FAU # 1003251030

New York State Department of Health Wadsworth Center and Health Research Science Board

Request for Applications

PETER T. ROWLEY BREAST CANCER SCIENTIFIC RESEARCH PROJECTS

RELEASE DATE: October 19, 2011

APPLICANT CONFERENCE Registration Due:November 7, 2011 by 4:00 PM **APPLICANT CONFERENCE:**November 9, 2011 at 2:00 PM

Location: New York State Department of Health

David Axelrod Institute, Auditorium A

120 New Scotland Avenue

Albany, NY 12208

QUESTIONS DUE: November 15, 2011

LETTER OF INTENT DUE (strongly encouraged): November 15, 2011 by 4:00 PM

QUESTIONS, ANSWERS AND UPDATES POSTED: November 22, 2011

APPLICATIONS DUE: December 16, 2011 by 4:00 PM

ESTIMATED CONTRACT START DATE: January 1, 2013

DOH CONTACT NAME AND ADDRESS:

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Extramural Grants Administration
New York State Department of Health
Wadsworth Center
Empire State Plaza, Room D350
PO Box 509, Albany, NY 12201-0509
Email: hrsb@wadsworth.org
(518) 474-7002 (phone)
(518) 486-2191 (fax)

This RFA, questions and answers, as well as any updates and modifications, may be downloaded from: http://www.health.ny.gov/funding/ and at: http://www.health.ny.gov/funding/ and at: http://www.wadsworth.org/extramural/breastcancer.htm.

New York State Health Research Science Board

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Health Research Science Board

Peter T. Rowley Breast Cancer Scientific Research Projects

I. INTRODUCTION

A. Background

In 1996, the Health Research Science Board (HRSB) was established to make scientifically sound funding recommendations to the Commissioner of Health following review of applications for breast cancer research studies and education projects. To support the funded projects, the state's Breast Cancer Research and Education Fund (the Fund) was initiated. The Fund is financed primarily by individual and corporate income tax check-off contributions and donations. Those funds are matched by the state, essentially doubling funds available for breast cancer research and education awards. In addition, the Fund accepts proceeds from the sale of specialty "Drive for the Cure" license plates. To date, the Fund has received in excess of \$7.5 million from over half a million contributions, and over \$10 million has been awarded.

The HRSB also supports activities related to studying the possible links between exposure to pesticides and breast cancer, including review of researcher applications requesting confidential data from the Pesticide Registry maintained by the State Department of Environmental Conservation. The HRSB 2007-2008 Biennial Report and other useful information can be found at: http://www.wadsworth.org/extramural/breastcancer/.

The New York State Department of Health, Wadsworth Center, Breast Cancer Research and Education Program (Program) provides administrative support for the HRSB and the Fund.

B. Purpose of Funds

The purpose of the Rowley awards is to provide initial support for preliminary testing of novel, exploratory or developmental hypotheses related to breast cancer. Applications in response to this Request for Applications (RFA) may address any topic or issue related to breast cancer biology, causation, prevention, detection or screening, treatment (including treatment of its effects), survivorship or cure. Any investigative approach appropriate to the application topic may be pursued, including, but not limited to, basic, translational, clinical, demographic, epidemiological, environmental, behavioral or psychosocial research.

C. Available Funds

All awards will be financed by the Fund. The number of awards will be contingent upon the quality of the applications received as well as the size and scope of the proposed projects. Approximately \$3.6 million is available to support approximately ten awards from this RFA. The funding is for a period of up to two years. The annual direct costs for a single award are capped at \$150,000 per year. Additionally, funds will be available to support Facilities and Administrative costs up to 20 percent of modified total direct costs. Based on its assessment that the field is ready to pursue additional investigations, the Board may determine that additional funds should be made available under this RFA to support additional awards.

II. WHO MAY APPLY?

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

To be eligible, the Principal Investigator (PI) will be employed by the applicant institution and have the skills, knowledge, and resources necessary to carry out the proposed Workplan. The HRSB encourages applications from early-stage, as well as established, researchers from all related fields, including those disciplines that historically have not focused on breast cancer, provided the hypothesis relates directly to breast cancer. Postdoctoral fellows and other dependent research staff are not eligible to apply. Collaborations between experienced and less experienced researchers, and between New York State and non-New York State researchers are encouraged.

