

FAU # 0708160112

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

2008 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

Issued 10/31/07

LETTER OF INTENT DUE: 11/30/07

QUESTIONS DUE: 12/5/07

QUESTIONS, ANSWERS AND UPDATES POSTED: 12/14/07

APPLICATIONS DUE: 1/2/08 by 4:00 PM

ESTIMATED CONTRACT START DATE: 10/01/08

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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/new/rfa/scirb/index.htm>

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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 2006 SCIRB Annual Report can be found at <http://www.wadsworth.org/new/rfa/index.htm>.

This RFA reflects the SCIRB's intention to issue awards for each eligible grant mechanism on a consistent basis in order to stabilize program expenditures and provide the opportunity for continued scientific progress. Specifically, the SCIRB desires to issue this RFA each year 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.

B. Research Topic Areas

The SCIRB welcomes basic, clinical and translational neurological research applications on topics bearing on its mission to reverse paralysis and restore function, or to minimize and prevent damage occurring during the acute phase of injury, and is especially interested in receiving translational and clinical research applications.

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 progenitor cells, adult stem cells or human embryonic stem cells are also welcome. Applicants are encouraged to review awards from the Program's previously funded studies at <http://www.wadsworth.org/new/rfa/index.htm>

C. Grant Mechanisms

The estimated contract start date is 10/01/08. 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 grants mechanism is to foster the translation of results from basic (preclinical) research into the next research phase by supporting synergistic partnerships of scientific disciplines and/or organizations. This mechanism is expected to contribute to the more rapid translation of basic science findings to potential therapeutic applications or clinical research through novel or innovative treatment strategies.
 - Duration of four years.
 - Annual **direct costs** are capped at \$300,000.

- 2. Innovative, Developmental or Exploratory Activities (IDEA) Award**
 - The intent of the IDEA awards is to provide initial support for preliminary testing of novel or high-risk hypotheses related to spinal cord injury. 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, or that the project's results can be integrated rapidly into policy or practice in New York State.
 - Duration of two years.
 - Annual **direct costs** are capped at \$150,000.

- 3. Postdoctoral Fellowship Award**
 - The intent of the Postdoctoral Fellowship awards 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.
 - Duration of two years.
 - Each fellow's stipend shall be based upon the number of years' experience of the postdoctoral candidate (see Section V.A. Budget – Form 6).
 - Annual **direct costs**, in excess of stipend amount, are capped at \$20,000.

- 4. Mentored Research Scientist Development Award**
 - The intent of the Mentored Research Scientist Development awards is to underwrite the transition of neuroscientists into SCI research careers in New York State institutions.
 - Duration of three years.
 - Annual **direct costs** are capped at \$200,000.

- 5. Mentored Clinical Scientist Development Award**
 - The intent of the Mentored Clinician Scientist Development awards is to underwrite the transition of clinicians into SCI research careers in New York State institutions.
 - Duration of three years.
 - Annual **direct costs** are capped at \$200,000.

Current CART Principal Investigators may apply to this RFA for consideration of scientific merit for the purpose of continuing a research project presently funded under a current CART award. Current recipients of an IDEA award, Postdoctoral Fellowship award, or Mentored Research or Clinical Scientist Development award are not eligible to apply for continued funding of any such existing contract.

D. 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. The amount of funds awarded will be contingent upon the quality of applications submitted. The amount of funds for each mechanism has not been pre-determined.

E. Definitions

The term "innovative" is defined as:

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

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

The term “inter-disciplinary” is used to indicate the integration of conceptual and methodological viewpoints not normally brought together.

II. Who May Apply?

A. Institutional Eligibility

Applications must be submitted by New York State not-for-profit organizations on behalf of a New York State-based principal investigator and research team. The applicant institution may be any not-for-profit organization, including an academic institution, research organization, public or private organization, medical center or other entity with demonstrated capability to conduct grant funded research. Organizations awarded funds must have the ability to monitor funds, maintain individual accounts and fulfill other fiscal management criteria. Unaffiliated individuals are ineligible to apply for awards. Collaborations between New York State and non-New York State researchers are encouraged. Subcontracting organizations need not be not-for-profit. Applicants may submit more than one application provided they are scientifically distinct. However, no more than one award for the same grant mechanism will be made to the same laboratory or clinic, although more than one may be made to the same institution.

For all mentored awards (fellowships, clinical scientist and research scientist) the institution will be able to demonstrate a commitment to development of the candidate as a productive, independent investigator, and have qualified faculty to serve as mentors. In addition, the applicant institution for all clinical scientist development and research scientist development awards will have a well-established curative (non-rehabilitative) spinal cord injury research and clinical career development program.

B. Principal Investigator (PI) Eligibility

Individuals with a doctoral-level degree (e.g., Ph.D., M.D., D.V.M, Psy.D., Ed.D., etc.) of any nationality or citizenship status may apply as principal investigators. The SCIRB is also interested in applications from established investigators new to the field, from junior researchers, and from those in disciplines that have not historically focused on SCI. Junior investigators are encouraged to partner with established investigators. Women and minorities are encouraged to apply.

1. CART Award

PI's/Co-PI's must each commit at least 10 percent FTE research effort to the project.

2. IDEA Award

There are no additional requirements.

3. Postdoctoral Fellowship Award

The Postdoctoral Fellow must have earned a doctoral-level degree (e.g., Ph.D., M.D., D.V.M, Psy.D., Ed.D., etc.) by the award start date. Fellowship nominees 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 may have more than one sponsor to enhance training, but only one sponsor of record is permitted. Applications from nominees with more than three years total fellowship experience by the expected start date of the award will not be accepted. For purposes of this application, the fellow will be considered the principal

investigator and must commit 100 percent full time equivalent (FTE) effort to the research project.

4. Mentored Research Scientist Award

The Mentored Research Scientist Development award (K01-like 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 must be able to 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 must be in a research area new to the applicant and/or one in which an additional supervised research experience will substantially add to the research capabilities of the applicant. The candidate must provide a plan for achieving independent research support by the end of the award period. For purposes of this application, the mentored research scientist will be considered the principal investigator.

Candidates for the Mentored Research Scientist Development awards must have a research or health-professional doctorate or its equivalent by the award start date and, at the time of application, and must have demonstrated the capacity or potential for highly productive independent research in the period after the doctorate. The candidate must identify a mentor with extensive research experience. The candidate must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development during the entire award period. The candidate must clearly describe the need for intensive research supervision for a period lasting three years leading to research independence.

