ineligible for support and will not be reviewed.

Applications must identify a specific clinical application and include a detailed **Translation Plan** from the starting point for the application to the envisioned patient health outcome. **The Translation Plan must explicitly state how results that are to be obtained within the period of the award 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 (June 1, 2016). If overlap with SCIRB awards is present, the TRP application will not be funded (also see Sections V.C. and V.G).

Prior to beginning the application process, potential applicants are strongly encouraged to complete the Self-Assessment Checklist (RFA Attachment 10). 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 (Department), Wadsworth Center, Spinal Cord Injury Research Program. The Department is responsible for the requirements specified herein and for the evaluation of all applications.

B. Question and Answer Phase

All substantive questions must be submitted in writing to:

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

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

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

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

- www.grantsreform.ny.gov/grantees
- Grants Reform Videos (includes a document vault tutorial and an application tutorial) on YouTube: http://www.youtube.com/channel/UCYnWskVc7B3ajjOVfOHL6UA
- Agate Technical Support Help Desk

Phone: 1-800-820-1890

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

(Technical questions)

Grants Team Email: <u>Grantsreform@budget.ny.gov</u>
 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://www.grantsgateway.ny.gov/IntelliGrants_NYSGG/module/nysgg/goportal.aspx and the Department of Health's public website at http://www.health.ny.gov/funding. Questions and answers, as well as any updates and/or modifications, will also be posted on these websites. All such updates will be posted by the date identified on the cover sheet of this RFA.

C. Letter of Intent

The prospective applicant institution is **strongly encouraged** to complete and submit a Letter of Intent (**see RFA Attachment 1**). This form will be used to develop the review panel in a timely manner. Letters of Intent should be e-mailed to scirb@health.ny.gov.

The file should be named so that content can be readily identified and associated with the application (e.g., DOH01-TRANSL-2015-000XX-LOI.doc). Please ensure that the file name is noted in the e-mail subject line. A copy of the Letter of Intent should also be uploaded via the Grants Gateway in the Pre-Submission Uploads section of the online application. Submit the Letter of Intent via both formats by the date posted on the cover of the RFA.

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

D. Applicant Conference

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

E. How to Complete and File an Application

Applications must be submitted online via the Grants Gateway by the date and time posted on the cover of this RFA. Tutorials (training videos) for use of the Grants Gateway are available at the following web address (and upon user log in): https://www.grantsgateway.ny.gov/IntelliGrants_NYSGG/module/nysgg/goportal.aspx.

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

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

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

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

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

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

Applicants should submit their applications, <u>at a minimum</u>, one (1) hour prior to the submission deadline. The system will perform an application error check and all identified issues must be resolved before the application is successfully submitted. Failure to leave adequate time to address issues identified during this process may jeopardize an applicant's ability to submit their application. The Grants Gateway will notify applicants of successful submission.

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

F. Department of Health Reserved Rights

The Department of Health reserves the right to:

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

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

G. Term of Contract

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

It is expected that contracts resulting from this RFA will begin on June 1, 2016 for a multi-year term of up to five years. Contracts will not be renewable.

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

H. Payment and Reporting Requirements

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

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

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

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

Payment terms will be:

- The contractor will be reimbursed for actual expenses incurred as allowed in the Contract Budget and Translational 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 progress reports:
 - Written progress reports in accordance with the forms and formats provided by the SCI Research Program, no later than 30 days after the end of each reporting period.
 - A final cumulative progress report in accordance with the forms and formats provided by the SCI Research Program, no later than 60 days after the end of the contract term.

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

I. Minority & Woman-Owned Business Enterprise Requirements

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

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

Business Participation Opportunities for MWBEs

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

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

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

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

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

J. Limits on Administrative Expenses and Executive Compensation

On July 1, 2013, limitations on administrative expenses and executive compensation contained within Governor Cuomo's Executive Order #38 and related regulations published by the Department (Part 1002 to 10 NYCRR – Limits on Administrative Expenses and Executive Compensation) went into effect. Applicants agree that all state funds dispersed under this procurement will, if applicable to them, be bound by the terms, conditions, obligations and regulations promulgated by the Department. To provide assistance with compliance regarding Executive Order #38 and the related regulations, please refer to the Executive Order #38 website at: http://executiveorder38.nv.gov.

K. Vendor Identification Number

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

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

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

L. Vendor Responsibility Questionnaire

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

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

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

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

M. Vendor Pregualification for Not-for-Profits

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

Pursuant to the New York State Division of Budget Bulletin H-1032, dated June 7, 2013, New York State has instituted key reform initiatives to the grant contract process which requires not-for-profits to register in the Grants Gateway and complete the Vendor

Prequalification process in order for applications to be evaluated. Information on these initiatives can be found on the Grants Reform Website.

