FAU # 0806061218

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

2009 Request for Applications

CART (Collaborations to Accelerate Research Translation) Awards
IDEA (Innovative, Developmental or Exploratory Activities) Awards
Postdoctoral Fellowship Awards
Mentored Research Scientist Development Awards
Mentored Clinical Scientist Development Awards

RELEASE DATE:	April 1, 2009
QUESTIONS DUE:	April 30, 2009
LETTER OF INTENT DUE (Mandatory):	April 30, 2009
QUESTIONS, ANSWERS AND UPDATES POSTED:	May 13, 2009
APPLICATIONS DUE:	May 27, 2009
ESTIMATED CONTRACT START DATE:	June 1, 2010

DOH CONTACT NAME AND ADDRESS:

Lani Rafferty
New York State Department of Health
Wadsworth Center
Empire State Plaza, Room D350
PO Box 509, Albany, NY 12201-0509

This RFA, questions and answers, as well as any updates and modifications, may be downloaded at http://www.nyhealth.gov/funding/ and at http://www.wadsworth.org/extramural/spinalcord.htm

New York State Spinal Cord Injury Research Board
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State University of New York
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Robert D. Trotta, Esq.
Davis and Trotta, Attorneys-at-Law

Jonathan R. Wolpaw, M.D.
Wadsworth Center, NYS Department of Health

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CART (Collaborations to Accelerate Research Translation), IDEA (Innovative, Developmental or Exploratory Activities), Postdoctoral Fellowship, Mentored Research Scientist Development and Mentored Clinical Scientist Development Awards

I. Introduction

A. 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, legislation was enacted to create 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 SCIRB's mission is to stimulate high-quality, innovative SCI research that will help promote treatment and cure for spinal cord injury, including methods for reversing paralysis or restoring function caused by injury, or for minimizing or preventing damage occurring during acute phases of injury. To achieve this mission, SCIRB 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. A copy of the 2007 SCIRB Annual Report can be found at http://www.wadsworth.org/extramural/spinalcord.htm.

B. Purpose of Funds

This RFA reflects the SCIRB's intention to issue awards on an annual basis to provide the opportunity for continued scientific progress. Specifically, the SCIRB desires to:

- Support the development of spinal cord injury research in New York State;
- Stimulate the growth of inter-disciplinary and collaborative approaches to spinal cord injury research;
- 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 investigators conducting spinal cord injury research in New York's biomedical research institutions.

The SCIRB welcomes basic, translational and clinical neurological research applications on topics bearing on its mission. Although the SCIRB has not formally developed a list of research priorities, projects targeting tissue regeneration, repair, or restoration of function through biomedical and bioengineering research are of strongest interest, as are the under-studied areas of bowel and bladder function. Projects including the use of pluripotent stem cells are also welcome. Applicants are encouraged to review awards from the SCIRB Program's previously funded studies at http://www.wadsworth.org/extramural/spinalcord.htm.

C. Available Funds

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. Approximately $6 million is available to support these awards. The amount of funds awarded will be contingent upon the quality of applications submitted. In determining final awards, the Department reserves the right to allocate funds between the five funding mechanisms offered within this RFA as it deems appropriate.

Institutions and their investigators are invited to submit applications for one of the following funding mechanisms:

1. **Collaborations to Achieve Research Translation (CART) Award**
   The intent of the CART award is to foster the translation of results from basic (preclinical) research into the next research phase by supporting synergistic inter-disciplinary partnerships. CART awards are expected to contribute to rapid movement of findings to potential therapeutic applications or treatment strategies.
   - Contract term will be up to four years.
   - Annual direct costs are capped at $275,000.
   - Facilities and Administrative costs are capped at 20 percent of modified total direct costs.

2. **Innovative, Developmental or Exploratory Activities (IDEA) Award**
   The intent of the IDEA award is to provide initial support for:
     - preliminary testing of novel or high-risk hypotheses
     - applying novel approaches and methods
     - challenging existing paradigms or developing new paradigms
     - considering an existing problem from a new perspective.
   - The SCIRB seeks to fund research projects in which there is a high likelihood that the results will yield the opportunity to apply for future funding from other sources.
   - Contract term will be up to two years.
   - Annual direct costs are capped at $150,000.
   - Facilities and Administrative costs are capped at 20 percent of modified total direct costs.

3. **Postdoctoral Fellowship Award**
   The intent of the Postdoctoral Fellowship award is to support the continued training of basic or clinical investigators with exceptional potential for making significant contributions to the cures of SCI and SCI-induced paralysis.
   - Each fellow's stipend shall be based upon the number of years' experience of the postdoctoral candidate (see Section V.A. Budget – Form 6).
   - Fringe benefits may be requested in accordance with institutional guidelines for each position.
   - Annual expenses for supplies, equipment, travel and consultants are limited to $20,000 in direct costs.
   - Facilities and Administrative costs are capped at 8 percent of modified total direct costs.
   - Contract term will be up to two years.

4. **Mentored Research Scientist Development Award**
   The intent of the Mentored Research Scientist Development award is to support the transition of neuroscientists into SCI research careers in New York State institutions.
   - Contract term will be up to three years.
   - Annual direct costs are capped at $200,000.
   - Facilities and Administrative costs are capped at 8 percent of modified total direct costs.

5. **Mentored Clinical Scientist Development Award**
   The intent of the Mentored Clinician Scientist Development awards is to support the transition of clinicians into SCI research careers in New York State institutions.
   - Contract term will be up to three years.
   - Annual direct costs are capped at $200,000.
   - Facilities and Administrative costs are capped at 8 percent of modified total direct costs.

Applications may be submitted for the purpose of continuing a currently funded CART award. However, applications to continue currently funded IDEA, Postdoctoral Fellowship, Mentored Research or Clinical Scientist Development awards will not be considered.

II. Who May Apply?

The applicant must be a New York State not-for-profit organization or a governmental organization within New York State. The applicant must also be one of the following: an academic institution; a research organization; a medical center; or an entity with demonstrated capability to conduct externally-funded research. Organizations awarded funds will be expected to monitor funds, maintain individual accounts and fulfill other fiscal management criteria.

Subcontracting and collaborating organizations may include public, not-for-profit and for-profit entities. Such entities may be located in or outside of New York State.

The Principal Investigator (PI) will be employed by the applicant institution and have the skills, knowledge, and resources necessary to carry out the proposed Work Plan. The SCIRB is interested in applications from established investigators, including those new to the field of spinal cord injury research, junior researchers, and those in disciplines that have not historically focused on spinal cord injury research. Collaborations between experienced and less-experienced researchers, and between New York State and non-New York State researchers, are encouraged. Principal investigators may apply to multiple funding mechanisms offered under this RFA, provided that the applications are separate and distinct.*

* this requirement is part of the Peer Review Panel's evaluation - see Section V.D.

III. Project Narrative/Work Plan Outcomes

A. General Expectations for Each Funding Mechanism

1. Collaborations to Accelerate Research Translation (CART) Award

The collaborative partnership should be inter-disciplinary and facilitate expansion of the body of knowledge/expertise applied to research problems in spinal cord injury. The CART mechanism supports interactions and cooperation among experts from diverse fields to study and develop creative solutions to intractable problems in spinal cord injury treatment that have a clear translational path to clinical application.

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.

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. Proposed projects should be cohesive and sharply focused. Translational aspects of the study may involve either animal or human studies. The research may be

applied or may integrate fundamental and applied approaches. Applications that seek to apply knowledge gleaned from lower order mammals to appropriate non-human primate models are also eligible. The application will include at least one translational aim/goal, and should explicitly state how results will inform and enable the next research stage, (e.g., preclinical or clinical research).

Research centers and Phase III clinical trials are ineligible for CART support and will not be reviewed. Other applications considered non-responsive to this RFA include those seeking to expand clinical trial enrollment into ongoing trials and those lacking a specific translational or clinical goal (i.e., incremental applications leading only to another basic research grant application).

PIs/Co-PIs must each commit at least 10 percent of their total professional effort* to the project.

* professional effort is all professional activities performed, regardless of how or whether the individual receives compensation.

2. Innovative, Developmental or Exploratory Activities (IDEA) Award

The IDEA mechanism provides researchers the opportunity to try new methods and approaches to investigate the problems associated with spinal cord injury. IDEA projects are self-contained, hypothesis-driven research, and are not intended to fund smaller components of larger research projects, for data collection or incremental or correlative research aims, or for compression of a larger project into a smaller time frame. Responsive applications include the following projects:

- highly speculative, exploratory, or high-risk – may not have pilot data, but have the potential for high scientific payoff
- application or development of state-of-the-art technologies, tools or resources for spinal cord injury research
- innovative, developmental – focus on exceptionally promising topics and have some pilot data, but not yet sufficiently mature to compete successfully for funding for a full-scale study
- testing new hypotheses based on research grounded in a non-spinal cord injury research area

PIs/Co-PIs must each commit at least 10 percent of their total professional effort* to the project.

* professional effort is all professional activities performed, regardless of how or whether the individual receives compensation.

3. Postdoctoral Fellowship Award

The Postdoctoral Fellow candidate will have earned a doctoral-level degree by the award start date and may have no more than two years of prior postdoctoral training under the current sponsor's supervision by the expected start date of the award. Candidates with more than three years total fellowship experience by the expected start date of the award will not be considered. For purposes of this application, the fellow will be considered the principal investigator and must commit 100 percent professional effort* to the research project. The proposed research project should be formulated and agreed upon by the mentor and the candidate, and described in detail in the application.

To encourage new or cross-disciplinary approaches to curative spinal cord injury research, fellowship mentors need not be well established neurologists or neuroscientists in the non-rehabilitative spinal cord injury field, although they should be highly qualified to supervise the proposed project. Candidates may choose more than one mentor to enhance the training

experience, but only one mentor of record is permitted. As part of the application, the mentor will provide an outline of the training to be provided to the candidate and include the approximate amount of time to be devoted working with the fellow. The mentor should have sufficient research support to cover the costs of the proposed research project that are in excess of the allowable costs of this award.

* professional effort is all professional activities performed, regardless of how or whether the individual receives compensation.

