FAU # 0903091046

New York State Department of Health and the Empire State Stem Cell Board

Request for Applications

Targeted Projects in Human Embryonic Stem Cell Research

RELEASE DATE: July 8, 2009

LETTER OF INTENT DUE (Mandatory): August 5, 2009 by 2:00 PM

APPLICANT CONFERENCE: July 24, 2009 at 2:00 PM
NYS Department of Health Central Region Office
217 S. Salina Street, Conference Room 4A/4B
Syracuse, NY

July 27, 2009 at 2:00 PM
NYS Department of Health Metropolitan Area Regional Office
90 Church Street, 4th floor Conference Room 4A/4B
New York, NY

Registration Due: July 21, 2009

QUESTIONS DUE: July 27, 2009

QUESTIONS, ANSWERS AND UPDATES POSTED: August 7, 2009

APPLICATIONS DUE: September 10, 2009 by 2:00 PM

ESTIMATED CONTRACT START DATE: September 1, 2010

DOH CONTACT NAME AND ADDRESS:
Bonnie Jo Brautigam
Extramural Grants Administration
New York State Department of Health
Wadsworth Center
Empire State Plaza, Room D350
PO Box 509, Albany NY 12201-0509

This RFA, questions and answers, as well as any updates and modifications, may be downloaded at http://www.nyhealth.gov/funding/ and at http://stemcell.ny.gov/

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Executive Vice President
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I. Introduction

A. Background

New discoveries in stem cell research are encouraging leading scientists to investigate the potential of cell-based therapies to treat life threatening disease. In April 2007, legislation was enacted creating the Empire State Stem Cell Board (ESSCB) and authorizing the investment of six hundred million dollars in state funding over the next eleven years. The 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. All awards will be financed by the Empire State Stem Cell Trust Fund.

The New York State Department of Health's NYSTEM is the program charged with administering stem cell research funding based on recommendations and advice from the ESSCB. In conjunction with NYSTEM, the ESSCB solicits, reviews, and makes funding recommendations for creative and innovative biomedical research projects to be supported by the Fund. Information about the ESSCB and NYSTEM can be found at http://stemcell.ny.gov.

There are several compelling reasons to support the creation and characterization of **new** human embryonic stem cell lines in New York State without delay:

- Recent scientific discoveries raise the question of whether alternate pluripotent states not represented in the currently available human embryonic stem cell lines may exist. Generation of new stem cell lines will be required to test this possibility;
- To make available genetically diverse human embryonic stem cell lines that are representative of the genetic diversity within the population of the State;
- To develop disease-specific human embryonic stem cell lines for comparison with other disease-specific pluripotent cell lines;
- To increase the availability of cell lines of low passage that are isolated under optimized protocols;
- To generate cell lines that meet current standards for informed consent and provenance.

It is essential to optimize the conditions under which human embryonic stem cells are derived because:

- increased efficiency will allow production of more human embryonic stem cell lines from fewer embryos;
- improved conditions may improve potency, stability or other desirable characteristics, and may reduce reliance on mouse feeder cells for derivation.

Further, standardization of protocols is essential:

- for comparison between human embryonic stem cell lines and pluripotent cells derived by other approaches;
- to enhance potential for clinical application.

B. Purpose of the Funds

The ESSCB wishes to stimulate and support research related to the derivation, standardization, characterization and optimization of new human embryonic stem cell lines. **Specifically this Request for Applications (RFA) will only support efforts to derive and characterize new human embryonic stem cell lines to:** devise novel and improved derivation methods; increase efficiency in the production of new cell lines; standardize protocols to improve comparisons between human embryonic stem cells (hESC) and induced pluripotent stem cells; and enhance their potential for clinical application.

This RFA supports research projects as outlined in the specific objectives below:

- Derivation of new hESC lines using excess, genetically diseased, or rejected early stage human embryos generated by *in vitro* fertilization

- Derivation of new hESC lines from other sources using alternative methods, techniques or culture conditions

- Generation of new clinical grade hESC lines with different human lymphocyte antigen (HLA) genetic background suitable for future clinical therapy or other biomedical applications to overcome the challenge of immune rejection

- Generation of new hESC lines that may be optimal for differentiation along selective lineages, for drug/small molecules screening or for studies of diseases

- Creation of new hESC lines that may add genetic diversity in the existing hESC lines

- Development of new technology or culture conditions that may increase hESC derivation efficiency or pluripotency.

C. Available Funds

Projects will be supported by the Empire State Stem Cell Trust Fund. The number of awards and total funds awarded per application will be contingent upon the quality of applications submitted as well as the size and scope of the proposed projects. Approximately $6.5 million is available to support these awards. In determining final awards, the Department reserves the right to reallocate funds between the two funding mechanisms in this RFA as it deems appropriate.

Eligible institutions are invited to submit applications for the following funding mechanisms:

1. Investigator Initiated Research Project (NIH R01-like mechanism)

- The intent of the Investigator Initiated Research Project award is to support well developed basic, applied (mechanistic, technological), translational, pre-clinical or clinical research;

- Contract term will be up to three years; and

- Annual **direct costs** are capped at $300,000.

2. Innovative, Developmental or Exploratory Activities (IDEA) Award (NIH R21-like mechanism)

- The intent of the IDEA award is to provide initial support for preliminary testing of novel or high-risk hypotheses or approaches. The ESSCB seeks to fund research projects in which there is a high likelihood that the results will yield the opportunity to apply for future funding;

- Contract term will be up to two years; and

- Annual **direct costs** are capped at $150,000 with a maximum of $275,000 in direct costs to be spent over the two year period.

Principal Investigators (PIs) may apply to both funding mechanisms offered under this RFA provided that both applications are separate and distinct.

On July 8, 2009, the Department issued two RFAs seeking to advance stem cell research in New York State. The table below shows the expected allocation of available funds among these two RFAs. In determining final awards, the Department reserves the right to reallocate funds between these RFAs as it deems appropriate.

RFA #	RFA Title	$ Allocated
0812220315	Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) Awards for Stem Cell Research	$15 million
0903091046	Targeted Projects in Human Embryonic Stem Cell Research	$6.5 million

II. Who May Apply?

The applicant must be a New York State not-for-profit organization or a governmental organization within New York State. The applicant must also be one of the following: an academic institution; a research organization; a medical center; or an entity with demonstrated capability to conduct externally-funded research. Organizations awarded funds must have the ability to monitor funds, maintain individual accounts and fulfill other fiscal management criteria. Subcontracting and collaborating organizations may include public, not-for-profit and for-profit entities. Such entities may be located in or outside of New York State.

The PI for the proposal must be employed by the applicant institution and have the skills, knowledge, and resources necessary to carry out the proposed Work Plan. The ESSCB is interested in applications from established investigators, including those new to the field of stem cell research, junior researchers, and those in disciplines that have not historically focused on stem cell research. Collaborations between experienced and less-experienced researchers, and between New York State and non-New York State researchers, are encouraged.