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

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

1) Register for the Grants Gateway

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

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

2) Complete your Prequalification Application

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

3) Submit Your Prequalification Application

After completing your Prequalification Application, click the Submit Document
 Vault Link located below the Required Documents section to submit your

Prequalification Application for State agency review. Once submitted the status of the Document Vault will change to *In Review*.

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

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

N. General Specifications

- 1. By submitting the "Application Form" each applicant attests to its express authority to sign on behalf of the applicant.
- 2. Contractors will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.
- 3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer Phase (Section IV.B.) must be clearly noted in a cover letter attached to the application.
- 4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.

5. Provisions Upon Default

- a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.
- b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
- c. If, in the judgment of the Department, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive

equitable compensation for such services as shall, in the judgment of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

V. Application Review and Award Process

A. Application Acceptance

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

B. Freedom of Information Law

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

C. Review and Scoring

The Department contracts with an independent peer review organization to develop and coordinate the review and scoring of applications. Each eligible application will be evaluated by an Independent Peer Review Panel (the Review Panel) assigned by the Peer Review Contractor. The Review Panel members will be selected from among non-New York State experts in the fields appropriate to the nature of the applications received. The Peer Review Contractor has established a standing Review Panel to which expertise will be added to evaluate the merit of specific applications submitted in response to the RFA.

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

- 1. pre-meeting review with adjectival scoring (see table below)
- 2. on-line conferral among assigned reviewers
- 3. discussion via teleconference, videoconference or in-person (review method chosen at the discretion of the Department) with numerical scoring (see table below).

During the Review Panel meeting discussion, 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. Panel members' individual numeric scores given to each criterion will be totaled and divided by the number of panel members who scored the application for that criterion, then multiplied by that criterion's weight and rounded to one decimal place to give an overall panel score for the application.

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

The Review Panel will identify potential overlap with other resources/projects. Additionally, the Review Panel will comment on the application with regard to the Contract Policy Statements and Conditions (NYS Master Grant Contract Attachment A-1 Part B). The Review Panel may recommend administrative review and resolution prior to contract execution. In addition, award recommendations made by the SCIRB may be contingent upon the applicant's acceptance of required revisions. The primary reviewer will prepare a written overall evaluation of each assigned application that is discussed by the Review Panel.

D. Application Penalties and Summary Statements

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

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

E. Review Criteria

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

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 Translation 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?
- 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 workplan for the contract term will be successfully completed within five years?
- 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 Translation 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%)

- Is the need for each budget item explained?
- Is each budget line 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 no excessive or unnecessary budget items?

Note: the entire Panel will review and comment on, but not score, the Budget section. Scores will be given by the assigned reviewers.

F. Spinal Cord Injury Research Board Review

The SCIRB will consider each research application that was reviewed. The SCIRB will discuss the application strengths and weaknesses, administrative and budget recommendations. When making funding recommendations, the SCIRB will consider responsiveness to the mission of the SCIRB, responsiveness to the RFA, programmatic balance and availability of funds. The SCIRB will vote on each application until available funds are exhausted and in compliance with SCIRB bylaws as well as applicable laws and regulations.

The SCIRB is not obligated to recommend funding for any application. Scoring ties will be resolved on the basis of the above and with consideration of the score for "Feasibility and Translational/Clinical Potential" among those applications involved in the tie. If an application for which there are available funds is not recommended for funding, the SCIRB will fully justify in writing why the application was not approved.

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

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

G. Award Decisions and Pre-Funding Requirements

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
- Funding overlap
- Areas of possible concern with regard to Program Specific Clauses (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. Please note the debriefing will be limited only to the strengths and weaknesses of the subject application and will not include any discussion of other applications. Requests must be received no later than ten (10) business days from date of award or non-award announcement.

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.

