FAU # 0911051012

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: August 31, 2011

APPLICANT CONFERENCE: October 21, 2011 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

Registration Due: October 18, 2011

QUESTIONS DUE: October 25, 2011

QUESTIONS, ANSWERS AND UPDATES POSTED: November 15, 2011

APPLICATION PART ONE DUE: October 17, 2011 by 6:00 PM

APPLICATION PART TWO DUE: March 12, 2012 by 6:00 PM

ESTIMATED CONTRACT START DATE: March 1, 2013

DOH CONTACT NAME AND ADDRESS:

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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 and at http://stemcell.ny.gov/

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I. Introduction

A. Background

New stem cell research discoveries are encouraging leading scientists to investigate the potential of cell-based therapies to treat life-threatening disease. If researchers can develop safe, reliable methods for prevention and treatment of disease, millions of Americans living with devastating diseases such as diabetes or amyotrophic lateral sclerosis, or injuries such as severe spinal cord injury, could benefit.

Now in its fifth year, 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 solicits reviews and 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.

While developing its Strategic Plan in its first year of operation, the ESSCB authorized the issuance of two important Requests for Applications (RFAs) to stimulate and encourage the development of a strong stem cell research community in New York State: "Institutional Development Awards in Stem Cell Research" and "Planning Grants for Emerging Opportunities and Consortia Development for Stem Cell Research." These were followed by additional RFAs designed to: support the development of a solid research infrastructure; provide training and education opportunities for undergraduates in stem cell science; and fund investigational research proposals. Through these early efforts, particularly the planning and infrastructure development awards, the strengths of the stem cell research community in New York have become more evident and the strategic efforts of the ESSCB with regard to the multi-disciplinary nature of stem cell research have evolved. The present RFA as authorized by the ESSCB, "Consortia to Accelerate Therapeutic Applications of Stem Cells," is one outcome of those early experiences, reflecting the evolving needs of, and input from, New York State's stem cell science community.

B. Purpose of the Funds

Through this RFA, the ESSCB wishes to accelerate translational and preclinical through clinical applications of stem cell research 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 or will apply a new technology or platform based on stem cells. 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.

C. Available Funds

All awards will be financed by the Empire State Stem Cell Trust Fund. The number of awards will be contingent upon the quality of the applications received as well as the size and scope of the proposed projects. A maximum of $80 million is available to support approximately five 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. Additionally, funds will be available to support Facilities and Administrative costs of up to 20 percent of the modified total direct costs. Based on its assessment that the field is ready to pursue additional investigations, the ESSCB Funding Committee may determine that additional funds should be made available under this RFA to support additional awards.

II. Who May Apply?

The applicant must be a New York State not-for-profit or governmental organization. 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.

Applicants to this RFA need not have received an award in response to FAU# 0802071100, "Planning Grants for Emerging Opportunities and Consortia Development for Stem Cell Research."

The eligible Principal Investigator (PI) is employed by the applicant institution and has the skills, knowledge, and resources necessary to carry out the proposed Workplan. Collaborations between investigators at multiple institutions 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. An individual may serve as a PI on only one application in response to this RFA and only one application will be accepted from any single institution. **In the event that more than one application is received from a PI or institution, all applications from that PI or institution will be disqualified.** Individuals and institutions may appear in any number of applications as collaborators, subcontractors, consultants or contributors.

This RFA will use a two-part application process to enable prospective applicants to assess both their readiness for a competitive response and the appropriateness of the application to this funding mechanism. This 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

A successful application will present a strong, plausible explanation of the capability to achieve a significant measurable advance toward clinical application within the period of the award. The Workplan will establish quantifiable milestones. 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 proposed project will have a patient-oriented, health outcome focus with the intent to proceed through clinical application. It may focus on any disease/condition, group of

diseases/conditions or organ system(s). The goal(s) of a proposed project may be based on a specific platform or technology such as new methods for the production or differentiation of stem cells and their derivatives to desired cell types, new methods for tracking or delivering stem cells or their derivatives *in vivo*, or use of a new animal model. **Importantly, however, the goal of this funding mechanism is not to develop new platforms or technologies but to develop new clinical applications.** Further, it is expected that applicants will have previously established proof-of-principle data to support the feasibility and timeliness/readiness of the proposed project. Because Good Laboratory Practice (GLP) and Good Manufacturing Practice (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.

1. Leadership

   The percent effort required of the PI must be at least 30 percent throughout the contract term. 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). **The percent effort required of each designated Co-PI must be at least 20 percent throughout the contract term**. 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 other investigators is not prescribed; it should be dependent upon the nature of their role and may vary during the course of the award.

   A 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 relevant experience. The Project Manager need not be identified at the time of application, but must be engaged prior to the first meeting with the independent Oversight Panel (see below).

   Together, these individuals 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.

2. Oversight

   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. 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 Form 3.

In the first half of the first year 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 Section V.B., Part Two Application Content and Format, instructions for Budget – 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 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 therapeutic or technology/platform 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. Use of Funds

Funds may be used, as appropriate to support salaries, fringe benefits, stipends, supplies, equipment, subcontractors, travel, consultant costs, animals and their care, core facility use charges, publication, meeting and communication costs, and other related research costs (also see Section V.B., Form 8, Budget, Allowable Expenses) up to the annual maximum amounts outlined in Section V.B., Part Two Application Content and Format. Facilities and Administrative (F&A) costs are limited to a maximum of 20 percent of modified total direct costs (see Section V.B.).

No funds shall be directly or indirectly utilized for research involving human reproductive cloning. No funds shall be used for patient care.

C. Reporting Obligations

If awarded, the contractor will be required to submit financial reports and scientific progress reports in accordance with the forms and formats 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 Appendix A-2 and Appendix C of the executed contract, and to monitor subcontractor compliance. A sample of these contract appendices can be found in Attachment 4 to this RFA.

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

- on-site monitoring visits;
- annual visits and other necessary Oversight Panel activities and meetings; and
- travel to and participation of the PI and Co-PI in ESSCB-sponsored annual or other meeting.

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

IV. Administrative Requirements

A. Issuing Agency

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

B. Question and Answer Phase

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

Questions of a technical nature can be addressed in writing or via telephone by calling 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 date identified on the cover sheet of this RFA.

C. Letter of Intent

Letters of Intent are not requested for this RFA (see Section V., Instructions for Completing the Application).

D. Applicant Conference

An applicant conference will be held to give potential applicants the opportunity to receive an overview of the RFA and ask specific questions. The 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 Department requests that potential applicants register for the conference by calling (518) 474-7002 to insure access through security, adequate accommodations for the number of prospective attendees and to insure 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 D350 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 D350
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 D350
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.

For detailed content requirements, see Section V., Instructions for Completing the Application. The application should be submitted in a single package that is clearly labeled with the RFA name and FAU 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 and supporting documents and an exact paper copy. The package should be clearly marked with the PI's name and the name of the applicant institution. 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 March 1, 2013 for a term of up to four years and will not be renewable.

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.

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

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

Grant contractors shall provide complete and accurate billing vouchers to the Department's designated payment office in order to receive payment. Billing vouchers submitted to the Department must contain all information and supporting documentation required by the Contract, the Department and the State Comptroller. Payment for vouchers 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 ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures 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 epunit@osc.state.ny.us or by telephone at (518) 486-1255. CONTRACTOR acknowledges that it will not receive payment on any vouchers 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 check as set forth above.

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

- The contractor will be reimbursed for actual expenses incurred as allowed in the Contract Budget and Workplan.

- All vouchers submitted by the contractor pursuant to this agreement shall be submitted to the State no later than 60 days after the end of the quarter for which reimbursement is being claimed.

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

- The final voucher 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 shall submit the following progress reports:

   - Milestone-based progress reports in accordance with the forms and formats provided by NYSTEM as outlined in Section III.C., 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 Appendix C of the final grant contract.

I. 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, 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 www.osc.state.ny.us/vendrep or may contact the Office of the State Comptroller's Help Desk for a copy of the paper form.

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

J. General Specifications

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

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

3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer Phase (Section IV.B.) must be clearly noted in a cover letter attached to the application.

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

5. Provisions Upon Default

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

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

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

K. Appendices

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

APPENDIX A - Standard Clauses for All New York State Contracts

APPENDIX A-1 - Agency Specific Clauses

APPENDIX A-2 - Program Specific Clauses

APPENDIX B - Budget

APPENDIX C - Payment and Reporting Schedule

APPENDIX D - Workplan

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

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

- **CE-200** -- Certificate of Attestation For New York Entities With No Employees And Certain Out of State Entities, That New York State

Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR

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

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

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

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

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

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

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

APPENDIX F – Request for Applications

APPENDIX G – Notifications

V. Instructions for Completing the Application

A two-part application process will be utilized.

A. Part One Content and Format

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 Project Overview from Part One and the Workplan from Part Two of the application will be included in any awarded contract; therefore, they should be sufficiently detailed to allow monitoring of progress toward project goals. Together, these elements 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 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.

Applicants should note that peer review panel member selection will be conducted on the basis of Part One of the application.

ALL PART ONE APPLICATIONS SHOULD USE THE FORMS AND FORMATS PRESCRIBED IN THIS SECTION V.A. (see Attachment 1A – Part One Application Forms 1-4). Part One applications should be submitted in electronic format on a CD or DVD. An exact paper copy should also be submitted and will be used if the CD or DVD is damaged. If an electronic copy has not been submitted, the paper copy will be scanned. Please note that if the electronic copy is damaged and a paper copy has not been submitted, the application will not pass administrative review and will not be sent to peer review.