III. Project Narrative/Work Plan Outcomes

A. General Expectations

The scope of acceptable applications will include basic, applied (mechanistic, technological), translational, pre-clinical and clinical studies focusing on the objectives outlined in Section I.B., Purpose of the Funds. **Awards will only be made to support the research projects conducting the derivation and characterization of new hESC lines.** Although collaborations are not required, they are strongly encouraged.

1. Investigator Initiated Research Project Award (NIH R01-like)

The Investigator Initiated Research Project mechanism is designed to investigate a well-developed problem or research hypothesis or to develop technologies or resources that are essential to overcome existing barriers to progress towards therapeutic applications. An application for this mechanism should include sufficient preliminary data to support the hypothesis or proposed resolution of the problem, provide data relevant to support the Food and Drug Administration (FDA) approval process, or provide advances in translational research.

The percent effort required of the PI must be at least 20% throughout the contract term.

2. Innovative, Developmental or Exploratory Activities (IDEA) Award (NIH R21-like)

The IDEA mechanism allows new or established researchers to enter the stem cell research field. Additionally, it provides the opportunity for experienced researchers to try new methods and approaches. IDEA projects are self-contained, hypothesis-driven research. Projects should be considered innovative, developmental or exploratory in nature, targeting new avenues of stem cell research. Responsive applications include those considered highly speculative, exploratory, or high-risk that may not have pilot data, but that have the potential for high scientific payoff. Also encouraged are proposals seeking to apply or develop state-of-the-art technologies, tools or resources for stem cell research. Additionally welcomed are innovative, developmental projects that focus on exceptionally promising topics and have some pilot data, but are not yet sufficiently mature to compete successfully for funding for a full-scale study. Researchers testing new hypotheses or developing new technologies that are based on research grounded in a non-stem cell research area may also apply.

IDEA awards are not intended to fund smaller components of larger Investigator Initiated Research Projects, or for compression of a larger project into a smaller time frame.

Upon project completion, the PI should have (1) opened a new area of investigation, (2) satisfactorily tested a novel or innovative hypothesis, or (3) produced viable data for preparation of a full-scale research application. It is the intent of the ESSCB that successful IDEA projects will be eligible to apply for future Investigator Initiated Research Project awards.

The percent effort required of the PI must be at least 10% throughout the contract term.

B. Use of Funds

Funds may be used, as appropriate to the funding mechanism, to support salaries, fringe benefits, stipends, supplies, equipment, travel, consultant costs, animals and their care, core facility use charges, publication and communication costs, and other related research costs.

Facilities and Administrative costs are allowed but are limited to a maximum of 20 percent of modified total direct costs (see Section V.A., Application Content and Format).

By law, funds must not be used for any activities related to human reproductive cloning.

C. Reporting Obligations

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

Contractors will participate in, and cooperate with, evaluation activities sponsored or conducted by NYSTEM staff, such as:

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

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

IV. Administrative Requirements

A. Issuing Agency

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

C. Letter of Intent

The prospective applicant institution is **required** to submit a Letter of Intent using the form provided in this RFA (Attachment 4). Letters of Intent will be used for the purpose of developing the highest quality review panel in a timely manner. Letters of Intent infer no obligation upon the institution to submit an application in response to this RFA. **However, applications that are not preceded by a Letter of Intent WILL NOT be reviewed.** The Letter of Intent must be received by the date and time indicated on the cover sheet to this RFA and must be mailed to the address listed below in Section IV.E. Alternatively, a scanned Portable Document Format (.pdf) file of the Letter of Intent with original signatures may be forwarded to nystemgrants@wadsworth.org or faxed to 518-486-2191. In any case, the Letter of Intent must be received by the date and time indicated on the cover sheet to this RFA.

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

If the designated PI named on the Letter of Intent is changed before the application submission, Program staff must be notified of this change prior to or at the time of application submission. An application number is specific to the institution to which it is assigned; it cannot be transferred to another institution.

D. Applicant Conference

Two conferences will be held (see location, date and time posted on the cover sheet of this RFA). The Department requests that potential applicants register for this conference by calling 518-474-7002 to insure that adequate accommodations be made for the number of prospective attendees. 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

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

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

Regular Mail Services (all 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

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

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

F. The Department Of Health Reserves The Right To:

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

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

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

4. Adjust or correct cost figures with the concurrence of the applicant if errors exist and can be documented to the satisfaction of DOH and the State Comptroller.

5. Negotiate with applicants responding to this RFA within the requirements to serve the best interests of the State.

6. Eliminate mandatory requirements unmet by all applicants.

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

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

G. Term of Contract

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

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

- Investigator Initiated Research Project award – up to 3 years
- IDEA award – up to 2 years.

H. Payment & Reporting Requirements

1. The State (NYS Department of Health) may, at its discretion, make an advance payment to not for profit grant contractors in an amount not to exceed 25 percent.

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

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

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

   - The Contractor will be reimbursed for actual expenses incurred as allowed in the Contract Budget and Work Plan.
   - All vouchers submitted by the contractor pursuant to this agreement shall be submitted to the State no later than 30 days after the end of the quarter for which reimbursement is being claimed.
   - Quarterly vouchers will not be paid until all required progress reports are submitted and deemed acceptable by 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:

   - Semi-annual progress reports in accordance with the forms and formats provided by NYSTEM as outlined in Section III.C. Reporting Obligations, above – no later than 30 days after the end of each six month reporting period.

   - 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

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

J. General Specifications

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

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

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

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 - Work Plan

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

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

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

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

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

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

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

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

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

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

V. Completing the Application

A. Application Content and Format

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

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

ALL APPLICATIONS SHOULD USE THE FORMS (see Attachment 1 – Forms 1-16) AND FORMATS PRESCRIBED IN THIS SECTION V.A. APPLICATIONS THAT DEVIATE FROM THESE INSTRUCTIONS OR THOSE FOUND ON THE FORMS WILL BE PENALIZED 0.1 POINTS.

Applications must be submitted in hard copy and electronic formats as described in this section. The paper copy will be used if the CD-ROM is damaged. Applications will ONLY be accepted in the formats detailed in this section. Applications sent in other formats or by fax or e-mail will NOT be accepted.

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

- **Contractor Forms 1 – 5 in a single Microsoft Word (.doc) file;**
- **Contractor Forms 1 – 5 in a single Portable Document Format (.pdf) file;**
- **Forms 6 – 16 and all appendix material in a single .pdf file of not greater than 12MB; and**
- **Signed Forms 1 (Face Pages for the Contractor and all Subcontractors) in a single Portable Document Format (.pdf) file**.

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared. Applicants are strongly encouraged to seek appropriate technical support in the creation of electronic files and to review the electronic files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at http://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. Under no circumstances should electronic files contain any password protection whatsoever.

