RFA # 1212030210

New York State Department of Health
and the
Empire State Stem Cell Board
Request for Applications
Consortia to Accelerate Therapeutic Applications of Stem Cells

RELEASE DATE: November 15, 2013

APPLICANT CONFERENCE #1 Registration Due: December 11, 2013

APPLICANT CONFERENCE #1: December 13, 2013 at 10:00 AM
NYS Department of Health
Metropolitan Area Regional Office
90 Church Street, 4th floor
Conference Room 4A/4B
New York, NY
Or by telephone conference call at:
1-866-394-2346 Conference Code: 4474608059

PART ONE QUESTIONS DUE: December 17, 2013

PART ONE QUESTIONS, ANSWERS AND UPDATES POSTED: December 23, 2013

APPLICATION PART ONE DUE: January 14, 2014 by 5:00 PM

APPLICANT CONFERENCE #2 Registration Due: January 22, 2014

APPLICANT CONFERENCE #2: January 24, 2014 at 10:00 AM
by telephone conference call at:
1-866-394-2346 Conference Code: 4474608059

PART TWO QUESTIONS DUE: January 28, 2014

PART TWO QUESTIONS, ANSWERS AND UPDATES POSTED: February 6, 2014

APPLICATION PART TWO DUE: March 12, 2014 by 5:00 PM

DOH CONTACT NAME AND ADDRESS:

Bonnie Jo Brautigam
Extramural Grants Administration
New York State Department of Health
Wadsworth Center
Empire State Plaza, Room C345
PO Box 509, Albany NY 12201-0509
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This RFA, questions and answers, as well as any updates and modifications, may be downloaded at http://www.health.ny.gov/funding.

TABLE OF CONTENTS

I. Introduction

Advances in stem cell research are encouraging scientists to investigate the potential of stem cells to treat disease. The Empire State Stem Cell Board (ESSCB) is authorized to provide funding for basic, applied, translational and other research designed to advance scientific discoveries in fields related to stem cell biology. In conjunction with NYSTEM (the New York State Stem Cell Science Program), the ESSCB makes funding recommendations for creative and innovative biomedical research projects to be supported by the Empire State Stem Cell Trust Fund. Information about the ESSCB and NYSTEM can be found at http://stemcell.ny.gov.

The ESSCB wishes to accelerate development of **new clinical applications** of stem cells for prevention and/or treatment of disease. The intent of these milestone-based awards is to support disease-focused, health outcome-based, multi-disciplinary collaborative research proposals. Such proposals will address an unmet medical need using stem cells as a basis for the development of clinical treatments/therapies. This RFA seeks to fund applications presenting a coherent, goal-oriented project and is not intended to address a series of separate but inter-related projects as would an NIH Program Project or Center grant. Proposed projects may focus on any disease/condition, group of diseases/conditions or organ system(s). **The Funding Committee has sole discretion to reject an application that overlaps an existing NYSTEM consortium award under RFA# 0911051012.**

All awards will be financed by the Empire State Stem Cell Trust Fund. The number of awards will be contingent upon the quality and content of the applications as well as the scale and scope of the proposed projects. A maximum of $32 million is available to support approximately two awards from this RFA. This funding is for a period of up to four years. The total direct costs for the duration of a single award are capped at $13.3 million.

II. Who May Apply?

The applicant must be a not-for-profit or governmental organization in New York State. Organizations awarded funds will be expected to monitor funds, maintain individual accounts and fulfill other fiscal management criteria. Subcontracting and collaborating organizations may include public, not-for-profit and for-profit entities within or outside of New York State.

The eligible Principal Investigator (PI) is designated by the applicant organization and has the skills, knowledge, and resources necessary to carry out the proposed Workplan. Collaborations between investigators at multiple organizations and for-profit entities are not required, but are encouraged when necessary to engage the most appropriate expertise and achieve the goals of the project.

Only one application will be accepted from any single organization. An individual may serve as a PI on only one application in response to this RFA. **In the event that more than one application is received from a PI or organization, all applications from that PI or organization will be disqualified.** Individuals and organizations may appear in any number of applications as collaborators, subcontractors, consultants or contributors.
The Funding Committee has sole discretion to reject an application that overlaps an existing NYSTEM consortium award under RFA# 0911051012.

At the time of application and award acceptance, the PI must not be restricted from receiving Public Health Service (PHS) funding or debarred by the United States Food and Drug Administration (FDA) or any other federal or New York State government entity.

This RFA will use a two-part application process to enable prospective applicants to self-assess their readiness for a competitive response and the appropriateness of their application to this funding mechanism. Part One will also facilitate assembly of the peer review panels for applications received (see Section V., Instructions for Completing the Application).

Submission of a signed application certifies that the applicant organization and the PI meet the eligibility criteria stated here.

III. Project Narrative/Workplan Outcomes

A. General Expectations

1. The Application

   A successful application will focus on the objectives outlined in Section I. **The application will include data developed by the participating investigators that demonstrate proof-of-principle in an appropriate pre-clinical model.** It will present a strong explanation of the capability to achieve a significant measurable advance toward clinical application within the period of the award. The term "clinical application" for purposes of this RFA is defined as the ability to utilize the resulting outcome(s) of the research project to improve patient health in a medical setting.

   The Workplan will establish quantifiable milestones and key decision points, outlining the critical path to accomplish the goals of the Workplan by the end of the contract term (within four years). The consortium may involve investigators engaged in basic, translational and clinical stem cell research. The roles and relevant expertise of each investigator, collaborator, contributor and consultant should be clearly detailed. The participation of investigators with clinical and commercial experience should be included in any aspect of the project that relates to clinical activities or products, as appropriate.

   The application should not include any scientific, budgetary or commitment overlap with NYSTEM awards that will be active beyond the anticipated start date of the consortia awards (see cover page). If overlap is present, the consortia application will not be funded (also see Sections VI.B and VI.F).

2. Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP)

   Because GLP and GMP will be necessary for development of clinical therapies and devices, it is expected that the experimental design and implementation will be carried out in accordance with GLP and GMP standards consistent with the requirements of the Food and Drug Administration (FDA).

3. Leadership

The PI, functioning as a team leader, will provide vision, strategy and overall project direction, have scientific and fiscal accountability, and should be a doctoral level investigator with a record of effective scientific leadership. Prior success working with relevant for-profit entities is desirable among the leadership team from the PI, Co-PI(s) or consultant(s).

Designation of Co-PI(s) is not a requirement of this award and should be guided by the scientific goals of the proposed project and the need for shared responsibility for oversight of the entire project among more than one individual (the PI). Whereas a Co-PI shares oversight responsibility for the entire project, another investigator may be responsible for a specific component of the research project.

The percentage effort for investigators is not prescribed; it should be dependent upon the nature of their role and may vary during the course of the award.

A single full time, 100 percent professional effort Project Manager must be included in the staffing plan throughout the contract term. The Project Manager will oversee project operations and ensure that the activities progress according to established milestones. The Project Manager should have an advanced science or science management background and experience in scientific Project Management. The Project Manager need not be identified at the time of application, but is expected to be engaged as soon after the award announcement as possible and sufficiently in advance of the first meeting with the independent Oversight Panel (see below) to take responsibility for meeting planning and preparations. **NOTE:** Project Management is a recognized discipline that uses techniques and tools to plan, control, monitor and manage resources to achieve a time- and resource-limited specific end result.

Together, the PI and Project Manager, with the support of any Co-PIs, will be responsible for developing and maintaining strategy, keeping the consortium focused, achieving expectations and milestones, and providing ongoing communication with NYSTEM and the independent Oversight Panel.

4. Oversight

NYSTEM scientific staff will establish an independent Oversight Panel for each funded consortium and act as liaison to the Oversight Panel and the consortium. The Oversight Panel will be responsible for advising NYSTEM regarding: removal or addition of investigators, staff, consultants and subcontractors; revision or addition of milestones; and, whether to proceed at key decision points, including the identification of specific activities and next steps. As such, the Oversight Panel and NYSTEM will be provided confidential access to the peer review critique and all data and materials supported by the award including but not limited to scientific progress reports and unpublished data.

The Oversight Panel will have an appropriate range of expertise and experience relevant to the funded project. Its composition will be dependent upon the specific goals of the funded project. Each consortium will have input to the composition and membership of the Oversight Panel; NYSTEM will have final approval of Oversight

Panel member and chairperson selections. Also see Part Two Application Instructions for Form 3.

In the first six months of the award period, NYSTEM will arrange for the Oversight Panel to meet with the PI and any Co-PIs, the Project Manager, investigators and NYSTEM staff to review the peer review critique, research plan, milestones and other aspects of the overall project (see Part Two Application Instructions for Form 8 regarding costs related to meetings of the Oversight Panel), establish progress report deadlines for the consortium and establish general guidelines for materials to be provided by the consortium in advance of each milestone meeting. Beyond the initial meeting, they will meet at least annually, and at other time periods as appropriate to the project milestones and key decision points, to evaluate scientific progress and individual contributions. In general, Oversight Panel meetings will include presentation of project data including progress toward project milestones, critical scientific assessment, proposed updates to the contract Workplan, discussion of related budget issues and recommendations for action. Possible outcomes of these meetings include: project continuation, redirection or discontinuation. Continued funding and "Go/No-go" determinations will be made by NYSTEM following receipt and review of progress reports and the subsequent recommendations of the Oversight Panel. Additionally, the Oversight Panel may be called upon to advise the consortium and NYSTEM regarding key decision points.

Review criteria used to evaluate the scientific merit of the full application (see Section VI.D.) will form the general basis of the Oversight Panel evaluation. In addition, the Oversight Panel will consider:

a. Performance: The consortium has achieved the milestones approved by the Oversight Panel and NYSTEM staff and has presented quantifiable study outcomes. The consortium has achieved the milestones within budget and in appropriate time frames.

b. Responsiveness: The consortium leadership has implemented the recommendations of the Oversight Panel, as approved by NYSTEM, in a timely manner. The project remains responsive to the overall goals of the proposed project.

c. Impact: The data presented indicate that the clinical application continues to offer an advantage over other alternatives in practice or in the development pipeline. Results achieved to date demonstrate satisfactory progress toward clinical significance.

d. Feasibility and Next Steps: Feasible strategies and steps to ensure successful achievement of the future milestones are outlined in the updated Workplan.

If the consortium is unable to achieve its milestones within budget and in appropriate time frames or is unresponsive to recommendations as required by NYSTEM, the Oversight Panel may recommend to NYSTEM that the contract be terminated; the final decision regarding contract termination will be made by NYSTEM.

B. Reporting Obligations

The contractor will be required to submit financial reports and scientific progress reports in accordance with the forms, formats and timeframes provided by NYSTEM. Submission of detailed quarterly financial reports will be required. Written reports will also be required to substantiate progress corresponding to the tasks and milestones outlined in the Workplan as well as responsiveness to, and implementation of, the Oversight Panel recommendations approved by NYSTEM. These reports will also include Workplan updates as recommended by the Oversight Panel and approved by NYSTEM. All progress reports will require approval by NYSTEM staff prior to payment of the voucher that corresponds to the last quarter of the reporting period. The contractor will also be required to follow all reporting obligations outlined in Attachment D and Attachment A-1 of the executed contract, and to monitor subcontractor compliance. A sample contract with these attachments can be found in Attachment 4 to this RFA.

The contractor will be required to submit Intellectual Property Activity reports in accordance with the forms, formats and timeframes provided by NYSTEM.

Awarded organizations will be required to certify other active and pending support prior to contract execution. **Scientific, budgetary and commitment overlap with another funded project cannot be resolved by amending a NYSTEM-funded award.** Throughout the contract term, the PI and the contracting organization are responsible for providing notice and documentation to NYSTEM regarding any changes in other funding and any measures taken to avoid or eliminate overlap with the NYSTEM contract.

Prior to contract execution, awarded organizations will also be required to provide copies of protocol approvals for research projects that involve human subjects, vertebrate animals, recombinant DNA, or human stem cells as defined herein. In addition, certification that proper education requirements have been met will also be required prior to contract execution.

The contractor PI and appropriate staff will participate in, and cooperate with, evaluation and dissemination activities sponsored or conducted by NYSTEM staff, such as:

- on-site monitoring visits;
- Oversight Panel activities and meetings; and
- NYSTEM annual scientific meetings.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the New York State Department of Health (Department). 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:

Bonnie Jo Brautigam
Director, Extramural Grants Administration
nystemgrants@wadsworth.org
(518) 486-2191 (fax)

To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. Written questions for each part of the application will be accepted until the dates posted on the cover of this RFA.

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

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

This RFA has been posted on the Department of Health's public website at: http://www.health.ny.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 dates identified on the cover sheet of this RFA.

C. Letter of Intent

Letters of Intent are not requested for this RFA.

D. Applicant Conference

Two applicant conferences will be held to give potential applicants the opportunity to receive an overview of the RFA and ask specific questions. The first conference will be held at the location, date and time posted on the cover sheet of this RFA. Potential applicants may attend in person or by phone. The second conference will be held by phone only. The Department requests that potential applicants register for each conference by calling (518) 474-7002 to insure access through security, adequate accommodations for the number of prospective attendees and a sufficient number of conference phone lines. The deadline for reservations is posted on the cover page of this RFA. Failure to attend the applicant conference will not preclude the submission of an application.

E. How to File an Application

This Paragraph E applies to both Part One and Part Two of the 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 the application is delivered to Room C345 prior to the date and time specified. **Any late Part One application will result in disqualification of Part Two of the application.**

US Postal Service deliveries:
New York State Department of Health
Wadsworth Center, Room C345
Extramural Grants Administration
Empire State Plaza
PO Box 509
Albany, NY 12201-0509

Courier (Express) Mail services:
New York State Department of Health
Wadsworth Center, Room C345
Extramural Grants Administration
Empire State Plaza
Dock J – P1 Level
Albany, NY 12237

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

See RFA Attachments 1 and 2 for detailed content requirements, forms and instructions. It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared. Submit the application in a single package that is clearly labeled with the RFA name and RFA number listed on the cover of this RFA. Inside the package, a separately sealed package should contain a CD or DVD of the entire application with supporting documents and an exact paper copy. Clearly mark the package with the PI's name and the name of the applicant organization. Hand deliveries will be accepted but should be in a sealed envelope as described in the previous sentence. **Applications WILL NOT be accepted via fax or e-mail.**

F. The Department of Health Reserves the Right to:

1. Reject any or all applications received in response to this RFA.

2. Withdraw the RFA at any time, at the Department's sole discretion.

3. Make an award under the RFA in whole or in part.

4. Disqualify any applicant whose conduct and/or proposal fails to conform to the requirements of the RFA.

5. Seek clarifications and revisions of applications.

6. Use application information obtained through site visits, management interviews and the state's investigation of an applicant's qualifications, experience, ability or financial standing, and any material or information submitted by the applicant in response to the agency's request for clarifying information in the course of evaluation and/or selection under the RFA.

7. Prior to application opening, amend the RFA specifications to correct errors or oversights, or to supply additional information, as it becomes available.

8. Prior to application opening, direct applicants to submit proposal modifications addressing subsequent RFA amendments.

9. Change any of the scheduled dates.

10. Waive any requirements that are not material.

11. Award more than one contract resulting from this RFA.

12. Conduct contract negotiations with the next responsible applicant, should the Department be unsuccessful in negotiating with the selected applicant.

13. Utilize any and all ideas submitted with the applications received.

14. Unless otherwise specified in the RFA, every offer is firm and not revocable for a period of 60 days from the bid opening.

15. Waive or modify minor irregularities in applications received after prior notification to the applicant.

16. Require clarification at any time during the procurement process and/or require correction of arithmetic or other apparent errors for the purpose of assuring a full and complete understanding of an offerer's application and/or to determine an offerer's compliance with the requirements of the RFA.

17. Negotiate with successful applicants within the scope of the RFA in the best interests of the State.

18. Eliminate any mandatory, non-material specifications that cannot be complied with by all applicants.

19. Award grants based on geographic or regional considerations to serve the best interests of the State.

G. Term of Contract

Any contract resulting from this RFA will be effective only upon approval by the New York State Office of the State Comptroller. It is expected that contracts resulting from this RFA will begin on July 1, 2015 for a term of up to four years and will not be renewable.

Continued funding through this period is contingent upon availability of funding and state budget appropriations. The Department also reserves the right to revise the amount as necessary due to changes in the availability of funding.

H. Payment & Reporting Requirements

1. The Department may, at its discretion, make an advance payment to a not-for-profit grant contractor in an amount not to exceed 0 percent. No advances will be allowed for contracts resulting from this procurement.

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

   New York State Department of Health
   Wadsworth Center
   Extramural Grants Administration
   Empire State Plaza, Room C345
   PO Box 509
   Albany, NY 12201-0509

   Grant contractors shall provide complete and accurate billing invoices to the Department's designated payment office in order to receive payment. Billing invoices submitted to the Department must contain all information and supporting documentation required by the Contract, the Department and the Office of the State Comptroller (OSC). Payment for invoices submitted by the CONTRACTOR shall only be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with OSC's procedures and practices to authorize electronic payments. Authorization forms are available at the State Comptroller's website at: www.osc.state.ny.us/epay/index.htm, by email at: epayments@osc.state.ny.us or by telephone at 855-233-8363. CONTRACTOR acknowledges that it will not receive payment on any claims for reimbursement submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

   Payment of such claims for reimbursement 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 claims for payment submitted by the contractor pursuant to this agreement shall be submitted to the State no later than 60 days after the end of the quarter for which reimbursement is being claimed.

   - Quarterly claims for payment will not be paid until all required progress reports for that period are submitted and deemed acceptable by NYSTEM program staff.

   - The final claim for payment will not be paid until after acceptance of the final progress report.

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

3. The grant contractor will be required to submit the following progress reports:

   - Progress reports in accordance with the forms and formats provided by NYSTEM as outlined in Section III.B., Reporting Obligations, no later than 30 days after each milestone.

   - A final cumulative progress report in accordance with the forms and formats provided by NYSTEM, no later than 60 days after the end of the contract term.

   All payment and reporting requirements will be detailed in Attachment D of the final NYS Master Grant Contract.

I. Limits on Administrative Expenses and Executive Compensation

Effective July 1, 2013, limitations on administrative expenses and executive compensation contained within Governor Cuomo's Executive Order #38 and related regulations published by the Department (Part 1002 to 10 NYCRR – Limits on Administrative Expenses and Executive Compensation) went into effect. Applicants agree that all state funds dispersed under this procurement will, if applicable to them, be bound by the terms, conditions, obligations and regulations promulgated by the Department. To provide assistance with compliance regarding Executive Order #38 and the related regulations, please refer to the Executive Order #38 website at: http://executiveorder38.ny.gov.

J. Vendor Identification Number

Effective January 1, 2012, in order to do business with New York State, you must have a vendor identification number. As part of the Statewide Financial System (SFS), the Office of the State Comptroller's Bureau of State Expenditures has created a centralized vendor repository called the New York State Vendor File. In the event of an award and in order to initiate a contract with the New York State Department of Health, vendors must be registered in the New York State Vendor File and have a valid New York State Vendor ID.

If already enrolled in the Vendor File, please include the Vendor Identification number on the application cover sheet. If not enrolled, to request assignment of a Vendor Identification number, please submit a New York State Office of the State Comptroller Substitute Form W-9, which can be found on-line at: http://www.osc.state.ny.us/vendor_management/issues_guidance.htm.

Additional information concerning the New York State Vendor File can be obtained on-line at: http://www.osc.state.ny.us/vendor_management/index.htm, by contacting the SFS Help Desk at 855-233-8363 or by emailing at helpdesk@sfs.ny.gov.

K. Vendor Responsibility Questionnaire

The New York State Department of Health recommends that vendors file the required Vendor Responsibility Questionnaire online via the New York State VendRep System. To enroll in and use the New York State VendRep System, see the VendRep System Instructions available at http://www.osc.state.ny.us/vendrep/vendor_index.htm or go directly to the VendRep system online at: https://portal.osc.state.ny.us.

Vendors must provide their New York State Vendor Identification Number when enrolling. To request assignment of a Vendor ID or for VendRep System assistance, contact the Office of the State Comptroller's Help Desk at 866-370-4672 or 518-408-4672 or by email at ciohelpdesk@osc.state.ny.us.

Vendors opting to complete and submit a paper questionnaire can obtain the appropriate questionnaire from the VendRep website at: http://www.osc.state.ny.us/vendrep/forms_vendor.htm or may contact the Office of the State Comptroller's Help Desk for a copy of the paper form.

Applicants should complete and submit the Vendor Responsibility Attestation (Attachment 3).

L. Vendor Prequalification for Not-for-Profits

Beginning July 31, 2013, all not-for-profit vendors subject to prequalification will be required to prequalify prior to grant application and execution of contracts.

Prequalification is a new statewide process designed to facilitate prompt contracting for not-for-profit vendors. Interested vendors will be asked to submit commonly requested documents, and answer frequently asked questions once. The application requests organizational information about the vendor's *capacity, legal compliance,* and *integrity.*

Not-for-profit vendors subject to prequalification will submit their responses online in the new Grants Gateway, and all information will be stored in a virtual, secured vault. Once a vendor is registered with the system, State agencies will have ready access to the vault, eliminating redundant submissions of such information by the vendor. Not-for-profits will only have to prequalify every three years, with responsibility to keep their information current throughout the three year period. To obtain access to the Grants Gateway, vendors should submit a registration form downloadable on the Grants Reform website at: http://grantsreform.ny.gov/Grantees.

M. General Specifications

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

2. Contractors 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, 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.

V. Completing the Application

A two-part application process will be utilized. Peer review panel selection will be conducted on the basis of Part One of the application. Peer review for scientific merit of an application will not take place until both Parts One and Two have passed administrative review.

See RFA Attachments 1 and 2 for detailed content requirements, forms and instructions. It is the applicant's responsibility to ensure that all materials to be included in Part One and Part Two of the application have been properly prepared using the forms and instructions provided in this RFA as Attachments 1 and 2, respectively.

VI. Application Review and Award Process

A. Application Acceptance

Part One applications will first be examined against mandatory Pass/Fail requirements by NYSTEM administrators **(see Attachment 1).** Part One applications that do not meet these mandatory requirements will not be considered for review, and the applicant organization and PI will be notified. Part One applications that meet the mandatory requirements will be assigned an application number by NYSTEM for inclusion on the Face Page for Part Two of the application. Notifications of disqualification or application number assignments may be anticipated two weeks after the submission date for Part One.

Each eligible Part One application will be forwarded to the Peer Review Contractor for development of an Independent Scientific Merit Peer Review Panel (the Review Panel).

Part Two applications will first be examined against mandatory Pass/Fail requirements by NYSTEM administrators **(see Attachment 2)**. Part Two applications that do not meet these mandatory requirements will not be considered for review, and the applicant organization and PI will be notified.

B. Review and Scoring

The Department contracts with an independent peer review organization to develop and coordinate the review and scoring of applications. Each eligible application (Part One and Part Two) will be evaluated by an Independent Scientific Merit Peer Review Panel (the Review Panel) assigned by the Peer Review Contractor. The Review Panel members will be selected from among non-New York State experts in the appropriate fields based on the nature of the applications received. NYSTEM does not convene pre-established peer review panels. Instead, each panel is formed based upon the expertise needed to evaluate the merit of actual applications submitted in response to each RFA.

