

RFA # 1610070403
Grants Gateway # DOH01-TRANS2-2017

Translational Research Projects (TRP) in Spinal Cord Injury (Round 2)

MODIFICATIONS, QUESTIONS and ANSWERS

January 11, 2017 – March 3, 2017
Including an applicant conference on March 1, 2017

Please note that the slides from the Applicant Conference are attached to the end of this Question and Answer document for reference.

MODIFICATION/ISSUE WITH GRANTS GATEWAY COMPETITIVE OPPORTUNITY

Pre-Submission Uploads: Attachment #11 - Self-Assessment Checklist

It was brought to the Department's attention that Attachment 11 – Self-Assessment Checklist is not present in the Pre-Submission Uploads section in the New York State Grants Gateway for this opportunity. This is an optional form for applicant use only; it is not part of the application submission.

The form has been emailed to all interested parties that received the eAlert for this RFA and those who submitted a Letter of Intent. Any other organization applying for this opportunity and is using sub-applicant(s) may request the form by emailing scirb@health.ny.gov.

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 2/24/17. 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. 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. How specific does the Letter of Intent have to be?
 - A. It is important to submit a detailed LOI and supply sufficient information so the peer review contractor, American Institute of Biological Sciences (AIBS), can recruit experts suitable for your application.

Project Narrative / Workplan Outcomes (RFA Section III)

- 6. The SCIRBs mission appears to be primarily targeting research focused on curing SCI, reversing paralysis or preventing damage occurring during the acute phases of the injury. Will submissions that will add to the body of research related to physical rehabilitative interventions in the post-acute phase of recovery be considered under this RFA?
 - A. Research projects related to physical rehabilitative interventions are currently being funded and will be considered under this RFA. Please note that on the bottom of Form 4 there is drop down box to indicate if the application's research category is "Rehabilitation" or "Cellular Regeneration & Therapeutics". It would appear your proposed research fits the funding mechanism. You can see the subject matter of applications that are currently being funded here:

<https://www.wadsworth.org/extramural/spinalcord/research-support>
- 7. Why are there two workplans in the application?
 - A. The Translational Plan 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.
- 8. What are the format specifications of the Translational Plan Narrative (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.

9. My proposed research will include human patients. If I do not know how many patients will be utilized, should I provide an estimate?
- A. You can provide an estimate, but you should clearly describe how you will determine the number of patients that will be used in the research.
10. How important is it to consider FDA accepted practices in the research?
- A. It is very important to consider the FDA's good laboratory, clinical, clinical laboratory manufacturing practices, as applicable, in the proposed research. If the research makes it to the FDA for approval and these practices have not been incorporated into the research, this research may need to be repeated.

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 two applications. A PI can be a collaborator on other applications.
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.F. 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 work at an out state for profit business. 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. Please note that the peer reviewers are required to note any excessive and/or unnecessary costs in budgets. Further, the Spinal Cord Injury Research Boards' members will receive all applications with critiques and they may have an opinion as to whether or not the amount subcontracted is reasonable.
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 pre-qualified 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 performed with collaborator's at the applicant's institution, is a subcontract required?
- A. No. These expenses should be included in the applicant's budget.
24. We are going to work with a hospital for a clinical component of the proposed research. Should the hospital be designated as a collaborator or a sub applicant?
- A. It depends on the extent of the relationship and it is your responsibility to make that determination. If the hospital will be paid with funds awarded from this RFA, a subcontract will be necessary.

Submitting the Application

25. 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 and time.
26. 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 4pm on April 28, 2017.
27. 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 questions should be directed to the DOH contact listed on the cover of the RFA up until the application deadline. For application completion, policy, and registration questions, contact the Grants Gateway Team at the following email: grantsgateway@its.ny.gov or by phone:

518-474-5595; Monday thru Friday 8am to 4:30pm. For technical issues regarding the NYS Grants Gateway, contact the Gateway Help Desk, Monday-Friday from 8am – 8pm at 1-800-820-1890 or helpdesk@agatesoftware.com.

28. 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.
29. I accidentally started a duplicate application in the NYS Grants Gateway. How do I cancel the duplicate application?
- A. Only a “Grantee System Administrator” or “Grantee Contract Signatory” role can cancel an application. They will have to log into the NYS Grants Gateway go into the application and in the Status Changes section, where they would submit the application there is an option to cancel the application. Apply that status and it will be cancelled.
30. 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.
31. 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.
32. 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

33. Regarding forms 11 and 12, can IRB and IACUC approvals be pending before signing the contract?
- A. Yes, these approvals may be pending until the proposed research begins. Our contract management staff will request the approved protocols just prior to executing the contract.
34. The biographical sketch form looks very similar to the form the NIH uses. Can I use my NIH biographical sketch form? Will I be penalized if I include a biographical sketch that is not required?
- A. If you do not use the form provided in the RFA you will be penalized 0.1 point. Use only the forms provided to avoid being penalized. You will not be penalized if you include a biographical sketch that is not required.
35. We are required to make a PDF of Excel budget spreadsheets. Do you have any advice for creating these documents properly?
- A. Yes, be certain that all cells of the workbook(s) are fully expanded so that the entire content is viewable (in wrapped text where necessary). Then, print the entire workbook to a PDF and delete any blank pages.
36. 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. Note that if a completed fillable pdf is not submitted with your application a 0.1 penalty will be applied.
37. 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, 9 and 10, 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.
38. 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.

39. Is Form 8 – Facilities and Resources limited to 2 pages per facility?

A. Yes there is a 2-page limit for this form.

40. I do not understand the Vendor Responsibility Attestation form. Can you explain this?

A. Information about vendor responsibility for New York State contracts can be found at the following url: <http://www.osc.state.ny.us/vendrep/>

Budget

41. 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 Gateway website at: www.grantsreform.ny.gov and RFA Attachment 2.