Electronic files should not exceed 12 MB each and should not be password protected. The CD or DVD should be clearly labeled with the applicant's name. The CD or DVD should contain a single Portable Document Format (PDF) file including the following four 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

It is the applicant's responsibility to ensure that all materials to be included in Part One of the application have been properly prepared.

Forms are pre-set with acceptable fonts and margins. Part One applications should be single-spaced and typed using an 11-12 point font. Smaller font sizes are acceptable for use in tables and figure legends. Each page should be numbered consecutively. **Do not exceed the page limits stated above.** Figures and illustrations are included in the page limits. Appendices should not be submitted.

Each content section and form described below should be provided in the application.

Part One 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 institutions.

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 "0911051012."

Principal Investigator. Provide the information requested. The PI is the investigator employed by the applicant institution 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 institution 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 choice from the dropdown box (Governmental or Nonprofit).

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

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 institution is eligible to apply 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.

Project Overview – Form 2
Provide the information requested such that persons from diverse scientific backgrounds can easily understand the objective. Do not exceed 3 pages.

Overall Objective and Aims
Describe the targeted disease(s), conditions(s) or organ system(s). Summarize the scientific rationale, the nature of the candidate preventive, therapeutic or platform, 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 preventive, therapeutic or application of the platform 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.

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 Form 2 the Project Manager will execute). If an individual currently fills that role, please list them by name.

Part One Assessment Checklist – Form 4
This checklist is a means by which 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.

B. Part Two Application Content and Format

For each Part One application that meets the mandatory requirements **(see Attachment 1B)**, NYSTEM will assign and provide an application number to the PI for use when submitting Part Two of the application. **The consortia PI and 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.

ALL PART TWO APPLICATIONS SHOULD USE THE FORMS (see Attachment 2A – Part Two Application Forms 1-16) AND FORMATS PRESCRIBED IN THIS SECTION V.B. APPLICATIONS THAT DEVIATE FROM SPECIFIC ELEMENTS OF THESE INSTRUCTIONS OR THOSE FOUND ON THE FORMS WILL BE ASSESSED A PENALTY (see Attachment 2B).

Part Two applications should be submitted in electronic format on a CD or DVD. An exact paper copy of Part Two applications should also be submitted and will be used if the CD or DVD is damaged. If an electronic copy has not been submitted, the paper copy will be scanned. Please note that if the electronic copy is damaged and a paper copy has not been submitted, the application will not pass administrative review and will not be sent to peer review.

Electronic files should not exceed 12 MB each and should not be password protected. The CD or DVD should be clearly labeled with the applicant's name and application number. The CD or DVD should contain the following four 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
- Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned and saved as a separate PDF file.

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared. Applicants are strongly encouraged to seek appropriate technical support in the creation of electronic files and to review the electronic files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at http://stemcell.ny.gov/research_support.html. Applicants should also be aware that while color figures may be included, applications may be printed in black and white. Applicants may wish to annotate the figure legend directing the reader to the electronic file if color is an important aspect of the figure.

Forms are pre-set with acceptable fonts and margins. Applications should be single-spaced and typed using an 11-12 point font. Smaller font sizes are acceptable for use in tables and figure legends. The header should contain the PI's last name, first initial and applicant institution name, with the exception of Forms 1-6. Each page should be numbered consecutively. Figures and illustrations are included in the page limits. Appendices may not be used to circumvent page limitations.

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, must 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.

Each content section and form described below should be provided in the application.

Applicant Face Page – Form 1

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

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

FAU number. This box should read "0911051012."

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.**

Principal Investigator. Provide the information requested. The PI is the New York State investigator employed by the applicant institution 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 institution 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 institution, provide the information requested for the Co-PI. If the institutional 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 Sub-applicant 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 project.

Type of Organization. Select the appropriate choice from the dropdown box (Governmental or Nonprofit).

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

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

Human Subjects. Select the appropriate choice from the dropdown box. For applications that include any use of human subjects or tissues/fluids from human subjects, select 'YES.' If human subjects or tissues/fluids from human subjects will not be used, select 'NO.' Required assurances must be provided before contract development. Also see instructions for Form 14, *Human Subjects*.

Vertebrate Animals. Select the appropriate choice from the dropdown box. For applications that include any use of vertebrate animals or their tissues/fluids, select 'YES.' If vertebrate animals or their tissues/fluids will not be used, select 'NO.' Required assurances must be provided before contract development. Also see instructions for Form 15, *Vertebrate Animals*.

Human Pluripotent Stem Cells. Select the appropriate choice from the dropdown box. For applications that include any use of human pluripotent stem cells, select 'YES.' If human pluripotent stems cells will not be used, select 'NO.' Required assurances must be provided before contract development. Also see instructions for Form 16, *Human Stem Cells*.

Recombinant DNA. Select the appropriate choice from the dropdown box. For applications that include any use of recombinant DNA, select 'YES.' If no recombinant DNA will not be used, select 'NO.' Required assurances must be provided before contract development.

Project Start and End Dates. Record the anticipated project duration of: March 1, 2013 through February 28, 2017.

Year One Grand Total Costs. Enter Year One Grand Total Costs from Form 8, Line 14. This figure includes direct and Facilities and Administrative (F&A) costs for the applicant and all sub-applicant costs.

Grand Total Costs (all years). Enter the Grand Total Costs (all years) from Form 8, Line 14. This figure includes direct and F&A costs for the applicant and all sub-applicant costs.

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 institution) and organizational official 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 institution is eligible to apply 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.

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

Sub-applicant Face Page – Form 1-S

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."

FAU number. This box should read "0911051012."

Application Number. Enter the application number provided by NYSTEM after the submission of Part One of the application.

Principal Investigator. Provide the information requested. The sub-applicant PI is the investigator employed by the sub-applicant institution responsible for planning, coordinating and implementing the subcontracted portion of the contract if a sub-award is made. The sub-applicant PI will act as liaison with the contractor PI and be required to fulfill technical reporting requirements and submit any revised budgets co-signed by an authorized organizational representative. If this individual is also considered to be a 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 institution is designated, provide the information requested for the Co-PI of the sub-applicant. The Co-PI and the sub-applicant institution'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 choice from the dropdown box (Governmental, Nonprofit, For Profit).

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

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

Human Subjects. Select the appropriate choice from the dropdown box. For applications that include any use of human subjects or tissues/fluids from human subjects, select 'YES.' If human subjects or tissues/fluids from human subjects will not be used, select 'NO.' Required assurances must be provided before contract development. Also see instructions for Form 14, *Human Subjects*.

Vertebrate Animals. Select the appropriate choice from the dropdown box. For applications that include any use of vertebrate animals or their tissues/fluids, select 'YES.' If vertebrate animals or their tissues/fluids will not be used, select 'NO.' Required assurances must be provided before contract development. Also see instructions for Form 15, *Vertebrate Animals*.

Human Pluripotent Stem Cells. Select the appropriate choice from the dropdown box. For applications that include any use of human pluripotent stem cells, select 'YES.' If human pluripotent stems cells will not be used, select 'NO.' Required assurances must be provided before contract development. Also see instructions for Form 16, *Human Stem Cells*.

Recombinant DNA. Select the appropriate choice from the dropdown box. For sub-applications that include any use of recombinant DNA, select 'YES.' If recombinant DNA will not be used, select 'NO.' Required assurances must be provided before contract development.

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

Year One Grand Total Costs. Enter Year One Grand Total Costs from Form 8, Line 14. This figure includes direct and F&A costs for the sub-applicant.

Grand Total Costs (all years). Enter the Grand Total Costs (all years) from Form 8, Line 14. This figure includes direct and F&A costs 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. This individual will be notified in the event of a sub-award.

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.

Certifications and Assurance. Prior to award recommendation, the PI, Co-PI (if from the same institution) and organizational official are required to sign and date the form. Signatures denote certification that the statements herein are true and complete to the best of the signatories' knowledge and agreement to comply with the terms and conditions of any subcontract awarded as a result of this application.

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

Staff, Collaborators, Consultants and Contributors – Form 2
List (spell out) the full name, title and institutional 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. 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.

Independent Oversight Panel – Form 3
Provide a list of suggested experts to serve on the Oversight Panel. Spell out the full name, title and institutional affiliation of any recommended member, include contact information where available, and state the specific rationale for each suggestion, as related to the proposed project.

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.

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 that 300 words). This information will be excerpted and edited for use in various public documents. 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.

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. Do not include confidential information in the scientific abstract. **NOTE:** Applicants proposing use of human pluripotent stem cells should clearly indicate the specific cell line planned for use, as well as its source, in the space provided.

Table of Contents – Form 7
Complete the table of contents, entering page numbers as appropriate or entering "N/A" when not applicable. Additional table rows may be added to identify specific appendix material.

Budget – Form 8
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 3, Sample Contract, Appendix A-1, section 3). Record the amount requested for each category, subtotal and total for each year or portion thereof. Provide an additional form for each proposed subcontract.

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. 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. 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, changes of more than 10% between Personal Services and Other Than Personal Services and additions to equipment may render all 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.

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 institutional policies and proportional to the percent of expended professional effort. No individual salary rate paid through this award will exceed $199,700 for the term of the award. Fringe benefits may be requested in accordance with institutional guidelines for each position, provided such benefits are applied consistently by the applicant organization as a direct cost to all sponsors.

The percent effort of the Principal Investigator must be at least 30% throughout the contract term. The percent effort of each Co-PI must be at least 20% throughout the contract term. The percent effort of the Project Manager must be 100% throughout the contract term. The percentage effort for each co-investigator is not prescribed; it should be dependent upon the nature of their role and may vary during the course of the award.