Applications will be reviewed based on the criteria specified in Section VI.D. The Review Panel will use an established combination of processes to evaluate each application: pre-meeting review and adjectival scoring; on-line conferral among assigned reviewers; assessment of proof-of-principle; panel meeting discussion; and numerical scoring. Applications that are reviewed by the full panel will receive scores from each participating panel member for each evaluation criterion using an integer scale of 1 (highest merit) to 9 (lowest merit). The numerical score given each criterion will be multiplied by that criterion's weight. Each panel member's weighted scores for each criterion will be added together to give their individual total score. Review Panel members' individual total scores will be added together and divided by the number of Review Panel members who scored the application to give an overall panel score for the application. The numerical scores correspond to adjectival scores, as follows:

Numerical Score	Adjectival Score
1	Exceptional
2	Outstanding
3	Excellent
4	Very Good
5	Good
6	Satisfactory
7	Fair
8	Marginal
9	Poor

The Review Panel will identify potential overlap with other resources and existing NYSTEM consortia awards under RFA# 0911051012. Additionally, the Review Panel will comment on the application with regard to the Contract Policy Statements and Conditions (Contract Attachment A-1 Part B). The Review Panel may recommend administrative review and resolution prior to contract execution. In addition, award recommendations made by the ESSCB Funding Committee may be contingent upon the applicant's acceptance of required revisions.

The primary reviewer will prepare a written overall evaluation of each assigned application that is discussed by the Review Panel.

C. Application Penalties and Summary Statements

For each application that scores 3.9 or better, the Peer Review Contractor will assess a penalty of 0.1 point if the application deviates from the instructions **(see Attachments 1 and 2)**.

The Peer Review Contractor will calculate final scores and compile a Summary Statement for each application for NYSTEM. The Summary Statements will document the scientific merit evaluation and serve as the primary basis for the panel recommendation for the applications.

D. Review Criteria

Four criteria will be considered by the Review Panel:

Proof-of-Principle (10%)

- Has the assembled team of investigators demonstrated proof-of-principle, and directly contributed to the available data, using a pre-clinical model that is appropriate to the clinical goals of the project? **NOTE:** If the assigned reviewers find that this criterion does not merit a score of Excellent (corresponding to a score of 3) or better and no other panel members object to that assessment, the application will not be reviewed during the panel meeting discussion and will be disqualified from further consideration.

Significance, Impact and Approach (40%)

- Is the objective achievable within the award period based on the data presented, the research design and methods, the availability of resources and the overarching research environment?
- Does the proposal address an unmet medical need?
- Will successful completion of the project achieve a significant measurable advance toward clinical application and lead to improved health outcomes or contribute to the prevention or treatment of the targeted disease(s) or condition(s)?
- Are the uses of human subjects, vertebrate animals and human pluripotent stem cells appropriate to and necessary for the overall goals of the project?
- Are potential problems discussed and alternative strategies provided?
- Are there identifiable barriers, beyond the scope of the work proposed, to successful development of clinical applications?
- If applicable, is the preclinical or clinical plan sufficiently developed to enable regulatory approval?

Investigators and Management (30%)

- Does the assembled consortium have all of the expertise necessary for successful completion of the project?
- Does the leadership and management team have the experience relevant and necessary to execute, lead and manage the project of the size and scope proposed?
- Is the staffing plan, including staff qualifications and percentages of effort, appropriate for successful and timely completion of the project?
- Are plans for integrating efforts, communication and data/resource sharing among investigators, and with NYSTEM and the Oversight Panel, clearly developed?
- Is the management strategy effectively designed to achieve established goals and milestones?
- Are the timeline and milestones realistic, appropriate and quantifiable? Will they provide appropriate opportunities for progress review by the Oversight Panel?

Budget (20%)

- Are the items for each budget line explained? Are they adequately justified as necessary for completion of the project? Are any necessary items missing or unaddressed/not provided for?
- Are the annual budget line allocations sufficient to accomplish the research aims?
- Are the annual line-item budgeted amounts reasonable and cost effective?
- Are there specific excessive or unnecessary budget items?
- Does the budget reflect understanding of the human, material and financial resources needed, and the timeframes in which they are needed, for successful completion of the project within the contract term?

E. Empire State Cell Board Funding Committee Review

The ESSCB Funding Committee will consider applications that receive a final score (after penalties are assessed) of 1.0 through 3.9. The ESSCB Funding Committee will not consider applications that receive a final score of 4.0 to 9.

The Funding Committee has sole discretion to reject an application that overlaps an existing NYSTEM consortium award under RFA# 0911051012.

The Funding Committee will discuss the application's strengths and weaknesses, and budget recommendations. When making funding recommendations, the Funding Committee will consider responsiveness to the mission of the ESSCB, responsiveness to the RFA, programmatic balance, availability of funds, and compliance with Public Health Law Article 2, Title 5-A, Section 265. The ESSCB Funding Committee is not obligated to recommend funding for any application. Scoring ties will be resolved on the basis of the above and with consideration of the score for Significance, Impact and Approach among those applications involved in the tie.

The ESSCB Funding Committee will vote on each application that scores 3.9 or better until available funds are exhausted and in compliance with ESSCB bylaws as well as applicable laws and regulations. If an application for which there are available funds is not recommended for funding, the ESSCB Funding Committee will fully justify in writing why the application was not approved. The ESSCB Funding Committee will make recommendations for funding to the Commissioner of Health.

F. Award Decisions and Pre-Funding Requirements

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

Following the Commissioner's approval of awards, PIs and their applicant organizations will receive formal notification in writing.

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

- Revisions to Workplan, project duration or budget
- Overlap (budgetary, scientific and commitment)
- Areas of possible concern with regard to Contract Policy Statements and Conditions (Attachment A-1 Part B)
- Approved Facilities and Administrative Cost Rate

Once an award has been made, applicants may request a debriefing of their application. Please note the debriefing will be limited only to the strengths and weaknesses of the subject application and will not include any discussion of other applications. Requests must be received no later than ten (10) business days from date of award or non-award announcement.

In the event unsuccessful applicants wish to protest the award resulting from this RFA, applicants should follow the protest procedures established by the Office of the State Comptroller (OSC). These procedures can be found on the OSC website at http://www.osc.state.ny.us/agencies/guide/MyWebHelp.

G. Award Announcements

NYSTEM makes public in press releases and annual reports to the Governor and Legislature, the project title, the PIs/PDs, the name of the organization, total projects costs and duration. The project abstract and progress report abstracts may also be edited and made public.

VII. Attachments

Attachment 1: Part One Application Checklist, Forms 1- 4 and Instructions
Attachment 2: Part Two Application Checklist, Forms 1-16 and Instructions
Attachment 3: Vendor Responsibility Attestation
Attachment 4: NYS Master Grant Contract with Attachments

ATTACHMENT 1
PART ONE APPLICATION CHECKLIST, INSTRUCTIONS AND FORMS 1-4

PART ONE APPLICATION CHECKLIST
Consortia to Accelerate Therapeutic Applications of Stem Cells

All items are mandatory. Part One Applications that do not include mandatory items will not be reviewed.

- ☐ The application was received by due date and time. *(see pg. 7 and cover sheet)*
- ☐ The application was submitted digitally on a single CD or DVD *(see pg. 7)*
- ☐ If the digital files are damaged, an exact paper copy has been submitted (*see pg. 19)*
- ☐ The organization is a New York State not-for-profit or governmental organization. *(see pg. 1)*
- ☐ The PI submitted only one application in response to this RFA. *(see pg. 2)*
- ☐ The applicant organization submitted only one application in response to this RFA. *(see pg. 2)*

REMINDER: The PI and any named Co-PIs must be the same as those described in Part Two of the application and the overall goals of the project proposed must be the same as those described in Part Two of the application (see pg. 20).

PART ONE APPLICATION INSTRUCTIONS
Consortia to Accelerate Therapeutic Applications of Stem Cells

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared using the forms and instructions provided in this RFA. Deviations from these instructions may affect the peer review score.

Use the Part One application forms provided in Attachment 1 (Forms 1-4). All forms must be completed and submitted. Forms are pre-set with acceptable fonts and margins. Applications should be single-spaced and typed using the font previously set within each form. Smaller font sizes are acceptable for use in tables and figure legends. The header should contain the PI's last name, first name, and applicant organization name, with the exception of Form 1. Each page should be numbered consecutively. **Do not exceed the page limits stated below.** Figures and illustrations are included in the page limits. Appendices should not be submitted.

Applications must be submitted in digital format on a single CD or DVD. An exact paper copy should also be submitted; it will be used only if the CD or DVD is damaged. If a digital copy of the application is not submitted on CD or DVD, the application will fail administrative review and will not be sent to peer review. Also, if the digital copy is damaged and a paper copy has not been submitted, the application will fail administrative review and will not be sent to peer review.

Digital files should not exceed 12 MB each and should not be password protected. Applicants are strongly encouraged to seek appropriate technical support in the creation of digital files and to review the digital files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at http://www.stemcell.ny.gov/research-support. Applicants should also be aware that while color figures may be included, applications may be printed in black and white. Applicants may wish to annotate the figure legend directing the reader to the digital file if color is an important aspect of the figure.

The CD or DVD should be clearly labeled with the applicant's name. It should contain a single Portable Document Format (PDF) file including the following items:

- Form 1 – Part One Face Page (signed and dated by the PI and the Official Signing for the Applicant Organization)
- Form 2 – Project Overview (not to exceed 3 pages)
- Form 3 – Consortia Leadership (not to exceed 1 page)
- Form 4 – Part One Assessment Checklist

Information submitted to NYSTEM is subject to the Freedom of Information Law (FOIL) (New York State Public Officers' Law, Article 6, Sections 84 to 90). To the extent permitted by law, an application will not be disclosed, except for purposes of evaluation, prior to approval by the Comptroller of the resulting contract. All material submitted becomes the property of the Department and may be returned at the Department's discretion. Submitted applications may be reviewed and evaluated by any person, other than one associated with a competing applicant, designated by the Department. Any information supplied by an applicant, which is believed to

be exempt from disclosure under FOIL, will be clearly marked and identified as such upon submission by the applicant. Marking the information as "confidential" or "proprietary" on its face or in the document header or footer shall not be sufficient without specific explanation of the basis for the claim of exemption from disclosure. Acceptance of the claimed materials by the Department does not constitute a determination on the exemption request. A determination of whether such information is exempt from FOIL will be made at the time of any request for disclosure under FOIL in accordance with statutory procedure.

Part One applications should emphasize the significance and feasibility of the proposed project and explain how the project will result in a significant measurable advance toward clinical application(s) within the period of the award. The content of Parts One and Two of the application should present information in sufficient detail to allow monitoring of progress toward project goals and convey clearly and concisely to reviewers that:

- the application's basis is conceptually well-founded and substantiated by the literature and preliminary data;
- the assembled team of investigators demonstrated proof-of-principle, and directly contributed to the available data, using a pre-clinical model that is appropriate to the clinical goals of the project;
- the proposed approach is the most appropriate strategy to use as evidenced, in part, by consideration of alternatives; and
- the research team and available resources enhance the likelihood of the project's success.

Part One Applicant Face Page – Form 1

Do not provide information for Co-PIs on this form. Do not complete additional forms for Co-PIs or sub-applicant organizations.

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

Application Type. This box should read "Stem Cell Consortia Part One."

FAU number. This box should read "1212030210."

Principal Investigator. Provide the information requested. The PI is the investigator designated by the applicant organization within New York State who is responsible for planning, coordinating and implementing the contract if an award is made. The PI will act as liaison between the awarded organization and NYSTEM, and be required to fulfill technical reporting requirements and submit any revised budgets co-signed by an authorized organizational representative.

Type of Organization. Select the appropriate type from the dropdown box (Governmental or Not-for-profit).

NYS Vendor ID Number. Enter the applicant organization's 10-digit Vendor ID number assigned b the New York State Office of the Comptroller.

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

Contracts and Grants Official. Provide the information requested.

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 contract should an award be made. *Note:* This individual typically is not the PI.

Certifications and Assurance. Prior to award recommendation, the PI and the organizational official are required to sign and date this form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; certification that the organization and PI are eligible to apply and the organization has the capability to conduct and administer externally-funded research (see Section II of the RFA); and, agreement to comply with the terms and conditions of any contract awarded as a result of this application.

Part One Project Overview – Form 2

Provide the information requested such that persons from diverse scientific backgrounds can easily understand the objective. Use the available space to your best advantage. Do not exceed 3 pages.

Overall Goals, Objective and Aims

Describe the targeted disease(s), conditions(s) or organ system(s). Summarize the scientific rationale and the expected outcome(s). List the aims of the proposed application of stem cell research. **Note that the overall goals of the project proposed in Part Two must be the same as those described in Part One of the application, otherwise the application will be disqualified. Also note that the peer review selection will have been based upon the goals described in Part One of the application.**

Significance and Readiness

Explain how the proposed research will result in a clinical application to address an unmet medical need and how successful development of the proposed therapy would impact the prevention or treatment of the targeted disease(s) or condition(s). Justify the readiness of the project emphasizing recent advances and proof-of principle data that make the proposed work timely. Explain the need for a multi-disciplinary collaborative approach for successful completion of the project.

Overall Plan

Describe the overall plan for the project. Briefly summarize the experimental approaches, methods and techniques proposed for accomplishing the project that will be fully detailed in Part Two of the application.

Part One Consortia Leadership – Form 3

Provide the information requested. Do not exceed 1 page.

List the PI, Co-PIs (if applicable) and co-investigators for the research team. Include: name and a brief description of their role on the project (i.e., describe which activities identified on Form 2 each will supervise or execute). Describe the leadership credentials of the PI and Co-PIs (if applicable). Describe the qualifications of the PI and Co-PIs to lead their component of the project. **NOTE: the PI and any named Co-PIs must be the same as those identified in Part Two of the application.**

Describe the specific qualifications and role of the Project Manager on the project (i.e., describe which activities identified on Part One Form 2 the Project Manager will execute). If an individual currently fills that role, please list them by name.

Part One Self-Assessment Checklist – Form 4

This checklist is a means for the applicant to gauge the appropriateness of the intended project for this specific funding mechanism and **is to be included in Part One of the application submission**. The prospective applicant is advised to consider each question carefully before investing time in the development of Part Two of the application. A checklist with affirmative (Yes) responses indicates that the project is likely to be considered responsive to the RFA and "ready" for this consortia funding mechanism. No additional determination of responsiveness will be made based on Part One applications.

The Funding Committee has sole discretion to reject an application that overlaps an existing NYSTEM consortium award under RFA# 0911051012.

Part One Applicant Face Page – Form 1

Project Title:					
Application Type: Stem Cell Consortia Part One			FAU #: 1212030210		
Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) , , ,					
Organization:					
Department:					
Mailing Address (Street, MS, P.O. Box, City, State, Zip): Street 1 Street 2 City State NY Zip					
Phone:		Fax:		Type of Organization:	
E-mail:				NYS Vendor ID # (10 digits):	
New York State Applicant Organization:					
Mailing Address (Street, MS, PO Box, City, State, Zip): Street 1 Street 2 City State NY Zip					
Contracts and Grants Official: Last Name First Name Title				Official Signing for the Organization: Last Name First Name Title	
Mailing Address (Street, PO Box, MS, City, State, Zip): Street 1 Street 2 City State NY Zip				Organization Mailing Address (Street, PO Box, MS, City, State, Zip): Street 1 Street 2 City State NY Zip	
Phone:		Fax:		Phone:	Fax:
E-mail:				E-mail:	
CERTIFICATIONS AND ASSURANCE: Prior to award recommendation, the PI and organizational official are required to sign and date this form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; certification that the organization and PI are eligible to apply and the organization has the capability to conduct and administer externally-funded research (see Section II of the RFA); and, agreement to comply with the terms and conditions of any contract awarded as a result of this application.					
SIGNATURE OF PRINCIPAL INVESTIGATOR:					
X DATE:					
SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION:					
X DATE:					

Part One Project Overview – Form 2

Overall Goals, Objectives and Aims

Significance and Readiness

Overall Plan

Part One Consortia Leadership – Form 3

Part One Self-Assessment Checklist – Form 4

Self-Assessment Criteria	Yes	No
1. Is the proposed objective consistent with the intent of the RFA (see Section I, Introduction)?		
• Will it accelerate development of clinical applications of stem cells for prevention and/or treatment of disease? AND	☐	☐
• Is it disease-focused, health outcome-based, and multi-disciplinary collaborative research? AND	☐	☐
• Does it address an unmet medical need using stem cells as a basis for the development of clinical treatments/therapies? AND	☐	☐
• Is it a coherent project with a focused goal rather than a series of separate but related projects? AND	☐	☐
• Does it focus on a disease/condition, group of diseases/conditions or organ system(s)?	☐	☐
2. Is the proposed project consistent with the General Expectations of the RFA (see Section III.A.)?		
• Does the data developed by the participating investigators demonstrate proof-of-principle in an appropriate pre-clinical model? AND	☐	☐
• Is it sufficiently mature to achieve a significant, measurable advance toward clinical application, as defined in the RFA, within the period of the award? AND	☐	☐
• Can quantifiable milestones be identified to track progress toward clinical application, and will the application contain a specific and reasonable time line for completion of the project? AND	☐	☐
• Does it involve investigators with clinical and commercial experience in aspects that relate to clinical activities or products? AND	☐	☐
• Will the experimental design and implementation be carried out in accordance with GLP and GMP standards as necessary?	☐	☐
3. Leadership and Oversight		
• Can the PI provide vision, strategy and overall project direction? AND	☐	☐
• Can the PI provide scientific and fiscal accountability based on a record of effective scientific leadership? AND	☐	☐
• Does the team of investigators have prior success working with relevant for-profit entities? AND	☐	☐
• Will the Project Manager have advanced science or science management background and experience in Scientific Project Management, as defined in the RFA? AND	☐	☐
• Are data/resource sharing plans developed that include access to all data and materials by NYSTEM and an Oversight Panel?	☐	☐
4. Overlap		
• No scientific, budgetary or commitment overlap exists between the application and any other funded project.	☐	☐

The Funding Committee has sole discretion to reject an application that overlaps an existing NYSTEM consortium award under RFA# 0911051012.

ATTACHMENT 2
PART TWO APPLICATION CHECKLIST, INSTRUCTIONS AND FORMS 1 – 16

PART TWO APPLICATION CHECKLIST
Consortia to Accelerate Therapeutic Applications of Stem Cells

The following items are mandatory (Pass/Fail). Part Two applications that do not include mandatory items will not be reviewed.

- ☐ The application was assigned a number by NYSTEM. *(see pg. 11)*
- ☐ The application was submitted digitally on a single CD or DVD (see pg. 7 and 29)
- ☐ If the digital files are damaged, an exact paper copy has been submitted (see pg. 29)
- ☐ The organization is a New York State not-for-profit or governmental organization. *(see pg. 1)*
- ☐ The application was received by due date and time. *(see pg. 6 and cover sheet)*
- ☐ The percent effort of the Project Manager is 100% throughout the contract term. *(see pg. 3 and 35)*
- ☐ The PI and **named** Co-PIs are the same as those described in Part One of the application. *(see pg. 21 and 29)*
- ☐ The overall goals of the proposed project are the same as those described in Part One of the application. *(see pg. 20 and 29)*

The following items are not mandatory. Appendices may include items such as:

- ☐ Vendor Responsibility Attestation (Attachment 3)
- ☐ Letters of collaboration or support; commitment(s) to provide research resources; subcontract letter(s) from consultant(s)
- ☐ Memoranda of Understanding, Subcontracts or Contractual Agreements
- ☐ Up to two highly relevant publications or manuscripts (published or in press) may be included if essential to document the investigator's capability to undertake the work proposed
- ☐ Facilities and Administrative rate agreements
- ☐ Equipment quotes

APPLICATION PENALTIES:

A total penalty of 0.1 point will be assessed to a Part Two application if:

- Digital submission is password protected
- Forms provided in this RFA are not used
- Submission does not adhere to page (or word count) limits (Forms 5, 6, 9, 10, 12, and 13)
- Submission does not include:
  - Applicant Forms 1 – 6 in a single Microsoft Word (DOC or DOCX) file
  - Applicant Forms 1 – 6 in a single Portable Document Format (PDF) file
  - Forms 7 – 16 and all appendix material in a single PDF file
  - Sub-applicant Form 1-S for each Sub-applicant in Microsoft DOC or DOCX file (Form 1-S may be omitted if there are no Sub-applicants included in the application) **NOTE:** No other forms may be omitted
  - Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned together as a single PDF file. **NOTE:** Form 1-S may be omitted if there are no sub-applicants. No other forms may be omitted
  - Budget and Justification – Form 8 – one for each year of the applicant and one for each year of each sub-applicant organization
  - Biographical Sketch – Form 9 – one for each key personnel listed on each Form 9
  - Facilities and Resources – Form 10 – one for the applicant and one for each sub-applicant organization
  - Other Support – Form 11– one for each key personnel listed on each Form 9
  - Introduction – Form 12 – may be left blank or marked "N/A" if application is not a resubmission
  - Workplan – Form 13 – limited to 35 pages for parts a-c
  - Human Subjects – Form 14 – at least one per applicant and sub-applicant; and one for each protocol used for this research project
  - Vertebrate Animals – Form 15 – at least one per applicant and sub-applicant; and one for each protocol used for this research project
  - Human Stem Cells – Form 16 – at least one per applicant and sub-applicant; and one for each protocol used for this research project

PART TWO APPLICATION INSTRUCTIONS
Consortia to Accelerate Therapeutic Applications of Stem Cells

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared using the forms and instructions provided in this RFA. Deviations from these instructions may affect the peer review score. In addition, a 0.1 point penalty will be assessed for specific deviations detailed in Attachment 2 (Part Two Application Checklist, above).

For each Part One application that meets the mandatory requirements **(see Attachment 1)**, NYSTEM will assign and provide an application number to the PI for use when submitting Part Two of the application. **The consortia PI and named Co-PIs and the overall goals of the project proposed in Part Two must be the same as those described in Part One of the application, otherwise the application will be disqualified.***

*Under extraordinary circumstances (i.e., death or disability), substitution of the PI or Co-PIs may be considered by NYSTEM. Such consideration will be based on the overall impact of the substitution to the merit of the project.

Use the Part Two application forms provided in Attachment 2 (Forms 1-16). Omit Form 1-S if there are no sub-applicants. All other forms must be submitted, whether blank, not applicable (NA) or completed. Forms are pre-set with acceptable fonts and margins. Applications should be single-spaced and typed using the font previously set within each form. Smaller font sizes are acceptable for use in tables and figure legends. The header should contain the PI's last name, first name, and applicant organization name, with the exception of Forms 1-6. Each page should be numbered consecutively. **Do not exceed the page limits stated below.** Figures and illustrations referenced in the Workplan are included in the page limits. Appendices may not be used to circumvent page limitations.