5. Mentored Clinical Scientist Award

The Mentored Clinical Scientist Development Award (K08-like award) provides support for the development of outstanding clinician research scientists. This mechanism provides specialized study for individuals with a health professional doctoral degree committed to a career in laboratory or clinical research. Candidates must have the potential to develop into independent investigators. The award supports a three year period of supervised research experience that may integrate didactic studies with laboratory or clinically-based research. The proposed research must have intrinsic research importance as well as serving as a suitable vehicle for learning the methodology, theories, and conceptualizations necessary for a well- trained independent researcher. For purposes of this application, the mentored clinical scientist will be considered the principal investigator.

Candidates for the Mentored Clinical Scientist Development awards must have a clinical doctoral degree or its equivalent by the award start date. Illustrative examples include, but are not limited to: M.D., D.D.S., D.M.D., D.O., O.D., D.V.M. or Pharm.D. Individuals with the Ph.D. or other doctoral degrees in clinical disciplines (such as clinical genetics) are also eligible. The candidate must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development during the entire award period. The candidate must be able to identify a mentor with extensive translational or clinical research experience.

III. Project Narrative/Workplan Outcomes

A. General Expectations for Each Grant Mechanism

1. Collaborations to Accelerate Research Translation (CART) Award

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

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. The proposed project should be inter-disciplinary, cohesive, and sharply focused. The translational aspect may involve either animal or human studies. The research may be fundamental or applied or an integrated combination of the two approaches. Also eligible are applications that seek to apply knowledge gleaned from lower order mammals to appropriate non-human primate models. The research team must make explicit how results will facilitate transition to the next research stage, (e.g., preclinical or clinical research).

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

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

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

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

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

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

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

Responsive applications include those considered highly speculative, exploratory, or high-risk that may not have pilot data, but that have the potential for high scientific payoff. Also encouraged are proposals seeking to apply or develop state-of-the-art technologies, tools or resources for SCI research. Additionally welcomed are innovative, developmental projects that focus on exceptionally promising topics and have some pilot data, but are not yet sufficiently mature to compete successfully for funding for a full-scale study.

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

Researchers who are testing new hypotheses on spinal cord injury that are based on research grounded in a non-spinal cord injury research area may also apply.

3. Postdoctoral Fellowship Award

The proposed research project must be formulated and agreed upon by the sponsor and the candidate, and described in detail in the application. **Postdoctoral fellowship candidates must include three signed, sealed reference letters with the original copy of the application.**

To encourage new or cross-disciplinary approaches to curative spinal cord injury research, fellowship sponsors 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. Mentors with less than five years in their first permanent position are asked to identify a more senior collaborator as co-mentor. Mentors may support more than one fellowship application; however, only one award will be made per mentor. Candidates may choose more than one mentor to enhance the training experience, but only one mentor of record is permitted. Candidates must devote 100 percent effort to the project.

4. Mentored Research Scientist Award

The proposed research project must be formulated and agreed upon by the sponsor and the candidate, and described in detail in the application. The mentor must provide an outline or summary of the training to be provided to the candidate and include the approximate amount of time to be devoted working with the trainee.

At least 75 percent of the recipient's full-time professional effort must be devoted to the goals of this award. 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 must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the career goals of the candidate.

Because of the focus on progression to independence as a researcher, candidates for the award should propose a period of study and career development consistent with her or his previous research experience. For example, a candidate with limited experience in the proposed field of research may find a phased developmental program lasting three years that includes a designated period of didactic training followed by a period of closely supervised research experience the most efficient means of attaining independence. A candidate with previous research experience in a related field may not require extensive additional didactic preparation and a program that focuses on an intensive, supervised research experience may be appropriate. All programs must be tailored to meet the individual needs of the candidate ensuring that he/she will gain the skills and knowledge necessary to carry out high-quality spinal cord injury-related research. The candidate and the mentor are jointly responsible for the preparation of the plan for this program. The mentor may form an advisory committee to assist with the development of a program of study or to monitor the candidate's progress through the career development program.

Candidates must name a primary mentor, who together with the applicant is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished investigator in the spinal cord injury field and have a track record of success in training independent investigators. The mentor should have sufficient independent

research support to cover the costs of the proposed research project in excess of the allowable costs of this award. Candidates may also nominate co-mentors as appropriate to the goals of the program.

5. Mentored Clinical Scientist Award

The proposed research project must be formulated and agreed upon by the sponsor and the candidate, and described in detail in the application. The mentor must provide an outline or summary of the training to be provided to the candidate and include the approximate amount of time to be devoted working with the trainee.

At least 75 percent of the recipient's full-time professional effort must be devoted to the goals of this award. 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 must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the career goals of the candidate.

Because of the focus on progression to independence as a researcher, candidates for the award should propose a period of study and career development consistent with her or his previous research experience. For example, a candidate with limited experience in the proposed field of research may find a phased developmental program lasting three years that includes a designated period of didactic training followed by a period of closely supervised research experience the most efficient means of attaining independence. A candidate with previous research experience in a related field may not require extensive additional didactic preparation and a program that focuses on an intensive, supervised research experience may be appropriate. All programs must be tailored to meet the individual needs of the candidate ensuring that he/she will gain the skills and knowledge necessary to carry out high-quality spinal cord injury-related research. The candidate and the mentor are jointly responsible for the preparation of the plan for this program. The mentor may form an advisory committee to assist with the development of a program of study or to monitor the candidate's progress through the career development program.

Candidates must name a primary mentor, who together with the applicant is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished clinical researcher in the spinal cord injury field and have a track record of success in training independent investigators. The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award. Candidates may also nominate co-mentors as appropriate to the goals of the program.

B. Use of Funds for Each Grant Mechanism

1. CART

Funds should be budgeted for:

- Travel to New York City to present project results to the SCIRB
- Travel to participate at one national scientific meeting

Remaining funds may be applied to other allowable costs, e.g., salary, fringe benefits and purchase of research supplies (see budget instructions in section V.A. Form 6, Budget.)

Facilities and Administration costs are limited to 20 percent of total project costs.

2. IDEA

Funds should be budgeted for:

- Travel to New York City to present project results to the SCIRB
- Travel to participate at one national scientific meeting

Remaining funds may be applied to other allowable costs, e.g., salary, fringe benefits and purchase of research supplies (see budget instructions in section V.A. Form 6, Budget.)

