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**

27.	Is the vendor currently insolvent, or does vendor currently have reason to believe that an involuntary bankruptcy proceeding may be brought against it? ***Provide financial information to support the vendor's current position, for example, Current Ratio, Debt Ratio, Age of Accounts Payable, Cash Flow and any documents that will provide the agency with an understanding of the vendor's situation.***	☐ **Yes** ☐ **No**
28.	Has the vendor been a contractor or subcontractor on any contract with any New York State agency in the past five (5) years? ***List the agency name, address, and contract effective dates. Also provide state contract identification number, if known.***	☐ **Yes** ☐ **No**
29.	In the past five (5) years, has the vendor or any affiliates[1]: **a)** defaulted or been terminated on, or had its surety called upon to complete, any contract (public or private) awarded; **b)** received an overall unsatisfactory performance assessment from any government agency on any contract; or **c)** had any liens or claims over $25,000 filed against the firm which remain undischarged or were unsatisfied for more than 90 days ? ***Indicate if this is applicable to the submitting vendor or affiliate. Detail the situation(s) that gave rise to the negative action, any corrective action taken by the vendor and the name of the contracting agency.***	☐ **Yes** ☐ **No**

[1] "Affiliate" meaning: (a) any entity in which the vendor owns more than 50% of the voting stock; (b) any individual, entity or group of principal owners or officers who own more than 50% of the voting stock of the vendor; or (c) any entity whose voting stock is more than 50% owned by the same individual, entity or group described in clause (b). In addition, if a vendor owns less than 50% of the voting stock of another entity, but directs or has the right to direct such entity's daily operations, that entity will be an "affiliate" for purposes of this questionnaire.

State of:)
) ss:
County of:)

CERTIFICATION:

The undersigned: recognizes that this questionnaire is submitted for the express purpose of assisting the State of New York or its agencies or political subdivisions in making a determination regarding an award of contract or approval of a subcontract; acknowledges that the State or its agencies and political subdivisions may in its discretion, by means which it may choose, verify the truth and accuracy of all statements made herein; acknowledges that intentional submission of false or misleading information may constitute a felony under Penal Law Section 210.40 or a misdemeanor under Penal Law Section 210.35 or Section 210.45, and may also be punishable by a fine and/or imprisonment of up to five years under 18 USC Section 1001 and may result in contract termination; and states that the information submitted in this questionnaire and any attached pages is true, accurate and complete.

The undersigned certifies that he/she:

- has not altered the content of the questions in the questionnaire in any manner;
- has read and understands all of the items contained in the questionnaire and any pages attached by the submitting vendor;
- has supplied full and complete responses to each item therein to the best of his/her knowledge, information and belief;
- is knowledgeable about the submitting vendor's business and operations;
- understands that New York State will rely on the information supplied in this questionnaire when entering into a contract with the vendor; and
- is under duty to notify the procuring State Agency of any material changes to the vendor's responses herein prior to the State Comptroller's approval of the contract.

Name of Business Signature of Owner/Officer_____

Address Printed Name of Signatory

City, State, Zip Title

Sworn to before me this _____ day of _____, 20____;

_____
Notary Public

_____

Print Name

_____

Signature

_____

Date

19.2 Contract Policy Statement and Conditions

New York State Department of Health
Competitive Grants

Spinal Cord Injury Research Board

General Specifications

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

2. Contractor will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.

3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA. If this applicant does not accept a certain condition or term, this must be clearly noted in a cover letter to the application.

4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.

5. Provisions Upon Default

    a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.

    b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.

    c. If, in the judgement of the Department of Health, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive equitable compensation for such services as shall, in the judgement of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

Appendices (Included at the end of this package)

The following will be incorporated as appendices into any contract(s) resulting from this Request for Applications.

APPENDIX A - Standard Clauses for All New York State Contracts

APPENDIX A-1 Agency Specific Clauses

APPENDIX A-2 Program Specific Clauses

APPENDIX B - Budget

APPENDIX C - Payment and Reporting Schedule

APPENDIX D - Workplan

APPENDIX E - Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof, completed by the CONTRACTOR'S insurance carrier and/or the Workers' Compensation Board, of coverage for:

Workers' Compensation, for which one of the following is incorporated into this contract as **Appendix E-1**:

- **WC/DB-100**, Affidavit For New York Entities And Any Out-Of-State Entities With No Employees, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage Is Not Required; OR

  WC/DB -101, Affidavit That An OUT-OF STATE OR FOREIGN EMPLOYER Working In New York State Does Not Require Specific New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage; OR

- **C-105.2** -- Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the **U-26.3**; OR

- **SI-12** -- Certificate of Workers' Compensation Self-Insurance, OR **GSI-105.2** -- Certificate of Participation in Workers' Compensation Group Self-Insurance

Disability Benefits coverage, for which one of the following is incorporated into this contract as **Appendix E-2**:

- **WC/DB-100**, Affidavit For New York Entities And Any Out-Of-State Entities With No Employees, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage Is Not Required; OR

  WC/DB -101, Affidavit That An OUT-OF STATE OR FOREIGN EMPLOYER Working In New York State Does Not Require Specific

New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage; OR

- **DB-120.1** -- Certificate of Disability Benefits Insurance OR the **DB-820/829** Certificate/Cancellation of Insurance; OR

- **DB-155** -- Certificate of Disability Benefits Self-Insurance

NOTE: Do not include the Workers' Compensation and Disability Benefits forms with your application. These documents will be requested as a part of the contracting process should your agency receive an award.

20. Spinal Cord Injury Research Board Membership Roster

CHAIR
Moses V. Chao, Ph.D.
New York University Medical Center

Allen L. Carl, M.D.
Albany Medical College

Mary E. Hatten, Ph.D.
The Rockefeller University

Deborah A. Hrustich, M.D.
Albany-Troy Neurosurgical Associates, P.C.

Barbara S. Koppel, M.D.
Metropolitan Hospital Center

David Carmel
California Research and Cures Coalition

Gerard Kelly
United Spinal Association

Lorne Mendell, Ph.D.,
State University of New York, Stony Brook

Paul Richter
Spinal Cord Society

David S. Whalen, Esq.
Spinal Cord Society

Jonathan R. Wolpaw, M.D.
Department of Health

Robert Trotta, Esq.
Davis and Trotta, Attorneys at Law

21. 2002 Research Grant Competition Award Recipients

CART
(Collaborations to Accelerate Research Translation)

Marie Filbin, Ph.D., Hunter College of CUNY
Barbara Bregman, Ph.D., Georgetown University School of Medicine
Overcoming Myelin Inhibitors to Promote Regeneration in Vivo

George Forrest, M.D., Albany Medical College
Ronald Triolo, Ph.D., Case Western Reserve University
Functional Electric Stimulation

Thomas Jessel, Ph.D., Columbia University
Robert Brown Jr., M.D., Massachusetts General Hospital
Analysis Of ES Cell Derived Motor Neurons

Zaven Kaprielian, Ph.D., Albert Einstein College of Medicine
Jane Johnson, Ph.D., University of Texas, Southwestern Medical Center
Regulating Axon Guidance in the Vertebrate Spinal Cord

Maiken Nedergaard, M.D., Ph.D., New York Medical College
Armed Rawanduzy, M.D., New York Medical College
Purinergic Signaling In Spinal Cord Injury

IDEA
(Innovative, Developmental or Exploratory Activities)

Anthony Caggiano, M.D., Ph.D.
Acorda Therapeutics, Inc.
Effect of Chondroitinase Treatment on Spinal Cord Injury

Blair Calancie, Ph.D.
State University of New York, Upstate Medical University
Origin of Autonomic Dysreflexia after SCI in Humans

Steven Goldman, M.D., Ph.D.
University of Rochester School of Medicine
Use of Telomerase-Immortalized Progenitor Cells for Repair

Giacinto Grieco, M.D.
New York University School of Medicine
Validity and Reliability of Spinal Cord Injury Assessments

Barbara Hempstead, M.D., Ph.D., Weill Medical College of Cornell University
Sung Ok Yoon, Ph.D., Ohio State University
Proneurotrophin Actions in Acute Spinal Cord Injury

Edward Laufer, Ph.D.
Columbia University
Control of Limb Motor Neuron Dorsoventral Projections

Amy MacDermott, Ph.D.
Columbia University
Synaptic Plasticity in the Dorsal Horn Pain Pathway

James Salzer, M.D., Ph.D., New York University School of Medicine
Dean Hillman, Ph.D., New York University School of Medicine
Role of Neurotrimin in Spinal Cord Motor Pathways

Neil Shneider, M.D., Ph.D., Columbia University
Thomas Jessell, Ph.D., Columbia University
Molecular Mechanisms of Spinal Reflex Circuit Development

Styliana-Anna Tsirka, Ph.D., State University of New York at Stony Brook
Joel Levine, Ph.D., State University of New York at Stony Brook
Glycosaminoglycan Degradation, Proteolysis and Axon Regeneration

22. 2001 Collaborative Grant Competition Award Recipients

Sally Temple, Ph.D., *Albany Medical College*
Jerry Silver, Ph.D., *Case Western Reserve University*
Regulating the Neuron/Glial Choice of Neural Stem Cells

David Colman, Ph.D., *Mount Sinai School of Medicine*
Ben Barres, M.D., Ph.D., *Stanford University*
Overcoming Reactive Glial Inhibition of Spinal Cord Regeneration

Francesco Ramirez, Ph.D., *Mount Sinai School of Medicine*
Luis Parada, Ph.D., *University of Texas Southwestern Medical Center (Dallas)*
Genetic Analysis of a Candidate Neuronal Regulator

Gordon Fishell, Ph.D., *New York University School of Medicine*
Notch Signaling in the Promotion of Radial Glial

Mitchell Chesler, M.D., Ph.D., *New York University School of Medicine*
Mechanisms of Early Glial Cell Death in Spinal Cord Injury

Dimitar Nikolov, Ph.D., *Sloan-Kettering Institute for Cancer Research*
Structural Study of Axon Guidance in the Spinal Cord

