Request for Applications
 # 0503280336

New York State

SPINAL CORD INJURY RESEARCH PROGRAM

Award Year 2007

Guidelines, Instructions and Application Forms
for

CART (Collaborations to Accelerate Research Translation)
and
IDEA (Innovative, Developmental or Exploratory Activities)

Research Grants

Issued 01/25/06
by

The NYS Spinal Cord Injury Research Board
and the
Wadsworth Center
Office of Extramural Funding
New York State Department of Health

LETTER OF INTENT DEADLINE: 03/22/06
APPLICATION DEADLINE: 07/19/06
ESTIMATED CONTRACT START DATE: 04/01/07

The NYS Spinal Cord Injury Research Program Request for Applications is also available at: http://www.nyhealth.gov/funding/ Application forms may be completed on-line and then printed for submission with the rest of the mailed application.

Table of Contents

1. Background

More than 600 New York residents suffer a traumatic spinal cord injury (SCI) each year, joining the estimated 16,000 New Yorkers 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.

In 1998, Governor George Pataki signed legislation creating the New York State Spinal Cord Injury Research Board (SCIRB) and allocating funding to the Spinal Cord Injury Research Trust Fund. The SCIRB is mandated to solicit and review applications, and administer research contracts focused on cures of SCI and SCI-induced paralysis. (The Board's membership roster appears in Section 20 of this RFA).

The Board's mission is: (1) to stimulate high-quality, innovative spinal cord injury research that will help promote development of new methods for reversing paralysis or restoring function caused by injury, or for minimizing or preventing damage occurring during acute phases of injury; and (2) to communicate these results to all concerned parties. To achieve this mission, the Board supports a program of grant awards designed to assist New York State scientists from a variety of biomedical disciplines in initiating and pursuing creative SCI-related research. The Board is especially interested in receiving translational and clinical research applications. SCIRB also hopes to stimulate inter-disciplinary research.

2. Invitation to Submit Grant Applications

The estimated contract start date is 04/01/07. In this, our fifth competitive cycle, we invite investigators to submit applications for one of the following funding mechanisms:

A. **Collaborations to Achieve Research Translation (CART)**

- Duration of up to four years
- Average annual **direct costs** expected to range between $200,000 - $300,000

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

- Duration of 24 months
- **Total project costs** capped at $300,000

3. Who May Apply?

Applications must be submitted by New York State organizations for a New York-based principal investigator and research team. The applicant institution may be any organization, including an academic institution, research organization, public or private organization, medical center or other entity with demonstrated capability to conduct grant funded research. Unaffiliated individuals are ineligible for awards.
Collaborations between New York State and non-New York State researchers are encouraged. **Subcontractor overhead expenses should be included in the main applicant's direct costs.**

Applicants are very strongly encouraged to submit Letters of Intent. These will be used to determine the number and types of reviewers who will be retained to score applications. Refer to Section 11 for information regarding Letters of Intent.

3.1 Principal Investigators

Individuals of any nationality or citizenship status may apply as principal investigators.

The Board is also interested in applications from established investigators new to the field, from junior researchers, and from those in disciplines that have not historically focused on SCI. Junior investigators are encouraged to partner with established investigators.

Individuals who submitted applications in previous cycles may re-submit applications in this cycle if the applications are consistent with the requirements of the CART or IDEA funding mechanisms. The reviewers' comments should be explicitly addressed. (Also see Section 15, Revised Applications).

4. Research Topic Areas

The Board welcomes basic, clinical and translational research applications on topics bearing on its mission to reverse paralysis and restore function, or to minimize and prevent damage occurring during the acute phase of injury. Although the Board has not formally developed a list of research priorities, projects targeting tissue regeneration, repair, or restoration of function through biomedical research are of strongest interest. Projects including the use of progenitor cells, adult stem cells or NIH-approved lines of human embryonic stem cells are also welcome.

Physical rehabilitation treatment projects are ineligible for funding. Applicants are encouraged to review awards from the Program's 2002, 2001 and 2000 funded studies (Sections 21, 22, and 23.).

5. Available Funds

Funded projects will be supported by the Spinal Cord Injury Research Trust Fund, which is financed by surcharges from certain motor vehicle traffic moving violations in New York State. The amount of funds awarded will be contingent upon the quality of applications submitted. The amount of funds for each mechanism has not been pre-determined.

6. Goals for CART and IDEA Grants

The funding mechanisms used in this cycle reflect the Board's desire to:

- Support the development of spinal cord injury research in New York State;
- Accelerate the pace with which basic (preclinical) findings are translated into clinical benefits for spinal cord-injured persons;
- Fill fundamental gaps in knowledge that are barriers to scientific advances in SCI research;
- Develop a diverse research portfolio that complements research funded by SCIRB and other agencies; and,
- Encourage the growth of the group of investigators conducting spinal cord injury research in New York's biomedical research institutions.

7. Collaborations to Accelerate Research Translation (CART)

7.1 Purpose

The intent of the CART grants mechanism is to foster the translation of results from basic (preclinical) research into the next research phase by supporting synergistic partnerships of scientific disciplines and/or organizations. This mechanism is expected to contribute to the more rapid translation of basic science findings to potential therapeutic applications or clinical research through novel or innovative treatment strategies.

The collaborative partnership must facilitate expansion of the body of knowledge/expertise applied to research problems in spinal cord injury. It is hoped that the CART mechanism will encourage experts from other fields to bring their knowledge to bear on problems in spinal cord injury research. By supporting interactions and cooperation, and facilitating cross-disciplinary research, it is anticipated that creative solutions to intractable problems in spinal cord injury treatment can be developed.

7.2 Collaborations

Possible collaborations include those between:

- An experienced spinal cord injury investigator and an investigator new to the field from a discipline whose perspective has not yet been fully applied to spinal cord injury research;

- Pairs or teams of investigators new to spinal cord injury research who provide compelling evidence that their partnership will propel part of the field forward;

- Basic scientists and clinicians with relevant expertise in spinal cord or related traumatic injuries;

- Outstanding junior investigators new to the field with more senior scientists.

7.3 Research Projects

The CART mechanism is designed to investigate a well-developed problem or research hypothesis focusing on cures for spinal cord injury paralysis or the prevention of paralysis following trauma. The proposed project should be cross-disciplinary, cohesive, and sharply focused. The translational aspect may involve either animal or human studies. The research may be fundamental or applied or an integrated combination of the two approaches. Also eligible are applications that seek to apply knowledge gleaned from lower order mammals to appropriate non-human primate models. The research team must make explicit how results will facilitate transition to the next research stage, (e.g., preclinical or clinical research).

Program projects, research centers, or large-scale clinical trials are ineligible for CART support and will not be reviewed. Other applications considered non-responsive include those seeking to expand accruals into ongoing trials; and those lacking a specific translational/clinical goal (i.e., incremental applications leading only to another research grant application).

Collaborations that seek to investigate a problem or hypothesis not yet well developed or that have not yet solidified the logistics of collaboration essential to a successful partnership should apply for support through the IDEA mechanism.

7.4 Award Size and Duration

The CART award is for a total period of up to 4 years. Although there is no dollar cap, project direct costs are expected to average $200,000 - 300,000 per year.

PIs/Co-PIs must each commit at least 10% FTE research effort to the project.

7.5 Definitions

The term translational is intended to indicate research taken from bench to bedside or other appropriate clinical settings.

The term cross-disciplinary is used to indicate conceptual and methodological viewpoints not normally brought together.

7.6 CART Merit Review Criteria

Six elements determine CART scientific merit.

Innovativeness (15%)
The originality of the research question(s) and the approach taken in its investigation. The unique features of the cross-disciplinary team and the translational/clinical approach.

Approach (15%)
Integration of the cross-disciplinary approach with a coherent hypothesis, and specific aims. The importance of the research questions and their basis in the scientific literature. The suitability of research design and methods to achieve the application's spinal cord injury-related aims. **To be reviewed, applications must discuss the applicability of the proposed research to spinal cord injury.**

Feasibility (15%)
The likelihood of successful completion of the study based on the research design, background and experience of the investigators, and the availability of resources.

Translational/Clinical Potential (20%)
The potential and time needed for the proposed work to have an impact on contributing to novel treatments and cures for spinal cord injury-induced paralysis or to prevent paralysis following acute injury.