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 principal investigator's last name, first initial and applicant institution name, and should be placed at the top right-hand corner of each page. Each page should be numbered consecutively. **Do not exceed page limits for the Work Plan (Form 12) sections A through D (see below).** Figures and illustrations referenced in the Work Plan are included in the page limits. Appendices may not be used to circumvent page limitations.

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

1. **Investigator Initiated Awards** – 12 pages
2. **IDEA Awards** – 10 pages

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

Face Page – Form 1

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

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

Application Type. Select the appropriate type from the dropdown box for the application funding mechanism.

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

Early Stage Investigator. Select 'Yes' from the dropdown box if the PI is within ten years of completing a terminal degree or within ten years of completing a medical residency. Early Stage Investigators will be identified and their career stage will be considered at the time of review. Otherwise, select 'No.'

Principal Investigator. Provide the information requested. The PI is the New York State investigator employed by the applicant institution responsible for planning, coordinating and implementing the research project 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. Provide the information requested. If the institutional affiliation of the Co-PI is different from that of the PI, complete a Face Page for each Co-PI. This form is to be signed by the subcontracting institution's authorized agent.

Type of Organization. Select the appropriate choice from the dropdown box (Governmental, Nonprofit, For Profit).

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

DUNS number. Enter applicant organization's Dun and Bradstreet number, if any.

Charities' Identification Number. In the space provided, enter the charities' identification number or, **if exempt, indicate the exemption category**. For information on identification numbers, contact the Department of State, Office of Charities Registration, 162 Washington Avenue, Albany, NY 12231, (518) 474-3720. Additional information and descriptions of exemption categories may be found at: http://nysosc3.osc.state.ny.us/agencies/gbull/g-79.htm.

Facilities and Administrative Costs. Select the appropriate choice from the dropdown box (DHHS Agreement Date, Agreement being negotiated, No agreement but rate established). Provide the information requested to document that the F&A rate does not exceed that which would be recovered applying the applicant organizations' negotiated Facilities and Administrative (F&A) rate. A copy of the United States Department of Health and Human Services (DHHS) agreement should be included as an application appendix.

Human Subjects. 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' and include a completed Form 15*, Human Subjects*. Appropriate assurances must be provided before contract execution.

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' and include a completed Form 16, *Vertebrate Animals*. Appropriate assurances must be provided before contract execution.

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' and include a completed Form 17, *Human Stem Cells*. Appropriate assurances must be provided before contract execution.

Recombinant DNA. Select the appropriate choice from the dropdown box. For applications that include any use of recombinant DNA, select "YES." Appropriate assurances must be provided before contract execution.

Project Duration. Record the anticipated project duration of:
September 1, 2010 through August 31, 2013 for Investigator Initiated Research Projects; and
September 1, 2010 through August 31, 2012 for IDEA Awards

Year One Grand Total Costs. Enter Year One Grand Total Costs from Form 7, Line 14.

Grand Total Costs. Enter the Grand Total Costs from Form 7, Line 14.

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

Research Performing Sites. List all sites (organization and location) where the work described 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 Principal Investigator.

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

Principal Investigator/Co-Principal Investigator Certification and Assurance. The PI is required to sign and date the form and the designated Co-PI, if from the same institution, is required to also sign and date the form. Failure to do so will prevent the application from being processed.

Organization Certification and Acceptance. The organizational representative must sign and date the form certifying compliance with all applicable assurances and certifications referenced in this RFA. Failure to do so will prevent the application from being processed.

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

Staff, Collaborators, Consultants and Contributors – Form 2
List the name, title and institutional affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid) for this project. This list is used in indentifying potential members of the Independent Scientific Merit Peer Review panel.

Acronyms Used in Application – Form 3
Provide a list of all acronyms 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 4
Provide the information requested on the form, limiting the information to 300 words. The abstract should be written so that the general public can easily understand the work proposed. Do not include confidential information in the lay abstract. Information presented on this form will be condensed, edited and used for public dissemination.

Scientific Abstract – Form 5
Provide the information requested on the form. The abstract should be written so that persons from diverse scientific backgrounds can easily understand the work proposed. Do not include confidential information in the scientific abstract. **NOTE:** Applicants proposing use of human pluripotent stem cells should clearly indicate the specific cell line planned for use, as well as its source, in the box provided.

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

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

Budget – Form 7
Report the amount requested for each category, subtotal and total for each year or portion thereof. For any sub-contractual costs, provide additional copies of the form for each subcontract.

<u>Allowable Expenses</u>

1. Personal Service

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

Salary and stipends should be consistent with institutional policies and proportional to their percent of expended effort. Fringe benefits may be requested in accordance with institutional guidelines for each position, provided such benefits are applied consistently by the applicant organization as a direct cost to all sponsors.

For an Investigator Initiated Research Project, the percent effort required of the Principal Investigator must be at least 20% throughout the contract term.

For an IDEA application, the percent effort required of the Principal Investigator must be at least 10% throughout the contract term.

2. Other Than Personal Service

Support may be requested for:
- Supplies
- Equipment
- Travel
- Consultant costs
- Other Expenses (see below)
- Subcontracts

Support for the following should be listed in 'Other Expenses' in the proposed budget:
- Human Subjects
- Animals and Their Care
- Core Facility Usage Fees
- Communication
- Meeting Registration Costs
- Publication Costs
- Miscellaneous

Requests for purchase of equipment may be granted if strongly justified as essential to the proposed project; a current price quote should be included in the application appendix. During the course of the contract term, prior approval will be required for all equipment purchases that were not detailed in the application and its appendix.

Patient care and tuition reimbursement costs are not allowable expenses.

3. Facilities and Administrative Costs

F&A support is limited to a maximum of twenty 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. Subcontractor F&A costs are likewise limited and will be included in the primary applicant's direct costs.

Personal Effort and Budget Justification – Form 8
Applicants should request funds appropriate for cost-effective performance of the proposed goal. 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 required of the Principal Investigator must be at least 20% for Investigator-Initiated Research Project awards and at least 10% for IDEA awards.

Provide the information requested for key personnel and technical staff at the applicant organization, regardless whether financial support is requested. Insert additional lines as necessary. The 'Total Salary + Fringe Requested' amount should equal Line 3, Year One, from Form 7.

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

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

Biographical Sketch – Form 9
Provide two-page biographical sketches for all key personnel listed on each Form 8, including collaborators and consultants. Start with the Principal Investigator followed by Co-PI(s), and then include remaining key personnel in alphabetical order.

Facilities and Resources – Form 10
Applications should describe the facilities available for performance of the proposed project, starting with the applicant institution and followed by collaborating or subcontracting institutions. Also indicate the institutional commitment, including any additional facilities or equipment requested in support of the project or available for use at no cost to the proposed project.