Joel Levine, Ph.D., *State University of New York at Stony Brook*
J.H. Pate Skene, Ph.D., *Duke University*
Overcoming Inhibitory Barriers to Nerve Regeneration

Roman Giger, Ph.D., *University of Rochester School of Medicine*
Christoph Rader, Ph.D, *The Scripps Research Institute*
Promoting Neuronal Repair: Attacking Myelin by Phage Display

Shey-Shing Sheu, Ph.D., *University of Rochester School of Medicine*
Mitochondrial Glutathione: Protection Against Spinal Cord Injury

23. 2000 Pilot Research Grant Competition Award Recipients

Zaven Kaprielian, *Albert Einstein College of Medicine*
Axon Guidance in the Spinal Cord: A Transgenic Approach

Marie Filbin, *Hunter College*
Role of cAMP in Regeneration after a Conditioning Lesion

David Colman, *Mount Sinai School of Medicine*
Adhesion Molecules of Spinal Cord Synaptic Junctions

Maiken Nedergaard, *New York Medical College*
Spreading Depression in Spinal Cord Injury

John Martin, *Columbia University*
Peripheral and Central Plasticity after Nerve Transfer

Victor Arvanian, *State University of New York at Stony Brook*
Neurotrophins and Function of the Injured Spinal Cord

Joseph Fetcho, *State University of New York at Stony Brook*
Regeneration in a Transparent Vertebrate

Dennis Stelzner, *State University of New York, Upstate Medical University*
Olfactory Ensheathing Cells and Spinal Cord Regeneration

Mark Noble, *University of Rochester School of Medicine*
Regulated Enhancement of CNS Cell Replacement Therapies

Jay Yang, *University of Rochester School of Medicine*
Neuronal Calcium/Calmodulin and Neuropathic Pain

APPLICATION FORMS 1 - 17

NYS SPINAL CORD RESEARCH PROGRAM PI (s): _____

Face Page Last name(s), First Initial

PROJECT TITLE (Do not exceed 60 characters and spaces)			APPLICATION HISTORY
			NEW Θ REVISED Θ
		Funding Mechanism:	CART Θ IDEA Θ
Research Area:			

PRINCIPAL INVESTIGATOR #1 *Last Name, First Name, Middle Initial; Degree(s)*	CO-PRINCIPAL INVESTIGATOR #2 *Last Name, First Name, Middle Initial; Degree(s)*
Institution	Institution
Department	Department
MAILING ADDRESS (Street, MS, PO Box, City, State, Zip)	MAILING ADDRESS (Street, MS, PO Box, City, State, Zip)
Phone / Fax	Phone / Fax
E-mail	E-mail

Part of Budget Θ	Part of Budget Θ Subcontract * Θ
HUMAN SUBJECTS YES Θ NO Θ	VERTEBRATE ANIMALS YES Θ NO Θ
PROJECT DURATION / YR ONE DIRECT COSTS / TOTAL DIRECT COSTS	

NEW YORK STATE APPLICANT ORGANIZATION	RESEARCH PERFORMING SITES
MAILING ADDRESS (Street, MS, PO Box, City, State, Zip)	

CONTRACTS AND GRANTS OFFICIAL	OFFICIAL SIGNING FOR ORGANIZATION
MAILING ADDRESS (Street, PO Box, MS, City, State, Zip)	MAILING ADDRESS (Title and Organization, Street, MS, PO Box, City, State, Zip)
Phone / Fax	Phone / Fax
E-mail	E-mail

PRINCIPAL, CO-INVESTIGATOR'S CERTIFICATION AND ASSURANCE: I certify that the statements herein are true and complete to the best of my knowledge. I agree to accept responsibility for the scientific conduct and integrity of the research, and as the PI, to provide the required progress reports if a contract is awarded as a result of this application.

SIGNATURES OF PRINCIPAL/CO-INVESTIGATORS ("Per" not allowed)

#1 X DATE:

#2 X DATE:

CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and I accept the obligation to comply with the New York State Spinal Cord Injury Research Board terms and conditions if a contract is awarded as a result of this application.

SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION ("Per" not allowed)

X DATE:

Form 1 - 2005 Competition **Not to exceed one page.** PAGE ____

***** If yes, insert signed copies for subcontracting organizations behind the applicant organization face page.

Table of Contents Last name(s), First Initial

This form is required and may be used as a checklist.

[I] Insert "N/A" if not applicable.

A complete application package consists of:
1) Two (2) original signed copies of the application face page (Form 1);
2) 1 CD-ROM containing a single Portable Document Format (PDF) file containing the entire application;
3) A self-addressed US postcard labeled "SCI CART" or "SCI IDEA" Application; and
4) Six paper copies of the entire application.

Scientific Abstract Last name(s), First Initial

Present the information requested. Use available space to your best advantage; comply with font guidelines (e.g. Arial 11 or Times Roman 12).

Background:

Hypothesis:

Objectives/Aims:

Methods:

Impact on Treatments or Cures for Spinal Cord Injury Paralysis:

Present the information requested below in non-technical terms. Failure to do so could adversely affect the application's Programmatic Review. Use available space to your best advantage; comply with font guidelines (e.g. Arial 11 or Times Roman 12).

Introduction/Background to the research topic:

The question(s) or central hypothesis of the research:

The general methodology to be used:

Innovative elements of the project:

Impact on Treatments or Cures for Spinal Cord Injury Paralysis: (Do not overstate this section.)

For all applications:
Describe future plans to bring anticipated research results to the next developmental stage. Include a discussion of the evolution of models to be used in such future investigations (i. e., cell culture, invertebrate models, vertebrate models, non-human primates or humans). Recognizing the uncertainty of forward-looking projections, provide a realistic estimate of the time until human clinical research. Articulate a five-year plan of research that delineates specific goals and objectives with outcomes aimed at discovering new knowledge that directly affects the clinical practice with spinal cord injured persons. Discuss how the clinical interface with research findings will result in the improved treatment of individuals with spinal cord injury.

For CART applications:
Describe how your collaborative effort will grow spinal cord injury research in New York State and how the distribution of effort and funds is in the best interests of the program and the State. Include a discussion of how the synergy created by your partnership and the disciplines represented will accelerate the pace that basic or pre-clinical research is translated to clinical usefulness.

For IDEA applications:
Discuss how your application's expected results will advance spinal cord injury research by dispelling scientific myths, filling essential gaps in knowledge, testing high-risk hypotheses/ideas or developing the foundation for new techniques or therapies. If your IDEA application includes collaboration, also describe the opportunities created through this partnership and how it is in the best interest of the program and State.

	BUDGET CATEGORY	Year One	Year Two	Year Three	Year Four	TOTAL (all years)
PERSONAL SERVICE (PS)						
1	SALARY AND STIPENDS					
2	FRINGE BENEFITS					
3	**SUBTOTAL PS**					
OTHER THAN PERSONAL SERVICE (OTPS)						
4	SUPPLIES					
5	EQUIPMENT					
6	TRAVEL					
7	CONSULTANT COSTS					
8	OTHER EXPENSES					
9	**SUBTOTAL OTPS**					
10	TOTAL PS & OTPS					
11	TOTAL SUBCONTRACT PS & OTPS * **(record detail separately)**					
12	TOTAL DIRECT COSTS (sum of lines 10 + 11)					

13	UNRECOVERED COSTS Required if line 5 > $25,000					

*** Applicant organization budget page is to be followed by detailed subcontractor budget page(s) on additional copies of Form 6A.**

NYS SPINAL CORD RESEARCH PROGRAM PI (s): _____

Budget - IDEA Last name(s), First Initial , Institution

	BUDGET CATEGORY	Year One	Year Two	TOTAL (all years)
PERSONAL SERVICE (PS)				
1	SALARY AND STIPENDS			
2	FRINGE BENEFITS			
3	**SUBTOTAL PS**			
OTHER THAN PERSONAL SERVICE (OTPS)				
4	SUPPLIES			
5	EQUIPMENT			
6	TRAVEL			
7	CONSULTANT COSTS			
8	OTHER EXPENSES			
9	**SUBTOTAL OTPS**			
10	TOTAL PS & OTPS			
11	TOTAL SUBCONTRACT PS & OTPS * **(record detail separately)**			
12	TOTAL DIRECT COSTS **(sum of lines 10 + 11)**			

13	UNRECOVERED COSTS Required if line 5 > $25,000			

Form 6B – 2005 Competition PAGE ____

*** Applicant organization budget page is to be followed by detailed subcontractor budget page(s) on additional copies of Form 6B.**

Key Personnel *		Percent FTE			Dollar Amount Requested (Year One)		
Name	**Role in Project**	**Appt.**	**On project**	**For Salary Requested**	**Salary**	**Fringe**	**Total**
Support Personnel *		**Percent FTE**			**Dollar Amount Requested (Year One)**		
Total Salary + Fringe Requested – should equal Year One, line 3, Form 6							

*** Insert additional lines as necessary under Key Personnel or Support Personnel.**

Describe the items that will be included in *Other than Personal Service* Costs.

Biographical Sketch Last name(s), First Initial

NAME	POSITION/TITLE

EDUCATION/TRAINING (Begin with baccalaureate or other professional education, and include postdoctoral training).

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Beginning with present position, list in chronological order, previous employment experience, and professional activities and honors. Include any present membership on a federal, state, or local public advisory committee. List in chronological order, the titles, and all authors of, as well as complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications for the last three years exceeds two pages, select the most pertinent publications. The five publications most pertinent to the proposed project are to be marked with an asterisk (*). **Do not exceed two pages.**

EXPERIENCE

PROFESSIONAL ACTIVITIES AND HONORS

SELECT PUBLICATIONS

Not to exceed two pages per individual. Present the principal investigator first, followed by co-PI(s) and then remaining key personnel in alphabetical order. The NIH Biosketch Form may be substituted for Form 8, but SCIRB instructions must be followed.

FACILITIES: Specify the facilities to be used to conduct the proposed research. Indicate the performance site(s) and describe pertinent site capabilities, relative proximity and extent of availability to the project. Under "Other", identify support services such as machine shop and electronics shop, and specify the extent to which such services will be available to the project. Use one additional continuation page, if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

NYS SPINAL CORD RESEARCH PROGRAM PI (s): _____

Other Support Last name(s), First Initial

This form must be used.