42. Can we budget for less money than the available funds for each mechanism?

A. Yes, you should only request funds appropriate for the cost-effective performance of the proposed program.

43. 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.

44. Can I list someone by title on the budget instead of by name?

A. Detailed budget justifications are required for each budget line. All PIs and Co-PIs should be identified by name. If other positions are yet to be filled, you should specify the title of the position and list “TBD” for the name of the individual for the budget justification.

45. 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.

46. Would an application with a commitment of matching funds have an advantage over applications without optional matching funds? Are matching funds cash only or can they be in-kind assistance? How many applicants from round 1 of this RFA utilized matching funds?

A. Matching funds was not a required of this RFA. RFA Section I, C. Available Funds states: "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)." Attachment 2 states: "While not required, applicant and sub-applicant organizations are encouraged to contribute additional cash to support the project. However, if additional funds are included and an award is made, they will become a requirement of the contract. Additional cash support may not be drawn from other grant awards from any source." This additional cash, also referred to as in-kind, should be listed under the Other Funds column on the budget if an applicant is including as part of their application. No applications from Translational Research Projects (TRP) in Spinal Cord Injury (Round 1) utilized a commitment of additional funds.

47. May I delete non applicable tabs from the subcontractor budget forms (Form 6-S) before I print to a PDF?

A. After the deadline, the NYS Grants Gateway concatenates your application into one PDF file. This PDF file is sent for review by the review panel. To minimize blank pages from your application's concatenated PDF, you should delete unused Sub-applicant Budgets and Justifications before you print these forms to a PDF.

48. Does the applicant need to budget/spend the maximum of money for all years?

A. No. Each annual budget should reflect the true needs of the project (see RFA Attachment 2 and RFA Section V.F., Review Criteria). 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.

49. 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.F. for review criteria for budget and other aspects of the application.

50. Should project milestones be described in terms of the amount of funding needed at those point?

A. The budget detail and justification should match the workplan. Projected spending does not have to be consistent throughout the contract term; it is expected that there will be periods during the contract term where more expenditures are made.

Minority and Woman-Owned Business Enterprise Requirements

51. 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 10.
52. We cannot identify MWBEs on the <https://ny.newnycontracts.com> website that we can provide the supplies and equipment we need for our research. Are there any other resources available for identifying MWBEs that we can use?
- A. No. The <https://ny.newnycontracts.com> website that identifies approved MWBEs 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 MWBEs. **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. If you cannot meet the goal, you have to apply for an exemption.

Application Review and Award Process

53. Do you know what the scoring cut off is for this award?
- A. There is no triage or funding cut off score. 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 make recommendations for funding to the Commissioner of Health.
54. How many applications were funded for the first round of this RFA?
- A. 3 applications were funded for Translational Research Projects (TRP) in Spinal Cord Injury (Round 1).



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**Translational Research Projects (TRP) in
Spinal Cord Injury (Round 2) RFA
Applicant Conference**



March 7, 2017

Presenter: Charles Burns

Today's Agenda

1. Administrative Items
 - Important deadlines and requirements
2. Overview
 - RFA currently posted in the NYS Grants Gateway
3. RFA Attachments
 - Attachments 1-11
 - Expenditure Budget
 - Online Work Plan
4. Review and Award Process
5. Grants Gateway Overview
6. Your Questions

March 7, 2017

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Administrative Items

See RFA cover sheet

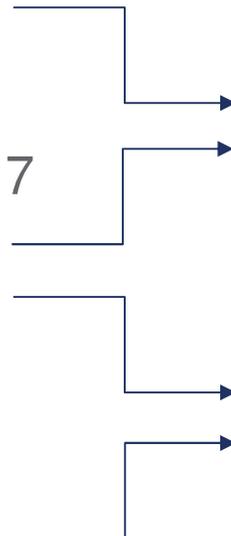
Important Dates

Letter of intent due: 2/24/17

Substantive questions due: 3/3/17

Questions, answers
and updates posted: 3/8/17

Applications due: 4/28/17
by 4PM EST



EMAIL
scirb@health.ny.gov

<https://grantsgateway.ny.gov>



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Administrative Requirements

- Not-for-profits must be Registered and Prequalified in the NYS Grants Gateway (*RFA Section IV. M.*)
- Properly prepare and submit all required Forms (*RFA and RFA Attachment 2*)
- Freedom of Information Law (*RFA Section V. B.*)
- The experimental design and implementation of clinical therapies and devices must be carried out in accordance with GLP, GCP, GCLP and GMP standards consistent with the requirements of the FDA (*RFA Section III.*)

★ 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	✓				
Grantee		✓	✓		
Grantee Contract Signatory		✓	✓	✓	
Grantee Payment Signatory		✓	✓		
Grantee System Administrator		✓	✓	✓	
Grantee View Only					✓



See RFA cover sheet & pg. 6

Quick Contacts & Links

Extramural Grants Administration

New York State Department of Health

Wadsworth Center

Empire State Plaza, Room C345

PO Box 509,

Albany, New York 12201-0509

Phone: 518-474-7002

scirb@health.ny.gov

Agate Technical Support Help Desk

Phone: 1-800-820-1890

Hours: Monday thru Friday 8am-8pm

helpdesk@agatesoftware.com

(Technical Questions)

Grants Gateway Team

Phone: 518-474-5595

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

grantsgateway@its.ny.gov

(Application Completion, Policy, and
Registration Questions)

<https://grantsreform.ny.gov/Grantees>

<http://grantsreform.ny.gov/youtube>

<http://grantsreform.ny.gov/training-calendar>

Grantee Quick Start Guide

https://grantsreform.ny.gov/sites/default/files/grantee_quick_start_guide.pdf



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RFA Overview

SCIRB's Mission & Goal

Stimulate high-quality, innovative spinal cord injury (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.

