RFA # 1206180230

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

Investigator Initiated Research Projects (IIRP) and
Innovative, Developmental or Exploratory Activities (IDEA)
in Stem Cell Research

RELEASE DATE: April 16, 2013

LETTER OF INTENT DUE (Strongly Encouraged): June 5, 2013 by 5:00 PM

APPLICANT CONFERENCE: June 7, 2013 at 10:00 AM
David Axelrod Institute
120 New Scotland Avenue
Albany, NY 12208

Or by telephone conference call at:
1-866-394-2346 Conference Code: 4474608059

Applicant Conference Registration Due: June 5, 2013

QUESTIONS DUE: June 13, 2013

QUESTIONS, ANSWERS AND UPDATES POSTED: July 1, 2013

APPLICATIONS DUE: July 30, 2013 **by 5:00 PM**

ESTIMATED CONTRACT START DATE: **June 1, 2014**

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
(518) 474-7002 (phone)
nystemgrants@wadsworth.org
(518) 486-2191 (fax)

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

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I. Introduction

A. Background

Advances in stem cell research are encouraging scientists to investigate the potential of cell-based therapies to treat disease. Now in its sixth year, the Empire State Stem Cell Board (ESSCB) is authorized to provide funding for basic, applied, translational and other research designed to advance scientific discoveries in fields related to stem cell biology.

NYSTEM, the New York State Stem Cell Science Program, is 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 Empire State Stem Cell Trust Fund. Information about the ESSCB and NYSTEM can be found at http://stemcell.ny.gov.

B. Purpose of the Funds

The ESSCB wishes to stimulate and support basic, applied (mechanistic, technological), translational, pre-clinical and clinical scientific investigations on any aspect of stem cell biology that will lead to a better understanding of the unique properties of stem cells and allow their utilization to treat disease.

C. Available Funds

All awards will be financed by the Empire State Stem Cell Trust Fund. The number of awards and total funds awarded per application will be contingent on the quality and content of applications received as well as the scale and scope of the proposed projects. Approximately $25 million is available to support approximately 34 awards from this RFA. In determining final awards, the Department reserves the right to allocate 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 (IIRP)**

   - Contract term will be up to three years; and
   - Annual **direct costs** are capped at $300,000; and
   - Requires a minimum of 20% professional effort by the Principal Investigator (PI) throughout the contract term.

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

   - 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; and
   - Requires a minimum of 10% professional effort by the PI throughout the contract term.

II. Who May Apply?

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

The eligible Principal Investigator (PI) is designated by the applicant institution, has the skills, knowledge, and resources necessary to carry out the proposed Workplan, and is not a postdoctoral fellow or other dependent research staff. At the time of application and award acceptance, the PI must not be restricted from receiving Public Health Service (PHS) funding or debarred by the United States Food and Drug Administration (FDA) or any other federal or New York State government entity.

An eligible organization is not limited to the number of applications it can submit in response to this RFA. However, the eligible PI may submit only one application per funding mechanism in response to this RFA, regardless of the organization under which (s)he submits the applications. If a PI submits more than one application for an IDEA award and/or more than one application for an IIRP award, all applications from the PI for that funding mechanism will be disqualified and will not be forwarded to peer review.

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

III. Project Narrative/Workplan Outcomes

A. General Expectations

A successful application will propose a basic, applied (mechanistic, technological), translational, pre-clinical or clinical study focusing on the objectives outlined in Section I.B., Purpose of the Funds.

Research in the area of human embryonic stem cells is encouraged, as are studies that promote translation of stem cell science to therapeutic applications, such as new approaches of directed differentiation.

The ESSCB is interested in supporting established and early career stage investigators from applicant organizations. Investigators can include those new to the field of stem cell research and those in disciplines that have not historically focused on stem cell research.

Although collaborations are not required, they are strongly encouraged.

1. **Investigator Initiated Research Project (IIRP)**

The Investigator Initiated Research Project mechanism is designed to:

- investigate a well-developed problem or research hypothesis; or
- develop technologies or resources that are essential to overcome existing barriers to progress toward therapeutic applications.

An application for this mechanism should:

- include sufficient preliminary data to support the hypothesis or proposed resolution of the problem; or
- provide data relevant to support the Food and Drug Administration (FDA) approval process; or

- provide advances in translational research.

The PI must commit a minimum of 20% professional effort throughout the contract term.

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

The IDEA mechanism is designed to:

- open a new area of investigation; or
- test a novel or innovative hypothesis; or
- produce viable data for preparation of a full-scale research application; or
- apply or develop state-of-the-art technologies, tools or resources for stem cell research.

An application for this mechanism should be highly speculative, exploratory, or high-risk and have the potential for high scientific payoff (with or without pilot data). 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. However, it is the intent of the ESSCB that successful IDEA projects will be eligible to apply for future IIRP awards.

The PI must commit a minimum of 10% professional effort throughout the contract term.

B. Use of Funds

Funds may be used to support salaries and stipends, fringe benefits, supplies, equipment, travel, subcontractor and consultant costs, animals and their care, core facility use charges, publication and communication costs, and other related research costs. In addition, Facilities and Administrative (F&A) costs are allowed but are limited to a maximum of 20 percent of modified total direct costs (see Section V., Instructions for Completing the Application).

No funds shall be directly or indirectly utilized for research involving human reproductive cloning. No funds shall be used for patient care. Funds awarded by this program may not be used to supplant or duplicate other existing support for the same work.

C. Reporting Obligations

The contractor will be required to submit financial reports and scientific progress reports in accordance with the forms, formats and time frames provided by NYSTEM. Submission of detailed quarterly financial reports will be required. Written reports will also be required and will substantiate progress corresponding to the tasks and milestones outlined in the Workplan. All progress reports will require approval by NYSTEM staff prior to payment of the voucher that corresponds to the last quarter of the reporting period. The contractor will also be required to follow all reporting obligations outlined in Appendix A-2 and Appendix C of the executed contract, and to monitor subcontractor compliance. A sample of these contract appendices can be found in Attachment 5 of this RFA.

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

Prior to contract execution, awarded organizations will also be required to provide copies of protocol approvals for research projects that involve human subjects, vertebrate animals, recombinant DNA, or

human stem cells as defined herein. In addition, certification that proper education requirements have been met will also be required prior to contract execution.

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

- on-site monitoring visits; and
- any NYSTEM-sponsored annual or other meeting.

IV. Administrative Requirements

A. Issuing Agency

This RFA is issued by the New York State Department of Health (Department), NYSTEM program. 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 include the title of the RFA and cite the 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 contacting Bonnie Jo Brautigam at the address or telephone number listed on the cover of this RFA. Questions are of a technical nature if they are limited to how to prepare the application (e.g., formatting) rather than relating to the substance of the application.

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

This RFA has been posted on the Department of Health's public website at: http://www.health.ny.gov/funding. Questions and answers, as well as any updates and/or modifications, will also be posted on the Department'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 **strongly encouraged** to submit a Letter of Intent using the form provided in this RFA (Attachment 3). This form will be used to develop the highest quality review panels in a timely manner. Please do not submit additional information about the application with the form. Letters of Intent infer no obligation upon the institution to submit an application in response to this RFA. Applications may be submitted without first having submitted a Letter of Intent.

The Letter of Intent should be received by the date and time indicated on the cover sheet to this RFA and 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.

D. Applicant Conference

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

E. How to File an Application

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

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

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

Courier Service:
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., Instructions for Completing the Application. The application should be submitted in a single package that is clearly labeled with the RFA name and RFA number listed on the cover of this RFA. Inside the package, a separately sealed package should contain a CD or DVD of the entire application and supporting documents, and an exact paper copy. The package should be clearly marked with the PI's name and the institution name. Hand deliveries will be accepted but should be in a sealed envelope as described in the previous sentence. **Applications WILL NOT be accepted via fax or e-mail.**

F. The Department of Health Reserves the Right to:

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

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

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

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

5. Seek clarifications and revisions of applications.

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

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

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

9. Change any of the scheduled dates.

10. Waive any requirements that are not material.

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

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

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

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

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

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

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

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

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

G. Term of Contract

Any contract resulting from this RFA will be effective only upon approval by the New York State Office of the State Comptroller. It is expected that contracts resulting from this RFA will begin on **June 1, 2014** and have the following time periods and will not be renewable:

- IIRP award – up to 3 years

- IDEA award – up to 2 years.

H. Payment & Reporting Requirements

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

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

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

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

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

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

   - All vouchers submitted by the contractor pursuant to this agreement shall be submitted to the State no later than 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 for that period are submitted and deemed acceptable by NYSTEM program staff.

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

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

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

   - Written progress reports in accordance with the forms and formats provided by NYSTEM as outlined in Section III.C. Reporting Obligations, no later than 30 days after the end of each 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 Identification Number

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

If already enrolled in the Vendor File, please include the Vendor Identification number on the application cover sheet. If not enrolled, to request assignment of a Vendor Identification number, please submit a New York State Office of the State Comptroller Substitute Form W-9, which can be found on-line at: http://www.osc.state.ny.us/vendors/substitute_formw9.pdf or by referencing Attachment 4 (Statewide Vendor File Registration SFS Portal Format).