Other Research Support – Form 11
Provide the information requested for the PI and all other key personnel, on all existing and pending research support. Applications submitted to NYSTEM should not duplicate other funded research projects. The PI and the contracting organization are responsible for notifying NYSTEM administration staff of any changes in funding overlap information.

Work Plan – Form 12
The Work Plan 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;

- The proposed approach is the most appropriate strategy to use as evidenced, in part, by consideration of alternatives;
- The research team and available resources enhance the likelihood of the project's success; and
- Successful completion of the project will advance ESSCB's mission.

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

b) Significance
Provide a succinct description for each proposed aim, indicating how its attainment will advance stem cell biology or development of therapies.

c) Background and Preliminary Results
Review the literature that underlies the proposed research and present available preliminary data. The scientific rationale for the project should be extremely compelling. Preliminary data is essential to Investigator Initiated Research Project applications, although not required for IDEA applications.

d) Research Design and Methods
Describe the experimental design, methodological approaches, statistical analyses and interpretation to accomplish the specific aims. Information provided should convey the applicant's understanding of the strengths and limitations of the proposed study's design, methodologies, and 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.

NOTE: Applicants proposing use of human pluripotent stem cells should clearly indicate in the research plan the specific cell line to be used, as well as its source.

e) Literature Cited
References are not counted against work plan page limitations, and the number of references is not restricted. However, applicants are urged to select references that comprehensively reflect the relevant literature. Provide complete citations to references.

Time Line and Collaboration Strategy – Form 13
Complete the table provided. Describe strategies for information and/or resource exchange to ensure the efficient and effective completion of the project. Include frequency and methods of communications. Note barriers to communication and resource exchange and propose alternative strategies to overcome potential problems.

Human Subjects – Form 14
All applicants will include a completed Form 14*, Human Subjects*. If no Institutional Review Board review is required for this research project, check the box on the form and do not complete the remainder of the form. If IRB review is required, follow instructions below.

Appropriate oversight and management of human subjects research projects are essential to ethical conduct of research. **Certification of Institutional Review Board**

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

If the IRB has not deemed the project to be Exempt prior to submission of the application, the following narrative must be submitted as part of the application. **The eight points to be addressed in narrative are presented in full below. APPLICATIONS THAT FAIL TO APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE EIGHT POINTS BELOW WILL BE PENALIZED 0.2 POINTS.**

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

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

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

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

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

   If the proposed research includes a clinical trial intervention, in a subsection labeled Data and Safety Monitoring, describe the oversight and monitoring plan to ensure the safety of participants and the validity and integrity of the data

obtained. An appropriate plan must be submitted to the applicant's IRB for approval and subsequently to NYSTEM prior to accrual of human participants.

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

7) *Importance of the Knowledge to Be Gained*
Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

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

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

Vertebrate Animals – Form 15
All applicants include a completed Form 15*, Vertebrate Animals*. If no vertebrate animal review is required for this research project, check the box on the form and do not complete the remainder of the form. For those projects using vertebrate animals, follow instructions below.

Appropriate oversight and management of the use of vertebrate animals are essential to the ethical conduct of research. **Certification of Institutional Animal Care and Use Committee (IACUC) review and approval is not required prior to application review; however, a standard IACUC 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.

Succinctly address the following four points on Form 15. **APPLICATIONS THAT FAIL TO APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE FOUR POINTS BELOW WILL BE PENALIZED 0.2 POINTS.**

1) *Description of Proposed Animal Use*
   Provide a detailed description of the animal use proposed in the Work Plan, including identification of species, 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 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
If the ESCRO has not deemed the project to be permissible without review (i.e. exempt) prior to submission of the application, the following narrative must be submitted as part of the application. **The five points to be addressed in narrative are presented in full below. APPLICATIONS THAT FAIL TO APPROPRIATELY ADDRESS ANY ONE OR MORE OF THE FIVE POINTS BELOW WILL BE PENALIZED 0.2 POINTS.**

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 reveiwed and approved by an appropriate Embryonic Stem Cell Research Oversight (ESCRO) Committeee.** 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.

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.

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*
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.

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.

B. Review & Award Process

1. Review and Scoring Process

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

Each eligible application will be evaluated by an Independent Scientific Merit Peer Review Panel (the Panel) assigned by the Peer Review Contractor. The Panel will evaluate and score each proposal according to specified criteria (see Section V.D.).

The Panel members will be selected from among non-New York State experts in the appropriate fields based on the nature of the applications received.

Applications will receive scores from each participating panel member for each evaluation criterion using a scale of 1 (high merit) to 5 (low merit). The numerical score given each criterion will be multiplied by that criterion's weight (i.e., 20%). The weighted scores will be added together to give their individual total score. Panel member's individual total scores are then added together and divided by the number of panel members who voted on the application to give an overall panel score for the application. The overall panel score is then translated into an adjectival score, as follows.

Numerical	Adjectival
1.0 – 1.5	Outstanding
1.6 – 2.0	Excellent
2.1 – 2.5	Very Good
2.6 – 3.5	Good
3.1 – 5.0	Fair

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

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

The Peer Review Contractor will deduct penalty points for each application that deviates from the instructions for completion of the application and will compile, prepare and forward all application scores, summary statements, recommendations and comments to NYSTEM.

Applications with a score ranging from 3.1 to 5.0 will not be considered by the ESSCB Funding Committee.

Funding is available to support approximately five Investigator Initiated awards and four IDEA awards. The ESSCB Funding Committee will consider each application through a score of 3.0 by funding mechanism (Investigator Initiated Research Project, IDEA). 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, career stage of the investigator, availability of funds, and compliance with Public Health Law Article 2, Title 5-A, Section 265.

All award recommendations made by the ESSCB Funding Committee may be made contingent upon acceptance of revisions to items about which the reviewers noted concerns or made recommendations.

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.

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

2. Award Decisions and Pre-Funding Requirements

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

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

3. Award Announcements

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

C. Review Criteria

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

- Work Plan, project duration and budget
- Research funding overlap
- Concerns with regard to Contract Policy Statements and Conditions (Contract Appendix A-2)

The Independent Scientific Merit Peer Review Panel may recommend revisions to the ESSCB Funding Committee based on the above. Awards may be made contingent upon acceptance of revisions to these items.

Specific review criteria by funding mechanism:

1. **Investigator Initiated Research Award**

   Five evaluation criteria are considered by the Independent Scientific Merit Peer Review Panel:

   Innovativeness and Significance (20%)
   - The originality of the research question(s) and the approach taken in its investigation.
   - The importance of the research questions and their basis in the scientific literature.
   - The extent to which successful completion of the project will advance ESSCB's mission and have potential therapeutic significance.
   - The Work Plan is responsive to this single funding mechanism.