Facilities and Administration costs are limited to 20 percent of total project costs.

3. Postdoctoral Fellowship

Fellowship funding is provided to the host institution, except as otherwise noted. A Postdoctoral Fellowship consists of a stipend, a travel allowance, and research related expenses.

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.

Basic and clinical research fellows are to participate in their proposed training full-time. Research clinicians must restrict clinical duties to those directly related to the research training experience.

Funds should be budgeted for:

- Travel to New York City to present project results to the SCIRB
- Travel for the fellow to participate at one national scientific meeting

Remaining funds may be applied to other allowable costs, e.g., fringe benefits and purchase of research supplies (see Section V.A. Budget as above). **Note: the SCIRB expects the sponsor, the institution or other external funding source(s) to contribute to the cost of supplies and other expenses for each fellow's research project.**

Facilities and Administration costs are limited to eight percent of modified total direct costs and, if waived, may be used to supplement the fellow's stipend.

4. Mentored Research Scientist Award

Funding is provided 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 must be consistent both with 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 must be appropriately related to the existing salary structure. Salary limits on career awards are not uniform and are determined independently. Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

Funds may also be used for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; (d) statistical and computational services

including personnel and computer time. All expenses must be directly related to the proposed research career development program.

In addition, funds should be budgeted for:

- Travel to New York City to present project results to the SCIRB
- Travel to participate at one national scientific meeting

Remaining funds may be applied to other allowable costs, e.g., fringe benefits and purchase of research supplies (see Section V.A. Form 6, Budget).

Facilities and Administration costs are limited to 8 percent of modified total direct costs.

5. Mentored Clinician Scientist Award

Funding is provided 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 must be consistent both with 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 must be appropriately related to the existing salary structure. Salary limits on career awards are not uniform and are determined independently. Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

Funds may also be used for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; (d) statistical and computational services including personnel and computer time. All expenses must be directly related to the proposed research career development program.

In addition, funds should be budgeted for:

- Travel to New York City to present project results to the SCIRB
- Travel to participate at one national scientific meeting

Remaining funds may be applied to other allowable costs, e.g., fringe benefits and purchase of research supplies (see Section V.A., Form 6, Budget).

Facilities and Administration costs are limited to 8 percent of modified total direct costs.

C. Reporting Obligations

Institutions must submit annual financial reports and scientific progress reports in accordance with the forms and formats provided by the Program.

All publications, abstracts, and posters resulting from the recipient's work are to include the following acknowledgement: "This research was supported by a Spinal Cord Injury Research grant from the New York State Department of Health, contract # ____."

A portable document format (PDF) of each final publication should be included with the annual progress report.

Contractors are required to present research findings at a minimum of one SCIRB-sponsored meeting or symposium during the term of the contract. Contractors will participate in and cooperate with evaluation activities sponsored or conducted by the SCIRB. In addition, Program staff and/or selection committee members will conduct at least one evaluation/site visit over the course of the award period.

Institutions are to submit separate requests for budget modifications, personnel changes, and for equipment purchases over \$5,000.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the NYS Department of Health Wadsworth Center. 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 Spinal Cord Injury Research Board program administrators via e-mail at scirb@wadsworth.org or fax at (518) 402-5540. 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 Bonnie Jo Brautigam, Program Director, Wadsworth Center, at (518) 473-5217. 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.

If prospective applicants would like to receive notification when updates/modifications are posted (including responses to written questions received), please complete and submit a letter of interest (see Attachment 2). Prospective applicants may also use the letter of interest to request hard copy documents containing update information. **Submission of a letter of interest is not a requirement for submitting an application.**

C. Applicant Conference

An Applicant Conference will not be held for this RFA.

D. 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 C345 prior to the date and time specified. 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
NYS Spinal Cord Injury Research Board
Empire State Plaza, Room C345
PO Box 509
Albany, NY 12201-0509

Express Mail Services:
New York State Department of Health
Wadsworth Center
NYS Spinal Cord Injury Research Board
Empire State Plaza, Room C345
Dock J – P1 Level
Albany, NY 12201-0509

For detailed content requirements, see Section V, Completing the Application. Application packages should be clearly labeled with the name and number of the RFA as listed on the cover of this RFA document. Applications WILL NOT be accepted via fax or e-mail.

E. 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.

F. 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 10/1/08 and have the following time periods:

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

G. Payment & Reporting Requirements

1. The State (NYS Department of Health) will not make advance payment on contracts resulting from this RFA.

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
NYS Spinal Cord Injury Research Board
Empire State Plaza, Room C345
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 Workplan.
- 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.
- 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 periodic 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 the six month reporting period.
- Annual scientific progress report no later than 60 days after the end of the project.

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

H. Vendor Responsibility Questionnaire

New York State Procurement Law requires that state agencies award contracts only to responsible vendors. Vendors are invited 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 also complete and submit the Vendor Responsibility Attestation (Attachment 4).

I. 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.) must be clearly noted in a cover letter attached to the application.
4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.
5. Provisions Upon Default
 - a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.
 - b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
 - c. If, in the judgment of the Department 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.

J. Appendices

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

APPENDIX A - Standard Clauses for All New York State Contracts

APPENDIX A-1 - Agency Specific Clauses

APPENDIX A-2 - Program Specific Clauses

APPENDIX B - Budget

APPENDIX C- Payment and Reporting Schedule

APPENDIX D - Workplan

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

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

- **WC/DB-100**, Affidavit For New York Entities 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
- **C-105.2** -- Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the U-26.3; OR
- **SI-12** -- Certificate of Workers' Compensation Self-Insurance, OR **GSI-105.2** -- Certificate of Participation in Workers' Compensation Group Self-Insurance

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

- **WC/DB-100**, Affidavit For New York Entities 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

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

V. Completing the Application

A. Application Content

Applications must be submitted as a Microsoft Word document (DOC) file or a Portable Document Format (PDF) file on a CD-ROM. All related materials and appendices must be included as part of a single application file. The CD-ROM should be clearly labeled with the applicant's name and address.

Please note that if the RFA and forms were not downloaded from <http://www.wadsworth.org/new/rfa/scirb/index.htm> and the applicant is uses printed copies of required forms, those forms will need to be scanned into the Microsoft Word DOC file or PDF file.