H. Award Announcements

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

VI. Attachments

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

Attachment 1: Letter of Intent

Attachment 2: Application Checklist and Instructions

Attachment 3: Application Forms 1-5

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: Vendor Responsibility Attestation

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

Attachment 10: Self-Assessment Checklist

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

RFA # 1502050120 Grants Gateway # DOH01-TRANS1-2015

Translational Research Projects (TRP) in Spinal Cord Injury (Round 1)

QUESTIONS and ANSWERS

May 21, 2015 – June 22, 2015 Including an applicant conference on June 8, 2015

Letter of Intent (RFA Section IV.C and Attachment 1)

- 1. When is the Letter of Intent due?
 - A. The Letter of Intent form (Attachment 1) was due on 6/15/15. The Letter of Intent is not mandatory but is strongly encouraged. See Section IV.C. of the RFA for submission instructions. Letters of Intent will still be accepted after the deadline.
- 2. Do we need to include any information (e.g., summary of aims) in addition to the Letter of Intent form?
 - A. Submit only the information requested on the form. No additional information will be considered. So we rely on title, key words, lay summary paragraph and names to help identify potential peer reviewers.
- 3. Who should we list on the Letter of Intent form?
 - A. Identify all participants involved in the proposed project, both internal and external to your organization. It is understood that these names may change; they are used only as a preliminary screening for conflict of interest among potential peer reviewers. Sections may be added, if necessary, to list all participants.
- 4. To what extent does the Letter of Intent commit the title and research proposed in the application?
 - A. There is no commitment inferred by the submission of a Letter of Intent.
- 5. Will staff evaluate and assess submitted Letters of Intent to provide applicants with feedback regarding the appropriateness of proposed research to this Request for Applications?
 - A. No. Letters of Intent are only used to recruit members of the peer review panel(s) and screen for potential conflicts of interest. Please use the Self-Assessment Checklist (Attachment 10) to gauge the appropriateness of your intended project for this funding mechanism. Also review questions 7-10.

Project Narrative / Workplan Outcomes (RFA Section III)

- 6. Can I talk to a Spinal Cord Research Injury Board member about my proposed application?
 - A. Individuals should not discuss their applications with SCIRB members because of ethical considerations. Such communication can be viewed as an attempt to bias or influence the board member. The New York State Department of Health is responsible for the procurement process and all questions and concerns regarding the RFA must be directed to the contact person designated in the RFA.
- 7. I applied for CART and IDEA awards. If I am awarded either of these, can I overlap the CART /IDEA research with the research I propose in the Translational Research Projects RFA?
 - A. It is unlikely that any research conducted under a CART or IDEA is suitable to be included in an application for a Translational Research Project. However, if overlapping aims do exist between such awards, the PI would have the option to terminate the CART or IDEA contract or decline the Translational Research Project award.
- 8. Our team is considering whether to pair our non-human primate invasive studies with our human non-invasive studies to move our therapeutic approach forward to clinical trials. We worry that our animal research will not be viewed as "translational enough." Can you provide feedback regarding this concern?
 - A. It sounds as if there might be two separate therapeutic approaches here. Focus the application to a single project. Use the Self-Assessment Checklist (Attachment 10) to evaluate the status of the most fully developed project. If the project is not yet in an early "development" phase (still includes hypothesis driven research aims), it is not responsive to the goals of this RFA.
- 9. How does one demonstrate competing effective approaches? Do you expect a single focused project?
 - A. The purpose of this RFA is to bring one approach from the stage of robust proof-of-principle developed within the labs of the applicant research team members forward to clinical application. Comparison studies between competing approaches are not consistent with the intent of this RFA.
- 10. Can the focus of the application be limited to pre-clinical work?
 - A. Yes if the application is not hypothesis driven and if the pre-clinical work provides a clear and feasible translational path to clinical application.

Eligibility (RFA Section II)

- 11. Can I submit two applications, one as PI and the other as Co-PI?
 - A. Yes, as long as they are separate projects. You cannot be a PI on more than one application.
- 12. Will participating in more than one application impact the score of an application?
 - A. It could. The peer review panel is charged with identifying potential overlap (see RFA Section V.C). If scientific, budgetary or time commitment overlap among the pending and active research is of potential concern, the applicant should clearly delineate the differences among the projects using Application Form 9 Other Support. Section V.E. of the RFA outlines the specific evaluation criteria and weights; the criteria do include assessment of the availability of time and resources to accomplish the project.
- 13. I am a business owner. Can my company apply for funding under this RFA?
 - A. No, not directly. Eligible institutions are not-for-profit or governmental organizations in New York State. A for-profit organization may be a subcontractor in collaboration with an eligible organization.
- 14. Can the research be done in other states or only in New York State?
 - A. Applicants must be New York State institutions. However, those institutions are permitted to subcontract with collaborators world-wide. Please note that all research done outside of NYS must be performed in accordance with New York State laws, regulations and applicable contract provisions.