III. PROJECT NARRATIVE/WORKPLAN OUTCOMES

A. General Expectations

A successful application will present a self-contained, hypothesis-driven research project that is either (1) new and exploratory, such as one that opens a new area of investigation or satisfactorily tests a novel or innovative hypothesis, and/or (2) new and developmental, with a goal of producing viable data for preparation of a full-scale research application to another organization. Although collaborations are not required, they are strongly encouraged.

The HRSB prefers to fund applications that are high risk/high reward and those that propose to study underexplored or unexplored areas of significance. Thus, responsive applications include those that (1) are considered highly speculative, (2) apply or develop state-of-the-art technologies, tools or resources for breast cancer research and/or (3) focus on exceptionally promising topics derived from some pilot data, but are not yet sufficiently mature to compete successfully for funding as full-scale studies.

Notably, Rowley awards are not intended to fund smaller components of larger R01-type projects, data collection, incremental or correlative research aims, or the compression of a larger project into a smaller timeframe.

B. Use of Funds

Funds may be used to support salaries and stipends, fringe benefits, supplies, equipment, subcontractor and consultant costs, travel, and other expenses, including human subjects and related research costs, animals and their care, core facilities usage fees, communication costs, meeting costs, publication expenses, and miscellaneous research costs (see Section V., Instructions for Completing the Application). Funds should be budgeted for travel to present project results to the HRSB.

Facilities and Administrative 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).

C. Reporting Obligations

If awarded, the contractor will be required to submit financial reports and scientific progress reports in accordance with the forms, formats and timeframes required by the Program. Submission of detailed guarterly financial reports will be required.

Additionally, the contractor will be required to submit written reports that substantiate progress corresponding to the tasks and milestones outlined in the Workplan. All progress reports will require approval by Program 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. A sample of these contract appendices can be found in Attachment 5 of this RFA.

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

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

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

IV. ADMINISTRATIVE REQUIREMENTS

A. Issuing Agency

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

B. Question and Answer Phase

All substantive questions must be submitted in writing to the Health Research Science Board Program administrators via e-mail at: hrsb@wadsworth.org or fax at (518) 486-2191. To the degree possible, each inquiry should include the title of the RFA and should cite the section to which it refers. Substantive questions will be accepted through the date listed on the cover of this RFA.

Questions of a technical nature may be addressed in writing or via telephone by contacting Lani Rafferty, Health Program Administrator, Extramural Grants Administration, Wadsworth Center, at (518) 474-7002. Questions are of a technical nature if they are limited to how to prepare the application (e.g., formatting) rather than relating to the substance of the application.

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

This RFA has been posted on the Department of Health's public Website at: http://www.health.ny.gov/funding/. Questions and answers, as well as any updates and/or modifications, will also be posted on the Department of Health's Website 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 4). Letters of Intent will be used to develop the highest quality review panel in a timely manner. Letters of Intent infer no obligation upon the institution to submit an application in response to this RFA. 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 hrsb@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 date, time and location posted on the cover of this RFA. The Department requests that potential applicants register for the conference by calling (518) 474-7002 to insure access through security, and adequate accommodations for the number of prospective attendees. The deadline for reservations is posted on the cover page of this RFA. Failure to attend an 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 listed on the cover sheet of this RFA. Late applications will not be accepted.* It is the applicant's responsibility to ensure 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 (Express) Services:

New York State Department of Health Wadsworth Center, Room D350 Extramural Grants Administration Empire State Plaza Dock J – P1 Level Albany, NY 12237 For detailed content requirements, see Section V., Instructions for Completing the Application. The application should be submitted in a single package that is clearly labeled with the RFA name and FAU number listed on the cover of this RFA. Inside the package, a separately sealed package should contain a CD or DVD of the entire application and supporting documents and an exact paper copy. The package should be clearly marked with the PI's name and the 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 Comptroller. It is expected that contracts resulting from this RFA will begin January 1, 2013 for a term of up to two years and will not be renewable.