Applications are ONLY accepted as a Microsoft Word DOC or PDF file on CD-ROM. Applications sent in other formats or by fax or email will NOT be accepted.

Applicants are advised to seek appropriate technical support from their institutions in the creation of the files for submission. Some materials, such as letters of support and publication reprints may require scanning and insertion into the file. Discretion should be exercised in the resolution for scanning such materials and figures for inclusion in the application. Excess resolution will increase the size of the file without any appreciable increase in viewing quality when viewed on a computer screen or printed. Applicants should also be aware that while color figures may be included, applications are printed in black and white, and will not be reproduced in color. 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 the files contain any password protection whatsoever. During processing for review the sections of the application must be able to be saved as separate files, and it may be necessary to append additional information such as a cover sheet to the document.

Applicants are strongly encouraged to review their final file prior to submission. It is the applicant's responsibility to ensure that all materials to be included in the application have been properly converted and inserted into the DOC or PDF file. If appendices are included, the applicant is responsible for scanning the documents and submitting them as a part of the application file.

Failure to provide a complete application package will result in disqualification of the application. A complete application package contains:

- **2 original - signed copies of the application Face Page (Attachment 1 – Form 1);**
- **1 CD-ROM containing a single Microsoft Word document (DOC) file or a single Portable Document Format (PDF) file containing the entire application; and,**
- **6 paper copies of the application.**

The application content should be consistent with the details provided in this Section V. and must use the corresponding forms and formats for each grant mechanism (see Attachment 1 – Forms 1-14). Each content section described below should be provided in the application. Any form or section that is not applicable (e.g., human subjects or vertebrate animals), should be noted on the form. APPLICATIONS THAT DEVIATE FROM THE PRESCRIBED FORMAT MAY BE PENALIZED UP TO 0.2 POINTS. In addition to instructions below, supplemental instructions may be provided on the forms themselves.

Face Page – Form 1

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

Application Type. 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.

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

Co-Principal Investigator #2. Provide the information requested for each essential partner on all applications proposing collaborations. If the affiliation of the Co-PI is different than that of the PI, complete a Face Page for each Co-PI. This form must be signed by the subcontracting institution's authorized agent.

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 Administration Costs. Provide the information requested to document that the F&A rate does not exceed that which would be recovered applying the applicant organizations' negotiated F&A rate. A copy of the United States Department of Health and Humane 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 must check 'YES' and complete Form 13, *Human Subjects*. Appropriate assurances must be provided before implementation of the workplan.

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

Project Duration. Report the project duration requested.

Year One 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 work described in the research plan will be performed.

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

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

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

Principal Investigator/Co-Principal Investigator or Mentor Certification and Assurance. Sign and date the form. Failure to do so will prevent the application from being processed.

Organization Certification and Acceptance. Sign and date the form. Failure to do so will prevent the application from being processed. *Applications that include sub-contractual arrangements must insert additional Face Pages signed by the lead co-investigator and official signing for the subcontracting organization certifying their compliance with all applicable assurances and certifications referenced in these application guidelines.*

Table of Contents – Form 2

Complete the table of contents, entering page numbers as appropriate or entering "N/A" when not applicable. Please flag with asterisks (*) all page numbers containing information that, if released,

would put the applicant at a competitive disadvantage (e.g., financial or commercial confidential information, including trade secrets). Information submitted to the SCIRB is subject to the Freedom of Information Law (New York State Public Officers' Law, Article 6, Sections 84 to 90).

Scientific Abstract – Form 3

Provide the information requested on the form. The abstract should be written so that persons from diverse scientific backgrounds can easily understand the work proposed. Do not include confidential information in the scientific abstract. NOTE: Applicants proposing use of human pluripotent stem cells should clearly indicate the specific cell line planned for use, as well as its source.

Lay Abstract – Form 4

Provide the information requested on the form. 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.

Program Responsiveness – Form 5

The information requested on this form is essential for both merit and programmatic review. Delete questions not applicable to the grant mechanism that corresponds to the application. Describe future plans to bring anticipated research results to the next developmental stage. Include a discussion of the evolution of models to be used in such future investigations (i.e., cell culture, invertebrate models, vertebrate models, non-human primates, or humans). For projects with subcontracts involving non-New York State institutions, collaborations must clearly contribute to the achievement of the SCIRB's goals as presented in Form 5, and serve the best interests of New York State.

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.

Allowable Expenses

1. Personal Service

Salary 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 limited to:

<1 year - \$37,000

1 year - \$39,000

2 year - \$41,800

3 year - \$43,500

4 year - \$45,100

5 year - \$47,000

with 100% effort required on this project.

Salary support for mentored scientists and mentored clinicians is limited to the percent effort required by the RFA (75-100%).

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
- Travel – including reasonable expenses for the costs and durations appropriate to the collaboration; costs of travel to international conferences are not allowed
- Consulting services

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

- Animals and their care
- Centers/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. Prior approval is required for all equipment over \$5,000.

Fees related to patient care costs are not allowed, nor is tuition reimbursement an allowable expense.

3. Facilities and Administration Costs

F&A support is limited to the percent specified in the RFA. 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 total modified 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 must be included in the primary applicant’s direct costs.

Personal Effort and Budget Justification – Form 7

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

Prepare Form 7 for the applicant institution first, followed by additional forms for collaborating or subcontracting institutions. In the table, provide the information requested for key personnel and technical staff at the applicant organization, regardless 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.

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

Provide a detailed justification for each ‘Other Than Personal Service’ (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), 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 Support – Form 10

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

Research Plan – Form 11

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

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

A. SPECIFIC AIMS

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

B. SIGNIFICANCE

Provide a succinct description for each proposed aim, indicating how its attainment will advance treatment 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 use of human pluripotent stem cells should clearly indicate in the research plan the specific cell line to be used, as well as its source.

E. LITERATURE CITED

References are not counted against research plan page limitations, nor is the number of references restricted. However, applicants are urged to select references that comprehensively reflect the relevant literature. Provide complete citations to references.

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

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 for contract execution.

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

1) Involvement of Human Subjects and Population Characteristics

Describe the involvement of human subjects as outlined in the research plan. Include descriptions of the subject population, e.g., number of subjects, age range and health status. Provide inclusion or exclusion criteria of any subpopulation (including women or minorities), and explain why such inclusion or exclusion is necessary to accomplish the research goals. Explain the rationale for the involvement of special classes of subjects, such as minors, mentally disabled adults, prisoners, institutionalized individuals or others likely to be vulnerable. Discuss proposed outreach programs for recruiting women and minorities 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, in a subsection labeled Data and Safety Monitoring, describe the oversight and monitoring plan to ensure the safety of participants

and the validity and integrity of the data obtained. An appropriate plan must be submitted to the applicant's IRB for approval and subsequently to the SCIRB 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 reasonably may be expected to result.