Cross-disciplinary nature of the research team (15%)
The knowledge, skills, research tools and experiences of the research team in relation to the scientific, translational/clinical and innovative potential of the work. The feasibility of collaboration plans. The extent to which the composition of the team provides the potential for innovative research solutions and applications.

Budget (20%)
The appropriateness of the budget allocations to the accomplishment of the research aims.

8. Innovative, Developmental or Exploratory Activities (IDEA)

8.1 Purpose

The intent of the IDEA awards is to support innovative scientific approaches to spinal cord injury research that, although as yet untested, hold out significant likelihood of leading to breakthroughs or new avenues of investigation. Researchers are also encouraged to explore new concepts, to challenge existing paradigms, or to fill overlooked gaps in knowledge.

The IDEA research grant allows established researchers to enter the spinal cord injury field, as well as giving existing spinal cord injury researchers the opportunity to try new methods and approaches to investigate the problems of spinal cord injury (e.g., implantable nanobiotechnological devices to create new neuromotor replacements for nerves damaged by spinal cord injury).

Upon project completion, the PI should have (1) opened a new area of investigation, 2) satisfactorily tested a novel or innovative hypothesis, or 3) produced viable data for preparation of a full-scale research application to the SCIRB program or another agency. It is the intent of the Board that successful IDEA projects also are eligible to apply for CART awards.

8.2 Collaborations

Although collaborations are not required, they are strongly encouraged. This mechanism may be used to solidify the organizational structure and logistics of a new collaborative partnership and to collect pilot data.

8.3 Projects

IDEA projects are self-contained, hypothesis-driven research. Projects should be considered innovative, developmental or exploratory in nature, targeting new avenues of spinal cord injury research.

Responsive projects include those considered highly speculative, exploratory, or high-risk that may not have pilot data, but that have the potential for high scientific payoff. Also encouraged are applications seeking to apply or develop state-of-

the-art technologies, tools or resources for SCI research. Innovative, developmental projects that focus on exceptionally promising topics and that have some pilot spinal cord injury data, but that are not yet sufficiently mature to compete successfully for funding for a full-scale study would also be responsive to this mechanism.

IDEA awards are not intended to fund smaller portions of larger R01-type projects; for data collecting or incremental or correlative research aims; or for the compression of a larger project into a smaller time frame.

Researchers who are testing new hypotheses on spinal cord injury that are based on research grounded in a non-spinal cord injury research area should apply for an IDEA award.

8.4 Award Size and Duration

The IDEA award is for a period of 24 months. Total project costs are capped at $300,000 per project.

8.5 Definitions

For the purpose of the program, "innovative" is defined as:

- Applying novel methods and approaches to spinal cord injury research.
- Challenging existing paradigms or developing new paradigms.
- Considering an existing problem from a new perspective.

8.6 IDEA Merit Review Criteria

Five elements determine IDEA scientific merit.

Innovativeness (20%)
The extent to which the basic concept and hypotheses are speculative, exploratory, develop new paradigms, and are high risk-high reward. The extent to which the project challenges existing principles/dogma, develops new methodologies or technologies, or addresses important under- or unexplored areas.

Impact (20%)
The extent to which the project, if successfully completed, would make an original and important contribution to the cure of spinal cord injury paralysis.

Approach (20%)
The extent, to which the conceptual framework, design, methods and analyses are developed, well integrated and appropriate to the aims of the project. **To be reviewed, applications must discuss the applicability of the proposed research to spinal cord injury.**

Feasibility (20%)
The extent to which the investigators have maximized their chances for success through demonstrated skill, knowledge, expertise, appropriate resources, and collaborations and, if available, relevant spinal cord injury-related preliminary data.

Budget (20%)
The appropriateness of the budget allocations to the accomplishment of the research aims.

9. Application Review Procedure and Feedback

All applications will be reviewed for compliance with instructions and guidelines. Ineligible applications will NOT be reviewed. Incomplete applications, missing required information, will be considered non-responsive and will not be considered for review.. For incomplete applications containing only minor issues, the Principal Investigator will be contacted to provide the missing information.

Complete applications will be reviewed using a two-tiered process modeled after that of the National Institutes of Health (NIH). The first level of review for scientific merit will be conducted by a scientific advisory committee (SAC) composed of non-New York State referees. In the second level of review, Spinal Cord Injury Research Board members will determine programmatic relevance of meritorious applications and recommend these for funding to the Commissioner of Health.

When preparing your application, carefully consider how the project will be evaluated and the criteria involved (see Sections 7.6 and 8.6, respectively). In addition to mechanism-specific merit review criteria, the SAC and Board members will evaluate the following:

Project Duration, Effort or Other Overlap. The SAC will consider the appropriateness of the project duration, budget, effort or other overlap and may recommend revisions to the Board. Awards may be made contingent upon acceptance of revisions to the budget, research plan or project duration.
PIs and other key personnel are required to report other non-research and research funding, and state the distinction between the application and other funded research. The SAC and Board members will examine these and make comments on research overlap. No project activity can be supported by more than one sponsor.

Research Risks. If a project proposes activities that pose unacceptable potential for risk to human subjects or animals, a recommendation may be made not to fund or to delay funding until resolution of the issue. Please provide appropriate IRB, IACUC or DSMB approvals.

9.1 Scientific Merit Peer Review Evaluation (first level of review)

An evaluation of each eligible application received will be conducted following the NIH-style scientific merit peer review process. Scientific advisory committee (SAC) members will be selected by the Peer Review Organization, from among non-New York State spinal cord injury research experts in the appropriate fields. In order to avoid conflict of interest, experts or collaborators on previously funded SCIRB projects or proposed on submitted SCIRB applications will not be eligible to serve as peer reviewers.

At least two reviewers will be assigned as primary and secondary reviewers to each application. Reviewers will receive electronic copies of all applications on their panel and printed copies of the applications to which they are specifically assigned. Applications will be reviewed based on the evaluation criteria presented in the RFA, using previously designed rating forms and reviewer instructions.

Applications will receive scores for each evaluation criterion using a scale of 1 (low merit) to 10 (high merit). In addition, applications will receive a single global priority score on a scale of 1 to 5 according to the NIH model (i.e., 1 denotes high merit and 5 reflects low merit).

Applications rated 'Outstanding' and 'Excellent' will be forwarded for approval. If 'Outstanding' and 'Excellent' applications do not utilize all available funding, applications rated 'Very Good' will be reviewed, considering programmatic diversity. Then 'Good' applications will be considered. Applications receiving a global score of less than 'Good' (higher than 3.5) will not be reviewed by the SCIR Board.

The names and institutional affiliations of peer reviewers will be published after the award process is complete. Specific reviewer assignments will not be released, to protect the confidentiality of peer review.

Applicants will receive a summary statement documenting the committee's consensus review of the application. The summary statement includes an overview of the application's strengths and weaknesses as well the pre-meeting critiques submitted by the assigned reviewers. Applicants will receive a copy of the summary statement after the awards process is complete.

Once an award has been made, bidders may request a debriefing of their application. Please note that the debriefing will be limited only to the strengths and weaknesses of the bidder's application and will not include any discussion of other bidder's applications.

9.2 Programmatic Review (second and third levels of review)

Following scientific merit review, the Spinal Cord Injury Research Board, whose membership includes advocates, clinicians and scientists from a variety of disciplines (see Section 20) will consider the applications in light of the summary statements, average merit scores and program relevance statements resulting from the Scientific Merit Panel Peer Review, as well as the lay and scientific abstracts. The Board will consider the scientifically sound applications in rank order as resulting from the Scientific Merit Panel Peer Review, recommending those meeting the following conditions to the Commissioner of Health for approval:

- The application is for a project which focuses on research related to the development of a cure of spinal cord injury or treatment of its effects, in furtherance of the SCIRB's program and mission.
- The application is from a public or private agency or organization that is a qualified research institution.
- The Scientific Merit Panel Peer Review Evaluation resulted in a "passing" score for the application.

If the pool of applications recommended for approval does not include programmatic diversity, the Board will continue to recommend applications to the Commissioner of Health for funding, until the pool of such applications includes such diversity.