Purpose of the RFA

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.

See RFA pg. 4

Successful Applications Should

- ★ Identify a specific *clinical application** and include a detailed Translational Plan from the starting point of the application to the envisioned patient health outcome.
- **Clinical application:* the ability to utilize the resulting outcomes(s) in a medical setting by curing/preventing SCI paralysis following acute injury or trauma.



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See RFA pgs. 4-5

Successful Applications Should

- ★ Include a detailed Translational Plan that will
 - Establish quantifiable milestones and key decision points,
 - Provide contingency plans to address impediments that could require a revision to the timeline,
 - Outline the critical path to accomplish goals, and
 - If Phase I and/or Phase II clinical trials are proposed, there must be patient monitoring and follow up that extends beyond the contract term.

Available Funds

Approximately
\$6 million is available to
support approximately
two (2) awards.



Anticipated Contract

Five (5) years

- Anticipated Contract start date: 1/1/2018
- Annual direct costs are capped at \$1,000,000 per year
 - Facilities and Administrative (F&A) costs up to 20% of modified total direct costs

See RFA pg. 5

Who Should Apply?

- **Research Team** should be comprised of investigators that has prior success working with relevant for-profit and regulatory entities.
- Each member's role should be relevant and evident that they are essential to the project.

See RFA pg. 4

Who May Apply?

- **Lead applicant** must be a New York State not-for-profit organization or governmental organization.
- The eligible Principal Investigator (PI), designated by the applicant organization, will have a record of effective scientific leadership and provide the vision, strategy, direction and fiscal accountability to the overall project.
- A PI may only submit one (1) application in response to this RFA, regardless of the organization under which (s)he submits the applications.

See RFA pg. 4

Eligibility to Apply Also Includes the Following Items

- The PI can 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 (see RFA Section II.)
- The application cannot propose:
 - support for a research center,
 - support for a Phase III clinical trial, or
 - expansion of enrollment for an ongoing clinical trial



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RFA Attachments 1-11

See RFA pg. 5

Prior to beginning the application process

- Complete the Self-Assessment Checklist: Attachment 11

**ATTACHMENT 11
Self-Assessment Checklist**

This checklist is a means for the applicant to gauge the appropriateness of the intended project for this specific funding mechanism. The prospective applicant is advised to consider each question carefully before deciding and investing time in the preparation of an application. A checklist with affirmative (Yes) responses indicates that the project is likely to be considered responsive to the RFA and "ready" for this funding mechanism. NOTE: This form is optional and will not be submitted as part of the application.

Self-Assessment Criteria	Yes	No
1. Is the proposed objective consistent with the mission of the SCIRB and the intent of the RFA (see Section I, Introduction)?		
• Will it advance well-proven hypotheses and early translational findings into mid/late-stage translational and/or pre-clinical research? OR	<input type="checkbox"/>	<input type="checkbox"/>
• Will it validate and optimize or iteratively refine devices, tools and technologies to treat or cure of SCI paralysis in ways that significantly improve current capabilities? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Will it 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?	<input type="checkbox"/>	<input type="checkbox"/>
2. Will the application meet the expectations for the funding mechanism (see Section III., Project Narrative/Translational Workplan Outcomes)?		
• Is the data developed by the participating investigators robust and does it demonstrate proof-of-principle in an appropriate pre-clinical model? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Have early translational findings indicated that mid/late-stage translational research is warranted? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Is the proposed project intended to result in the development and commercialization of products, technology, tools, treatments and therapies for SCI? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Is the project streamlined and focused to provide a clear and direct path to clinical application? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Will the work be completed within the period of the award achieve a significant, measurable advance toward a specific clinical application? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Can quantifiable milestones and key decision points be identified to track progress toward clinical application, and are the timelines for completion of the project specific and reasonable? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Will there be a detailed Translation Plan from the starting point for the application to the envisioned patient health outcome? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Will the Translation Plan explicitly state how results that are to be obtained within the period of the award will inform and enable the next steps toward clinical application (does it clearly outline a plan 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)? AND	<input type="checkbox"/>	<input type="checkbox"/>
• Does the application capitalize on collaborative approaches between research institutions, businesses and regulatory agencies? AND	<input type="checkbox"/>	<input type="checkbox"/>
• If the application timeline includes Phase I or Phase II clinical or device trials, is there	<input type="checkbox"/>	<input type="checkbox"/>

Download in the Pre-Submission Uploads Section of the Grants Gateway



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See RFA pg. 6

Attachment 1: Letter Of Intent (LOI)

Provide the following using the LOI Form:

- Descriptive title of the proposed project
- Summary paragraph of the intended project
- List all participants involved in the proposed project

*Download & Upload
in the Pre-
Submission
Uploads Section of
the Grants Gateway*

*Email to
scirb@health.ny.gov*



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Attachment 2: Application Checklist and Instructions

- Mandatory Pass/Fail Items
- Appendices
- Application Penalties
- Prescribed Format

*Download in the
Pre-Submission
Uploads Section
of the Grants
Gateway*



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Attachment 3: Application Forms 1-5

1. Applicant Face Page
2. Staff, Collaborators, Consultants and Contributors
3. Acronyms and Abbreviations Used in Application
4. Lay Abstract
5. Scientific Abstract

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Uploads Section
of the Grants
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*Upload in the
Program Specific
Questions
Section of the
Grants Gateway*



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Attachment 3: Application Forms 1-5 (continued)

Form 1 - Applicant Face Page

Project Title: Award Mechanism (e.g. 10/EN/LAW/04/13)

PI First Name: PI Last Name: Co-PI First Name: Co-PI Last Name:

PI Middle Initial: PI Degree: Co-PI Middle Initial: Co-PI Degree:

PI Organization: Co-PI Organization:

PI Department: Co-PI Department:

PI Mailing Address (Street, MS, PO Box, City, State, Zip):
PI Street 1: PI Street 2: PI City: PI State: NY PI Zip:

Co-PI Mailing Address (Street, MS, PO Box, City, State, Zip):
Co-PI Street 1: Co-PI Street 2: Co-PI City: Co-PI State: NY Co-PI Zip:

PI Phone: PI Fax: Co-PI Phone: Co-PI Fax:

PI E-mail: Co-PI E-mail:

PI FIC: Co-PI FIC:

PI FIC: Co-PI FIC:

PI FIC: Co-PI FIC:

PI E-mail: Co-PI E-mail:

Project Start Date: Year One Total Cost:
Project End Date: Grand Total Cost:

New York State Applicant Organization (NYO):
NYO Name:
NYO Street 1: NYO Street 2: NYO City: NYO State: NY NYO Zip:

Contracts or Grants Official (GO):
GO Last Name: GO First Name: GO Title:

GO Mailing Address:
GO Street 1: GO Street 2: GO City: GO State: NY GO Zip:

GO Phone: GO Fax: GO E-mail:

PI Home Phone:

Attachment 3: Application Forms 1-5 (continued)

Form 2 – Staff, Collaborators, Consultants and Contributors

Last Name	First Name	Title	Institutional Affiliation	Role in Project
				PVPD
				PVPD PI (Sponsor) Co-PI/Co-PD Research Scientist Co-Investigator Collaborator Mentor Consultant Postdoc Applicant Fellow PVPD
				PVPD

Application Form 2



Attachment 3: Application Forms 1-5 (continued)

Form 3 Acronyms and Abbreviations Used in Application

Acronym	Full Text/Definition/Description

Application Form 3



Attachment 3: Application Forms 1-5 (continued)

The screenshot shows a web browser window with a purple header bar. Below the header, a grey bar contains the text "Form 4 - Lay Abstract", which is highlighted with an orange box. Underneath, the text "Lay Abstract" is visible. The main content area is a large blue rectangle with the text "Application Form 4" centered inside it. A vertical scrollbar is on the right side of the form area.

The screenshot shows a dropdown menu labeled "Research Category", highlighted with an orange box. The menu is open, showing two options: "Rehabilitation" and "Cellular Regeneration & Therapeutics".

The screenshot shows a text input field labeled "Comments", highlighted with an orange box. The field is currently empty.

Attachment 3: Application Forms 1-5 (continued)

Form 5 - Scientific Abstract

Scientific Abstract

Application Form 5

Contains Confidential or Proprietary Material

- No
- Yes

Comments

[Empty comment text area]



Attachment 4: Application Form 1-S

The screenshot displays the 'Form 1-S - Sub-Applicant Face Page' with various input fields. A large watermark 'Application Form 1-S' is overlaid diagonally across the center. The form is organized into several sections:

- Project Title:** A single-line text input field.
- PIF#::** A single-line text input field.
- Principal Investigator/Program Director/Sponsor:** Fields for PI Last Name, PI First Name, Co-PI Last Name, and Co-PI First Name.
- Overall Project Co-PI:** Radio buttons for 'Yes' and 'No'.
- PI Organization:** Fields for PI Department, PI Mailing Address (Street, MS, PO Box, City, State, Zip), PI Phone, PI Fax, and PI Email.
- Co-PI Information:** Fields for Co-PI Mailing Address (Street, MS, PO Box, City, State, Zip), Co-PI Phone, Co-PI Fax, and Co-PI Email.
- Sub-Applicant Organization (SAO):** Fields for SAO Name, SAO Street1, SAO Street2, SAO City, SAO State, SAO Zip, SAO Phone, SAO Fax, and SAO Email.
- Contracts or Grants Official (GO):** Fields for GO Last Name, GO First Name, GO Title, GO Street1, GO Street2, GO City, GO State, GO Zip, GO Phone, GO Fax, and GO Email.

*Download in the
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*Upload in the
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Online Budget and Justification (Year 1)

[Menu](#)
[Forms Menu](#)
[Status Changes](#)
[Management Tools](#)
[Related Documents and Messages](#)

Translational Research Projects (TRP) in Spinal Cord Injury (Round 2) Menu - Forms

Please complete all required forms below.

Forms Menu → Scroll down to Expenditure Budget Section

- Complete each form and narrative of the Online Budget for Year One



<https://grantsgateway.ny.gov>



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Attachment 5: Application Form 6 (Years 2-5)

Download in the Pre-Submission Uploads Section of the Grants Gateway

Upload in the Program Specific Questions Section of the Grants Gateway as a PDF and XLS or XLSX file

FORM 6 - EXPENDITURE BASED BUDGET
YEAR TWO SUMMARY

PROJECT NAME: Translational Research Projects (TRPs) in Spinal Cord Injury (Rd 2)

CONTRACTOR SFS PAYEE NAME:

YEAR TWO CONTRACT PERIOD From: 11/1/2018 To: 10/31/2019

CATEGORY OF EXPENSE	GRANT FUNDS	MATCH FUNDS	MATCH %	OTHER FUNDS	TOTAL
1. Personal Services					
a) Salary	\$ 0	0	0	\$ -	\$ -
b) Fringe	\$ -	0	0	\$ -	\$ -
Subtotal	\$ -	0	0	\$ -	\$ -
2. Non Personal Services					
a) Contractual Services	\$ -	0	0	\$ -	\$ -
b) Travel	\$ -	0	0	\$ -	\$ -
c) Equipment	\$ -	0	0	\$ -	\$ -
d) Space/Property & Utilities	\$ -	0	0	\$ -	\$ -
e) Operating Expenses	\$ -	0	0	\$ -	\$ -
f) Other	\$ -	0	0	\$ -	\$ -
Subtotal	\$ -	0	0	\$ -	\$ -
TOTAL	\$ -	0	0	\$ -	\$ -