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

8) *Education*

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

Vertebrate Animals – Form 14

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 for contract execution.

If vertebrate animals or tissues are to be used in the proposed study, Form 14 must be completed for each participating institution and performance site where used (including the four points listed below) as part of the application. Acquisition and use of animals at all performance sites must comply with New York State Public Health Law, Article 5, Title I, Sections 504, 505-a.

If the applicant organization does not have an approved Animal Welfare Assurance form on file with Office of Laboratory Animal Welfare or 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 the official's signature on the Face Page, is declaring that it will comply with U.S. Public Health Service policy on the care and use of animals by establishing an IACUC, and submitting an Animal Welfare Assurance form and verification of IACUC approval whenever requested to do so. If required, the applicant organization must also register its facility with the USDA.

Succinctly address the following four points on Form 14.

- 1) Provide a detailed description of the animal use proposed in the research work plan, including identification of species, strains, ages, sexes and numbers of animals to be used.
- 2) Justify the use of animals, the choice of species and the number to be used. 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) Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. As appropriate, describe the use of analgesic, anesthetic and tranquilizing drugs, and comfortable restraining devices to minimize discomfort, distress, pain and injury.
- 4) Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following those recommendations.

B. Application Format

ALL APPLICATIONS SHOULD CONFORM TO THE FORMAT PRESCRIBED BELOW. APPLICATIONS THAT DEVIATE FROM THE PRESCRIBED FORMAT MAY BE PENALIZED UP TO 0.2 POINTS.

1. General Formatting

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. Except for forms provided, margins should equal one inch. The header should contain principal investigator's last name and first initial, 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 Research Plan are included in the page limits. The application should be fully collated and unbound. The value assigned to each section is an indication of the relative weight accorded when scoring the application. Appendices may not be used to circumvent page limitations and should be limited to 30 pages.

Page limits for Sections A-D of the Research 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

C. Revised Applications

Individuals who 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. "Revised Application" should be checked off 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. Reviewers' comments from the previous application submitted should be included in the appendix of the application.

If the following requirements are not met, the revised application will be rejected. A revision must include a section entitled "Revisions and Comments" immediately preceding the Research Plan. In no more than two pages, this section should summarize the substantial additions, deletions and changes that have been made. **It also must include responses to criticisms in the previous review evaluation.** This material does not count against the normal page limit for the Research Plan. It is recommended that the Research Plan emphasize any relevant work done since the previous application.

D. Review & Award Process

1. Review Process

Applications will first be examined against Pass/Fail requirements by Wadsworth Center program administrators. Applications that do not meet the mandatory requirements will not be considered for review.

Each eligible application will be evaluated following the National Institutes of Health (NIH)-style scientific merit peer review process. Scientific Merit Peer Review Panel members will be selected from among non-New York State spinal cord injury research experts in the appropriate fields. In order to avoid conflict of interest, experts or collaborators on previously funded or submitted SCIRB applications will not be eligible to serve as peer reviewers.

Applications will receive scores from each participating panel member for each evaluation criterion using a scale of 1 (high merit) to 5 (low merit). The numerical score given each criterion will be multiplied by that criterion's weight (i.e., 15%). The weighted scores will be added together to determine a single global priority score for the application, according to the NIH model. The global priority score is then translated into an adjectival score, as follows:

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 Scientific Merit Peer Review Panel will consider the appropriateness of the requested project duration, budget, effort, overlap with other research (no project activity can be supported by more than one sponsor), human subject protections, and vertebrate animal considerations and may recommend revisions to the SCIRB.

The SCIRB members will conduct a second level of review for programmatic balance. All award recommendations made by the SCIRB members may be made contingent upon acceptance of revisions to items on which the reviewers noted concerns or recommendations made by the Scientific Merit Peer Review Panel with regard to project duration, budget, percent effort, overlap with other research, human subject protections, and vertebrate animal considerations. A scoring tie for applications may be broken using the following criterion as justification for each funding mechanism:

- CART – Translational/Clinical Potential
- IDEA – Innovativeness
- Postdoctoral Fellowship – Research Application
- Mentored Research Scientist – Research Application
- Mentored Clinician Scientist – Research Application

The applications will be sorted in rank order (strongest to weakest score, or 1.0 to 3.5) by funding mechanism/category (CART, IDEA, Postdoctoral Fellowship, Mentored Research Scientist and Mentored Clinician Scientist). For CART, IDEA, Mentored Research Scientist and Mentored Clinician Scientist, the two applications with the best scores in the range of 1.0 to 3.5 will be reviewed and recommended by the Board for funding. For Postdoctoral Fellowships, the five applications with the best scores in the range of 1.0 to 3.5 will be reviewed and recommended by the Board for funding.

The remaining ranked application scores among all funding categories will be merged. Then, the applications will be reviewed in rank order, beginning with the “Outstanding” and “Excellent” applications.

Applications will be reviewed until the recommended total award funds equal the funds available or until the remainder is too small to award the next highest-scoring application. If the “Outstanding” and “Excellent” applications do not use all the funds available for this RFA, SCIRB will vote on the “Very Good” applications and, if funding allows, SCIRB will then vote on the “Good” applications. For each of these “Very Good” and “Good” applications, programmatic diversity will be considered by the SCIRB. Programmatic diversity will be assessed by the Program staff with regard to the range of projects focusing on topics bearing on SCIRB’s mission to reverse paralysis and restore function, or to minimize and prevent damage occurring during the acute phase of injury, and its interest in translational and clinical research applications.

The SCIRB will vote on each selected application. Seven affirmative votes are required to approve an application. If a passing application, for which there are available funds, does not receive seven affirmative votes, 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.

Following the award of grants from this RFA, applicants may request a debriefing from the NYS Department of Health Wadsworth Center, 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.

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

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

- Research funding overlap
- Revisions to workplan, project budget or duration
- Program requirements pertaining to research administration or research risks
- Current human subjects research approval or exemption documents
- Current vertebrate animal approvals
- Approved Facilities and Administrative Cost Rate

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 made public.