PIs, Co-PIs and Co-Investigators (RFA Attachment 2 re: Application Forms 1, 1-S and 2)

- 15. What's the difference between a co-investigator and a Co-PI?
 - A. A Co-PI is designated by the PI as an individual who has equal responsibility and authority for ensuring the completion of the entire project. A co-investigator may be responsible for a specific component of the research project. The PI is the point of contact for all aspects of the application and contract. See RFA Attachment 2 for further delineation.
- 16. What if my Co-PI is from a different institution?
 - A. That is fine. See the instructions (RFA Attachment 2) for Forms 1 and 1-S for further details.
- 17. Is joint Co-PI leadership from the same institution allowed?

- A. Multiple PIs are not recognized. One individual from the applicant institution must be designated as the PI. If one or more Co-PIs are also designated, those individuals may or may not be from the applicant institution. See instructions (RFA Attachment 2) for Forms 1 and 1-S.
- 18. I have more than one Co-PI from my institution. How do I list all Co-PI's on the application?
 - A. Form 1 allows only one Co-PI to be listed. Use Form 2 and the work plan narrative to designate the others.
- 19. Is there a required percentage of effort for the PI and/or Co-PI?
 - A. No. See RFA Attachment 2 instructions for completion of the Online Budget and Justification.

Subcontractors in the Application

- 20. Is there a limit to the percentage of work or the amount of funding that can be subcontracted to out of state collaborators?
 - A. No limit is imposed by the RFA.
- 21. Are we required to provide a copy of the subcontract, or the subcontract indirect cost rate, as part of the application or at any time after award?
 - A. Draft subcontracts in excess of \$100,000 will be requested at time of award. See the NYS Master Grant Contract Section IV.B. The sub-applicant indirect cost rate need not be submitted.
- 22. Do sub-applicants/subcontractors need to be registered in the NYS Grants Gateway, be prequalified and have an SFS Vendor ID number?
 - A. Sub-applicants are not required to do so. However, at time of award, the State may require the applicant/sub-applicant to provide information the State needs to determine whether a proposed subcontractor is a responsible vendor. See the NYS Master Grant Contract Section IV.B.
- 23. If proposed work is to be done at a shared core facility at the applicant's institution, is a subcontract required?
 - A. No. These expenses should be included in the applicant's budget.

Submitting the Application

- 24. What is to be submitted by the application due date?
 - A. Refer to RFA Section IV.E. How to Complete and File an Application. Applications may only be submitted through the NYS Grants Gateway; no paper, facsimile or any other type of electronic submissions will be accepted. No other documents will be accepted after the due date.
- 25. What is the application due date and time?
 - A. The application must be successfully uploaded, found to be error-free and accepted through the New York State Grants Gateway by 6pm on July 22, 2015.
- 26. How do I get help using the Grants Gateway?
 - A. Applicants should access the guides, videos and training opportunities available via the Grants Reform website at: www.grantsreform.ny.gov. Technical issues regarding the NYS Grants Gateway should be directed to the Gateway Help Desk, Monday-Friday from 8am 8pm at 1-800-820-1890 or helpdesk@agatesoftware.com.
- 27. Who can submit an application in the NYS Grants Gateway?
 - A. See RFA Section IV.E for information about "roles." Roles are assigned by the Grants Gateway Delegated Administrator within your organization. Applicants are strongly encouraged to watch the training videos provided on the NYS Grants Gateway website.
- 28. The upload time for forms and documents can be lengthy. How could this impact a timely submission of my application?
 - A. Applicants are strongly encouraged to start completing an application in the NYS Grants Gateway no less than seven days before the due date. The application should be submitted more than an hour before it is due in case there are technical problems or global errors with the submission.
- 29. If there are multiple errors uploading completed application forms to the NYS Grants Gateway, will the applicant be notified of all errors at once, or only one at a time?
 - A. A single list of global errors will be produced.
- 30. Is there a checklist that a PI can use to see whether they have completed everything for application submission?
 - A. To ensure that all mandatory pass/fail items and penalty items are adequately addressed, see RFA Attachment 2 page 1. The Grants Gateway requires other forms to be completed and submitted as well. See the instructions provided in Pre-Submission

Uploads and Program Specific Questions. If files are not uploaded you will receive an error message describing what is missing. NOTE: the Grants Gateway does not assess the content or file format of an upload, only if a file upload was successful.