   Approach (20%)
   - The integration and suitability of design, methods, and conceptual framework with a coherent scientific rationale and specific aims.
   - The acknowledgement of potential problem areas and consideration of alternative tactics.

   Feasibility (20%)
   - The likelihood of successful completion of the study based on the research design, background and experience of the investigators, the availability of resources and the overarching research environment.

   Investigators (20%)
   - The knowledge, skills, research tools and experiences of the researcher(s) in relation to the proposed work.
   - The extent to which the composition of the research team provides the potential for innovative research solutions and applications.

   Budget (20%)
   - The appropriateness of the budget allocations to the accomplishment of the research aims.
   - Reasonableness of costs and cost effectiveness.

2. **IDEA Award**

   Five evaluation criteria are considered by the Independent Scientific Merit Peer Review Panel:

   Innovativeness (20%)
   - The extent to which the basic concept or hypotheses are speculative, exploratory, develop new paradigms, and are high risk/high reward.

- The extent to which the project challenges existing principles/dogma, develops new methodologies or technologies, or addresses important under- or unexplored areas.
- The Work Plan is responsive to this single funding mechanism.

Impact (20%)

- The extent to which the project, if successfully completed, would make an original and important contribution to the field of stem cell research.
- The extent to which successful completion of the project will advance ESSCB's mission and have potential therapeutic signficance.

Approach (20%)

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

Feasibility (20%)

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

Budget (20%)

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

ATTACHMENT 1

APPLICATION FORMS 1 – 16

Face Page

Project Title:		
Application Type:	NYSTEM Application #:	Early Stage Inv.:

Principal Investigator: Last Name, First Name, Middle Initial, Degree(s)	Co-Principal Investigator: Last Name, First Name, Middle Initial, Degree(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 Zip	Street 1 Street 2 City State Zip
Phone: Fax:	Phone: Fax:
E-mail:	E-mail:

Type of Organization:					
Federal Employer ID # (9 digits):			DUNS Number:		
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:	

New York State Applicant Organization:	Research Performing Sites:
Mailing Address (Street, MS, PO Box, City, State, Zip): Street 1 Street 2 City State Zip	
Contracts and Grants Official:(Last Name, First Name)	Official Signing for the Organization (Name and Title):
Last Name , First Name	Last Name First Name Title
Mailing Address (Street, PO Box, MS, City, State, Zip):	Organization Name and Mailing Address: (Street, MS, PO 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:

Address where reimbursement should be sent if contract is awarded (Street, MS,PO Box, City, NY, Zip): Street 1 Street 2 City State Zip
CERTIFICATION AND ASSURANCE: I certify that the statements herein are true and complete to the best of my knowledge. I agree to accept responsibility for the scientific conduct and integrity of the research, and to provide the required progress reports if a contract is awarded as a result of this application.
SIGNATURES OF PRINCIPAL INVESTIGATOR and CO-PI:
X DATE:
X DATE:

Form 1

Submit Applicant Forms 1-5 together in two formats: one signed PDF file and one Word document file.

ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and I accept the obligation to comply with the Empire State Stem Cell Board's terms and conditions if a contract is awarded as a result of this application.
SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION:
X DATE:

Form 1
Submit Applicant Forms 1-5 together in two formats: one signed PDF file and one Word document file.

Face Page for Subcontracting Entities

Project Title:				
Application Type:	NYSTEM Application #:	Revised:	Original Application #:	Early Stage Inv:

Principal Investigator: Last Name, First Name, Middle Initial, Degree(s)	Co-Principal Investigator: Last Name, First Name, Middle Initial, Degree(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 Zip	Street 1 Street 2 City State Zip
Phone: Fax:	Phone: Fax:
E-mail:	E-mail:

Type of Organization:			
Federal Employer ID # (9 digits):		DUNS Number:	
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:	

New York State Applicant Organization:	Research Performing Sites:
Mailing Address (Street, MS, PO Box, City, State, Zip):	
Street 1 Street 2 City State Zip	

Contracts and Grants Official:(Last Name, First Name)	Official Signing for the Organization (Name and Title):
Last Name , First Name	Last Name First Name Title
Mailing Address (Street, PO Box, MS, City, State, Zip):	Organization Name and Mailing Address: (Street, MS, PO 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:

Address where reimbursement should be sent if contract is awarded (Street, MS,PO Box, City, NY, Zip):
Street 1 Street 2 City State Zip

Form 1
Submit a signed Face Page for each Subcontracting Entity in a single PDF file.

CERTIFICATION AND ASSURANCE: I certify that the statements herein are true and complete to the best of my knowledge. I agree to accept responsibility for the scientific conduct and integrity of the research, and to provide the required progress reports if a contract is awarded as a result of this application.
SIGNATURES OF PRINCIPAL INVESTIGATOR and CO-PI:
X DATE:
X DATE:
ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and I accept the obligation to comply with the Empire State Stem Cell Board's terms and conditions if a contract is awarded as a result of this application.
SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION:
X DATE:

Form 1
Submit a signed Face Page for each Subcontracting Entity in a single PDF file.

Staff, Collaborators, Consultants and Contributors
List the name, title and institutional affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid). This list is used for identifying potential members of the Independent Scientific Merit Peer Review Panel.

Last Name	First Name	Title	Institutional Affiliation	Role in Project

Form 2
Submit Applicant Forms 1-5 together in two formats: one signed PDF file and one Word document file.

Acronyms Used in Application

List each acronym and its full text/definition/description as used in the application. 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 300 word summary of the application, in non-technical terms. 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 Innovative Elements of the Project.

Form 4

Not to exceed 300 words. Submit Applicant Forms 1-5 together in two formats: one signed PDF file and one Word document file.

Scientific Abstract

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

Provide a scientific summary of the application. This information will be excerpted and edited for use in various public documents. Specifically, address the following topics: Background, Hypothesis, Specific Objectives/Aims, Methods and Impact of the Research.

Form 5
Not to exceed one page.
Submit Forms 1-5 together in two formats: one signed PDF file and one Word document file.

Table of Contents

* Indicate “N/A” if not applicable.

Budget – Name of Contractor or Subcontractor _____

	BUDGET CATEGORY	Year One	Year Two	Year Three	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)**				

Form 7
Attach subcontractor budgets using additional copies of Form 7.

OTHER THAN PERSONAL SERVICE (OTPS)					
	SUPPLIES				
4	LAB SUPPPLIES				
	OFFICE SUPPLIES				
	SUBTOTAL SUPPLIES				
5	EQUIPMENT				
6	TRAVEL				
7	CONSULTANT COSTS				
	OTHER EXPENSES				
	HUMAN SUBJECTS				
	ANIMALS & CARE				
8	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)				

Form 7
Attach subcontractor budgets using additional copies of Form 7.