10. General Instructions

Please read and follow the instructions carefully.

Questions about application procedures may be submitted to SCIRB program administrators through 04/05/06 via e-mail (scirb@wadsworth.org) or fax at (518) 486-2798.

Letter of Intent. Potential applicants are **very strongly encouraged** to submit a non-binding Letter of Intent.

Electronic Submission. Applications are to be submitted as a Portable Document Format (PDF) file on CD-ROM. Printed copies of applications or appendices may not be substituted for the CD. See *Application Submission and Receipt* (Section 13) below for more information

Formatting. 11 or 12 point font. Smaller font sizes are acceptable for use in tables and figure legends. The maximum line number should be six lines per vertical inch.

Page Margins. Use 8 ½ inch by 11 inch paper. Except for forms provided, body text margins should be one inch on all sides.

Headers and Footers. The principal investigator's name should be at the top right-hand corner of each page (last name, first initial).

Page Limitations. **Do not exceed the page limits stated for each section**. **Applications that exceed section page limits will not be reviewed.** Figures and illustrations referenced in the research plan are included in the page limits. Pages should be numbered consecutively.

Appendices. Limit appendices to 20 pages. Appendices may not be used to circumvent page limitations. Appropriate materials for appendices include:

(1) The proposed informed consent document for each performance site, even if not yet approved.
(2) Institutional Review Board (IRB) approval.
(3) Institutional Animal Care and Use Committee (IACUC) approvals.
(4) Memoranda of Understanding, subcontracts or contractual agreements.
(5) Letters of collaboration or support.
(6) Up to two highly relevant publications or manuscripts (in press).
(7) Facilities and Administration rate agreements.

Appendices must be included on the CD-ROM as part of the application file.

Application Package. Information presented in the application package is the sole basis for the determination of scientific merit and programmatic relevance.

11. Letter of Intent

Letters of Intent are **very strongly encouraged**. The Letter of Intent should be printed on the organization's letterhead paper and be accompanied by the Face Page with all fields completed (see Section 12.1).

Letters of Intent should be submitted by mail, fax, or email and **must** be **received** no later **than 5:00 p.m. on 03/22/06**. **Only those applicants that submit a Letter of Intent will automatically receive all of the Questions and Answers** (refer to Section 10, General Instructions). Questions and answers, as well as any updates or modifications to the RFA will be posted on the the Department's website at http://www.nyhealth.gov/funding/.

Regular Mail Services:
NYS Spinal Cord Injury Research Program
New York State Department of Health
Wadsworth Center, P O Box 509
Office of Extramural Funding, Rm. C675
Empire State Plaza
Albany, N Y 12201-0509

Express Mail Services:
NYS Spinal Cord Injury Research Program
Office of Extramural Funding
New York State Department of Health
Wadsworth Center, Room C675
Empire State Plaza
Dock J – P1 Level
Albany, New York 12237

Fax:
518-486-2798

Email:
SCIRB@wadsworth.org

12. Form Instructions

In addition to instructions below, supplemental instructions may be provided on the forms.

12.1 Face Page – Form 1

Project Title. In **no more than** 60 characters, describe the focus or purpose of the proposed project.

Application History. Check if this is a new or revised application. Resubmissions must be responsive to the new funding mechanism as well

as reviewers' comments. Please see *Revised Applications* (Section 15) below for additional information.

Research Areas. Select **one** of the following that best describes the area addressed by the application: (1) Acute Injury Events and Processes; (2) Regeneration or developmental programs; (3) Reinnervation; (4) Transplantation/Grafting; or (5) Other – (specify).

Funding Mechanism. Check **one**: CART (Collaborations to Accelerate Research Translation) or IDEA (Innovative, Developmental or Exploratory Activity) application.

Principal Investigator #1. Provide the information requested. The principal investigator (PI) is the New York State investigator responsible for planning, coordinating and implementing the research program if an award is made. The PI will act as liaison between the grantee institution and the SCIRB program, be required to fulfill technical reporting requirements and submit any revised budgets co-signed by an authorized organizational representative.

Co-Principal Investigator #2. Provide the information requested. The Co-Principal Investigator (Co-PI) is an essential partner on all responsive CART applications and those IDEA applications proposing collaborations.

If the Co-PI's affiliation is different than the PI's, complete a second face page, listing the Co-PI. This form is to be signed by the subcontracting institution's authorized agent.

Part of Budget. Indicate if activities performed by the Co-PI are reflected in the PI's budget or through a subcontractual agreement.

Human Subjects. All applications that include **any** use of human subjects or tissues/fluids from human subjects must check 'YES' and complete Form 13*, Human Subjects*. Appropriate assurances **must** be provided before implementation of the workplan.

Vertebrate Animals. All applications that include any use of vertebrate animals or tissues/fluids from them **must** check 'YES' and complete Form 14, *Vertebrate Animals*. Appropriate assurances must be provided before implementation of the workplan.

Project Duration. Report the project duration requested.

Year One Direct Costs. Enter Year One Direct Costs from Form 6A or 6B, Line 12.

Total Direct Costs. Enter the Total Direct Costs from Form 6A or 6B, Line 12.

New York State Applicant Organization. Enter the legal name and address of the applicant organization. Additional information about the applicant institution as well as other institutions expected to receive funds from the New York State Department of Health, Spinal Cord Injury Research Trust Fund is requested on Form 15.

Research Performing Sites. List all sites (organization and location) where the work described in the research plan will be performed.

Contracts and Grants Official. Provide the information requested. This individual will be notified in the event of an award.

Official Signing for Applicant Organization. Provide the name and contact information for the individual authorized to act for the applicant organization. This individual will be responsible for administration and fiscal management of the research program should an award be made. *Note:* This individual typically is not the principal investigator.

Principal, Co-Investigator's Certification and Assurance. By signing and dating the application in the space provided, the principal investigator (PI) (and Co-Investigator, if applicable) certifies to the truthfulness, completeness and accuracy of the information provided.

Organization Certification and Acceptance. The official signing for the applicant organization should sign and date the Face Page. Failure to do so will prevent the application from being processed. By signing, the duly authorized organizational representative has verified and certifies that the organization will comply with all applicable assurances and certifications referenced in the application guidelines.

The signer further certifies that the applicant organization will be accountable for both the appropriate use of any funds awarded, and for performance of the grant contract-supported project or resulting activities.

Applications that include sub-contractual arrangements must insert additional Face Pages signed by the lead co-investigator and official signing for the subcontracting organization certifying their compliance with all applicable assurances and certifications referenced in these application guidelines.

Assurances/Certifications. Each application to the SCIRB program requires that the following

assurances and certifications be verified by the official signing for the applicant organization on the Face Page of the application.

- Human Subjects
- Research on Transplantation of Human Fetal Tissue
- Women and Minority Inclusion in Clinical Research Policy
- Research Using Human Pluripotent Stem Cells
- Recombinant DNA and Human Gene Transfer Research
- Vertebrate Animals
- Debarment and Suspension
- Drug-free Workplace
- Research Misconduct
- Assurance of Compliance
  - Civil rights
  - Handicapped individuals
  - Sex discrimination
  - Age discrimination
- Financial conflict of interest

12.2 Table of Contents – Form 2

Complete the table of contents, entering page numbers as appropriate or entering "N/A" when not applicable. Please flag with asterisks (*) all page numbers containing information that, if released, would put the applicant at a competitive disadvantage (e.g., financial or commercial confidential information, including trade secrets). Information submitted to the SCIRB program is subject to the Freedom of Information Law (New York State Public Officers' Law, Article 6, Sections 84 to 90).

12.3 Scientific Abstract – Form 3

Provide the information requested on the form provided. The abstract should be written so that persons from diverse scientific backgrounds can easily understand the work proposed. Do not include confidential information in the scientific abstract. NOTE: Applicants proposing use of human pluripotent stem cells should clearly indicate the specific cell line they plan to use (http://stemcells.nih.gov/research/registry/).

12.4 Lay Abstract – Form 4

Provide the information requested. The abstract should be written so that the general public can easily understand the work proposed. Do not include confidential information in the lay abstract. Information presented on this form will be condensed and used for public dissemination, subject to the PI's approval.