4. Mentored Research Scientist Development Award

The candidate will have earned a research or health-professional doctorate or its equivalent by the award start date. For purposes of this application, the candidate will be considered the principal investigator and must commit at least 75 percent professional effort* to the goals of this award for the entire award period. The remainder may be devoted to clinical, teaching, or other research pursuits consistent with the objectives of the award. Both the didactic and the research phases of an award period should be designed to develop the necessary knowledge and research skills in scientific areas relevant to the career goals of the candidate.

The Mentored Research Scientist Development Award provides support for an intensive, supervised career development experience in one of the biomedical, behavioral, or clinical sciences leading to research independence. The candidate should demonstrate the need for a three year period of supervised research as well as the capacity and/or the potential for highly productive independent research. The proposed career development experience should be in a research area new to the candidate and/or one in which an additional supervised research experience will substantially add to the spinal cord injury research capabilities of the candidate.

The career development plan should be tailored to meet the individual needs of the candidate and provide a means for the candidate to achieve independent research support by the end of the award period. For example, a candidate with limited experience in the proposed field of research may find the most efficient means of attaining independence is through a phased developmental program that lasts three years and includes a designated period of didactic training, followed by a period of closely supervised research experience. A candidate with previous research experience in a related field may not require extensive additional didactic preparation; therefore a program that focuses on an intensive, supervised research experience may be appropriate.

The candidate and the mentor are jointly responsible for the planning, direction and execution of the research and career development plan. The proposed research project should be formulated and agreed upon by the mentor and the candidate, and described in detail in the application. As part of the application, the mentor will provide a detailed outline of the training to be provided to the candidate and include the approximate amount of time to be devoted working with the candidate. An advisory committee may be formed to assist with the development of a program of study or to monitor the candidate's progress through the career development program. The mentor should be recognized as an accomplished investigator with extensive research experience in the spinal cord injury field, have a track record of success in training independent investigators, and should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.

* professional effort is all professional activities performed, regardless of how or whether the individual receives compensation.

5. Mentored Clinical Scientist Development Award

The candidate will have earned a clinical doctoral degree or its equivalent by the award start date. For purposes of this application, the candidate will be considered the principal investigator and must commit at least 75 percent professional effort* to the goals of this

award for the entire award period. The remainder may be devoted to clinical, teaching, or other research pursuits consistent with the objectives of the award. Both the didactic and the research phases of an award period should be designed to develop the necessary knowledge and research skills in scientific areas relevant to the career goals of the candidate.

The Mentored Clinical Scientist Development Award provides support for the development of outstanding clinician research scientists. This mechanism provides specialized study for individuals with a clinical doctoral degree committed to a career in laboratory or clinical research. The candidate should demonstrate the need for a three year period of supervised research as well as the capacity and/or the potential for highly productive independent research.

The career development plan should be tailored to meet the individual needs of the candidate and provide a means for the candidate to achieve independent research support by the end of the award period, consistent with her or his previous research experience. For example, a candidate with limited experience in the proposed field of research may find the most efficient means of attaining independence is through a phased developmental program that lasts three years and includes a designated period of didactic training, followed by a period of closely supervised research experience. A candidate with previous research experience in a related field may not require extensive additional didactic preparation; therefore a program that focuses on an intensive, supervised research experience may be appropriate.

The candidate and the mentor are jointly responsible for the planning, direction and execution of the research and career development plan. The proposed research project should be formulated and agreed upon by the mentor and the candidate, and described in detail in the application. As part of the application, the mentor will provide a detailed outline of the training to be provided to the candidate and include the approximate amount of time to be devoted working with the candidate. An advisory committee may be formed by the mentor to assist with the development of a program of study or to monitor the candidate's progress through the career development program. The mentor should be recognized as an accomplished clinical researcher with extensive experience in the spinal cord injury field, have a track record of success in training independent investigators, and should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.

* professional effort is all professional activities performed, regardless of how or whether the individual receives compensation.

B. Use of Funds

1. CART

Funds may be used to support salaries, fringe benefits, stipends, supplies, equipment, subcontractors, consultants, travel, registration fees, publication costs, animal care, human subjects and related research costs (see budget instructions in section V.A. Form 6, Budget). Funds should be budgeted for travel to present project results to the SCIRB. PIs/Co-PIs must each commit at least 10 percent professional effort for the duration of project.

Facilities and Administrative costs are allowed but are limited to a maximum of 20 percent of modified total direct costs. Modified total direct costs consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from modified total direct costs.

2. IDEA

Funds may be used to support salaries, fringe benefits, stipends, supplies, equipment, subcontractors, consultants, travel, registration fees, publication costs, animal care, human subjects and related research costs (see budget instructions in section V.A. Form 6, Budget). Funds should be budgeted for travel to present project results to the SCIRB. PIs/Co-PIs must each commit at least 10 percent professional effort for the duration of the project.

Facilities and Administrative costs are allowed but are limited to a maximum of 20 percent of modified total direct costs. Modified total direct costs consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from modified total direct costs.

3. Postdoctoral Fellowship

Funds may be used to support the stipend, fringe benefits, travel, supplies, equipment, subcontractors, consultants, travel, registration fees, publication costs, animal care, human subjects and related research costs (see budget instructions in section V.A. Form 6, Budget). Funds should be budgeted for travel to present project results to the SCIRB. The fellow must commit 100 percent professional effort for the duration of the project.

Each fellow's stipend shall be based upon the total years of experience of the postdoctoral candidate (see Section V.A. Form 6, Budget). The stipend may be supplemented by sources other than the grant contract to offset the cost of living; however, in such case additional effort may not be required from the fellow. Support for fringe benefits may be requested in accordance with institutional guidelines for postdoctoral fellows, provided that such support is administered consistently by the applicant organization as a direct cost to all sponsors.

In addition, funds may be requested to support Other Than Personal Services (OTPS) costs including supplies, travel, equipment, consultants, and other, not to exceed $20,000 per year.

Facilities and Administrative costs are limited to eight percent of modified total direct costs, and if waived, may be used to supplement the fellow's stipend. Modified total direct costs consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from modified total direct costs.

4. Mentored Research Scientist Development Award

Funds may be used to support the salary and fringe benefits for the career award recipient. The total salary requested is normally based on a full-time, 12-month staff appointment. The salary will be consistent with both the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed will be appropriately related to the existing salary structure. Salary limits on career awards are not uniform and are determined independently. The mentored scientist must commit at least 75 percent professional effort for the duration of the project. Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

Funds may be used to support salaries, fringe benefits, stipends, supplies, equipment, subcontractors, consultants, travel, registration fees, publication costs, animal care, human subjects and related research costs (see budget instructions in section V.A. Form 6, Budget). Funds should be budgeted for travel to present project results to the SCIRB. Funds may also be used for tuition, fees, and books related to career development. All expenses should be directly related to the proposed research career development program.

Facilities and Administrative costs are limited to eight percent of modified total direct costs. Modified total direct costs consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from modified total direct costs.

5. Mentored Clinician Scientist Development Award

Funds may be used to support the salary and fringe benefits for the career award recipient. The total salary requested is normally based on a full-time, 12-month staff appointment. It will be consistent with both the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed will be appropriately related to the existing salary structure. Salary limits on career awards are not uniform and are determined independently. The mentored scientist must commit at least 75 percent professional effort for the duration of the project. Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

Funds may be used to support salaries, fringe benefits, stipends, supplies, equipment, subcontractors, consultants, travel, registration fees, publication costs, animal care, human subjects and related research costs (see budget instructions in section V.A. Form 6, Budget). Funds should be budgeted for travel to present project results to the SCIRB. Funds may also be used for tuition, fees, and books related to career development. All expenses should be directly related to the proposed research career development program.

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C. Reporting Obligations

The contractor will be required to submit financial reports and progress reports in accordance with the forms and formats provided by the Extramural Grants Administration Program (Program). Submission of detailed quarterly financial reports will be required.

Additionally, the contractor will be required to submit written semi-annual reports that substantiate progress corresponding to the tasks and milestones outlined in the Work Plan. All progress reports will require approval by Program staff prior to payment of the corresponding quarterly vouchers. The contractor will also be required to follow all reporting obligations outlined in Appendix A-2 and Appendix C of the executed contract. A sample of these contract appendices can be found in Attachment 5 of this RFA.

The contractor will be required to participate in and cooperate with evaluation activities sponsored or conducted by the Program. This may include activities such as:

- on-site monitoring visits; and
- travel to and participation in at least one SCIRB-sponsored meeting or symposium during the contract period.

The contractor will be required to submit separate requests for budget modifications (including all equipment purchases), personnel changes, and requests for carry-forward of funds that were not detailed in the application and its appendix.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the NYS Department of Health. The Department is responsible for the requirements specified herein and for the evaluation of all applications.

B. Question and Answer Phase

All substantive questions must be submitted in writing to the Program via e-mail at scirb@wadsworth.org or fax at (518) 486-2191. To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. Substantive questions will be accepted through the date listed on the cover of this RFA.

Questions of a technical nature can be addressed in writing or via telephone by calling Lani Rafferty, Health Program Administrator 2, Extramural Grants Administration, Wadsworth Center, at (518) 474-7002. Questions are of a technical nature if they are limited to how to prepare the application (e.g., formatting) rather than relating to the substance of the application.

Prospective applicants should note that all clarifications and exceptions, including those relating to the terms and conditions of the contract, are to be raised prior to the submission of an application.

This RFA has been posted on the Department of Health's public website at http://www.nyhealth.gov/funding/. Questions and answers, as well as any updates and/or modifications, will also be posted on the Department of Health's website. All such updates will be posted by the date identified on the cover sheet of this RFA.

C. Letter of Intent

The prospective applicant institution is **required** to submit a Letter of Intent using the form provided in this RFA (Attachment 4). Letters of Intent will be used for the purpose of developing the highest quality review panel in a timely manner. Letters of Intent infer no obligation upon the institution to submit an application in response to this RFA. **However, applications that are not preceded by a Letter of Intent WILL NOT be reviewed.** The Letter of Intent must be must be mailed to the address listed below in Section IV.E. and must be received by the date and time indicated on the cover sheet to this RFA.