Personnel Effort and Budget Justification

Key Personnel *				**Dollar Amount Requested (Year One)**		
Name	**Role in Project**	**% of Total Professional Effort****	**Total Salary at Institution**	**Salary Requested**	**Fringe Requested**	**Total $ Requested**
Support Personnel *				**Dollar Amount Requested (Year One)**		
Name	**Role in Project**	**% Professional Effort****	**Total Salary at Institution**	**Salary Requested**	**Fringe Requested**	**Total $ Requested**
Total Salary + Fringe Requested – Should equal Year One, line 3, Form 7.						

***** Insert additional lines as necessary under Key Personnel or Support Personnel.
** Professional effort is all professional activities performed, regardless how or whether the individual receives compensation.

Form 8
Not to exceed 3 pages per organization. Attach Subcontractor Personnel Effort and Budget Justification using additional copies of Form 8.

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 8
Not to exceed 3 pages per organization. Attach Subcontractor Personnel Effort and Budget Justification using additional copies of Form 8.

Biographical Sketch

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

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

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

Form 9
Not to exceed 2 pages per individual. Present PI first, followed by Co-PI(s) and the remaining key personnel in alphabetical order using additional copies of Form 9.

Facilities and Resources

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

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

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

Form 10
Not to exceed two pages per collaborating institution.

Other Research Support

Name of Key Personnel: _____

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

TITLE OF PROJECT: ☐ Pending ☐ Active

PROJECT PI:

FUNDING AGENCY/GRANT ID NO.:

PERIOD OF SUPPORT: % FTE _____

THIS PROJECT INVOLVES STEM CELL RELATED RESEARCH: ☐ *Yes ☐No

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

Form 11
Repeat the format presented above for each research project. Use additional pages as needed. Present the Principal Investigator first, followed by Co-PI(s) and the remaining key personnel in alphabetical order. For any "Yes" answer, explain the distinction between the project and this application, directly below the item. Indicate a possible resolution, if this application is funded.

Work Plan:

Time Line and Collaboration Strategy

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

Describe strategies for information and/or resource exchange to ensure efficient and effective completion of the project. Include frequency and methods of communications. Note barriers to communication and resource exchange and propose alternative strategies to overcome potential problems.

Form 13

Human Subjects

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

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

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

Institution: _____

Institutional OHRP Federal-wide Assurance of Compliance Number: _____

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

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

Project Title: _____

_____

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

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

If "Yes", date of next review: _____

Repeat table as often as necessary.

If the IRB Approval Status (above) is Pending or Approved, attach a narrative to address the eight points listed below (see Section V.A. Application Content).

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

Form 14
Use additional sheets as necessary.

Vertebrate Animals

If Institutional Animal Care and Use Committee review is not required for this research project, check the box ☐ and do not complete below this line.

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

Institution: _____

Institutional Animal Care & Use Number: _____

NYS DOH Animal Care & Use Certificate Number: _____

USDA Registration Number (if applicable to species): _____

Vertebrate Animal Approval Status: ☐ Approved ☐ Pending

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

Project Title: _____

_____

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

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

If "Yes", date of next review: _____

Repeat table as often as necessary.

All applications proposing vertebrate animal research are required to address the four points below. Acquisition and use of animals at all performance sites must comply with New York State Public Health Law, Article 5, Title I, Sections 504 and 505-a.

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

Form 15
Use additional sheets as necessary.

Human Stem Cells

If instituitonal stem cell committee (ESCRO) review is not required for this research project, check the box and do not complete below this line. ☐

Complete separate tables for **ALL** human stem cell protocols to be used with the application if funded. Present information from the applicant organization first, followed by subcontracting or consortium organizations. It is the responsibility of the applicant organization to ensure that all performance sites comply with the human stem cell guidelines as specified by NYSTEM and all other statutes, regulations or policies pertaining to use of such stem cell lines.

Institution: _____

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

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

Project Title: _____

_____

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

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

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

Repeat table as often as necessary.

If the ESCRO Approval Status (above) is Pending or Approved, attach a narrative to address the five points listed below (see Section Human Stem Cell Application Contents).

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

Form 16
Use additional sheets as necessary.

ATTACHMENT 2

APPLICATION CHECKLIST
Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) Awards for Stem Cell Research

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

- ☐ Applicant institution filed a letter of intent for the PI by the due date and time
- ☐ Application was submitted by due date and time
- ☐ The institution is a New York State not-for-profit organization or a governmental organization within New York State that is an academic institution, a research organization, a medical center, or an entity with demonstrated capability to conduct externally- funded research
- ☐ One electronic (on CD-ROM) and one original paper copy of the application
- ☐ The original paper copy of the application includes original signatures on the Face Page(s) (Form 1).

- ☐ Professional effort of the Principal Investigator on the project is at least 20% for Investigator Initiated Research Projects and at least 10% for IDEA. See Form 8, 'Percent Total Professional Effort' column.

Appendices may include:

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

ATTACHMENT 3

Vendor Responsibility Attestation
Targeted Projects in Human Embryonic Stem Cell Research

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

Letter of Intent

New York State Department of Health, NYSTEM and the ESSCB
Targeted Projects in Human Embryonic Stem Cell Research

A Letter of Intent is required of prospective applicants in order to develop appropriate Review Panels in a timely manner. This form is mandatory and must be completed and filed as instructed in Section IV.C. of this RFA.

On the lines below, enter the number of applications of each type that will be submitted by a single PI in response to this RFA:

Investigator Initiated Research Project (IIRP) application(s) _____

IDEA application(s) _____

I. Investigator Information (please print or type)

Principal Investigator:					
Sponsoring Institution:					
Address:					
City:		State:		ZIP Code:	
E-Mail:					

II. Collaborator Information (please print or type)

Primary Contact:					
Collaborating Institution:					
Address:					
City:		State:		ZIP Code:	
E-Mail:					

Primary Contact:					
Collaborating Institution:					
Address:					
City:		State:		ZIP Code:	
E-Mail:					

Collaborator Information (cont.)