Applications must be submitted in digital format on a single CD or DVD. An exact paper copy should also be submitted; it will be used only if the CD or DVD is damaged. If a digital copy of the application is not submitted on CD or DVD, the application will fail administrative review and will not be sent to peer review. Also, if the digital copy is damaged and a paper copy has not been submitted, the application will fail administrative review and will not be sent to peer review.

Digital files should not exceed 12 MB each and should not be password protected. Applicants are strongly encouraged to seek appropriate technical support in the creation of digital files and to review the digital files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at http://www.stemcell.ny.gov/research-support. Applicants should also be aware that while color figures may be included, applications may be printed in black and white. Applicants may wish to annotate the figure legend directing the reader to the digital file if color is an important aspect of the figure.

The CD or DVD should be clearly labeled with the applicant's name. It should contain a single Portable Document Format (PDF) file including the following items:

- Applicant Forms 1 – 6 in a *single* Microsoft Word (DOC or DOCX) file;
- Applicant Forms 1 – 6 in a *single* Portable Document Format (PDF) file;
- Forms 7 – 16 and all appendix material in a *single* PDF; and
- Sub-applicant Form 1-S for each Sub-applicant in Microsoft DOC or DOCX file (Form 1-S may be omitted if there are no Sub-applicants included in the application); and
- Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned together and saved as a *single* PDF file.

Information submitted to NYSTEM is subject to the Freedom of Information Law (FOIL) (New York State Public Officers' Law, Article 6, Sections 84 to 90). To the extent permitted by law, an application will not be disclosed, except for purposes of evaluation, prior to approval by the Comptroller of the resulting contract.

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

Part Two Applicant Face Page – Form 1

Application Type. This box should read "Stem Cell Consortia Part Two," and RFA # "1212030210."

Application Number. Enter the application number provided by NYSTEM after the submission of Part One of the application. **This number must have been provided by NYSTEM for the application to be considered by the peer reviewers.**

New Application. Select "Yes" or "No." A "New" application is one submitted to NYSTEM for the first time, or one that includes substantial changes in all portions of the Workplan from an application previously submitted to NYSTEM but not funded.

Resubmission Application. Select "Yes" or "No." A "Resubmission" application includes proposed research that was reviewed by NYSTEM during a previous cycle, but was not funded and is being resubmitted for new consideration.

Original Application Number. If this is a Resubmission application, enter the number of the originally submitted application. This number can be found on the reviewer critiques from the previous application or requested from NYSTEM.

Principal Investigator. Provide the information requested. The PI is the investigator designated by the applicant organization within New York State who is responsible for planning, coordinating and implementing the research project if an award is made. The PI will act as liaison between the awarded organization and NYSTEM, and be required to fulfill technical reporting requirements and submit any revised budgets co-signed by an authorized organizational representative.

Co-Principal Investigator. If the Co-PI is from the applicant organization, provide the information requested for the Co-PI. If the organizational affiliation of the Co-PI is different from that of the PI, do not list him/her on the Applicant Face Page; complete a separate Face Page for each Co-PI (see Form 1-S, below). **NOTE:** A Co-PI shares responsibility with the PI for oversight of the entire project; a co-investigator may be responsible for a specific component of the research project.

Type of Organization. Select the appropriate box (Governmental or Not-for-profit).

NYS Vendor ID Number. Enter the applicant organization's 10-digit Vendor ID number assigned by the New York State Office of the State Comptroller.

Charities Registration Number. Enter the 6-digit New York State Charities Registration Number. If the state Office of the Attorney General determined that the organization is exempt based on its CHAR410 Series, Schedule E filing, indicate the approved exemption category in the space provided. For more information on registration numbers, see http://www.charitiesnys.com or telephone the Office of the Attorney General at 212-416-8402.

Project Start and End Dates. Record the anticipated project duration of: July 1, 2015 through June 30, 2019.

Year One Grand Total Costs. Enter Year One Total Costs from the applicant Form 8 Summary page.

Grand Total Costs (all years). Enter the Total Costs for each of the four years from all applicant Form 8 Summary pages. This figure includes **all** requested funds to complete the project.

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

Research Performing Sites. List all sites (organization and location) where the work described 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 contract should an award be made. **NOTE:** This individual typically is not the PI.

Certifications and Assurance. Prior to award recommendation, the PI, Co-PI (if from the same organization) and the organizational official each are required to sign and date the form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; certification that the organization and PI are eligible to apply; certification that the applicant is pre-qualified with NYS; and the organization has the capability to conduct and administer externally-funded research (see Section II of the RFA); and, agreement to comply with the terms and conditions of any contract awarded as a result of this application.

Reminder: A separate face page will need to be completed, signed and dated for the applicant organization and each sub-applicant organization participating in the project.

Part Two Sub-applicant Face Page – Form 1-S

Complete a separate face page for **each** sub-applicant organization participating in the project. Omit Form 1-S if there are no sub-applicants.

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

Application Type. This box should read "Stem Cell Consortia Part Two," and RFA # "1212030210."

Principal Investigator. Provide the information requested. The sub-applicant PI is the investigator designated by the sub-applicant organization responsible for planning, coordinating and implementing the subcontracted portion of the project if a subaward is made. The sub-applicant PI will act as liaison with the applicant PI and be required to fulfill technical reporting requirements of the subcontract and submit any revised budgets co-signed by an authorized organizational representative. If this individual is also considered to be the Co-PI of the overall application to NYSTEM, also check the 'Overall Project Co-PI' box.

Co-Principal Investigator. If a Co-PI from the sub-applicant organization is designated, provide the information requested for the Co-PI of the sub-applicant. The Co-PI and the sub-applicant organization's authorized agent should sign the form on which his/her name appears. **NOTE:** A Co-PI shares responsibility with the PI for oversight of the entire project; a co-investigator may be responsible for a specific component of the project.

Type of Organization. Select the appropriate box (Governmental, Not-for-profit or For Profit).

Charities Registration Number. Enter the 6-digit New York State Charities Registration Number. If the state Office of the Attorney General determined that the organization is exempt based on its CHAR410 Series, Schedule E filing, indicate the approved exemption category in the space provided. For more information on registration numbers, see http://www.charitiesnys.com or telephone the Office of the Attorney General at 212-416-8402.

Project Start and End Dates. Enter the anticipated project duration for the subcontract.

Year One Grand Total Costs. Enter Year One Total Costs from the sub-applicant Form 8 Summary page.

Grand Total Costs (all years). Enter the Total Costs for each of the four years from sub-applicant Form 8 Summary pages. This figure includes **all** requested funds to complete the project for the sub-applicant.

Sub-applicant Organization. Enter the legal name and address of the sub-applicant organization/contracting entity.

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

Contracts and Grants Official. Provide the information requested.

Official Signing for Sub-applicant Organization. Provide the name and contact information for the individual authorized to act for the sub-applicant organization. This individual will be responsible for administration and fiscal management of the subcontract should an award be made. **Note:** This individual typically is not the sub-applicant PI.

Principal Investigator and Co-PI Certification and Assurance. Prior to award recommendation, the sub-applicant PI is required to sign and date the form and the sub-applicant Co-PI, if from the same organization, is also required to sign and date the form.

Organization Certification and Acceptance. Prior to award recommendation, the organizational representative of the sub-applicant is required to sign and date the form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; certification that the applicant is pre-qualified with NYS; and agreement to comply with the terms and conditions of any contract awarded as a result of this application.

Reminder: A separate face page will need to be completed, signed and dated for the applicant organization and each sub-applicant organization participating in the project.

DO NOT OMIT ANY OF THE REMAINING FORMS FROM THE APPLICATION

Part Two Staff, Collaborators, Consultants and Contributors – Form 2

List (spell out) the full name, title and organizational affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid) associated with this project. Do not include the PI and Co-PIs named on any Form 1 or 1-S in the application (see page 31). Do not include unnamed or "to be determined" staff positions. For each individual listed, select the most applicable role from the dropdown box. This list is used to determine possible conflicts of interest at various stages of the review and award process.

- Principal Investigator – the lead researcher on the project. The PI is designated by the New York State applicant organization and is responsible for planning, coordinating and implementing the research project
- Co-Principal Investigator – the Co-PI shares responsibility with the PI for oversight of the entire project
- Co-Investigator – an independent researcher responsible for a specific component of the project
- Research Scientist – a dependent researcher who assists in completion of the project
- Postdoc – a researcher who holds a PhD but is not independent
- Predoc – one who is in graduate school for a Doctoral degree
- Grad Student – one who is in graduate school for a Masters degree
- Technician – one who works in the lab for the PI and has technical skills but is not a predoc, postdoc, grad student or research scientist
- Admin/Support Staff – one who provides support services and does not participate in the scientific work, such as a secretary, budget analyst, lab administrator or some other administrative title
- Consultant – one who provides specific advice or applies specialized skills or services for the project; can be paid or unpaid
- Collaborator – One who provides generalized advice or a service for the project; can be paid or not paid
- Other – all others who cannot be categorized as above

The Funding Committee has sole discretion to reject an application that overlaps an existing NYSTEM consortium award under RFA# 0911051012.

Part Two Independent Oversight Panel – Form 3

Provide a list of suggested experts to serve on the Oversight Panel. Spell out the full name, title and organizational affiliation of any recommended member, include contact information where available, and state the specific rationale for each suggestion, as related to the proposed project.

Part Two Acronyms and Abbreviations Used in Application – Form 4

Provide a list of all acronyms and abbreviations used in the application. Also include the full text/definition/ description as used in the application. This will allow the Peer Review Panel to fully comprehend the proposed experimental design and may be particularly important for the identification of specific protein cascades, for example. Common acronyms such as hESC (human embryonic stem cells) need not be identified.

Part Two Lay Abstract – Form 5

Provide a summary of the proposed project, in non-technical terms; limit 300 words (do a word count, as the fill-in box may allow more than 300 words). This information will be excerpted and edited for use in various public documents. **Do not include confidential information.** Specifically, provide an Introduction/Background, a Summary of Goals and Objectives, and describe the Impact that successful completion of the project will have on clinical therapies for the targeted disease/condition.

Part Two Scientific Abstract – Form 6

Provide a scientific summary of the proposed project. The abstract should be written so that persons from diverse scientific backgrounds can easily understand the work proposed. **NOTE:** Applicants proposing use of human embryonic stem cells should clearly indicate the specific cell line(s) planned for use, as well as the source. If applicable, include the name and/or NIH Registration number from http://stemcells.nih.gov/research/registry. Do not exceed one page.

Part Two Table of Contents – Form 7

Complete the table of contents, entering page numbers as appropriate or entering "N/A" when not applicable.

Part Two Budget and Justification – Form 8

Form 8 is fillable as a Microsoft Excel workbook consisting of six spreadsheets. Complete a separate Form 8 for each budget year of the proposed project. In addition, complete a separate Form 8 for each proposed budget year for each sub-applicant (e.g., an application with two sub-applicants in each year will submit a total of twelve Form 8s).

Request funds appropriate for cost-effective performance of the proposed project. Budgets must be developed and managed in accordance with appropriate accounting standards for the organization including, but not limited to, applicable Circulars from the federal Office of Management and Budget (OMB) (see Attachment 5, Sample NYS Master Grant Contract, Appendix A-1). Record the amount requested for each category, subtotal and total for each year or portion thereof.

Care should be taken to record the true budgetary needs of the application. Proposed budgets are expected to incorporate cost of living increases and other reasonably-anticipated adjustments that may be necessary throughout the contract term. 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.

No funds shall be directly or indirectly utilized for research involving human reproductive cloning. Patient care is not an allowable expense. Funds awarded by this program may not be used to supplant or duplicate other existing support for the same work (also see Sample NYS Master Grant Contract Paragraph III.C., Claims for Reimbursement regarding duplicate reimbursement and replacement funds). Ineligible budget items will be removed from the budget prior to contracting; the budget amount requested will be reduced to reflect the removal of the ineligible items.

Subsequent requests for changes to the budget are not guaranteed approval and may be subject to review beyond the program level (also see the Contractor Manual at: http://www.stemcell.ny.gov/awardee-information. Such requests include budget modifications (including requests for equipment purchases that were not detailed in the application and its appendices), carry forwards, and no cost extensions. Specifically, any proposed modification to the contract which results in a cumulative change equal to or greater than 10 percent (for contracts less than five million dollars) or 5 percent (for contracts more than five million dollars) of the total contract value between Personal Services and Non Personal Services may render those funds unavailable for an extended period (4-6 months). Thus, it is of critical importance that the application budget is prepared as accurately as possible, equipment needs are anticipated, and the scope of work can clearly be accomplished within the stated contract term. Further, no annual budget may exceed the maximum direct costs and maximum F&A costs as stipulated in the table below.

Budget Year	Maximum Direct Costs	Maximum F&A
Year 1	$ 2.6 million	$ 520,000
Year 2	$ 3.1 million	$ 620,000
Year 3	$ 3.6 million	$ 720,000
Year 4	$ 4.0 million	$ 800,000
Grand Total	$13.3 million	$2,660,000

Allowable Expenses of the Applicant and Sub-applicants

1. Personal Service

All personal services costs must be directly related to the research project described in the Workplan. Support may be requested for investigator(s) and technical staff, as well as for pre- and postdoctoral fellows, and students. Salary and stipends are to be paid according to established organizational policies. Fringe benefits may be requested in accordance with organizational guidelines for each position, provided such benefits are applied consistently by the applicant organization as a direct cost to all sponsors. Maximum salary is limited to $199,700 in each budget year and is not adjustable as the federal salary cap changes.

The percent effort of the Project Manager must be 100% throughout the contract term. The percentage of professional effort for other personnel is not prescribed; it should be dependent upon the role of each individual at various time points during the project and should be sufficient to complete the work within the contract period.

2. Non Personal Services

Support may be requested for:

- Contractual Services (subcontracts)
- Travel
- Equipment
- Travel
- Operating expenses (lab supplies, consumables)
- Other Expenses
    - ❖ Human Subjects
    - ❖ Animals and Their Care
    - ❖ Core Facility Usage Fees (including NYSTEM-funded shared facilities)
    - ❖ Communication Costs
    - ❖ Meeting Costs**
    - ❖ Publication Costs
    - ❖ Consultants
    - ❖ Facilities and Administrative Costs (see below)

Meeting costs specifically associated with meetings of the Oversight Panel (venue, food and refreshments, and panel member honoraria/travel/lodging) **should not be included in the budget. Costs associated with consortium member participation in these and other meetings **should be included** in the budget.

3. Proposed Subcontracts (Sub-applicants)

Allowable expenses for sub-applicants will be consistent with those established herein for the applicant. Sub-applicant amounts will be carried forward from sub-applicant budget forms to Contractual Services of the applicant budget, Form 8. Such amount will include sub-applicant F&A costs. Note that any expenses budgeted for the sub-applicant will reduce the allowable expenses for the applicant organization.

4. Facilities and Administrative Costs (F&A)

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

If an award is made, F&A costs will be re-calculated from recommended and approved budget amounts. F&A costs will be calculated as the lower of the RFA-specified percentage of modified total direct costs or the amount recovered using the organization's current DHHS F&A rate. A copy of the DHHS F&A rate agreement should be included in the application appendix. In the absence of a DHHS agreement, an equivalently documented rate for the organization may be used. Sub-applicant F&A costs are likewise limited and will be included in the primary applicant's direct costs.

Complete the Summary Page using **only** the column labeled Grant Funds and the column labeled Total. Complete each column of the Personal Services Detail page. Add rows as necessary for Salary and Fringe. Complete all other sections as appropriate.

Justification

On the last page of Form 8, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered, are reasonable and are consistent with the approaches described in the Workplan. Justify funding for each budget year and budget line for the applicant and each sub-applicant. Budget lines that are not well-justified may be decreased or disallowed during the peer review and award process.

Starting with personnel, **fully justify** amounts requested in each budget category and budget line. Regardless of whether financial support is requested, describe and substantiate the roles and essential contributions to the project of the PI and other staff involved in the project. In addition, provide a **detailed** justification for each 'Non Personal Service' (e.g., travel, equipment, operating expenses and other expenses).

The percent effort of the Project Manager must be 100% throughout the contract term. The percentage of professional effort for other personnel is not prescribed; it should be dependent upon the role of each individual at various time points during the project and should be sufficient to complete the work within the contract period.

"Professional effort" is defined as all professional activities performed, regardless how or whether the individual receives compensation. Provide the information requested for key personnel and technical staff at the applicant organization, regardless of whether financial support is requested. Insert additional lines as necessary. "Key personnel" are defined as the PI and any others who contribute to the development and execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

Part Two Biographical Sketch – Form 9

Provide biographical sketches for **all key personnel**, including collaborators and consultants. Start with the PI followed by Co-PI(s) and the Project Manager, and then include remaining co-investigators and other key personnel in alphabetical order using additional copies of Form 9. Complete the information requested on the form. Do not exceed three pages for each. In Section A, include a brief personal statement to describe how the experience and qualifications make the individual particularly well-suited for the identified role in the project. In Section B, 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. In Section C, enter the total number of peer reviewed publications in the individual's history in the section heading and list relevant publications in chronological order.

Part Two Facilities and Resources – Form 10

Describe the facilities available within the applicant organization for performance of the proposed project. Use headings for: Laboratory, Clinical, Animal, Computer, Office and Other (such as machine shop and electronics shop). Under the heading for Major Equipment, list the most important equipment items already available for this project, noting the location and pertinent capabilities of each. Specify the extent to which services will be available to the project. Indicate the performance site(s) and describe pertinent site capabilities and relative proximity to the project. Also indicate organizational commitment, including any additional facilities or equipment to be provided in support of the project or available for use at no cost to the project. **Complete an additional form for each proposed sub-applicant organization.** Do not exceed two pages for each.

Part Two Other Support – Form 11

Repeating the format shown, provide the current information requested for **all key personnel** on all existing and pending support. Use additional pages as needed. Present the PI first, followed by the Co-PI(s) and the remaining key personnel in alphabetical order.

Applications submitted to NYSTEM should not duplicate other funded projects in whole or in part. **Scientific, budgetary or commitment overlap between this application and any other funding that is active as of the anticipated contract start date listed on the cover page of the RFA will preclude NYSTEM from awarding a contract under this RFA.** The PI and the contracting organization are responsible for identifying and notifying NYSTEM administration staff of any changes in funding overlap information from time of application submission throughout the contract term.

If the individual listed has no active or pending support other than this application, type an "X" in the box and go on to the next person. For each entry of other support, provide a project title. Type an "X" in the box to indicate whether the support is active or pending. Provide a brief description of the project. List the name of the PI awarded funding for the project. Provide the name of the funding agency, the assigned grant/contract number, and the period of support for the project. Provide the percent of effort the individual devotes to this project. Type a "X" in the box to indicate whether the project involves stem cell research. If 'Yes,' list the specific aims of the project and explain the distinction between the project and this application. Type an "X" in the box to indicate whether the project includes any scientific or budgetary overlap with this application. If 'Yes,' provide the intended resolution if the project is funded.

Part Two Introduction – Form 12

If the application is **not** a "Resubmission" this form may be left blank or marked "Not Applicable (N/A)." A "Resubmission" application includes research that was reviewed by NYSTEM during a previous cycle, but was not funded and is being resubmitted for new consideration. Resubmission applications should be responsive to the funding mechanism as well as reviewers' comments to the previous application.

If the application is a "Resubmission," in no more than three pages, summarize the substantial additions, deletions and changes that have been made to the original application. Include responses to the issues and criticism raised in the original review. The Workplan should incorporate any relevant work done since the original application. All changes in the Workplan from the original submission should be indicated by bracketing, indenting or change in typography. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. **Reviewers' comments from the original application will be provided by NYSTEM to the reviewers of the revised application.**

Part Two Workplan – Form 13

Enter the requested information at the top of the Summary Page. Paste the text from Part Two Scientific Abstract (Form 6) into the box on the Summary Page.

On the Detail Page, list each Specific Aim in the column labeled Objective. List each sub-aim in the column labeled Tasks. Add rows as necessary. Within each column, as appropriate, summarize the scientific rationale and the expected outcome(s) for each. Explain clearly how the specific aims of the proposal will facilitate clinical development, and include any plans to file an Investigational New Drug (IND) application and obtain other regulatory approvals. Do not type any information in the columns labeled Budget Category/Deliverable and Performance Measures.

Include the Workplan narrative below the table. Do not exceed 35 pages for Sections a-c. The Workplan should be sufficiently detailed to allow monitoring of progress toward project goals. It should present information in sufficient detail to convey clearly and concisely to reviewers that:

- The application's basis is conceptually well-founded and substantiated by the literature and preliminary data;
- The assembled team of investigators demonstrated proof-of-principle, and directly contributed to the available data, using a pre-clinical model that is appropriate to the clinical goals of the project.
- The proposed approach is the most appropriate strategy to use as evidenced, in part, by consideration of alternatives;
- The research team and available resources enhance the likelihood of the project's success; and
- The project can be completed within the length of the contract term and with the proposed budget.

a) Significance

Describe the targeted disease(s), conditions(s) or organ system(s) that are the focus of the application and briefly summarize the scientific basis for the project. Explain how the proposed research will meet an unmet medical need and how successful development would impact the prevention or treatment of the targeted disease(s) or condition(s).

b) Background and Preliminary Results

Review the current understanding of the targeted disease(s)/condition(s) and the underlying basis for the approaches proposed, citing appropriate medical and scientific literature. Detail preliminary results and provide proof-of-principle data developed by the participating investigators in an appropriate pre-clinical model. This section should substantiate that project development is sufficient to ensure a significant measurable advance toward clinical application, as defined in the RFA, within the period of the award.

c) Research and Development Plan

It is expected that the project goals will include significant measurable advances within the award period. Describe the overall research and development plan in detail. Describe experimental approaches, methods, techniques, statistical analyses and interpretation sufficient to demonstrate the plan will **accomplish the specific aims within the award period.** Information provided should convey the applicants' understanding of the strengths and limitations of the proposed study's design, methodologies, and pre-clinical stem cell models, and convince reviewers that this approach is the most effective strategy. Discuss potential problems and strategies to overcome them. Ensure that important unpublished information is presented in sufficient detail to enable reviewers to assess its quality and relevance. Aspects of the plan that are to be conducted by collaborating investigators should be indicated, and the rationale for inclusion of each collaborator should be well justified. **NOTE:** The plan should be structured as a single coherent, goal-oriented project; it should not present a series of separate but inter-related projects as would an NIH Program Project or Center grant.

d) Milestones and Timeline

This section is not counted against page limitations. In the context of the Research and Development Plan, provide a detailed timeline that outlines specific project activities, key decision points and milestones. Milestones should note specific measurable outcomes of key objectives and tasks (activities) that provide landmarks of progress toward achieving the specific aims of the project, including an estimate of the timing of key decision points. For the purposes of this application, "milestones" are precise, quantifiable study outcomes for key project activities, not simply the work to be conducted or the aims to be met. Also include the outcome of interactions with regulatory bodies as milestones. In addition, outline the critical path to accomplish the goals of the Workplan by the end of the contract term (within four years). **Note:** Milestone achievement will be an important indicator of progress and a major factor in progress reviews; insufficient progress may lead to termination of funding.

e) Project Management and Coordination Strategy

This section is not counted against page limitations. Describe the plan for project management, the role, training and qualifications of the Project Manager. Describe strategies for information and/or resource exchange to ensure efficient and effective completion of the project. Provide sufficient detail to provide a clear understanding of how every aspect of the project will be completed on time and within budget. Include frequency and methods of communications. Discuss management of intellectual property rights and related issues, including compliance with anticipated contract provisions (see Attachment 4, Sample Master Grant Contract). Include strategies to overcome potential problems with communication and/or data and resource sharing.

f) Literature Cited

This section is not counted against page limitations and the number of references is not restricted. Provide complete citations to all references noted in the body of the Workplan. Applicants are urged to select references that comprehensively reflect the relevant literature.