A separate Letter of Intent, signed by the PI and applicant institution, is required to be filed for each PI, indicating on the Letter of Intent form, the number of applications the PI intends to file for each mechanism. This information is vital to ensure that the applicant institution is assigned sufficient application identification numbers that are to be used at filing. Letters of Intent that do not have both signatures will be disqualified and will not receive an application number that is required for application submission.

If the designated PI named on the Letter of Intent is changed before the application submission, the applicant institution will notify the Program of this change prior to or at the time of application

submission. An application number is specific to the institution it is assigned to; it cannot be transferred to another institution.

D. Applicant Conference

An applicant conference will not be held for this RFA.

E. How to File an Application

Applications **must be received** at the following address by the date and time posted on the cover sheet of this RFA. Late applications will not be accepted.* It is the applicant's responsibility to see that applications are delivered to Room D350 prior to the date and time specified. Applications for which a Letter of Intent was not received by the specified due date and time will not be accepted.

* Late applications due to a documented delay by the carrier may be considered at the Department of Health's discretion.

Regular Mail Services:
New York State Department of Health
Wadsworth Center
Extramural Grants Administration
Empire State Plaza, Room D350
PO Box 509
Albany, NY 12201-0509

Express Mail Services:
New York State Department of Health
Wadsworth Center
Extramural Grants Administration
Empire State Plaza, Room D350
Dock J – P1 Level
Albany, NY 12237

For detailed content requirements, see Section V, Completing the Application.
Applications should be submitted in a single mailing package that is clearly labeled with the application number assigned by Program staff as well as the name and number of the RFA listed on the cover of this RFA document. Inside the mailing package, a separately sealed package should contain the application, CD-ROM and supporting documents clearly marked with the PI's name, the institution name, and the application number provided by Program staff. Hand deliveries will be accepted but should be in a sealed envelope as described in the previous sentence. Applications WILL NOT be accepted via fax or e-mail.

F. 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 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. Eliminate mandatory requirements unmet by all applicants.

7. If the Department of Health is unsuccessful in negotiating a contract with the selected applicant within an acceptable time frame, the Department of Health may begin contract negotiations with the next qualified applicant(s) in order to serve and realize the best interests of the State.

8. The Department of Health reserves the right to award grants based on geographic or regional considerations to serve the best interests of the State.

G. Term of Contract

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

It is expected that contracts resulting from this RFA will begin on June 1, 2010 and have the following time periods:

- CART Award – up to 4 years
- IDEA Award – up to 2 years
- Postdoctoral Fellowship Award – up to 2 years
- Mentored Research Scientist Development Award – up to 3 years
- Mentored Clinical Scientist Development Award – up to 3 years

H. Payment & Reporting Requirements

1. The State (NYS Department of Health) may, at its discretion based on appropriate justification from the contractor, make an advance payment to a not-for-profit grant contractor in an amount not to exceed 25 percent in the first year only.

2. The grant contractor shall submit quarterly invoices and required reports of expenditures to the State's designated payment office:

   New York State Department of Health
   Wadsworth Center
   Extramural Grants Administration
   Empire State Plaza, Room D350
   PO Box 509
   Albany, NY 12201-0509

   Payment of such invoices by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law. Payment terms will be:

   - The Contractor will be reimbursed for actual expenses incurred as allowed in the Contract Budget and Work Plan.

   - All vouchers submitted by the contractor pursuant to this agreement shall be submitted to the State no later than 30 days after the end of the quarter for which reimbursement is being claimed.

   - Quarterly vouchers will not be paid until all required progress reports are submitted and deemed acceptable by the Program.

   - The final voucher will not be paid until after acceptance of the final annual scientific progress report.

   - In no event shall the amount received by the contractor exceed the amount approved by the State.

3. The grant contractor shall submit the following progress reports:

   - Semi-annual scientific progress reports in accordance with the forms and formats provided by the Program no later than 30 days after the end of each six month reporting period.

   - Annual scientific progress report in accordance with the forms and formats provided by the Program no later than 60 days after the end of the contract term.

All payment and reporting requirements will be detailed in Appendix C of the final grant contract.

I. Vendor Responsibility Questionnaire

New York State Procurement Law requires that state agencies award contracts only to responsible vendors. Vendors are strongly encouraged to file the required Vendor Responsibility Questionnaire online via the New York State VendRep System or may choose to complete and submit a paper questionnaire. To enroll in and use the New York State VendRep System, see the VendRep System Instructions available at www.osc.state.ny.us/vendrep or go directly to the VendRep system online at https://portal.osc.state.ny.us. For direct VendRep System user assistance, the OSC Help Desk may be reached at 866-370-4672 or 518-408-4672 or by email at helpdesk@osc.state.ny.us. Vendors opting to file a paper questionnaire can obtain the appropriate questionnaire from the VendRep website www.osc.state.ny.us/vendrep or may contact the Department of Health or the Office of the State Comptroller for a copy of the paper form. Applicants must complete and submit the Vendor Responsibility Attestation (Attachment 3) and corresponding Vendor Responsibility Questionnaire (if not exempt) prior to contract award.

J. 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, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer phase (Section IV.B.) will be clearly noted in a cover letter attached to the application.

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

5. Provisions Upon Default

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

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

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

K. Appendices

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

APPENDIX A -	Standard Clauses for New York State Contracts
APPENDIX A-1 -	Agency Specific Clauses for all Department of Health Contracts
APPENDIX A-2 -	Spinal Cord Injury Research Board Contract Policy Statement and Conditions
APPENDIX B -	Budget (Sample Format)
APPENDIX C-	Payment and Reporting Schedule
APPENDIX D -	Work Plan
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**:

- **CE-200 --** Certificate of Attestation For New York Entities With No Employees And Certain Out of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; 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**:

- **CE-200 --** Certificate of Attestation For New York Entities With No Employees And Certain Out of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- **DB-120.1** -- Certificate of Disability Benefits Insurance OR
- **DB-155** -- Certificate of Disability Benefits Self-Insurance

V. Completing the Application

A. Application Content and Format

Multiple funding mechanisms may be applied for, provided they are separate and distinct; each should be a separate application.*

*this requirement is part of the Peer Review Panel's evaluation - see Section V.D.

ALL APPLICATIONS SHOULD USE THE FORMS (see Attachment 1 – Forms 1-14) AND FORMATS PRESCRIBED IN THIS SECTION V.A. APPLICATIONS THAT DEVIATE FROM THESE INSTRUCTIONS OR THOSE FOUND ON THE FORMS WILL BE PENALIZED 0.1 POINTS.

Applicants must submit an electronic copy of the application, along with a paper copy. Applications sent in other formats or by fax or e-mail will NOT be accepted.

Electronic files must be submitted on a CD-ROM. The CD-ROM should be clearly labeled with the applicant's name and application number. The CD-ROM should contain:

- **Contractor Forms 1 – 4 in a *single* Microsoft Word (.doc) file;**
- **Contractor Forms 1 – 4 in a *single* Portable Document Format (.pdf) file;**
- **Forms 5 – 14 and all appendix material in a *single* .pdf file of not greater than 12MB; and**
- **Signed Forms 1 (Face Pages for the Contractor and all Subcontractors) in a *single* Portable Document Format (.pdf) file.**

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared. Applicants are strongly encouraged to seek appropriate technical support in the creation of electronic files and to review the electronic files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at http://www.wadsworth.org/extramural/spinalcord//tip_pdfilesize.html. Applicants should also be aware that while color figures may be included, applications may be printed in black and white. Applicants 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 electronic files contain any password protection whatsoever.

The single paper copy of the entire contents of the CD-ROM must be included in the submission, with an original signed face page. The paper copy will be used if the CD-ROM is damaged. The application should be fully collated and unbound. **Additionally, postdoctoral fellowship candidates must include three signed, sealed reference letters with the original paper copy of the application.**

Forms are pre-set with acceptable fonts and margins. Applications should be single-spaced and typed using an 11-12 point font. Smaller font sizes are acceptable for use in tables and figure legends. Where additional continuation pages are needed, margins should equal one inch. The header should contain the principal investigator's last name, first initial and applicant institution name, and should be placed at the top right-hand corner of each page. Each page should be numbered consecutively. **Do not exceed the page limits stated for each section (see below).** Figures and illustrations referenced in the Work Plan are included in the page limits. Appendices may not be used to circumvent page limitations and should be limited to 30 pages.

Page limits for Sections A-D of the Work Plan, including text and figures, are limited to:

1. **CART Awards** – 15 pages
2. **IDEA Awards** – 10 pages
3. **Postdoctoral Fellowship Awards** – 10 pages
4. **Mentored Research Scientist Development Awards** – 10 pages
5. **Mentored Clinical Scientist Development Awards** – 10 pages

The page limit for Section F of the Work Plan, where required, is limited to an additional two pages.

Each content section described below should be provided in the application. Any section that is not applicable should be noted on the form.

Face Page – Form 1

A separate face page will be completed, signed and dated for the applicant institution and each subcontracting institution participating in the project.

Project Title. The title should describe the focus or purpose of the proposed project.

Application Type. Each application should be for a single mechanism/project. Check off the appropriate box for application funding mechanism. Check off New or Revised application. Revised applications must be responsive to the funding mechanism as well as reviewers' comments.

SCIRB Application Number: Enter the SCIRB application number provided to your organization in response to the Letter of Intent filed for this RFA.

Principal Investigator. Provide the information requested. The principal investigator (PI) is the investigator responsible for planning, coordinating and implementing the research program for the institution if an award is made. The PI will be required to fulfill reporting requirements in conjunction with the authorized organizational representative.

Co-Principal Investigator/Mentor. Provide the information requested for the designated Co-PI or Mentor, if applicable.

Type of Organization. Check off appropriate box(es).

Federal Employer 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, (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.

Facilities and Administrative Costs. Provide the information requested to document that the F&A rate does not exceed the rate that would be recovered by applying the applicant organizations' negotiated F&A rate. A copy of the United States Department of Health and Human Services (DHHS) agreement should be included as an application appendix.

Human Subjects. All applications that include any use of human subjects or tissues/fluids from human subjects check 'YES' and include a completed Form 13, *Human Subjects*. In addition,

appropriate assurances must be provided before contract execution.