E. Review Criteria

In addition to the specific criteria delineated in this section for each grant mechanism, the Scientific Merit Peer Review Panel will consider the appropriateness of:

- project duration
- budget
- effort
- overlap with other research
- human subjects protections
- vertebrate animal considerations

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

1. CART Award

Six criteria are considered by the peer reviewers:

Innovativeness (15%)

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

Approach (15%)

Integration of the inter-disciplinary approach with a coherent hypothesis, and specific aims. The importance of the research questions and their basis in the scientific literature. The suitability of research design and methods to achieve the application's spinal cord injury-related aims.

Feasibility (15%)

The likelihood of successful completion of the study based on the research design, background and experience of the investigators, and the availability of resources.

Translational/Clinical Potential (20%)

The potential and time needed for the proposed work to have an impact on contributing to novel treatments and cures for spinal cord injury-induced paralysis or to prevent paralysis following acute injury.

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

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

Budget (20%)

The appropriateness of the budget allocations to the accomplishment of the research aims.

2. IDEA Award

Five criteria are considered by the peer reviewers:

Innovativeness (20%)

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

Impact (20%)

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

Approach (20%)

The extent to which the conceptual framework, design, methods and analyses are developed, integrated and appropriate to the aims of the project.

Feasibility (20%)

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

Budget (20%)

The appropriateness of the budget allocations to the accomplishment of the research aims.

3. Postdoctoral Fellowship Award

Six criteria are considered by the peer reviewers:

Candidate (15%)

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

Sponsor and Training Environment (15%)

The quality of the training environment and the qualifications of the sponsor(s) as mentor(s) to facilitate the proposed research training experience.

Training Plan (15%)

The value of the proposed 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.

Research Application (20%)

The scientific merit of the application.

Significance (15%)

Does the project address an area of importance to spinal cord injury? What is the likelihood the project will lead to further funding, be translated into practice, or impact policy?

Budget (20%)

The appropriateness of the budget allocations to the accomplishment of the research aims.

4. Mentored Research Scientist Award

Six criteria are considered by the peer reviewers:

Candidate (15%)

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.

Sponsor and Training Environment (15%)

The quality of the training environment and the qualifications of the sponsor(s) as mentor(s) to facilitate the proposed research training experience.

Training Plan (15%)

The value 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.

Research Application (20%)

The scientific merit of the application

Significance (15%)

Does the project address an area of importance to spinal cord injury? What is the likelihood the project will lead to further funding, be translated into practice, or impact policy?

Budget (20%)

The appropriateness of the budget allocations to the accomplishment of the research aims.

5. Mentored Clinical Scientist Award

Six criteria are considered by the peer reviewers:

Candidate (15%)

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.

Sponsor and Training Environment (15%)

The quality of the training environment and the qualifications of the sponsor(s) as mentor(s) to facilitate the proposed research training experience.

Training Plan (15%)

The value 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.

Research Application (20%)

The scientific merit of the application.

Significance (15%)

Does the project address an area of importance to spinal cord injury? What is the likelihood the project will lead to further funding, be translated into practice, or impact policy?

Budget (20%)

The appropriateness of the budget allocations to the accomplishment of the research aims.

ATTACHMENT 1
APPLICATION FORMS 1 - 14

Table of Contents

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

Form	Form Name	Page
1	Face Page	1
1	Face Page - Subcontracting Organization(s) [□]	
2	Table of Contents	
3	Scientific Abstract	
4	Lay Abstract	
5	Program Responsiveness	
6	Budget	
7	Personnel and Budget Justification	
6	Budget –Subcontracting Organization(s) [□]	
7	Personnel and Budget Justification – Subcontracting Organization(s) [□]	
8	Biographical Sketch(es)	
9	Facilities and Resources	
10	Other Support	
	Revisions and Comments (<i>Required for 'Revised Applications', See Section V.C</i>) [□]	
11	Research Plan	
	Specific Aims	
	Significance	
	Background and Preliminary Results	
	Research Design and Methods	
	Literature Cited - <i>Not included in page limitations</i>	
12	Time Line and Collaboration Strategy	
13	Human Subjects - <i>Required if 'YES' checked on Face Page</i> [□]	
14	Vertebrate Animals - <i>Required if 'YES' checked on Face Page</i> [□]	

[□] Indicate "N/A" if not applicable.

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:****Form 3**

Not to exceed one page.

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: (If pluripotent stem cells, indicate specific cell line and source)

Innovative Elements of the Project:

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

Program Responsiveness

Clearly describe the application of diverse fields applying complementary approaches to work on an important well-defined problem and discuss the increased synergy and effectiveness gained from combining the specific projects proposed. Describe future plans to bring anticipated research results to the next developmental stage. Include a discussion of the evolution of models to be used in such future investigations (i.e., cell culture, invertebrate models, vertebrate models, non-human primates, or humans).

Budget

BUDGET CATEGORY		Year One	Year Two	Year Three (CART or Mentored only)	Year Four (CART only)	TOTAL (all years)
PERSONAL SERVICE (PS)						
1	SALARY AND STIPENDS					
2	FRINGE BENEFITS					
3	SUBTOTAL PS					
OTHER THAN PERSONAL SERVICE (OTPS)						
4	SUPPLIES					
5	EQUIPMENT					
6	TRAVEL					
7	CONSULTANT COSTS					
8	OTHER EXPENSES					
9	SUBTOTAL OTPS					
10	TOTAL PS & OTPS					
11	TOTAL SUBCONTRACT 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)					

Form 6

Attach subcontractor budgets using additional copies of Form 6.

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.

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 one additional continuation page, if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

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

Form 9

Not to exceed two pages per collaborating institution.

Other 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: % FTE _____

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

THIS 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, directly below the item. Indicate a possible resolution, if this application is funded.

Research Plan

A. Specific Aims

B. Significance

C. Background and Preliminary Results

D. Research Design and Methods

E. Literature Cited

Form 11

Follow all page limitations, font and margin requirements.

Time Line and Collaboration Strategy

Aim	Investigator Responsible Name of Institution	Activities	Time Frame

If this application involves an inter-institutional collaboration, describe strategies for information and/or resource exchange to ensure the efficient and effective completion of the project.

Human Subjects

This form is required only for projects to which protections for use of human subjects on the face page.

Ethnically/Racially diverse populations **included**.

Ethnically/Racially diverse populations **excluded**.