12.5 Program Responsiveness – Form 5

The information requested is essential for both merit and programmatic review. You may delete questions not applicable to your application.

12.6 Budget – CART Form 6A, IDEA Form 6B

- For each year (or part thereof) of support requested, report the amount requested for each category, as well as subtotals and totals requested. If there are sub-contractual costs (line 11), provide additional copies of Form 6A or Form 6B, as applicable, for each subcontract.

- **Total direct costs for Year Two, Three or Four, if requested, may not exceed the amount requested for Year One.**

- Applications with equipment requests (line 5) that equal or exceed $25,000 are required to demonstrate cost sharing of at least 50 percent of the equipment request from sources other than unrecovered Facilities and Administration (F&A) costs (e.g., salaries, wages and benefits; travel; and institutional or industrial gifts available to the PI to complement the proposed research support (duplication is prohibited)).

ALLOWABLE EXPENSES

PERSONAL SERVICE

Salary may be requested for investigator(s) and technical staff, as well as for pre- and postdoctoral fellows.

Salary support for the principal and any co-investigator(s) is limited to $25,000 or 20 percent of each investigator's institutional base salary, whichever is less, regardless of percent effort devoted to the project. Requests for support of technical staff or fellows should be consistent with institutional policies and proportionate to their percent of expended effort. Fringe benefits may be requested in accordance with institutional guidelines for each position, provided such benefits are applied consistently by the applicant organization as a direct cost to all sponsors.

Tuition reimbursement is not an allowable expense.

OTHER THAN PERSONAL SERVICE

Support may be requested for:

- Materials and supplies;
- Travel and per diem – including reasonable expenses for the costs of collaboration for durations appropriate to the collaboration; not to

exceed a project total of $20,000; costs of travel to international conferences are not allowed;
- Consulting services;

Support for the following may be included in "Other Expenses" in the proposed budget:

- Animals and their care;
- Rental fees;
- Centers/core service charges;
- Communication;
- Meeting registration costs; and
- Publication expenses.

Fees related to patient care costs are not allowed.

Requests for purchase of equipment may be granted if strongly justified as essential to the proposed project; a current price quote should be included in the application appendix. Requests for equipment in excess of $25,000 should document 50-percent cost sharing by the applicant organization (exclusive of unrecovered F&A).

Facilities and Administration Costs

If an award is made, F&A costs will be calculated from recommended and approved budget amounts. F&A will be the lower of 20 percent of total modified direct costs or the amount recovered using the institution's current F&A rate negotiated with its cognizant agency. This comparison is documented in the application checklist. A copy of the F&A rate statement may be included in the Appendix, or provided before contract execution. In the absence of a federal agreement, an equivalently documented rate for the organization may be used. For-profit entities are ineligible for F&A recovery. An additional one-time flat fee of $20,000 to cover costs associated with establishing and monitoring four-year subcontractual agreements may be provided to the applicant organization.

12.7 Personal Effort and Budget Justification – Form 7

Applicants should request funds appropriate for cost-effective support of the proposed research project. Funds awarded by this program may not be used to supplant other existing support for the same work.

For projects with subcontracts involving non-New York State institutions, collaborations must clearly contribute to the achievement of the Board's goals for CART and IDEA grants (Section 6, and presented in Form 5) and be in the interest of New York State.

Prepare Form 7 for the applicant institution first, following it with additional forms for collaborating or subcontracting institutions. In the table, provide the information requested for key personnel and technical staff at the applicant organization, regardless of whether financial support is requested. Insert additional lines as necessary. The 'Total Salary + Fringe Requested' should equal Line 3, Year One, from Form 6A or Form 6B.

Starting with personnel, justify amounts requested in each budget category. Regardless of whether financial support is requested, describe briefly the roles and expected contributions to the project of all key personnel, fellows and technical staff.

Provide a detailed justification for each 'Other Than Personal Service' line requested.

Describe the necessity for equipment requested, noting the impact on the project if the equipment requested is not approved; provide alternative approaches to completing the work proposed without the equipment purchase. Describe the value and source of cost sharing if the equipment requested equals or exceeds $25,000.

12.8 Biographical Sketch – Form 8

Provide two-page biographical sketches for all key personnel listed on Form 7, including collaborators and consultants. Start with the principal investigator followed by the remaining key personnel.

12.9 Facilities and Resources – Form 9

Describe the facilities available for performance of the proposed research, starting with the applicant institution and followed by collaborating or subcontracting institutions. Also indicate the institutional commitment, including any additional facilities or equipment requested in support of the project or available for use at no cost to the project.

12.10 Other Support – Form 10

For the PI and all other key personnel, provide the information requested for all existing and pending non-research (e.g., clinical, teaching, or extension duties) and research support. Applications submitted to the SCIRB research program should not duplicate other funded research projects. The PI and the contracting organization are responsible for notifying SCIRB program staff of changes in funding overlap information.

12.11 Research Plan – Form 11

The research plan for CART applications is limited to **15** pages and for IDEA applications is limited to **10** pages. These page limits include text and figures but exclude literature cited.

The research plan should present the application in sufficient detail to convey clearly and concisely to reviewers that:

- The application's basis is conceptually well-founded and substantiated by the literature;
- The proposed approach is the most appropriate strategy to use as evidenced, in part, by consideration of alternatives;
- The research team and available resources enhance the likelihood of the project's success; and
- Successful completion of the project will advance SCIRB's mission.

A. Specific Aims
List the objectives, hypotheses to be tested, gaps in knowledge to be filled, or technologies/tools to be developed or tested.

B. Significance
Provide a succinct description for each proposed aim indicating how its attainment will advance treatment for chronic or acute SCI.

C. Background and Preliminary Results
Review the literature that underlies the proposed research and present available preliminary data. The scientific rationale for the project should be extremely compelling. Preliminary data are essential to successful CART applications, although not essential to IDEA applications.

D. Research Design and Methods
Describe the experimental design, methodological approaches, statistical analyses and interpretation to be used to accomplish the specific aims. Information provided should convey the applicant's understanding of the strengths and limitations of the proposed study's design, methodologies, and SCI models and convince reviewers that this approach is the most effective strategy. Discuss alternative approaches, as appropriate. Ensure that important unpublished information is presented in sufficient detail to enable reviewers to assess its quality and relevance.

NOTE: Applicants proposing use of human pluripotent stem cells should clearly indicate in the research plan the specific cell line they plan to use (http://stemcells.nih.gov/research/registry/). Also include this information in the Scientific Abstract.

NOTE: The NYS SCIRB will not fund studies exceeding NIH guidelines for use of human embryonic stem cells, germ cells, and cell-derived test articles. See http://stemcells.nih.gov/index.asp for further information.

E. Literature Cited
References are not counted in research plan page limitations, nor is the number of references restricted. However, applicants are urged to select references that comprehensively reflect the relevant literature. Provide complete citations to references (i.e., include titles).

12.12 Time Line and Collaboration Strategy – Form 12
Complete the table provided. If the application involves an inter-institutional collaboration, describe strategies to be used for information and/or resource exchange to assure the efficient and effective completion of the project. Include frequency and methods of communications. Note barriers to communication and resource exchange and propose alternative strategies to overcome potential problems.

12.13 Human Subjects – Form 13
Appropriate oversight and administration of human subjects research are essential to the ethical conduct of clinical and translational research. In addition to the information requested on Form 13, applicants must include in the Appendix informed consent document(s) for all performing sites, even if not yet reviewed and approved. Approval of consent procedures and forms at all collaborating sites at which human subjects will be involved in funded research must precede involvement of subjects there.

Complete Form 13, following instructions provided. The eight points to be addressed on Form 13 are presented in full below. Please note these points vary slightly from those presented in NIH 398. Human subjects research considered "exempt" from regulations are to respond to these points in sufficient detail to justify exemption to merit reviewers and program staff.

Certification of IRB review and approval is not required prior to application review; however, a signed New York State Spinal Cord Injury Research Program Human Subjects Research Certification (Form 17), each participating institution's standard IRB approval form or signed exemption will be required for contract execution.