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

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

Grant contractors shall provide complete and accurate billing vouchers to the Department's designated payment office in order to receive payment. Billing vouchers submitted to the Department must contain all information and supporting documentation required by the Contract, the Department and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall only be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epunit@osc.state.ny.us or by telephone at 518-486-1255. CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's

electronic payment procedures, except where the Commissioner has expressly authorized payment by check as set forth above.

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

- 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 claimed.
- Quarterly vouchers will not be paid until all required progress reports are submitted and deemed acceptable by Program staff.
- The final voucher will not be paid until after acceptance of the final progress report.
- In no event shall the amount received by the contractor exceed the amount approved by the State.
- 3. The grant contractor shall submit the following periodic reports:
 - Written scientific progress reports in accordance with the forms and formats provided by the Program, as outlined in Section III.C., Reporting Obligations, no later than 30 days after the end of each six-month reporting period.
 - A final cumulative progress report in accordance with the forms and formats provided by the Program, no later than 60 days after the end of the contract term

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

I. Vendor Responsibility Questionnaire

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

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

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

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

J. General Specifications

- 1. By signing the Application Form each applicant attests to its express authority to sign on behalf of the applicant.
- 2. Contractor will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.
- 3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer Phase (Section IV.B.) must be clearly noted in a cover letter attached to the application.
- 4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.

5. Provisions Upon Default

- a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.
- b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
- c. If, in the judgment of the Department of Health, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive equitable compensation for such services as shall, in the judgment of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

K. Appendices

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

APPENDIX A Standard Clauses for NYS 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 G - Notices

V. INSTRUCTIONS FOR COMPLETING THE APPLICATION

ALL APPLICATIONS SHOULD USE THE FORMS (see Attachment 1 – Forms 1-15) AND FORMATS PRESCRIBED IN THIS SECTION V. APPLICATIONS THAT DEVIATE FROM SPECIFIC ELEMENTS OF THESE INSTRUCTIONS OR THOSE FOUND ON THE FORMS WILL BE ASSESSED A PENALTY (see Attachment 2).

Applications should be submitted in electronic format on a CD or DVD. An exact paper copy should also be submitted and will be used if the CD or DVD is damaged. If an electronic copy has not been submitted, the paper copy will be scanned.

Please note that if the electronic copy is damaged and a paper copy has not been submitted, the application will not pass administrative review and will not be sent to peer review.

Electronic files should not exceed 12 MB each and should not be password protected. The CD or DVD should be clearly labeled with the applicant's name. The CD or DVD should contain the following four items:

- Applicant Forms 1 5 in a *single* Microsoft Word (DOC or DOCX) file;
- Applicant Forms 1 5 in a *single* Portable Document Format (PDF) file;
- Forms 6 15 and all appendix material in a single PDF file of not greater than 12MB;
 and
- Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Subapplicants) scanned and saved as a separate PDF file.

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared. Applicants are strongly encouraged to seek appropriate technical support in the creation of electronic files and to review the electronic files prior to submission. Some materials may require scanning and insertion into the file. Discretion should be exercised in the resolution of figures and scanned materials. Excess resolution will increase the size of the file without any appreciable increase in viewing quality. Tips for managing graphics and file sizes are available at

http://www.wadsworth.org/extramural/breastcancer/tip pdfilesize.html. Applicants should also be aware that while color figures may be included, applications may be printed in black and white. Applicants may wish to annotate the figure legend directing the reader to the electronic file if color is an important aspect of the figure.

Forms are pre-set with acceptable fonts and margins. Applications should be single-spaced and typed using an 11-12 point font. Smaller font sizes are acceptable for use in tables and figure legends. The header should contain the principal investigator's last name, first initial, and applicant institution name. Each page should be numbered consecutively. Figures and

illustrations referenced in the Workplan are included in the page limits (see instructions for Form 12, below). Appendices may not be used to circumvent page limitations.

Information submitted to HRSB 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 that 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.

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

Applicant Face Page – Form 1

<u>Project Title</u>. The title should describe the focus or purpose of the proposed project.

<u>Application Type</u>. This box should read "Peter T. Rowley Breast Cancer Scientific Research Projects."