Complete separate tables for **ALL** human subjects protocols to be used with the grant application if funded. Present information from the applicant organization first, followed by subcontracting or consortium organizations. It is the responsibility of the applicant organization to 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 you listed as an approved investigator on this protocol:** Yes No

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

If "Yes", 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 Contents).

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

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

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

Institution: _____

Institutional Animal Care & Use Number: _____

NYS DOH Animal Care & Use Certificate Number: _____

USDA Registration Number (if applicable to species): _____

Vertebrate Animal Approval Status: Approved Pending

Protocol Number: _____ Principal Investigator: _____

Project Title: _____

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

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

If "**Yes**", 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 must comply with New York State Public Health Law, Article 5, Title I, Sections 504 and 505-a.

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

**Sample Letter of Interest
or
Letter to Receive RFA Updates and Modifications**

DOH Contact
DOH Address

Re: RFA #
RFA Title

Dear _____:

This letter is to indicate our interest in the above Request for Applications (RFA) and to request that our organization be placed on the mailing list: (please check one)

- To be notified when any updates, written responses to questions, or amendments to the RFA are posted on the official Department of Health website <http://www.nyhealth.gov/funding/>
- To receive actual documents of any updates, written responses to questions, or amendments to the RFA.

Please use the following address to send the notification/documentation: (please check one)

- E-mail address: _____
- Street Address: _____

Sincerely,

**ATTACHMENT 3
APPLICATION CHECKLIST**

Mandatory items are indicated by bold text.

- 2 original signed copies of the application Face Page (Attachment 1 – Form 1)**
- 1 CD-ROM containing a single DOC or single PDF containing the entire application**

6 paper copies of the following:

- Attachment 1 - Forms 2-12
- Human Subjects (Attachment 1 – Form 13) – and include the 8-point narrative If the IRB has not deemed the project to be Exempt prior to submission of the application**
- Vertebrate Animals (Attachment 1 – Form 14) - If vertebrate animals or tissues are to be used, Form 14 must be completed (including the 4 points listed)**
- Vendor Responsibility Attestation (Attachment 4)

For Revised Applications ONLY:

- “Revised Application” checked on Face Page (Attachment 1 – Form 1)
- Must have the same Principal Investigator as the original application**
- “Revisions and Comments” section immediately preceding Research Plan indicating changes made and responses to comments from the previous review**
- Includes responses to criticisms in the previous review**

Appendices:

- Three signed, sealed references letters (postdoctoral fellowship applications only)**
- Institutional Review Board (IRB) approvals or exemptions
- Institutional Animal Care and Use Committee (IACUC) approvals
- Memoranda of Understanding, subcontracts or contractual agreements
- Letters of collaboration or support, commitment(s) to provide research resources, subcontract letter(s) from consultant(s); subcontractual or consortium agreement letters
- 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 Administration rate agreements
- Previous reviewers’ comments from the previous submission (for revised applications only)

ATTACHMENT 4
Vendor Responsibility Attestation

To comply with the Vendor Responsibility Requirements outlined in Section IV, Administrative Requirements, H. 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: _____

APPENDICES

Table of Contents

1. Grant Contract
2. Appendix A (Standard NYS Contract Terms)
3. Appendix A-1 (NYSDOH Standard Contract Terms)
4. Appendix A-2 (SCIRB- Contract Policy Statement and Conditions)
5. Appendix B (Budget – attached here in sample form)
6. Appendix C (Payment and Reporting Schedule)
7. Appendix D (Program Workplan)
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): _____ . NYS COMPTROLLER'S NUMBER: _____

_____ . ORIGINATING AGENCY CODE: _____

CONTRACTOR (Name and Address): _____ . TYPE OF PROGRAM(S) _____

_____ .

FEDERAL TAX IDENTIFICATION NUMBER: _____ . INITIAL CONTRACT PERIOD _____

_____ . FROM: _____

MUNICIPALITY NO. (if applicable): _____ . TO: _____

_____ . FUNDING AMOUNT FOR INITIAL PERIOD: _____

CHARITIES REGISTRATION NUMBER: _____ .

____ - ____ - ____ or () EXEMPT: _____

(If EXEMPT, indicate basis for exemption): _____

_____ . MULTI-YEAR TERM (if applicable): _____

CONTRACTOR HAS() HAS NOT() TIMELY . FROM: _____

FILED WITH THE ATTORNEY GENERAL'S . TO: _____

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

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 11/06)
- _____ APPENDIX B Budget
- _____ APPENDIX C Payment and Reporting Schedule
- _____ APPENDIX D Program Workplan
- _____ APPENDIX X Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)

OTHER APPENDICES

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

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

CONTRACTOR

By: _____
(Print Name)

Title: _____
Date: _____

- . "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 _____)

. _____
. Contract No. _____

. STATE AGENCY

. By: _____
. (Print Name)

. Title: _____
. Date: _____

. State Agency Certification:

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-1.

VI. Safeguards for Services and Confidentiality

- A. Services performed pursuant to this AGREEMENT are secular in nature and shall be performed in a manner that does not discriminate on the basis of religious belief, or promote or discourage adherence to religion in general or particular religious beliefs.
- B. Funds provided pursuant to this AGREEMENT shall not be used for any partisan political activity, or for activities that may influence legislation or the election or defeat of any candidate for public office.
- C. Information relating to individuals who may receive services pursuant to this AGREEMENT shall be maintained and used only for the purposes intended under the contract and in conformity with applicable provisions of laws and regulations, or specified in Appendix A-1.

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.

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June, 2006

APPENDIX A-1 (REV 11/06)

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. 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 an 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 of 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. Other Modifications

- a. Modifications of this AGREEMENT as specified below may be made within an existing PERIOD by mutual written agreement of both parties:
 - ◆ Appendix B - Budget line interchanges;
 - ◆ Appendix C - Section 11, Progress and Final Reports;
 - ◆ Appendix D - Program Workplan.

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

12. Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof, completed by the CONTRACTOR's insurance carrier and/or the Workers' Compensation Board, of coverage for Workers' Compensation, for which one of the following is incorporated into this contract as **Appendix E-1**:

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

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

- **C-105.2** --Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the **U-26.3**; OR
- **SI-12** --Certificate of Workers' Compensation Self-Insurance, OR **GSI-105.2** --Certificate of Participation in Workers' Compensation Group Self-Insurance

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

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

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

- **DB-120.1** --Certificate of Disability Benefits Insurance OR the DB-820/829 Certificate/Cancellation of Insurance; OR
- **DB-155** --Certificate of Disability Benefits Self-Insurance

13. 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.