1) Involvement of Human Subjects and Population Characteristics
Describe the involvement of human subjects as outlined in the research plan. Include descriptions of the subject population, e.g., number of subjects, age range and health status. Provide inclusion or exclusion criteria of any subpopulation (including women or minorities), and explain why such inclusion or exclusion is necessary to accomplish

the research goals. Explain the rationale for the involvement of special classes of subjects, such as minors, mentally disabled adults, prisoners, institutionalized individuals or others likely to be vulnerable. Discuss proposed outreach programs for recruiting women and minorities in clinical research as participants.

2) Sources of Materials - Confidentiality
Identify the sources of research material obtained from individual living human subjects in the form of specimens, records, or data, and whether identifiable. Indicate whether the material or data will be obtained specifically for research purposes, or whether existing specimens, records or data will be used. Discuss the system for maintaining subjects' confidentiality.

3) Risks
Describe potential risks to subjects (physical, psychological, social, legal or other), and assess their likelihood and seriousness. As appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

4) Recruitment and Consent
Describe recruitment plans for subjects and the consent procedures to be followed, including, but not limited to, procedures for assessing capacity of mentally disabled adults. Describe when consent will be requested and obtained, who will seek it, the information to be provided to prospective subjects, and the methods of documenting consent. *Include pending or approved informed consent form(s) in the Appendix.*

5) Protection from Risk
Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects.

If your proposed research includes a clinical trial intervention, in a subsection labeled Data and Safety Monitoring, discuss your oversight and monitoring plan to ensure the safety of participants and the validity and integrity of the data obtained. An appropriate plan must be submitted to the applicant's IRB for approval and subsequently to the SCI program prior to accrual of human participants. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html and http://grants.nih.gov/grants/guide/notice-files/NOT98-084.html for additional information.

6) Potential Benefits of the Proposed Research to the Subjects and Others
Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

7) Importance of the Knowledge to Be Gained
Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

NOTE: If a test article (investigational new drug, device or biologic) is involved, name the test article and state whether the 30-day interval between submission of the applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

8) Education
Individuals who are identified as key personnel and who are involved with human subject research must document education received in the protection of human research participants. For each individual, provide the title and date of the education program completed.

9) Conflict of Interest
Indicate how the PI and Co-PIs plan to comply with US Office of Research Integrity conflict of interest guidelines and indicate whether any key staff have been debarred.

12.14 Vertebrate Animals – Form 14

Complete Form 14 for each participating institution and performance site. Acquisition and use of animals at all performance sites must comply with New York State Public Health Law, Article 5, Title I, Sections 504, 505-a.

If the applicant organization does not have an approved Animal Welfare Assurance form on file with OLAW or a USDA registration number, if required, insert "NONE" in the space provided on Form 14. In this case, the applicant organization, by the official's signature on the face page, is declaring that it will comply with U.S. Public Health Service policy on the care and use of animals by establishing an IACUC, and submitting an Animal Welfare Assurance form and verification of IACUC approval whenever requested to do so. If required, the applicant organization must also register its facility with the USDA.

Succinctly address the following four points on Form 14.

1) Provide a detailed description of the animal use proposed in the research work plan, including identification of species, strains, ages, sexes and numbers of animals to be used.

2) Justify the use of animals, the choice of species and the number to be used; provide power calculations to justify your application. If animals are in short supply, costly or to be used in large numbers, provide additional rationale for their selection and numbers.

3) Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. As appropriate, describe the use of analgesic, anesthetic and tranquilizing drugs, and comfortable restraining devices to minimize discomfort, distress, pain and injury.

4) Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following those recommendations.

12.15 Organizational Profile – Form 15

This form is required for the New York State applicant organization. Complete the table, providing the information requested.

Type of Organization. Check appropriate box(es). A small business is an independently owned and operated entity not dominant in the field in which research is proposed and employing 500 or fewer persons. A "WMO" is a woman- or minority-owned business.

Federal Identification Number. Enter the applicant organization's nine-digit Internal Revenue Service employer identification number.

DUNS number. Enter applicant organization's Dun and Bradstreet number, if any.

Charities' Identification Number. In the space provided, enter the charities' identification number or, if exempt, indicate the exemption category. For information on identification numbers, contact the Department of State, Office of Charities Registration, 162 Washington Avenue, Albany, NY 12231, and (518) 474-3720. Additional information and descriptions of exemption categories may be found at: http://nysosc3.osc.state.ny.us/agencies/gbull/g-79.htm.

Legislative District Numbers. Enter the New York State Senate and Assembly District numbers corresponding to the *address provided for the New York State applicant organization listed on the Face Page*. Senate district information may be found at: www.senate.state.ny.us, and Assembly district information obtained by calling (518) 455-4100.

Address to which reimbursement is to be sent: Many institutions request that payment be sent to locations other than the official mailing address (e.g., Research Foundation of State University of New York). Provide appropriate information or indicate "N/A".

Assurances/Certifications. Each application to the New York State Department of Health requires that the assurances and certifications listed on the Organizational Profile page are verified by the official(s) signing for the applicant and subcontracting organization(s) on the Face Page(s) of the application.

Facilities and Administration Costs. Provide the information requested. The information requested will be used to document that the 20% total modified direct cost F&A rate does not exceed that which would be recovered using the applicant organizations' negotiated F&A rate. In the event of an award, a copy of the agreement will be requested.

12.16 Appendix Cover Sheet – Form 16

This form is required for all applications with appendices. If human subjects research is proposed, the pending or approved informed consent document(s) must be included in the Appendix or the application will be rejected. If available, copies of the organization's IRB approval and the New York State Spinal Cord Injury Research Program Human Subjects Certification (Form 17) are also to be included. The appendix may also contain IACUC approvals, documentation of contractual/consortium agreements, or letters of support from collaborators. Reprints of up to two papers (published or in press) may be included only if essential to document the investigator's capability to undertake the work proposed.

12.17 New York State Spinal Cord Injury Research Program Human Subjects Certification – Form 17

Prior to contract execution, Form 17 must be submitted.

13. Application Submission and Receipt

Applications must be submitted as a Portable Document Format (PDF) file on CD-ROM. All related materials and appendices must be included as part of a single application file. The CD-ROM should be clearly labeled with the NYS SCIRP-assigned log number and the applicant's name and address.

Please note that if you did not download the RFA and all required forms from
http://www.nyhealth.gov/funding/
and are using printed copies of required forms they will need to be scanned into the Portable Document Format (PDF) file.

Applications are ONLY accepted as a PDF file on CD-ROM. Applications sent by fax or email will not be accepted.

Applicants are advised to seek appropriate technical support from their institutions in the creation of PDF files for submission. Some materials, such as letters of support and publication reprints may require scanning and insertion into the PDF file. Discretion should be used in the resolution used to scan such materials and figures for inclusion in the application. Excess resolution will increase the size of the PDF file without any appreciable increase in viewing quality when the file is viewed on a computer screen or printed. Applicants should also be aware that while color figures can be included, applications are printed in black and white and will not be reproduced in color. You may wish to annotate the figure legend directing the reader to the electronic file if color is an important aspect of the figure.

Under no circumstances should the PDF files have any password protection on them whatsoever. During processing for review the abstract or other sections of the application must be able to be saved as separate files and it may be necessary to append additional information such as a cover sheet to the document. Files that are password protected will be rejected.

Applicants are strongly encouraged to review their final PDF file prior to submission. It is the applicant's responsibility to ensure that all materials to be included in the application have been properly converted and inserted into the PDF file.

Applications should be sent to the address below appropriate to the mail service used. The exterior of the package should also be clearly labeled with the applicant's name and address.

The application package must be received no later than 5:00 p.m., 07/19/06. Late submissions will not be accepted.

Regular Mail Services:
NYS Spinal Cord Injury Research Program
New York State Department of Health
Wadsworth Center, P.O. Box 509
Office of Extramural Funding, Rm. C675
Empire State Plaza
Albany, N Y 12201-0509

Express Mail Services:
NYS Spinal Cord Injury Research Program
Office of Extramural Funding
New York State Department of Health
Wadsworth Center, Room C675
Empire State Plaza
Dock J – P1 Level
Albany, New York 12237

A complete application package contains:

- **2 original - signed copies of the application face page (Form 1);**
- **1 CD-ROM containing a single Portable Document Format (PDF) file containing the entire application; and,**
- **six paper copies of the entire application.**

If appendices are included, the applicant is responsible for scanning the documents and including them as a part of the application PDF file.