Name of Key Personnel: _____

Non-research Activities:

Check if there is no non-research other support for the individual listed: ☐

Item #1 _____

NATURE OF ACTIVITY:

SOURCE OF SUPPORT:

PERIOD OF ACTIVITY (OR PENDING START DATE):

PERCENT FTE DEVOTED TO THIS ACTIVITY:

OVERLAP WITH APPLICATION:

PROPOSED RESOLUTION, IF ANY:

Copy this form and repeat as often as necessary.

Research Activities:

Check if there is no research other support for the individual listed: ☐

Item # _____

TITLE OF PROJECT: ☐ Pending ☐ Active

PROJECT PI:

FUNDING AGENCY/GRANT ID NO.:

PERIOD OF SUPPORT: % FTE _____

THIS PROJECT INVOLVES SPINAL CORD INJURY-RELATED RESEARCH: ☐ *Yes ☐ No

THIS PROJECT OVERLAPS A RESEARCH AIM IN THIS APPLICATION: ☐ *Yes ☐ No

Copy this format and repeat as often as necessary.

Add additional pages as needed. Present the principal investigator first, followed by co-PI(s) and then remaining key personnel in alphabetical order. For any "Yes" answer, explain the distinction between the project and this application, directly below the item. Indicate a possible resolution, if this application is funded.

A. Specific Aims.
B. Significance.
C. Background and Preliminary Results.
D. Research Design and Methods.
E. Literature Cited.

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. ADDITIONAL PAGES WILL NOT BE READ.

Time Line and Collaboration Strategy Last name(s), First Initial

This form must be used.

Aim	Investigator Responsible Name of Institution	Activities	Time Frame

If this 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.

Use an additional sheet if necessary.

This form is required only for applications that checked "**Yes**" for human subjects on the face page.

☐ Ethnically/Racially diverse populations **included**.

☐ Ethnically/Racially diverse populations **excluded**.

Complete separate tables for **ALL** human subjects protocols to be used with the grant application if funded. Present information from the applicant organization first, followed by subcontracting or consortium organizations. It is the responsibility of the applicant organization to assure that all performance sites comply with the regulations in 45 CFR Part 46 and all other statutes, regulations or policies pertaining to human subject participants and tissues.

Institution: _____

Institutional OHRP Assurance of Compliance Number: _____

IRB Approval Status: ☐ Approved ☐ Pending ☐ Exemption # _____

Protocol Number: _____ **Principal Investigator:** _____

Project Title: _____

_____

Approval Date: _____ **Are you listed as an approved investigator on this protocol:** ☐ Yes ☐ No

Does your institution require annual (or more frequent) reviews of this protocol: ☐ Yes ☐ No

If "Yes", when is the next review: _____

Repeat table as often as necessary.

Address the eight points listed below. See the application guidelines in Section 12.13. Note the information requested differs slightly from NIH current 398 instructions. Applications "Exempt" from regulations are to respond to these points in sufficient detail to justify exemption to merit reviewers. Insert your response after each point.

1. Involvement of Human Subjects and Population Characteristics
2. Sources of Materials – Confidentiality
3. Risks
4. Recruitment and Consent
5. Protection from Risk
6. Potential Benefits of the Proposed Research to the subjects and others
7. Importance of Knowledge to be Gained
8. Training

This form is required only for applications that checked "**Yes**" for vertebrate animals on the face page.

Complete separate tables for **ALL** vertebrate animal protocols to be used with the grant application if funded. Present information from the applicant organization first, followed by subcontracting or consortium organizations.

Institution: _____

Institutional Animal Care & Use Number: _____

NYS DOH Animal Care & Use Certificate Number: _____

USDA Registration Number (if applicable to species): _____

Vertebrate Animal Approval Status ☐ Approved ☐ Pending

Protocol Number: _____ **Principal Investigator:** _____

Project Title: _____

_____

Approval Date: _____ **Are <u>you</u> listed as an approved investigator on this protocol:** ☐ Yes ☐ No

Does your institution require annual (or more frequent) reviews of this protocol: ☐ Yes ☐ No

If "<u>Yes</u>", when is the next review: _____

Repeat table as often as necessary.

All applications proposing vertebrate animal research are required to address the five points below. 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.

1. Provide a detailed description of the animal use proposed in the research work plan, including identification of the species, strains, ages, sex, and number 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.

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 the recommendations.

This form is required for the New York State applicant organization.

Legal Name			
Date of Incorporation			
Type of Organization	Public ☐ Federal ☐ State ☐ Local Private Nonprofit ☐ For profit ☐ General ☐ Small Business ☐ WMO		
Federal Tax ID Number (nine-digits)			
DUNS number			
Charities Registration Number (or "Exempt")			
Legislative District Numbers	Senate	Assembly	
Name of External Auditor			
Date of Audit			
Address to which reimbursement is sent, if contract is awarded.	Street, MS, PO Box, City, New York, Zip		

Assurances and Certifications

The following assurances and certification have been verified by signature of the Official Signing for the Applicant Organization on the Face Page of the application. Definitions are provided in Section 12.15 of the guidelines.

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

Facilities and Administration Costs

The United States Department of Health and Human Services (DHHS) has been designated as the cognizant agency responsible for negotiating indirect, fringe benefit (and other specialty) rates and issuing related Rate Agreements for a significant number of organizations receiving Federal awards.

DHHS Agreement Date: _____
DHHS Agreement being negotiated: _____
No DHHS Agreement, but rate established by (explain and DATE): _____

A copy of the Agreement will be requested prior to contract execution.

F&A rate applied to (Check appropriate box);

~ Salary and wages base
~ Modified total direct costs base
~ Other base *(explain)*
~ Off-site, other special rate, or more than one rate involved.

This form is required for all applications with appendices.

Check the boxes for items enclosed: Describe and list, as needed.

☐ Informed consent document(s) for human subjects research must be provided even if not yet approved. *Present NYS applicant followed by other organizations*.

☐ Human Subjects assurance(s) (*must include PI name, project title, approval date and period*).

☐ Vertebrate Animal assurance(s) (*must include PI name, project title, approval date and period*).

☐ Letters of Collaboration, commitment(s) to provide research resources, subcontract letter(s) from consultant(s); subcontractual or consortium agreement letters.

☐ Publications – no more than two may be included. *Do not include manuscripts submitted but not yet accepted for publication*.

☐ Other materials

The project entitled,_____, has been reviewed and

approved by the Institutional Review Board (IRB) of _____.

The review process, protocol and informed consent documents(s) have been determined to be in compliance with New York State Public Health Law (PHL) Article 24-A, 45 CFR Part 46, unless exempt from the provisions of that Part; and, if applicable, 21 CFR Parts 50,56, 312, 361 and 812.

In addition, the IRB has determined that:

- informed consent will be obtained from all study participants, or their legally authorized representatives, unless the study is exempt from the requirements of 45 CFR Part 46 and is not human research as defined by PHL Section 2441 (2);

- if applicable, the IRB has received and reviewed written approval from an authorized representative of each site where the study will take place;

- the risks of the research study, including pain or discomfort, have been minimized consistent with sound research design, and proposed research procedures do not unnecessarily expose research participants to risk or discomfort;

- any use of race, ethnicity or gender as a research study inclusion or exclusion criterion, other than use of such criterion to reflect the racial, ethnic or gender composition of the general population of New York State or the United States, is necessary to accomplish the research goals:

- the investigator will immediately withdraw a subject from the research study if continued participation would be detrimental to a subject's well-being; and

- the IRB will communicate to Spinal Cord Injury Research Program (SCIRB) program administrators at the Department of Health; (i) any unanticipated problems at any site(s) involving risks to subjects; or (ii) any serious or continuing noncompliance with the IRB's policy or requirements; or (iii) any suspension or termination of IRB approval;

In addition to the above, for research involving participants who are minors, mentally disabled adults who lack capacity to provide informed consent to research participation, or prisoners, the IRB has also determined that:

- the research study constitutes either: (i) research with a prospect of direct benefit to participants; or (ii) research with no prospect of direct benefit to participants, but which presents minimal risk;

- all research participants have suffered spinal cord injuries;

- the research study, involving one or more mentally disabled adults, uses IRB approved methodologies and procedures for initial capacity assessment, including: (i) notice to a prospective subject that his/her capacity to consent to research is under consideration; (ii) notice to a prospective subject of a determination that he/she lacks the capacity to consent to research; and (iii) the opportunity for a prospective subject to contest such a determination of incapacity prior to enrollment in the research through a second opinion and a judicial proceeding;[1] and

- prior to involving in a research study a minor, a mentally disabled adult who lacks the capacity to provide informed consent to research participation, or a prisoner, the investigator will obtain such individual's assent to research participation[2].

_____
Signature

_____
Typed Name

_____
Title

[1] With respect to unconscious prospective subjects, notice of a determination of incapacity and the opportunity to contest that determination must be given to the prospective subject's next-of-kin or legally authorized representative. While unconscious, the prospective subject need not be given such notice and opportunity to contest an incapacity determination. However, upon regaining consciousness, the individual must promptly be provided with notice of the determination of incapacity as well as the opportunity to contest such a determination through a second opinion and a judicial proceeding. This requirement applies whether the individual remains a prospective subject or has been enrolled in the research study when he or she regains consciousness.

[2] A minor's objection need not be honored if an independent physician determines that the research intervention or procedure holds out a prospect of direct benefit that is important to the health or well-being of the minor, and is available only within the context of the research project.

APPENDICES

Table of Contents

NOTE: State Contract forms are included for informational purposes, only. DO NOT COMPLETE THEM AT THIS TIME.