Vertebrate Animals. All applications that include any use of vertebrate animals or their tissues/fluids check 'YES' and include a completed Form 14, *Vertebrate Animals*. In addition, appropriate assurances must be provided before contract execution.

Human Pluripotent Stem Cells. Applications that include any use of human pluripotent stem cells check 'YES'.

Project Start/End. Report the anticipated project duration of:

June 1, 2010 through May 30, 2014 for CART (Collaborations to Accelerate Research Translation) Awards

June 1, 2010 through May 30, 2012 for IDEA (Innovative, Developmental or Exploratory Activities) Awards

June 1, 2010 through May 30, 2012 for Postdoctoral Fellowship Awards

June 1, 2010 through May 30, 2013 for Mentored Research Scientist Development Awards

June 1, 2010 through May 30, 2013 for Mentored Clinical Scientist Development Awards

Year One Grand Total Costs. Enter Year One Grand Total Costs from Form 6, Line 14.

Grand Total Costs (all years). Enter the Grand Total Costs (all years) from Form 6, Line 14.

New York State Applicant Organization. Enter the legal name and address of the applicant organization.

Research Performing Sites. List all sites (organization and location) where the research described in the Work 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.

Address Where Reimbursement is to be Sent. Many institutions request that payment be sent to locations other than the official mailing address. Provide appropriate information or indicate "N/A".

Principal Investigator/Co-Principal Investigator or Mentor Certification and Assurance. The PI is required to sign and date the form, and the designated Co-PI, if from the same institution, is also required to sign and date the form.

Organization Certification and Acceptance. The organizational representative is required to sign and date the form certifying compliance with all applicable assurances and certifications referenced in this RFA.

Reminder: A separate face page will be completed, signed and dated for the applicant institution and each subcontracting institution participating in the project.

Staff, Collaborators, Consultants and Contributors – Form 2

List the name, title and institutional affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid).

Lay Abstract – Form 3

Provide the information requested on the form, limiting the information to 300 words or less. 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.

Scientific Abstract – Form 4

Provide the information requested on the form, limiting the information to 300 words or less. The abstract should be written so that persons from diverse scientific backgrounds may 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 planned for use, as well as its source.

Table of Contents – Form 5

Complete the table of contents, entering page numbers as appropriate or entering "N/A" when not applicable. Information submitted to SCIRB is subject to the Freedom of Information Law (FOIL) (New York State Public Officers' Law, Article 6, Sections 84 to 90).

To the extent permitted by law, an application will not be disclosed, except for purposes of evaluation, prior to approval by the Comptroller of the resulting contract. All material submitted becomes the property of the Department and may be returned at the Department's discretion. Submitted applications may be reviewed and evaluated by any person, other than one associated with a competing applicant, designated by the Department. Any information supplied by an applicant that is believed to be exempt from disclosure under FOIL will be clearly marked and identified as such upon submission by the applicant. Marking the information as "confidential" or "proprietary" on its face or in the document header or footer shall not be sufficient without specific explanation of the basis for the claim of exemption from disclosure. Acceptance of the claimed materials by the Department does not constitute a determination on the exemption request. A determination of whether such information is exempt from FOIL will be made at the time of any request for disclosure under FOIL in accordance with statutory procedure.

Budget – Form 6

Using the form, report the amount requested for each category, subtotal and total for each year or portion thereof. For any sub-contractual costs, provide additional copies of the form for each subcontract.

<u>Allowable Expenses</u>

1. Personal Service

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

   The maximum stipend to be paid from the Postdoctoral Fellowship award is determined by the number of years since the candidate obtained a postdoctoral degree, and is limited to:

<1 year - $37,500
1 year - $39,500
2 year - $42,250
3 year - $44,000
4 year - $45,500
5 year - $47,500
with 100% professional effort required on this project.

Mentored research scientists and mentored clinician scientists must contribute at least 75% professional effort to the project. IDEA and CART PIs and co-PIs must contribute at least 10% professional effort to the project.

For all grants, salary support for the principal investigator, co-investigators, technical staff, fellows and students 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.

2. Other Than Personal Service

For Postdoctoral Fellowships, these expenses are limited to a maximum of $20,000.

For all types of awards, support may be requested for:

- Supplies
- Equipment
- Travel
- Consultant Costs
- Subcontracts

Support for the following should be listed in “Other Expenses” in the proposed budget:

- Animals and their care
- Core service charges
- Communication
- Meeting registration costs
- Publication expenses

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. During the course of the contract term, prior approval will be required for all equipment purchases that were not detailed in the application and its appendix.

Fees related to patient care costs are not allowed. Tuition is reimbursable only for mentored research and clinical scientist development awards.

3. Facilities and Administrative Costs

F&A support is limited to the percent specified in the RFA. Modified total direct costs consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from modified total direct costs.

If an award is made, F&A costs will be re-calculated from recommended and approved budget amounts. F&A costs will be calculated as the lower of the RFA-specified percentage

of modified total direct costs or the amount recovered using the institution's current DHHS F&A rate. **A copy of the DHHS F&A rate statement should be included in the application appendix**. In the absence of a federal agreement, an equivalently documented rate for the organization may be used. Subcontractor F&A costs are likewise limited, and are to be included in the primary applicant's direct costs.

Personnel Effort and Budget Justification – Form 7

Applicants should request funds appropriate for cost-effective support of the proposed Work Plan and meet the requirements of Section III.A., General Expectations for Each Funding Mechanism. Funds awarded by this program may not be used to supplant other existing support for the same work. Provide the information requested for key personnel and technical staff at the applicant organization, regardless whether financial support is requested. Insert additional lines as necessary. The 'Total Salary + Fringe Requested' amount should equal Line 3, Year One, from Form 6. Follow with additional forms for collaborating or subcontracting institutions.

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

Provide a detailed justification for each 'Other Than Personal Service' (e.g., supplies, equipment, travel, consultant costs and other expenses). In the justification for equipment, describe the necessity for equipment requested, noting the impact on the project if the request is not approved; provide alternative approaches to completing the work proposed without the equipment purchase.

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 Co-PI/Mentor(s)/ advisory committee members, and then include remaining key personnel in alphabetical order.

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.

Other Research Support – Form 10

Provide the information requested regarding all existing and pending research support for the PI and all other key personnel. Applications submitted to the SCIRB should not duplicate other funded research projects. The PI and the contracting organization are responsible for notifying the Program of any changes in funding overlap information.

Work Plan – Form 11

The Work Plan should present 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.

Include timeframes for accomplishing related tasks and meeting established milestones.

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 of 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 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 to use human pluripotent stem cells should clearly indicate in the Work Plan the specific cell line to be used, as well as its source.

E. Literature Cited
References are not counted against Work 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.

F. Career Development and Mentor Commitment (for Postdoctoral Fellowships, Mentored Research Scientist Development and Mentored Clinical Scientist Development Applications)
Provide a detailed outline of the candidate's individualized training plan, including identification of the mentor's time commitment to the PI's development.

Time Line and Collaboration Strategy – Form 12

Complete the table provided. If the application involves an inter-institutional collaboration, describe strategies for information and/or resource exchange to ensure 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.

Human Subjects – Form 13

All applicants will include a completed Form 13*, Human Subjects*. If no Institutional Review Board review is required for this research project, check the box on the form and do not fill out the remainder of the form. If IRB review is required, follow instructions below.

Appropriate oversight and administration of human subjects research projects are essential to the ethical conduct of research.

Certification of Institutional Review Board (IRB) review and approval is not required prior to application review; however, appropriate standard IRB approval form or signed exemption will be required prior to contract award.

If the IRB has not deemed the project to be Exempt prior to submission of the application, the following narrative needs to be submitted as part of the application. **The eight points to be addressed in narrative are presented in full below. APPLICATIONS THAT FAIL TO**

APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE EIGHT POINTS BELOW WILL BE PENALIZED 0.2 POINTS.

1) *Involvement of Human Subjects and Population Characteristics*
Describe the involvement of human subjects as outlined in the Work 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 as participants in clinical research.

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 the capacity of mentally disabled adults. Describe the time frame for requesting and obtaining consent, 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 section of this application.

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

If the proposed research includes a clinical trial intervention, include a subsection labeled *Data and Safety Monitoring* that describes the oversight and monitoring plan to ensure the safety of participants and the validity and integrity of the data obtained. An appropriate plan will be submitted to the applicant's IRB for approval and subsequently to the Program prior to accrual of human participants.

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 may reasonably 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 will document the education they received in the protection of human research participants. For each individual, provide the title and date of the education/training program completed.

Vertebrate Animals – Form 14

All applicants include a completed Form 14*, Vertebrate Animals*. If no vertebrate animal review is required for this research project, check the box on the form and do not fill out the remainder of the form. For those projects using vertebrate animals, follow instructions below.

Appropriate oversight and administration of the use of vertebrate animals is essential to the ethical conduct of research.

Certification of Institutional Animal Care and Use Committee (IACUC) review and approval is not required prior to application review; however, a standard IACUC approval form will be required prior to contract award.

If vertebrate animals or tissues are to be used in the proposed study, Form 14 is required for each participating institution and performance site where they will be used (including the four points listed below) as part of the application. Acquisition and use of animals at all performance sites are required to 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 the Office of Laboratory Animal Welfare or does not have a U.S. Department of Agriculture (USDA) registration number, if required, insert "NONE" in the space provided on Form 14. In this case, the applicant organization, by having their official sign 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 will also register its facility with the USDA.

Succinctly address the following four points on Form 14. **APPLICATIONS THAT FAIL TO APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE FOUR POINTS BELOW WILL BE PENALIZED 0.2 POINTS.**

1) *Description of Proposed Animal Use*
Provide a detailed description of the animal use proposed in the Work Plan, including identification of species, strains, ages, sexes and numbers of animals to be used.

2) *Justification*
Justify the use of animals, the choice of species and the number to be used. If animals are in short supply, costly, or to be used in large numbers, provide additional rationale for their selection and numbers, and include power calculations as justification.

3) *Description of Procedures to Ensure the Discomfort, Distress, Pan and Injury will be Limited*
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) *Description of Any Method of Euthanasia*
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.