Questions about application submission may be submitted to:
Email: (www.scirb@wadsworth.org)
Fax: (518) 486-2798

Potential applicants may submit written questions concerning other provisions of the RFA through 04/05/06**.** These should be sent to www.scirb@wadsworth.org or faxed to the Office of Extramural Funding, at (518) 486-2798. Responses will be posted on the same Wadsworth SCIRP website.

Upon receipt, applications received will be logged for time and date. An acknowledgment of receipt of submission is not an acknowledgment that an applicant has adhered to submission requirements or instructions. Applications received on time will be reviewed for compliance within 5 business days of the receipt deadline. Any compliance issues identified will be presented to the SCIRP for final determination. Applicants deemed noncompliant with the RFA or ineligible will be administratively withdrawn by NYS SCIRP (pass/fail) and will

receive email notification of their status within 48 hours of the decision.

14. Anticipated Timeline

RFA distributed	01/25/06
Letter of Intent deadline	03/22/06
Deadline for questions	04/05/06
Answers to questions	04/19/06
Applications due	07/19/06
Estimated contract start date	04/01/07

15. Revised Applications

A revised application requests support for research that was reviewed during a previous cycle, but not funded. Applicants who wish to submit a revised application should review these guidelines carefully. There are new elements and requirements for this competition. If the following requirements are not met, the application will be rejected.

"Revised Application" must be indicated in the upper, right-hand corner of the face page. A revised application must have the same principal investigator as the original application. When possible, it should have the same title as the original.

A revision must include a section called "Revisions and Comments" immediately preceding the Research Plan. In not more than two pages, this section should summarize the substantial additions, deletions and changes that have been made. It also must include responses to criticisms in the previous review evaluation. This material does not count in the normal page limit for the Research Plan. We also recommend emphasizing in the research plan any relevant work done since the previous application.

Reviewers' comments from the previous submission may be included in the appendices.

16. Award Decisions and Pre-Funding Requirements

Final approval for funding is made by the Commissioner of the New York State Department of Health.

Principal investigators recommended for support, and their applicant organizations, will receive formal notification of award by mail.

Prior to contract execution, program administrators will require resolution of the following issues, as relevant to each application:

- Research funding overlap;
- Revisions to workplan, project budget or duration;
- Other program requirements pertaining to research administration or research risks;
- Current human subjects research approval or exemption documents and New York State certification (Form 17);
- Current animal approval documents; or
- Acceptable lay abstract or project title.

17. Award Announcements

For applications that are funded, the spinal cord injury research program makes public in press releases or annual reports to the Governor and Legislature, the project title, the principal investigator(s), the name of the organization, total projects costs and duration. The project abstract and progress report abstracts may also be made public.

If the program receives a request for additional information on a funded grant, the PI/institution will be notified prior to the program's response to the request.

18. Award Contracts and Conditions of Awards

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

The contracting organization is fully responsible for the conduct, and fiscal and legal management of the project, as well as oversight of any subcontractual agreements.

18.1 Contract Components

Contracts will consist of several appendices and an addendum, (see attached Contract Supplement)

which the applicant should read but not complete at this time.

General Conditions of Award

Grant awardees must *agree to:*

- Use award funds only as approved by the Spinal Cord Injury Research Program. The program must approve changes in the specific aims of a contract.
- Maintain accounts, records and other evidence pertaining to work performed and costs incurred.
- File regular progress reports and a final scientific report.
- Participate in New York State Spinal Cord Injury Research Program sponsored activities to disseminate research results as able and as requested.
- Make good faith efforts to ensure the timely translation of research results into clinical applications and report these efforts to the program.
- Make good faith efforts to communicate with other scientists and the public about the funded work.
- Attend an annual SCIRB meeting, if scheduled.
- Subject to possible cancellation of the contract, PIs must indicate during interviews and appearances with members of the press, including those representing professional journals, that their work is supported by the NYS Department of Health Spinal Injury Research Board grant #_____, titled " _____"

Following notification of the intention to fund an application, the PI and applicant organization must*:*

- Provide up-to-date human and animal subjects assurances from a federally approved review board.
- Modify titles and lay abstracts, if requested.
- Agree to any changes in specific aims, award budget or project duration as recommended by the Scientific Advisory Committee and program.
- Resolve conflicts in Other Support and percent Full Time Effort.
- Supply up-to-date documentation for approved indirect rate agreements.

Administration and Records. The institution as grantee must maintain a separate financial account for the Spinal Cord Injury Research Grant and this must be available for audit. Reports of expenditures by line item must accompany each quarterly voucher in order for payment to be approved. The final voucher, should be filed no more than 45 days following the final date of the contract and must be accompanied by a final report indicating how the funds assisted in the furtherance of the research, key developments and findings, a list and copies of any publications and manuscripts resulting from grant funding.

Publications. Publications, manuscripts and abstracts of conference presentations and posters supported by a grant, must carry the following exact acknowledgment: "This research was supported by a Spinal Cord Injury Research Grant from the New York State Department of Health, Grant No. _____."

Grant Transferability and Termination. Grants are not transferable to another institution without the prior approval of the Program following a written request of the investigator received 3 months before the date of the proposed transfer.

A grant may be terminated by written request of the institution or investigator prior to completion of the contract period. Unexpended funds received must be returned to the New York State Department of Health and any unpaid balance of the award will be canceled. A final report is also required.

18.2 Award Period

The estimated contract start date for the competition is **04/01/07**.

Continuation funding for additional project years is contingent upon:

- Receipt of the first year's and subsequent year's progress reports and demonstration of acceptable research progress.
- No overlaps with Other Support.
- Maintenance of sufficient FTE percent by the PI(s).
- Continuing approval of human and animal subjects use.
- Submission of publication copies, and reporting any changes in key personnel
- Availability of funds.

If funding is delayed or if all funds are not expended in the normal award period, the investigator may request that funds be carried over.

Budget-line interchanges must be approved in advance by a program administrator.

19. THE DEPARTMENT OF HEALTH RESERVES THE RIGHT TO:

1. Reject any or all applications received in response to this RFA.
2. Award more than one contract resulting from this RFA.
3. Waive or modify minor irregularities in applications received after prior notification to the applicant.
4. Adjust or correct cost or cost figures with the concurrence of the applicant if errors exist and can be documented to the satisfaction of DOH and the State Comptroller.
5. Negotiate with applicants responding to this RFA within the requirements to serve the best interests of the State.
6. Modify the detailed specifications should no applications be received that meet all these requirements.
7. If the Department of Health is unsuccessful in negotiating a contract with a selected applicant within an acceptable time frame, the Department of Health may begin contract negotiations with the next most qualified applicant(s) in order to serve and realize the best interests of the State.

19.1 Vendor Responsibility Requirements

New York State Procurement Law requires that state agencies award contracts only to responsible vendors. Applicants are required to provide Vendor Responsibility information in the event they are chosen as part of the final selection process.

The "Vendor Responsibility Questionnaire" that all applicants other than governmental agencies will be asked to complete in the event they are chosen as part of the final selection process follows this section. (Note: Governmental agencies are defined as: State agencies, counties, cities, towns, villages, school districts, community colleges, Board of Cooperative Education Services (BOCES), Vocational Education Extension Boards (VEEB;s), water, fire, and sewer districts, public libraries, and water and soil districts.)

In addition to the questionnaire, applicants will be required to provide the following in the event they are chosen as part of the final selection process:

· Proof of financial stability in the form of audited financial statements, Dunn & Bradstreet Reports, etc.
· Department of State Registration
· Charities Registration
· Certificate of Article of Incorporation

VENDOR RESPONSIBILITY QUESTIONNAIRE

As of January 1, 2005 the Office of the State Comptroller requires that all contracts valued at $100,000 or more for the life of the contract, be tested for vendor responsibility. This questionnaire needs to be completed by potential applicants and submitted with their application.