GRANT CONTRACT

STATE AGENCY (Name and Address):

_____

CONTRACTOR (Name and Address):

_____

FEDERAL TAX IDENTIFICATION NUMBER:

MUNICIPALITY NO. (if applicable):

CHARITIES REGISTRATION NUMBER:
__ __ - __ __ - __ __ or ( ) EXEMPT:
(If EXEMPT, indicate basis for exemption):

_____

CONTRACTOR HAS( ) HAS NOT( ) TIMELY FILED WITH THE ATTORNEY GENERAL'S CHARITIES BUREAU ALL REQUIRED PERIODIC OR ANNUAL WRITTEN REPORTS.

_____

CONTRACTOR IS( ) IS NOT( ) A SECTARIAN ENTITY

CONTRACTOR IS( ) IS NOT( ) A NOT-FOR-PROFIT ORGANIZATION

NYS COMPTROLLER'S NUMBER: _____

ORIGINATING AGENCY CODE:

_____

TYPE OF PROGRAM(S)

_____

INITIAL CONTRACT PERIOD

FROM:

TO:

FUNDING AMOUNT FOR INITIAL PERIOD:

_____

MULTI-YEAR TERM (if applicable):

FROM:

TO:

APPENDICES ATTACHED AND PART OF THIS AGREEMENT

_____	APPENDIX A	Standard clauses as required by the Attorney General for all State contracts.
_____	APPENDIX A-1	Agency-Specific Clauses (Rev 02/03)
_____	APPENDIX B	Budget
_____	APPENDIX C	Payment and Reporting Schedule
_____	APPENDIX D	Program Workplan
_____	APPENDIX X	Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)

OTHER APPENDICES

_____	APPENDIX A-2	Program-Specific Clauses
_____	APPENDIX E-1	Proof of Workers' Compensation Coverage
_____	APPENDIX E-2	Proof of Disability Insurance Coverage
_____	APPENDIX H	Federal Health Insurance Portability and Accountability Act Business Associate Agreement
_____	APPENDIX ___	_____
_____	APPENDIX ___	_____
_____	APPENDIX ___	_____

IN WITNESS THEREOF, the parties hereto have executed or approved this AGREEMENT on the dates below their signatures.

_____	.	_____
	.	Contract No. _____
_____	.	_____
CONTRACTOR	.	STATE AGENCY
_____	.	_____
By: _____	.	By: _____
(Print Name)		(Print Name)
_____	.	_____
Title: _____	.	Title: _____
Date: _____	.	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."
_____	.	_____

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

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	.	STATE COMPTROLLER'S SIGNATURE
_____	.	_____
Title: _____	.	Title: _____
Date: _____	.	Date: _____

STATE OF NEW YORK

AGREEMENT

This AGREEMENT is hereby made by and between the State of New York agency (STATE) and the public or private agency (CONTRACTOR) identified on the face page hereof.

WITNESSETH:

WHEREAS, the STATE has the authority to regulate and provide funding for the establishment and operation of program services and desires to contract with skilled parties possessing the necessary resources to provide such services; and

WHEREAS, the CONTRACTOR is ready, willing and able to provide such program services and possesses or can make available all necessary qualified personnel, licenses, facilities and expertise to perform or have performed the services required pursuant to the terms of this AGREEMENT;

NOW THEREFORE, in consideration of the promises, responsibilities and convenants herein, the STATE and the CONTRACTOR agree as follows:

I. Conditions of Agreement

A. This AGREEMENT may consist of successive periods (PERIOD), as specified within the AGREEMENT or within a subsequent Modification Agreement(s) (Appendix X). Each additional or superseding PERIOD shall be on the forms specified by the particular State agency, and shall be incorporated into this AGREEMENT.

B. Funding for the first PERIOD shall not exceed the funding amount specified on the face page hereof. Funding for each subsequent PERIOD, if any, shall not exceed the amount specified in the appropriate appendix for that PERIOD.

C. This AGREEMENT incorporates the face pages attached and all of the marked appendices identified on the face page hereof.

D. For each succeeding PERIOD of this AGREEMENT, the parties shall prepare new appendices, to the extent that any require modification, and a Modification Agreement (the attached Appendix X is the blank form to be used). Any terms of this AGREEMENT not modified shall remain in effect for each PERIOD of the AGREEMENT.

To modify the AGREEMENT within an existing PERIOD, the parties shall revise or complete the appropriate appendix form(s). Any change in the amount of consideration to be paid, or change in the term, is subject to the approval of the Office of the State Comptroller. Any other modifications shall be processed in accordance with agency guidelines as stated in Appendix A-1.

E. The CONTRACTOR shall perform all services to the satisfaction of the STATE. The CONTRACTOR shall provide services and meet the program objectives summarized in the Program Workplan (Appendix D) in accordance with: provisions of the AGREEMENT; relevant laws, rules and regulations, administrative and fiscal

guidelines; and where applicable, operating certificates for facilities or licenses for an activity or program.

F. If the CONTRACTOR enters into subcontracts for the performance of work pursuant to this AGREEMENT, the CONTRACTOR shall take full responsibility for the acts and omissions of its subcontractors. Nothing in the subcontract shall impair the rights of the STATE under this AGREEMENT. No contractual relationship shall be deemed to exist between the subcontractor and the STATE.

G. Appendix A (Standard Clauses as required by the Attorney General for all State contracts) takes precedence over all other parts of the AGREEMENT.

II. Payment and Reporting

A. The CONTRACTOR, to be eligible for payment, shall submit to the STATE's designated payment office (identified in Appendix C) any appropriate documentation as required by the Payment and Reporting Schedule (Appendix C) and by agency fiscal guidelines, in a manner acceptable to the STATE.

B. The STATE shall make payments and any reconciliations in accordance with the Payment and Reporting Schedule (Appendix C). The STATE shall pay the CONTRACTOR, in consideration of contract services for a given PERIOD, a sum not to exceed the amount noted on the face page hereof or in the respective Appendix designating the payment amount for that given PERIOD. This sum shall not duplicate reimbursement from other sources for CONTRACTOR costs and services provided pursuant to this AGREEMENT.

C. The CONTRACTOR shall meet the audit requirements specified by the STATE.

III. Terminations

A. This AGREEMENT may be terminated at any time upon mutual written consent of the STATE and the CONTRACTOR.

B. The STATE may terminate the AGREEMENT immediately, upon written notice of termination to the CONTRACTOR, if the CONTRACTOR fails to comply with the terms and conditions of this AGREEMENT and/or with any laws, rules and regulations, policies or procedures affecting this AGREEMENT.

C. The STATE may also terminate this AGREEMENT for any reason in accordance with provisions set forth in Appendix A-1.

D. Written notice of termination, where required, shall be sent by personal messenger service or by certified mail, return receipt requested. The termination shall be effective in accordance with the terms of the notice.

E. Upon receipt of notice of termination, the CONTRACTOR agrees to cancel, prior to the effective date of any prospective termination, as many outstanding obligations as possible, and agrees not to incur any new obligations after receipt of the notice without approval by the STATE.

F. The STATE shall be responsible for payment on claims pursuant to services provided and costs incurred pursuant to terms of the AGREEMENT. In no event shall the STATE be liable for expenses and obligations arising from the program(s) in this AGREEMENT after the termination date.

IV. Indemnification

A. The CONTRACTOR shall be solely responsible and answerable in damages for any and all accidents and/or injuries to persons (including death) or property arising out of or related to the services to be rendered by the CONTRACTOR or its subcontractors pursuant to this AGREMENT. The CONTRACTOR shall indemnify and hold harmless the STATE and its officers and employees from claims, suits, actions, damages and costs of every nature arising out of the provision of services pursuant to this AGREEMENT.

B. The CONTRACTOR is an independent contractor and may neither hold itself out nor claim to be an officer, employee or subdivision of the STATE nor make any claims, demand or application to or for any right based upon any different status.

V. Property

Any equipment, furniture, supplies or other property purchased pursuant to this AGREEMENT is deemed to be the property of the STATE except as may otherwise be governed by Federal or State laws, rules and regulations, or as stated in Appendix A-1.

VI. Safeguards for Services and Confidentiality

A. Services performed pursuant to this AGREEMENT are secular in nature and shall be performed in a manner that does not discriminate on the basis of religious belief, or promote or discourage adherence to religion in general or particular religious beliefs.

B. Funds provided pursuant to this AGREEMENT shall not be used for any partisan political activity, or for activities that may influence legislation or the election or defeat of any candidate for public office.

C. Information relating to individuals who may receive services pursuant to this AGREEMENT shall be maintained and used only for the purposes intended under the contract and in conformity with applicable provisions of laws and regulations, or specified in Appendix A-1.

APPENDIX A
STANDARD CLAUSES FOR NYS CONTRACTS

The parties to the attached contract, license, lease, amendment or other agreement of any kind (hereinafter, "the contract" or "this contract") agree to be bound by the following clauses which are hereby made a part of the contract (the word "Contractor" herein refers to any party other than the State, whether a contractor, licenser, licensee, lessor, lessee or any other party):

1. EXECUTORY CLAUSE. In accordance with Section 41 of the State Finance Law, the State shall have no liability under this contract to the Contractor or to anyone else beyond funds appropriated and available for this contract.

2. NON-ASSIGNMENT CLAUSE. In accordance with Section 138 of the State Finance Law, this contract may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet or otherwise disposed of without the previous consent, in writing, of the State and any attempts to assign the contract without the State's written consent are null and void. The Contractor may, however, assign its right to receive payment without the State's prior written consent unless this contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

3. COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds $15,000 (or the minimum thresholds agreed to by the Office of the State Comptroller for certain S.U.N.Y. and C.U.N.Y. contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount, or if, by this contract, the State agrees to give something other than money when the value or reasonably estimated value of such consideration exceeds $10,000, it shall not be valid, effective or binding upon the State until it has been approved by the State Comptroller and filed in his office. Comptroller's approval of contracts let by the Office of General Services is required when such contracts exceed $30,000 (State Finance Law Section 163.6.a).

4. WORKERS' COMPENSATION BENEFITS. In accordance with Section 142 of the State Finance Law, this contract shall be void and of no force and effect unless the Contractor shall provide and maintain coverage during the life of this contract for the benefit of such employees as are required to be covered by the provisions of the Workers' Compensation Law.