2. Other Than Personal Service

Support may be requested for:

- Supplies
- Equipment
- Travel
- Consultant costs
- Other Expenses (see below)

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

- Human Subjects
- Animals and Their Care
- Core Facility Usage Fees (including NYSTEM-funded shared facilities)
- Communication Costs
- Meeting Costs**
- Publication Costs
- Miscellaneous

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 Line 11 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 institution.

4. Facilities and Administrative Costs

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 institution'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.

Personal Effort and Budget Justification – Form 9

For each budget line, 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. Budget lines that are not well-justified may be decreased or disallowed during the peer review and award process.

For any sub-applicant costs, provide additional copies of the form for each sub-applicant. Funds awarded by this program may not be used to supplant other existing support for the same work. **Throughout the contract term, the percent effort of the Principal Investigator must be at least 30%. The percent effort of each Co-PI must be at least 20% throughout the contract term. The percent effort of the Project Manager must be 100% throughout the contract term.** The percentage effort for each co-investigator is not prescribed; it should be dependent upon the nature of their role and may vary during the course of the award.

Provide the information requested for key personnel* and technical staff at the applicant organization, regardless of whether financial support is requested. Insert additional lines as necessary. The 'Total Salary + Fringe Requested' amount should equal Line 3, Year One, from Form 8.

*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.

Starting with personnel, **fully justify** amounts requested in each budget category. 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 'Other Than Personal Service' (e.g., supplies, equipment, travel, consultant costs and other expenses). In the justification for equipment, describe the necessity for equipment requested, noting the impact on the project if the request is not approved; provide alternative approaches to completing the work proposed without the equipment purchase.

Biographical Sketch – Form 10
Provide two-page biographical sketches for **all key personnel** listed on each Form 9, 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 10.

Facilities and Resources – Form 11
Describe the facilities available for performance of the proposed project, starting with the applicant institution and followed by collaborating or sub-applicant institutions. Also indicate the institutional 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.

Other Support – Form 12
Provide the information requested for the PI, Co-PI(s) and all other **key personnel**, on all existing and pending support. Applications submitted to NYSTEM should not duplicate other funded projects. The PI and the contracting organization are responsible for notifying NYSTEM administration staff of any changes in funding overlap information.

Workplan – Form 13
Do not exceed the 40 page limit for the Workplan Sections a-d. The Project Overview from Part One and the Workplan from Part Two of the application will be included in any awarded contract; therefore, they should be sufficiently detailed to allow monitoring of progress toward project goals. Together, these elements 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 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.

a) Overall Objectives and Specific Aims
Describe the targeted disease(s), conditions(s) or organ system(s) and list the specific aims of the application.

Summarize the scientific rationale, the nature of the candidate treatment/therapeutic or technology/platform, and the expected outcome(s). Explain clearly how the objectives of the proposal will facilitate clinical development, and include any plans to file an Investigational New Drug (IND) application and obtain other regulatory approvals.

b) Significance
Describe the disease or injury target and briefly summarize the scientific basis for the project. Explain how the proposed research will result in a preventive or therapeutic

candidate that meets an unmet medical need and how successful development would impact the prevention or treatment of the targeted disease(s) or condition(s).

c) 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 proof-of-principle data to substantiate that project development is sufficient to ensure a significant measurable advance toward clinical application within the period of the award.

d) 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 stem cell models, and convince reviewers that this approach is the most effective strategy. Discuss alternative approaches, as appropriate. Ensure that important unpublished information is presented in sufficient detail to enable reviewers to assess its quality and relevance. 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.

e) 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 and milestones. Milestones should note specific measurable outcomes of key activities that provide landmarks of progress toward achieving the specific aims of the project, including an estimate of the timing of key decision points. Also include interactions with regulatory bodies as milestones. 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. **Note:** Milestone achievement will be an important indicator of progress and a major factor in annual progress reviews; insufficient progress may lead to termination of funding.

f) Project Management and Coordination Strategy
This section is not counted against page limitations. Describe the plan for project management, the role and qualifications of the Project Manager. Describe strategies for information and/or resource exchange to ensure efficient and effective completion of the project. 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 Grant Contract). Include strategies to overcome potential problems with communication and/or data and resource sharing.

g) 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.

Human Subjects – Form 14

Each applicant and sub-applicant will complete Form 14*, Human Subjects*. Where multiple human subject protocols pertain to the completion of the proposed research project, **complete a separate form for each protocol.**

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 IRB approval form or signed exemption will be required prior to contract award.

Complete the information requested on the form. If the Protocol Status is Approved or Pending, provide a complete narrative to address the eight points listed on the form. **APPLICATIONS THAT FAIL TO ADDRESS ANY ONE OR MORE OF THE EIGHT POINTS BELOW IN ACCORDANCE WITH THESE INSTRUCTIONS WILL BE PENALIZED (see Attachment 2B for details).**

1) *Involvement of Human Subjects and Population Characteristics*
Describe the involvement of human subjects as outlined in the Research Plan. Include descriptions of the subject population, e.g., number of subjects, age range and health status. Provide inclusion or exclusion criteria of any subpopulation (including women or minorities), and explain why such inclusion or exclusion is necessary to accomplish the research goals. Explain the rationale for the involvement of special classes of subjects, such as minors, mentally disabled adults, prisoners, institutionalized individuals or others likely to be vulnerable. Discuss proposed outreach programs for recruiting women and minorities as participants in clinical research.

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

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

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

5) *Protection from Risk*
Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. As appropriate,

discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects.

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

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

7) *Importance of the Knowledge to Be Gained*
Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result. NOTE: If a test article (investigational new drug, device or biologic) is involved, name the test article and state whether the 30-day interval between submission of the applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

8) *Education of Key Personnel*
Individuals who are identified as key personnel and who are involved with human subject research must document education received in the protection of human research participants. For each individual, provide the title and date of the education/training program completed. **"Not applicable" is not an acceptable response.**

Vertebrate Animals – Form 15
Each applicant and sub-applicant will complete Form 15*, Vertebrate Animals*. Where multiple vertebrate animal protocols pertain to the completion of the proposed research project, **complete a separate form for each protocol.**

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, an IACUC approval form will be required prior to contract award.

Acquisition and use of animals at all performance sites must comply with New York State Public Health Law, Article 5, Title I, Sections 504, 505-a.

If the applicant organization does not have an approved Animal Welfare Assurance form on file with Office of Laboratory Animal Welfare and an assigned Institutional Animal Care and Use Number or a U.S. Department of Agriculture (USDA) registration number, if required, insert "NONE" in the space(s) provided on Form 15. In this case, the applicant organization, by the official's signature on the Face Page, is declaring that it will comply with U.S. Public Health Service policy on the care and use of animals by establishing an IACUC, and submitting an Animal Welfare Assurance form and verification of IACUC approval whenever requested to do so. If required, the applicant organization must also register its facility with the USDA.

Complete the information requested on the form. If the Protocol Status is Approved or Pending, provide a complete narrative to address the four points listed on the form. **APPLICATIONS THAT FAIL TO ADDRESS ANY ONE OR MORE OF THE FOUR POINTS BELOW IN**

ACCORDANCE WITH THESE INSTRUCTIONS WILL BE PENALIZED (see Attachment 2B for details).

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 as justification.

3) *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. As appropriate, describe the use of analgesic, anesthetic and tranquilizing drugs, and comfortable restraining devices to minimize discomfort, distress, pain and injury.

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

Human Stem Cells – Form 16
Each applicant and sub-applicant will complete Form 16*, Human Stem Cells.* Where multiple human stem cell protocols pertain to the completion of the proposed research project, **complete a separate form for each protocol.**

Certification of Embryonic Stem Cell Research Oversight committee (ESCRO) review and approval is not required prior to application review; however, an appropriate ESCRO approval form or signed exemption will be required prior to contract award.

Appropriate oversight and administration of human stem cell research projects are essential to the ethical conduct of research. Human stem cell research involving human embryonic stem cells; human totipotent or pluripotent cells; human pluripotent stem cell lines; human neural and gonadal progenitor stem cells; or other human somatic tissues for stem cell research (excluding cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential) must be reviewed and approved by an appropriate Embryonic Stem Cell Research Oversight (ESCRO) Committee. Use of any of the above specified stem cells at all performance sites must comply with the ESSCB requirements in effect at the time of the application due date.

Complete the information requested on the form. If the Protocol Status is Approved or Pending, provide a complete narrative to address the five points listed on the form. **APPLICATIONS THAT FAIL TO ADDRESS ANY ONE OR MORE OF THE FIVE POINTS BELOW IN ACCORDANCE WITH THESE INSTRUCTIONS WILL BE PENALIZED (see Attachment 2B for details).**

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 submitted.

2) *Sources of Materials - Confidentiality*
If specified human stem cell lines are to be obtained from sources outside the awarded institution 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) *Education of Key Personnel*
Individuals who are identified as key personnel and who are involved with human stem cell research must document education received in the issues involved as specified by their institutional ESCRO as applicable. **If the ESCRO does not require education, enter on the form "Education Not Required"; do not use the phrase "Not Applicable," as this is not an acceptable response.**

5) *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 Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the biological has been withheld or restricted by the Food and Drug Administration.

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 1B).** Part One applications that do not meet these mandatory requirements will not be considered for review, and the applicant institution and PI will be notified. Part One applications that do 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 within two weeks of 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 2B)**. Part Two applications that do not meet these mandatory requirements will not be considered for review, and the applicant institution and PI will be notified.

B. Review and Scoring

Each eligible application (Part One and Part Two) will be evaluated by 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. The Review Panel will evaluate and score each application according to the criteria specified in Section VI.D.