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

J. Vendor Responsibility Questionnaire

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

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

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

Applicants should also complete and submit the Vendor Responsibility Attestation (Attachment 2).

K. 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, 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.

L. 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 - Detailed Budget

APPENDIX C - Payment and Reporting Schedule

APPENDIX D - Workplan

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

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

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

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

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

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

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

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

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

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

APPENDIX F – Request for Applications

APPENDIX R – On-going Vendor Responsibility

V. Instructions for Completing the Application

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared using the forms and instructions provided in this RFA. Deviations from the instructions provided in this section and on the forms may affect the peer review score. In addition, a 0.1 point penalty will be assessed for specific deviations detailed in Attachment 1 (Application Checklist).

Use the application forms provided in Attachment 1 (Forms 1-18). Omit Form 1-S if there are no sub-applicants. All other forms must be submitted, whether blank, not applicable (NA) or completed. Forms are pre-set with acceptable fonts and margins. Applications should be single-spaced and typed using the font previously set within each form. Smaller font sizes are acceptable for use in tables and figure legends. The header should contain the PI's last name, first name, and applicant organization name, with the exception of Forms 1-6. Each page should be numbered consecutively. Figures and illustrations referenced in the Workplan are included in the page limits. Appendices may not be used to circumvent page limitations.

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

Digital files should not exceed 12 MB each and should not be password protected. Applicants are strongly encouraged to seek appropriate technical support in the creation of digital files and to review the digital files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will

increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at http://www.stemcell.ny.gov/research-support. Applicants should also be aware that while color figures may be included, applications may be printed in black and white. Applicants may wish to annotate the figure legend directing the reader to the digital file if color is an important aspect of the figure.

The CD or DVD should be clearly labeled with the applicant's name. It should contain the following items:

- Applicant Forms 1 – 6 in a *single* Microsoft Word document (DOC or DOCX) file (Form 6 must be submitted but may be left blank);
- Applicant Forms 1 – 6 in a *single* Portable Document Format (PDF) file (Form 6 must be submitted but may be left blank);
- Forms 7 – 18 and all appendix material in a *single* PDF file (Form 13 must be submitted but may be left blank if the application is not a "Resubmission");
- Sub-applicant Form 1-S for each Sub-applicant in Microsoft DOC or DOCX file (Form 1-S may be omitted if there are no Sub-applicants included in the application); and
- Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned and saved as a *single* PDF file

Information submitted to NYSTEM is subject to the Freedom of Information Law (FOIL) (New York State Public Officers' Law, Article 6, Sections 84 to 90). To the extent permitted by law, an application will not be disclosed, except for purposes of evaluation, prior to approval by the Comptroller of the resulting contract. All material submitted becomes the property of the Department and may be returned at the Department's discretion. Submitted applications may be reviewed and evaluated by any person, other than one associated with a competing applicant, designated by the Department. Any information supplied by an applicant, which is believed to be exempt from disclosure under FOIL, will be clearly marked and identified as such upon submission by the applicant. Marking the information as "confidential" or "proprietary" on its face or in the document header or footer shall not be sufficient without specific explanation of the basis for the claim of exemption from disclosure. Acceptance of the claimed materials by the Department does not constitute a determination on the exemption request. A determination of whether such information is exempt from FOIL will be made at the time of any request for disclosure under FOIL in accordance with statutory procedure.

Applicant Face Page – Form 1

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

NYSTEM Application Number. For NYSTEM USE ONLY; do not enter any data in this field.

Application Type. The RFA # should read "1206180230." Select the appropriate type from the dropdown box for the application funding mechanism (IDEA or IIRP).

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

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

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

Continuation. Select the appropriate box. If any part of the workplan is based on a previously funded NYSTEM award the application is considered to be a Continuation. A previously funded IDEA award cannot be continued as an IDEA award. However, an IDEA award can be continued through an IIRP application and an IIRP award can be continued through a subsequent IIRP application. In any case, peer review is required.

Early Stage Investigator. Select "Yes" or "No." An "Early Stage Investigator" is a PI who at the time of application, 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.

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

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

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

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

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

Project Start and End Dates. Record the anticipated project duration of:
June1, 2014 through May 31, 2017 for IIRP Awards; and
June 1, 2014 through May 31, 2016 for IDEA Awards.

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

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

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

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

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

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

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

Sub-applicant Face Page – Form 1-S

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

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

Application Type. The RFA # should read "1206180230."

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

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

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

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

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

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

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

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

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

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

Contracts and Grants Official. Provide the information requested.

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

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

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

DO NOT OMIT ANY OF THE REMAINING FORMS FROM THE APPLICATION

Staff, Collaborators, Consultants and Contributors – Form 2
List (spell out) the full name, title and organizational affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid) associated with this project. Do not include the PI and Co-PIs named on any Form 1 in the application. Do not include unnamed or "to be determined" staff positions. For each individual listed, select the most applicable role from the dropdown box. This list is used to determine possible conflicts of interest at various stages of the review and award process.

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

Acronyms and Abbreviations Used in Application – Form 3
Provide a list of all acronyms and abbreviations used in the application. Also include the full text/definition/description as used in the application. This will allow the Peer Review Panel to fully comprehend the proposed experimental design. Common acronyms such as hESC (human embryonic stem cells) need not be identified.

Lay Abstract – Form 4
Provide a summary of the proposed project in non-technical terms; limit to 300 words (do a word count, as the fill-in box may allow more than 300 words). This information will be excerpted and edited for use in various public documents. **Do not include confidential information.** Specifically, provide an Introduction/Background, Summary of Goals and Objectives, and Significance and Expected Impact of the Project.

Scientific Abstract – Form 5
Provide a scientific summary of the proposed project. The abstract should be written so that persons from diverse scientific backgrounds can easily understand the work proposed. Do not include confidential information. **NOTE:** Applicants proposing use of human embryonic stem cells should clearly indicate the specific cell line(s) planned for use, as well as the source, in the space provided. If applicable, include the name and/or NIH Registration number from http://stemcells.nih.gov/research/registry. Information provided on this form should not exceed one page.

Peer Review Panel Identification – Form 6 - OPTIONAL
Historically, applications in response to this NYSTEM RFA have fallen into several categories. To facilitate assembly of review panels, the applicant may suggest up to two review panel categories most closely suited to the application. This identification does not guarantee assignment of the application to either of those review panels. In addition, applicants may provide a list of up to 10 most relevant Key Words to describe the project, which will also be used to identify potential peer reviewers. **NOTE:** This form may be left blank if the applicant chooses, but it must be submitted.

Table of Contents – Form 7
Complete the table of contents, entering page numbers as appropriate or entering "N/A" when not applicable.

Budget – Form 8
Complete an additional form for each proposed sub-applicant organization.
Request funds appropriate for cost-effective performance of the proposed project. Budgets must be developed and managed in accordance with appropriate accounting standards for the organization including, but not limited to, applicable Circulars from the federal Office of Management and Budget (OMB) (see Attachment 5, Sample Contract, Appendix A-1, section 3). Record the amount requested for each category, subtotal and total for each year or portion thereof.

Care should be taken to record the true budgetary needs of the application. Proposed budgets are expected to incorporate cost of living increases and other reasonably-anticipated adjustments that may be necessary throughout the contract term. Requests for purchase of equipment may be granted if strongly justified as essential to the proposed project; a current price quote should be included in the application appendix.

No funds shall be directly or indirectly utilized for research involving human reproductive cloning. Patient care is not an allowable expense. Funds awarded by this program may not be used to supplant or duplicate other existing support for the same work. Ineligible budget items will be removed from the budget prior to contracting; the budget amount requested will be reduced to reflect the removal of the ineligible items.

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

Allowable Expenses of the Applicant and Sub-applicants

1. Personal Service

Support may be requested for the PI, Co-PI (if applicable) and other staff necessary to support the research. Salary and stipends are to be paid according to established organizational policies. Fringe benefits may be requested in accordance with organizational guidelines for each position, provided such benefits are applied consistently by the applicant organization as a direct cost to all sponsors. Maximum salary is limited to $199,700 in each budget year and is not adjustable as the federal salary cap changes.

IIRP applications require a minimum of 20% professional effort commitment by the PI throughout the contract term.

IDEA applications require a minimum of 10% professional effort commitment by the PI throughout the contract term.

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

2. Other Than Personal Service

Support may be requested for:

- Supplies
- Equipment
- Travel
- Consultant costs
- Other Expenses:

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

3. Proposed Subcontracts (Sub-applicants)

Allowable expenses for sub-applicants will be consistent with those established herein for the applicant. Sub-applicant amounts will be carried forward from sub-applicant budget forms to Line 11 of the applicant budget, Form 8. Such amount will include sub-applicant F&A costs. Note that any expenses budgeted for the sub-applicant will reduce the allowable expenses for the applicant organization.