Application Forms

- 31. We are required to make a PDF of Excel budget spreadsheets. Do you have any advice for creating these documents properly?
 - A. Yes. There are three steps to creating a legible PDF from an Excel file: in Page Layout, Scale must be set to 100%; in Print Settings, select Print Entire Workbook and; in Print Settings, select No Scaling.
- 32. Why is spell check turned off on some of the application forms and why can't we cut and paste into them?
 - A. Forms 1-5 are set up as protected fillable forms so the data can be exported to databases used to facilitate peer review and award processes. Spell checking is disabled in Forms 1-5 only; it is available in other form sets. The cut/paste function will work on Forms 1-5; be sure to insert text inside the gray boxes.
- 33. We download all the forms from the Pre-submission Uploads section of the Grants Gateway. Where do we upload them?
 - A. Most completed application forms will be uploaded in response to Program Specific Questions. The exceptions are RFA Attachments 1, 8 and 9, which are uploaded in the Pre-submission Uploads section. Please do not upload other forms in the Pre-submission uploads section as this will cause duplicate uploads. Duplicate pages make it difficult for the reviewers to navigate the complete application and have resulted in different versions of the file being uploaded in those two locations. This can adversely impact the final score of the application.
- 34. Where should I include letters of collaboration (not co-PI) and collaborators' biographical sketches?
 - A. Letters of collaboration may be included in the appendices (in the same file as Forms 7-12). Biographical sketches of collaborators named in the workplan and budget should be incorporated to the other biographical sketches using Form 7. The biographical sketches of other collaborators may be included in the appendices. See RFA Attachment 2 for further details.
- 35. Why are there two workplans in the application?
 - A. The Workplan Narrative Form 10, will be used by the peer reviewers to understand the full context and details of the proposed research plan. See RFA Attachment 2 for instructions. The On-line Workplan will be included in a system-generated contract

- using a standardized format. Both are peer reviewed, so consistency between the two is important.
- 36. What are the format specifications of the workplan (font, margins, etc.)?
 - A. The forms are pre-set with acceptable fonts, margins, etc. Please refer to RFA Attachment 2 for additional details, page limitations and penalties.
- 37. Are there instructions about how to complete the online portions of the application, workplan and budget?
 - A. Yes. See the Grantee User Guide, videos and training materials on the Grants Reform website at: www.grantsreform.ny.gov and RFA Attachment 2.
- 38. Are there salary limits for PIs, postdocs or graduate students?
 - A. The maximum salary is limited to \$199,700 per person in each budget year and is not adjustable as the federal salary cap changes.
- 39. Is overhead allowed? Is it the same as the National Institutes of Health (NIH)?
 - A. Overhead is allowed but it is not the same as the NIH. Facilities and Administrative Costs are limited to 20% of modified direct costs. See RFA Attachment 2 for details.
- 40. Can funds be spent on patent fees or patient care?
 - A. No direct costs can be spent on patent/legal support or patient care.
- 41. Does the applicant need to budget/spend the maximum of money for all five years?
 - A. No. Each annual budget should reflect the true needs of the project (see RFA Attachment 2 and RFA Section V.E., Review Criteria). An annual budget may not exceed \$1 million plus Facilities and Administrative Costs in any year. The project duration may be less than or equal to five years. All aims of the project are expected to be completed prior to the end of the contract. Requests for carry forward of unspent funds and no cost extensions may not be granted.
- 42. Do we have to submit a budget for the first year or all years? Do we need to have budgets for sub-applicants?
 - A. Detailed line item budgets and justifications for applicants and sub-applicants must be submitted for the entire length of the award. The applicant's Year 1 budget is entered directly into the Grants Gateway while Years 2-5 are entered to an Excel file that also must be printed to a PDF file. The sub-applicant's Years 1-5 budgets are entered into an Excel file that also must be printed to a PDF file. Detailed instructions are provided in RFA Attachment 2.

- 43. How much budget justification is necessary?
 - A. Fully justify each budget line for each year. Provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered. Also see RFA Section V.E. for review criteria for budget and other aspects of the application.

Minority and Woman-Owned Business Enterprise Requirements

- 44. Are Minority and Woman-Owned Business Enterprise Requirement forms required to be submitted with the application? Do they have to be submitted if we will not exceed the \$25,000 threshold?
 - A. Yes. A completed Form 1 and/or Form 2 must be included in the application submission. See RFA Section IV.I and Attachment 9.
- 45. We cannot identify MWBE's on the https://ny.newcontracts.com website that we can provide the supplies and equipment we need for our research. Are there any other resources available for identifying MWBE's that we can use?
 - A. No. The https://ny.newcontracts.com website that identifies approved MWBE's is always being updated as new vendors are approved so you can periodically check back for new vendors. As part of completing the forms, you must document your efforts to identify MWBE's. NOTE: Failure to do due diligence, fill out the forms completely and correctly and attach sufficient documentation in the Pre-submission Uploads section of the application will delay processing for all awarded contracts.

Application Review and Award Process

- 46. What happens to applications that are not funded? Can we reapply?
 - A. The SCIRB has not yet determined whether the RFA will be reissued.