RFA Number: # 1610070403
Page 1 of 5, Attachment B-1 - Expenditure Based Budget

BUDGET

PROJECT NAME: Translational Research Projects (TRPs) in Spinal Cord Injury (Rd 2)

CONTRACTOR SFS PAYEE NAME: 0

BUDGET YEAR (YEAR 5): From: 11/1/2021 To: 10/31/2022

CATEGORY OF EXPENSE	BUDGETED
1. Personal Services	
a) Salary	
1.1.	\$ -
2.2.	\$ -
3.3.	\$ -
4.4.	\$ -
5.5.	\$ -
6.6.	\$ -
7.7.	\$ -
8.8.	\$ -
9.9.	\$ -
10.10.	\$ -
11.11.	\$ -
12.12.	\$ -
13.13.	\$ -
14.14.	\$ -

JUSTIFICATION

Tab 1, Total Budget

Tab 2, Justification



Attachment 6: Application Form 6-S (Years 1-5)

Download in the Pre-Submission Uploads Section of the Grants Gateway

Upload in the Program Specific Questions Section of the Grants Gateway as a PDF and XLS or XLSX file

FORM 6-S - EXPENDITURE BASED BUDGET
YEAR ONE SUMMARY (SUBCONTRACT #1)

PROJECT NAME: Translational Research Projects (TRPs) in Spinal Cord Injury (Rd 2)

SUBCONTRACTOR #1 NAME: _____

YEAR ONE CONTRACT PERIOD From: 11/1/2017 To: 10/31/2018

Sub-Applicant Budget

CATEGORY OF EXPENSE	GRANT FUNDS	MATCH FUNDS	MATCH %	OTHER FUNDS	TOTAL
1. Personal Services					
a) Salary	\$ -	0	0	0	\$ -
b) Fringe	\$ -	0	0	0	\$ -
Subtotal	\$ -	0	0	0	\$ -
2. Non Personal Services					
a) Contractual Services	\$ -	0	0	0	\$ -
b) Travel	\$ -	0	0	0	\$ -
c) Equipment	\$ -	0	0	0	\$ -
d) Space/Property & Utilities	\$ -	0	0	0	\$ -
e) Operating Expenses	\$ -	0	0	0	\$ -
f) Other	\$ -	0	0	0	\$ -
Subtotal	\$ -	0	0	0	\$ -
TOTAL	\$ -	0	0	0	\$ -

RFA Number: # 161007043
Page 1 of 5, Attachment B-1 - Expenditure Based Budget

FORM 6-S - EXPENDITURE BASED BUDGET
PERSONAL SERVICES DETAIL

POSITION TITLE	SALARY				TOTAL
	ANNUALIZED SALARY PER	STANDARD WORK	PERCENT OF	NUMBER OF	
SUBCONTRACT #1 TOTAL BUDGET					
SUBCONTRACT #1 JUSTIFICATION					



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Attachment 7: Application Forms 7-12

7. Biographical Sketch
8. Facilities and Resources
9. Other Support
10. Translational Plan Narrative
11. Human Subjects
12. Vertebrate Animals

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*Upload in the
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Attachment 7: Application Forms 7-12

Form 7 – Biographical Sketch

NAME: _____

POSITION TITLE: _____

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY

Application Form 7

A. Personal Statement

B. Positions and Honors

C. Contribution to Science

D. Research Support

Attachment 7: Application Forms 7-12

Form 8 – Facilities and Resources

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

MAJOR EQUIPMENT:

Application Form 8

2

Attachment 7: Application Forms 7-12

Form 9 – Other Support

NAME OF KEY PERSONNEL: _____
Check here if this person has no other source of Active or Pending support:

TITLE OF PROJECT: _____
Check here to indicate whether this support is Active or Pending: ACTIVE PENDING

BRIEF PROJECT DESCRIPTION:

NAME OF PROJECT PI: _____
FUNDING AGENCY: _____
AWARD # (e.g., NIH 5R01GM000000-01): _____
PERIOD OF SUPPORT (Start and End Dates): _____ - _____
PROFESSIONAL EFFORT: _____%

THIS PROJECT INVOLVES SPINAL CORD INJURY RESEARCH: *YES NO
**For any "Yes" answer, list the specific aims of the project and explain the distinction between the project and this NYS-funded contract.*

THIS PROJECT OVERLAPS A RESEARCH AIM OR A BUDGETARY ITEM IN THE APPLICATION:
 **YES NO
***For any "Yes" answer, provide the intended resolution if the project is funded.*

Application Form 9

3



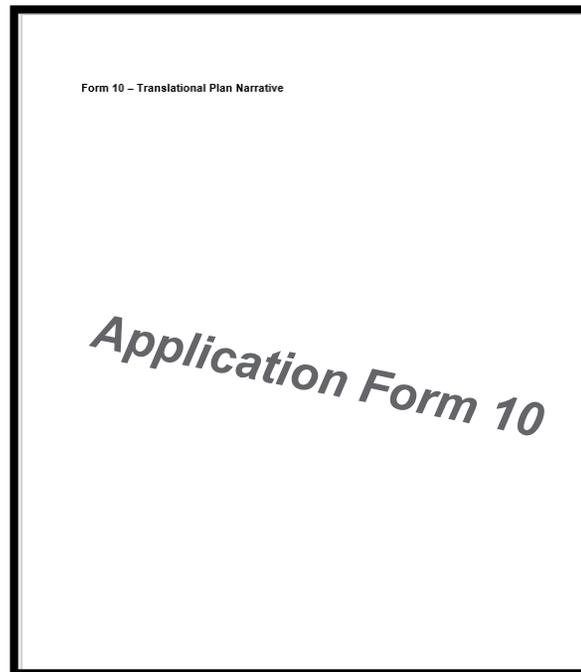
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YORK
STATE