5. NON-DISCRIMINATION REQUIREMENTS. To the extent required by Article 15 of the Executive Law (also known as the Human Rights Law) and all other State and Federal statutory and constitutional non-discrimination provisions, the Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, sex, national origin, sexual orientation, age, disability, genetic predisposition or carrier status, or marital status. Furthermore, in accordance with Section 220-e of the Labor Law, if this is a contract for the construction, alteration or repair of any public building or public work or for the manufacture, sale or distribution of materials, equipment or supplies, and to the extent that this contract shall be performed within the State of New York, Contractor agrees that neither it not its subcontractors shall, by reason of race, creed, color, disability, sex, or national origin: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. If this is a building service contract as defined in Section 230 of the Labor Law, then, in accordance with Section 239 thereof, Contractor agrees that neither it nor its subcontractors shall by reason of race, creed, color, national origin, age, sex or disability: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. Contractor is subject to fines of $50.00 per person per day for any violation of Section 220-e or Section 239 as well as possible termination of this contract and forfeiture of all moneys due hereunder for a second or subsequent violation.

6. WAGE AND HOURS PROVISIONS. If this is a public work contract covered by Article 8 of the Labor Law or a building service contract covered by Article 9 thereof, neither Contractor's employees nor the employees of its subcontractors may be required or permitted to work more than the number of hours or days stated in said statutes, except as otherwise provided in the Labor Law and as set forth in prevailing wage and supplement schedules issued by the State Labor Department. Furthermore, Contractor and its subcontractors must pay at least the prevailing wage rate and pay or provide the prevailing supplements, including the premium rates for overtime pay, as determined by the State Labor Department in accordance with the Labor Law.

7. NON-COLLUSIVE BIDDING CERTIFICATION. In accordance with Section 139-d of the State Finance Law, if this contract was awarded based upon the submission of bids, Contractor warrants, under penalty of perjury, that its bid was arrived at independently and without collusion aimed at restricting competition. Contractor further warrants that, at the time Contractor submitted its bid, an authorized and responsible person executed and delivered to the State a non-collusive bidding certification on Contractor's behalf.

8. INTERNATIONAL BOYCOTT PROHIBITION. In accordance with Section 220-f of the Labor Law and Section 139-h of the State Finance Law, if this contract exceeds $5,000, the Contractor agrees, as a material condition of the contract, that neither the Contractor nor any substantially owned or affiliated person, firm, partnership or corporation has participated, is participating, or shall participate in an international boycott in violation of the federal Export Administration Act of 1979 (50 USC App. Sections 2401 et seq.) or regulations thereunder. If such Contractor, or any of the aforesaid affiliates of Contractor, is convicted or is otherwise found to have violated said laws or regulations upon the final determination of the United States Commerce Department or any other appropriate agency of the United States subsequent to the contract's execution, such contract, amendment or modification thereto shall be rendered forfeit and void. The Contractor shall so notify the State Comptroller within five (5) business days of such conviction, determination or disposition of appeal (2NYCRR 105.4).

9. SET-OFF RIGHTS. The State shall have all of its common law, equitable and statutory rights of set-off. These rights shall include, but not be limited to, the State's option to withhold for the purposes of set-off any moneys due to the Contractor under this contract up to any amounts due and owing to the State with regard to this contract, any other contract with any State department or agency, including any contract for a term commencing prior to the term of this contract, plus any amounts due and owing to the State for any other reason including, without limitation, tax delinquencies, fee delinquencies or monetary penalties relative thereto. The State shall exercise its set-off rights in accordance with normal State practices including, in cases of set-off pursuant to an audit, the finalization of such audit by the State agency, its representatives, or the State Comptroller.

10. RECORDS. The Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance under this contract (hereinafter, collectively, "the Records"). The Records must be kept for the balance of the calendar year in which they were made and for six (6) additional years thereafter. The State Comptroller, the Attorney General and any other person or entity authorized to conduct an examination, as well as

the agency or agencies involved in this contract, shall have access to the Records during normal business hours at an office of the Contractor within the State of New York or, if no such office is available, at a mutually agreeable and reasonable venue within the State, for the term specified above for the purposes of inspection, auditing and copying. The State shall take reasonable steps to protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law (the "Statute") provided that: (i) the Contractor shall timely inform an appropriate State official, in writing, that said records should not be disclosed; and (ii) said records shall be sufficiently identified; and (iii) designation of said records as exempt under the Statute is reasonable. Nothing contained herein shall diminish, or in any way adversely affect, the State's right to discovery in any pending or future litigation.

11. IDENTIFYING INFORMATION AND PRIVACY NOTIFICATION. (a) FEDERAL EMPLOYER IDENTIFICATION NUMBER and/or FEDERAL SOCIAL SECURITY NUMBER. All invoices or New York State standard vouchers submitted for payment for the sale of goods or services or the lease of real or personal property to a New York State agency must include the payee's identification number, i.e., the seller's or lessor's identification number. The number is either the payee's Federal employer identification number or Federal social security number, or both such numbers when the payee has both such numbers. Failure to include this number or numbers may delay payment. Where the payee does not have such number or numbers, the payee, on its invoice or New York State standard voucher, must give the reason or reasons why the payee does not have such number or numbers.

(b) PRIVACY NOTIFICATIO**N.** (1) The authority to request the above personal information from a seller of goods or services or a lessor of real or personal property, and the authority to maintain such information, is found in Section 5 of the State Tax Law. Disclosure of this information by the seller or lessor to the State is mandatory. The principal purpose for which the information is collected is to enable the State to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purpose authorized by law.
(2) The personal information is requested by the purchasing unit of the agency contracting to purchase the goods or services or lease the real or personal property covered by this contract or lease. The information is maintained in New York State's Central Accounting System by the Director of Accounting Operations, Office of the State Comptroller, AESOB, Albany, New York 12236.

12. EQUAL EMPLOYMENT OPPORTUNITIES FOR MINORITIES AND WOMEN. In accordance with Section 312 of the Executive Law, if this contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of $25,000.00, whereby a contracting agency is committed to expend or does expend funds in return for labor, services, supplies, equipment, materials or any combination of the foregoing, to be performed for, or rendered or furnished to the contracting agency; or (ii) a written agreement in excess of $100,000.00 whereby a contracting agency is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon; or (iii) a written agreement in excess of $100,000.00 whereby the owner of a State assisted housing project is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon for such project, then:

(a) The Contractor will not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status, and will undertake or continue existing programs of affirmative action to ensure that minority group members and women are afforded equal employment opportunities without discrimination. Affirmative action shall mean recruitment, employment, job assignment, promotion, upgradings, demotion, transfer, layoff, or termination and rates of pay or other forms of compensation;

(b) at the request of the contracting agency, the Contractor shall request each employment agency, labor union, or authorized representative of workers with which it has a collective bargaining or other agreement or understanding, to furnish a written statement that such employment agency, labor union or representative will not discriminate on the basis of race, creed, color, national origin, sex, age, disability or marital status and that such union or representative will affirmatively cooperate in the implementation of the contractor's obligations herein; and

(c) the Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status. Contractor will include the provisions of "a", "b", and "c" above, in every subcontract over $25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (the "Work") except where the Work is for the beneficial use of the Contractor. Section 312 does not apply to: (i) work, goods or services unrelated to this contract; or (ii) employment outside New York State; or (iii) banking services, insurance policies or the sale of securities. The State shall consider compliance by a contractor or subcontractor with the requirements of any federal law concerning equal employment opportunity which effectuates the purpose of this section. The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall waive the applicability of Section 312 to the extent of such duplication or conflict. Contractor will comply with all duly promulgated and lawful rules and regulations of the Governor's Office of Minority and Women's Business Development pertaining hereto.

13. CONFLICTING TERMS. In the event of a conflict between the terms of the contract (including any and all attachments thereto and amendments thereof) and the terms of this Appendix A, the terms of this Appendix A shall control.

14. GOVERNING LAW. This contract shall be governed by the laws of the State of New York except where the Federal supremacy clause requires otherwise.

15. LATE PAYMENT. Timeliness of payment and any interest to be paid to Contractor for late payment shall be governed by Article 11-A of the State Finance Law to the extent required by law.

16. NO ARBITRATION. Disputes involving this contract, including the breach or alleged breach thereof, may not be submitted to binding arbitration (except where statutorily authorized), but must, instead, be heard in a court of competent jurisdiction of the State of New York.

17. SERVICE OF PROCESS. In addition to the methods of service allowed by the State Civil Practice Law & Rules ("CPLR"), Contractor hereby consents to service of process upon it by registered or certified mail, return receipt requested. Service hereunder shall be complete upon Contractor's actual receipt of process or upon the State's receipt of the return thereof by the United States Postal Service as refused or undeliverable. Contractor must promptly notify the State, in writing, of each and every change of address to which service of process can be made. Service by the State to the last known address shall be sufficient. Contractor will have thirty (30) calendar days after service hereunder is complete in which to respond.

18. PROHIBITION ON PURCHASE OF TROPICAL HARDWOODS. The Contractor certifies and warrants that all wood products to be used under this contract award will be in accordance with, but not limited to, the specifications and provisions of State

Finance Law §165. (Use of Tropical Hardwoods) which prohibits purchase and use of tropical hardwoods, unless specifically exempted, by the State or any governmental agency or political subdivision or public benefit corporation. Qualification for an exemption under this law will be the responsibility of the contractor to establish to meet with the approval of the State. In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

19. MACBRIDE FAIR EMPLOYMENT PRINCIPLES. In accordance with the MacBride Fair Employment Principles (Chapter 807 of the Laws of 1992), the Contractor hereby stipulates that the Contractor either (a) has no business operations in Northern Ireland, or (b) shall take lawful steps in good faith to conduct any business operations in Northern Ireland in accordance with the MacBride Fair Employment Principles (as described in Section 165 of the New York State Finance Law), and shall permit independent monitoring of compliance with such principles.