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

Numerical Score	Adjectival Score
1.0 – 1.5	Outstanding
1.6 – 2.0	Excellent
2.1 – 2.5	Very Good
2.6 – 3.0	Good
3.1 – 4.0	Fair
4.1 – 5.0	Poor

The Review Panel will also consider the appropriateness of the requested project duration and percent effort, and identify potential overlap with other resources. Additionally, the Review Panel will evaluate and comment on the application with regard to the Contract Policy Statements and Conditions (Contract Appendix A-2).

The Review Panel will prepare a written summary of each application that includes a description of the application's strengths and weaknesses, note concerns and may recommend revisions based on the above considerations. Awards recommendations may be made contingent upon acceptance of revisions to these items.

C. Application Penalties

The Peer Review Contractor will assess penalty points (up to 0.3 points) for each application that deviates from the instructions for completion of the application **(see Attachment 2B)**. The Peer Review Contractor will compile, prepare and forward all application scores, summary statements, recommendations and comments to NYSTEM.

D. Review Criteria

Five criteria will be considered by the Review Panel:

Significance and Impact (20%)

- Is the objective for the proposed therapeutic or technology/platform appropriate, achievable and timely?
- Does the proposal address an unmet medical need?
- Does the proposed therapeutic or technology 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)?

Investigators and Leadership (20%)

- To what extent do the PI, Co-PIs and co-investigators each contribute research experience relevant and necessary to successful completion of the project?
- Have the PI and Co-PIs made specific contributions to the scientific underpinnings of the proposed therapy or technology and the proposed plan to develop the therapy or technology for clinical use?
- To what extent are each of the roles defined and are they clearly essential to completion of the project?
- Is there a strong justification for a multi-disciplinary collaborative approach?
- To what extent do the PI and Co-PI have the skills and experience necessary to lead a project of the size and scope proposed?
- Does the assembled consortium have all of the expertise, including clinical and technological, necessary for successful completion of the project?

Feasibility and Approach (20%)

- Is there convincing evidence (proof-of-principle data) to demonstrate that development of the proposed therapeutic or technology is 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?
- Is the scientific rationale strong for the proposed approach? Is the likelihood of successful completion of the study high based on the research design and methods, the availability of resources and the overarching research environment?
- Are potential problem areas acknowledged and are alternative approaches proposed?
- Are there identifiable barriers, beyond the scope of the work proposed, to successful development of clinical applications?

Management and Oversight (20%)

- Is an appropriate and effective management structure described in the application, including the role and expected qualifications of the Project Manager, who is distinct from the Principal Investigator?
- 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 clearly focused on achieving established goals and milestones?
- To what extent are the timeline and milestones realistic, appropriate and quantifiable? Will they provide appropriate opportunities for progress review by the Oversight Panel?

Budget (20%)

- To what extent are the items for each budget line explained? Are they adequately justified as 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?
- Are there specific excessive or unnecessary budget items?

E. Empire State Cell Board Funding Committee Review

The ESSCB Funding Committee will consider each application through a score of 2.5. Applications with a score ranging from 2.6 to 5.0 will not be considered by the ESSCB Funding Committee.

The Funding Committee will discuss the application 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. Scoring ties will be resolved on the basis of the above and with consideration of the score for Significance and Impact among those applications involved in the tie.

The ESSCB Funding Committee will vote on each selected application 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
- Funding overlap
- Areas of possible concern with regard to Contract Policy Statements and Conditions (Appendix A-2)
- 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/gbull/g_232.htm.

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.

ATTACHMENT 1A

PART ONE APPLICATION FORMS 1-4

Part One Applicant Face Page

Project Title:					
Application Type: Stem Cell Consortia Part One				FAU #: 0911051012	
Principal Investigator: Last Name, First Name, Middle Initial, Degree(s)					
, , ,					
Institution:					
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:				Federal Employer ID # (9 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)				Official Signing for the Organization (Name and Title):	
Last Name First Name Title				Last Name First Name Title	
Mailing Address (Street, PO Box, MS, City, State, Zip):				Organization Mailing Address (Street, PO Box, MS, City, State, Zip):	
Street 1 Street 2 City State NY 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 institution is eligible to apply (see Section II of the 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.

SIGNATURE OF PRINCIPAL INVESTIGATOR:

X DATE:

SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION:

X DATE:

Form 1

Submit Part One Applicant Forms 1-4 in two formats: one signed PDF file and paper copy.

Project Overview

Provide the information requested such that persons from diverse scientific backgrounds can easily understand the objective. Do not exceed 3 pages.

Overall Objectives and Aims

Significance and Readiness

Overall Plan

Form 2
Submit Part One Applicant Forms 1-4 in two formats: one signed PDF file and paper copy.
Use the available space to your best advantage. Do not exceed 3 pages.

Form 2
Submit Part One Applicant Forms 1-4 in two formats: one signed PDF file and paper copy.
Use the available space to your best advantage. Do not exceed 3 pages.

Form 2
Submit Part One Applicant Forms 1-4 in two formats: one signed PDF file and paper copy.
Use the available space to your best advantage. Do not exceed 3 pages.

Consortia Leadership
Provide the information requested. Do not exceed 1 page.

Form 3
Submit Part One Applicant Forms 1-4 in two formats: one signed PDF file and paper copy.
Do not exceed 1 page.

Part One Assessment Checklist

This checklist is a means by which to gauge the appropriateness of the intended project for this specific funding mechanism. 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 and competitive.

Assessment Criteria	Yes	No
1. Is the proposed objective consistent with the intent of the RFA (see Section I.B., Purpose of the Funds)?		
• Is it disease-focused, health outcome-based, and does it address an unmet medical need? AND		
• Will it accelerate translational and preclinical through clinical applications of stem cell research for prevention and/or treatment of disease? AND		
• Is it a multi-disciplinary collaborative effort that will use stem cells as a basis for development of clinical treatments/therapies or will apply a new technology or platform based on stem cells to that end? AND		
• Is it a coherent project with a focused goal rather than a series of separate but related projects? AND		
• Is a multi-disciplinary collaborative approach essential to success of this project?		
2. Is the proposed project consistent with the General Expectations of the RFA (see Section III.A.)?		
• Does it focus on a disease/condition, group of diseases/conditions or organ system(s)? AND		
• If the proposal is based on a specific platform or technology, is the goal to apply that platform or technology to develop new clinical applications? AND		
• Is it sufficiently mature to achieve a significant, measurable advance(s) toward clinical application within the period of the award? AND		
• Will the application contain sufficient proof-of-principle data to demonstrate the above? AND		
• Does it involve investigators engaged in basic, translational and clinical research? AND		
• Will the experimental design and implementation be carried out in accordance with GLP and GMP standards as necessary? 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?		
3. Leadership and Oversight		
• Have the PI and Co-PIs made significant contributions to the underpinnings of the proposed project, and demonstrated successful leadership? AND		
• Are data/resource sharing plans developed that include access to all data and materials by NYSTEM and an Oversight Panel?		

ATTACHMENT 1B
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. 6 and cover sheet)*
- ☐ The institution is a New York State not-for-profit or governmental organization. *(see pg. 2)*
- ☐ The PI submitted only one application in response to this RFA. *(see pg. 2)*
- ☐ The applicant institution 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. 14).

ATTACHMENT 2A
PART TWO APPLICATION FORMS 1 - 16

Part Two Applicant Face Page

Project Title:		
Application Type: Stem Cell Consortia Part Two	FAU #: 0911051012	Application Number from NYSTEM:

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)***
, , ,	, , ,
Institution:	Institution:
Department:	Department:
Mailing Address (Street, MS, P.O. Box, City, State, Zip):	Mailing Address (Street, MS, P.O. Box, City, State, Zip):
Street 1 Street 2 City State NY Zip	Street 1 Street 2 City State NY Zip
Phone: Fax:	Phone: Fax:
E-mail:	E-mail:

Type of Organization:			
Federal Employer ID # (9 digits):		NYS Vendor ID # (10 digits):	
Charities Registration Number (or "Exempt category"):			
Human Subjects:	Vertebrate Animals:	Human Pluripotent Stem Cells:	Recombinant DNA:
Project Start/End: -		Year One Grand Total Costs:	Grand Total Costs (all years):

New York State Applicant Organization:	Research Performing Sites:
Mailing Address: 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 1 Street 2 City State NY Zip	Organization Name and Mailing Address: Name Street 1 Street 2 City State NY Zip
Phone: Fax: E-mail:	Phone: Fax: 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:

Form 1

Submit Applicant Forms 1-6 together in two formats: a PDF file and a Word document file. In addition, scan ***SIGNED*** Forms 1 and 1-S, save together as an additional PDF file and submit.

Part Two Sub-Applicant Face Page

Project Title:					
Application Type: Stem Cell Consortia			FAU #: 0911051012		Application Number from NYSTEM:
Principal Investigator: Last Name, First Name, Middle Initial, Degree(s)			Co-PI: Last Name, First Name, Middle Initial, Degree(s)		
, , ,		Overall Project Co-PI? ☐	, , ,		
Institution:			Institution:		
Department:			Department:		
Mailing Address (Street, MS, P.O. Box, City, State, Zip):			Mailing Address (Street, MS, P.O. Box, City, State, Zip):		
Street 1 Street 2 City State Zip			Street 1 Street 2 City State Zip		
Phone:		Fax:	Phone:		Fax:
E-mail:			E-mail:		
Type of Organization:					
Federal Employer ID # (9 digits):			Charities Registration Number (or "Exempt category"):		
F&A Costs:	Status of DHHS Agreement: please explain and give a date here:				
Human Subjects:	Vertebrate Animals:		Human Pluripotent Stem Cells:		Recombinant DNA:
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 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:	

Form 1-S

Submit a separate Form 1-S for each sub-applicant. Submit in two formats: a PDF file and a Word Document file. In addition, scan ***SIGNED*** Forms 1 and 1-S, save together as an additional PDF file and submit.