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Attachment 7: Application Forms 7-12

- A. Significance
- B. Background and Preliminary Results
- C. Research and Development Plan
- D. Milestones, Key Decision Points Timeline
- E. Project Management and Coordination Strategy
- F. Literature Cited



***PAGE LIMITS
Sections A-C:***

- ***25 page limit***



Attachment 7: Application Forms 7-12

Form 11 – Human Subjects
SECTION A:

1. Applicant/Sub-applicant Institution: _____

2. Are Human Subjects involved? Yes No

3. Is the project Exempt from federal regulations? Yes No

4. If YES to #3, what is the Exemption number? 1 2 3 4 5 6

5. If NO to #3, is the IRB review Pending? Yes No

6. IRB Approval Date (leave blank only if Yes to #5): _____

7. IRB Protocol Approval Number (leave blank only if Yes to #5): _____

SECTION B – NARRATIVE (use additional pages if necessary)

Application Form 11

5

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Gateway*

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Section of the
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Attachment 7: Application Forms 7-12

Form 12 – Vertebrate Animals

SECTION A:

1. Applicant/Sub-applicant Institution: _____
2. Are Vertebrate Animals involved? <input type="checkbox"/> Yes <input type="checkbox"/> No
3. Is the IACUC Review Pending? <input type="checkbox"/> Yes <input type="checkbox"/> No
4. IACUC Approval Date (leave blank only if YES to #3): _____
5. IACUC Protocol Approval Number (leave blank only if YES to #3): _____

SECTION B – NARRATIVE (use additional pages if necessary)

Application Form 12

6

*Download in the
Pre-Submission
Uploads Section
of the Grants
Gateway*

*Upload in the
Program Specific
Questions
Section of the
Grants Gateway*



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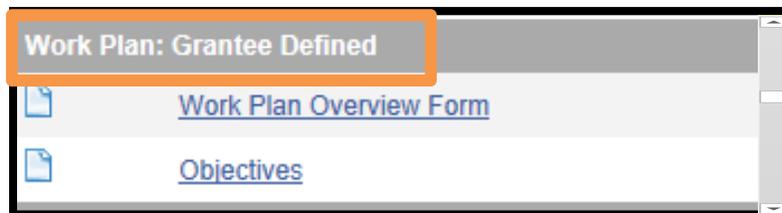
Online Workplan

[Menu](#) [Forms Menu](#) [Status Changes](#) [Management Tools](#) [Related Documents and Messages](#)

Translational Research Projects (TRP) in Spinal Cord Injury (Round 2) Menu - Forms

Please complete all required forms below.

Forms Menu → Scroll down to Work Plan: Grantee Defined



- Complete the Work Plan Overview Form and
- Objectives

<https://grantsgateway.ny.gov>

Project Narrative/Translational Plan Outcomes

- 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 award.
- Funded projects may include program implementation (Phase I and/or Phase II clinical or device trials) which goes beyond the contract period and there should be documented institutional commitment from an appropriate official for patient monitoring and follow-up.

See RFA pg. 13

Attachment 9: Vendor Responsibility Attestation

ATTACHMENT 9
Vendor Responsibility Attestation

To comply with the Vendor Responsibility Requirements outlined in Section IV, Administrative Requirements, L. Vendor Responsibility Questionnaire, I hereby certify:

Choose one:

An on-line Vendor Responsibility Questionnaire has been updated or created at OSC's website: <https://portal.osc.state.ny.us> within the last six months.

A Vendor Responsibility Questionnaire is not required due to an exempt status. Exemptions include governmental entities, public authorities, public colleges and universities, public benefit corporations and Indian Nations.

Signature of Organization Official: _____

Print/type Name: _____

Title: _____

Organization: _____

Date Signed: _____

*Download &
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Attachment 10: Minority & Women-Owned Business Enterprise Requirement Forms

See RFA pg. 11

- MWBE Utilization Plan (3 pages)
- MWBE Utilization Waiver Request
- Staffing Plan
- Equal Opportunity Policy Statement
- Instructions

MWBE Form #1
New York State Department of Health
MWBE UTILIZATION PLAN

Applicant/Grantee Name: <input type="text"/>	
Vendor ID: <input type="text"/>	Telephone No. <input type="text"/>
RFA Contract Title: <input type="text"/>	RFA Contract No. <input type="text"/>

Description of Plan to Meet MWBE Goals (Use pages 2-3 to provide specific M and W subcontractor information)

Attachment 10

PROJECTED MWBE USAGE	%	Amount
1. Total Dollar Value of Eligible Expenditures on Budget (Does not include Personal Services, Fringe, Rent, Space, Utilities)	<input type="text"/>	\$ <input type="text"/>
2. MWBE Goal Applied to Eligible Expenditures	<input type="text"/>	\$ <input type="text"/>
3. WBE Goal Applied to Eligible Expenditures	<input type="text"/>	\$ <input type="text"/>
4. MWBE Combined Eligible Expenditure Totals*	<input type="text"/>	\$ <input type="text"/>

*Making false representation or including information evidencing a lack of good faith as part of or in conjunction with the submission of a Utilization Plan is prohibited by law and may result in penalties including, but not limited to, termination of a contract for cause, loss of eligibility to submit future bids, and/or withholding of payments. Firms that do not perform commercially useful functions may not be counted toward MWBE utilization.