20. OMNIBUS PROCUREMENT ACT OF 1992. It is the policy of New York State to maximize opportunities for the participation of New York State business enterprises, including minority and women-owned business enterprises as bidders, subcontractors and suppliers on its procurement contracts. Information on the availability of New York State subcontractors and suppliers is available from:

NYS Department of Economic Development
Division for Small Business
30 South Pearl St -- 7 th Floor
Albany, New York 12245
Telephone: 518-292-5220

A directory of certified minority and women-owned business enterprises is available from:

NYS Department of Economic Development
Division of Minority and Women's Business Development
30 South Pearl St -- 2nd Floor
Albany, New York 12245
http://www.empire.state.ny.us

The Omnibus Procurement Act of 1992 requires that by signing this bid proposal or contract, as applicable, Contractors certify that whenever the total bid amount is greater than $1 million:

(a) The Contractor has made reasonable efforts to encourage the participation of New York State Business Enterprises as suppliers and subcontractors, including certified minority and women-owned business enterprises, on this project, and has retained the documentation of these efforts to be provided upon request to the State;

(b) The Contractor has complied with the Federal Equal Opportunity Act of 1972 (P.L. 92-261), as amended;

(c) The Contractor agrees to make reasonable efforts to provide notification to New York State residents of employment opportunities on this project through listing any such positions with the Job Service Division of the New York State Department of Labor, or providing such notification in such manner as is consistent with existing collective bargaining contracts or agreements. The Contractor agrees to document these efforts and to provide said documentation to the State upon request; and

(d) The Contractor acknowledges notice that the State may seek to obtain offset credits from foreign countries as a result of this contract and agrees to cooperate with the State in these efforts.

21. RECIPROCITY AND SANCTIONS PROVISIONS. Bidders are hereby notified that if their principal place of business is located in a country, nation, province, state or political subdivision that penalizes New York State vendors, and if the goods or services they offer will be substantially produced or performed outside New York State, the Omnibus Procurement Act 1994 and 2000 amendments (Chapter 684 and Chapter 383, respectively) require that they be denied contracts which they would otherwise obtain. NOTE: As of May 15, 2002, the list of discriminatory jurisdictions subject to this provision includes the states of South Carolina, Alaska, West Virginia, Wyoming, Louisiana and Hawaii. Contact NYS Department of Economic Development for a current list of jurisdictions subject to this provision.

22. PURCHASES OF APPAREL. In accordance with State Finance Law 162 (4-a), the State shall not purchase any apparel from any vendor unable or unwilling to certify that: (i) such apparel was manufactured in compliance with all applicable labor and occupational safety laws, including, but not limited to, child labor laws, wage and hours laws and workplace safety laws, and (ii) vendor will supply, with its bid (or, if not a bid situation, prior to or at the time of signing a contract with the State*)*, if known, the names and addresses of each subcontractor and a list of all manufacturing plants to be utilized by the bidder.

APPENDIX A-1
(REV 02/03)

AGENCY SPECIFIC CLAUSES FOR ALL
DEPARTMENT OF HEALTH CONTRACTS

1. If the CONTRACTOR is a charitable organization required to be registered with the New York State Attorney General pursuant to Article 7-A of the New York State Executive Law, the CONTRACTOR shall furnish to the STATE such proof of registration (a copy of Receipt form) at the time of the execution of this AGREEMENT. The annual report form 497 is not required. If the CONTRACTOR is a business corporation or not-for-profit corporation, the CONTRACTOR shall also furnish a copy of its Certificate of Incorporation, as filed with the New York Department of State, to the Department of Health at the time of the execution of this AGREEMENT.

2. The CONTRACTOR certified that all revenue earned during the budget period as a result of services and related activities performed pursuant to this contract shall be used either to expand those program services funded by this AGREEMENT or to offset expenditures submitted to the STATE for reimbursement.

3. Administrative Rules and Audits:

   a. If this contract is funded in whole or in part from federal funds, the CONTRACTOR shall comply with the following federal grant requirements regarding administration and allowable costs.

      i. For a local or Indian tribal government, use the principles in the common rule, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments," and Office of Management and Budget (OMB) Circular A-87, "Cost Principles for State, Local and Indian Tribal Governments".

      ii. For a nonprofit organization other than
      - an institution of higher education,
      - a hospital, or
      - an organization named in OMB Circular A-122, "Cost Principles for Non-profit Organizations", as not subject to that circular,

      use the principles in OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-profit Organizations," and OMB Circular A-122.

      iii. For an Education Institution, use the principles in OMB Circular A-110 and OMB Circular A-21, "Cost Principles for Educational Institutions".

      iv. For a hospital, use the principles in OMB Circular A-110, Department of Health and Human Services, 45 CFR 74, Appendix E, "Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals" and, if not covered for audit purposes by OMB Circular A-133, "Audits of States and Local Governments and Non-profit Organizations", then

subject to program specific audit requirements following Government Auditing Standards for financial audits.

b. If this contract is funded entirely from STATE funds, and if there are no specific administration and allowable costs requirements applicable, CONTRACTOR shall adhere to the applicable principles in “a” above.

c. The CONTRACTOR shall comply with the following grant requirements regarding audits.

i. If the contract is funded from federal funds, and the CONTRACTOR spends more than $300,000 in federal funds in their fiscal year, an audit report must be submitted in accordance with OMB Circular A-133.

ii. If this contract is funded from other than federal funds or if the contract is funded from a combination of STATE and federal funds but federal funds are less than $300,000, and if the CONTRACTOR receives $300,000 or more in total annual payments from the STATE, the CONTRACTOR shall submit to the STATE after the end of the CONTRACTOR's fiscal year an audit report. The audit report shall be submitted to the STATE within thirty days after its completion but no later than nine months after the end of the audit period. The audit report shall summarize the business and financial transactions of the CONTRACTOR. The report shall be prepared and certified by an independent accounting firm or other accounting entity, which is demonstrably independent of the administration of the program being audited. Audits performed of the CONTRACTOR's records shall be conducted in accordance with Government Auditing Standards issued by the Comptroller General of the United States covering financial audits. This audit requirement may be met through entity-wide audits, coincident with the CONTRACTOR's fiscal year, as described in OMB Circular A-133. Reports, disclosures, comments and opinions required under these publications should be so noted in the audit report.

d. For audit reports due on or after April 1, 2003, that are not received by the dates due, the following steps shall be taken:

i. If the audit report is one or more days late, voucher payments shall be held until a compliant audit report is received.

ii. If the audit report is 91 or more days late, the STATE shall recover payments for all STATE funded contracts for periods for which compliant audit reports are not received.

iii. If the audit report is 180 days or more late, the STATE shall terminate all active contracts, prohibit renewal of those contracts and prohibit the execution of future contracts until all outstanding compliant audit reports have been submitted.

4. The CONTRACTOR shall accept responsibility for compensating the STATE for any exceptions which are revealed on an audit and sustained after completion of the normal audit procedure.

5. FEDERAL CERTIFICATIONS: This section shall be applicable to this AGREEMENT only if any of the funds made available to the CONTRACTOR under this AGREEMENT are federal funds.

a. LOBBYING CERTIFICATION

1) If the CONTRACTOR is a tax-exempt organization under Section 501 (c)(4) of the Internal Revenue Code, the CONTRACTOR certifies that it will not engage in lobbying activities of any kind regardless of how funded.

2) The CONTRACTOR acknowledges that as a recipient of federal appropriated funds, it is subject to the limitations on the use of such funds to influence certain Federal contracting and financial transactions, as specified in Public Law 101 -121, section 319, and codified in section 1352 of Title 31 of the United States Code. In accordance with P.L. 101-121, section 319, 31 U.S.C. 1352 and implementing regulations, the CONTRACTOR affirmatively acknowledges and represents that it is prohibited and shall refrain from using Federal funds received under this AGREEMENT for the purposes of lobbying; provided, however, that such prohibition does not apply in the case of a payment of reasonable compensation made to an officer or employee of the CONTRACTOR to the extent that the payment is for agency and legislative liaison activities not directly related to the awarding of any Federal contract, the making of any Federal grant or loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan or cooperative agreement. Nor does such prohibition prohibit any reasonable payment to a person in connection with, or any payment of reasonable compensation to an officer or employee of the CONTRACTOR if the payment is for professional or technical services rendered directly in the preparation, submission or negotiation of any bid, proposal, or application for a Federal contract, grant, loan, or cooperative agreement, or an extension, continuation, renewal, amendment, or modification thereof, or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan or cooperative agreement.

3) This section shall be applicable to this AGREEMENT only if federal funds allotted exceed $100,000.

a) The CONTRACTOR certifies, to the best of his or her knowledge and belief, that:

- No federal appropriated funds have been paid or will be paid, by or on behalf of the CONTRACTOR, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal amendment or modification of any federal contract, grant, loan, or cooperative agreement.

- If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the CONTRACTOR shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying" in accordance with its instructions.

b) The CONTRACTOR shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

c) The CONTRACTOR shall disclose specified information on any agreement with lobbyists whom the CONTRACTOR will pay with other Federal appropriated funds by completion and submission to the STATE of the Federal Standard Form-LLL, "Disclosure Form to Report Lobbying", in accordance with its instructions. This form may be obtained by contacting either the Office of Management and Budget Fax Information Line at (202) 395-9068 or the Bureau of Accounts Management at (518) 474-1208. Completed forms should be submitted to the New York State Department of Health, Bureau of Accounts Management, Empire State Plaza, Corning Tower Building, Room 1315, Albany, 12237-0016.

d) The CONTRACTOR shall file quarterly updates on the use of lobbyists if material changes occur, using the same standard disclosure form identified in (c) above to report such updated information.