Primary Contact:					
Collaborating Institution:					
Address:					
City:		State:		ZIP Code:	
E-Mail:					

Primary Contact:					
Collaborating Institution:					
Address:					
City:		State:		ZIP Code:	
E-Mail:					

Primary Contact:					
Collaborating Institution:					
Address:					
City:		State:		ZIP Code:	
E-Mail:					

SIGNATURES OF PRINCIPAL INVESTIGATOR (“Per” not allowed): X DATE:
ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge. SIGNATURE OF THE OFFICAL SIGNING FOR THE APPLICANT ORGANIZATION (“Per” not allowed) : X DATE:

ATTACHMENT 5

Sample Contract *

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

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

GRANT CONTRACT

STATE AGENCY (Name and Address):

_____

CONTRACTOR (Name and Address):

_____

FEDERAL TAX IDENTIFICATION NUMBER:

MUNICIPALITY NO. (if applicable):

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

_____

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

_____

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

NYS COMPTROLLER'S NUMBER: _____

ORIGINATING AGENCY CODE:

_____

TYPE OF PROGRAM(S)

_____

INITIAL CONTRACT PERIOD

FROM:

TO:

FUNDING AMOUNT FOR INITIAL PERIOD:

_____

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

APPENDICES ATTACHED AND PART OF THIS AGREEMENT

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

OTHER APPENDICES

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

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

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

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

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

_____

(Signature and office of the individual taking acknowledgement)

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

STATE OF NEW YORK

AGREEMENT

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

WITNESSETH:

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

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

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

I. Conditions of Agreement

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

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

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

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

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

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

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

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

II. Payment and Reporting

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

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

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

III. Terminations

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

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

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

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

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

F. The STATE shall be responsible for payment on claims pursuant to services provided and costs incurred pursuant to terms of the AGREEMENT. In no event shall the STATE be liable

for expenses and obligations arising from the program(s) in this AGREEMENT after the termination date.

IV. Indemnification

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

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

V. Property

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

VI. Safeguards for Services and Confidentiality

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11. IDENTIFYING INFORMATION AND PRIVACY NOTIFICATION. (a) FEDERAL EMPLOYER IDENTIFICATION NUMBER and/or FEDERAL SOCIAL SECURITY NUMBER. All invoices or New York State standard vouchers submitted for payment for the sale of goods or services or the lease of real or personal property to a New York State agency must include the payee's identification number, i.e., the seller's or lessor's identification number. The number is either the payee's Federal employer identification number or Federal social security number, or both such numbers when the payee has both such numbers. Failure to include this number or numbers may delay payment. Where the payee does not have such number or numbers, the payee, on its invoice or New York State standard voucher, must give the reason or reasons why the payee does not have such number or numbers.
(b) PRIVACY NOTIFICATION. (1) The authority to request the above personal information from a seller of goods or services or a lessor of real or personal property, and the authority to maintain such information, is found in Section 5 of the State Tax Law. Disclosure of this information by the seller or lessor to the State is mandatory. The principal purpose for which the information is collected is to enable the State to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purpose authorized by law.

(2) The personal information is requested by the purchasing unit of the agency contracting to purchase the goods or services or lease the real or personal property covered by this contract or lease. The information is maintained in New York State's Central Accounting System by the Director of Accounting Operations, Office of the State Comptroller, 110 State Street, Albany, New York 12236.

12. EQUAL EMPLOYMENT OPPORTUNITIES FOR MINORITIES AND WOMEN. In accordance with Section 312 of the Executive Law, if this contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of $25,000.00, whereby a contracting agency is committed to expend or does expend funds in return for labor, services, supplies, equipment, materials or any combination of the foregoing, to be performed for, or rendered or furnished to the contracting agency; or (ii) a written agreement in excess of $100,000.00 whereby a contracting agency is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon; or (iii) a written agreement in excess of $100,000.00 whereby the owner of a State assisted housing project is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon for such project, then:
(a) The Contractor will not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status, and will undertake or continue existing programs of affirmative action to ensure that minority group members and women are afforded equal employment opportunities without discrimination. Affirmative action shall mean recruitment, employment, job assignment, promotion, upgradings, demotion, transfer, layoff, or termination and rates of pay or other forms of compensation;
(b) at the request of the contracting agency, the Contractor shall request each employment agency, labor union, or authorized representative of workers with which it has a collective bargaining or other agreement or understanding, to furnish a written statement that such employment agency, labor union or representative will not discriminate on the basis of race, creed, color, national origin, sex, age, disability or marital status and that such union or representative will affirmatively cooperate in the implementation of the contractor's obligations herein; and
(c) the Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status.

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

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

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

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

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

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

18. PROHIBITION ON PURCHASE OF TROPICAL HARDWOODS. The Contractor certifies and warrants that all wood products to be used under this contract award will be in accordance with, but not limited to, the specifications and provisions of State Finance Law §165. (Use of Tropical Hardwoods) which prohibits purchase and use of tropical hardwoods, unless specifically exempted, by the State or any governmental agency or political subdivision or public benefit corporation. Qualification for an exemption under this law will be the responsibility of the contractor to establish to meet with the approval of the State.

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

19. MACBRIDE FAIR EMPLOYMENT PRINCIPLES. In accordance with the MacBride Fair Employment Principles (Chapter 807 of the Laws of 1992), the Contractor hereby stipulates that the Contractor either (a) has no business operations in Northern Ireland, or

(b) shall take lawful steps in good faith to conduct any business operations in Northern Ireland in accordance with the MacBride Fair Employment Principles (as described in Section 165 of the New York State Finance Law), and shall permit independent monitoring of compliance with such principles.

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

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

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

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

The Omnibus Procurement Act of 1992 requires that by signing this bid proposal or contract, as applicable, Contractors certify that whenever the total bid amount is greater than $1 million:
(a) The Contractor has made reasonable efforts to encourage the participation of New York State Business Enterprises as suppliers and subcontractors, including certified minority and women-owned business enterprises, on this project, and has retained the documentation of these efforts to be provided upon request to the State;

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

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

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

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

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

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June, 2006

APPENDIX A-1

Agency Specific Clauses for ALL Department of Health Contracts
(REV 10/08)

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

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

ii. 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.

iii. 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.

iv. 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.

v. 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.

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

vii. 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.

viii. 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.

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

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

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

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

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

7. The CONTRACTOR will not discriminate in the terms, conditions and privileges of employment, against any employee, or against any applicant for employment because of race, creed, color, sex, national origin, age, disability, sexual orientation or marital status. The CONTRACTOR has an affirmative duty to take prompt, effective, investigative and remedial action where it has actual or constructive notice of discrimination in the terms,

conditions or privileges of employment against (including harassment of) any of its employees by any of its other employees, including managerial personnel, based on any of the factors listed above.

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

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

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

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

12. Other Modifications

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

        - Appendix B - Budget line interchanges; Any proposed modification to the contract which results in a change of greater than 10 percent to any budget category, must be submitted to OSC for approval;
        - Appendix C - Section 11, Progress and Final Reports;
        - Appendix D - Program 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 6/09

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. Representatives of 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. 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 be approved for funding recommendation by ESSCB unless it is demonstrated that all the following requirements are satisfied:

- The research study will comply with New York State Public Health Law (PHL) Article 24-A, Sections 2440 to 2446, unless the research is subject to, and in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.

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

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

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

- If applicable, the applicant organization's IRB has received, 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 Public Health Law, 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** 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 of Health reserves the right to revise or expand requirements applicable to human subjects research as part of negotiation of any contract arising from this request for applications.[1]

[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. Research applications submitted to the Board for consideration must have 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. 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.; Public Health Law Article 5, TitleV, sections 570 to 581; Article 24-A, sections 2440 to 2446; Article 43, sections 4301 to 4309; Article 43-B, sections 4360 to 4366; and 10 NYCRR Part 52.