4. Facilities and Administrative Costs

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

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

Personal Effort and Budget Justification – Form 9
For each budget year and budget line, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered, are reasonable and are consistent with the approaches described in the workplan. Budget lines that are not well-justified may be decreased or disallowed during the peer review and award process. **Complete an additional form for each proposed sub-applicant organization.**

The percentage of effort for personnel other than the PI is not prescribed; it should be dependent upon the nature of the role of each individual at various time points during the project and should be sufficient to complete the work within the contract period.

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

*Key personnel are defined as individuals who contribute in a substantive, measurable way to the scientific development or execution of a project, whether or not salaries are requested.

Starting with personnel, **fully justify** amounts requested in each budget category. Regardless of whether financial support is requested, describe and substantiate the roles and essential contributions to the project of the PI and other staff involved in the project.

In addition, provide a **detailed** justification for each 'Other Than Personal Service' (e.g., supplies, equipment, travel, consultant costs and other expenses).

Biographical Sketch – Form 10
Provide three-page biographical sketches for **all key personnel** listed on each Form 9. Start with the PI followed by Co-PI(s), and then include remaining key personnel in alphabetical order using

additional copies of Form 10. Include a brief personal statement to describe how the experience and qualifications make the individual particularly well-suited for the identified role in the project.

Facilities and Resources – Form 11
Describe the facilities available for performance of the proposed project including headings for: Laboratory, Clinical, Animal, Computer, Office and Other (such as machine shop and electronics shop), as appropriate. Specify the intent to which such services will be available to the project. Indicate the performance site(s) and describe pertinent site capabilities, relative proximity and extent of availability to the project. Also indicate institutional commitment, including any additional facilities or equipment to be provided in support of the project or available for use at no cost to the project. **Complete an additional form for each proposed sub-applicant organization.**

Other Support – Form 12
Repeating the format shown, provide the current information requested for **all key personnel** on all existing and pending support. Use additional pages as needed.

If the individual listed has no active or pending support other than this application, check the box by double-clicking and changing the "default value" to 'Checked,' and go on to the next person. For each entry of other support, provide a project title. Check the box to indicate whether the support is active or pending. Provide a brief description of the project. List the name of the PI awarded funding for the project. Provide the name of the funding agency, the assigned grant/contract number, and the period of support for the project. Provide the percent of effort the individual devotes to this project. Indicate whether the project involves stem cell research. If 'Yes,' list the Specific Aims of the project and explain the distinction between the project and this application. Indicate whether the project includes any scientific or budgetary overlap with this application. If 'Yes,' provide the intended resolution to eliminate/prevent overlap if the application is funded.

Introduction – Form 13
If the application is **not** a "Resubmission" this form may be left blank or marked "Not Applicable (N/A)." A "Resubmission" application includes research that was reviewed by NYSTEM during a previous cycle, but was not funded and is being resubmitted for new consideration. Resubmission applications should be responsive to the funding mechanism as well as reviewers' comments to the previous application.

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

Workplan – Form 14
Do not exceed the following page limits for Sections A-D of the Workplan:

1. **Investigator Initiated Research Project (IIRP)** – 12 pages
2. **Innovative, Developmental or Exploratory Activities (IDEA)** – 10 pages

The content of Form 14 will be included in any awarded contract; therefore, it should be sufficiently detailed to allow monitoring of progress toward project goals. The Workplan 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
- The project can be completed within the length of the contract term and with the proposed budget.

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 IIRP applications, although not required for IDEA applications.

If any part of the current application is based upon the receipt of a prior IIRP or IDEA award (a Continuation application), this section of the workplan must include a summary of the goals and accomplishments of the prior award and describe the relationship of the current proposal to the prior award. NOTE: A previously funded IDEA award cannot be continued as an IDEA award. However, an IDEA award can be continued through an IIRP application and an IIRP award can be continued through a subsequent IIRP application.

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 embryonic stem cells should clearly indicate in the research plan the specific cell line(s) to be used, as well as the source. If applicable, include the name and/or NIH Registration number from http://stemcells.nih.gov/research/registry.

e) Literature Cited
References are not counted against Workplan page limitations, and the number of references is not restricted. However, applicants are urged to select references that comprehensively reflect the relevant literature. For Continuation applications, be sure to include citations for publications resulting from work previously funded by NYSTEM. Provide complete citations to references.

Time Line and Collaboration Strategy – Form 15
Complete the table provided. The content of Form 15 will be included in any awarded contract; therefore, it should be sufficiently detailed to allow monitoring of progress toward achievement of project goals. Describe strategies for information and/or data/resource sharing to ensure efficient and effective achievement of the timeline and completion of the project. Discuss management of intellectual property rights and related issues, including compliance with anticipated contract provisions (see Attachment 5, Sample Contract). Include frequency and methods of communications. Include strategies to overcome potential problems with communication and/or data and resource sharing.

Human Subjects – Form 16

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

Section A

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

2. If activities involving human subjects are planned at any time during the proposed project, check YES to #2. Check YES even if the proposed project is exempt from Regulations for the Protection of Human Subjects.

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

   If activities involving human subjects, specimens, cells, cell lines or data are not planned at any time during the proposed project, check NO to #2 and skip the rest of the form.

3. If YES is checked in #2, is the project Exempt from federal regulations? Check YES or NO.

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

5. If NO is checked in #3, is the IRB review pending? Check YES or NO.

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

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

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

Section B

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

   The explanation could include: a description of the source of the data/biological specimens, and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected. Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research. Research involving the use of coded private information or biological

specimens may not constitute human subjects research if the conditions of the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens have been met (http://www.hhs.gov/ohrp/policy/cdebiol.html). Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as "living individuals." The use of cadaver specimens is not regulated by 45 CFR Part 46, but may be governed by other federal, state or local laws.

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

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

Vertebrate Animals – Form 17
Submit a separate Form 17 for the applicant and each sub-applicant. Accurately complete at least Section A of each form. In addition, if more than one vertebrate animal protocol will be required to complete the proposed research project, complete a separate form for each protocol.

Section A
1. Enter the name of the applicant or sub-applicant institution.

2. If activities involving vertebrate animals are planned at any time during the proposed project, check YES to #2.

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

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

3. If YES is checked in #2, is the IACUC review pending? Check YES or NO.

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

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

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

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

Section B

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

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

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

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

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

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

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

Human Stem Cells – Form 18

Submit a separate Form 18 for the applicant and each sub-applicant. Accurately complete at least Section A of each form. In addition, if more than one human stem cell protocol will be required to complete the proposed research project, complete a separate form for each protocol.

Section A

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

2. If activities involving human stem cells as defined below are planned at any time during the proposed project, check YES to #2. Check YES even if the project is Exempt under NAS or ISSCR guidelines.

   The use of the following types of human cells require ESCRO review and oversight: embryonic stem cells, totipotent or pluripotent cells, pluripotent stem cell lines, neural and gonadal progenitor stem cells, or other somatic tissues for stem cell research (excluding cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential). For guidance, ask the ESCRO staff from your organization and refer to Section E of Appendix A-2 of the Sample Contract found here as Attachment 5 to this RFA.

If activities involving human stem cells **as defined above** are not planned at any time during the proposed project, check NO to #2 and skip the rest of the form.

3. If YES is checked in #2, is the project Exempt from National Academy of Sciences (NAS) or International Society for Stem Cell Research (ISSCR) guidelines for human stem cell research? Check YES or NO.

4. If YES is checked in #3, check the appropriate exemption. **NOTE:** This exemption must be determined and documented by the ESCRO. Exemptions are outlined in Section E of Appendix A-2 of the Sample Contract found here as Attachment 5 to this RFA.

5. If NO is checked in #3, is the ESCRO review pending? Check YES or NO.

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

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

Section B

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

1) *Involvement of Human Stem Cells*
Describe the involvement of human stem cells as outlined in the research plan. Include descriptions of the cell lines to be used, e.g., source or means of derivation of the cell lines, donor consent procedures specific to stem cell derivation including donor reimbursement or payment as applicable, and characterization of the stem cell lines or embryonic sources as known. If new cell lines are to be derived, explain the justification for such new derivation. For any new derivation of the specified human stem cell lines *Form 16, Human Subjects* research must also be completed. For any use of the specified human stem cells in conjunction with animal studies, *Form 17, Vertebrate Animals* must also be completed.

2) *Sources of Materials - Confidentiality*
If specified human stem cell lines are to be obtained from sources outside the awarded 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) *Therapeutics*
If a therapeutic or biological is involved, describe the product and state whether the 30-day interval between submission of the applicant certification to the FDA and its response has

elapsed or has been waived and/or whether use of the biological has been withheld or restricted by the FDA.