Staff, Collaborators, Consultants and Contributors
List (spell out) the full name, title and institutional 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. 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.

Last Name	First Name	Title	Institutional	Role in Project

Independent Oversight Panel – Form 3

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

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

Form 3

Submit Applicant Forms 1-6 together in two formats: one signed PDF file and one Word document file.

Acronyms and Abbreviations Used in Application

Provide a list of all acronyms and abbreviations used in the application. Also include the full text/definition/description. This will allow the Peer Review Panel to fully comprehend the proposed experimental design. This 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.

Acronym	Full Text/Definition/Description

Lay Abstract

Provide a summary of the proposed project, in non-technical terms; limit to 300 words (do a word count, as the fill-in box may allow more than 300 words). The information will be excerpted and edited for use in various public documents. 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.

Form 5

Not to exceed 300 words. Submit Applicant Forms 1-6 together in two formats: one signed PDF file and one Word document file.

Scientific Abstract

Do not exceed one page.

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

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. Do not include confidential information in the scientific abstract. **NOTE:** Applicants proposing use of human pluripotent stem cells should clearly indicate the specific cell line planned for use, as well as its source, in the box provided.

Form 6

Not to exceed one page.

Submit Forms 1-6 together in two formats: one signed PDF file and one Word document file.

Table of Contents

* Indicate “N/A” if not applicable.

Form 7

Additional table rows may be added to identify specific appendix material. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Budget – Name of Applicant or Sub-Applicant_____

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

Form 8
Attach sub-applicant budgets using additional copies of Form 8. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

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

Form 8
Attach sub-applicant budgets using additional copies of Form 8. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Personnel Effort and Budget Justification

Key Personnel *				**Dollar Amount Requested (Year One)**		
Name	**Role in Project**	**% of Total Professional Effort****	**Total Salary at Institution**	**Salary Requested**	**Fringe Requested**	**Total $ Requested**
	PI					
	Co-PI					
	Prj. Mgr.	100%				
Support Personnel *				**Dollar Amount Requested (Year One)**		
Name	**Role in Project**	**% Professional Effort****	**Total Salary at Institution**	**Salary Requested**	**Fringe Requested**	**Total $ Requested**
Total Salary + Fringe Requested – Should equal Year One, Line 3, Form 8						

* **Insert additional lines as necessary under Key Personnel or Support Personnel. PI cannot be less than 30%, each Co-PI cannot be less than 20% and the Project Manager must be 100%.**

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

Form 9

Attach sub-applicant justifications using additional copies of Form 9. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Describe and justify the key personnel and technical staff.

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

Supplies

Equipment

Travel

Consultant Costs

Other Expenses

Form 9
Attach sub-applicant justifications using additional copies of Form 9. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Form 9
Attach sub-applicant justifications using additional copies of Form 9. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Biographical Sketch

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

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

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

Form 10

Not to exceed 2 pages per individual. Present PI first, followed by Co-PI(s) and the Project Manager, then remaining key personnel in alphabetical order using additional copies of Form 10. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Form 10
Not to exceed 2 pages per individual. Present PI first, followed by Co-PI(s) and the Project Manager, then remaining key personnel in alphabetical order using additional copies of Form 10. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Facilities and Resources

FACILITIES: Describe the facilities available for performance of the proposed project. Indicate the performance site(s) and describe pertinent site capabilities, relative proximity and extent of availability to the project. Under "Other", identify support services such as machine shop and electronics shop, and specify the extent to which such services will be available to the project. Also indicate institutional 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.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

Form 11
Not to exceed 2 pages per collaborating institution. Attach sub-applicant information using additional copies of Form 11. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

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

Form 11
Not to exceed 2 pages per collaborating institution. Attach sub-applicant information using additional copies of Form 11. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Other Support

Provide the information requested for the PI, Co-PI(s) and all other **key personnel**, on all existing and pending support. Applications submitted to NYSTEM should not duplicate other funded projects. The PI and the contracting organization are responsible for notifying NYSTEM administrative staff of any changes in funding overlap information.

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

Name of Key Personnel: _____
Check if there is no other support for the individual listed: ☐

TITLE OF PROJECT: ☐ Pending ☐ Active
BRIEF PROJECT DESCRIPTION:
PROJECT PI:
FUNDING AGENCY/GRANT ID #:
PERIOD OF SUPPORT: % FTE _____
THIS PROJECT INVOLVES STEM CELL RELATED RESEARCH: ☐ *Yes ☐No
THIS PROJECT OVERLAPS A RESEARCH AIM IN THIS APPLICATION: ☐ *Yes ☐No
*For any "Yes" answer, explain the distinction between the project and this application, directly below the item. Indicate a possible resolution, if this application is funded.

Form 12
Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Form 13 Workplan:
Follow all page limitations, font and margin requirements. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Human Subjects

Each applicant and sub-applicant will complete this form. Where multiple protocols will be followed in completion of the proposed research project, **complete a separate form for each protocol.** It is the responsibility of the applicant organization to ensure that all performance sites comply with the regulations in 45 CFR Part 46, and all other statutes, regulations or policies pertaining to human subject participants and tissues.

Applicant/Sub-applicant Institution: _____

Institutional OHRP Federal-wide Assurance of Compliance Number: _____

IRB Protocol Status:

☐ Approved _____(Date) ☐ Pending ☐ Exempt # ___ ☐ Not required for this research project*

***If 'Not required for this research project,' do not complete the remainder of the form.**

If Protocol Status (above) is Approved, Pending or Exempt, also complete the box below.

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

Project Title: _____

_____

Are <u>all appropriate staff</u> listed on this protocol? ☐Yes ☐ No

Does the IRB require annual (or more frequent) reviews of this protocol? ☐Yes ☐No

If "<u>Yes</u>", date of next review: _____

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

If Protocol Status (above) is Approved or Pending, also address the eight points listed below in narrative (see Section V.B., Part Two Application Content and Format).

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

Form 14

Use additional pages and forms as necessary. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Form 14

Use additional pages and forms as necessary. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Vertebrate Animals

Each applicant and sub-applicant will complete this form. Where multiple protocols will be followed in completion of the proposed research project, **complete a separate form for each protocol.** It is the responsibility of the applicant organization to ensure that all performance sites comply with New York State Public Health Law, Article 5, Title I, Sections 504, 505a.

Applicant/Sub-applicant Institution: _____

Institutional Animal Care & Use Number: _____

NYS DOH Animal Care & Use Certificate Number: _____

USDA Registration Number (if applicable to species): _____

Vertebrate Animal Protocol Status:

☐ Approved _____(Date) ☐Pending ☐Not required for this research project*

***If 'Not required for this research project,' do not complete the remainder of the form.**

If Protocol Status (above) is Approved or Pending, also complete the box below.

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

Project Title: _____

_____

Are all appropriate staff listed on this protocol? ☐ Yes ☐ No

Does the IACUC require annual (or more frequent) reviews of this protocol? ☐Yes ☐No

If "Yes", date of next review: _____

If Protocol Status (above) is Approved or Pending, also address the four points listed below in narrative (see Section V.B., Part Two Application Content and Format).

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

Form 15

Use additional pages and forms as necessary. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Human Stem Cells

Each applicant and sub-applicant will complete this form. Where multiple protocols will be followed in completion of the proposed research project, **complete a separate form for each protocol**. It is the responsibility of the applicant organization to ensure that all performance sites comply with the human stem cell guidelines as specified by NYSTEM and all other statutes, regulations or policies pertaining to use of such stem cell lines.

Applicant/Sub-applicant Institution: _____

ESCRO Protocol Status:
☐ Approved _____(Date) ☐ Pending ☐ ☐ Exempt # _____ ☐Not required for this research project*****

***If 'Not required for this research project,' do not complete the remainder of the form.**

If Protocol Status (above) is Approved or Pending, also complete the box below.

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

Project Title: _____

_____

Are all appropriate staff listed on this protocol? ☐ Yes ☐ No

Does the ESCRO require annual (or more frequent) reviews of this protocol? ☐Yes ☐ No

If "Yes", date of next review: _____

If Protocol Status (above) is Approved or Pending, also address the five points listed below in narrative (see Section V.B., Part Two Application Content and Format).

1. Involvement of Human Stem Cells
2. Sources of Materials – Confidentiality
3. Importance of the Knowledge to be Gained
4. Education of Key Personnel
5. Therapeutics

Form 16
Use additional pages and forms as necessary. Submit Forms 7-16 and all appendix material in a single PDF file of not greater than 12MB.

Form 16
Use additional pages as necessary.