*If less than the stated goal in RFA, Form #2 is required. Form #1 - Page 1 of 3

Page 2 of 11 Revised: 4/2015

Download & Upload in the Pre-Submission Uploads Section of the Grants Gateway

<https://ny.newnycontracts.com>



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March 7, 2017

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Review and Award Process

Review and Award Process

- Administrative Pass/Fail
- Peer Review Process
- Spinal Cord Injury Research Board (SCIRB) Review
- Contract Execution



Review Criteria

1. Feasibility and Translational/Clinical Potential **40%**
2. Innovativeness and Approach **25%**
3. Investigators and Environment **15%**
4. Budget **20%**



Debriefing

- All applicants may request a debriefing by sending an email to scirb@health.ny.gov.
- Requests must be received no later than 15 business days from date of award or non-award announcement.

March 7, 2017

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Grants Gateway Overview

https://grantsgateway.ny.gov/

New York State
Grants Gateway

Grants Gateway Login

SHOW HELP

Grant Opportunity Portal - Home

Welcome to the Grants Gateway

The **Grant Opportunity Portal** is online and available to the public, providing a one-stop shop for anyone interested in locating grant funding opportunities with State agencies.

The **Grantee Document Vault** is also available, allowing existing grantees and potential applicants to store key organizational information in a single secure online location for use by all State agencies. In order to use the Document Vault, a grantee must register as a user on the system and provide information on a Delegated Administrator who will manage their user account. This requires submission of a Registration form and accompanying organizational diagram. Note that your Registration form must be signed, notarized and mailed to Gateway Administrators. Plan accordingly to avoid potential delays in applying for upcoming grant opportunities.

Check back regularly as efforts to integrate with the Statewide Financial System are underway.

For additional information see the Grants Reform Website. www.grantsreform.ny.gov

BROWSE
Looking for a listing of funding opportunities? Use the Browse feature to get started.
[Browse Now!](#)

SEARCH
Looking for information about a specific funding opportunity? Use the Search feature to narrow your focus.
[Search Now!](#)

NOTIFICATION
Want to be kept informed of upcoming and available funding opportunities? Provide your email address, and identify the types of grants that interest you.
[Sign-up Now!](#)
[Already Signed-up?](#)
[Click here to update preferences.](#)

REGISTRATION
If you are already a vendor with NYS or are interested in becoming a vendor request access here.
[Request Access Now!](#)

For a complete listing of all New York State procurement and grant opportunities, please visit the [Contract Reporter](#).

Grants Gateway FAQ

1. How do I apply for an opportunity?
2. Where's a copy of the RFA Attachments?
3. How do I retrieve an application I've already started?
4. How do I retrieve the Q & A document?

Q1: How do I apply for an Opportunity in the Grants Gateway?

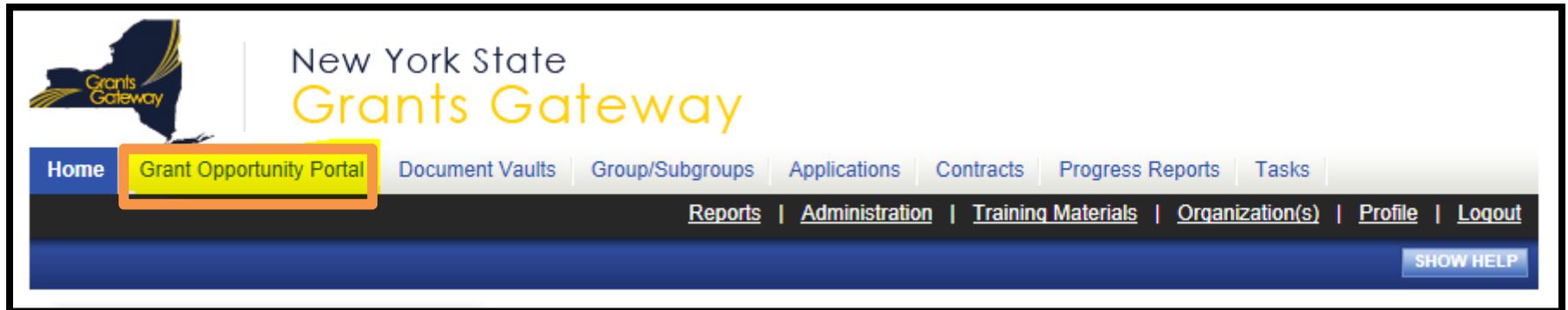
- You must be registered in the Grants Gateway to apply
 - See RFA, Section IV. M.
 - Grantee Quick Start Guide <https://grantsreform.ny.gov/Grantees>
 - Delegated Administrator

<https://grantsgateway.ny.gov>



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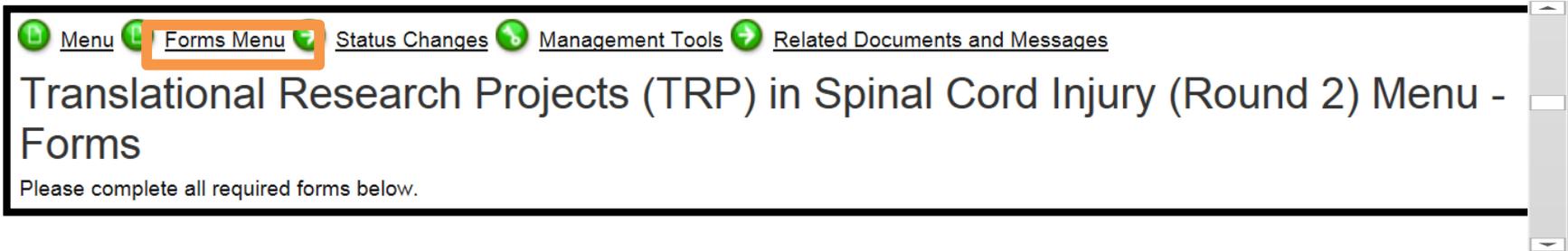
- Login
- Click on the Grants Opportunity Portal tab
- Search using the keywords (Translational), and select the Department of Health as the Funding Agency
- Click on the Grant Opportunity name
- Click Apply for Grant Opportunity to start an application



<https://grantsgateway.ny.gov>



Q2: Where do I download the RFA Attachments?