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 or conflicting requirements of this Contract.

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 1.2 (a) of the NAS Guidelines shall not require ESCRO review if notification is provided to the ESCRO Committee.[2]

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 or conflicting requirements of this Contract.

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.

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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 1.2(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."

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 of Health 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]

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[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.

b) *Re-consent*: Consent to donation should 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 ISSCR Guideline 11.2[6], but may choose to use the stricter standards set forth in NAS Guideline 3.2.[7]

c) *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.

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

e) *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.

f) *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

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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.

[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….

[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 11.3(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.

matched to the donor. Donors must also be provided with the disclosures mandated by ISSCR Guideline 11.3(a) (vii).[9]

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

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

i) *Application*: The standards set forth in this subsection shall apply to research funded pursuant to this contract involving the derivation of new stem cell lines. Contractors may use biological materials obtained prior to the execution of this contract and/or cell lines derived without the use of funds provided under this contract so long as the informed consent obtained from the donor(s) adhered to the provisions of the NAS or ISSCR Guidelines. In addition, grantees may use cell lines in existence on or prior to August 9, 2001 that were approved by the National Institutes of Health for use in federally-funded research.

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[9] ISSCR 11.3(a) - The informed consent document and process should cover, at a minimum, the following statements:…

vii) disclosure of what donor medical or other information and what potential donor identifiers will be retained; specific steps taken to protect donor privacy and the confidentiality of retained information; and whether the identity of the donor will be readily ascertainable to those who derive or work with the resulting stem cell lines, or any other entity or person, including specifically any oversight bodies and government agencies.

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

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

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

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

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

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

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

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

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

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 Guidelines 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 for more than 60 days after the manuscript is completed. Research results are to be submitted promptly for publication in internationally recognized scientific journals. Publication should not be delayed for commercial or other reasons beyond the editorial period needed to ensure scientific accuracy and presentation.

a. All publications reporting research supported by 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. Within 60 days of publication, the investigator must submit to NYSTEM program administrators a 500 word abstract of the publication suitable for the general public, highlighting the research findings. A full literature citation and a brief biographical sketch of the NYSTEM-funded Principal Investigator must also be submitted. This information will be made available to the public through the NYSTEM website.

d. 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 ESSCB 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. Within 60 days of such disclosure the contractor shall notify NYSTEM of the invention disclosure. The contractor shall notify NYSTEM upon the filing of any patent application in the progress report pursuant to the contract. The contractor shall provide NYSTEM with advance written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Fund. Any such assignment or transfer must acknowledge, and be subject to the rights retained by the State pursuant to the above paragraph #2.

Assignment and ownership allocation of intellectual and industrial property rights generated from research supported by the Fund is to be determined by the parties concerned (researchers, and their research organizations or institutions), consistent with organizational policies. Prior to execution of a negotiated contract, appropriate arrangements (existing or proposed) regarding intellectual and industrial property rights must be made by the contracting organization and communicated to NYSTEM program administrators. Such arrangements may include: provisions about dissemination of information such as disclosure and methods of publication, and provisions regarding

ownership and exploitation of the results arising from the research supported by the Fund. However, to protect the State's interests and to streamline invention reporting procedures, contracts between the New York State Department of Health and the contracting institution will, except to the extent inconsistent with this paragraph, incorporate the provisions of 37 CFR 401.14 with the following modifications throughout: *Federal* or *Government* will refer to New York State, and *agency* will refer to the Department of Health.

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

G. Reporting Requirements

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

H. Equipment

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

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

I. Other Information

1. Documents submitted to the Department of Health 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 New York State Department of Health 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 of Health nor the State of New York will assume any responsibility for any damage or injuries caused or resulting from research conducted with the financial support of the Fund.

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

6. Assurances and Certifications. The New York State 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 of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight.

APPENDIX B

BUDGET (sample format)

Budget – Name of Contractor or Subcontractor _____

	BUDGET CATEGORY	**Year One**	**Year Two**	**Year Three**	**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)**				

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
Investigator Initiated Research Projects and IDEA
Rev. approved 5/08

I. Payment and Reporting Terms and Conditions

A. The State (NYS Department of Health) may, at its discretion, make an advance payment to the CONTRACTOR, during the initial or any subsequent PERIOD, in an amount to be determined by the STATE but not to exceed 25 percent of the maximum amount indicated in the budget as set forth in the most recently approved Appendix B. If this payment is to be made, it will be due thirty calendar days, excluding legal holidays, after the later of either:

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

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

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

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

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

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

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

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

D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the Work Plan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller.

E. The CONTRACTOR will provide the STATE with the reports of progress or other specific work products pursuant to this AGREEMENT as described in this Appendix below. In addition, a final

report must be submitted by the CONTRACTOR no later than 60 days after the end of this AGREEMENT. All required reports or other work products developed under this AGREEMENT must be completed as provided by the agreed upon work schedule in a manner satisfactory and acceptable to the STATE in order for the CONTRACTOR to be eligible for payment.

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

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

All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than thirty (30) days after the end date of the period for which reimbursement is claimed (see Table I for annual schedule). In no event shall the amount received by the CONTRACTOR exceed the budget amount approved by the STATE, and, if actual expenditures by the CONTRACTOR are less than such sum, the amount payable by the STATE to the CONTRACTOR shall not exceed the amount of actual expenditures. All contract advances in excess of actual expenditures will be recouped by the STATE prior to the end of the applicable budget period.

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

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

II. Progress and Final Reports

A. Semi-Annual Progress Report

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

Progress Reports shall be submitted via e-mail as MS Word attachments. Documents should be single-spaced, in Arial 12 font or similar. Tables, graphs, photographs, etc. should be sent as separate .bmp or .tif files attached to the e-mail. Publications, abstracts and other products resulting from Fund support during the reporting period should be attached as .pdf file to the e-mail. All reports and forms are to be sent to 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. No vouchers shall be paid until the corresponding progress report is received and approved pursuant to this AGREEMENT.

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

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

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

TABLE I

Voucher / Report	Period Covered	Due Date
Voucher 1	September 1 – November 30	December 30
Voucher 2	December 1 – February 29	March 30
Semi-Annual Report 1	September 1 – February 29	March 30
Voucher 3	March 1 – May 31	June 30
Voucher 4	June 1 – August 31	September 30
Semi-Annual Report 2	March 1 – August 31	September 30
Final Report	Entire Contract Period	October 30, 2012*

*The due date shown for the Final Report assumes a contract end date of August 31, 2012. If a contract extension is granted, the contractor must continue to follow the Semi–Annual Progress Report schedule as described above AND file the Final Progress Report as described below after the end of the contract extension.

C. Final Progress Report

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

APPENDIX D

WORK PLAN

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

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:_____