Part Two Human Subjects – Form 14

Submit a separate Form 14 for the applicant and each sub-applicant. Accurately complete at least Section A of each form. In addition, if more than one human subject protocol will be required to complete the proposed research project, complete a separate form for each protocol.

Section A

1. Enter the name of the applicant or sub-applicant organization.

2. Type an "X" in the appropriate box (YES or NO) to indicate whether activities involving human subjects are planned at any time during the proposed project. Select YES even if the proposed project is exempt from Regulations for the Protection of Human Subjects.

   To determine whether the planned use of human specimens, cells, cell lines or data is considered to be human subjects research, ask the IRB staff from your organization and refer to http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm and the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens (http://www.hhs.gov/ohrp/policy/cdebiol.html) for guidance. If the use of human specimens, cells, cell lines or data are not considered to be human subjects research, skip the rest of Section A and follow the instructions for Section B.1, below.

   If activities involving human subjects, specimens, cells, cell lines or data are not planned at any time during the proposed project, select NO and skip the rest of the form.

3. If YES is checked in #2, type an "X" in the appropriate box (YES or NO) to indicate whether the project is Exempt from federal regulation.

4. If YES is checked in #3, type an "X" in the box to identify the appropriate exemption number (1 through 6). NOTE: This exemption must be determined and documented by the IRB. Exemptions are defined in Part III: Policies, Assurances, Definitions, and Other Information found at http://grants.nih.gov/grants/funding/424/index.htm#inst.

5. If NO is checked in #3, type an "X" in the appropriate box (YES or NO) to indicate whether the IRB review is pending.

6. Enter the IRB approval date. This field may only be left blank if the review is Pending (if YES is checked in #5).

7. Enter the IRB protocol approval number assigned by the IRB. This field may only be left blank if the review is Pending (if YES is checked in #5).

8. Enter the OHRP Federal-wide Assurance number for the organization (this is not the IRB protocol approval number).

Section B

1. If the proposed studies using human specimens, cells, cell lines or data are not considered to be human subjects research (see Section A #2), provide an explanation of why the proposed studies do not constitute research involving human subjects.

   The explanation could include: a description of the source of the data/biological specimens, and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected. Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research. Research involving the use of coded private information or biological specimens may not constitute human subjects research if the conditions of the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens have been met (http://www.hhs.gov/ohrp/policy/cdebiol.html). Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as "living individuals." The use of cadaver specimens is not regulated by 45 CFR Part 46, but may be governed by other federal, state or local laws.

2. If YES is checked in #2 of Section A, provide a thorough narrative according to the instructions for the appropriate scenario (B, D, E or F) found in Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan found at http://grants.nih.gov/grants/funding/424/index.htm#inst.

Appropriate oversight and management of human subjects research projects are essential to ethical conduct of research. Certification of Institutional Review Board (IRB) review and approval is not required prior to application review; however, an appropriate standard IRB protocol approval form or signed exemption will be required prior to contract execution. In addition, the organization will be required to certify that all key personnel who are involved in the design and conduct of human subject research have completed the required education/training requirements in the protection of human research participants.

Part Two Vertebrate Animals – Form 15

Submit a separate Form 15 for the applicant and each sub-applicant. Accurately complete at least Section A of each form. In addition, if more than one vertebrate animal protocol will be required to complete the proposed research project, complete a separate form for each protocol.

Section A

1. Enter the name of the applicant or sub-applicant organization.

2. Type an "X" in the appropriate box (YES or NO) to indicate whether activities involving vertebrate animals are planned at any time during the proposed project.

   To determine whether the planned use of vertebrate animals, tissues or custom antibodies are considered to be vertebrate animal research, ask the IACUC staff from your organization and refer to http://grants.nih.gov/grants/olaw/references/phspol.htm and http://grants.nih.gov/grants/olaw/faqs.htm#A for guidance.

   If activities involving vertebrate animals are not planned at any time during the proposed project, select NO to #2 and skip the rest of the form.

3. If YES is checked in #2, type an "X" in the appropriate box (YES or NO) to indicate whether the IACUC review is pending.

4. If NO is checked in #3, enter the IACUC approval date. This field may only be left blank if the review is Pending (if YES is checked in #3).

5. Enter the IACUC protocol approval number assigned by the IACUC. This field may only be left blank if the review is Pending (if YES is checked in #3).

6. Enter the OLAW Assurance Number for your organization. This is not the IACUC approval number.

7. Enter the USDA Registration Number for your organization. This field should be left blank if the animal species is not covered by the USDA. This is not the IACUC or OLAW approval number.

Section B

If YES is checked in #2 of Section A, provide a thorough narrative to address the following five points. For additional guidance on this narrative, refer to Part I: Instructions for Preparing and Submitting an Application found at http://grants.nih.gov/grants/funding/424/index.htm#inst.

1) *Description of Proposed Animal Use*
   Provide a detailed description of the animal use proposed in the Workplan, including identification of species, strain, age, sex and number of animals to be used.

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

3) *Veterinary Care*
   Provide information on the veterinary care of the animals.

4) *Description of Procedures to Ensure that the Discomfort, Distress, Pain and Injury will be Limited*
   Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic,

anesthetic and tranquilizing drugs, and comfortable restraining devices to minimize discomfort, distress, pain and injury.

5) *Description of Any Method of Euthanasia*
Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

Appropriate oversight and management of the use of vertebrate animals are 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 protocol approval form will be required prior to contract execution.

Part Two Human Stem Cells – Form 16

Submit a separate Form 16 for the applicant and each sub-applicant. Accurately complete at least Section A of each form. In addition, if more than one human stem cell protocol will be required to complete the proposed research project, complete a separate form for each protocol.

Section A

1. Enter the name of the applicant or sub-applicant organization.

2. Type an "X" in the appropriate box (YES or NO) to indicate whether activities involving human stem cells as defined below are planned at any time during the proposed project. Select YES even if the project is Exempt under NAS or ISSCR guidelines.

   The use of the following types of human cells require SCRO review and oversight: embryonic stem cells, totipotent or pluripotent cells, pluripotent stem cell lines, neural and gonadal progenitor stem cells, or other somatic tissues for stem cell research (excluding cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential). For guidance, ask the SCRO staff from your organization and refer to Attachment A-1 Part B of the Sample Contract found here as Attachment 4 to this RFA.

   If activities involving human stem cells as defined above are not planned at any time during the proposed project, select NO and skip the rest of the form.

3. If YES is checked in #2, type an "X" in the appropriate box to indicate whether the project is Exempt from National Academy of Sciences (NAS) or International Society for Stem Cell Research (ISSCR) guidelines for human stem cell research.

4. If YES is checked in #3, type an "X" to indicate the appropriate exemption. NOTE: This exemption must be determined and documented by the SCRO. Exemptions are outlined in Attachment A-1 Part B of the Sample Contract found here as Attachment 5 to this RFA.

5. If NO is checked in #3, type an "X" in the appropriate box (YES or NO) to indicate whether the SCRO review is pending.

6. Enter the SCRO approval date. This field may only be left blank if the review is Pending (if YES is checked in #5).

7. Enter the SCRO protocol approval number assigned by the SCRO. This field may only be left blank if the review is Pending (if YES is checked in #5).

Section B

If YES is checked in #2 of Section A, provide a thorough narrative to address the following four points.

1) *Involvement of Human Stem Cells*
   Describe the involvement of human stem cells as outlined in the research plan. Include descriptions of the cell lines to be used, e.g., source or means of derivation of the cell lines, donor consent procedures specific to stem cell derivation including donor reimbursement or payment as applicable, and characterization of the stem cell lines or embryonic sources as known. If new cell lines are to be derived, explain the justification for such new derivation. For any new derivation of the specified human stem cell lines *Form 14, Human Subjects* research must also be completed. For any use of the specified human stem cells in conjunction with animal studies, *Form 15, Vertebrate Animals* must also be completed.

2) *Sources of Materials - Confidentiality*
   If specified human stem cell lines are to be obtained from sources outside the awarded organization or the primary investigator's laboratory, identify the sources of the research cell lines. This description should include the provenance of such cell lines and the source of any accompanying records or data, and whether the records are traceable to the original gamete donors, or other donors. Describe any agreements, material transfer agreements or confidentiality agreements executed in the transfer of such materials.

   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 also be submitted to the applicant's IRB for approval and subsequently to NYSTEM prior to accrual of human participants.

3) *Importance of the Knowledge to be Gained*
   Discuss why the use of the specified human stem cell lines is reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

4) *Therapeutics*
   If a therapeutic or biological is involved, describe the product and state whether the 30-day interval between submission of the applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the biological has been withheld or restricted by the FDA.

Appropriate oversight and administration are essential to the ethical conduct of research. Certification of Stem Cell Research Oversight committee (SCRO) review and approval is not required prior to application review; however, an appropriate SCRO protocol approval form or signed exemption will be required prior to contract award. In addition, the organization will be required to certify that all key personnel who are involved with human stem cell research have completed education/training requirements required by their institutional SCRO, as applicable, before funds are awarded.

Part Two Applicant Face Page – Form 1

Project Title:					
Application Type: Stem Cell Consortia Part Two RFA #: 1212030210			Application Number from NYSTEM:		
New: ☐Yes ☐ No			Resubmission: ☐ Yes ☐ No	Original Application #:	
Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) , , ,			Co-Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) ***(If different organization, do not complete this section – requires sub-applicant face page, Form 1-S)*** , , ,		
Organization:			Organization:		
Department:			Department:		
Mailing Address (Street, MS, P.O. Box, City, State, Zip): Street 1 Street 2 City State NY Zip			Mailing Address (Street, MS, P.O. Box, City, State, Zip): Street 1 Street 2 City State NY Zip		
Phone:		Fax:	Phone:		Fax:
E-mail:			E-mail:		
Type of Organization:			NYS Vendor ID # (10 digits):		
Charities Registration Number (or "Exempt category"):					
Project Start/End:	-	Year One Grand Total Costs:		Grand Total Costs (all years):	
New York State Applicant Organization: Mailing Address: Street 1 Street 2 City State NY Zip			Research Performing Sites:		
Contracts and Grants Official: Last Name First Name Title			Official Signing for the Organization: Last Name First Name Title		
Mailing Address: Street 1 Street 2 City State NY Zip			Organization Name and Mailing Address: Name Street 1 Street 2 City State NY Zip		
Phone:		Fax:	Phone:		Fax:
E-mail:			E-mail:		
CERTIFICATIONS AND ASSURANCE: Prior to award recommendation, the PI and Co-PI (if from the same organization) and organizational official are required to sign and date this form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; certification that the organization is eligible to apply (see Section II of RFA) and has the capability to conduct and administer externally-funded research; and, agreement to comply with the terms and conditions of any contract awarded as a result of this application.					
SIGNATURES OF PRINCIPAL INVESTIGATOR and CO-PI:					
X				DATE:	
X				DATE:	
SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION:					
X				DATE:	

Part Two Sub-Applicant Face Page – Form 1-S

Project Title:							
Application Type: Stem Cell Consortia Part Two RFA#: 1212030210							
Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) , , ,		Overall Project Co-PI? ☐		Co-PI: Last Name, First Name, Middle Initial, Degree(s) , , ,			
Organization:				Organization:			
Department:				Department:			
Mailing Address (Street, MS, P.O. Box, City, State, Zip): Street 1 Street 2 City State Zip				Mailing Address (Street, MS, P.O. Box, City, State, Zip): Street 1 Street 2 City State Zip			
Phone:		Fax:		Phone:		Fax:	
E-mail:				E-mail:			
Type of Organization: ☐ Governmental ☐ Not-for-profit ☐Profit							
Charities Registration Number (or "Exempt category"):							
Project Start/End:	-	Year One Grand Total Costs:		Grand Total Costs (all years):			
Sub-applicant Organization:				Research Performing Sites:			
Mailing Address: Street 1 Street 2 City State Zip							
Contracts and Grants Official: Last Name First Name Title				Official Signing for the Organization: Last Name First Name Title			
Mailing Address: Street 1 Street 2 City State Zip				Organization Name and Mailing Address: Name Street 1 Street 2 City State Zip			
Phone:		Fax:		Phone:		Fax:	
E-mail:				E-mail:			
CERTIFICATIONS AND ASSURANCE: Prior to award recommendation, the sub-applicant PI and organizational official are required to sign and date this form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; certification that the applicant is pre-qualified with NYS; and agreement to comply with the terms and conditions of any subcontract awarded as a result of this application.							
SIGNATURES OF SUB-APPLICANT PRINCIPAL INVESTIGATOR and CO-PI:							
X DATE:							
X DATE:							
SIGNATURE OF THE OFFICAL SIGNING FOR THE SUB-APPLICANT ORGANIZATION:							
X DATE:							

Part Two Staff, Collaborators, Consultants and Contributors – Form 2

Last Name	First Name	Title	Organizational	Role in Project

Part Two Independent Oversight Panel – Form 3

Last Name	First Name	Middle Initial	Title	Organizational Affiliation	Phone	E-mail	Rationale for Suggestion

Part Two Acronyms and Abbreviations Used in Application – Form 4

Acronym	Full Text/Definition/Description

Part Two Lay Abstract – Form 5

Part Two Scientific Abstract – Form 6

Part Two Table of Contents – Form 7

Applicant Organization
PI Last Name, First Name

* Indicate “N/A” if not applicable.

Part Two Budget and Justification – Form 8

EXPENDITURE BASED BUDGET
SUMMARY

PROJECT NAME: _____

CONTRACTOR SFS PAYEE NAME: _____

BUDGET YEAR From: _____

To: _____

CATEGORY OF EXPENSE	GRANT FUNDS	MATCH FUNDS	MATCH %	OTHER FUNDS	TOTAL
1. Personal Services					
a) Salary	$ -	$ -	0.00%	$ -	$ -
b) Fringe	$ -	$ -	0.00%	$ -	$ -
Subtotal	$ -	$ -	0.00%	$ -	$ -
2. Non Personal Services					
a) Contractual Services	$ -	$ -	0.00%	$ -	$ -
b) Travel	$ -	$ -	0.00%	$ -	$ -
c) Equipment	$ -	$ -	0.00%	$ -	$ -
d) Space/Property & Utilities	$ -	$ -	0.00%	$ -	$ -
e) Operating Expenses	$ -	$ -	0.00%	$ -	$ -
f) Other	$ -	$ -	0.00%	$ -	$ -
Subtotal	$ -	$ -	0.00%	$ -	$ -
TOTAL	$ -	$ -	0.00%	$ -	$ -

EXPENDITURE BASED BUDGET

PERSONAL SERVICES DETAIL

SALARY					
POSITION TITLE	**ANNUALIZED SALARY PER POSITION**	**STANDARD WORK WEEK HOURS**	**PERCENT OF EFFORT FUNDED**	**NUMBER OF MONTHS FUNDED**	**TOTAL**
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
				Subtotal	
FRINGE - TYPE/DESCRIPTION					
				PERSONAL SERVICES TOTAL	

EXPENDITURE BASED BUDGET
NON-PERSONAL SERVICES DETAIL

CONTRACTUAL SERVICES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

TRAVEL - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

EXPENDITURE BASED BUDGET

EQUIPMENT - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	
SPACE/PROPERTY EXPENSES: RENT - TYPE/DESCRIPTION	**TOTAL**
1.	
2.	
3.	
TOTAL	
SPACE/PROPERTY EXPENSES: OWN - TYPE/DESCRIPTION	**TOTAL**
1	
2	
3	
TOTAL	
TYPE/DESCRIPTION OF UTILITY EXPENSES	**TOTAL**
1.	
2.	
3.	
TOTAL	

EXPENDITURE BASED BUDGET

OPERATING EXPENSES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

OTHER - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

PROJECT NAME: _____

CONTRACTOR SFS PAYEE NAME: _____

CONTRACT PERIOD: From: **xx/xx/xxxx**

To: **xx/xx/xxxx**

CATEGORY OF EXPENSE	BUDGETED	JUSTIFICATION
1. Personal Services		
a) Salary		
1. 0	$0	
2. 0	$0	
3. 0	$0	
4. 0	$0	
5. 0	$0	
6. 0	$0	
7. 0	$0	
8. 0	$0	
9. 0	$0	
10. 0	$0	
b) Fringe		
Personal Services Subtotal	**$0**	
2. Non Personal Services		
a) Contractual Services		
1. 0	$0	
2. 0	$0	
3. 0	$0	
b) Travel		

1. 0	$0	
2. 0	$0	
3. 0	$0	
c) Equipment		
1. 0	$0	
2. 0	$0	
3. 0	$0	
d) Space/Property & Utilities		
Rent		
1. 0	$0	
2. 0	$0	
3. 0	$0	
Own		
1. 0	$0	
2. 0	$0	
Utilities		
1. 0	$0	
2. 0	$0	
3. 0	$0	
e) Operating Expenses		
1. 0	$0	
2. 0	$0	
3. 0	$0	
f) Other		
1. 0	$0	
2. 0	$0	
3. 0	$0	
4. 0	$0	
5. 0	$0	
Non Personal Services Subtotal	**$0**	
TOTAL	**$0**	

Part Two Biographical Sketch – Form 9

NAME	**POSITION/TITLE**		
EDUCATION/TRAINING (Begin with baccalaureate or other professional education, and include postdoctoral training)			
ORGANIZATION AND LOCATION	**DEGREE**	**YEAR(s)**	**FIELD OF STUDY**

A. Personal Statement.

B. Positions and Honors.

C. Selected peer-reviewed publications or manuscripts in press (in chronological order) from a total of _____.

Part Two Facilities and Resources – Form 10

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

MAJOR EQUIPMENT:

Part Two Other Support – Form 11

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

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

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

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

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

Part Two Introduction – Form 12

Part Two WORK PLAN – Form 13
SUMMARY

PROJECT NAME: _____

CONTRACTOR SFS PAYEE NAME: _____

CONTRACT PERIOD: From: _____

To: _____

Provide an overview of the project including goals, tasks, desired outcomes and performance measures:

Part Two WORK PLAN – Form 13
DETAIL

OBJECTIVE	BUDGET CATEGORY/ DELIVERABLE (if applicable)	TASKS	PERFORMANCE MEASURES
1:		a.	i.
			ii.
			iii.
		b.	i.
			ii.
			iii.
		c.	i.
			ii.
			iii.

Part Two WORK PLAN – Form 13
DETAIL

OBJECTIVE	BUDGET CATEGORY/ DELIVERABLE (if applicable)	TASKS	PERFORMANCE MEASURES
2:		a.	i.
			ii.
			iii.
		b.	i.
			ii.
			iii.
		c.	i.
			ii.
			iii.

Part Two WORK PLAN – Form 13
DETAIL

OBJECTIVE	BUDGET CATEGORY/ DELIVERABLE (if applicable)	TASKS	PERFORMANCE MEASURES
3:		a.	i.
			ii.
			iii.
		b.	i.
			ii.
			iii.
		c.	i.
			ii.
			iii.

Part Two Workplan – Form 13

Part Two Human Subjects – Form 14

SECTION A:

1. **Applicant/Sub-applicant Organization: _____**
2. **Are Human Subjects involved? __Yes __No**
3. **Is the project Exempt from federal regulations?__Yes __No**
4. **If YES to #3, what is the Exemption number? __1 __ 2 __3 __ 4 __5 __6**
5. **If NO to #3, is the IRB review Pending? __Yes __No**
6. **IRB Approval Date (leave blank only if Yes to #5): _____**
7. **IRB Protocol Approval Number: _____**
8. **OHRP Federal-wide Assurance Number: _____**

SECTION B – NARRATIVE (use additional pages if necessary):

Part Two Vertebrate Animals – Form 15

SECTION A:

1. **Applicant/Sub-applicant Organization: _____**
2. **Are Vertebrate Animals involved? __Yes __No**
3. **Is the IACUC review Pending? __Yes __ No**
4. **IACUC Approval Date (leave blank only if YES to #3): _____**
5. **IACUC Protocol Approval Number: _____**
5. **Animal Welfare (OLAW) Assurance Number: _____**
6. **USDA Registration Number (if applicable to species): _____**

SECTION B – NARRATIVE (use additional pages if necessary):

Part Two Human Stem Cells – Form 16

SECTION A:

1. **Applicant/Sub-applicant Organization: _____**
2. **Are Human Stem Cells involved? __Yes __No**
3. **Is the project Exempt under NAS or ISSCR? __Yes __No**
4. **If YES to #3, check the appropriate exemption: __NAS 1.3(a) __ISSCR Category 1**
5. **If NO to #3, is the SCRO review pending? __Yes __No**
6. **SCRO Approval Date (leave blank only if NO to #5): _____**
7. **SCRO Protocol Approval Number: _____**

SECTION B – NARRATIVE (use additional pages if necessary):

ATTACHMENT 3

Vendor Responsibility Attestation

Consortia to Accelerate Therapeutic Applications of Stem Cells

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

Choose one:

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

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

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

Signature of Organization Official: _____

Print/type Name: _____

Title: _____

Organization: _____

Date Signed: _____

ATTACHMENT 4

NYS Master Grant Contract
(4/13)

NOTE: State Contract forms are included for informational purposes only.

DO NOT COMPLETE THEM AT THIS TIME.