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

VI. Application Review and Award Process

A. Application Acceptance

Applications will first be examined against mandatory Pass/Fail requirements by NYSTEM administrators **(see Attachment 1)**. Applications that do not meet the mandatory requirements will not be considered for review, and the applicant institution and PI will be notified.

B. Review and Scoring

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

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

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

The Review Panel will identify potential overlap with other resources. Additionally, the Review Panel will comment on the application with regard to the Contract Policy Statements and Conditions (Sample Contract Appendix A-2). The Review Panel may recommend administrative review and resolution prior to contract execution. In addition, award recommendations made by the ESSCB Funding Committee may be contingent upon the applicant's acceptance of required revisions.

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

C. Application Penalties and Summary Statements

The Peer Review Contractor will assess a penalty of 0.1 point for each application that scores between 1.0 and 4.0 and deviates from the instructions in Section V. above or those found on the forms **(also see Attachment 1)**.

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

D. Review Criteria

Three evaluation criteria are considered by the Review Panel:

SIGNIFICANCE AND IMPACT (50%)

- Does the research project address an important problem or critical barrier to progress in a defined field of stem cell research?
- Is the proposed work a refinement, an improvement or a new application of concepts, methodologies, instrumentation or clinical practice in stem cell science?
- Does the application challenge paradigms of current research or clinical practice?
- Is stem cell related scientific knowledge, technical capability or clinical practice likely to be improved by the proposed project? **and/or**
- Is the project likely to have potential therapeutic significance?
- Is the project likely to have a sustained impact on the field?

APPROACH AND FEASIBILITY (30%)

- Are the overall strategy, proposed methods and analyses well-reasoned and the most appropriate to accomplish the specific aims of the project within the award period?
- Are the uses of human subjects, vertebrate animals and human pluripotent stem cells appropriate to the overall goals of the project?
- If the project is in an early stage of development, speculative or exploratory (as may be the case with IDEA proposals, for example), will the proposed work establish feasibility if successful?
- Are potential problems discussed and alternative strategies provided?

- Are the knowledge, skills, research tools, experience, and time commitments of the research team appropriate to complete the proposed work?
    - For Early Stage Investigators, do they have appropriate training and experience to lead the project?
    - For established investigators, have they demonstrated a track record of achievements advancing their field?
    - Are other team members appropriate for their roles in the project?
- Does the overall environment contribute to the likelihood of success? Are the scientific resources, equipment and institutional support available to investigators adequate for the proposed work? Are there unique features of the project environment that strengthen the application, such as access to research samples or subject populations?

BUDGET (20%)

- Are the items for each budget line explained?
- Are budget line items adequately justified as necessary for completion of the project?
- Are the budgeted amounts reasonable, cost effective and appropriate to accomplish the research aims?
- Are there specific excessive or unnecessary budget items?

E. Empire State Stem Cell Board Funding Committee Review

The ESSCB Funding Committee will consider applications that receive a final score (after penalties are assessed) of 1.0 through 4.0. The ESSCB Funding Committee will not consider applications that receive a final score of 4.1 to 9.

The ESSCB Funding Committee will discuss the application strengths and weaknesses, administrative and budget recommendations. When making funding recommendations, the ESSCB Funding Committee will consider responsiveness to the mission of the ESSCB, responsiveness to the RFA, programmatic balance, availability of funds, and compliance with Public Health Law Article 2, Title 5-A, §265. Scoring ties will be resolved on the basis of the above and with consideration of the score for Significance and Impact among those applications involved in the tie.

The ESSCB Funding Committee will vote on each application that scores 4.0 or better until available funds are exhausted and in compliance with ESSCB bylaws as well as applicable laws and regulations. The ESSCB Funding Committee has allocated an approximate amount of funding to this RFA. When that funding level has been reached, it may decide to "approve but not fund" a small number of applications. In the event that one or more of the funded awards is not accepted or cannot be finalized, funds may be made available to one or more of the "approved but not funded" applications. If an application that scores between 1.0 and 4.0, for which there are available funds is not recommended for funding, the ESSCB Funding Committee will fully justify in writing why the application was not approved. The ESSCB Funding Committee will make recommendations for funding to the Commissioner of Health.

F. Award Decisions and Pre-Funding Requirements

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

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

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

- Revisions to Workplan, project duration or budget
- Funding overlap
- Areas of possible concern with regard to Contract Policy Statements and Conditions (Attachment A-2)
- Approved Facilities and Administrative Cost Rate.

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

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

Applicants agree that all state funds dispersed under this procurement will, if applicable to them, be bound by the terms, conditions, obligations and regulations promulgated or to be promulgated by the Department in accordance with Executive Order 38, ("Limits on State Funded Administrative Costs and Executive Compensation"), signed in 2012.

G. Award Announcements

NYSTEM makes public in press releases and annual reports to the Governor and Legislature, the project title, the PI(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.

ATTACHMENT 1
APPLICATION CHECKLIST AND FORMS 1-18

APPLICATION CHECKLIST

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

- ☐ The application was received by due date and time *(see cover sheet and pg. 5)*
- ☐ Application was submitted digitally on a single CD or DVD (see pg. 10)
- ☐ If the digital files are damaged, an exact paper copy has been submitted *(see pg. 10)*
- ☐ The applicant is a New York State not-for-profit or governmental organization *(see pg. 2)*
- ☐ The PI serves in that role for only one application per funding mechanism in response to this RFA *(see pg. 2)*
- ☐ Professional effort of the Principal Investigator on the project is at least 20% for IIRP and at least 10% for IDEA throughout the contract term *(see pg. 3 and Instructions for completion of Form 8)*

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

- ☐ Vendor Responsibility Attestation (Attachment 2)
- ☐ Letters of collaboration or support; commitment(s) to provide research resources; subcontract letter(s) from consultant(s)
- ☐ Memoranda of Understanding, Subcontracts or Contractual Agreements
- ☐ Up to two highly relevant publications or manuscripts (published or in press) may be included if essential to document the investigator's capability to undertake the work proposed
- ☐ Facilities and Administrative rate agreements
- ☐ Equipment quotes

APPLICATION PENALTIES:

A total penalty of 0.1 point will be assessed to an application if:

- Digital submission is password protected
- Forms provided in this RFA are not used
- Submission does not adhere to page (or word count) limits (Forms 4, 10, 13 and 14)
- Submission does not include:
  - Applicant Forms 1 – 6 in a single Microsoft Word (DOC or DOCX) file (Form 6 may be blank)
  - Applicant Forms 1 – 6 in a single Portable Document Format (PDF) file (Form 6 may be blank)
  - Forms 7 – 18 and all appendix material in a single PDF file
  - Sub-applicant Form 1-S for each Sub-applicant in Microsoft DOC or DOCX file (Form 1-S may be omitted if there are no Sub-applicants included in the application) **NOTE:** No other forms may be omitted
  - Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned as a single PDF file **NOTE:** Form 1-S may be omitted if there are no sub-applicants; No other forms may be omitted
  - Budget – Form 8 – one for the applicant and one for each sub-applicant organization
  - Personal Effort and Budget Justification – Form 9 – one for the applicant and one for each sub-applicant organization
  - Biographical Sketch – Form 10 – one for each key personnel listed on each Form 9
  - Facilities and Resources – Form 11 – one for the applicant and one for each sub-applicant organization
  - Other Support – Form 12 – one for each key personnel listed on each Form 9
  - Introduction – Form 13 – may be left blank or marked "N/A" if application is not a resubmission
  - Human Subjects – Form 16 – at least one per applicant and each sub-applicant, and one for each protocol used for this research project (Section A, and Section B if required, must be completed on each)
  - Vertebrate Animals – Form 17 – at least one per applicant and each sub-applicant, and one for each protocol used for this research project (Section A, and Section B if required, must be completed on each)
  - Human Stem Cells – Form 18 – at least one per applicant and each sub-applicant, and one for each protocol used for this research project (Section A, and Section B if required, must be completed on each)

Form 1 - Applicant Face Page

Project Title:				NYSTEM Application #: **FOR NYSTEM USE ONLY**	
RFA #:1206180230 Application Type: ☐ IDEA ☐ IIRP	New: ☐Yes ☐ No	Resubmission: ☐ Yes ☐ No	Original Application #:	Continuation: ☐IDEA to IIRP ☐IIRP Continuation ☐Not a Continuation	Early Stage Inv.: ☐ Yes ☐ No

Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) , , ,	Co-Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) ***(If different organization, do not complete this section – requires sub-applicant face page, Form 1-S)*** , , ,
Organization:	Organization:
Department:	Department:
Mailing Address (Street, MS, PO Box, City, State, Zip): Street 1 Street 2 City State NY Zip	Mailing Address (Street, MS, PO Box, City, State, Zip): Street 1 Street 2 City State NY Zip
Phone: Fax:	Phone: Fax:
E-mail:	E-mail:
Type of Organization: ☐ Governmental ☐ Not-for-profit	
NYS Vendor ID # (10 digits):	Charities Registration Number (or "Exempt category"):
Project Start/End: - Year One Grand Total Costs:	Grand Total Costs:
New York State Applicant Organization: Mailing Address: Street 1 Street 2 City State NY Zip	Research Performing Sites:
Contracts and Grants Official: Last Name First Name Title	Official Signing for the Organization: Last Name First Name Title
Mailing Address: Street 1 Street 2 City State NY Zip	Organization Name and Mailing Address: Name Street 1 Street 2 City State NY Zip
Phone: Fax:	Phone: Fax:
E-mail:	E-mail:

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

SIGNATURES OF PRINCIPAL INVESTIGATOR and CO-PI:

X DATE:

X DATE:

SIGNATURE OF THE OFFICIAL SIGNING FOR THE APPLICANT ORGANIZATION:

X DATE:

Form 1

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

Form 1-S – Sub-Applicant Face Page

Project Title:			
RFA #: 1206180230			
Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) , , , Overall Project Co-PI? ☐		Co-Principal Investigator: Last Name, First Name, Middle Initial, Degree(s) , , ,	
Organization:		Organization:	
Department:		Department:	
Mailing Address (Street, MS, PO Box, City, State, Zip): Street 1 Street 2 City State Zip		Mailing Address (Street, MS, PO Box, City, State, Zip): Street 1 Street 2 City State Zip	
Phone:	Fax:	Phone:	Fax:
E-mail:		E-mail:	
Type of Organization: ☐ Governmental ☐ Not-for-profit ☐ Profit			
Federal Employer ID # (9 digits):		Charities Registration Number (or "Exempt category"):	
Project Start/End: -	Year One Grand Total Costs:		Grand Total Costs:
Sub-applicant Organization: Mailing Address: Street 1 Street 2 City State Zip		Research Performing Sites:	
Contracts and Grants Official: Last Name First Name Title		Official Signing for the Organization: Last Name First Name Title	
Mailing Address: Street 1 Street 2 City State NY Zip		Organization Name and Mailing Address: Name Street 1 Street 2 City State NY Zip	
Phone:	Fax:	Phone:	Fax:
E-mail:		E-mail:	
CERTIFICATIONS AND ASSURANCE: Prior to award recommendation, the sub-applicant PI, Co-PI and organizational official are required to sign and date this form. Signatures denote the following: certification that the statements herein are true and complete to the best of the signatories' knowledge; and agreement to comply with the terms and conditions of any contract awarded as a result of this application.			
SIGNATURES OF SUB-APPLICANT PRINCIPAL INVESTIGATOR and CO-PI:			
X		DATE:	
X		DATE:	
SIGNATURE OF THE OFFICIAL SIGNING FOR THE SUB-APPLICANT ORGANIZATION:			
X		DATE:	

Form 1-S
Submit a separate Form 1-S for each sub-applicant as a Word document file. Also submit each Form 1-S as part of a single PDF file containing the scanned copies of all ***SIGNED*** Forms 1 and 1-S. If no sub-applicants are part of the application, omit this form.

Form 2 – Staff, Collaborators, Consultants and Contributors
List (spell out) the full name, title and institutional affiliation of all staff, collaborators, consultants and contributors (both paid and unpaid) associated with this project. Do not include the PI and Co-PIs named on any Form 1 or 1-S in the application. Do not include unnamed or “to be determined” staff positions. For each individual listed, select the most applicable role from the dropdown box. This list is used to determine possible conflicts of interest at various stages of the review and award process.

Last Name	First Name	Title	Institutional Affiliation	Role in Project

Form 3 – Acronyms and Abbreviations Used in Application

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

Acronym	Full Text/Definition/Description

Form 4 – Lay Abstract

Provide a summary of the proposed project, in non-technical terms; limit to 300 words (do a word count, as the fill-in box may allow more than 300 words). Do not include confidential information. This information will be excerpted and edited for use in various public documents. Specifically, provide an Introduction/Background, Summary of Goals and Objectives, and Significance and Expected Impact of the Project.

Form 5 – Scientific Abstract

List any human embryonic cell lines and the source of such lines. If applicable, include the name and/or NIH Registration number from http://stemcells.nih.gov/research/registry.

Provide a scientific summary of the proposed project. The abstract should be written so that persons from diverse scientific backgrounds can easily understand the work proposed. Do not include confidential information. Do not exceed one page for information on this form.

Form 5
Submit Forms 1-6 together in two formats: one PDF file and one Word document file.

Form 6 – Peer Review Panel Identification - OPTIONAL

Applicants are not required to complete this form. It must be submitted, but may be left blank

Historically, applications in response to this NYSTEM RFA have fallen into several categories. To facilitate assembly of review panels, the applicant may suggest up to two review panel categories most closely suited to the application. This identification does not guarantee assignment of the application to those review panels.

In addition, applicants may provide a list of up to 10 most relevant Key Words to describe the project, which will also be used to identify potential peer reviewers.

General Application Categories

1. Stem Cells and Cancer
2. Cardiovascular Stem Cells
3. Hematopoietic Stem Cells
4. Neural Stem Cells
5. Stem Cell Characterization and Lineage
6. Reprogramming and Directed Differentiation
7. Stem Cell Engineering and Technology
8. Translational Science and Therapy
9. Other

Select up to two categories that the applicant feels are most closely suited to the application.

Primary Category #
Secondary Category # If #9, please specify:

In addition, please provide a list of up to 10 most relevant Key Words to describe this project.
(This information will be used to identify potential peer reviewers):

Key Words

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

Form 7 – Table of Contents

* Indicate “N/A” on the Table of Contents if not applicable for these forms **only:**
  - 1-S Sub-applicant Face page
  - 8 Budget, Sub-Applicant Organization(s)
  - 9 Personnel and Budget Justification, Sub-applicant Organization(s)
  - 13 Introduction

Additional table rows may be added to identify specific appendix material.

Submit Forms 7-18 and all appendix material in a single PDF file of not greater than 12MB.

Form 8 – Budget – Name of Applicant or Sub-Applicant_____

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

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				
	MISCELLANEOUS				
	SUBTOTAL OTHER EXPENSES				
9	**SUBTOTAL OTPS** (sum of lines 4 thru 8)				
10	**TOTAL PS & OTPS** (lines 3+9)				
11	**TOTAL SUBCONTRACT COSTS** (sum of line 14 of all sub-applicant budgets)				
12	**TOTAL DIRECT COSTS** (lines 10+11)				
13	FACILITIES AND ADMINISTRATIVE COSTS				
14	**GRAND TOTAL COSTS** (lines 12+13)				

Form 9 – Personal 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 8.						

***** Insert additional lines as necessary under Key Personnel or Support Personnel. A PI for IIRP must commit a minimum of 20% professional effort throughout the contract term, and a PI for IDEA must commit a minimum of 10% professional effort throughout the contract term.

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

Submit Forms 7-18 and all appendix material in a single PDF file of not greater than 12MB.

Describe and justify the key personnel and technical staff.

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

Supplies

Equipment

Travel

Consultant Costs

Other Expenses

Form 10 – Biographical Sketch

Not to exceed 3 pages per individual. Present PI first, followed by Co-PI(s) and the remaining key personnel in alphabetical order using additional copies of Form 10.

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. Personal Statement. Include a brief personal statement to describe how the experience and qualifications make the individual particularly well-suited for the identified role in the project.

B. 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.

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

Form 11 – Facilities and Resources

Not to exceed two pages per collaborating institution. Attach sub-applicant information using additional copies of Form 11.

FACILITIES:

Describe the facilities available for performance of the proposed project including headings for: Laboratory, Clinical, Animal, Computer, Office and Other (such as machine shop and electronics shop), as appropriate. Specify the extent to which such services will be available to the project. Indicate the performance site(s) and describe pertinent site capabilities, relative proximity and extent of availability to the project. Also indicate institutional commitment, including any additional facilities or equipment to be provided in support of the project or available for use at no cost to the project.

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

Form 12 – Other Support

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

Provide the current information requested for **all key personnel** on all existing and pending support. Applications submitted to NYSTEM should not duplicate other funded projects in whole or in part. The PI and the contracting organization are responsible for identifying and notifying NYSTEM administration staff of any changes in funding overlap information from time of application submission throughout the contract term.

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

NAME OF KEY PERSONNEL: _____

Check here if this person has no other source of Active or Pending support: ☐

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

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

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

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

Form 13 – Introduction
If the application is **not** a Resubmission, leave blank or mark 'Not Applicable (N/A).'

If the application is a Resubmission, in no more than one page, summarize the substantial additions, deletions and changes that have been made to the original application. Include a response to the issues and criticism raised in the original review. The Workplan should incorporate any relevant work done since the previous application. All changes in the Workplan from the previous submission should be indicated by bracketing, indenting or change in typography. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction.