B. Revised Applications

Institutions that submitted applications in previous cycles may resubmit applications in this cycle, provided they are consistent with the requirements of the funding mechanisms. The reviewers' comments should be explicitly addressed.

A revised application should request support for research that was reviewed during a previous cycle, but not funded. The "Revised Application" box should be checked on the Face Page. **A revised application must have the same Principal Investigator as the original application,** and when possible, the same title as the original.

If the following requirements in this Section V.B. are not met, the revised application will be rejected: a revision must include a section entitled "Revisions and Comments" immediately preceding the Work Plan. In no more than two pages, this section should summarize the substantial additions, deletions and changes that have been made. It also should include responses to criticisms in the previous review evaluation. This material does not count against the normal page limit for the Work Plan. It is recommended that the Work Plan emphasize any relevant work done since the previous application. Reviewers' comments from the previous application submitted must be included in the appendix of the application. If the applicant cannot locate reviewers' comments, they should contact the Program for assistance.

C. Review & Award Process

1. Review and Scoring

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

Each eligible application will be evaluated by an Independent Scientific Merit Peer Review Panel (the Panel) assigned by the Peer Review Contractor. The Panel members will be selected from among non-New York State experts in the appropriate fields based on the nature of the applications received. The Panel will evaluate each proposal according to specified criteria (see Section V.D.) and will score each criterion except Budget, which will be scored by three representatives from the Panel.

Applications will receive scores from each participating panel member for each evaluation criterion using a scale of 1.0 (high merit) to 5.0 (low merit). The numerical score given each criterion will be multiplied by that criterion's weight (i.e.; 20%). Each panel member's weighted scores for each criterion will be added together to give their individual total score. Panel member's individual total scores are then added together and divided by the number of panel members who voted on the application to give an overall panel score for the application. The overall panel score is translated into an adjectival score, as follows:

Numerical	Adjectival
1.0 – 1.5	Outstanding
1.6 – 2.0	Excellent
2.1 – 2.5	Very Good
2.6 – 3.5	Good
3.6 – 5.0	Fair

The Panel will also consider the appropriateness of the requested project duration, effort and overlap with other resources. The Panel will assess the budget based on the appropriateness of the budget allocations to the accomplishment of the research aims, effort, reasonableness of costs and cost effectiveness. Additionally, the Panel will evaluate the application with regard to

the Contract Policy Statements and Conditions (Contract Appendix A-2).

The Panel will prepare a written summary of each application that includes a description of the application's strengths and weaknesses, note concerns, and may recommend revisions.

The Peer Review Contractor will add penalty points for each application that deviates from the instructions for completion of the application. The Peer Review Contractor will prepare and compile scores, summary statements, lay abstracts, recommendations and comments. Applications with a score ranging from 2.6 to 5.0 will not be considered for funding. For those applications that receive a score of 1.0 to 2.5, the Peer Review Contractor will forward scores, summary statements, lay abstracts, recommendations and comments to the SCIRB.

Funding is available to support approximately two CART, four IDEA, six Postdoctoral Fellowship, one Mentored Research Scientist Development, and one Mentored Clinical Scientist Development awards. The SCIRB will consider each application in rank order up to 2.0 (strongest to weakest score) by funding mechanism/category (e.g., CART, IDEA, etc.), provided funds are available. The SCIRB may reallocate funds between funding mechanisms in consideration of programmatic balance and availability of funds.

If funds are available, all remaining applications with a score of 2.1 to 2.5, regardless of the funding mechanism, will be sorted in rank order. The SCIRB will consider programmatic balance in its recommendation regarding these applications but is not obligated to recommend funding.

All award recommendations made by the SCIRB may be made contingent upon acceptance of revisions to items on which the reviewers noted concerns or recommendations made by the Panel.

The SCIRB will vote on each selected application in compliance with SCIRB bylaws as well as applicable laws and regulations. If an application for which there are available funds is not recommended for funding, the SCIRB will fully justify in writing why the application was not approved.

The SCIRB will then make recommendations for funding to the Commissioner of Health. For applications that are not recommended for funding, the applicant institution and PI will be notified.

Following the award of grants from this RFA, applicants may request a debriefing from the SCIRB Program staff no later than three months from the date of the award announcement. This debriefing will be limited to the positive and negative aspects of the subject application.

2. Award Decisions and Pre-Funding Requirements

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

Following approval by the Commissioner, applicant organizations and PIs recommended for support will receive formal notification in writing.

Prior to contract execution, the Program will require resolution/submission/confirmation of the following items, as relevant to each application:

- Revisions to Work Plan, project duration or budget
- Research funding overlap
- Areas of possible concern with regard to the Contract Policy Statements and Conditions (Contract Appendix A-2)
- Approved Facilities and Administrative Cost Rate

- Postdoctoral Fellowship Awards:
  - Postdoctoral degree by anticipated contract start date
  - Less than three years fellowship experience by anticipated contract start date
  - Less than two years prior training under mentor by anticipated contract start date
  - Proposed project formulated/agreed upon by mentor and candidate
- Mentored Research Scientist Development Award:
  - Postdoctoral degree by anticipated contract start date
- Mentored Clinical Scientist Development awards)
  - Postdoctoral degree by anticipated contract start date

3. Award Announcements

The SCIRB 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 edited and made public.

D. Review Criteria

In addition to the specific criteria delineated in this section for each funding mechanism, the Panel will consider the appropriateness of:

- project duration
- effort
- overlap with other resources
- budget
- Contract Policy Statements and Conditions (Contract Appendix A-2)

The Panel may recommend revisions to the SCIRB based on the above. Awards may be made contingent upon acceptance of revisions to these items.

The following evaluation criteria are considered for scoring:

1. CART Award

Research Plan (45%)

- The originality of the research question(s) and the approach taken in its investigation through a collaborative research effort.
- 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.
- The integration of an inter-disciplinary approach to a coherent hypothesis and specific aims.
- The likelihood of successful completion of the study (feasibility) based on the research design, methods, background and experience of the investigators, the research environment and the availability of resources.
- The Work Plan is required to include at least one translational aim/goal.
- The Work Plan will not include Phase III Clinical Trial or Center
- The Work Plan is responsive to this single funding mechanism.

Translational/Clinical Potential (20%)

- The potential and time needed for the proposed work to contribute to therapeutic applications or treatment strategies and cures for spinal cord injury-induced paralysis or to prevent paralysis following acute injury.

Inter-disciplinary nature of the research team (15%)

- The knowledge, skills, research tools, diversity and experiences of the research team in relation to the scientific, translational/clinical and innovative potential of the work.
- The feasibility and inter-disciplinary nature of the collaboration.
- The extent to which the inter-disciplinary 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.
- Reasonableness of costs and cost effectiveness.

(Note: the entire Panel will review and comment on, but not score, this section. Scores will be given by three representatives of the Panel).

2. IDEA Award

Research Plan (60%)

- The extent to which the project is self-contained, hypothesis-driven research; the project should not be a smaller component of a larger research project, for data collection or incremental or correlative research aims, or for compression of a larger project into a smaller time frame.
- The extent to which basic concept and hypotheses are speculative, exploratory, or develop new paradigms.
- The extent to which the project applies or develops state-of-the-art technologies, methods, tools or resources for spinal cord injury research, or addresses important under- or unexplored areas.
- The innovative and developmental potential of the project, with a focus on exceptionally promising topics.
- The originality of the research question(s) and the approach taken in its investigation.
- The importance of the research questions and their basis in the scientific literature.
- The likelihood of successful completion of the study aims (feasibility) based on the research design, methods, background and experience of the investigators, the research environment and the availability of resources.
- The Work Plan is responsive to this single funding mechanism.

Impact (20%)

- The extent to which the project, if successfully completed, would make an original and important contribution to treatments and cures for spinal cord injury-induced paralysis or to prevent paralysis following acute injury (high-risk/high-reward).
- The likelihood the project will lead to further funding or be translated into practice.

Budget (20%)

- The appropriateness of the budget allocations to the accomplishment of the research aims.
- Reasonableness of costs and cost effectiveness.

(Note: the entire Panel will review and comment on, but not score, this section. Scores will be given by three representatives of the Panel).

3. Postdoctoral Fellowship Award

Candidate and Training (45%)

- The candidate's previous academic and research performance and his/her potential to become an important contributor to the biomedical, behavioral or clinical sciences related to spinal cord injury and cures of spinal cord injury-induced paralyses.

- The value of the proposed training experience as it relates to the candidate's needs in preparing for a career as an independent researcher in the field of spinal cord injury research.
- The quality of the training environment and the qualifications of the mentor(s) to facilitate the proposed research training experience.

Research Plan (35%)

- The potential for the project to address an area of importance to spinal cord injury.
- The originality of the research question(s) and the approach taken in its investigation.
- The importance of the research questions and their basis in the scientific literature.
- The likelihood of successful completion of the study aims (feasibility) based on the research design, methods, background and experience of the investigators, the research environment and the availability of resources.
- The likelihood the project will lead to further funding or be translated into practice.
- The Work Plan is responsive to this single funding mechanism.

Budget (20%)

- The appropriateness of the budget allocations to the accomplishment of the research aims.
- Reasonableness of costs and cost effectiveness.

(Note: the entire Panel will review and comment on, but not score, this section. Scores will be given by three representatives of the Panel).

4. Mentored Research Scientist Development Award

Candidate and Training (45%)

- The candidate's previous academic and research performance and his/her potential to become an independent contributor to the biomedical, behavioral or clinical sciences related to spinal cord injury.
- The value and intensity of the proposed experience as it relates to the candidate's needs in preparation for a career as an independent researcher in the field of spinal cord injury research.
- The quality of the training environment and the qualifications of the sponsor(s) as mentor(s) to facilitate the proposed research training experience.

Research Plan (35%)

- The potential for the project to address an area of importance to spinal cord injury that is new to the candidate or is in an area that will substantially add to the spinal cord injury research capabilities of the candidate.
- The potential for the project to lead to highly productive, independent research.
- The originality of the research question(s) and the approach taken in its investigation.
- The importance of the research questions and their basis in the scientific literature.
- The likelihood of successful completion of the study aims (feasibility) based on the research design, methods, background and experience of the investigators, the research environment and the availability of resources.
- The Work Plan is responsive to this single funding mechanism.