1. VENDOR IS: ☐ **PRIME CONTRACTOR** ☐ **SUB-CONTRACTOR**		
2. VENDOR'S LEGAL BUSINESS NAME	**3. IDENTIFICATION NUMBERS** **a) FEIN #** **b) DUNS #**	
4. D/B/A – Doing Business As (if applicable**) & COUNTY FILED:**	**5. WEBSITE ADDRESS** (if applicable)	
6. ADDRESS OF PRIMARY PLACE OF BUSINESS/EXECUTIVE OFFICE	**7. TELEPHONE NUMBER**	**8. FAX NUMBER**
9. ADDRESS OF PRIMARY PLACE OF BUSINESS/EXECUTIVE OFFICE ***IN NEW YORK STATE***, if different from above	**10. TELEPHONE NUMBER**	**11. FAX NUMBER**
12. PRIMARY PLACE OF BUSINESS IN NEW YORK STATE IS: ☐ **Owned** ☐ **Rented** If rented, please provide landlord's name, address, and telephone number below:	**13. AUTHORIZED CONTACT FOR THIS QUESTIONNAIRE** **Name** **Title** **Telephone Number** **Fax Number** **e-mail**	

14. VENDOR'S BUSINESS ENTITY IS (please check appropriate box and provide additional information):		
a) ☐ Business Corporation	**Date of Incorporation**	**State of Incorporation***
b) ☐ Sole Proprietor	**Date Established**	
c) ☐ General Partnership	**Date Established**	
d) ☐ Not-for-Profit Corporation	**Date of Incorporation**	**State of Incorporation*** **Charities Registration Number**
e) ☐ Limited Liability Company (LLC)	**Date Established**	
f) ☐ Limited Liability Partnership	**Date Established**	
g) ☐ Other – Specify:	**Date Established**	**Jurisdiction Filed (if applicable)**

* If not incorporated in New York State, please provide a copy of authorization to do business in New York.

15. PRIMARY BUSINESS ACTIVITY - (Please identify the primary business categories, products or services provided by your business)

16. NAME OF WORKERS' COMPENSATION INSURANCE CARRIER:

17. LIST ALL OF THE VENDOR'S PRINCIPAL OWNERS AND THE THREE OFFICERS WHO DIRECT THE DAILY OPERATIONS OF THE VENDOR (Attach additional pages if necessary):

a) NAME (print)	**TITLE**	**b) NAME** (print)	**TITLE**
c) NAME (print)	**TITLE**	**d) NAME** (print)	**TITLE**

A DETAILED EXPLANATION IS REQUIRED FOR EACH QUESTION ANSWERED WITH A "YES," AND MUST BE PROVIDED AS AN ATTACHMENT TO THE COMPLETED QUESTIONNAIRE. YOU MUST PROVIDE ADEQUATE DETAILS OR DOCUMENTS TO AID THE CONTRACTING AGENCY IN MAKING A DETERMINATION OF VENDOR RESPONSIBILITY. PLEASE NUMBER EACH RESPONSE TO MATCH THE QUESTION NUMBER.

18.	Is the vendor certified in New York State as a (check please): ☐ **Minority Business Enterprise (MBE)** ☐ **Women's Business Enterprise (WBE)** ☐ **Disadvantaged Business Enterprise (DBE)?** *Please provide a copy of any of the above certifications that apply.*	☐ **Yes** ☐ **No**
19.	Does the vendor use, or has it used in the past ten (10) years, any other Business Name, FEIN, or D/B/A other than those listed in items 2-4 above? ***List all other business name(s), Federal Employer Identification Number(s) or any D/B/A names and the dates that these names or numbers were/are in use. Explain the relationship to the vendor.***	☐ **Yes** ☐ **No**
20.	Are there any individuals now serving in a managerial or consulting capacity to the vendor, including principal owners and officers, who now serve or in the past three (3) years have served as:	
	a) An elected or appointed public official or officer? ***List each individual's name, business title, the name of the organization and position elected or appointed to, and dates of service.***	☐ **Yes** ☐ **No**
	b) A full or part-time employee in a New York State agency or as a consultant, in their individual capacity, to any New York State agency? ***List each individual's name, business title or consulting capacity and the New York State agency name, and employment position with applicable service dates.***	☐ **Yes** ☐ **No**
	c) If yes to item #20b, did this individual perform services related to the solicitation, negotiation, operation and/or administration of public contracts for the contracting agency? ***List each individual's name, business title or consulting capacity and the New York State agency name, and consulting/advisory position with applicable service dates. List each contract name and assigned NYS number.***	☐ **Yes** ☐ **No**
	d) An officer of any political party organization in New York State, whether paid or unpaid? ***List each individual's name, business title or consulting capacity and the official political party position held with applicable service dates.***	☐ **Yes** ☐ **No**

21.	Within the past five (5) years, has the vendor, any individuals serving in managerial or consulting capacity, principal owners, officers, major stockholder(s) (10% or more of the voting shares for publicly traded companies, 25% or more of the shares for all other companies), affiliate[1] or any person involved in the bidding or contracting process:	
	a) 1. been suspended, debarred or terminated by a local, state or federal authority in connection with a contract or contracting process;	☐ **Yes** ☐ **No**
	2. been disqualified for cause as a bidder on any permit, license,	

	concession franchise or lease; 3. entered into an agreement to a voluntary exclusion from bidding/contracting; 4. had a bid rejected on a New York State contract for failure to comply with the MacBride Fair Employment Principles; 5. had a low bid rejected on a local, state or federal contract for failure to meet statutory affirmative action or M/WBE requirements on a previously held contract; 6. had status as a Women's Business Enterprise, Minority Business Enterprise or Disadvantaged Business Enterprise denied, de-certified, revoked or forfeited; 7. been subject to an administrative proceeding or civil action seeking specific performance or restitution in connection with any local, state or federal government contract; 8. been denied an award of a local, state or federal government contract, had a contract suspended or had a contract terminated for non-responsibility; or 9. had a local, state or federal government contract suspended or terminated for cause prior to the completion of the term of the contract?	
b)	been indicted, convicted, received a judgment against them or a grant of immunity for any business-related conduct constituting a crime under local, state or federal law including but not limited to, fraud, extortion, bribery, racketeering, price-fixing, bid collusion or any crime related to truthfulness and/or business conduct?	☐ **Yes** ☐ **No**
c)	been issued a citation, notice, violation order, or are pending an administrative hearing or proceeding or determination for violations of: 1. federal, state or local health laws, rules or regulations, including but not limited to Occupational Safety & Health Administration (OSHA) or New York State labor law; 2. state or federal environmental laws; 3. unemployment insurance or workers' compensation coverage or claim requirements; 4. Employee Retirement Income Security Act (ERISA); 5. federal, state or local human rights laws; 6. civil rights laws; 7. federal or state security laws;	☐ **Yes** ☐ **No**

	8. federal Immigration and Naturalization Services (INS) and Alienage laws; 9. state or federal anti-trust laws; or 10. charity or consumer laws? ***For any of the above, detail the situation(s), the date(s), the name(s), title(s), address(es) of any individuals involved and, if applicable, any contracting agency, specific details related to the situation(s) and any corrective action(s) taken by the vendor.***	
22.	In the past three (3) years, has the vendor or its affiliates[1] had any claims, judgments, injunctions, liens, fines or penalties secured by any governmental agency?	☐ **Yes** ☐ **No**

	Indicate if this is applicable to the submitting vendor or affiliate. State whether the situation(s) was a claim, judgment, injunction, lien or other with an explanation. Provide the name(s) and address(es) of the agency, the amount of the original obligation and outstanding balance. If any of these items are open, unsatisfied, indicate the status of each item as "open" or "unsatisfied."	
23.	Has the vendor (for profit and not-for profit corporations) or its affiliates[1], in the past three (3) years, had any governmental audits that revealed material weaknesses in its system of internal controls, compliance with contractual agreements and/or laws and regulations or any material disallowances? ***Indicate if this is applicable to the submitting vendor or affiliate. Detail the type of material weakness found or the situation(s) that gave rise to the disallowance, any corrective action taken by the vendor and the name of the auditing agency.***	☐ **Yes** ☐ **No**
24.	Is the vendor exempt from income taxes under the Internal Revenue Code? ***Indicate the reason for the exemption and provide a copy of any supporting information.***	☐ **Yes** ☐ **No**
25.	During the past three (3) years, has the vendor failed to:	
	a) file returns or pay any applicable federal, state or city taxes? ***Identify the taxing jurisdiction, type of tax, liability year(s), and tax liability amount the vendor failed to file/pay and the current status of the liability.***	☐ **Yes** ☐ **No**
	b) file returns or pay New York State unemployment insurance? ***Indicate the years the vendor failed to file/pay the insurance and the current status of the liability.***	☐ **Yes** ☐ **No**
26.	Have any bankruptcy proceedings been initiated by or against the vendor or its affiliates[1] within the past seven (7) years (whether or not closed) or is any bankruptcy proceeding pending by or against the vendor or its affiliates regardless of the date of filing? ***Indicate if this is applicable to the submitting vendor or affiliate. If it is an affiliate, include the affiliate's name and FEIN. Provide the court name, address and docket number. Indicate if the proceedings have been initiated, remain pending or have been closed. If closed, provide the date closed.***	☐ **Yes** ☐ **No**