4) The reporting requirements enumerated in subsection (3) of this paragraph shall not apply to the CONTRACTOR with respect to:

a) Payments of reasonable compensation made to its regularly employed officers or employees;

b) A request for or receipt of a contract (other than a contract referred to in clause (c) below), grant, cooperative agreement, subcontract (other than a subcontract referred to in clause (c) below), or subgrant that does not exceed $100,000; and

c) A request for or receipt of a loan, or a commitment providing for the United States to insure or guarantee a loan, that does not exceed $150,000, including a contract or subcontract to carry out any purpose for which such a loan is made.

b. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE:

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by federal programs whether directly or through State or local governments, by federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this AGREEMENT, the CONTRACTOR certifies that it will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act. The CONTRACTOR agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

c. CERTIFICATION REGARDING DEBARMENT AND SUSPENSION

Regulations of the Department of Health and Human Services, located at Part 76 of Title 45 of the Code of Federal Regulations (CFR), implement Executive Orders 12549 and 12689 concerning debarment and suspension of participants in federal programs and activities. Executive Order 12549 provides that, to the extent permitted by law, Executive departments and agencies shall participate in a government-wide system for non-procurement debarment and suspension. Executive Order 12689 extends the debarment and suspension policy to procurement activities of the federal government. A person who is debarred or suspended by a federal agency is excluded from federal financial and non-financial assistance and benefits under federal programs and activities, both directly (primary covered transaction) and indirectly (lower tier covered transactions). Debarment or suspension by one federal agency has government-wide effect.

Pursuant to the above-cited regulations, the New York State Department of Health (as a participant in a primary covered transaction) may not knowingly do business with a person who is debarred, suspended, proposed for debarment, or subject to other government-wide exclusion (including any exclusion from Medicare and State health care program participation on or after August 25, 1995), and the Department of Health must require its prospective contractors, as prospective lower tier participants, to provide the certification in Appendix B to Part 76 of Title 45 CFR, as set forth below:

1) APPENDIX B TO 45 CFR PART 76 - CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION-LOWER TIER COVERED TRANSACTIONS

Instructions for Certification

a) By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

b) The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

c) The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.

d) The terms *covered transactions, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded,* as used in this clause, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

e) The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

f) The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled “Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions,” without modification, in all lower tier covered transactions.

g) A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may

decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded From Federal Procurement and Non-procurement Programs.

h) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

i) Except for transactions authorized under paragraph "e" of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

2) Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions

a) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by a Federal department agency.

b) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

6. The STATE, its employees, representatives and designees, shall have the right at any time during normal business hours to inspect the sites where services are performed and observe the services being performed by the CONTRACTOR. The CONTRACTOR shall render all assistance and cooperation to the STATE in making such inspections. The surveyors shall have the responsibility for determining contract compliance as well as the quality of service being rendered.

7. The CONTRACTOR will not discriminate in the terms, conditions and privileges of employment, against any employee, or against any applicant for employment because of race, creed, color, sex, national origin, age, disability, sexual orientation or marital status. The CONTRACTOR has an affirmative duty to take prompt, effective, investigative and remedial action where it has actual or constructive notice of discrimination in the terms, conditions or privileges of employment against (including harassment of) any of its employees by any of its other employees, including managerial personnel, based on any of the factors listed above.

8. The CONTRACTOR shall not discriminate on the basis of race, creed, color, sex, national origin, age, disability, sexual orientation or marital status against any person seeking services for which the CONTRACTOR may receive reimbursement or payment under this AGREEMENT.

9. The CONTRACTOR shall comply with all applicable federal, State and local civil rights and human rights laws with reference to equal employment opportunities and the provision of services.

10. The STATE may cancel this AGREEMENT at any time by giving the CONTRACTOR not less than thirty (30) days written notice that on or after a date therein specified, this AGREEMENT shall be deemed terminated and cancelled.

11. Other Modifications

    a. Modifications of this AGREEMENT as specified below may be made within an existing PERIOD by mutual written agreement of both parties:

        - Appendix B – Budget line interchanges;
        - Appendix C – Section 11, Progress and Final Reports;
        - Appendix D – Program Workplan

    b. To make any other modification of this AGREEMENT within an existing PERIOD, the parties shall revise or complete the appropriate appendix form(s), and a Modification Agreement (Appendix X is the blank form to be used), which shall be effective only upon approval by the Office of the State Comptroller.

12. Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof, completed by the CONTACTOR's insurance carrier and/or the Workers' Compensation Board, of coverage for:

    a. Workers' Compensation, for which one of the following is incorporated into this contract as Appendix E-1:

        - Certificate of Workers' Compensation Insurance, on the Workers' Compensation Board form C-105.2 or the State Insurance Fund Form U-26.3 (naming the Department of Health, Corning Tower, Room 1315, Albany, 12237-0016), or

        - Affidavit Certifying That Compensation Has Been Secured, form SI-12 or form GSI 105.2, or

        - Statement That Applicant Does Not Require Workers' Compensation or Disability Benefits Coverage, form 105.21, completed for workers' compensation; and

    b. Disability Benefits coverage, for which one of the following is incorporated into this contract as Appendix E-2:

- Certificate of Disability Benefits Insurance, form DB-120.1, or

- Notice of Qualification as Self Insurer Under Disability Benefits Law, form DB-155, or

- Statement That Applicant Does Not Require Workers' Compensation or Disability Benefits Coverage, form 105.21, completed for disability benefits insurance.

13. Additional clauses as may be required under this AGREEMENT are annexed hereto as appendices and are made a part hereof if so indicated on the face page of this AGREEMENT.

APPENDIX A-2

Spinal Cord Injury Research Board

Contract Policy Statement and Conditions

A. Ethical Considerations

The Spinal Cord Injury Research Board (SCIRB) stipulates that each awarded grant contract satisfy the following requirements:

> In accepting an award from the New York State Department of Health for support from the Spinal Cord Injury Research Trust Fund, each project investigator agrees to conform strictly to the codes of practice, regulations and laws governing ethical conduct of scientific research in his/her own laboratory/institution. He/she is solely responsible if any of these regulations are infringed. If experimental procedures conducted pursuant to this project are performed in another state or country, either directly by the principal investigator (PI) and any co-investigators, or in collaboration with other persons, the PI and contracting organization agree to ensure that such research does not violate New York State laws and regulations applicable to such research if performed in New York State. Representatives of the contracting organization will inform SCIRB program administrators of any and all instances of actual or potential lapses in scientific integrity by any project participant as soon as this information becomes known to the contracting entity. The contracting organization is fully responsible for investigation of these instances. (See Section G.8(d), page 68.)

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning spinal cord injury (SCI) and the health of persons with such injuries. In carrying out such research, the rights and welfare of all individual research participants are of critical importance. Furthermore, additional safeguards must protect especially vulnerable research subjects, including minors, mentally disabled adults who lack capacity to provide informed consent to research participation, and prisoners.

Accordingly, no research study shall be approved for funding recommendation by SCIRB unless it is demonstrated that all the following requirements are satisfied:

- The research study will comply with New York State Public Health Law (PHL) Article 24-A, Sections 2440 to 2446.

- The research study will comply with 45 CFR Part 46 (unless exempt from the requirements of this Part) and, if applicable, 21 CFR Parts 50 and 56; 21 CFR 312; 21 CFR 361; 21 CRF 812.

- The research study will comply with all other applicable federal and New York State laws, regulations and guidelines.

- The research study has been approved by an Institutional Review Board (IRB).

- If applicable, the applicant organization's IRB has received and reviewed written approval from an authorized representative of each site where the study will take place.

- The IRB has determined that the investigator will immediately withdraw a subject from the research study if continued participation would be detrimental to the subject's well-being.

- The IRB will communicate to SCIRB program administrators (i) any unanticipated problems involving risks to subjects, (ii) any serious or continuing noncompliance with IRB policy or requirements; and (iii) any suspension or termination of IRB approval.

Vulnerable Populations

Under New York State law (Article 24-A of the Public Health Law), research with no prospect of direct benefit and posing more than minimal risk is prohibited for research participants who are minors, mentally disabled adults who lack capacity to provide informed consent to research participation, or prisoners. No research study in which any research participant is a minor, a mentally disabled adult who lacks capacity to provide informed consent to research participation or a prisoner shall be approved by SCIRB unless it is demonstrated to the Board, and the Board determines, that all the following requirements, in addition to the requirements set forth above, are satisfied:

- The IRB has determined that the research study constitutes either: research with a prospect of direct benefit to research participants; or research with no prospect of direct benefit to research participants that presents minimal risk.

- The IRB has determined that all research participants have suffered SCI.

- If the research involves one or more mentally disabled adults, each investigator must use IRB approved methodologies and procedures for initial capacity assessment, including: procedures for notice to a prospective subject that his/her capacity to consent to research is under consideration; notice to a prospective subject of a determination that he/she lacks the capacity to consent to research; and the opportunity for a prospective subject to contest such a determination of incapacity through a second opinion and a judicial proceeding prior to enrollment in the research.

- The IRB has determined that, prior to involving in a research study a minor, a mentally disabled adult who lacks the capacity to provide informed consent to

research participation, or a prisoner, each investigator will obtain such individual's assent to research participation.[2]

The Department of Health reserves the right to revise or expand requirements applicable to human subjects research as part of negotiation of any contract arising from this request for applications.

C. Animal Use

SCIRB requires that all individuals and institutions that conduct research using animals supported by the SCI Research Trust Fund adhere to all federal, state and local laws pertaining to humane care and use of animals for research purposes. Research applications submitted to the Board for consideration are expected to be reviewed by an Institutional Animal Care and Use Committee (IACUC) whose guidelines are in compliance with the U.S. Public Health Service's *Policy on Humane Care and Use of Laboratory Animals,* and *Guide for the Care and Use of Laboratory Animals,* as well as any other federal, state and local laws or regulations (e.g., the federal Animal Welfare Act and its implementing regulations; and PHL Article 5, Title I, Sections 504 and 505-a).

D. Tissue

SCIRB will support research using human tissue, other than human pluripotent stem cells, and requires that such research adhere to all federal, state, and local laws, regulations and guidelines pertaining to use of such tissue, including, but not limited to, PHL Article 5, Title V, Sections 570 to 581; Article 24-A, Sections 2440 to 2446; Article 43, Sections 4301 to 4309; Article 43-B, Sections 4360 to 4366; and 42 USC Section 289g et seq. Research proposing to use pluripotent stem cells requires appropriate and rigorous legal and ethical oversight.