STATE OF NEW YORK MASTER CONTRACT FOR GRANTS FACE PAGE

STATE AGENCY (Name & Address):	BUSINESS UNIT/DEPT. ID: CONTRACT NUMBER: CONTRACT TYPE: ☐ Multi-Year Agreement ☐ Simplified Renewal Agreement ☐ Fixed Term Agreement
CONTRACTOR SFS PAYEE NAME:	TRANSACTION TYPE: ☐ New ☐ Renewal ☐ Amendment
CONTRACTOR DOS INCORPORATED NAME:	PROJECT NAME:
CONTRACTOR IDENTIFICATION NUMBERS: NYS Vendor ID Number: Federal Tax ID Number: DUNS Number (if applicable):	AGENCY IDENTIFIER: CFDA NUMBER (Federally Funded Grants Only):
CONTRACTOR PRIMARY MAILING ADDRESS: CONTRACTOR PAYMENT ADDRESS: ☐ Check if same as primary mailing address CONTRACT MAILING ADDRESS: ☐ Check if same as primary mailing address	CONTRACTOR STATUS: ☐ For Profit ☐ Municipality, Code: ☐ Tribal Nation ☐ Individual ☐ Not-for-Profit Charities Registration Number: Exemption Status/Code: ☐ Sectarian Entity

STATE OF NEW YORK MASTER CONTRACT FOR GRANTS FACE PAGE

CURRENT CONTRACT TERM:

From: To:

CURRENT CONTRACT PERIOD:

From: To:

AMENDED TERM:

From: To:

AMENDED PERIOD:

From: To:

CONTRACT FUNDING AMOUNT
(*Multi-year* - enter total projected amount of the contract; *Fixed Term/Simplified Renewal* - enter current period amount):

CURRENT:

AMENDED:

FUNDING SOURCE(S)

- ☐ State
- ☐ Federal
- ☐ Other

FOR MULTI-YEAR AGREEMENTS ONLY - CONTRACT PERIOD AND FUNDING AMOUNT:
(Out years represent projected funding amounts)

#	CURRENT PERIOD	CURRENT AMOUNT	AMENDED PERIOD	AMENDED AMOUNT
1				
2				
3				
4				
5				

ATTACHMENTS PART OF THIS AGREEMENT:

☐ Attachment A:
- ☐ A-1 Program Specific Terms and Conditions
- ☐ A-2 Federally Funded Grants

☐ Attachment B:
- ☐ B-1 Expenditure Based Budget
- ☐ B-2 Performance Based Budget
- ☐ B-3 Capital Budget
- ☐ B-1(A) Expenditure Based Budget (Amendment)
- ☐ B-2(A) Performance Based Budget (Amendment)
- ☐ B-3(A) Capital Budget (Amendment)

☐ Attachment C: Work Plan
☐ Attachment D: Payment and Reporting Schedule
☐ Other:

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

CONTRACTOR:	STATE AGENCY:
_____	_____
_____	_____
By:_____	By:_____
_____ Printed Name	_____ Printed Name
Title:_____	Title:_____
Date:_____	Date:_____

STATE OF NEW YORK

County of_____

On the ___ day of _____, ____, before me personally appeared_____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, that he/she is the _____ of the _____, the contractor described herein which executed the foregoing instrument; and that he/she signed his/her name thereto as authorized by the contractor named on the face page of this Master Contract.

(Notary)_____

ATTORNEY GENERAL'S SIGNATURE	STATE COMPTROLLER'S SIGNATURE
_____	_____
_____ Printed Name	_____ Printed Name
Title:_____	Title:_____
Date:_____	Date:_____

STATE OF NEW YORK
MASTER CONTRACT FOR GRANTS

This State of New York Master Contract for Grants (Master Contract) is hereby made by and between the State of New York acting by and through the applicable State Agency (State) and the public or private entity (Contractor) identified on the face page hereof (Face Page).

WITNESSETH:

WHEREAS, the State has the authority to regulate and provide funding for the establishment and operation of program services, design or the execution and performance of construction projects, as applicable and desires to contract with skilled parties possessing the necessary resources to provide such services or work, as applicable; and

WHEREAS, the Contractor is ready, willing and able to provide such program services or the execution and performance of construction projects and possesses or can make available all necessary qualified personnel, licenses, facilities and expertise to perform or have performed the services or work, as applicable, required pursuant to the terms of the Master Contract;

NOW THEREFORE, in consideration of the promises, responsibilities, and covenants herein, the State and the Contractor agree as follows:

STANDARD TERMS AND CONDITIONS

I. GENERAL PROVISIONS

A. Executory Clause: In accordance with Section 41 of the State Finance Law, the State shall have no liability under the Master Contract to the Contractor, or to anyone else, beyond funds appropriated and available for the Master Contract.

B. Required Approvals: In accordance with Section 112 of the State Finance Law (or, if the Master Contract is with the State University of New York (SUNY) or City University of New York (CUNY), Section 355 or Section 6218 of the Education Law), if the Master Contract exceeds $50,000 (or $85,000 for contracts let by the Office of General Services, or the minimum thresholds agreed to by the Office of the State Comptroller (OSC) for certain SUNY and CUNY contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount including, but not limited to, changes in amount, consideration, scope or contract term identified on the Face Page (Contract Term), it shall not be valid, effective or binding upon the State until it has been approved by, and filed with, the New York Attorney General Contract Approval Unit (AG) and OSC. If, by the Master 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, and filed with, the AG and OSC.

***Budget Changes*:** An amendment that would result in a transfer of funds among program activities or budget cost categories that does not affect the amount, consideration, scope or other terms of such contract may be subject to the approval of the AG and OSC where the amount of such modification is, as a portion of the total value of the contract, equal to or greater than ten percent for contracts of less than five million dollars, or five percent for contracts of more than

five million dollars; and, in addition, such amendment may be subject to prior approval by the applicable State Agency as detailed in Attachment D (Payment and Reporting Schedule).

C. Order of Precedence:

In the event of a conflict among (i) the terms of the Master Contract (including any and all attachments and amendments) or (ii) between the terms of the Master Contract and the original request for proposal, the program application or other attachment that was completed and executed by the Contractor in connection with the Master Contract, the order of precedence is as follows:

1. Standard Terms and Conditions

2. Modifications to the Face Page

3. Modifications to Attachment A-2[1], Attachment B, Attachment C and Attachment D

4. The Face Page

5. Attachment A-2[2], Attachment B, Attachment C and Attachment D

6. Modification to Attachment A-1

7. Attachment A-1

8. Other attachments, including, but not limited to, the request for proposal or program application

D. Funding: Funding for the term of the Master Contract shall not exceed the amount specified as "Contract Funding Amount" on the Face Page or as subsequently revised to reflect an approved renewal or cost amendment. Funding for the initial and subsequent periods of the Master Contract shall not exceed the applicable amounts specified in the applicable Attachment B form (Budget).

E. Contract Performance: The Contractor shall perform all services or work, as applicable, and comply with all provisions of the Master Contract to the satisfaction of the State. The Contractor shall provide services or work, as applicable, and meet the program objectives summarized in Attachment C (Work Plan) in accordance with the provisions of the Master Contract, relevant laws, rules and regulations, administrative, program and fiscal guidelines, and where applicable, operating certificate for facilities or licenses for an activity or program.

F. Modifications: To modify the Attachments or Face Page, the parties mutually agree to record, in writing, the terms of such modification and to revise or complete the Face Page and all the appropriate attachments in conjunction therewith. In addition, to the extent that such modification meets the criteria set forth in Section I.B herein, it shall be subject to the approval of the AG and

[1] To the extent that the modifications to Attachment A-2 are required by federal requirements and conflict with other provisions of the Master Contract, the modifications to Attachment A-2 shall supersede all other provisions of this Master Contract. See Section I(V).

[2] To the extent that the terms of Attachment A-2 are required by federal requirements and conflict with other provisions of the Master Contract, the federal requirements of Attachment A-2 shall supersede all other provisions of this Master Contract. See Section I(V).

OSC before it shall become valid, effective and binding upon the State. Modifications that are not subject to the AG and OSC approval shall be processed in accordance with the guidelines stated in the Master Contract.

G. Governing Law: The Master Contract shall be governed by the laws of the State of New York except where the Federal Supremacy Clause requires otherwise.

H. Severability: Any provision of the Master Contract that is held to be invalid, illegal or unenforceable in any respect by a court of competent jurisdiction, shall be ineffective only to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions hereof; provided, however, that the parties to the Master Contract shall attempt in good faith to reform the Master Contract in a manner consistent with the intent of any such ineffective provision for the purpose of carrying out such intent. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances.

I. Interpretation: The headings in the Master Contract are inserted for convenience and reference only and do not modify or restrict any of the provisions herein. All personal pronouns used herein shall be considered to be gender neutral. The Master Contract has been made under the laws of the State of New York, and the venue for resolving any disputes hereunder shall be in a court of competent jurisdiction of the State of New York.

J. Notice:

1. All notices, except for notices of termination, shall be in writing and shall be transmitted either:

   a) by certified or registered United States mail, return receipt requested;

   b) by facsimile transmission;

   c) by personal delivery;

   d) by expedited delivery service; or

   e) by e-mail.

2. Notices to the State shall be addressed to the Program Office designated in Attachment A-1 (Program Specific Terms and Conditions).

3. Notices to the Contractor shall be addressed to the Contractor's designee as designated in Attachment A-1 (Program Specific Terms and Conditions).

4. Any such notice shall be deemed to have been given either at the time of personal delivery or, in the case of expedited delivery service or certified or registered United States mail, as of the date of first attempted delivery at the address and in the manner provided herein, or in the case of facsimile transmission or e-mail, upon receipt.

5. The parties may, from time to time, specify any new or different e-mail address, facsimile

number or address in the United States as their address for purpose of receiving notice under the Master Contract by giving fifteen (15) calendar days prior written notice to the other party sent in accordance herewith. The parties agree to mutually designate individuals as their respective representatives for the purposes of receiving notices under the Master Contract. Additional individuals may be designated in writing by the parties for purposes of implementation, administration, billing and resolving issues and/or disputes.

K. 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. The Contractor shall have thirty (30) calendar days after service hereunder is complete in which to respond.

L. 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 the Master Contract up to any amounts due and owing to the State with regard to the Master Contract, any other contract with any State department or agency, including any contract for a term commencing prior to the term of the Master 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 OSC.

M. Indemnification: 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 Master Contract. The Contractor shall indemnify and hold harmless the State and its officers and employees from claims, suits, actions, damages and cost of every nature arising out of the provision of services pursuant to the Master Contract.

N. Non-Assignment Clause: In accordance with Section 138 of the State Finance Law, the Master 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 State's previous written consent, and attempts to do so shall be considered to be null and void. Notwithstanding the foregoing, such prior written consent of an assignment of a contract, let pursuant to Article XI of the State Finance Law, may be waived at the discretion of the State Agency and with the concurrence of OSC, where the original contract was subject to OSC's approval, where the assignment is due to a reorganization, merger, or consolidation of the Contractor's business entity or enterprise. The State retains its right to approve an assignment and to require that the merged contractor demonstrate its responsibility to do business with the State. The Contractor may, however, assign its right to receive payments without the State's prior written consent unless the Master Contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

O. Legal Action: No litigation or regulatory action shall be brought against the State of New York, the State Agency, or against any county or other local government entity with funds provided under

the Master Contract. The term "litigation" shall include commencing or threatening to commence a lawsuit, joining or threatening to join as a party to ongoing litigation, or requesting any relief from any of the State of New York, the State Agency, or any county, or other local government entity. The term "regulatory action" shall include commencing or threatening to commence a regulatory proceeding, or requesting any regulatory relief from any of the State of New York, the State Agency, or any county, or other local government entity.

P. No Arbitration: Disputes involving the Master 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.

Q. Secular Purpose: Services performed pursuant to the Master Contract 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.

R. Partisan Political Activity and Lobbying: Funds provided pursuant to the Master Contract shall not be used for any partisan political activity, or for activities that attempt to influence legislation or election or defeat of any candidate for public office.

S. Reciprocity and Sanctions Provisions: The Contractor is hereby notified that if its 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 it offers shall 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 it be denied contracts which it would otherwise obtain.[3]

T. Reporting Fraud and Abuse: Contractor acknowledges that it has reviewed information on how to prevent, detect, and report fraud, waste and abuse of public funds, including information about the Federal False Claims Act, the New York State False Claims Act, and whistleblower protections.

U. Non-Collusive Bidding: By submission of this bid, the Contractor and each person signing on behalf of the Contractor certifies, and in the case of a joint bid each party thereto certifies as to its own organization, under penalty of perjury, that to the best of his or her knowledge and belief that its bid was arrived at independently and without collusion aimed at restricting competition. The Contractor further affirms that, at the time the Contractor submitted its bid, an authorized and responsible person executed and delivered to the State a non-collusive binding certification on the Contractor's behalf.

V. Federally Funded Grants: All of the Specific federal requirements that are applicable to the Master Contract are identified in Attachment A-2 (Federally Funded Grants) hereto. To the extent that the Master Contract is funded in whole or part with federal funds, (i) the provisions of the Master Contract that conflict with federal rules, federal regulations, or federal program specific requirements shall not apply and (ii) the Contractor agrees to comply with all applicable federal

[3]As of October 9, 2012, the list of discriminatory jurisdictions subject to this provision includes the states of Alaska, Hawaii, Louisiana, South Carolina, West Virginia and Wyoming. Contact NYS Department of Economic Development for the most current list of jurisdictions subject to this provision.

rules, regulations and program specific requirements including, but not limited to, those provisions that are set forth in Attachment A-2 (Federally Funded Grants) hereto.

II. TERM, TERMINATION AND SUSPENSION

A. Term: The term of the Master Contract shall be as specified on the Face Page, unless terminated sooner as provided herein.

B. Renewal:

1. *General Renewal*: The Master Contract may consist of successive periods on the same terms and conditions, as specified within the Master Contract (a "Simplified Renewal Contract"). Each additional or superseding period shall be on the forms specified by the State and shall be incorporated in the Master Contract.

2. *Renewal Notice to Not-for-Profit Contractors*:

a) Pursuant to State Finance Law §179-t, if the Master Contract is with a not-for-profit Contractor and provides for a renewal option, the State shall notify the Contractor of the State's intent to renew or not to renew the Master Contract no later than ninety (90) calendar days prior to the end of the term of the Master Contract, unless funding for the renewal is contingent upon enactment of an appropriation. If funding for the renewal is contingent upon enactment of an appropriation, the State shall notify the Contractor of the State's intent to renew or not to renew the Master Contract the later of: (1) ninety (90) calendar days prior to the end of the term of the Master Contract, and (2) thirty (30) calendar days after the necessary appropriation becomes law. Notwithstanding the foregoing, in the event that the State is unable to comply with the time frames set forth in this paragraph due to unusual circumstances beyond the control of the State ("Unusual Circumstances"), no payment of interest shall be due to the not-for-profit Contractor. For purposes of State Finance Law §179-t, "Unusual Circumstances" shall not mean the failure by the State to (i) plan for implementation of a program, (ii) assign sufficient staff resources to implement a program, (iii) establish a schedule for the implementation of a program or (iv) anticipate any other reasonably foreseeable circumstance.

b) Notification to the not-for-profit Contractor of the State's intent to not renew the Master Contract must be in writing in the form of a letter, with the reason(s) for the non-renewal included. If the State does not provide notice to the not-for-profit Contractor of its intent not to renew the Master Contract as required in this Section and State Finance Law §179-t, the Master Contract shall be deemed continued until the date the State provides the necessary notice to the Contractor, in accordance with State Finance Law §179-t. Expenses incurred by the not-for-profit Contractor during such extension shall be reimbursable under the terms of the Master Contract.

C. Termination:

1. *Grounds*:

a) Mutual Consent: The Master Contract may be terminated at any time upon mutual written consent of the State and the Contractor.

b) Cause: The State may terminate the Master Contract immediately, upon written notice of termination to the Contractor, if the Contractor fails to comply with any of the terms and conditions of the Master Contract and/or with any laws, rules, regulations, policies, or procedures that are applicable to the Master Contract.

c) Non-Responsibility: In accordance with the provisions of Sections IV(N)(6) and (7) herein, the State may make a final determination that the Contractor is non-responsible (Determination of Non-Responsibility). In such event, the State may terminate the Master Contract at the Contractor's expense, complete the contractual requirements in any manner the State deems advisable and pursue available legal or equitable remedies for breach.

d) Convenience: The State may terminate the Master Contract in its sole discretion upon thirty (30) calendar days prior written notice.

e) Lack of Funds: If for any reason the State or the Federal government terminates or reduces its appropriation to the applicable State Agency entering into the Master Contract or fails to pay the full amount of the allocation for the operation of one or more programs funded under this Master Contract, the Master Contract may be terminated or reduced at the State Agency's discretion, provided that no such reduction or termination shall apply to allowable costs already incurred by the Contractor where funds are available to the State Agency for payment of such costs. Upon termination or reduction of the Master Contract, all remaining funds paid to the Contractor that are not subject to allowable costs already incurred by the Contractor shall be returned to the State Agency. In any event, no liability shall be incurred by the State (including the State Agency) beyond monies available for the purposes of the Master Contract. The Contractor acknowledges that any funds due to the State Agency or the State of New York because of disallowed expenditures after audit shall be the Contractor's responsibility.

f) Force Majeure: The State may terminate or suspend its performance under the Master Contract immediately upon the occurrence of a "force majeure." For purposes of the Master Contract, "Force majeure" shall include, but not be limited to, natural disasters, war, rebellion, insurrection, riot, strikes, lockout and any unforeseen circumstances and acts beyond the control of the State which render the performance of its obligations impossible.

2. *Notice of Termination*:

a) Service of notice: Written notice of termination shall be sent by:

(i) personal messenger service; or

(ii) certified mail, return receipt requested and first class mail.

b) Effective date of termination: The effective date of the termination shall be the later of (i) the date indicated in the notice and (ii) the date the notice is received by the Contractor, and shall be established as follows:

(i) if the notice is delivered by hand, the date of receipt shall be established by the receipt given to the Contractor or by affidavit of the individual making such hand delivery attesting to the date of delivery; or

(ii) if the notice is delivered by registered or certified mail, by the receipt returned from the United States Postal Service, or if no receipt is returned, five (5) business days from the date of mailing of the first class letter, postage prepaid, in a depository under the care and control of the United States Postal Service.

3. ***Effect of Notice and Termination on State's Payment Obligations*:**

a) 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.

b) The State shall be responsible for payment on claims for services or work provided and costs incurred pursuant to the terms of the Master Contract. In no event shall the State be liable for expenses and obligations arising from the requirements of the Master Contract after its termination date.

4. *Effect of Termination Based on Misuse or Conversion of State or Federal Property*:

Where the Master Contract is terminated for cause based on Contractor's failure to use some or all of the real property or equipment purchased pursuant to the Master Contract for the purposes set forth herein, the State may, at its option, require:

a) the repayment to the State of any monies previously paid to the Contractor; or

b) the return of any real property or equipment purchased under the terms of the Master Contract; or

c) an appropriate combination of clauses (a) and (b) of Section II(C)(4) herein.

Nothing herein shall be intended to limit the State's ability to pursue such other legal or equitable remedies as may be available.

D. Suspension: The State may, in its discretion, order the Contractor to suspend performance for a reasonable period of time. In the event of such suspension, the Contractor shall be given a formal written notice outlining the particulars of such suspension. Upon issuance of such notice, the Contractor shall comply with the particulars of the notice. The State shall have no obligation to reimburse Contractor's expenses during such suspension period. Activities may resume at such time

as the State issues a formal written notice authorizing a resumption of performance under the Master Contract.

III. PAYMENT AND REPORTING

A. Terms and Conditions:

1. In full consideration of contract services to be performed, the State Agency agrees to pay and the Contractor agrees to accept a sum not to exceed the amount noted on the Face Page.

2. The State has no obligation to make payment until all required approvals, including the approval of the AG and OSC, if required, have been obtained. Contractor obligations or expenditures that precede the start date of the Master Contract shall not be reimbursed.

3. Contractor must provide complete and accurate billing invoices to the State in order to receive payment. Provided, however, the State may, at its discretion, automatically generate a voucher in accordance with an approved contract payment schedule. Billing invoices submitted to the State must contain all information and supporting documentation required by Attachment D (Payment and Reporting Schedule) and Section III(C) herein. The State may require the Contractor to submit billing invoices electronically.

4. Payment for invoices submitted by the Contractor shall only be rendered electronically unless payment by paper check is expressly authorized by the head of the State Agency, in the sole discretion of the head of such State Agency, due to extenuating circumstances. Such electronic payment shall be made in accordance with OSC's procedures and practices to authorize electronic payments.

5. If travel expenses are an approved expenditure under the Master Contract, travel expenses shall be reimbursed at the lesser of the rates set forth in the written standard travel policy of the Contractor, the OSC guidelines, or United States General Services Administration rates. No out-of-state travel costs shall be permitted unless specifically detailed and pre-approved by the State.

6. Timeliness of advance payments or other claims for reimbursement, 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.

7. Article 11-B of the State Finance Law sets forth certain time frames for the Full Execution of contracts or renewal contracts with not-for-profit organizations and the implementation of any program plan associated with such contract. For purposes of this section, “Full Execution” shall mean that the contract has been signed by all parties thereto and has obtained the approval of the AG and OSC. Any interest to be paid on a missed payment to the Contractor based on a delay in the Full Execution of the Master Contract shall be governed by Article 11-B of the State Finance Law.

B. Advance Payment and Recoupment:

1. Advance payments, which the State in its sole discretion may make to not-for-profit grant recipients, shall be made and recouped in accordance with State Finance Law Section 179(u), this Section and the provisions of Attachment D (Payment and Reporting Schedule).

2. Advance payments made by the State to not-for-profit grant recipients shall be due no later than thirty (30) calendar days, excluding legal holidays, after the first day of the Contract Term or, if renewed, in the period identified on the Face Page.

3. For subsequent contract years in multi-year contracts, Contractor will be notified of the scheduled advance payments for the upcoming contract year no later than 90 days prior to the commencement of the contract year. For simplified renewals, the payment schedule (Attachment D) will be modified as part of the renewal process.

4. Recoupment of any advance payment(s) shall be recovered by crediting the percentage of subsequent claims listed in Attachment D (Payment and Reporting Schedule) and Section III(C) herein and such claims shall be reduced until the advance is fully recovered within the Contract Term. Any unexpended advance balance at the end of the Contract Term shall be refunded by the Contractor to the State.

5. If for any reason the amount of any claim is not sufficient to cover the proportionate advance amount to be recovered, then subsequent claims may be reduced until the advance is fully recovered.

C. Claims for Reimbursement:

1. The Contractor shall submit claims for the reimbursement of expenses incurred on behalf of the State under the Master Contract in accordance with this Section and the applicable claiming schedule in Attachment D (Payment and Reporting Schedule).

Vouchers submitted for payment shall be deemed to be a certification that the payments requested are for project expenditures made in accordance with the items as contained in the applicable Attachment B form (Budget) and during the Contract Term. When submitting a voucher, such voucher shall also be deemed to certify that: (i) the payments requested do not duplicate reimbursement from other sources of funding; and (ii) the funds provided herein do not replace funds that, in the absence of this grant, would have been made available by the Contractor for this program. Requirement (ii) does not apply to grants funded pursuant to a Community Projects Fund appropriation.

2. Consistent with the selected reimbursement claiming schedule in Attachment D (Payment and Reporting Schedule), the Contractor shall comply with the appropriate following provisions:

a) <u>Quarterly Reimbursement:</u> The Contractor shall be entitled to receive payments for work, projects, and services rendered as detailed and described in Attachment C (Work Plan).

The Contractor shall submit to the State Agency quarterly voucher claims and supporting documentation. The Contractor shall submit vouchers to the State Agency in accordance with the procedures set forth in Section III(A)(3) herein.

b) Monthly Reimbursement: The Contractor shall be entitled to receive payments for work, projects, and services rendered as detailed and described in Attachment C (Work Plan).