APPENDIX C

PAYMENT AND REPORTING SCHEDULE

I. Payment and Reporting Terms and Conditions

A. The STATE may, at its discretion, make an advance payment to the CONTRACTOR, during the initial or any subsequent PERIOD, in an amount to be determined by the STATE but not to exceed _____ percent of the maximum amount indicated in the budget as set forth in the most recently approved Appendix B. If this payment is to be made, it will be due thirty calendar days, excluding legal holidays, after the later of either:

- the first day of the contract term specified in the Initial Contract Period identified on the face page of the AGREEMENT or if renewed, in the PERIOD identified in the Appendix X, OR

- if this contract is wholly or partially supported by Federal funds, availability of the federal funds;

provided, however, that a STATE has not determined otherwise in a written notification to the CONTRACTOR suspending a Written Directive associated with this AGREEMENT, and that a proper voucher for such advance has been received in the STATE's designated payment office. If no advance payment is to be made, the initial payment under this AGREEMENT shall be due thirty calendar days, excluding legal holidays, after the later of either:

- the end of the first monthly/quarterly period of this AGREEMENT; or

- if this contract is wholly or partially supported by federal funds, availability of the federal funds:

provided, however, that the proper voucher for this payment has been received in the STATE's designated payment office.

B. No payment under this AGREEMENT, other than advances as authorized herein, will be made by the STATE to the CONTRACTOR unless proof of performance of required services or accomplishments is provided. If the CONTRACTOR fails to perform the services required under this AGREEMENT the STATE shall, in addition to any remedies available by law or equity, recoup payments made but not earned, by set-off against any other public funds owed to CONTRACTOR.

C. Any optional advance payment(s) shall be applied by the STATE to future payments due to the CONTRACTOR for services provided during initial or subsequent PERIODS. Should funds for subsequent PERIODS not be appropriated or budgeted by the STATE for the purpose herein specified, the STATE shall, in accordance with Section 41 of the State Finance Law, have no liability under this AGREEMENT to the CONTRACTOR, and this AGREEMENT shall be considered terminated and cancelled.

D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the program workplan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller.

E. The CONTRACTOR will provide the STATE with the reports of progress or other specific work products pursuant to this AGREEMENT as described in this Appendix below. In addition, a final report must be submitted by the CONTRACTOR no later than ____ days after the end of this AGREEMENT. All required reports or other work products developed under this AGREEMENT must be completed as provided by the agreed upon work schedule in a manner satisfactory and acceptable to the STATE in order for the CONTRACTOR to be eligible for payment.

F. The CONTRACTOR shall submit to the STATE monthly/quarterly voucher claims and reports of expenditures on such forms and in such detail as the STATE shall require. The CONTRACTOR shall submit vouchers to the State's designated payment office located in the _____.

All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than _____ days after the end date of the period for which reimbursement is being claimed. In no event shall the amount received by the CONTRACTOR exceed the budget amount approved by the STATE, and, if actual expenditures by the CONTRACTOR are less than such sum, the amount payable by the STATE to the CONTRACTOR shall not exceed the amount of actual expenditures. All contract advances in excess of actual expenditures will be recouped by the STATE prior to the end of the applicable budget period.

II. Progress and Final Reports

Organization Name: _____

Report Type:

A. Narrative/Qualitative Report

_____ (Organization Name) will submit, on a quarterly basis, not later than _____ days from the end of the quarter, a report, in narrative form, summarizing the services rendered during the quarter. This report will detail how the _____ (Organization) _____ has progressed toward attaining the qualitative goals enumerated in the Program Workplan (Appendix D).

(Note: This report should address all goals and objectives of the project and include a discussion of problems encountered and steps taken to solve them.)

B. Statistical/Quantitative Report

_____ (Organization Name) will submit, on a quarterly basis, not later than _____ days from the end of the quarter, a detailed report

analyzing the quantitative aspects of the program plan, as appropriate (e.g., number of meals served, clients transported, patient/client encounters, procedures performed, training sessions conducted, etc.)

C. Expenditure Report

_____ (Organization Name) _____ will submit, on a quarterly basis, not later than _____ days after the end date for which reimbursement is being claimed, a detailed expenditure report, by object of expense. This report will accompany the voucher submitted for such period.

D. Final Report

_____ (Organization Name) _____ will submit a final report, as required by the contract, reporting on all aspects of the program, detailing how the use of grant funds were utilized in achieving the goals set forth in the program Workplan.

APPENDIX D

PROGRAM WORKPLAN
(sample format)

A well written, concise workplan is required to ensure that the Department and the contractor are both clear about what the expectations under the contract are. When a contractor is selected through an RFP or receives continuing funding based on an application, the proposal submitted by the contractor may serve as the contract's work plan if the format is designed appropriately. The following are suggested elements of an RFP or application designed to ensure that the minimum necessary information is obtained. Program managers may require additional information if it is deemed necessary.

I. CORPORATE INFORMATION

Include the full corporate or business name of the organization as well as the address, federal employer identification number and the name and telephone number(s) of the person(s) responsible for the plan's development. An indication as to whether the contract is a not-for-profit or governmental organization should also be included. All not-for-profit organizations must include their New York State charity registration number; if the organization is exempt AN EXPLANATION OF THE EXEMPTION MUST BE ATTACHED.

II. SUMMARY STATEMENT

This section should include a narrative summary describing the project which will be funded by the contract. This overview should be concise and to the point. Further details can be included in the section which addresses specific deliverables.

III. PROGRAM GOALS

This section should include a listing, in an abbreviated format (i.e., bullets), of the goals to be accomplished under the contract. Project goals should be as quantifiable as possible, thereby providing a useful measure with which to judge the contractor's performance.

IV. SPECIFIC DELIVERABLES

A listing of specific services or work projects should be included. Deliverables should be broken down into discrete items which will be performed or delivered as a unit (i.e., a report, number of clients served, etc.) Whenever possible a specific date should be associated with each deliverable, thus making each expected completion date clear to both parties.

Language contained in Appendix C of the contract states that the contractor is not eligible for payment "unless proof of performance of required services or accomplishments is provided." The workplan as a whole should be structured around this concept to ensure that the Department does not pay for services that have not been rendered.

APPENDIX X

Agency Code _____

Contract No. _____
Period _____
Funding Amount for Period _____

This is an AGREEMENT between THE STATE OF NEW YORK, acting by and through _____, having its principal office at _____ (hereinafter referred to as the STATE), and _____ (hereinafter referred to as the CONTRACTOR), for modification of Contract Number as amended in attached Appendix(ices)_____.

All other provisions of said AGREEMENT shall remain in full force and effect

IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT as of the dates appearing under this signatures.

_____

CONTRACTOR SIGNATURE

By: _____

_____

Printed Name

Title: _____

Date: _____

_____

STATE OF NEW YORK)
) SS:
County of _____)

_____

STATE AGENCY SIGNATURE

By: _____

_____

Printed Name

Title: _____

Date: _____

State Agency Certification:
"In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."

_____

On the ____ day of _____ 20__, before me personally appeared _____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, that he/she is the _____ of the _____, the corporation described herein which executed the foregoing instrument; and that he/she signed his/her name thereto by order of the board of directors of said corporation.

(Notary) _____

ATTORNEY GENERAL'S SIGNATURE

_____

Title: _____

Date: _____

STATE COMPTROLLER'S SIGNATURE

_____

Title: _____

Date: _____