FAU #: This box should read "1003251030."

<u>Principal Investigator</u>. Provide the information requested. The PI is the investigator employed 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 the Program, and will be required to fulfill technical reporting requirements and submit any revised budgets co-signed by an authorized organizational representative.

<u>Co-Principal Investigator</u>. 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 choice (Governmental or Not-For-Profit).

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

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

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

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

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

<u>Human Pluripotent Stem Cells</u>. Select the appropriate choice. For applications that include any use of human pluripotent stem cells, select "YES." If human pluripotent stem cells will not be used, check 'NO.'

Recombinant DNA. Select the appropriate choice. For applications that include any use of recombinant DNA, select "YES." If no recombinant DNA will be used, select "NO." Required assurances must be provided before contract development.

<u>Project Start/End</u>. Record the anticipated project duration of January 1, 2013 through December 31, 2014.

<u>Year-One Grand Total Cost</u>. Enter Year-One Grand Total Cost from Form 7, Line 14. This figure includes the direct and F&A costs for the applicant and all sub-applicants.

<u>Grand Total Cost (all years)</u>. Enter the Grand Total Costs (all years) from Form 7, Line 14. This figure includes the direct and F&A costs for the applicant and all sub-applicants.

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

Research Performance Sites. List all sites (organization and location) where the research described in the Workplan will be performed.

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

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

<u>Certifications and Assurance.</u> 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 institution has the capability to conduct and administer externally-funded research (see Section II of the RFA); and agreement to comply with the terms and conditions of any contract awarded as a result of this application.

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

Sub-applicant Face Page - Form 1-S

<u>Project Title</u>. The title should describe the focus or purpose of the proposed project.

<u>Application Type</u>. This box should read "Peter T. Rowley Breast Cancer Scientific Research Projects."

FAU #: This box should read "1003251030."

<u>Principal Investigator</u>. Provide the information requested. The sub-applicant PI is the investigator employed by the sub-applicant organization responsible for planning, coordinating and implementing the subcontract potion of the project if a sub-award 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 cosigned by an authorized organizational representative. If this individual is also considered to be the Co-PI of the overall application, also check the "Overall Project Co-PI" box.

<u>Co-Principal Investigator</u>. 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.

<u>Type of Organization</u>. Select the appropriate choice (Governmental, Not-For-Profit, For Profit).

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

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

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

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

<u>Human Pluripotent Stem Cells</u>. Select the appropriate box. For sub-applications that include any use of human pluripotent stem cells, select "YES." If human pluripotent stem cells will not be used, select "NO."

<u>Recombinant DNA</u>. Select the appropriate box. For sub-applications that include any use of recombinant DNA, select "YES." If no recombinant DNA will be used, select "NO." Required assurances must be provided before contract development.

Project Start/End. Enter the anticipated duration for the subcontract.

<u>Year-One Grand Total Cost</u>. Enter the Year-One Grand Total Cost from Form 7, Line 14. This figure includes the direct and F&A costs for the sub-applicant.

<u>Grand Total Cost (all years)</u>. Enter the Grand Total Cost (all years) from Form 7, Line 14. This figure includes the direct and F&A costs for the sub-applicant.

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

<u>Research Performance Sites</u>. List all sites (organization and location) where the research described in the Workplan will be performed.

<u>Contracts and Grants Official</u>. Provide the information requested. This individual will be notified in the event of a subaward.

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 research program, should a sub-award be made. *Note:* This individual typically is not the sub-applicant PI.

<u>Principal Investigator/Co-Principal Investigator Certification and Assurance.</u> 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.

<u>Organization Certification and Acceptance</u>. Prior to award recommendation, the organizational representative of the sub-applicant is required to sign and date the form certifying compliance with all applicable assurances and certifications referenced in this RFA.

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

Staff, Collaborators, Consultants and Contributors – Form 2
List (spell out) the full name, title and institutional affiliation of all staff, collaborators,

consultants and contributors (both paid and unpaid) associated with this project, including the PI and all Co-PIs and sub-applicants. Do not include unnamed or "to be determined" staff positions. For each individual listed, include the most applicable role (PI; Co-PI; investigator, etc.). This list is used to identify potential members of the Independent Scientific Merit Peer Review panel and determine possible conflicts of interest at various stages of the review and award process.