Budget (20%)

- The appropriateness of the budget allocations to the accomplishment of the research aims.
- Reasonableness of costs and cost effectiveness.

(Note: the entire Panel will review and comment on, but not score, this section. Scores will be given by three representatives of the Panel).

5. Mentored Clinical Scientist Development Award

Candidate and Training (45%)

- The candidate's previous academic and research performance and/or his/her potential to become an independent contributor to the biomedical, behavioral or clinical sciences related to spinal cord injury.
- The value and intensity of the proposed experience as it relates to the candidate's needs in preparation for a career as an independent researcher in the field of spinal cord injury research.
- The quality of the training environment and the qualifications of the sponsor(s) as mentor(s) to facilitate the proposed research training experience.

Research Plan (35%)

- The potential for the project to address an area of importance to spinal cord injury that is consistent with the candidate's previous research experience and will substantially add to the spinal cord injury research capabilities of the candidate.
- The potential for the project to lead to highly productive, independent research.
- The originality of the research question(s) and the approach taken in its investigation.
- The importance of the research questions and their basis in the scientific literature.
- The likelihood of successful completion of the study aims (feasibility) based on the research design, methods, background and experience of the investigators, the research environment and the availability of resources.
- The Work Plan is responsive to this single funding mechanism.

Budget (20%)

- The appropriateness of the budget allocations to the accomplishment of the research aims.
- Reasonableness of costs and cost effectiveness.

(Note: the entire Panel will review and comment on, but not score, this section. Scores will be given by three representatives of the Panel).

ATTACHMENT 1

APPLICATION FORMS 1 – 14

FAU # 0806061218

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

2009 Request for Applications

CART (Collaborations to Accelerate Research Translation) Awards
IDEA (Innovative, Developmental or Exploratory Activities) Awards
Postdoctoral Fellowship Awards
Mentored Research Scientist Development Awards
Mentored Clinical Scientist Development Awards

APPLICATION FORMS 1 - 14

Face Page

PROJECT TITLE					
Application Type: CART □ IDEA □□ Postdoctoral Fellowship □ Mentored Research Scientist □ Mentored Clinical Scientist □□				NEW □□ REVISED □□	
SCIRB Application #					
PRINCIPAL INVESTIGATOR *Last Name, First Name, Middle Initial, Degree(s)*			CO-PRINCIPAL INVESTIGATOR/MENTOR *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		
Type of Organization: □ Government □ Nonprofit □ For Profit					
Federal Employer ID # (9 digits):			DUNS Number:		
Charities Registration Number (or "Exempt category"):					
F&A Costs: □ DHHS Agreement Date: _____ □ DHHS Agreement Being Negotiated □ No DHHS Agreement, but rate established (explain and date):					
Human Subjects Yes □ No □□	Vertebrate Animals Yes □ No □□		Human Pluripotent Stem Cells Yes □ No □□		
PROJECT DURATION		YR ONE GRAND TOTAL COSTS		GRAND TOTAL 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		
Address where reimbursement should be sent if contract is awarded (street, MS,PO Box, city, NY, Zip):					
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 to provide the required progress reports if a contract is awarded as a result of this application.					
SIGNATURES OF PRINCIPAL INVESTIGATOR and CO-PI/MENTOR ("Per" not allowed)					
#1 X			DATE:		
#2 X			DATE:		
ORGANIZATION 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's 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
Submit Forms 1-4 together in two formats: one signed PDF file and one Word Document file.

Face Page for Subcontracting Entities

PROJECT TITLE							
Application Type: CART □ IDEA □ Postdoctoral Fellowship □□ Mentored Research Scientist □ Mentored Clinical Scientist □□				NEW □ REVISED □□			
SCIRB Application #							
PRINCIPAL INVESTIGATOR *Last Name, First Name, Middle Initial, Degree(s)*				CO-PRINCIPAL INVESTIGATOR/MENTOR *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			
Type of Organization: □ Government □ Nonprofit □ For Profit							
Federal Employer ID # (9 digits):				DUNS Number:			
Charities Registration Number (or "Exempt category"):							
F&A Costs: □ DHHS Agreement Date: _____ □ DHHS Agreement Being Negotiated □ No DHHS Agreement, but rate established (explain and date):							
Human Subjects Yes □ No □□		Vertebrate Animals Yes □ No □□		Human Pluripotent Stem Cells Yes □ No □□			
PROJECT DURATION		YR ONE GRAND TOTAL COSTS		GRAND TOTAL 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			
Address where reimbursement should be sent if contract is awarded (street, MS,PO Box, city, NY, Zip):							
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 to provide the required progress reports if a contract is awarded as a result of this application.							
SIGNATURES OF PRINCIPAL INVESTIGATOR and CO-PI/MENTOR ("Per" not allowed)							
#1 X DATE:							
#2 X DATE:							
ORGANIZATION 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's 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
Submit all signed Forms 1 for Subcontractors in a single PDF file, along with a Word Document File.

Staff, Collaborators, Consultants and Contributors

List the name, title and institutional affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid). This list is used in identifying conflicts of interest during formulation of the Independent Scientific Merit Peer Review Panel.

Name	Title	Institutional Affiliation	Role on Project

Form 2
Submit Forms 1-4 together in two formats: one signed PDF file and one Word Document file.

Lay Abstract

Present the information requested below in non-technical terms. Use available space to your best advantage; comply with font guidelines.

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.)

Form 3
Not to exceed 300 words. Submit Forms 1-4 together in two formats: one signed .pdf file and one Word document file.

Scientific Abstract
Present the information requested. Use available space to your best advantage; comply with font guidelines.

Research Areas: Identify key words that best describe the research areas addressed in your application. *Sample key words* include: (1) Acute Injury Events and Processes; (2) Regeneration and Development; (3) Reinnervation; (4) Transplantation/Grafting; (5) Intervention and Prosthetics; (6) Translational or Clinical Research or (7) Other – (specify).

Background:

Hypothesis:

Objectives/Aims:

Methods:

Impact on Treatments or Cures for Spinal Cord Injury Paralysis:

List any human pluripotent stem cell lines and the source of such lines:

Form 4
Not to exceed 300 words. Submit Forms 1-4 together in two formats: one signed .pdf file and one Word document file.

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Table of Contents

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

* Indicate "N/A" if not applicable.

Form 5
Not to exceed one page.
.

BUDGET Name of Contractor/Subcontractor_____

	BUDGET CATEGORY	Year One	Year Two	Year Three (CART and Mentored only)	Year Four (CART only)	TOTAL (all years)
PERSONAL SERVICE (PS)						
1	SALARY AND STIPENDS					
	Position (list each to be funded separately)					
	SUBTOTAL Salary & Stipends					
2	FRINGE BENEFITS					
3	**SUBTOTAL PS**					

Form 6
Attach subcontractor budgets using additional copies of Form 6.

OTHER THAN PERSONAL SERVICE (OTPS)						
4	SUPPLIES					
	LAB SUPPLIES					
	OFFICE SUPPLIES					
	SUBTOTAL SUPPLIES					
5	EQUIPMENT					
6	TRAVEL					
7	CONSULTANT COSTS					
8	OTHER EXPENSES					
	ANIMALS AND CARE					
	CORE SERVICE CHARGES					
	COMMUNICATION					
	MEETING REGISTRATION COSTS					
	PUBLICATION EXPENSES					
	SUBTOTAL OTHER EXPENSES					
9	**SUBTOTAL** OTPS (sum of lines 4 through 8)					
10	**TOTAL PS & OTPS** (sum of lines 3 + 9)					
11	**TOTAL SUBCONTRACT COSTS** (sum of line 14 of all subcontractor budgets)					
12	**TOTAL DIRECT COSTS** (sum of lines 10 + 11)					
13	FACILITIES AND ADMINISTRATIVE COSTS					
14	**GRAND TOTAL COSTS** (sum of lines 12 + 13)					

Form 6
Attach subcontractor budgets using additional copies of Form 6.

Personnel Effort and Budget Justification

Key Personnel *				**Dollar Amount Requested (Year One)**		
Name	**Role in Project**	**% of Total Professional Effort****	**Total Salary at Institution**	**Salary Requested**	**Fringe Requested**	**Total $ Requested**
Support Personnel *				**Dollar Amount Requested (Year One)**		
Name	**Role in Project**	**% of Total Professional Effort****	**Total Salary at Institution**	**Salary Requested**	**Fringe Requested**	**Total $ Requested**
Total Salary + Fringe Requested – should equal Year One, line 3, Form 6.						

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

****** professional effort is all professional activities performed, regardless of how or whether the individual receives compensation.

Form 7

Not to exceed two pages per applicant organization. Attach subcontractor Personnel Effort and Budget Justification using additional copies of Form 7.

Describe and justify the key personnel and technical staff.

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

Supplies

Equipment

Travel

Consultants

Other

Form 7

Not to exceed two pages per applicant organization. Attach subcontractor Personnel Effort and Budget Justification using additional copies of Form 7.

Biographical Sketch

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**

A. Positions and Honors. List in chronological order all previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference.

Form 8

Not to exceed two pages per individual. Present the PI first, followed by Co-PI(s) and the remaining key personnel in alphabetical order using additional copies of Form 8.

NAME	POSITION/TITLE

.

Form 8

Not to exceed two pages per individual. Present the PI first, followed by Co-PI(s) and the remaining key personnel in alphabetical order using additional copies of Form 8.

Facilities and Resources

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 available space to your best advantage; comply with font guidelines.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

Form 9

Not to exceed two pages per collaborating institution.

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

Form 9

Not to exceed two pages per collaborating institution.

Other Research Support

Name of Key Personnel: _____

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

TITLE OF PROJECT: ☐ Pending ☐ Active

PROJECT PI:

FUNDING AGENCY/GRANT ID NO.:

PERIOD OF SUPPORT: % Professional Effort ____

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

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

Form 10

Repeat the format presented above for each project. Use additional pages as needed. Present the principal investigator first, followed by Co-PI(s) and the remaining key personnel in alphabetical order.

*For any "Yes" answer, explain the distinction between the project and this application and indicate a possible resolution, if this application is funded.