The Contractor shall submit to the State Agency monthly voucher claims and supporting documentation. The Contractor shall submit vouchers to the State Agency in accordance with the procedures set forth in Section III(A)(3) herein.

c) Biannual Reimbursement: The Contractor shall be entitled to receive payments for work, projects, and services rendered as detailed and described in Attachment C (Work Plan).

The Contractor shall submit to the State Agency biannually voucher claims and supporting documentation. The Contractor shall submit vouchers to the State Agency in accordance with the procedures set forth in Section III(A)(3) herein.

d) Milestone/Performance Reimbursement:[4] Requests for payment based upon an event or milestone may be either severable or cumulative. A severable event/milestone is independent of accomplishment of any other event. If the event is cumulative, the successful completion of an event or milestone is dependent on the previous completion of another event.

Milestone payments shall be made to the Contractor when requested in a form approved by the State, and at frequencies and in amounts stated in Attachment D (Payment and Reporting Schedule). The State Agency shall make milestone payments subject to the Contractor's satisfactory performance.

e) Fee for Service Reimbursement:[5] Payment shall be limited to only those fees specifically agreed upon in the Master Contract and shall be payable no more frequently than monthly upon submission of a voucher by the contractor.

f) Rate Based Reimbursement:[6] Payment shall be limited to rate(s) established in the Master Contract. Payment may be requested no more frequently than monthly.

g) Scheduled Reimbursement:[7] The State Agency shall generate vouchers at the frequencies and amounts as set forth in Attachment D (Payment and Reporting Schedule),

[4] A milestone/ performance payment schedule identifies mutually agreed-to payment amounts based on meeting contract events or milestones. Events or milestones must represent integral and meaningful aspects of contract performance and should signify true progress in completing the Master Contract effort.
[5] Fee for Service is a rate established by the Contractor for a service or services rendered.
[6] Rate based agreements are those agreements in which payment is premised upon a specific established rate per unit.
[7] Scheduled Reimbursement agreements provide for payments that occur at defined and regular intervals that provide for a specified dollar amount to be paid to the Contractor at the beginning of each payment period (i.e. quarterly, monthly or bi-annually). While these payments are related to the particular services and outcomes defined in the Master Contract, they are not dependent upon particular services or expenses in any one payment period and provide the Contractor with a defined and regular payment over the life of the contract.

and service reports shall be used to determine funding levels appropriate to the next annual contract period.

h) Fifth Quarter Payments:[8] Fifth quarter payment shall be paid to the Contractor at the conclusion of the final scheduled payment period of the preceding contract period. The State Agency shall use a written directive for fifth quarter financing. The State Agency shall generate a voucher in the fourth quarter of the current contract year to pay the scheduled payment for the next contract year.

3. The Contractor shall also submit supporting fiscal documentation for the expenses claimed.

4. The State reserves the right to withhold up to fifteen percent (15%) of the total amount of the Master Contract as security for the faithful completion of services or work, as applicable, under the Master Contract. This amount may be withheld in whole or in part from any single payment or combination of payments otherwise due under the Master Contract. In the event that such withheld funds are insufficient to satisfy Contractor's obligations to the State, the State may pursue all available remedies, including the right of setoff and recoupment.

5. The State shall not be liable for payments on the Master Contract if it is made pursuant to a Community Projects Fund appropriation if insufficient monies are available pursuant to Section 99-d of the State Finance Law.

6. All vouchers submitted by the Contractor pursuant to the Master Contract shall be submitted to the State Agency no later than thirty (30) calendar days after the end date of the period for which reimbursement is claimed. In no event shall the amount received by the Contractor exceed the budget amount approved by the State Agency, and, if actual expenditures by the Contractor are less than such sum, the amount payable by the State Agency to the Contractor shall not exceed the amount of actual expenditures.

7. All obligations must be incurred prior to the end date of the contract. Notwithstanding the provisions of Section III(C)(6) above, with respect to the final period for which reimbursement is claimed, so long as the obligations were incurred prior to the end date of the contract, the Contractor shall have up to ninety (90) calendar days after the contract end date to make expenditures; provided, however, that if the Master Contract is funded in whole or in part with federal funds, the Contractor shall have up to sixty (60) calendar days after the contract end date to make expenditures.

D. Identifying Information and Privacy Notification:

1. Every voucher or New York State Claim for Payment submitted to a State Agency by the Contractor, for payment for the sale of goods or services or for transactions (e.g., leases, easements, licenses, etc.) related to real or personal property, must include the Contractor's Vendor Identification Number assigned by the Statewide Financial System, and any or all of the following identification numbers: (i) the Contractor's Federal employer identification number, (ii) the Contractor's Federal social security number, and/or (iii) DUNS number. Failure to

[8] Fifth Quarter Payments occurs where there are scheduled payments and where there is an expectation that services will be continued through renewals or subsequent contracts. Fifth Quarter Payments allow for the continuation of scheduled payments to a Contractor for the first payment period quarter of an anticipated renewal or new contract.

include such identification number or numbers may delay payment by the State to the Contractor. Where the Contractor does not have such number or numbers, the Contractor, on its voucher or Claim for Payment, must provide the reason or reasons for why the Contractor does not have such number or numbers.

2. 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 principle 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. The personal information is requested by the purchasing unit of the State Agency contracting to purchase the goods or services or lease the real or personal property covered by the Master Contract. This information is maintained in the Statewide Financial System by the Vendor Management Unit within the Bureau of State Expenditures, Office of the State Comptroller, 110 State Street, Albany, New York, 12236.

E. Refunds:

1. In the event that the Contractor must make a refund to the State for Master Contract-related activities, including repayment of an advance or an audit disallowance, payment must be made payable as set forth in Attachment A-1 (Program Specific Terms and Conditions). The Contractor must reference the contract number with its payment and include a brief explanation of why the refund is being made. Refund payments must be submitted to the Designated Refund Office at the address specified in Attachment A-1 (Program Specific Terms and Conditions).

2. If at the end or termination of the Master Contract, there remains any unexpended balance of the monies advanced under the Master Contract in the possession of the Contractor, the Contractor shall make payment within forty-five (45) calendar days of the end or termination of the Master Contract. In the event that the Contractor fails to refund such balance the State may pursue all available remedies.

F. Outstanding Amounts Owed to the State: Prior period overpayments (including, but not limited to, contract advances in excess of actual expenditures) and/or audit recoveries associated with the Contractor may be recouped against future payments made under this Master Contract to Contractor. The recoupment generally begins with the first payment made to the Contractor following identification of the overpayment and/or audit recovery amount. In the event that there are no payments to apply recoveries against, the Contractor shall make payment as provided in Section III(E) (Refunds) herein.

G. Program and Fiscal Reporting Requirements:

1. The Contractor shall submit required periodic reports in accordance with the applicable schedule provided in Attachment D (Payment and Reporting Schedule). All required reports or other work products developed pursuant to the Master Contract must be completed as provided by the agreed upon work schedule in a manner satisfactory and acceptable to the State Agency in order for the Contractor to be eligible for payment.

2. Consistent with the selected reporting options in Attachment D (Payment and Reporting Schedule), the Contractor shall comply with the following applicable provisions:

a) If the Expenditure Based Reports option is indicated in Attachment D (Payment and Reporting Schedule), the Contractor shall provide the State Agency with one or more of the following reports as required by the following provisions and Attachment D (Payment and Reporting Schedule) as applicable:

(i) *Narrative/Qualitative Report*: The Contractor shall submit, on a quarterly basis, not later than the time period listed in Attachment D (Payment and Reporting Schedule), a report, in narrative form, summarizing the services rendered during the quarter. This report shall detail how the Contractor has progressed toward attaining the qualitative goals enumerated in Attachment C (Work Plan). This report should address all goals and objectives of the project and include a discussion of problems encountered and steps taken to solve them.

(ii) *Statistical/Quantitative Report*: The Contractor shall submit, on a quarterly basis, not later than the time period listed in Attachment D (Payment and Reporting Schedule), a detailed report analyzing the quantitative aspects of the program plan, as appropriate (e.g., number of meals served, clients transported, patient/client encounters, procedures performed, training sessions conducted, etc.)

(iii) *Expenditure Report*: The Contractor shall submit, on a quarterly basis, not later than the time period listed in Attachment D (Payment and Reporting Schedule), a detailed expenditure report, by object of expense. This report shall accompany the voucher submitted for such period.

(iv) *Final Report*: The Contractor shall submit a final report as required by the Master Contract, not later than the time period listed in Attachment D (Payment and Reporting Schedule) which reports on all aspects of the program and detailing how the use of funds were utilized in achieving the goals set forth in Attachment C (Work Plan).

(v) *Consolidated Fiscal Report* (CFR): The Contractor shall submit a CFR, which includes a year-end cost report and final claim not later than the time period listed in Attachment D (Payment and Reporting Schedule).

b) If the Performance-Based Reports option is indicated in Attachment D (Payment and Reporting Schedule), the Contractor shall provide the State Agency with the following reports as required by the following provisions and Attachment D (Payment and Reporting Schedule) as applicable:

(i) *Progress Report*: The Contractor shall provide the State Agency with a written progress report using the forms and formats as provided by the State Agency, summarizing the work performed during the period. These reports shall detail the Contractor's progress toward attaining the specific goals enumerated in Attachment C (Work Plan). Progress reports shall be submitted in a format prescribed in the Master Contract.

(ii) *Final Progress Report*: Final scheduled payment is due during the time period set forth in Attachment D (Payment and Reporting Schedule). The deadline for submission of the final report shall be the date set forth in Attachment D (Payment and Reporting Schedule). The State Agency shall complete its audit and notify the Contractor of the results no later than the date set forth in Attachment D (Payment and Reporting Schedule). Payment shall be adjusted by the State Agency to reflect only those services/expenditures that were made in accordance with the Master Contract. The Contractor shall submit a detailed comprehensive final progress report not later than the date set forth in Attachment D (Payment and Reporting Schedule), summarizing the work performed during the entire Contract Term (i.e., a cumulative report), in the forms and formats required.

3. In addition to the periodic reports stated above, the Contractor may be required (a) to submit such other reports as are required in Table 1 of Attachment D (Payment and Reporting Schedule), and (b) prior to receipt of final payment under the Master Contract, to submit one or more final reports in accordance with the form, content, and schedule stated in Table 1 of Attachment D (Payment and Reporting Schedule).

H. Notification of Significant Occurrences:

1. If any specific event or conjunction of circumstances threatens the successful completion of this project, in whole or in part, including where relevant, timely completion of milestones or other program requirements, the Contractor agrees to submit to the State Agency within three (3) calendar days of becoming aware of the occurrence or of such problem, a written description thereof together with a recommended solution thereto.

2. The Contractor shall immediately notify in writing the program manager assigned to the Master Contract of any unusual incident, occurrence, or event that involves the staff, volunteers, directors or officers of the Contractor, any subcontractor or program participant funded through the Master Contract, including but not limited to the following: death or serious injury; an arrest or possible criminal activity that could impact the successful completion of this project; any destruction of property; significant damage to the physical plant of the Contractor; or other matters of a similarly serious nature.

IV. ADDITIONAL CONTRACTOR OBLIGATIONS, REPRESENTATIONS AND WARRANTIES

A. Contractor as an Independent Contractor/Employees:

1. The State and the Contractor agree that the Contractor is an independent contractor, and not an employee of the State and may neither hold itself out nor claim to be an officer, employee, or subdivision of the State nor make any claim, demand, or application to or for any right based upon any different status. The Contractor shall be solely responsible for the recruitment, hiring, provision of employment benefits, payment of salaries and management of its project personnel. These functions shall be carried out in accordance with the provisions of the Master Contract, and all applicable Federal and State laws and regulations.

2. The Contractor warrants that it, its staff, and any and all subcontractors have all the necessary licenses, approvals, and certifications currently required by the laws of any applicable local, state, or Federal government to perform the services or work, as applicable, pursuant to the

Master Contract and/or any subcontract entered into under the Master Contract. The Contractor further agrees that such required licenses, approvals, and certificates shall be kept in full force and effect during the term of the Master Contract, or any extension thereof, and to secure any new licenses, approvals, or certificates within the required time frames and/or to require its staff and subcontractors to obtain the requisite licenses, approvals, or certificates. In the event the Contractor, its staff, and/or subcontractors are notified of a denial or revocation of any license, approval, or certification to perform the services or work, as applicable, under the Master Contract, Contractor shall immediately notify the State.

B. Subcontractors:

1. If the Contractor enters into subcontracts for the performance of work pursuant to the Master Contract, 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 the Master Contract. No contractual relationship shall be deemed to exist between the subcontractor and the State.

2. The Contractor agrees not to enter into any subcontracts, or revisions to subcontracts, that are in excess of $100,000 for the performance of the obligations contained herein until it has received the prior written permission of the State, which shall have the right to review and approve each and every subcontract in excess of $100,000 prior to giving written permission to the Contractor to enter into the subcontract. All agreements between the Contractor and subcontractors shall be by written contract, signed by individuals authorized to bind the parties. All such subcontracts shall contain provisions for specifying (1) that the work performed by the subcontractor must be in accordance with the terms of the Master Contract, (2) that nothing contained in the subcontract shall impair the rights of the State under the Master Contract, and (3) that nothing contained in the subcontract, nor under the Master Contract, shall be deemed to create any contractual relationship between the subcontractor and the State. In addition, subcontracts shall contain any other provisions which are required to be included in subcontracts pursuant to the terms herein.

3. Prior to executing a subcontract, the Contractor agrees to require the subcontractor to provide to the State the information the State needs to determine whether a proposed subcontractor is a responsible vendor.

4. When a subcontract equals or exceeds $100,000, the subcontractor must submit a Vendor Responsibility Questionnaire (Questionnaire).

5. When a subcontract is executed, the Contractor must provide detailed subcontract information (a copy of subcontract will suffice) to the State within fifteen (15) calendar days after execution. The State may request from the Contractor copies of subcontracts between a subcontractor and its subcontractor.

6. The Contractor shall require any and all subcontractors to submit to the Contractor all financial claims for Services or work to the State agency, as applicable, rendered and required supporting documentation and reports as necessary to permit Contractor to meet claim deadlines and documentation requirements as established in Attachment D (Payment and Reporting Schedule) and Section III. Subcontractors shall be paid by the Contractor on a timely basis after submitting the required reports and vouchers for reimbursement of services or work, as

applicable. Subcontractors shall be informed by the Contractor of the possibility of non-payment or rejection by the Contractor of claims that do not contain the required information, and/or are not received by the Contractor by said due date.

C. Use Of Material, Equipment, Or Personnel:

1. The Contractor shall not use materials, equipment, or personnel paid for under the Master Contract for any activity other than those provided for under the Master Contract, except with the State's prior written permission.

2. Any interest accrued on funds paid to the Contractor by the State shall be deemed to be the property of the State and shall either be credited to the State at the close-out of the Master Contract or, upon the written permission of the State, shall be expended on additional services or work, as applicable, provided for under the Master Contract.

D. Property:

1. Property is real property, equipment, or tangible personal property having a useful life of more than one year and an acquisition cost of $1,000 or more per unit.

a) If an item of Property required by the Contractor is available as surplus to the State, the State at its sole discretion, may arrange to provide such Property to the Contractor in lieu of the purchase of such Property.

b) If the State consents in writing, the Contractor may retain possession of Property owned by the State, as provided herein, after the termination of the Master Contract to use for similar purposes. Otherwise, the Contractor shall return such Property to the State at the Contractor's cost and expense upon the expiration of the Master Contract.

c) In addition, the Contractor agrees to permit the State to inspect the Property and to monitor its use at reasonable intervals during the Contractor's regular business hours.

d) The Contractor shall be responsible for maintaining and repairing Property purchased or procured under the Master Contract at its own cost and expense. The Contractor shall procure and maintain insurance at its own cost and expense in an amount satisfactory to the State Agency, naming the State Agency as an additional insured, covering the loss, theft or destruction of such equipment.

e) A rental charge to the Master Contract for a piece of Property owned by the Contractor shall not be allowed.

f) The State has the right to review and approve in writing any new contract for the purchase of or lease for rental of Property (Purchase/Lease Contract) operated in connection with the provision of the services or work, as applicable, as specified in the Master Contract, if applicable, and any modifications, amendments, or extensions of an existing lease or purchase prior to its execution. If, in its discretion, the State disapproves of any Purchase/Lease Contract, then the State shall not be obligated to make any payments for such Property.

g) No member, officer, director or employee of the Contractor shall retain or acquire any interest, direct or indirect, in any Property, paid for with funds under the Master Contract, nor retain any interest, direct or indirect, in such, without full and complete prior disclosure of such interest and the date of acquisition thereof, in writing to the Contractor and the State.

2. For non-Federally-funded contracts, unless otherwise provided herein, the State shall have the following rights to Property purchased with funds provided under the Master Contract:

a) For cost-reimbursable contracts, all right, title and interest in such Property shall belong to the State.

b) For performance-based contracts, all right, title and interest in such Property shall belong to the Contractor.

3. For Federally funded contracts, title to Property whose requisition cost is borne in whole or in part by monies provided under the Master Contract shall be governed by the terms and conditions of Attachment A-2 (Federally Funded Grants).

4. Upon written direction by the State, the Contractor shall maintain an inventory of all Property that is owned by the State as provided herein.

5. The Contractor shall execute any documents which the State may reasonably require to effectuate the provisions of this section.

E. Records and Audits:

1. *General*:

a) The Contractor shall establish and maintain, in paper or electronic format, complete and accurate books, records, documents, receipts, accounts, and other evidence directly pertinent to its performance under the Master Contract (collectively, Records).

b) The Contractor agrees to produce and retain for the balance of the term of the Master Contract, and for a period of six years from the later of the date of (i) the Master Contract and (ii) the most recent renewal of the Master Contract, any and all Records necessary to substantiate upon audit, the proper deposit and expenditure of funds received under the Master Contract. Such Records may include, but not be limited to, original books of entry (e.g., cash disbursements and cash receipts journal), and the following specific records (as applicable) to substantiate the types of expenditures noted:

(i) personal service expenditures: cancelled checks and the related bank statements, time and attendance records, payroll journals, cash and check disbursement records including copies of money orders and the like, vouchers and invoices, records of contract labor, any and all records listing payroll and the money value of non-cash advantages provided to employees, time cards, work schedules and logs, employee personal history folders, detailed and general ledgers, sales records, miscellaneous reports and returns (tax and otherwise), and cost allocation plans, if applicable.

(ii) payroll taxes and fringe benefits: cancelled checks, copies of related bank statements, cash and check disbursement records including copies of money orders and the like, invoices for fringe benefit expenses, miscellaneous reports and returns (tax and otherwise), and cost allocation plans, if applicable.

(iii) non-personal services expenditures: original invoices/receipts, cancelled checks and related bank statements, consultant agreements, leases, and cost allocation plans, if applicable.

(iv) receipt and deposit of advance and reimbursements: itemized bank stamped deposit slips, and a copy of the related bank statements.

c) The OSC, AG and any other person or entity authorized to conduct an examination, as well as the State Agency or State Agencies involved in the Master Contract that provided funding, shall have access to the Records during the hours of 9:00 a.m. until 5:00 p.m., Monday through Friday (excluding State recognized holidays), 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.

d) The State shall protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law 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 Section 87 of the Public Officers Law, is reasonable.

e) Nothing contained herein shall diminish, or in any way adversely affect, the State's rights in connection with its audit and investigatory authority or the State's rights in connection with discovery in any pending or future litigation.

2. *Cost Allocation*:

a) For non-performance based contracts, the proper allocation of the Contractor's costs must be made according to a cost allocation plan that meets the requirements of OMB Circulars A-87, A-122, and/or A-21. Methods used to determine and assign costs shall conform to generally accepted accounting practices and shall be consistent with the method(s) used by the Contractor to determine costs for other operations or programs. Such accounting standards and practices shall be subject to approval of the State.

b) For performance based milestone contracts, or for the portion of the contract amount paid on a performance basis, the Contractor shall maintain documentation demonstrating that milestones were attained.

3. *Federal Funds*: For records and audit provisions governing Federal funds, please see Attachment A-2 (Federally Funded Grants).

F. Confidentiality: The Contractor agrees that it shall use and maintain information relating to individuals who may receive services, and their families pursuant to the Master Contract, or any other information, data or records deemed confidential by the State (Confidential Information) only

for the limited purposes of the Master Contract and in conformity with applicable provisions of State and Federal law. The Contractor (i) has an affirmative obligation to safeguard any such Confidential Information from unnecessary or unauthorized disclosure and (ii) must 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).

G. Publicity:

1. Publicity includes, but is not limited to: news conferences; news releases; public announcements; advertising; brochures; reports; discussions or presentations at conferences or meetings; and/or the inclusion of State materials, the State's name or other such references to the State in any document or forum. Publicity regarding this project may not be released without prior written approval from the State.

2. Any publications, presentations or announcements of conferences, meetings or trainings which are funded in whole or in part through any activity supported under the Master Contract may not be published, presented or announced without prior approval of the State. Any such publication, presentation or announcement shall:

a) Acknowledge the support of the State of New York and, if funded with Federal funds, the applicable Federal funding agency; and

b) State that the opinions, results, findings and/or interpretations of data contained therein are the responsibility of the Contractor and do not necessarily represent the opinions, interpretations or policy of the State or if funded with Federal funds, the applicable Federal funding agency.

3. Notwithstanding the above, the Contractor may submit for publication, scholarly or academic publications that derive from activity under the Master Contract (but are not deliverable under the Master Contract), provided that the Contractor first submits such manuscripts to the State forty-five (45) calendar days prior to submission for consideration by a publisher in order for the State to review the manuscript for compliance with confidentiality requirements and restrictions and to make such other comments as the State deems appropriate. All derivative publications shall follow the same acknowledgments and disclaimer as described in Section V(G)(2) (Publicity) hereof.

H. Web-Based Applications-Accessibility: Any web-based intranet and Internet information and applications development, or programming delivered pursuant to the Master Contract or procurement shall comply with New York State Enterprise IT Policy NYS-P08-005, Accessibility Web-Based Information and Applications, and New York State Enterprise IT Standard NYS-S08-005, Accessibility of Web-Based Information Applications, as such policy or standard may be amended, modified or superseded, which requires that State Agency web-based intranet and Internet information and applications are accessible to person with disabilities. Web content must conform to New York State Enterprise IT Standards NYS-S08-005, as determined by quality assurance testing. Such quality assurance testing shall be conducted by the State Agency and the results of such testing must be satisfactory to the State Agency before web content shall be considered a qualified deliverable under the Master Contract or procurement.

I. Non-Discrimination Requirements: Pursuant to 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 and sub-contractors will not discriminate against any employee or applicant for employment because of race, creed (religion), color, sex (including gender expression), national origin, sexual orientation, military status, age, disability, predisposing genetic characteristic, marital status or domestic violence victim status, and shall also follow the requirements of the Human Rights Law with regard to non-discrimination on the basis of prior criminal conviction and prior arrest. 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 the Master Contract shall be performed within the State of New York, the 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 the Master Contract. If this is a building service contract as defined in Section 230 of the Labor Law, then, in accordance with Section 239 thereof, the 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 the Master Contract. The Contractor shall be subject to fines of $50.00 per person per day for any violation of Section 220-e or Section 239 of the Labor Law.