E. Publication and Intellectual Property Rights

1. It is SCIRB's intent that the results of research it supports as well as the resources created through its sponsorship be disseminated and made easily available to the research community. Manuscript submission for publication of research funded by the Trust Fund cannot be delayed by investigators or their research institutions for more than 60 days after the manuscript is completed. Research results are to be submitted promptly for publication in internationally recognized scientific journals, and not delayed for more than such time period for commercial reasons or any other reasons unconnected with editorial delays to ensure scientific accuracy and presentation.

2. The State of New York shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to

[2] A minor's objection need not be honored if an independent physician determines that the research intervention or procedure holds out a prospect of direct benefit that is important to the health or well-being of the minor, and is available only within the context of the research.

use, any published or otherwise reproducible material, device, invention, technique or methodology developed under or in the course of performing this funded research, dealing with any aspect of the research activity, or of the results and accomplishments attained from the research. Use by those other than the State of New York under this license shall be limited to research and governmental purposes.

3. The State of New York shall be provided advance written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Trust Fund. Any such assignment or transfer must acknowledge, and be consistent with, the license rights granted the State pursuant to the above paragraph.

   Assignment of intellectual and industrial property rights generated from research supported by the Trust Fund is to be determined by the parties concerned (researchers, and their research organizations or institutions), consistent with organizational policies. Prior to execution of a negotiated contract, appropriate arrangements (existing or proposed) regarding intellectual and industrial property rights must be made by the contracting organization and communicated to SCIRB program administrators. Such arrangements may include: provisions about dissemination of information such as disclosure and methods of publication, and provisions regarding ownership and exploitation of the results arising from the research supported by the Trust Fund. However, to protect the State's interests and to streamline invention reporting procedures, contracts between the New York State Department of Health and the contracting institution will, except to the extent inconsistent with this paragraph, incorporate the provisions of 37 CFR 401.14 with the following modifications throughout: *Federal* or *Government* will refer to New York State, and *agency* will refer to the Department of Health.

4. Support by the New York State Spinal Cord Injury Trust Fund shall be acknowledged in all publications, presentations and products of research in a form consistent with the publication's guidelines, e.g.,:

   "…supported by the New York State Spinal Cord Injury Research Trust Fund through Department of Health Contract # <<>>. Opinions expressed are solely those of the author and do not necessarily reflect those of the Spinal Cord Injury Research Board, the New York State Department of Health, or the State of New York."

   The minimum acknowledgment is "NYS Spinal Cord Injury Trust Fund".

5. Contractor agrees, pursuant to the provisions of Chapter 647 of the Laws of 1999, and Chapter 229 of the Laws of 2000, both of the State of New York, to provide the Department with the study, any data supporting that study, and the identity of the principal person or persons who performed such study. If such study is used as the basis for the promulgation, amendment, or repeal of a rule, regulation, or guideline used in enforcement of a statute, rule, or regulation, the study, any data supporting that study, and the identity of the principal person or persons who performed the study shall be subject to disclosure in accordance with the provisions of Chapters 647 and 229.

F. Reporting Requirements

Reports shall be submitted as provided in Appendix C, and consistent with the following:

Scientific/Technical

The principal investigator's scientific/technical reporting obligations will include:
(1) submitting brief (two-page) semi-annual scientific progress reports;
(2) participating in an annual or biennial scientific meeting sponsored or co-sponsored by SCIRB;
(3) sponsoring one to two spinal cord injury-related seminars at the contracting (home) institution;
(4) submitting a detailed scientific report within 90 days of project termination;
(5) acknowledging support by the New York State Spinal Cord Injury Research Trust Fund in all products of research activity (such as publications, presentations, and abstracts).

Progress reports will describe:
(1) Project participants, including trainees and/or fellows;
(2) activities and findings corresponding to research aims; and
(3) research activity products resulting during the reporting period (e.g., abstracts, publications, presentations, or invention disclosures). Copies of published abstracts, publications and other products resulting from Trust Fund support should be submitted to SCIRB program administrators.

Reports should be submitted via e-mail as MS Word attachments. Documents should be single-spaced, in Arial 12 font or similar. Table, graphs, photographs, etc. should be sent as separate .bmp or .tif files attached to the email. All reports and forms are to be sent to scirb@wadsworth.org. The report being submitted should be identified on the subject line of the email (i.e., Progress Report-First, -Second, or Final Report. One (1) hard copy of each report, signed by the Principal Investigator, shall be submitted to the:

NYS Department of Health
Wadsworth Center, Room C675
Box 509
Empire State Plaza
Albany, NY 12201-0509

The Board also intends to support the current awardees' participation, when in non-awardee status, in future scientific meetings sponsored or co-sponsored by the SCIRB. The intent of this activity is to facilitate broad dissemination of research findings among investigators, as well as foster effective collaborations.

Financial

The Department of Health reimburses contractors for approved, allowable expenditures incurred under the awarded contract. After successful contract negotiation and execution, and at the start of the project period, up to 25 percent of the total annual award amount may be advanced to not-for-profit contracting organizations upon submission of a standard New York State voucher (available by written request from the

Office of the State Comptroller, Supply Room, Alfred E. Smith State Office Building, Albany, New York 12236). The contracting organization will be responsible for disbursing funds to any sub-contractors in accordance with the amounts approved for their research. If F&A costs are charged by a sub-contract, these must be limited to a maximum of 20 percent of the direct costs incurred by that institution for performance of the research or that calculated from its current F&A agreement, which ever is less. The New York State Department of Health will not establish contracts for the SCIRB with entities outside of New York State.

The contracting organization will submit quarterly vouchers within 90 days of the end date of the period for which reimbursement is being claimed, accompanied by accounting statements that report expenditures corresponding to approved budget categories. Prior approval from SCIRB program administrators will be required for budget line interchanges which on the most recent in a series of such interchanges cumulatively exceeds $5,000 or 10 percent of the original, approved total annual award.

Documentation of cost sharing will be required only for approved equipment costing $25,000 or more and should accompany requests for reimbursement.

G. Other Information

1. Documents submitted to the Department of Health on behalf of the SCIRB program will not be returned to the applicant.

2. The initial budgetary plan incorporated into a contract between the New York State Department of Health and the contracting organization may be reviewed and revised each year, depending on research progress and the availability of funds.

3. The New York State Department of Health may require reimbursement of all or a part of the award if ineligible expenses have been incurred or false accounting statements have been submitted.

4. The Department of Health or the State of New York will assume no responsibility for any damage or injuries caused in relation to research conducted with the support of the Trust Fund.

5. Detailed arrangements for starting the research program (e.g. start date, award amount, and work plan) will be negotiated by the contracting organization and SCIRB program administrators.

6. Recipient entities accept auditing of their expenditures by an appointed representative of the SCIRB research program at any time.

7. Incorporated into all contracts between the contracting organization and the New York State Department of Health will be Appendix A, “Standard Clauses for all New York State Contracts”; Appendix A-1, “Agency Specific Clauses for All Department of Health Contracts”; and Appendix A-2, “Spinal Cord Injury Research Program Specific Terms and Conditions.” These appendices are included in this document.

8. Assurances and Certifications. The New York State SCIRB has adopted the following federal regulatory mechanisms to ensure responsible administration of its awards and to preserve the integrity of the research enterprise it supports. By signing the face page of the application, the authorized representative of the applicant organization certifies that, in addition to all applicable state and local statutes and regulations, the applicant organization will comply with applicable federal regulations and statutes, including but not limited to:

a. Human Subjects:

- Protection of Human Subjects: 45 CFR 46.

b. Vertebrate Animals:

- The U.S. Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals.*
- The PHS *Guide for the Care and Use of Laboratory Animals*.
- Animal Welfare Act as amended (7 USC 2131 et sec.), if applicable, and other federal statutes and regulations relating to animal care and use.

c. Debarment and Suspension/Drug Free Workplace:

- 45 CFR 76, "Government-wide debarment and suspension (nonprocurement) and Government-wide requirements for drug-free workplace (Grants)," Appendix A.
- Contractors will be required to obtain a similar certification from subawardees, or lower tier participants (45 CFR 76, Appendices A and B).
- Even if unable to certify to these statements, the applicant organization must, nonetheless, submit the certification and attach an explanation.

d. Research Misconduct:

- 42 CFR Part 50, Subpart A, "Responsibilities for PHS awardees and applicant institutions for dealing with and reporting possible misconduct in science."
- 42 CFR 94, "Public Health Service standards for the protection of research misconduct whistleblowers" (effective on the date set forth in the final rule).
- Each covered institution must certify that it will comply with the above policies and the requirements of the Final Rule.
- A copy of the institution's Annual Report on Possible Research Misconduct (Form 6349), routinely sent to all PHS awardees by the Office of Research Integrity, shall be forwarded to SCIRB program administrators.

e. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination):

- The institution has filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (PL 88352, as amended), which prohibits discrimination on the basis of race, color or national origin; Section 504 of the rehabilitation Act of 1973 (PL 93-112, as amended) which prohibits discrimination on the basis of handicaps; Title IX of the Education

Amendments of 1972 (PL 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (PL 94-135), which prohibits discrimination on the basis of age.

Implementing regulations:

- 45 CFR 80: Civil Rights
- 45 CFR 84 and 85: Handicapped Individuals
- 45 CFR 86: Sex Discrimination
- 45 CFR 91: Age Discrimination

f. Conflict of Interest

- 42 CFR 50, Subpart F, "Responsibility of applicants for promoting objectivity in research for which PHS funding is sought."

10. Other documentation

The Department of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight, as part of the negotiation of any contract arising from this request for applications.

APPENDIX B

BUDGET
(sample format)

Organization Name: _____

Budget Period: Commencing on: _____ Ending on: _____

Personal Service

Number	Title	Annual Salary	% Time Devoted to This Project	Total Amount Budgeted From NYS

Total Salary _____
Fringe Benefits (specify rate) _____
TOTAL PERSONAL SERVICE: _____

Other Than Personal Service Amount

Category
- Supplies
- Travel
- Telephone
- Postage
- Photocopy
- Other Contractual Services (specify)
- Equipment _____

TOTAL OTHER THAN PERSONAL SERVICE _____

GRAND TOTAL _____

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: _____