Form 14 – Workplan

Follow all page limitations. Sections A-D are limited as follows: 12 pages for IIRP applications; and 10 pages for IDEA applications. Submit Forms 7-18 and all appendix material in a single PDF file of not greater than 12MB.

Form 15 – Time Line and Collaboration Strategy

Complete the table provided. Add table rows and pages as necessary to provide sufficient detail to allow monitoring of progress toward project goals. A copy of Form 15 will be included in any awarded contract; therefore, it should be sufficiently detailed to allow monitoring of progress toward project goals. Submit Forms 7-18 and all appendix material in a single PDF file of not greater than 12MB.

Number and Description of Aim or Sub-aim	Name of Responsible Investigator and Institution	Specific Activities	Time Frame

Also, describe strategies for information and/or data/resource sharing to ensure efficient and effective achievement of the timeline and completion of the project. Discuss management of intellectual property rights and related issues, including compliance with anticipated contract provisions (see Attachment 5, Sample Contract). Include frequency and methods of communications. Include strategies to overcome potential problems with communication and/or data and resource sharing.

Form 16 – Human Subjects
Instructions for the proper completion of this form are found in Section V., Instructions for Completing the Application.

SECTION A:

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

SECTION B – NARRATIVE (use additional pages if necessary)

.

Form 17 – Vertebrate Animals
Instructions for the proper completion of this form are found in Section V., Instructions for Completing the Application).

SECTION A:

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

SECTION B – NARRATIVE (use additional pages if necessary)

.

Form 18 – Human Stem Cells
Instructions for the proper completion of this form are found in Section V., Instructions for Completing the Application).

SECTION A:

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

SECTION B – NARRATIVE (use additional pages if necessary)

.

ATTACHMENT 2

Vendor Responsibility Attestation
Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) Awards for 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 3

Letter of Intent

New York State Department of Health, NYSTEM and the ESSCB
Investigator Initiated Research Projects (IIRP) and Innovative, Developmental or Exploratory Activities (IDEA) Awards for Stem Cell Research RFA# 1206180230

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

Please provide a separate Letter of Intent form for each anticipated application. NOTE: The PI may submit only one application *per funding mechanism* in response to this RFA.

Indicate the type of application that will be submitted in response to this RFA:

Investigator Initiated Research Project (IIRP) _____ **OR** IDEA _____

Please provide a descriptive title of the proposed project(s) and list up to 10 most relevant Key Words to describe the intended application (this information will be used to recruit potential peer reviewers):

Title: _____

Key Words: _____
_____
_____

I. Investigator Information (please print or type)

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

II. Collaborator Information (please print or type)

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

Collaborator Information (cont.)

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

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

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

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

Information for additional collaborators may be appended here, if necessary.

SIGNATURE OF PRINCIPAL INVESTIGATOR: 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 OFFICIAL SIGNING FOR THE APPLICANT ORGANIZATION: X	DATE:

ATTACHMENT 4

NEW YORK STATE DEPARTMENT OF HEALTH **Statewide Vendor File Registration**
Request for Information – SFS Portal Format

New Vendor Request

1*	**Vendor Name1:**				
2	**Vendor Name2:**				
3*	**Vendor Contact Name:**				
4	**Vendor Email ID:**				
5	**Withholding Class:**				
6*	**Vendor Tax ID Number:**				
7	**AddressID: 1**	**Description: Remit To**			
8	**Country: USA**				
9*	**Address Line 1:**				
	Address Line 2:				
	Address Line 3:				
	Address Line 4:				
10*	**City:**	**11**	**County:**	**12***	**Postal Code:**
13*	**State:**				

For DOH Use Only

14* Contact Name:	
15* Email ID:	

***** *indicates required field*

Field Descriptions

Field#	Title	Description
1*	**Vendor Name1**	Vendor name should denote 'Vendor Legal Name' as shown on W-9. Name fields are a maximum of 40 characters in length. Do not use a DBA name.
2	**Vendor Name 2**	Use only if Vendor Name 1 exceeds 40 characters in length.
3*	**Contact Name ("Primary Contact")**	Provide name of the individual who will act as the business's Primary Contact in the Statewide Vendor File and will receive the business's vendor ID and Vendor Self-Service login credentials from OSC upon successful registration.. This individual should be a person who makes legal and financial decisions for the business.
4	**Vendor EmailID***	Email address is that of the vendor contact.
5	**Withholding Class**	SFS default is withholding class 07, Non-Employee Compensation.
6*	**TIN**	Vendor's tax identification number (FEIN or SSN)
7	**Address ID and Description**	Registration address must be a primary remit-to address. Do not change default value = 1.
8	**Country**	Defaults to USA. Do **not** use this form for a non-US vendor. Contact OSC or the SFS Help Desk (855-233-8363 or 518-457-7717 for details regarding Statewide Vendor File registration for foreign entities.
9*	**Address Line 1-4**	At least one address line is required. Lines 2-4 provide additional details for the primary remit-to address—they do not represent additional vendor addresses.
10*	**City**	City associated with primary remit-to address.
11	**County**	Optional field, but associated with primary remit-to address.
12*	**Postal Code**	Zip code associated with primary remit-to address.
13*	**State**	State associated with primary remit-to address
For DOH Use Only		
14	**Contact Name**	Individual from Program area facilitating registration
16	**Contact Email**	Email for individual named in (13) – will receive email from OSC when vendor is registered.

*** = Required field**

ATTACHMENT 5
Sample Contract *
(11/12)

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

GRANT CONTRACT (MULTI YEAR)

STATE AGENCY(Name and Address):
New York State Department of Health
(Insert Specific Program/Address Here)

CONTRACT NUMBER:
_____

ORIGINATING AGENCY GLBU: DOH01

DEPARTMENT ID: _____

CONTRACTOR (Name and Address):

TYPE OF PROGRAM(S):

NYS VENDOR IDENTIFICATION NUMBER:

MUNICIPALITY NUMBER (If Applicable):

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

MULTI YEAR CONTRACT PERIOD:
FROM:
TO:

FUNDING AMT. FOR INITIAL PERIOD:

TOTAL MULTI-YEAR FUNDING AMT.:

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

THE CONTRACTOR ……. Is ☐ Is Not ☐
A Sectarian Entity

THE CONTRACTOR ……. Is ☐ Is Not ☐
A Not-For-Profit Organization

APPENDICES ATTACHED AND PART OF THIS AGREEMENT

____	Appendix A	Standard Clauses as required by the Attorney General for all State Contracts
____	Appendix A-1	Agency-Specific Clauses (Rev. 10/12)
____	Appendix B	Budget
____	Appendix C	Payment and Reporting Schedule
	Appendix D	Program Workplan
____	Appendix X	Modification Agreement Form [to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods]

OTHER APPENDICES

____	Appendix A-2	Program-Specific Clauses
____	Appendix E-1	Proof of Workers' Compensation Coverage
____	Appendix E-2	Proof of Disability Insurance Coverage
____	Appendix H	Federal Health Insurance Portability and Accountability Act Business Associate Agreement
____	Appendix R	On-going Vendor Responsibility
	Appendix ___	

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

CONTRACT NUMBER:
_____

CONTRACTOR:

By: _____

_____
Printed Name

Title: _____

Date: _____

STATE AGENCY:
New York State Department of Health

By: _____

_____
Printed Name

Title: _____

Date: _____

STATE AGENCY CLARIFICATION:
"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 _____, _____, before me personally appeared _____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, that he/she is the _____ of the _____, the corporation described herein which executed the foregoing instrument; and that he/she signed his/her name thereto by order of the board of directors of said corporation.

_____
(Notary)

ATTORNEY GENERAL'S SIGNATURE

Title: _____

Date: _____

STATE COMPTROLLER'S SIGNATURE

Title: _____

Date: _____

STATE OF NEW YORK
MULTI YEAR AGREEMENT

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

WITNESSETH:

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

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

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

I. Conditions of Agreement

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

B. Funding for the entire contract period shall not exceed the amount specified as “Total Multi-Year Funding Amount” on the face page hereof.

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

D. 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, change in scope or change in the term, is subject to the approval of the Office of the State Comptroller. Any other modifications shall be processed in accordance with agency requirements as stated in Appendix A-1.

E. Any proposed modification to a contract that will result in a transfer of funds among program activities or budget cost categories, but does not affect the amount, consideration, scope or other terms of such contract must be submitted to OSC for approval when:

The amount of the modification is equal to or greater than ten percent of the total value of the contract for contracts of less than five million dollars; or

The amount of the modification is equal to or greater than five percent of the total value of the contract for contracts of more than five million dollars.

F. 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 Work plan (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.

G. 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.

H. 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, 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 claim, 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 or 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 in confidence and used only for the purposes intended under the contract and in conformity with applicable provisions of laws and regulations, and as may be specified in Appendix A-1.