J. Equal Opportunities for Minorities and Women; Minority and Women Owned Business Enterprises: In accordance with Section 312 of the Executive Law and 5 NYCRR 143, if the Master Contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of $25,000.00, whereby a contracting State 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 State Agency; or (ii) a written agreement in excess of $100,000.00 whereby a contracting State 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 the Contractor certifies and affirms that (i) it is subject to Article 15-A of the Executive Law which includes, but is not limited to, those provisions concerning the maximizing of opportunities for the participation of minority and women-owned business enterprises and (ii) the following provisions shall apply and it is Contractor's equal employment opportunity policy that:

1. The Contractor shall not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status;

2. The Contractor shall make and document its conscientious and active efforts to employ and utilize minority group members and women in its work force on State contracts;

3. The Contractor shall 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, upgrading, demotion, transfer, layoff, or termination and rates of pay or other forms of compensation;

4. At the request of the State, 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 shall not discriminate on the basis of race, creed, color, national origin, sex, age, disability or marital status and that such union or representative shall affirmatively cooperate in the implementation of the Contractor's obligations herein; and

5. The Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants shall be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status.

The Contractor shall include the provisions of subclauses 1 – 5 of this Section (IV)(J), in every subcontract over $25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (Work) except where the Work is for the beneficial use of the Contractor. Section 312 of the Executive Law does not apply to: (i) work, goods or services unrelated to the Master Contract; or (ii) employment outside New York State. The State shall consider compliance by the Contractor or a subcontractor with the requirements of any Federal law concerning equal employment opportunity which effectuates the purpose of this section. The State 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 State shall waive the applicability of Section 312 of the Executive Law to the extent of such duplication or conflict. The Contractor shall comply with all duly promulgated and lawful rules and regulations of the Department of Economic Development's Division of Minority and Women's Business Development pertaining hereto.

K. 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.

1. If the total dollar amount of the Master Contract is greater than $1 million, the Omnibus Procurement Act of 1992 requires that by signing the Master Contract, the Contractor certifies the following:

a) The Contractor has made reasonable efforts to encourage the participation of 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 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 the Master Contract and agrees to cooperate with the State in these efforts.

L. Workers' Compensation Benefits:

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

2. If a Contractor believes they are exempt from the Workers Compensation insurance requirement they must apply for an exemption.

M. Unemployment Insurance Compliance: The Contractor shall remain current in both its quarterly reporting and payment of contributions or payments in lieu of contributions, as applicable, to the State Unemployment Insurance system as a condition of maintaining this grant.

The Contractor hereby authorizes the State Department of Labor to disclose to the State Agency staff only such information as is necessary to determine the Contractor's compliance with the State Unemployment Insurance Law. This includes, but is not limited to, the following:

1. any records of unemployment insurance (UI) contributions, interest, and/or penalty payment arrears or reporting delinquency;

2. any debts owed for UI contributions, interest, and/or penalties;

3. the history and results of any audit or investigation; and

4. copies of wage reporting information.

Such disclosures are protected under Section 537 of the State Labor Law, which makes it a misdemeanor for the recipient of such information to use or disclose the information for any purpose other than the performing due diligence as a part of the approval process for the Master Contract.

N. Vendor Responsibility:

1. If a Contractor is required to complete a Questionnaire, the Contractor covenants and represents that it has, to the best of its knowledge, truthfully, accurately and thoroughly completed such Questionnaire. Although electronic filing is preferred, the Contractor may obtain a paper form from the OSC prior to execution of the Master Contract. The Contractor further covenants and represents that as of the date of execution of the Master Contract, there are no material events, omissions, changes or corrections to such document requiring an amendment to the Questionnaire.

2. The Contractor shall provide to the State updates to the Questionnaire if any material event(s) occurs requiring an amendment or as new information material to such Questionnaire becomes available.

3. The Contractor shall, in addition, promptly report to the State the initiation of any investigation or audit by a governmental entity with enforcement authority with respect to any alleged violation of Federal or state law by the Contractor, its employees, its officers and/or directors in connection with matters involving, relating to or arising out of the Contractor's business. Such report shall be made within five (5) business days following the Contractor becoming aware of such event, investigation, or audit. Such report may be considered by the State in making a Determination of Vendor Non-Responsibility pursuant to this section.

4. The State reserves the right, in its sole discretion, at any time during the term of the Master Contract:

a) to require updates or clarifications to the Questionnaire upon written request;

b) to inquire about information included in or required information omitted from the Questionnaire;

c) to require the Contractor to provide such information to the State within a reasonable timeframe; and

d) to require as a condition precedent to entering into the Master Contract that the Contractor agree to such additional conditions as shall be necessary to satisfy the State that the Contractor is, and shall remain, a responsible vendor; and

e) to require the Contractor to present evidence of its continuing legal authority to do business in New York State, integrity, experience, ability, prior performance, and organizational and financial capacity. By signing the Master Contract, the Contractor agrees to comply with any such additional conditions that have been made a part of the Master Contract.

5. The State, in its sole discretion, reserves the right to suspend any or all activities under the Master Contract, at any time, when it discovers information that calls into question the responsibility of the Contractor. In the event of such suspension, the Contractor shall be given written notice outlining the particulars of such suspension. Upon issuance of such notice, the Contractor must comply with the terms of the suspension order. Contract activity may resume at such time as the State issues a written notice authorizing a resumption of performance under the Master Contract.

6. The State, in its sole discretion, reserves the right to make a final Determination of Non-Responsibility at any time during the term of the Master Contract based on:

a) any information provided in the Questionnaire and/or in any updates, clarifications or amendments thereof; or

b) the State's discovery of any material information which pertains to the Contractor's responsibility.

7. Prior to making a final Determination of Non-Responsibility, the State shall provide written notice to the Contractor that it has made a preliminary determination of non- responsibility. The State shall detail the reason(s) for the preliminary determination, and shall provide the Contractor with an opportunity to be heard.

O. Charities Registration: If applicable, the Contractor agrees to (i) obtain not-for-profit status, a Federal identification number, and a charitable registration number (or a declaration of exemption) and to furnish the State Agency with this information as soon as it is available, (ii) be in compliance with the OAG charities registration requirements at the time of the awarding of this Master Contract by the State and (iii) remain in compliance with the OAG charities registration requirements throughout the term of the Master Contract.

P. Consultant Disclosure Law:[9] If this is a contract for consulting services, defined for purposes of this requirement to include analysis, evaluation, research, training, data processing, computer programming, engineering, environmental, health, and mental health services, accounting, auditing, paralegal, legal, or similar services, then in accordance with Section 163 (4-g) of the State Finance Law (as amended by Chapter 10 of the Laws of 2006), the Contractor shall timely, accurately and properly comply with the requirement to submit an annual employment report for the contract to the agency that awarded the contract, the Department of Civil Service and the State Comptroller.

Q. 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. Additionally, effective April 28, 2008, if this is a public work contract covered by Article 8 of the Labor Law, the Contractor understands and agrees that the filing of payrolls in a manner consistent with Subdivision 3-a of Section 220 of the Labor Law shall be condition precedent to payment by the State of any State approved sums due and owing for work done upon the project.

[9] Not applicable to not-for-profit entities.

ATTACHMENT A-1
AGENCY AND PROGRAM SPECIFIC CLAUSES
Part A. Agency Specific Clauses

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):

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

B. Prohibition on Purchase of Tropical Hardwoods:

1. 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 Section 165 of the State Finance Law, (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.

2. 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.

C. 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.

D. 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
Albany, New York 12245
Telephone: 518-292-5100
Fax: 518-292-5884
email: opa@esd.ny.gov

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

633 Third Avenue
New York, NY 10017
212-803-2414
email: mwbecertification@esd.ny.gov
http://esd.ny.gov/MWBE/directorySearch.html

E. Procurement Lobbying: To the extent this agreement is a "procurement contract" as defined by State Finance Law Sections 139-j and 139-k, by signing this agreement the contractor certifies and affirms that all disclosures made in accordance with State Finance Law Sections 139-j and 139-k are complete, true and accurate. In the event such certification is found to be intentionally false or intentionally incomplete, the State may terminate the agreement by providing written notification to the Contractor in accordance with the terms of the agreement.

F. Certification of Registration to Collect Sales and Compensating Use Tax by Certain State Contractors, Affiliates, and Subcontractors: To the extent this agreement is a contract as defined by Tax Law Section 5-a, if the contractor fails to make the certification required by Tax Law Section 5-a or if during the term of the contract, the Department of Taxation and Finance or the covered agency, as defined by Tax Law 5-a, discovers that the certification, made under penalty of perjury, is false, then such failure to file or false certification shall be a material breach of this contract and this contract may be terminated, by providing written notification to the Contractor in accordance with the terms of the agreement, if the covered agency determines that such action is in the best interest of the State.

G. 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.

H. Administrative Rules and Audits:

1. 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:

a) 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".

b) For a nonprofit organization other than
   (i) an institution of higher education,
   (ii) a hospital, or
   (iii) 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.

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

d) 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.

2. 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 "1" above.

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

a) 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.

b) 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.

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

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

b) 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.

c) 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.

I. 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.

J. 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.

K. 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 race, creed, color, sex, national origin, age, disability, sexual orientation or marital status.

L. 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

M. 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.

N. 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:

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

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

   b) **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

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

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

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

   b) **DB-120.1 --** Certificate of Disability Benefits Insurance OR

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

O. 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 any 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.

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

Q. All bidders/contractors agree that all state funds dispersed under this bid/contract will be bound by the terms, conditions, obligations and regulations promulgated or to be promulgated by the Department in accordance with E.O. 38, signed in 2012, governing restrictions on executive compensation.

R. The CONTRACTOR shall submit to the STATE ***(monthly or 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:

<< Insert Address>>

S. 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 Attachment 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.

T. 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.

U. Pursuant to the Master Contract's Standard Terms and Conditions, I. (General Provisions); J. (Notices), such notices shall be addressed as follows or to such different addresses as the parties may from time to time designate:

State of New York Department of Health
Name:
Title:
Address:
Telephone Number:
Facsimile Number:
E-Mail Address:

Insert Vendor/Grantee Name Here
Name:
Title:
Address:
Telephone Number:
Facsimile Number:
E-Mail Address:

Part B. Program Specific Clauses

Additional Department of Health program specific clauses follow in Attachment A-1 Part B.

ATTACHMENT A-1
AGENCY AND PROGRAM SPECIFIC CLAUSES
Part B. Program Specific Clauses

New York State Department of Health

Department of Health Program Name: New York State Stem Cell Program (NYSTEM)

Initiative Name: Consortia to Accelerate Therapeutic Applications of Stem Cells

Part B. Program Specific Clauses

A. Research Integrity and Responsible Conduct of Research

In accepting an award from the New York State Department of Health for support from the Empire State Stem Cell Fund, the contractor shall ensure that each project investigator agrees to conform strictly to the codes of practice, regulations, policies and laws governing ethical conduct of scientific research, including but not limited to CFR 42 Part 93 and CFR 45 Part 94. The contractor and the Principal Investigator (PI) shall be responsible for any violation of these standards. If experimental procedures conducted pursuant to this project are performed in another state or country, either directly by the PI and any co-investigators, or in collaboration with other persons, the PI and contractor shall ensure that such research complies with New York State laws and regulations that would be applicable to such research if performed in New York State. The contractor will inform NYSTEM program administrators of any actual or suspected instances of research misconduct by any project participant as soon as this information becomes known to the contractor. The contractor is fully responsible for investigation of such instances.

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning stem cell biology. 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 commence unless it has been approved by an Institutional Review Board (IRB) and a copy of the current approval has been submitted to NYSTEM. Further, the following requirements shall be satisfied:

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

- The research study will comply with New York State Public Health Law (PHL) Article 24-A unless the research is subject to, and in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.

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

- If applicable, the contractor's IRB has received, reviewed, and accepted 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 NYSTEM 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 of the research study within 24 hours of such determination.

C. Animal Use

NYSTEM requires that all contractors that conduct research using animals supported by the Empire State Stem Cell Fund adhere to all federal, state and local laws pertaining to humane care and use of animals for research purposes. Accordingly, no research study shall commence unless it has been reviewed and approved 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 relating to animal care and use (*e.g.*, the federal Animal Welfare Act, (7 USC 2131 *et seq.*) and its implementing regulations; and PHL Article 5, Title I, §§504 and 505-a) and a copy of the current approval has been submitted to NYSTEM.

D. Other Compliance Requirements

1. Human Tissue

NYSTEM will support research using human tissue and require that such research adhere to all federal, state and local laws and regulations pertaining to the use of such tissue, including, but not limited to, 42 USC §289g *et seq.*; NYS PHL Article 43, §§4301 to 4309; Article 43-B, §§4360 to 4366; and 10 NYCRR Part 52. Any facility collecting, processing, storing, or distributing human tissue, even if for research purposes only, must consult with the Department regarding the need for an appropriate New York State tissue bank license, and if informed a license is necessary, obtain such a license. Accordingly, no research study shall commence unless such license is current.

2. Analytical Testing of Human Specimens

Any facility performing analytical testing of specimens from tissue donors or donated tissues where donor-identified test results are produced, which does not already hold such a permit, must consult with the Department regarding the need for an appropriate New York State Clinical Laboratory Permit in compliance with PHL Article 5, Title V, §§570 to 581, or verify that the facility performing the testing holds the appropriate permit. Accordingly, no research study shall commence unless such permit is current.

3. **Recombinant DNA**

Any facility in possession of recombinant DNA or performing recombinant DNA activities must comply with relevant state law (New York State PHL Article 32-A), state regulations (10 NYCRR Part 61) and federal guidelines (see http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). Accordingly, no research study shall commence unless it has been reviewed and approved by the appropriate institutional oversight committee and a copy of the current approval has been submitted to NYSTEM.

E. Human Stem Cell Research

1. **Scope**. Research using the following types of cells or tissues ("Human Stem Cell Research") is subject to the requirements of this section:

   a. human embryonic stem cells;

   b. human totipotent or pluripotent cells;

   c. human neural progenitor stem cells; and

   d. human gonadal progenitor stem cells.

2. **National Academy of Science (NAS) and International Society of Stem Cell Research (ISSCR) Guidelines.** Human Stem Cell Research must comply with either NAS or ISSCR Guidelines to the extent applicable, and must also comply with any additional requirements of this Contract. In the event of any conflict, the requirements of this Contract shall take precedence.

3. **Stem Cell Research Oversight (SCRO) Committees.**

   a. Human Stem Cell Research must be approved by a Stem Cell Research Oversight (SCRO) Committee that meets the standards set forth in the NAS or ISSCR Guidelines and in paragraph (d) below. However, research permissible without SCRO Committee review under Category 1 of the ISSCR Guidelines or Section 1.3 (a) of the NAS Guidelines shall not require SCRO

review if notification is provided to the SCRO Committee.[1] Research using all the cell types set forth at Section E.1. b-d which meets the above-referenced ISSCR and NAS requirements for exemption of human embryonic stem cell research shall also be exempt from full review. Accordingly, no such research study shall commence unless it is demonstrated that research protocols have been reviewed and approved by the SCRO committee.

b. The SCRO Committee shall be responsible for the initial and ongoing review and oversight of the research at the institution where the research is being conducted.

c. The SCRO Committee shall ensure that research complies with either NAS or ISSCR Guidelines to the extent such Guidelines are applicable, and also complies with any additional requirements of this Appendix A-2. In the event of conflict, the requirements of Appendix A-2 shall take precedence.

d. The SCRO Committee shall create and follow written policies that include the following standards:

(i.) Committee Membership: The membership of the SCRO Committee responsible for oversight for the contracting institution should have sufficient diversity among its members, including consideration of race, gender and background. Members should be sensitive to issues, such as community attitudes, in order to promote respect for the advice and counsel of the SCRO Committee. The SCRO Committee should be composed of qualified persons of both sexes. The members present at a meeting in which research funded under this contract is approved by the SCRO Committee must include at least one scientist with relevant expertise and one ethicist. The purpose of diverse membership on the SCRO Committee is to ensure that different perspectives are given a voice; the SCRO Committee should encourage different perspectives and voices in its discussion of protocols and in its minutes.

(ii.) Conflict of Interest Policies: The policies shall address conflicts of interest in a manner that is in alignment with other institutional conflict

[1] Category 1 of the ISSCR Guidelines (Section 10.1) provides: "Experiments that are permissible after review under existing mandates and by existing local committees, and are determined to be exempt from full SCRO review. These will include experiments with pre-existing human embryonic stem cell lines that are confined to cell culture or involve routine and standard research practice, such as assays of teratoma formation in immune-deficient mice. We recommend that all institutions pursuing such research establish a mechanism capable of determining that a) these projects can be adequately reviewed by committees with jurisdiction over research on human tissues, animals, biosafety, radiation, etc. and b) that full review by a SCRO mechanism or body is not required. This mechanism should include a determination that the provenance of the human embryonic stem cell lines to be used has been scrutinized and deemed acceptable according to the principles outlined in this document, and that such research is in compliance with scientific, legal and ethical norms."

Section 1.3(a) of the NAS Guidelines provides: "Purely in vitro hES cell research that uses previously derived hES cell lines is permissible provided that the ESCRO committee or equivalent body designated by the investigator's institution (see Section 2.0) receives documentation of the provenance of the cell lines including (i) documentation of the use of an acceptable informed consent process that was approved by an Institutional Review Board (IRB) or foreign equivalent for their derivation (consistent with Section 3.6); and (ii) documentation of compliance with any additional required review by an Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), or other institutionally mandated review."

of interest policies, including, but not limited to, those governing the activities of the IRB. Such policies shall preclude a member from participating in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the SCRO Committee.

(iii.) Recordkeeping: The policies shall address recordkeeping requirements for the activities of the SCRO Committee and for research reviewed by the Committee that are in alignment with the policies developed by the institution's IRB in accordance with the requirements of 45 CFR Part 46 and guidance issued by the Office for Human Research Protections. In addition, the SCRO Committee shall develop and adhere to policies for maintaining records relating to the provenance of all stem cell lines used in funded research, consent of gamete donors, applicable ethical research standards, and reports of adverse or unexpected outcomes that pose a threat to the health or safety of any individual or raise new ethical issues. Records relating to the activities and review of the SCRO Committee and to the research conducted shall be retained for at least six years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

4. Consent to Donation of Biological Materials: Contractors must ensure that the procurement of biological materials used in research funded pursuant to this contract complies with the informed consent provisions in either the NAS or ISSCR Guidelines, modified as follows:

a. *Obtaining Informed Consent*: Obtaining a person's fully informed, voluntary consent to a donation[2] must be accomplished through a dynamic process - *i.e.*, a dialogue that encourages the potential donor to ask questions, and prompts the potential donor to confirm his or her understanding of the information *being disclosed. Accordi*ngly, the informed consent process must adhere to the introductory paragraph of ISSCR Guideline 11.3[3] and all of ISSCR 11.6.[4]

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2 References to "donors" or "donations" in this paragraph apply to donations of all biological materials – gametes, embryos and somatic cells – to stem cell research, except where otherwise noted.

3 ISSCR 11.3 - Informed consent: Researchers should exercise care in communicating the concept of "informed consent" to ensure that such consent has actually been obtained. The informed consent process should take into account language barriers and the educational level of the subjects themselves….

4 ISSCR 11.6 - Steps to enhance the procurement process: Attempts should be made to improve the informed consent process for human materials procurement. The informed consent document is but one aspect of this process. The purpose of the informed consent document is to record that all the ethically relevant information has been discussed. The informed consent document alone can never take the place of an interactive dialogue between research staff and providers of human materials. Researchers are thus encouraged to focus on enriching the informed consent process itself, in addition to ensuring that the informed consent document includes all of the ethically relevant information. The informed consent process can be enhanced in the following ways:

b. *Donation of Embryos in Excess of Clinical Need*: SCRO Committees shall review available documentation to ensure that there was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate the embryos for research purposes. Providing a general authorization for research donation when providing consent for reproductive treatment does not violate this provision, so long as specific consent to the research donation is obtained at the time of donation for research purposes.

c. *Re-consent*: Consent to donation shall be obtained at the time of the proposed transfer of the materials to the research team. With respect to obtaining re-consent to donation, SCRO Committees should apply the standards set forth in ISSCR Guideline 11.2,[5] or may choose to use the stricter standards set forth in NAS Guideline 3.2.[6]

d. *No Affect on Medical Care*: Policies and procedures shall be in place and donors shall be informed that providing or declining to provide consent to donate biological materials to research will not affect the quality of care provided to the donor.

e. *Withdrawal of Consent*: Donors shall be informed that they retain the right to withdraw consent until the biological materials are actually used in research, in compliance with ISSCR Guideline 11.2,[7] or until information which could link the identity of the donor(s) with the biological material is no longer retained (if applicable).

(i) Whenever possible, the person conducting the informed consent dialogue should have no vested interest in the research protocol. If members of the research team participate in the informed consent process, their role must be disclosed and care must be taken to ensure that information is provided in a transparent and accurate manner.

(ii) Empirical research has shown that informed consent is most effective as a dynamic, interactive, and evolving process as opposed to a static, one-time disclosure event. Thus, researchers should provide ample opportunities for providers of human materials to discuss their involvement in the research protocol.

(iii) Counseling services should be made available upon request to any providers of human materials prior to procurement.

(iv) Procurement procedures should be revised in light of a) ongoing studies of the long-term risks associated with oocyte retrieval; and b) research on informed consent for all types of human biological materials procurement.

(v) Researchers should consider on a regular basis, subject to annual review, the possible use of alternatives to hormonally induced oocytes procured solely for stem cell research, such as oocytes derived from pluripotent stem cells, in vitro maturation of oocytes from ovariectomy samples, and egg sharing programs offered through infertility clinics.

[5] ISSCR 11.2 - Contemporaneous consent for donation: Consent for donation of materials for research should be obtained at the time of proposed transfer of materials to the research team. Only after a rigorous review by a SCRO mechanism or body can permission be granted to use materials for which prior consent exists but for which re-consent is prohibitively difficult. Consent must be obtained from all gamete donors for use of embryos in research.

[6] NAS 3.2 - Consent for donation should be obtained from each donor at the time of donation. Even people who have given prior indication of their intent to donate to research any blastocysts that remain after clinical care should nonetheless give informed consent at the time of donation….