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

APPENDIX A-2

Spinal Cord Injury Research Board

Contract Policy Statement and Conditions

A. Ethical Considerations

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

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

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.
- 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; 21CFR 361; 21 CRF 812.

- The research study will comply with all other applicable federal and New York State laws, regulations and guidelines.
- The research study has been approved by an Institutional Review Board (IRB).
- If applicable, the applicant organization's IRB has received and reviewed written approval from an authorized representative of each site where the study will take place.
- The IRB has determined that the investigator will immediately withdraw a subject from the research study if continued participation would be detrimental to the subject's well-being.
- The IRB will communicate to SCIRB program administrators (i) any unanticipated problems involving risks to subjects, (ii) any serious or continuing noncompliance with IRB policy or requirements; and (iii) any suspension or termination of IRB approval.

Vulnerable Populations

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

- The IRB has determined that the research study constitutes either: research with a prospect of direct benefit to research participants; or research with no prospect of direct benefit to research participants that presents minimal risk.
- The IRB has determined that all research participants have been diagnosed with spinal cord injury.
- 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).

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

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.

2. The State of New York shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, any published or otherwise reproducible material, device, invention, technique or methodology developed under or in the course of performing this funded research, dealing with any aspect of the research activity, or of the results and accomplishments attained from the research. Use by those other than the State of New York under this license shall be limited to research and governmental purposes.
3. The State of New York shall be provided advance written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Fund. Any such assignment or transfer must acknowledge, and be consistent with the license rights granted the State pursuant to the above paragraph.

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

4. Support by the New York State 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 New York State Spinal Cord Injury Research Trust Fund through 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."
5. Contractor agrees, pursuant to the provisions of Chapter 647 of the Laws of 1999, and Chapter 229 of the Laws of 2000, both of the State of New York, to provide the Department with the study, any data supporting that study, and the identity of the principal person or persons who performed such study. If such study is used as the basis for the promulgation, amendment, or repeal of a rule, regulation, or guideline used in enforcement of a statute, rule, or regulation, the study, any data supporting that study, and the identity of the principal person or persons who performed the

study shall be subject to disclosure in accordance with the provisions of Chapters 647 and 229.

F. Reporting Requirements

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

G. Equipment

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

APPENDIX B
BUDGET (sample format)

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

I. Payment and Reporting Terms and Conditions

- A. The initial payment under this AGREEMENT shall be due thirty calendar days, excluding legal holidays, after the end of the first quarterly period of this AGREEMENT 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 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. Should funds for subsequent PERIODS not be appropriated or budgeted by the STATE for the purpose herein specified, the STATE shall, in accordance with Section 41 of the State Finance Law, have no liability under this AGREEMENT to the CONTRACTOR, and this AGREEMENT shall be considered terminated and cancelled.
- D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the program workplan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller.
- E. The CONTRACTOR will provide the STATE with the reports of progress or other specific work products pursuant to this AGREEMENT as described in this Appendix below. 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 will be submitted in the forms and formats provided by the SCIRB, and will generally describe:

1. project participants, including trainees and/or fellows;
2. activities and findings corresponding to research aims; and
3. research activity products resulting during the reporting period (e.g., abstracts, publications, presentations, invention disclosures, etc.).

Reports should 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 PDFs to the e-mail. All reports and forms are to be sent to scirb@wadsworth.org. The contract number and report being submitted should be identified on the subject line of the email (i.e., Contract # <<>>, Progress Report-First, - Second, or Final Report. One (1) signed, hard copy of each report shall be submitted to the:

NYS Department of Health
Wadsworth Center, Room C345
Empire State Plaza
PO Box 509
Albany, NY 12201-0509

- F. The Department of Health will reimburse the contracting organization for approved, allowable expenditures incurred under the awarded contract subject to submission of a standard New York State voucher (available by written request from the Office of the State Comptroller, Supply Room, Alfred E. Smith State Office Building, Albany, New York 12236). The contracting organization is responsible for disbursing funds to any sub-contractors in accordance with the amounts approved for their research.

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 C345
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 30 days after the end date of the period for which reimbursement is being 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.

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

- 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 for 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 Reports

The CONTRACTOR will submit semi-annual progress reports in the forms and formats as provided by the SCIRB, summarizing the work performed during the period. (See Table I for annual schedule.) This report will detail how the CONTRACTOR has progressed toward attaining the specific aims enumerated in the Program Workplan (Appendix D).

B. Expenditure Reports

The CONTRACTOR will submit a detailed expenditure report by object of expense which will accompany the voucher submitted for each period. (See Table I for annual schedule.) Documentation of all expenses will be available upon request. The STATE may require documentation of expenses before payment of any voucher.

The CONTRACTOR will 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 use of funds. All final budget modification requests must be submitted prior to the end of the budget period.

The CONTRACTOR will submit the final voucher for the budget period no later than 30 days after the end date of the budget period. The final voucher must be marked as "Final".

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

TABLE I

<u>Voucher / Report</u>	<u>Period Covered</u>	<u>Due Date</u>
Voucher 1	October 1 – December 31	January 30
Voucher 2	January 1 – March 31	April 30
Semi-Annual Report 1	October 1 – March 31	April 30
Voucher 3	April 1 – June 30	July 30
Voucher 4	July 1 – September 30	October 30
Semi-Annual Report 2	April 1 – September 30	October 30

C. Final Progress Report

The CONTRACTOR will 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 SCIRB.

APPENDIX D

PROGRAM WORKPLAN (sample format)

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

I. CORPORATE INFORMATION

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

II. SUMMARY STATEMENT

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

III. PROGRAM GOALS

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

IV. SPECIFIC DELIVERABLES

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

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

APPENDIX X

Agency Code _____

Contract No. _____

Period _____

Funding Amount for Period _____

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

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

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

CONTRACTOR SIGNATURE

By: _____

Printed Name

Title: _____

Date: _____

STATE AGENCY SIGNATURE

By: _____

Printed Name

Title: _____

Date: _____

State Agency Certification:

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

STATE OF NEW YORK)

County of _____) SS:

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

Title: _____

Date: _____

STATE COMPTROLLER'S SIGNATURE

Title: _____

Date: _____