ATTACHMENT 2B
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. 15)*
- ☐ The institution is a New York State not-for-profit or governmental organization. *(see pg. 2)*
- ☐ The application was received by due date and time. *(see pg. 6 and cover sheet)*
- ☐ If the electronic files are damaged, a paper copy has been submitted. *(see pg. 15)*
- ☐ The percent effort of the PI is at least 30% throughout the contract term. *(see pg. 3)*
- ☐ The percent effort of each Co-PI is at least 20% throughout the contract term. *(see pg. 3)*
- ☐ The percent effort of the Project Manager is 100% throughout the contract term. *(see pg. 3)*
- ☐ The PI and named Co-PIs are the same as those described in Part One of the application. *(see pg. 15)*
- ☐ The overall goals of the proposed project are the same as those described in Part One of the application. *(see pg. 14)*

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

- ☐ Vendor Responsibility Attestation (Attachment 3)
- ☐ Completed Vendor Responsibility Questionnaire
- ☐ Approval notices from the institutional oversight committees for use of human subjects/tissues, vertebrate animals, human stem cells or recombinant DNA
- ☐ 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 an application if:

- Application is not submitted electronically on a CD or DVD.
- Electronic submission is password protected.
- Submission does not include:
  - Applicant Forms 1 – 6 in a single Microsoft Word document (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; and
  - Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned and saved as a separate PDF file.
  - Budget – Form 8 – one for the applicant and each sub-applicant institution
  - Personnel Effort and Budget Justification – Form 9 – one for the applicant and each sub-applicant institution
  - Biographical Sketch – Form 10 – one for each key personnel listed on each Form 9
  - Facilities and Resources – Form 11 – one for the applicant and each sub-applicant institution
  - Other Support – Form 12 – one for each key personnel listed on each Form 9
  - Workplan – Form 13 – limited to 40 pages for sections a-d
  - 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

An additional penalty of 0.2 point will be assessed if the narrative on Forms 14-16 is incomplete or does not conform to the instructions for completion. In no case will more than 0.3 penalty points be assessed to any single application.

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, I. Vendor Responsibility Questionnaire, I hereby certify:

Choose one:

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

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

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

Signature of Organization Official: _____

Print/type Name: _____

Title: _____

Organization: _____

Date Signed: _____

ATTACHMENT 4

Sample Contract *
(2/10)

1. Grant Contract
2. Appendix A (Standard Clauses for NYS Contracts)
3. Appendix A-1 (Agency Specific Clauses for All Department of Health Contracts)
4. Appendix A-2 (NYSTEM - Contract Policy Statement and Conditions)
5. Appendix B (Budget – Sample Format)
6. Appendix C (Payment and Reporting Schedule)
7. Appendix D (Program Workplan)
8. Appendix F (Request for Applications)
9. Appendix G (Notices)
10. Appendix X (Modification Agreement Form)

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

DO NOT COMPLETE THEM AT THIS TIME.

GRANT CONTRACT (MULTI YEAR)

STATE AGENCY (Name and Address):

NYS COMPTROLLER'S NUMBER: _____

ORIGINATING AGENCY CODE:

_____

CONTRACTOR (Name and Address):

TYPE OF PROGRAM(S)

_____

FEDERAL TAX IDENTIFICATION NUMBER:

INITIAL CONTRACT PERIOD

FROM:

MUNICIPALITY NO. (if applicable):

TO:

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

FUNDING AMOUNT FOR INITIAL PERIOD:

_____

MULTI-YEAR TERM (if applicable):
FROM:
TO:

_____

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

_____

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

APPENDICES ATTACHED AND PART OF THIS AGREEMENT

__X___	APPENDIX A	Standard clauses as required by the Attorney General for all State contracts.
__X___	APPENDIX A-1	Agency-Specific Clauses (Rev 8/08)
__X___	APPENDIX B	Budget
__X___	APPENDIX C	Payment and Reporting Schedule
__X___	APPENDIX D	Program Workplan
__X___	APPENDIX G	Notices
__X___	APPENDIX X	Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)

OTHER APPENDICES

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

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

_____	_____
	Contract No. _____
_____	_____
CONTRACTOR	STATE AGENCY
_____	_____
By: _____	By: _____
(Print Name)	(Print Name)
_____	_____
Title: _____	Title: _____
Date: _____	Date: _____
	State Agency Certification: "In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."
_____	_____

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

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

_____
(Signature and office of the individual taking acknowledgement)

ATTORNEY GENERAL'S SIGNATURE	**STATE COMPTROLLER'S SIGNATURE**
_____	_____
Title: _____	Title: _____
Date: _____	Date: _____

STATE OF NEW YORK

AGREEMENT

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

WITNESSETH:

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

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

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

I. Conditions of Agreement

A. The period of this AGREEMENT shall be as specified on the face page hereof. Should funding become unavailable, this AGREEMENT may be suspended until funding becomes available. In such event the STATE shall notify the CONTRACTOR immediately of learning of such unavailability of funds, however, any such suspension shall not be deemed to extend the term of this AGREEMENT beyond the end date specified on the face page hereof.

B. Funding for the entire contract period shall not exceed the amount specified as “Funding Amount for Initial Period” on the face page hereof.

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

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

E. The CONTRACTOR shall perform all services to the satisfaction of the STATE. The CONTRACTOR shall provide services and meet the program objectives summarized in the Program Workplan (Appendix D) in accordance with: provisions of the AGREEMENT; relevant laws, rules and regulations, administrative and fiscal guidelines; and where applicable, operating certificates for facilities or licenses for an activity or program.

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

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

II. Payment and Reporting

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

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

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

D. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall 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 ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures 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 epunit@osc.state.ny.us or by telephone at 518-486-1255. CONTRACTOR acknowledges that it will not receive payment on any vouchers 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.

In addition to the Electronic Payment Authorization Form, a Substitute Form W-9 must be on file with the Office of the State Comptroller, Bureau of Accounting Operations. Additional information and procedures for enrollment can be found at http://www.osc.state.ny.us/epay**.**

Completed W-9 forms should be submitted to the following address:

NYS Office of the State Comptroller
Bureau of Accounting Operations
Warrant & Payment Control Unit
110 State Street, 9th Floor
Albany, NY 12236

III. Terminations

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

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

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

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

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

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

IV. Indemnification

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

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

V. Property

Any equipment, furniture, supplies or other property purchased pursuant to this AGREEMENT is deemed to be the property of the STATE except as may otherwise be governed by Federal or State laws, rules and regulations, or as stated in Appendix A-2.

VI. Safeguards for Services and Confidentiality

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

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

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

STANDARD CLAUSES FOR NYS CONTRACTS

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

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

2. NON-ASSIGNMENT CLAUSE. In accordance with Section 138 of the State Finance Law, this contract may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet or otherwise disposed of without the State's previous written consent, and attempts to do so are 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 contracting agency and with the concurrence of the State Comptroller where the original contract was subject to the State Comptroller'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 any 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 this contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

3. COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds $50,000 (or the minimum thresholds agreed to by the Office of the State Comptroller for certain S.U.N.Y. and C.U.N.Y. contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount, or if, by this contract, the State agrees to give something other than money when the value or reasonably estimated value of such consideration exceeds $10,000, it shall not be valid, effective or binding upon the State until it has been approved by the State Comptroller and filed in his office. Comptroller's approval of contracts let by the Office of General Services is required when such contracts exceed $85,000 (State Finance Law Section 163.6.a).

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

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

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

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

8. INTERNATIONAL BOYCOTT PROHIBITION. In accordance with Section 220-f of the Labor Law and Section 139-h of the State Finance Law, if this contract exceeds $5,000, the Contractor agrees, as a material condition of the contract, that neither the Contractor nor any substantially owned or affiliated person, firm, partnership or corporation has participated, is participating, or shall participate in an international boycott in violation of the federal Export Administration Act of 1979 (50 USC App. Sections 2401 et seq.) or regulations thereunder. If such Contractor, or any of the aforesaid affiliates of Contractor, is convicted or is otherwise found to have violated said laws or regulations upon the final

determination of the United States Commerce Department or any other appropriate agency of the United States subsequent to the contract's execution, such contract, amendment or modification thereto shall be rendered forfeit and void. The Contractor shall so notify the State Comptroller within five (5) business days of such conviction, determination or disposition of appeal (2NYCRR 105.4).

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

10. RECORDS. The Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance under this contract (hereinafter, collectively, "the Records"). The Records must be kept for the balance of the calendar year in which they were made and for six (6) additional years thereafter. The State Comptroller, the Attorney General and any other person or entity authorized to conduct an examination, as well as the agency or agencies involved in this contract, shall have access to the Records during normal business hours at an office of the Contractor within the State of New York or, if no such office is available, at a mutually agreeable and reasonable venue within the State, for the term specified above for the purposes of inspection, auditing and copying. The State shall take reasonable steps to protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law (the "Statute") provided that: (i) the Contractor shall timely inform an appropriate State official, in writing, that said records should not be disclosed; and (ii) said records shall be sufficiently identified; and (iii) designation of said records as exempt under the Statute is reasonable. Nothing contained herein shall diminish, or in any way adversely affect, the State's right to discovery in any pending or future litigation.

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

(b) PRIVACY NOTIFICATION. (1) The authority to request the above personal information from a seller of goods or services or a lessor of real or personal property, and the authority to maintain such information, is found in Section 5 of the State Tax Law. Disclosure of this information by the seller or lessor to the State is mandatory. The principal purpose for which the information is collected is to enable the State to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purpose authorized by law. (2) The personal information is requested by the purchasing unit of the agency contracting to purchase the goods or services or lease the real or personal property covered by this contract or lease. The information is maintained in New York State's Central Accounting System by the Director of Accounting Operations, Office of the State Comptroller, 110 State Street, Albany, New York 12236.

12. EQUAL EMPLOYMENT OPPORTUNITIES FOR MINORITIES AND WOMEN. In accordance with Section 312 of the Executive Law and 5 NYCRR 143, if this contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of $25,000.00, whereby a contracting agency is committed to expend or does expend funds in return for labor, services, supplies, equipment, materials or any combination of the foregoing, to be performed for, or rendered or furnished to the contracting agency; or (ii) a written agreement in excess of $100,000.00 whereby a contracting agency is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon; or (iii) a written agreement in excess of $100,000.00 whereby the owner of a State assisted housing project is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon for such project, then the following shall apply and by signing this agreement the Contractor certifies and affirms that it is Contractor’s equal employment opportunity policy that:

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

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

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

Contractor will include the provisions of "a", "b", and "c" above, in every subcontract over $25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (the "Work") except where the Work is for the beneficial use of the Contractor. Section 312 does not apply to: (i) work, goods or services unrelated to this contract; or (ii) employment outside New York State. The State shall consider compliance by a contractor or subcontractor with the requirements of any federal law concerning equal employment opportunity which effectuates the purpose of this section. The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall waive the applicability of Section 312 to the extent of such duplication or conflict. Contractor will comply with all duly promulgated and lawful rules and regulations of the Department of Economic Development's Division of Minority and Women's Business Development pertaining hereto.