Work Plan

A. Specific Aims

B. Significance

C. Background and Preliminary Results

D. Research Design and Methods

E. Literature Cited

F. Career Development/Training Plan and Mentor Commitment

Form 11

Follow all page limitations, font and margin requirements.

Form 11

Follow all page limitations, font and margin requirements.

Time Line and Collaboration Strategy

Complete the table below. Also describe strategies for information and/or resource exchange to ensure the efficient and effective completion of the project.

Aim or Sub-aim	Investigator Responsible/ Name of Institution	Specific Activities	Time Frame

Form 12

Follow all font and margin requirements.

Human Subjects

If Institutional Review Board review is not required for this research project, check the box and do not complete below this line. ☐

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

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

Complete separate tables for **ALL** human subjects protocols to be used with the 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 ensure 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 Federal-wide Assurance of Compliance Number: _____

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

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>", date of next review: _____

Repeat table as often as necessary.

If the IRB Approval Status (above) is Pending or Approved, attach a narrative to address the eight points listed below (see Section V.A. Application Content). APPLICATIONS THAT FAIL TO APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE EIGHT POINTS BELOW WILL BE PENALIZED 0.2 POINTS, UNLESS THE PRESENT STATUS OF THE APPROVAL HAS BEEN DEEMED "EXEMPT" BY THE IRB.

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 the Knowledge to be Gained
8. Education

Form 13
Use additional sheets as necessary, following font and margin requirements.

Vertebrate Animals

If vertebrate animal review is not required for this research project, check the box and do not complete below this line. ☐

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

Institution: _____

Public Health Service Agency-wide Assurance Number _____

NYS DOH Certification of Approval for the Use of Living Animals 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>", date of next review: _____

Repeat table as often as necessary.

All applications proposing vertebrate animal research are required to address the four points below. Acquisition and use of animals at all performance sites are required to comply with New York State Public Health Law, Article 5, Title I, Sections 504 and 505-a. **APPLICATIONS THAT FAIL TO APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE FOUR POINTS BELOW WILL BE PENALIZED 0.2 POINTS.**

1. Description of proposed animal use
2. Justification
3. Description of procedures to ensure that discomfort, distress, pain and injury will be limited
4. Description of any method of euthanasia

Form 14
Use additional sheets as necessary, following font and margin requirements.

ATTACHMENT 2

Application Checklist

CART, IDEA, Postdoctoral Fellowship, and Mentored Research and Mentored Clinical Scientist Development Awards

All items are mandatory (Pass/Fail) with the exception of those listed under "Appendices." Applications that do not include mandatory items will not be reviewed.

- Applicant institution filed a letter of intent for the PI by the due date and time and was assigned an application number by the Program
- Application was submitted by due date and time
- Institution is a New York State not-for-profit organization or a governmental organization within New York State that is an academic institution, a research organization, a medical center, or an entity with demonstrated capability to conduct externally funded research
- One electronic (on CD-ROM) and one original paper copy of the application

Revised Applications:

- Same PI as original
- "Revisions and Comments" section immediately preceding Work Plan and no more than two pages, including responses to reviewers' comments
- Reviewers' comments included in appendices

CART Applications:

- Professional effort of PI and Co-PI on the project is at least 10% (see Form 7, '% Professional Effort')

IDEA Applications:

- Professional effort of PI and Co-PI on the project is at least 10% (see Form 7, '% Professional Effort')

Postdoctoral Fellowship Applications:

- Professional effort of the PI/candidate on the project is 100% (see Form 7, '% Professional Effort')
- The paper copy of the application contains three signed and sealed letters of reference

Mentored Research Scientist Applications:

- Professional effort of PI/candidate on the project is at least 75% (see Form 7, '% Professional Effort')

Mentored Clinical Scientist Applications:

- Professional effort of PI/candidate on the project is at least 75% (see Form 7, '% Professional Effort')

Appendices may include:

- Vendor Responsibility Attestation (Attachment 3)
- Completed Vendor Responsibility Questionnaire
- Required documentation relating to the use of test subjects (human or animal) as described in the instructions to the application forms.
- Letters of collaboration or support; commitment(s) to provide research resources; subcontract letter(s) from consultant(s)
- Memoranda of Understanding, Subcontracts or Contractual Agreements
- Up to two highly relevant publications or manuscripts (published or in press) may be included if essential to document the investigator's capability to undertake the work proposed
- Facilities and Administrative rate agreements
- Equipment quotes
- Other

ATTACHMENT 3

Vendor Responsibility Attestation

CART (Collaborations to Accelerate Research Translation), IDEA (Innovative, Developmental or Exploratory Activities), Postdoctoral Fellowship, Mentored Research Scientist Development and Mentored Clinical Scientist Development Awards

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

Choose one:

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

☐ A hard copy Vendor Responsibility Questionnaire is included with this application and is dated within the last six months.

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

Signature of Organization Official: _____

Print/type Name: _____

Title: _____

Organization: _____

Date Signed: _____

ATTACHMENT 5

Sample Contract*

1. Grant Contract
2. Appendix A (Standard Clauses for NYS Contracts)
3. Appendix A-1 (Agency Specific Clauses for all Department of Health Contracts)
4. Appendix A-2 (SCIRB - Contract Policy Statement and Conditions)
5. Appendix B (Budget - Sample Format)
6. Appendix C (Payment and Reporting Schedule)
7. Appendix D (Program Work Plan)
8. Appendix X (Modification Agreement Form)

*** 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 10/08)
_____	APPENDIX B	Budget
_____	APPENDIX C	Payment and Reporting Schedule
_____	APPENDIX D	Program Work Plan
_____	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 ___	_____

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 _____ in the year _____ before me, the undersigned, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is(are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their/ capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____

(Signature and office of the individual taking acknowledgement)

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 covenants 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 AGREEMENT. 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-2.

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.

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 $50,000 (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 $85,000 (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 nor 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 affirms, under penalty of perjury, that its bid was arrived at independently and without collusion aimed at restricting competition. Contractor further affirms 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. 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 NOTIFICATION. (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, 110 State Street, 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- 7th Floor
Albany, New York 12245
Telephone: 518-292-5220
Fax: 518-292-5884
http://www.empire.state.ny.us

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
Telephone: 518-292-5250
Fax: 518-292-5803
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 10/08)

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 certifies 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 Educational 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 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 $500,000 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 $500,000, 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 either 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 $1000 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 and 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 transaction, 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 Transaction,” 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 any 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. Where the STATE does not provide notice to the NOT-FOR-PROFIT CONTRACTOR of its intent to not renew this contract by the date by which such notice is required by Section 179-t(1) of the State Finance Law, then this contract shall be deemed continued until the date that the agency provides the notice required by Section 179-t, and the expenses incurred during such extension shall be reimbursable under the terms of this contract.

12. 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; Any proposed modification to the contract which results in a change of greater than 10 percent to any budget category, must be submitted to OSC for approval;
        - Appendix C - Section 11, Progress and Final Reports;
        - Appendix D - Program Work Plan will require OSC approval.

    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.

13. 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**:

    - **CE-200 -** Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; 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**:

    - **CE-200 --** Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disabilities Benefits Insurance Coverage is Not Required; OR
    - **DB-120.1** -- Certificate of Disability Benefits Insurance OR
    - **DB-155** -- Certificate of Disability Benefits Self-Insurance

14. Contractor shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208). Contractor shall be liable for the costs associated with such breach if caused by Contractor's negligent or willful acts or omissions, or the negligent or willful acts or omissions of Contractor's agents, officers, employees or subcontractors.

15. All products supplied pursuant to this agreement shall meet local, state and federal regulations, guidelines and action levels for lead as they exist at the time of the State's acceptance of this contract.

16. 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

New York State Spinal Cord Injury Research Board
Contract Policy Statement and Conditions
Rev. approved 10/08

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, the contracting organization shall ensure that 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 shall be solely responsible for any violation of these standards. 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.

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning spinal cord injury and the health of such injured persons. 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, unless the research is subject to, and in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.

- 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.

- 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. [1]

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 Spinal Cord Injury 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).

[1] 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.

D. Tissue

SCIRB will support research using human tissue and require 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, 42 USC Section 289g et seq.; Public Health Law 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 10 NYCRR Part 52. 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 through its sponsorship be disseminated and made easily available to the research community and the lay public. Manuscript submission for publication of research funded by the Spinal Cord Injury Research Trust Fund shall not 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. Publication should not be delayed for commercial or other reasons beyond the editorial period needed to ensure scientific accuracy and presentation.
    a. All publications reporting research supported by SCIRB funds published in peer reviewed journals must be deposited in the National Institutes of Health National Library of Medicine's PubMed Central (PMC). SCIRB encourages investigators to sign copyright agreements that specifically allow the published manuscript to be deposited for public posting on PMC. As investigators are encouraged to publish SCIRB-funded research findings as "open access" publications, contract funds may be used to cover costs required for such "open access" publication.
    b. An electronic copy of each such publication must be filed with the progress report pursuant to the contract.
    c. Within 60 days of publication, the investigator must submit to SCIRB Program administrators a 500 word abstract of the publication suitable for the general public, highlighting the research findings. A full literature citation and a brief biographical sketch of the SCIRB-funded Principal Investigator must also be submitted. This information will be made available to the public through the SCIRB website.
    d. Support by the Spinal Cord Injury Research 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 Spinal Cord Injury Research Trust Fund through New York State Department of Health Contract # <<>>. Opinions expressed here 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."

2. It is SCIRB's intent that the resources, materials and methods created through its sponsorship be disseminated and made easily available to the research community. All such materials described in invention disclosures, publications, or other public forums shall be made available to requesting investigators. The contractor may collect reasonable costs for provision of such resources and may require execution of appropriate material transfer agreements, licenses, or confidentiality agreements (see paragraph #4, below).

3. With regard to SCIRB funded research, where the grantee organization has not made reasonable efforts to protect the property interests or because the grantee has failed to share the research developments, the State shall retain march-in rights. The State shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, for research and governmental purposes only, any

published or otherwise reproducible material, device, invention, technique, material, 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.