The screenshot shows a web application interface with a navigation menu at the top. The menu items are: Menu, Forms Menu (highlighted with an orange box), Status Changes, Management Tools, and Related Documents and Messages. Below the menu, the main content area displays the title "Translational Research Projects (TRP) in Spinal Cord Injury (Round 2) Menu - Forms" and a sub-header "Please complete all required forms below." A vertical scrollbar is visible on the right side of the content area.

- Login
- Start an application or retrieve an application that you already started
- Click on the Forms Menu
- Scroll down to Click on Pre-Submission Uploads
- Download each attachment document template

<https://grantsgateway.ny.gov>



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Click on each document template to download each attachment

PRE-SUBMISSION UPLOADS

Instructions:

1. Select the **Browse** button to locate an upload.
2. Select the **Save** button above to load it into the system.
3. If the Grant Opportunity you are applying for requires that a specific document be uploaded, a link to the Document Template will appear under the upload row. Click the link to download and save the Document Template to your computer. Once you have filled out the Document Template you can use the associated **Upload** row to upload the document as part of your application.

Only upload the completed Vendor Responsibility Attestation (Attachment 9), Minority & Women-Owned Business Enterprise Requirement Forms (Attachment 10) and the optional Letter of Intent Form (Attachment 1) and Conflict of Interest Form (Attachment 8) in this Pre-Submission Uploads section. All other completed forms must be uploaded in the Program Specific Questions section.

Attachment 1 - Letter of Intent Form

The prospective applicant institution is strongly encouraged to complete and submit a Letter of Intent. This form will be used to develop the review panel in a timely manner. Letters of Intent should be submitted via the Grants Gateway in the Pre-Submission Uploads section of the online application. The file name should include applicant organization and PI names. A copy must also be e-mailed to scirb@health.ny.gov. Please ensure that the RFA number, organization name and PI name are noted in the e-mail subject line. Submit the Letter of Intent via both formats by the date posted on the cover of the RFA.

[Document Template Click here](#)

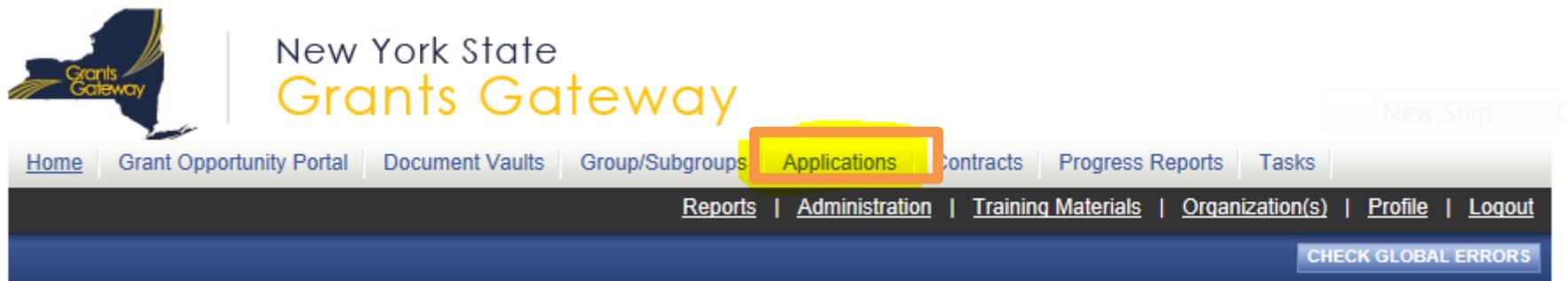
<https://grantsgateway.ny.gov>



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Q3: How do I retrieve an Application I've already started?



- Login
- Click on the Applications link located at the top of your home screen
- Enter search criteria to locate the application
- Click on the Application number to restart the application

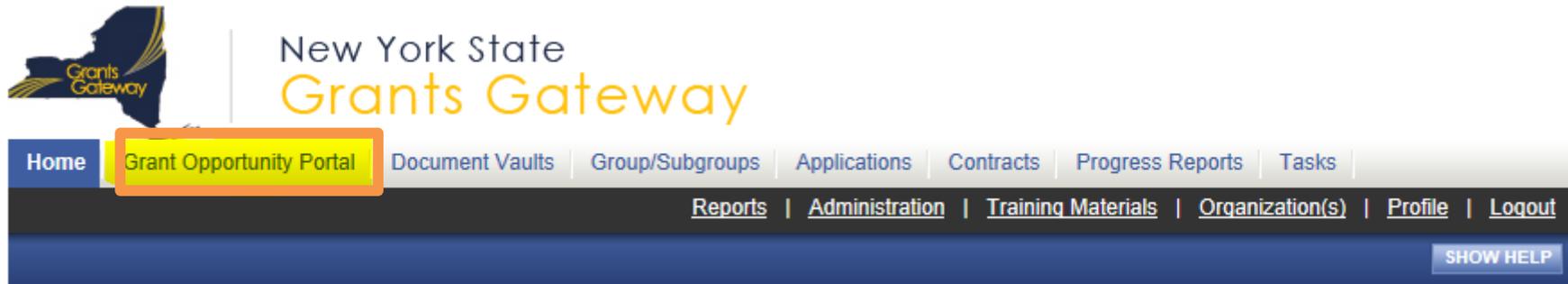
<https://grantsgateway.ny.gov>



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Q4: How do I retrieve the Q&A document?



- Click on Grant Opportunity Portal
- Search for Opportunities in the Portal using the keywords (Translational), and select the Department of Health as the Funding Agency.
- Click on the Grant Opportunity name
- Full Document details are listed on the Grant Opportunity Profile, which includes a Questions and Answers link

<https://grantsgateway.ny.gov>



Your Questions



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Thank you!!

March 7, 2017