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

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

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

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

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

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

In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

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

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

Information on the availability of New York State subcontractors and suppliers is available from:

NYS Department of Economic Development
Division for Small Business
30 South Pearl St -- 7th Floor
Albany, New York 12245
Telephone: 518-292-5220
Fax: 518-292-5884
http://www.empire.state.ny.us

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

NYS Department of Economic Development
Division of Minority and Women's Business Development
30 South Pearl St -- 2nd Floor
Albany, New York 12245
Telephone: 518-292-5250
Fax: 518-292-5803
http://www.empire.state.ny.us

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

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

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

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

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

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

22. COMPLIANCE WITH NEWYORK STATE INFORMATION SECURITY BREACH AND NOTIFICATION ACT. 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).

23. COMPLIANCE WITH CONSULTANT DISCLOSURE LAW. 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.

24. 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.

25. 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.

APPENDIX A-1

Agency Specific Clauses for ALL Department of Health Contracts
(REV 2/10)

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

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

3. Administrative Rules and Audits:

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

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

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

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

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

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

purposes by OMB Circular A-133, “Audits of States Local Governments and Non-profit Organizations”, then subject to program specific audit requirements following Government Auditing Standards for financial audits.

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

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

i. If the contract is funded from federal funds, and the CONTRACTOR spends more than $500,000 in federal funds in their fiscal year, an audit report must be submitted in accordance with OMB Circular A-133.

ii. If this contract is funded from other than federal funds or if the contract is funded from a combination of STATE and federal funds but federal funds are less than $500,000, and if the CONTRACTOR receives $300,000 or more in total annual payments from the STATE, the CONTRACTOR shall submit to the STATE after the end of the CONTRACTOR's fiscal year an audit report. The audit report shall be submitted to the STATE within thirty days after its completion but no later than nine months after the end of the audit period. The audit report shall summarize the business and financial transactions of the CONTRACTOR. The report shall be prepared and certified by an independent accounting firm or other accounting entity, which is demonstrably independent of the administration of the program being audited. Audits performed of the CONTRACTOR's records shall be conducted in accordance with Government Auditing Standards issued by the Comptroller General of the United States covering financial audits. This audit requirement may be met through entity-wide audits, coincident with the CONTRACTOR's fiscal year, as described in OMB Circular A-133. Reports, disclosures, comments and opinions required under these publications should be so noted in the audit report.

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

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

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

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

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

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

    a. LOBBYING CERTIFICATION

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

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

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

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

                - No federal appropriated funds have been paid or will be paid, by or on behalf of the CONTRACTOR, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the

awarding of any federal contract, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal amendment or modification of any federal contract, grant, loan, or cooperative agreement.

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

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

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

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

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

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

b) A request for or receipt of a contract (other than a contract referred to in clause (c) below), grant, cooperative agreement, subcontract (other

than a subcontract referred to in clause (c) below), or subgrant that does not exceed $100,000; and

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

b. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE:

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by federal programs either directly or through State or local governments, by federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a monetary penalty of up to $1000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

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

c. CERTIFICATION REGARDING DEBARMENT AND SUSPENSION

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

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

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

Instructions for Certification

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

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

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

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

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

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

g) A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded From Federal Procurement and Non-procurement Programs.

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

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

d. Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions

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

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

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

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

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

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

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

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

12. Other Modifications

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX A-2
Empire State Stem Cell Board
Contract Policy Statements and Conditions
Rev. approved 12/10

A. Ethical Considerations

The Empire State Stem Cell Board (ESSCB) stipulates that each awarded grant contract satisfy the following requirements:

> In accepting an award from the New York State Department of Health for support from the Empire State Stem Cell Fund, the contracting organization shall ensure that each project investigator agrees to conform strictly to the codes of practice, regulations and laws governing ethical conduct of scientific research in his/her own laboratory/institution. He/she shall be solely responsible for any violation of these standards. If experimental procedures conducted pursuant to this project are performed in another state or country, either directly by the Principal Investigator (PI) and any co-investigators, or in collaboration with other persons, the PI and contracting organization 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 contracting organization will inform NYSTEM program administrators of any and all instances of actual or potential lapses in scientific integrity by any project participant as soon as this information becomes known to the contracting entity, and by submitting the annual HHS report form 6349, or equivalent, with the progress report. The contracting organization is fully responsible for investigation of these instances.

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning 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 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 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 all other applicable federal and New York State laws, regulations and guidelines.

- If applicable, the applicant organization'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.

Vulnerable Populations

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

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

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

- The IRB has determined that, prior to involving in a research study a minor, a mentally disabled adult who lacks the capacity to provide informed consent to research participation, or a prisoner, each investigator will obtain such individual's assent to research participation.[1]

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

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

C. Animal Use

ESSCB requires that all individuals and institutions 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 (*e.g.*, the federal Animal Welfare Act and its implementing regulations; and PHL Article 5, Title I, Sections 504 and 505-a).

D. Other Compliance Requirements

1. *Human Tissue*

ESSCB will support research using human tissue and require that such research adhere to all federal, state and local laws and regulations pertaining to use of such tissue, including, but not limited to, 42 USC Section 289g *et seq.*; NYS PHL Article 43, sections 4301 to 4309; Article 43-B, sections 4360 to 4366; and 10 NYCRR Part 52. Any facility collecting, processing, storing, or distributing human tissue, even if for research purposes only, must seek and obtain an appropriate New York State tissue bank 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 must seek and obtain the appropriate New York State Clinical Laboratory Permit in compliance with PHL Article 5, Title V, Sections 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 federal guidelines http://oba.od.nih.gov/oba/rac/guidelines.02/NIH_Guidelines_Apr02.htm) and state statute and regulation, New York State PHL 32-A and 10 NYCRR 61. Accordingly, no research study shall commence unless it has been reviewed and approved by the appropriate institutional oversight committee.

E. Human Stem Cell Research

1. *Scope.* The following types of research ("Human Stem Cell Research" or "HSC Research") are subject to the requirements of this section.

   Research involving:

   a) human embryonic stem cells;

   b) human totipotent or pluripotent cells;

   c) human pluripotent stem cell lines;

   d) human neural and gonadal progenitor stem cells; or

   e) other human somatic tissues for stem cell research (excluding cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential).

2. *National Academy of Science (NAS) and International Society of Stem Cell Research (ISSCR) Guidelines*. HSC 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. *Embryonic Stem Cell Research Oversight (ESCRO) Committees*.

   a) HSC Research must be approved by an Embryonic Stem Cell Research Oversight (ESCRO) Committee that meets the standards set forth in the NAS or ISSCR Guidelines and in paragraph (d) below. However, research permissible without ESCRO Committee review under Category 1 of the ISSCR Guidelines or Section 1.3 (a) of the NAS Guidelines shall not require ESCRO review if notification is provided to the ESCRO Committee.[2] Accordingly, no research study shall commence unless it is demonstrated that research protocols have been reviewed and approved by the ESCRO committee.

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[2] 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."

b) The ESCRO 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 ESCRO 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 ESCRO Committee shall create and follow written policies that include the following standards:

i) Committee Membership: The membership of the ESCRO Committee responsible for oversight for the contracting institution should have sufficient diversity among its members, including consideration of race, gender and background, and should be sensitive to such issues as community attitudes, to promote respect for its advice and counsel. The ESCRO 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 ESCRO Committee must include at least one scientist with relevant expertise and one ethicist. The purpose of diverse membership on the ESCRO Committee is to ensure that different perspectives are given a voice; the ESCRO 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 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 ESCRO Committee.

iii) Recordkeeping: The policies shall address recordkeeping requirements for the activities of the ESCRO 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 ESCRO 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 ESCRO 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[3] 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. Accordingly, the informed consent process must adhere to the introductory paragraph of ISSCR Guideline 11.3[4] and all of ISSCR 11.6.[5]

b) *Donation of Embryos in Excess of Clinical Need*: ESCRO 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, ESCRO Committees should apply the standards set forth in

[3] 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.

[4] 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….

[5] 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:

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.

ISSCR Guideline 11.2,[6] or may choose to use the stricter standards set forth in NAS Guideline 3.2.[7]

d) *No Affect on Medical Care*: Policies and procedures shall be in place, and donors shall be so 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,[8] or until information which could link the identity of the donor(s) with the biological material is no longer retained (if applicable).

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, 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).[9]

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[6] 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.

[7] 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….

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

[9] 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.

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).[10]

k) *Counseling Services*: Donors shall be advised of the availability of counseling services pursuant to ISSCR Guideline 11.6(iii),[11] 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).[12] 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

[10] 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.

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

[12] 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.

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, grantees may use cell lines registered on the National Institutes of Health ("NIH") Registry,[13] 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 an ESCRO 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.

5. *Payments to Gamete Donors*:

a) Contractors may conduct research involving the use of stem cell lines, or deriving new stem cell lines, in which women donating oocytes solely for research purposes have been, or are being, reimbursed for out-of-pocket expenses, including payments for travel, housing, medical care, child care and similar expenses incurred as a result of the donation of the oocytes for research purposes and compensated for the time, inconvenience and burden associated with the donation in a manner consistent with the New York standards applicable to women who donate oocytes for reproductive purposes in an amount not to exceed the payments permitted by the guidelines of the American Society of Reproductive Medicine. 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 ESCRO 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 ESCRO 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 ESCRO 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.