[7] ISSCR 11.2 - Donors should be informed that they retain the right to withdraw consent until the materials are actually used in research.

f. *Restrictions on the Initial Use of Donated Materials:* Donors must be informed of the intended use of their biological materials to the extent such use is known, and that cell lines derived from the biological materials may be disseminated to other institutions or researchers, and/or may be stored in a tissue bank. Donors should be encouraged to provide their biological materials free of restrictions on use, but must be offered the opportunity to impose restrictions on the types of research in which their materials initially might be used (*e.g.*, somatic cell nuclear transfer) prior to, or in conjunction with, derivation of a cell line. Donors must be informed that adherence to restrictions beyond initial-use restrictions cannot be guaranteed, and that researchers may decline to use their biological materials or cell lines derived therefrom if such restrictions are imposed.

g. *Options for Disposition*: Donors shall be advised that there are alternatives to donating their gametes or embryos to research, and shall be provided with an explanation of what the alternatives are, including, but not limited to, all of the options available at the health care facility where the reproductive treatment was sought (*e.g.*, embryo adoption, donation for fertility treatment, and discarding).

h. *Financial Disclosures*: Donors must be provided with information that complies with financial disclosure provisions of ISSCR Guidelines 11.3(a)(viii) and (ix).[8]

i. *Reimbursement for Costs of Research-Related Injuries*: Contractors shall be responsible for donors' medical costs, including the costs of treating injuries that arise directly and proximately from the act[s] of donating.

j. *Genetic and Medical Information*: Donors must be informed that any resulting cells or cell lines derived from their biological materials will carry some or all of the DNA of the donor, and therefore, could be partially or completely genetically matched to the donor. Donors must also be provided with the disclosures mandated by ISSCR Guideline 11.3(a) (vii).[9]

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[8] ISSCR 11.3(a) - The informed consent document and process should cover, at a minimum, the following statements:…
(viii) disclosure of the possibility that any resulting cells or cell lines may have commercial potential, and whether the donor will or will not receive financial benefits from any future commercial development.
(ix) disclosure of any present or potential future financial benefits to the investigator and the institution related to or arising from proposed research.

[9] ISSCR 11.3(a) - The informed consent document and process should cover, at a minimum, the following statements:…
(vii) disclosure of what donor medical or other information and what potential donor identifiers will be retained; specific steps taken to protect donor privacy and the confidentiality of retained information; and whether the identity of the donor will be readily ascertainable to those who derive or work with the resulting stem cell lines, or any other entity or person, including specifically any oversight bodies and government agencies.

k. *Counseling Services*: Donors shall be advised of the availability of counseling services pursuant to ISSCR Guideline 11.6(iii),[10] which preferably shall be made available to the donor free of charge.

l. *Donation of Oocytes Solely for the Purpose of Research*: The informed consent process must assure compliance with the provisions of ISSCR Guideline 11.5(b).[11] Special care must be taken to disclose both the short- and long-term health risks arising out of the oocyte donation process in a manner that reflects the most current scientific knowledge of such risks.

m. *Application*: The standards set forth in this subsection shall apply to research funded pursuant to this contract involving the derivation of new stem cell lines. Contractors may use biological materials obtained prior to the execution of this contract and/or cell lines derived without the use of funds provided under this contract so long as the informed consent obtained from the donor(s) adhered to the provisions of the NAS or ISSCR Guidelines. In addition, contractors may use cell lines registered on the National Institutes of Health ("NIH") Registry,[12] and cell lines in existence on or prior to August 9, 2001 that were approved by the NIH for use in federally-funded research prior to initiation of the NIH Registry. Nothing in this paragraph shall preclude a SCRO from reviewing, if it so chooses, the procurement or derivation of such cell lines for compliance with additional ethical standards, such as those set forth in this contract, or by NAS and ISSCR.

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[10] ISSCR 11.6 (iii) - Counseling services should be made available upon request to any providers of human materials prior to procurement.

[11] ISSCR 11.5(b) - *For provision of oocytes for research, when oocytes are collected outside the course of clinical treatment*. In locales where oocyte donation for stem cell research is allowed, the SCRO mechanism or body is responsible for conducting rigorous review of any protocol to ensure the safety and the free and informed choice of oocyte providers, according to the following principles:

(i) There must be monitoring of recruitment practices to ensure that no vulnerable populations, for example, economically disadvantaged women, are disproportionately encouraged to participate as oocyte providers for research.

(ii) In locales where reimbursement for research, participation is allowed, there must be a detailed and rigorous review to ensure that reimbursement of direct expenses or financial considerations of any kind do not constitute an undue inducement.

(iii) At no time should financial considerations of any kind be given for the number or quality of the oocytes themselves that are to be provided for research.

(iv) Oocyte procurement must be performed only by medically qualified and experienced physicians, and nonaggressive hormone stimulation cycles and frequent monitoring must be used to reduce the risk of ovarian hyperstimulation syndrome (OHSS).

(v) Due to the unknown long-term effects of ovulation induction, women should not undergo an excessive number of hormonally induced ovarian stimulation cycles in a lifetime, regardless of whether they are induced for research or assisted reproduction. The limits should be determined by thoughtful review during the SCRO process, which should be informed by the latest available scientific information about the health risks.

(vi) There should be a provision to pay for the cost of any medical care required as a direct and proximate result of a woman's provision of oocytes for research.

(vii) An infertility clinic or other third party responsible for obtaining consent or collecting materials should not be paid specifically for the material obtained, but rather for specifically defined cost-based reimbursements and payments for professional services.

[12] *See* National Institutes of Health Guidelines on Human Stem Cell Research, §§ II.B - D (2009), *available at* http://stemcells.nih.gov/policy/2009guidelines.htm.

5. Payments to Gamete Donors:

a. Contractors may conduct research involving the use of stem cell lines, or may derive new stem cell lines, for which women donating oocytes solely for research purposes have been, or are being, reimbursed for out-of-pocket expenses as well as compensated for the time, inconvenience and burden associated with the donation process. Out-of-pocket expenses may include, but are not limited to, travel, housing, medical care, child care incurred as a result of the donation process. Compensation for the time, inconvenience and burden associated with the donation process must be consistent with New York State's standards applicable to women who donate oocytes for reproductive purposes and may not exceed amounts permitted by the guidelines of the American Society of Reproductive Medicine.[13] Payments made to oocyte donors in accordance with the provisions of this section are an allowable expense under this contract.

b. If reimbursement for oocyte donation is provided, there must be a detailed and rigorous review by the SCRO Committee, and the IRB, if required, to ensure that reimbursement of direct expenses and/or other compensation do not constitute an undue inducement.

c. At no time should financial consideration of any kind be given for the number or quality of the oocytes themselves that are provided for research.

d. The SCRO Committee should review information, where available, regarding the payment to donors who produced gametes originally for reproductive purposes to ensure compliance with the ISSCR Guideline 11.5(a). Where no such information is reasonably available, the SCRO Committee need not ensure that payment history complies with either NAS or ISSCR Guidelines.

F. Publication and Intellectual Property Rights

1. It is ESSCB's intent that the results of research it supports through its sponsorship be disseminated and made easily available to the research community and the lay public. Manuscript submission for publication of research funded by the Fund shall not be delayed by investigators or their research institutions. Research results are to be submitted promptly for publication in internationally recognized scientific journals. Publication should not be delayed for commercial or other reasons beyond the editorial period needed to ensure scientific accuracy and presentation.

a. All publications reporting research supported by NYSTEM funds published in peer reviewed journals must be deposited in the National Institutes of Health National Library of Medicine's PubMed Central (PMC).

[13] American Society of Reproductive Medicine (ASRM) Ethics Committee. Financial compensation of oocyte donors. *Fertil. & Steril.* 88(2), 305-309 (2006).

NYSTEM encourages investigators to sign copyright agreements that specifically allow the published manuscript to be deposited for public posting on PMC. As investigators are encouraged to publish NYSTEM-funded research findings as "open access" publications, contract funds may be used to cover costs required for such "open access" publication.

b. An electronic copy of each such publication must be filed with the progress report pursuant to this contract.

c. Support by the Empire State Stem Cell 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 Empire State Stem Cell Fund through New York State Department of Health Contract # <<>>. Opinions expressed here are solely those of the author and do not necessarily reflect those of the Empire State Stem Cell Board, the New York State Department of Health, or the State of New York").

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

3. The State retains march-in rights[14] with regard to NYSTEM-funded research. In the event that NYSTEM determines that the contractor has not made sufficient reasonable efforts to protect the various property interests in the research or has failed to share the research developments promptly, the State shall have the right, at its sole discretion, to exercise its march-in rights and take appropriate steps to achieve those goals**.** The State shall have the right to a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, for research and governmental purposes only, any published or otherwise reproducible material, device, invention, technique, material, or methodology developed under or in the course of performing this funded research, dealing with any aspect of the research activity, or of the results and accomplishments attained from the research.

[14] For purposes of this contract, "march-in right" shall mean the following: with respect to any subject invention in which the contractor has acquired in the course of performing this contract, the State shall have the right to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the State determines that such action is necessary either because the contractor, assignee, or their licensee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use or to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensee.

4. The contractor must have written agreements with researchers that require prompt disclosure of inventions made in the performance of ESSCB-funded research. The contractor shall notify NYSTEM of the invention disclosures and the filing of any patent application in the progress report pursuant to this contract. The contractor shall also provide NYSTEM with 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 subject to the rights retained by the State pursuant to paragraph 3, *supra*.

Assignment and ownership allocation of intellectual and industrial property rights generated from research supported by the Fund are 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 contractor. 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 of the research supported by the Fund. However, to protect the State's interests and to streamline invention reporting procedures, contracts between the Department and the contractor 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.

5. Contractor agrees, pursuant to the provisions of the New York State Administrative Procedure Act §104, to provide the Department with the study, any data supporting the research study, and the identity of the principal person or persons who performed such study. If such study is used as the basis for the promulgation, amendment, or repeal of a rule, regulation, or guideline used in enforcement of a statute, rule, or regulation, the study, any data supporting that study, and the identity of the principal person or persons who performed the study shall be subject to disclosure in accordance with the law.

G. Other

1. Equipment may not be purchased within ninety (90) days of contract termination. Upon satisfactory completion of the contract, as determined by the Department, all equipment purchased hereunder may be retained by the contractor.

2. Neither the Department nor the State of New York will assume any responsibility for any damage or injuries caused by or resulting from research conducted with the financial support of the Fund.

3. The contractor is required to participate in and cooperate with evaluation and dissemination activities sponsored or conducted by NYSTEM staff, such as:

a. on-site monitoring visits;

b. Oversight Panel activities and meetings; and
c. NYSTEM annual scientific meetings.

4. The contractor is required to submit separate requests for personnel changes, budget modifications, requests for carry-forward of funds and no-cost extension of funds. Prior approval is required for all equipment purchases and out-of-state travel that are not detailed in Attachment B-1, Budget. Requests for changes to the budget are not guaranteed approval and may be subject to review beyond the Program level (also see the Contractor Manual at http://stemcell.ny.gov/awardee-information).

5. Maximum funding allocated to payment of salaries is limited to $199,700 in each budget year and is not adjustable as the federal salary cap changes.

6. No funds shall be directly or indirectly utilized for research involving human reproductive cloning. Patient care is not an allowable expense.

7. Throughout the contract term, the PI and the contracting organization are responsible for providing notice and documentation to NYSTEM regarding any changes in other funding and any measures taken to avoid or eliminate overlap with the NYSTEM contract.

8. NYSTEM scientific staff will establish a confidential independent Oversight Panel for each funded consortium and act as liaison to the Oversight Panel and the consortium. The Oversight Panel will be responsible for advising NYSTEM regarding: removal or addition of investigators; revision or addition of milestones; and, whether to proceed at key decision points, including the identification of specific activities and next steps. As such, the Oversight Panel and NYSTEM will be provided access to the peer review critique and all data and materials supported by the award including but not limited to scientific progress reports and unpublished data.

The Oversight Panel will have an appropriate range of expertise and experience relevant to the funded project.

In the first six months of the award period, NYSTEM will arrange for the Oversight Panel to meet with the PI and any Co-PIs, the Project Manager, investigators and NYSTEM staff to review the peer review critique, research plan, milestones and other aspects of the overall project, establish progress report deadlines for the consortium and establish general guidelines for materials to be provided by the consortium in advance of each milestone meeting. Beyond the initial meeting, they will meet at least annually, and at other time periods as appropriate to the project milestones and key decision points, to evaluate scientific progress and individual contributions. In general, Oversight Panel meetings will include presentation of project data including progress toward project milestones, critical scientific assessment, proposed updates to the contract Workplan, discussion of related budget issues and recommendations for action.

Possible outcomes of these meetings include: project continuation, redirection or discontinuation. Continued funding and "Go/No-go" determinations will be made by NYSTEM following receipt and review of progress reports and the subsequent recommendations of the Oversight Panel. Additionally, the Oversight Panel may be called upon to advise the consortium and NYSTEM regarding key decision points.

The following review criteria will form the general basis of the Oversight Panel evaluation.

Significance and Impact

- Does the objective for the proposed therapeutic or technology remain achievable and timely?
- Does the proposed therapeutic or technology continue to address an unmet medical need?
- Does the proposed therapeutic or technology continue to offer an advantage over other therapies or technologies for treatment or prevention of disease?
- What is the likelihood that successful completion of the project will lead to improved health outcomes, and impact the prevention or treatment of the targeted disease(s) or condition(s)?

Feasibility and Approach

- Is there continuing evidence (proof-of-principle data) to demonstrate that development of the proposed therapeutic or technology remains feasible and timely?
- Is evidence presented to indicate that the project is sufficiently mature to achieve a significant measurable advance within the period of the award?
- Does the scientific rationale remain strong for the proposed approach? Does the likelihood of successful completion of the study remain high based on the research design and methods, the availability of resources, the progress to date and the overarching research environment?
- Are potential problem areas acknowledged and are alternative approaches proposed?
- Are there new identifiable barriers, beyond the scope of the work proposed, to successful development of clinical applications?
- If applicable, is the preclinical or clinical plan sufficiently developed to enhance regulatory approval?

Investigators and Leadership

- To what extent do the PI, Co-PIs and co-investigators each contribute research experience relevant and necessary to successful completion of the project from this point forward?
- To what extent are each of the roles defined and do they remain clearly essential to completion of the project?
- Does the assembled consortium have all of the expertise, including clinical and technological, necessary for successfully completing the remaining aspects of the project?

Management and Oversight

- Is an appropriate and effective management structure in place?
- Are plans for integrating efforts, communication and data/resource sharing among investigators, and with NYSTEM and the Oversight Panel, in place and functioning?

- Does the management strategy remain clearly focused on achieving established goals and milestones?
- To what extent are the timeline and milestones realistic, achievable and quantifiable? Will they provide sufficient opportunities for progress review by the Oversight Panel?

Budget
- Do the items for each budget line continue to be necessary for completion of the project?
- Are the annual budget line allocations sufficient to accomplish the research aims?
- Are the annual line-item budgeted amounts reasonable and cost effective?

In addition, the Oversight Panel will consider:

a. Performance: The consortium has achieved the milestones approved by the Oversight Panel and NYSTEM staff and has presented quantifiable study outcomes. The consortium has achieved the milestones within budget and in appropriate time frames.

b. Responsiveness: The consortium leadership has implemented the recommendations of the Oversight Panel, as approved by NYSTEM, in a timely manner. The project remains responsive to the overall goals of the proposed project.

c. Impact: The data presented indicate that the therapeutic continues to offer an advantage over other alternatives in practice or in the development pipeline. Results achieved to date demonstrate satisfactory progress toward clinical significance.

d. Feasibility and Next Steps: Feasible strategies and steps to ensure successful achievement of the future milestones are outlined in the updated Workplan.

If the consortium is unable to achieve its milestones within budget and in appropriate time frames or is unresponsive to recommendations as required by NYSTEM, the Oversight Panel may recommend to NYSTEM that the contract be terminated; the final decision regarding contract termination will be made by NYSTEM.

ATTACHMENT B-1 - EXPENDITURE BASED BUDGET
SUMMARY

PROJECT NAME: _____

CONTRACTOR SFS PAYEE NAME: _____

CONTRACT PERIOD: From: _____

To: _____

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

ATTACHMENT B-1 - EXPENDITURE BASED BUDGET
PERSONAL SERVICES DETAIL

SALARY					
POSITION TITLE	ANNUALIZED SALARY PER POSITION	STANDARD WORK WEEK (HOURS)	PERCENT OF EFFORT FUNDED	NUMBER OF MONTHS FUNDED	TOTAL
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
				Subtotal	
FRINGE - TYPE/DESCRIPTION					
				PERSONAL SERVICES TOTAL	

ATTACHMENT B-1 - EXPENDITURE BASED BUDGET
NON-PERSONAL SERVICES DETAIL

CONTRACTUAL SERVICES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

TRAVEL - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

EQUIPMENT - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

SPACE/PROPERTY EXPENSES: RENT - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
SPACE/PROPERTY EXPENSES: OWN - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
TYPE/DESCRIPTION OF UTILITY EXPENSES	TOTAL
1.	
2.	
3.	
TOTAL	

OPERATING EXPENSES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

OTHER - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

ATTACHMENT B-1(A) - EXPENDITURE BASED BUDGET (AMENDMENT)
SUMMARY

PROJECT NAME: _____

CONTRACTOR SFS PAYEE NAME: _____

CONTRACT PERIOD: From: _____

To: _____

AMENDMENT VERSION NUMBER: _____

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

ATTACHMENT B-1 (A) - EXPENDITURE BASED BUDGET (AMENDMENT)
PERSONAL SERVICES DETAIL

SALARY					
POSITION TITLE	ANNUALIZED SALARY PER POSITION	STANDARD WORK WEEK (HOURS)	PERCENT OF EFFORT FUNDED	NUMBER OF MONTHS FUNDED	TOTAL
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
				Subtotal	
FRINGE - TYPE/DESCRIPTION					
				PERSONAL SERVICES TOTAL	

ATTACHMENT B-1 (A) - EXPENDITURE BASED BUDGET (AMENDMENT)
NON-PERSONAL SERVICES DETAIL

CONTRACTUAL SERVICES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

TRAVEL - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

EQUIPMENT - TYPE/DESCRIPTION	TOTAL COST
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

SPACE/PROPERTY EXPENSES: RENT - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
SPACE/PROPERTY EXPENSES: OWN - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
UTILITY EXPENSES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
TOTAL	

OPERATING EXPENSES - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

OTHER - TYPE/DESCRIPTION	TOTAL
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
TOTAL	

ATTACHMENT B-1 (A) EXPENDITURE BASED BUDGET (AMENDMENT)
JUSTIFICATION

Please provide a justification for the amendments herein:

ATTACHMENT C – WORK PLAN
SUMMARY

PROJECT NAME: _____

CONTRACTOR SFS PAYEE NAME: _____

CONTRACT PERIOD: From: _____

To: _____

Provide an overview of the project including goals, tasks, desired outcomes and performance measures:

ATTACHMENT C – WORK PLAN
DETAIL

OBJECTIVE	BUDGET CATEGORY/ DELIVERABLE (if applicable)	TASKS	PERFORMANCE MEASURES
1:		a.	i.
			ii.
			iii.
		b.	i.
			ii.
			iii.
		c.	i.
			ii.
			iii.

ATTACHMENT C – WORK PLAN
DETAIL

OBJECTIVE	BUDGET CATEGORY/ DELIVERABLE (if applicable)	TASKS	PERFORMANCE MEASURES
2:		a.	i.
			ii.
			iii.
		b.	i.
			ii.
			iii.
		c.	i.
			ii.
			iii.

ATTACHMENT C – WORK PLAN
DETAIL

OBJECTIVE	BUDGET CATEGORY/ DELIVERABLE (if applicable)	TASKS	PERFORMANCE MEASURES
3:		a.	i.
			ii.
			iii.
		b.	i.
			ii.
			iii.
		c.	i.
			ii.
			iii.

ATTACHMENT D
PAYMENT AND REPORTING SCHEDULE

I. PAYMENT PROVISIONS

In full consideration of contract services to be performed the State Agency agrees to pay and the contractor agrees to accept a sum not to exceed the amount noted on the face page hereof. All payments shall be in accordance with the budget contained in the applicable Attachment B form (Budget), which is attached hereto.

A. Advance Payment and Recoupment Language (if applicable):

1. The State agency will make an advance payment to the Contractor, during the initial period, in the amount of _____ percent (__%) the budget as set forth in the most recently approved applicable Attachment B form (Budget).

2. Recoupment of any advance payment(s) shall be recovered by crediting (___%) of subsequent claims and such claims will be reduced until the advance is fully recovered within the contract period.

3. Scheduled advance payments shall be due in accordance with an approved payment schedule as follows:

   Period: _____ Amount: _____ Due Date: _____

   Period: _____ Amount: _____ Due Date: _____

   Period: _____ Amount: _____ Due Date: _____

   Period: _____ Amount: _____ Due Date: _____

B. Interim and/or Final Claims for Reimbursement

Claiming Schedule (*select applicable frequency*):

- ☐ Quarterly Reimbursement
  Due date _____
- ☐ Monthly Reimbursement
  Due date _____
- ☐ Biannual Reimbursement
  Due date _____
- ☐ Fee for Service Reimbursement
  Due date _____

☐ Rate Based Reimbursement
Due date _____

☐ Fifth Quarter Reimbursement
Due date _____

☐ Milestone/Performance Reimbursement
Due date/Frequency _____

☐ Scheduled Reimbursement
Due date/Frequency _____

II. REPORTING PROVISIONS

A. Expenditure-Based Reports (*select the applicable report type*):

☐ Narrative/Qualitative Report

The Contractor will submit, on a quarterly basis, not later than _____ days from the end of the quarter, the report described in Section III(G)(2)(a)(i) of the Master Contract

☐ Statistical/Quantitative Report

The Contractor will submit, on a quarterly basis, not later than ____ days from the end of the quarter, the report described in Section III(G)(2)(a)(ii) of the Master Contract.

☐ Expenditure Report

The Contractor will submit, on a quarterly basis, not later than ____ days after the end date for which reimbursement is being claimed, the report described in Section III(G)(2)(a)(iii) of the Master Contract.

☐ Final Report

The Contractor will submit the final report as described in Section III(G)(2)(a)(iv) of the Master Contract, no later than _____ days after the end of the contract period.

☐ Consolidated Fiscal Report (CFR)[1]

The Contractor will submit the CFR on an annual basis, in accordance with the time frames designated in the CFR manual. For New York City contractors, the due date shall be May 1 of each year; for Upstate and Long Island contractors, the due date shall be November 1 of each year.

[1] The Consolidated Fiscal Reporting System is a standardized electronic reporting method accepted by Office of Alcoholism & Substance Services, Office of Mental Health, Office of Persons with Developmental Disabilities and the State Education Department, consisting of schedules which, in different combinations, capture financial information for budgets, quarterly and/or mid-year claims, an annual cost report, and a final claim. The CFR, which must be submitted annually, is both a year-end cost report and a year-end claiming document.

B. Progress-Based Reports

1. Progress Reports

The Contractor shall provide the report described in Section III(G)(2)(b)(i) of the Master Contract in accordance with the forms and in the format provided by the State Agency, summarizing the work performed during the contract period (see Table 1 below for the annual schedule).

2. Final Progress Report

Final scheduled payment will not be due until ____ days after completion of agency's audit of the final expenditures report/documentation showing total grant expenses submitted by vendor with its final invoice. Deadline for submission of the final report is _____. The agency shall complete its audit and notify vendor of the results no later than _____. The Contractor shall submit the report not later than ____days from the end of the contract.

C. Other Reports

The Contractor shall provide reports in accordance with the form, content and schedule as set forth in Table 1.

TABLE I – REPORTING SCHEDULE

PROGRESS REPORT #	PERIOD COVERED	DUE DATE