STANDARD CLAUSES FOR NYS CONTRACTS

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

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

2. NON-ASSIGNMENT CLAUSE. In accordance with Section 138 of the State Finance Law, this contract may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet or otherwise disposed of without the State's previous written consent, and attempts to do so are null and void. Notwithstanding the foregoing, such prior written consent of an assignment of a contract let pursuant to Article XI of the State Finance Law may be waived at the discretion of the contracting agency and with the concurrence of the State Comptroller where the original contract was subject to the State Comptroller's approval, where the assignment is due to a reorganization, merger or consolidation of the Contractor's business entity or enterprise. The State retains its right to approve an assignment and to require that any Contractor demonstrate its responsibility to do business with the State. The Contractor may, however, assign its right to receive payments without the State's prior written consent unless this contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

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

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

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

6. WAGE AND HOURS PROVISIONS. If this is a public work contract covered by Article 8 of the Labor Law or a building service contract covered by Article 9 thereof, neither Contractor's employees nor the employees of its subcontractors may be required or permitted to work more than the number of hours or days stated in said statutes, except as otherwise provided in the Labor Law and as set forth in prevailing wage and supplement schedules issued by the State Labor Department. Furthermore, Contractor and its subcontractors must pay at least the prevailing wage rate and pay or provide the prevailing supplements, including the premium rates for overtime pay, as determined by the State Labor Department in accordance with the Labor Law. Additionally, effective April 28, 2008, if this is a public work contract covered by Article 8 of the Labor Law, the Contractor understands and agrees that the filing of payrolls in a manner consistent with Subdivision 3-a of Section 220 of the Labor Law shall be a condition precedent to payment by the State of any State approved sums due and owing for work done upon the project.

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

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

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

10. RECORDS. The Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance under this contract (hereinafter, collectively, "the Records"). The Records must be kept for the balance of the calendar year in which they were made and for six (6) additional years thereafter. The State Comptroller, the Attorney General and any other person or entity authorized to conduct an examination, as well as the agency or agencies involved in this contract, shall have access to the Records during normal business hours at an office of the Contractor within the State of New York or, if no such office is

available, at a mutually agreeable and reasonable venue within the State, for the term specified above for the purposes of inspection, auditing and copying. The State shall take reasonable steps to protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law (the "Statute") provided that: (i) the Contractor shall timely inform an appropriate State official, in writing, that said records should not be disclosed; and (ii) said records shall be sufficiently identified; and (iii) designation of said records as exempt under the Statute is reasonable. Nothing contained herein shall diminish, or in any way adversely affect, the State's right to discovery in any pending or future litigation.

11. IDENTIFYING INFORMATION AND PRIVACY NOTIFICATION.
(a) Identification Number(s). Every invoice or New York State Claim for Payment submitted to a New York State agency by a payee, for payment for the sale of goods or services or for transactions (e.g., leases, easements, licenses, etc.) related to real or personal property must include the payee's identification number. The number is any or all of the following: (i) the payee's Federal employer identification number, (ii) the payee's Federal social security number, and/or (iii) the payee's Vendor Identification Number assigned by the Statewide Financial System. Failure to include such number or numbers may delay payment. Where the payee does not have such number or numbers, the payee, on its invoice or Claim for Payment, 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 the Statewide Financial System by the Vendor Management Unit within the Bureau of State Expenditures, Office of the State Comptroller, 110 State Street, Albany, New York 12236.

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

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

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

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

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

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

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

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

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

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

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

In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the

prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

19. 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
Albany, New York 12245
Telephone: 518-292-5100
Fax: 518-292-5884
email: opa@esd.ny.gov

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

NYS Department of Economic Development
Division of Minority and Women's Business Development
633 Third Avenue
New York, NY 10017
212-803-2414
email: mwbecertification@esd.ny.gov
http://esd.ny.gov/MWBE/directorySearch.html

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

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

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

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

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

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

22. COMPLIANCE WITH NEW YORK STATE INFORMATION SECURITY BREACH AND NOTIFICATION ACT. Contractor shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208).

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

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

25. CERTIFICATION OF REGISTRATION TO COLLECT SALES AND COMPENSATING USE TAX BY CERTAIN STATE CONTRACTORS, AFFILIATES AND SUBCONTRACTORS.
To the extent this agreement is a contract as defined by Tax Law Section 5-a, if the contractor fails to make the certification required by Tax Law Section 5-a or if during the term of the contract, the Department of Taxation and Finance or the covered agency, as defined by Tax Law 5-a, discovers that the certification, made under penalty of perjury, is false, then such failure to file or false certification shall be a material breach of this contract and this contract may be terminated, by providing written notification to the Contractor in accordance with the terms of the agreement, if the covered agency determines that such action is in the best interest of the State.

APPENDIX A-1
(REV 10/12)

AGENCY SPECIFIC CLAUSES FOR ALL
DEPARTMENT OF HEALTH CONTRACTS

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

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

3. Administrative Rules and Audits:

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

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

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

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

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

      iv. For a hospital, use the principles in OMB Circular A-110, Department of Health and Human Services, 45 CFR 74, Appendix E, "Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals" and, if not covered for audit purposes by OMB Circular A-133, “Audits of States Local Governments and Non-profit Organizations”, then subject to program specific audit requirements following Government Auditing Standards for financial audits.

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

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

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

      ii. If this contract is funded from other than federal funds or if the contract is funded from a combination of STATE and federal funds but federal funds are less than $500,000, and if the CONTRACTOR receives $300,000 or more in total annual payments from the STATE, the CONTRACTOR shall submit to the STATE after the end of the CONTRACTOR's fiscal year an audit report. The audit report shall be submitted to the STATE within thirty

days after its completion but no later than nine months after the end of the audit period. The audit report shall summarize the business and financial transactions of the CONTRACTOR. The report shall be prepared and certified by an independent accounting firm or other accounting entity, which is demonstrably independent of the administration of the program being audited. Audits performed of the CONTRACTOR's records shall be conducted in accordance with Government Auditing Standards issued by the Comptroller General of the United States covering financial audits. This audit requirement may be met through entity-wide audits, coincident with the CONTRACTOR's fiscal year, as described in OMB Circular A-133. Reports, disclosures, comments and opinions required under these publications should be so noted in the audit report.

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

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

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

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

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

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

a. LOBBYING CERTIFICATION

i. 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.

ii. 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.

iii. 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 2701, 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.

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

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

b) A request for or receipt of a contract (other than a contract referred to in clause (c) below), grant, cooperative agreement, subcontract (other than a subcontract referred to in clause (c) below), or subgrant that does not exceed $100,000; and

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

b. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE:

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

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

c. CERTIFICATION REGARDING DEBARMENT AND SUSPENSION

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

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

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

Instructions for Certification

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12. Other Modifications

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

    - Appendix B - any proposed modification to the contract which results in a change equal to or greater than 10 percent (for contracts less than five million dollars) or 5 percent (for contracts more than five million dollars) to the total contract value 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:

    a. 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

    b. 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.

17. Notices:

    All notices permitted or required hereunder shall be in writing and shall be transmitted either: a) via certified or registered United States mail, return receipt requested; b) by facsimile transmission; c) by personal delivery; d) by expedited delivery service; or e) by e-mail.

    Such notices shall be addressed as follows or to such different addresses as the parties may from time to time designate:

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

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

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

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

ATTACHMENT A-2

Empire State Stem Cell Board
Contract Policy Statements and Conditions
Rev. 6/27/12

A. Research Integrity and Responsible Conduct of Research

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

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning stem cell biology. In carrying out such research, the rights and welfare of all individual research participants are of critical importance. Furthermore, additional safeguards must protect especially vulnerable research subjects, including minors, mentally disabled adults who lack capacity to provide informed consent to research participation, and prisoners. Accordingly, no research study shall commence unless it has been approved by an Institutional Review Board (IRB) and a copy of the current approval has been submitted to NYSTEM. Further, the following requirements shall be satisfied:

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

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

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

- If applicable, the 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 within 24 hours of such determination.

C. Animal Use

NYSTEM requires that all individuals and organizations that conduct research using animals supported by the Empire State Stem Cell Fund adhere to all federal, state and local laws pertaining to humane care and use of animals for research purposes. Accordingly, no research study shall commence unless it has been reviewed and approved by an Institutional Animal Care and Use Committee (IACUC) whose guidelines are in compliance with the U.S. Public Health Service's *Policy on Humane Care and Use of Laboratory Animals,* and *Guide for the Care and Use of Laboratory Animals,* as well as any other federal, state and local laws or regulations relating to animal care and use (*e.g.*, the federal Animal Welfare Act, (7 USC 2131 *et seq*.) and its implementing regulations; and PHL Article 5, Title I, §§504 and 505-a).

D. Other Compliance Requirements

1. *Human Tissue*

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

2. *Analytical Testing of Human Specimens*

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

3. *Recombinant DNA*

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

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:

   a) human embryonic stem cells;

   b) human totipotent or pluripotent cells;

   c) human pluripotent stem cell lines;

   d) human neural and gonadal progenitor stem cells; or

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

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

3. *Embryonic Stem Cell Research Oversight (ESCRO) Committees*.