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

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). 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 the 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. With regard to NYSTEM funded research, where the awarded organization has not made reasonable efforts to protect the property interests or because the awardee has failed to share the research developments, the State shall retain march-in rights*.* 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.

4. The contractor must have written agreements with researchers requiring 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 the 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 the above paragraph 3, *supra*.

Assignment and ownership allocation of intellectual and industrial property rights generated from research supported by the Fund is to be determined by the parties

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

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

G. Reporting Requirements

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

H. Equipment

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.

I. Other Information

1. Documents submitted to the Department on behalf of NYSTEM will not be returned to the applicant.

2. Appendix B (Budget) may be reviewed and revised each year, depending on research progress and the availability of funds.

3. The Department may require reimbursement of all or a part of the award if ineligible expenses have been incurred or inaccurate accounting statements have been submitted.

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

5. Recipient entities accept auditing of their contract expenditures by an appointed representative of NYSTEM at any reasonable time.

6. Assurances and Certifications. The ESSCB has adopted the following federal regulatory mechanisms to ensure responsible administration of its awards and to preserve the integrity of the research enterprise it supports. By signing this Grant Contract, the authorized representative of the organization certifies that, in addition to all applicable state and local statutes and regulations, the applicant organization will comply with applicable federal regulations and statutes, including but not limited to:

   a. Vertebrate Animals:

   - Animal Welfare Act as amended (7 USC 2131 *et sec*.), if applicable, and other federal statutes and regulations relating to animal care and use.

   b. Research Misconduct:

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

   c. Conflict of Interest

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

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

APPENDIX B Budget (sample format)

Budget – Name of Contractor or Subcontractor _____

	BUDGET CATEGORY	Year One	Year Two	Year Three	Year Four	Year Five	TOTAL
PERSONAL SERVICE (PS)							
1	SALARY AND STIPENDS						
	Position (list each to be funded separately)						
	SUBTOTAL Salary & Stipends						
2	FRINGE BENEFITS						
3	**SUBTOTAL PS (sum of lines 1+2)**						

	BUDGET CATEGORY	Year One	Year Two	Year Three	Year Four	Year Five	TOTAL
OTHER THAN PERSONAL SERVICE (OTPS)							
4	SUPPLIES						
	LAB SUPPPLIES						
	OFFICE SUPPLIES						
	SUBTOTAL SUPPLIES						
5	EQUIPMENT						
6	TRAVEL						
7	CONSULTANT COSTS						
8	OTHER EXPENSES						
	HUMAN SUBJECTS						
	ANIMALS & CARE						
	CORE FACILITIES						
	PUBLICATION						
	COMMUNICATION						
	MEETING REGISTRATION						
	MISC. OTHER EXPENSES						
	SUBTOTAL OTHER EXPENSES						
9	**SUBTOTAL OTPS** (sum of lines 4 thru 8)						
10	**TOTAL PS & OTPS** (lines 3+9)						
11	**TOTAL SUBCONTRACT COSTS** (sum of line 14 of all subcontractor budgets)						
12	**TOTAL DIRECT COSTS** (lines 10+11)						
13	FACILITIES AND ADMINISTRATIVE COSTS						
14	**GRAND TOTAL COSTS** (lines 12+13)						

APPENDIX C
PAYMENT AND REPORTING SCHEDULE
Consortia to Accelerate Therapeutic Applications of Stem Cells
Rev. approved 3/11

I. Payment and Reporting Terms and Conditions

A. The STATE may, at its discretion, make an advance payment to the CONTRACTOR, during the initial or any subsequent PERIOD, in an amount to be determined by the STATE but not to exceed 0 percent of the maximum amount indicated in the budget as set forth in the most recently approved Appendix B. If this payment is to be made, it will be due thirty calendar days, excluding legal holidays, after the later of either:

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

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

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

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

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

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

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

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

D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the program workplan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall 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 ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures 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 epunit@osc.state.ny.us or by telephone at 518-486-1255. The CONTRACTOR acknowledges that it will not receive payment on any vouchers 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.

In addition to the Electronic Payment Authorization Form, a Substitute Form W-9, must be on file with the Office of the State Comptroller, Bureau of Accounting Operations. Additional information and procedures for enrollment can be found at http://www.osc.state.ny.us/epay.

Completed W-9 forms should be submitted to the following address:

NYS Office of the State Comptroller
Bureau of Accounting Operations
Warrant & Payment Control Unit
110 State Street, 9th Floor
Albany, NY 12236

E. The CONTRACTOR will provide the STATE with the reports of progress or other specific work products pursuant to this AGREEMENT as described in this Appendix below. In addition, a final report must be submitted by the CONTRACTOR no later than 60 days after the end of this AGREEMENT. All required reports or other work products developed under this AGREEMENT must be completed as provided by the agreed upon work schedule in a manner satisfactory and acceptable to the STATE in order for the CONTRACTOR to be eligible for payment.

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

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

All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than sixty (60) days after the end date of the period for which reimbursement is claimed (see Table I for annual schedule). In no event shall the amount received by the CONTRACTOR exceed the budget amount approved by the STATE, and, if actual expenditures by the CONTRACTOR are less than such sum, the amount payable by the STATE to the CONTRACTOR shall not exceed the amount of actual expenditures. All contract advances in excess of actual expenditures will be recouped by the STATE prior to the end of the applicable budget period.

G. If the CONTRACTOR is eligible for an annual cost of living adjustment (COLA), enacted in New York State Law, that is associated with this grant AGREEMENT, payment of such COLA, or portion thereof, may be applied toward payment of amounts payable under Appendix B of this AGREEMENT or may be made separate from payments under this AGREEMENT, at the discretion of the STATE.

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

II. Progress and Final Reports

A. Periodic Progress Reports

The CONTRACTOR shall submit progress reports using the forms and formats as provided by NYSTEM (found online at http://stemcell.ny.gov), summarizing the work performed during the period. These reports shall detail the CONTRACTOR's progress toward attaining the specific aims enumerated in the Workplan (Appendix D). Additionally, the reports will substantiate responsiveness to and implementation of the Oversight Panel recommendations approved by NYSTEM, and Workplan updates as recommended by the Oversight Panel and approved by NYSTEM. A progress report schedule will be based on the project milestones as agreed upon by NYSTEM and the Oversight Panel at the first meeting of the Oversight Panel with the consortium and NYSTEM.

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

B. Expenditure Reports

The CONTRACTOR shall submit a detailed expenditure report by object of expense in the forms and formats as provided by NYSTEM (found online at http://stemcell.ny.gov) which shall accompany the voucher submitted for each period (see Table I for annual schedule). Documentation of all expenses shall be available upon request. The STATE may require documentation of expenses before payment of any voucher. 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 shall submit all budget modification requests to the STATE for approval. All budget modification requests must be approved by the STATE prior to the commitment and expenditure of funds. All final budget modification requests must be submitted prior to the end of the budget period.

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

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

TABLE I
Annual Voucher and Expenditure Reporting Schedule

Voucher and Expenditure Report #	Period Covered	Due Date*
1	March 1 – May 31	July 30
2	June 1– August 31	October 30
3	September 1 – November 30	January 30
4	December 1 – Feb 29	April 30

*****Vouchers and Expenditure Reports are due within 60 days of the end of each quarter of the contract term. The Final Voucher and Expenditure Report for the contract are due 90 days after the end of the contract term (or the end of the contract extension, if granted). The final voucher will not be paid until the final progress report is approved.

C. Final Progress Report

The CONTRACTOR shall submit a detailed comprehensive final progress report not later than 60 days from the end of the contract, summarizing the work performed during the entire contract period, in the forms and formats as provided by NYSTEM (found online at http://stemcell.ny.gov).

APPENDIX D

WORKPLAN

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

APPENDIX G

NOTICES

All notices permitted or required hereunder shall be in writing and shall be transmitted either:

(a) via 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.

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 Contractor Name*]
Name:
Title:
Address:
Telephone Number:
Facsimile Number:
E-Mail Address:

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 email, upon receipt.

The parties may, from time to time, specify any new or different address in the United States as their address for purpose of receiving notice under this AGREEMENT by giving fifteen (15) days written notice to the other party sent in accordance herewith. The parties agree to mutually designate individuals as their respective representative for the purposes of receiving notices under this AGREEMENT. Additional individuals may be designated in writing by the parties for purposes of implementation and administration/billing, resolving issues and problems, and/or for dispute resolution.

Agency Code 12000
APPENDIX X

Contract Number:_____ Contractor:_____

Amendment Number X-_____

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

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

_____ Modifies the contract period at no additional cost

_____ Modifies the contract period at additional cost

_____ Modifies the budget or payment terms

_____ Modifies the work plan or deliverables

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

_____ Adds the attached appendix(es) _____

_____ Other: (describe) _____

This amendment *is*__ *is not*__ a contract renewal as allowed for in the existing contract.

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

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

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

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

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

This will result in new contract terms of:

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

Signature Page for:

Contract Number:_____ Contractor:_____

Amendment Number: X-_____

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

CONTRACTOR SIGNATURE:

By:_____ Date: _____
(signature)

Printed Name:_____

Title:_____

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

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

_____
(Signature and office of the individual taking acknowledgement)

STATE AGENCY SIGNATURE

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

By:_____ Date:_____
(signature)
Printed Name:_____
Title:_____

ATTORNEY GENERAL'S SIGNATURE

By:_____ Date:_____

STATE COMPTROLLER'S SIGNATURE

By:_____ Date:_____