4. The contractor must have written agreements with researchers requiring prompt disclosure of inventions made in the performance of SCIRB-funded research. Within 60 days of such disclosure the contractor shall notify SCIRB Program staff of the invention disclosure. The contractor shall notify SCIRB Program staff upon the filing of any patent application in the progress report pursuant to the contract. The contractor shall provide SCIRB Program staff with advance written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Spinal Cord Injury Research Trust Fund. Any such assignment or transfer must acknowledge, and be subject to the rights retained by the State pursuant to the above paragraph #2.

   Assignment and ownership allocation of intellectual and industrial property rights generated from research supported by the 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 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.

5. Contractor agrees, pursuant to the provisions of the New York State Administrative Procedure Act relating to access to data, added by Chapter 647 of the Laws of 1999, and Chapter 229 of the Laws of 2000, 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 law.

F. Reporting Requirements

Scientific/Technical and Financial Reports shall be submitted as provided in Appendix C.

G. Equipment

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. During the course of the contract term, prior approval will be required for all equipment that was not detailed in the application and its appendix.

Equipment may not be purchased within ninety (90) days of contract termination.

Upon satisfactory completion of the contract, as determined by the State Department of Health, all equipment purchased hereunder may be retained by the contractor.

H. Other Information

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

2. Appendix B (Budget) 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. Neither the Department of Health nor the State of New York will assume any responsibility for any damage or injuries caused or resulting from research conducted with the financial support of the Fund.

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

6. 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 this Grant Contract, the authorized representative of the 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. *Vertebrate 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.

   b. *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.

   c. *Conflict of Interest*
      - 42 CFR 50, Subpart F, “Responsibility of applicants for promoting objectivity in research for which PHS funding is sought.”

7. The Department of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight.

8. Fees related to patient care costs are not reimbursable expenses. Tuition reimbursement is not an allowable expense for the CART, IDEA and Postdoctoral Fellowship awards.

APPENDIX B

Budget (Sample Format)

Name of Contractor/Subcontractor_____

	BUDGET CATEGORY	Year One	Year Two	Year Three (CART and Mentored only)	Year Four (CART only)	TOTAL (all years)
PERSONAL SERVICE (PS)						
1	SALARY AND STIPENDS					
	Position Title (separately list each position to be funded, indicating if position is vacant)					
	SUBTOTAL Salary & Stipends					
2	FRINGE BENEFITS					
3	**SUBTOTAL PS**					

OTHER THAN PERSONAL SERVICE (OTPS)						
4	SUPPLIES					
	LAB SUPPLIES					
	OFFICE SUPPLIES					
	SUBTOTAL SUPPLIES					
5	EQUIPMENT					
6	TRAVEL					
7	CONSULTANT COSTS					
8	OTHER EXPENSES					
	ANIMALS AND CARE					
	CORE SERVICE CHARGES					
	COMMUNICATION					
	MEETING REGISTRATION COSTS					
	PUBLICATION EXPENSES					
	SUBTOTAL OTHER EXPENSES					
9	**SUBTOTAL OTPS (sum of lines 4-8)**					
10	**TOTAL PS & OTPS** (lines 3 + 9)					
11	**TOTAL SUBCONTRACT COSTS** (line 14 of subcontractor budgets)					
12	**TOTAL DIRECT COSTS** (sum of lines 10 + 11)					
13	FACILITIES AND ADMINISTRATIVE COSTS					
14	**GRAND TOTAL COSTS** (sum of lines 12 + 13)					

APPENDIX C

Payment and Reporting Schedule
Rev. approved 5/08

CART (Collaborations to Accelerate Research Translation), IDEA (Innovative, Developmental or Exploratory Activities), Postdoctoral Fellowship, Mentored Research Scientist Development and Mentored Clinical Scientist Development Awards

I. Payment and Reporting Terms and Conditions

A. The State (NYS Department of Health) 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 25 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 setoff 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 the 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 Work Plan, 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 60 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.

   Progress Reports shall be submitted via e-mail as MS Word attachments. Documents should be single-spaced, in Arial 12 font or similar. Tables, graphs, photographs, etc. should be sent as separate .bmp or .tif files attached to the e-mail. Publications, abstracts and other products resulting from Fund support during the reporting period should be attached as .pdf file to the e-mail. All reports and forms are to be sent to scirb@wadsworth.org. The contract number and report being submitted shall be identified on the subject line of the e-mail (i.e., Contract # <<>>, Progress Report).

F. The CONTRACTOR shall submit to the STATE 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:

   NYS Department of Health
   Wadsworth Center, Room D350
   Extramural Grants Administration
   Empire State Plaza
   PO Box 509
   Albany, NY 12201-0509

   All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than thirty (30) days after the end date of the period for which reimbursement is claimed (see Table I for annual schedule). 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.

G. If the CONTRACTOR is eligible for an annual cost of living adjustment (COLA), enacted in New York State Law, that is associated with this grant AGREEMENT, payment of such COLA shall be made separate from payments under this AGREEMENT and shall not be applied toward or amend amounts payable under Appendix B of this AGREEMENT.

   Before payment of a COLA can be made, the STATE shall notify the CONTRACTOR, in writing, of eligibility for any COLA. The CONTRACTOR shall be required to submit a written certification attesting that all COLA funding will be used to promote the recruitment and retention of staff or respond to other critical non-personal service costs during the State fiscal year to which the cost of living adjustment was allocated, or provide any other such certification as may be required in the enacted legislation authorizing the COLA.

II. Progress and Final Reports

A. Semi-Annual Progress Report

The CONTRACTOR shall submit a semi-annual progress report using the forms and formats as provided by the Program (found online at http://www.wadsworth.org/extramural/spinalcord.htm), summarizing the work performed during the period (see Table I for schedule). These reports shall detail the CONTRACTOR's progress toward attaining the specific aims enumerated in the Work Plan (Appendix D).

Progress Reports shall be submitted via e-mail as MS Word attachments. Documents should be single-spaced, in Arial 12 font or similar. Tables, graphs, photographs, etc. should be sent as separate .bmp or .tif files attached to the e-mail. Publications, abstracts and other products resulting from Fund support during the reporting period should be attached as .pdf file to the e-mail. All reports and forms are to be sent to scirb@wadsworth.org. The contract number and report being submitted shall be identified on the subject line of the e-mail (i.e., Contract # <<>>, Progress Report).

B. Expenditure Reports

The CONTRACTOR shall submit a detailed expenditure report by object of expense in the forms and formats as provided by the Program (found online at http://www.wadsworth.org/extramural/spinalcord.htm) which shall accompany the voucher submitted for each period (see Table I for annual schedule). Documentation of all expenses shall be available upon request. The STATE may require documentation of expenses before payment of any voucher. No vouchers shall be paid until the corresponding progress report is received and approved pursuant to this AGREEMENT.

The CONTRACTOR shall submit all budget modification requests to the STATE for approval. All budget modification requests must be approved by the STATE prior to the commitment and expenditure of funds. All final budget modification requests must be submitted prior to the end of the budget period.

The CONTRACTOR shall submit the final voucher for the budget period no later than sixty (60) days after the end date of the budget period. The final voucher must be marked as "Final."

In no case shall the final voucher for the contract be paid prior to the submission of the final progress report.

TABLE I

Voucher / Report	Period Covered	Due Date
Voucher 1	June 1 – August 31	September 30
Voucher 2	September 1 – November 30	December 31
Semi-Annual Report 1	June 1 – November 30	December 31
Voucher 3	December 1 – February 28	March 31
Voucher 4	March 1 – May 31	June 30
Semi-Annual Report 2	December 1 – May 31	June 30
Final Report	Entire Contract Period	Contract end date + 60 days*

*The Final Report is due 60 days after the contract end date. If a contract extension is granted, the contractor must continue to follow the Semi–Annual Progress Report schedule as described above AND file the Final Progress Report as described below after the end of the contract extension.

C. Final Progress Report

The CONTRACTOR shall submit a detailed comprehensive final progress report not later than 60 days from the end of the contract, summarizing the work performed during the entire contract period, in the forms and formats as provided by the Program (found online at http://www.wadsworth.org/extramural/spinalcord.htm). The final report shall be accepted in lieu of the last semi-annual report.

APPENDIX D

PROGRAM WORK PLAN

[The final Work Plan approved at the time of the award will be inserted here in the final contract document.]

APPENDIX X

Modification Agreement Form
AGENCY CODE 12000

Contract Number:_____ Contractor:_____

Amendment Number X-_____

This is an AGREEMENT between THE STATE OF NEW YORK, acting by and through NYS Department of Health, having its principal office at Albany, New York, (hereinafter referred to as the STATE), and _____ (hereinafter referred to as the CONTRACTOR), for amendment of this contract.

This amendment makes the following changes to the contract (check all that apply**):**

_____ Modifies the contract period at no additional cost

_____ Modifies the contract period at additional cost

_____ Modifies the budget or payment terms

_____ Modifies the work plan or deliverables

_____ Replaces appendix(es) _____ with the attached appendix(es)_____

_____ Adds the attached appendix(es) _____

_____ Other: (describe) _____

This amendment *is__ is not__* a contract renewal as allowed for in the existing contract.

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

Prior to this amendment, the contract value and period were:

$_____ From ___/_____/____ to ____/____/_____.
(Value before amendment) (Initial start date)

This amendment provides the following addition (complete only items being modified):

$_____ From ___/_____/____ to ____/____/_____.

This will result in new contract terms of:

$ _____ From ___/_____/____ to ____/____/_____.
(All years thus far combined) (Initial start date) (Amendment end date)

Ver. 12/13/07

Signature Page for:

Contract Number:_____ Contractor:_____

Amendment Number: X-_____

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

CONTRACTOR SIGNATURE:

By:_____ Date: _____
(signature)

Printed Name:_____

Title:_____

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

On the _____ day of _____ in the year _____ before me, the undersigned, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is(are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their/ capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
(Signature and office of the individual taking acknowledgement)

STATE AGENCY SIGNATURE

"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."

By:_____ Date:_____
(signature)

Printed Name:_____

Title:_____

ATTORNEY GENERAL'S SIGNATURE

By:_____ Date:_____

STATE COMPTROLLER'S SIGNATURE

By:_____ Date:_____

Ver. 12/13/07