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

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

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

study shall commence unless it is demonstrated that research protocols have been reviewed and approved by the ESCRO committee.

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

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

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

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

ii) Conflict of Interest Policies: The policies shall address conflicts of interest in a manner that is in alignment with other institutional conflict of interest policies, including, but not limited to, those governing the activities of the IRB. Such policies shall preclude a member from participating in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the ESCRO Committee.

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

years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

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

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

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

c) *Re-consent*: Consent to donation shall be obtained at the time of the proposed transfer of the materials to the research team. With respect to obtaining re-consent to donation, ESCRO Committees should apply the standards set forth in

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

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

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

i) Whenever possible, the person conducting the informed consent dialogue should have no vested interest in the research protocol. If members of the research team participate in the informed consent process, their role must be disclosed and care must be taken to ensure that information is provided in a transparent and accurate manner.
ii) Empirical research has shown that informed consent is most effective as a dynamic, interactive, and evolving process as opposed to a static, one-time disclosure event. Thus, researchers should provide ample opportunities for providers of human materials to discuss their involvement in the research protocol.
iii) Counseling services should be made available upon request to any providers of human materials prior to procurement.
iv) Procurement procedures should be revised in light of a) ongoing studies of the long-term risks associated with oocyte retrieval; and b) research on informed consent for all types of human biological materials procurement.
v) Researchers should consider on a regular basis, subject to annual review, the possible use of alternatives to hormonally induced oocytes procured solely for stem cell research, such as oocytes derived from pluripotent stem cells, in vitro maturation of oocytes from ovariectomy samples, and egg sharing programs offered through infertility clinics.

ISSCR Guideline 11.2,[5] or may choose to use the stricter standards set forth in NAS Guideline 3.2.[6]

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

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

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

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

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

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

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

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

[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.

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

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

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

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

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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.

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

5. *Payments to Gamete Donors*:

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

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

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

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

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

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

F. Publication and Intellectual Property Rights

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

    a. All publications reporting research supported by NYSTEM funds published in peer reviewed journals must be deposited in the National Institutes of Health National Library of Medicine's PubMed Central (PMC). NYSTEM encourages investigators to sign copyright agreements that specifically allow the published manuscript to be deposited for public posting on PMC. As investigators are encouraged to publish NYSTEM-funded research findings as "open access" publications, contract funds may be used to cover costs required for such "open access" publication.

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

    c. Support by the Empire State Stem Cell Fund shall be acknowledged in all publications, presentations and products of research in a form consistent with the publication's guidelines, (*e.g.*, "supported by the Empire State Stem Cell Fund through New York State Department of Health Contract # <<>>. Opinions expressed here are solely those of the author and do not necessarily reflect those of the Empire State Stem Cell Board, the New York State Department of Health, or the State of New York").

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

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

4. The contractor must have written agreements with researchers that require prompt disclosure of inventions made in the performance of ESSCB-funded research. The contractor shall notify NYSTEM of the invention disclosures and the filing of any patent application in the progress report pursuant to this contract. The contractor shall also provide NYSTEM with written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Fund. Any such assignment or transfer must acknowledge, and be subject to the rights retained by the State pursuant to paragraph 3, *supra*.

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

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

G. Other

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

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

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 (IIRP) and IDEA
Rev. approved 9/12

I. Payment and Reporting Terms and Conditions

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

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

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

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

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

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

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

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

C. Any optional advance payment(s) shall be applied by the STATE to future payments due to the CONTRACTOR for services provided during initial or subsequent PERIODS. Should funds for subsequent PERIODS not be appropriated or budgeted by the STATE for the purpose herein specified, the STATE shall, in accordance with Section 41 of the

State Finance Law, have no liability under this AGREEMENT to the CONTRACTOR, and this AGREEMENT shall be considered terminated and cancelled.

D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the program workplan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epayments@osc.state.ny.us or by telephone at 855-233-8363. The CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

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

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

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

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

F. The CONTRACTOR shall submit to the STATE quarterly voucher claims and reports of expenditures on such forms and in such detail as the STATE shall require. The

CONTRACTOR shall submit vouchers to the STATE's designated payment office located in the:

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

All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than thirty (30) days after the end date of the period for which reimbursement is claimed. The CONTRACTOR shall submit the final voucher for the contract term no later than sixty (60) days after the end date of the contract term. The final voucher must be marked as "Final."

In no event shall the amount received by the CONTRACTOR exceed the budget amount approved by the STATE, and, if actual expenditures by the CONTRACTOR are less than such sum, the amount payable by the STATE to the CONTRACTOR shall not exceed the amount of actual expenditures. All contract advances in excess of actual expenditures will be recouped by the STATE prior to the end of the applicable budget period.

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

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

II. Reports

A. Expenditure Reports

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

reports will require approval by NYSTEM staff prior to payment of the voucher that corresponds to the last quarter of the reporting period.

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

No less than sixty (60) days prior to the beginning of a new budget period, the CONTRACTOR shall submit a detailed budget and justification for the upcoming period. The justification will be consistent with the progress reports previously approved by NYSTEM. If the CONTRACTOR fails to submit a detailed budget and justification in accordance with this paragraph, the application budget shall be enforced for that period.

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

TABLE I
Annual Voucher and Expenditure Reporting Schedule

Voucher and Expenditure Report	Period Covered	Due Date*
1st Quarter	June 1 – August 31	September 30
2nd Quarter	September 1 – November 30	December 30
3rd Quarter	December 1 – February 29	March 30
4th Quarter	March 1 – May 31	June 30
Final (IDEA) Final (IIRP)	March 1, 2016 – May 31, 2016 March 1, 2017 – May 31, 2017	July 30, 2016 (IDEA) July 30, 2017 (IIRP)

*This table assumes no extensions; IDEA contracts are 2 years and IIRP contracts are 3 years. In either case, Vouchers and Expenditure Reports are due within 30 days of the end of each quarter of the contract term. The Final Voucher and Expenditure Report are due 60 days after the end of the contract term (or the end of the contract extension, if granted).

B. Progress Reports

The CONTRACTOR shall submit a written 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 II for annual schedule). These reports shall detail the CONTRACTOR's progress toward attaining the specific aims enumerated in the Workplan (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 files to the e-mail. All reports and forms are to be sent to

nystemgrants@wadsworth.org. The contract number and report being submitted shall be identified on the subject line of the e-mail (i.e., Contract # <<>>, Progress Report).

TABLE II
Progress Reporting Schedule

Progress Report #	Period Covered	Due Date*
1	June 1, 2014 – April 30, 2015	May 30, 2015
2	May 1, 2015 – October 31, 2015	November 30, 2015
3	November 1, 2015 – April 30, 2016	May 30, 2016
4 (IIRP)	May 1, 2016 – October 31, 2016	November 30, 2016
Final (IDEA) Final (IIRP)	June1, 2014 – May 31, 2016 June 1, 2014 – May 31, 2017	July 30, 2016 (IDEA) July 30, 2017 (IIRP)

*This table assumes no extensions; IDEA contracts are 2 years and IIRP contracts are 3 years. In either case, Progress Reports are due within 30 days of the end of each reporting period of the contract term and the Final Progress Report is due 60 days after the end of the contract term (or the end of the contract extension, if granted).

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 (i.e., a cumulative report), in the forms and formats as provided by NYSTEM (found online at http://stemcell.ny.gov).

APPENDIX D

WORKPLAN

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

Appendix R
On-going Vendor Responsibility

1. General Responsibility Language

The Contractor shall at all times during the Contract term remain responsible. The Contractor agrees, if requested by the Commissioner of Health or his or her designee, to present evidence of its continuing legal authority to do business in New York State, integrity, experience, ability, prior performance, and organizational and financial capacity.

2. Suspension of Work (for Non-Responsibility)

The Commissioner of Health or his or her designee, in his or her sole discretion, reserves the right to suspend any or all activities under this Contract, at any time, when he or she discovers information that calls into question the responsibility of the Contractor. In the event of such suspension, the Contractor will be given written notice outlining the particulars of such suspension. Upon issuance of such notice, the Contractor must comply with the terms of the suspension order. Contract activity may resume at such time as the Commissioner of Health or his or her designee issues a written notice authorizing a resumption of performance under the Contract

3. Termination (for Non-Responsibility)

Upon written notice to the Contractor, and a reasonable opportunity to be heard with appropriate Department of Health officials or staff, the Contract may be terminated by Commissioner of Health or his or her designee at the Contractor's expense where the Contractor is determined by the Commissioner of Health or his or her designee to be non-responsible. In such event, the Commissioner of Health or his or her designee may complete the contractual requirements in any manner he or she may deem advisable and pursue available legal or equitable remedies for breach.

Agency Code 3450000
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 workplan 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 modification (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:_____