Acronyms and Abbreviations – 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 and may be particularly important for the identification of specific protein cascades, for example.

Lay Abstract - Form 4

Provide a summary of the application, in non-technical terms; limit to 300 words (perform 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. Specifically, provide a brief background and description of the Workplan, emphasizing the significance of the study and its expected impact on the field of breast cancer.

Scientific Abstract - Form 5

Provide a one page scientific summary of the proposed project. The abstract should be written so that persons from diverse scientific backgrounds may easily understand the work proposed. Do not include confidential information in the scientific abstract. List key words that best describe the areas addressed in the application. **NOTE**: Applicants proposing the use of human pluripotent stem cells should clearly indicate the specific cell line planned for use, as well as its source, in the box provided.

Table of Contents – Form 6

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

Budget – Form 7

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

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

Patient care and tuition reimbursement costs are not allowable expenses. Ineligible budget items will be removed from the budget prior to contracting; the budget amount requested will be reduced to reflect the removal of the ineligible items.

Subsequent requests for changes to the budget are not guaranteed approval and may be

subject to review beyond the Program level. Such requests include budget modifications (including requests for equipment purchases that were not detailed in the application and its appendices), carry forwards, and no cost extensions. Specifically, changes of more than 10% between Personal Services and Other Than Personal Services and additions to equipment may render all funds unavailable for an extended period (4-6 months). Thus, it is of critical importance that the application budget is prepared as accurately as possible, equipment needs are anticipated, and the scope of work can clearly be accomplished within the stated contract term.

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 and proportional to the percent of expended professional effort. 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.

2. Other Than Personal Service

Support may be requested for:

- Supplies
- Equipment
- Travel
- Consultant costs
- Subcontractors
- Other expenses
 - Human subjects and related research costs
 - Animals and their care
 - Core facility usage fees
 - Communication costs
 - Meeting costs
 - Publication costs
 - Miscellaneous research expenses

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

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 7. Such amount will include sub-applicant F&A costs.

Note that any expenses budgeted for the sub-applicant will reduce the allowable

expenses for the applicant institution.

4. Facilities and Administrative Costs

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

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

Personal Effort and Budget Justification – Form 8

For each budget line, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered, are reasonable and are consistent with the approaches described in the workplan. Budget lines that are not well-justified may be decreased or disallowed during the peer review and award process.

For any sub-applicant costs, provide additional copies of the form for each sub-applicant. Funds awarded by this program may not be used to supplant other existing support for the same work.

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

*Key personnel are defined as the PI and others who contribute to the development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

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

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

Biographical Sketch – Form 9

Provide two-page biographical sketches for all key personnel listed on each Form 8, including collaborators and consultants. Start with the principal investigator, followed by co-PI(s), and then include remaining key personnel in alphabetical order using additional copies of Form 9.

Facilities and Resources - Form 10

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.

Other Research Support - Form 11

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

Workplan – Form 12

A copy of Form 12 will be included in any awarded contract; therefore, it should be sufficiently detailed to allow monitoring of progress toward program goals. The Workplan should present sufficient details to clearly and concisely convey to reviewers that:

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

Do not exceed the 15 pages for Sections A-D for the Workplan.

A. SPECIFIC AIMS

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

B. SIGNIFICANCE

Provide a succinct description for each proposed aim, indicating how its attainment will advance prevention, detection, treatment or cure of breast cancer.

C. BACKGROUND AND PRELIMINARY RESULTS

Review the literature that underlies the proposed research and present any available preliminary data. The scientific rationale for the project should be extremely compelling. Preliminary data are not essential for Rowley applications.

D. RESEARCH DESIGN AND METHODS

Describe the experimental design, methodological approaches, statistical analyses and interpretations 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 breast cancer 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 the use of human pluripotent stem cells should clearly indicate in the Workplan the specific cell line planned for use, as well as its source.

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 reflect the relevant literature comprehensively. Provide complete citations to references.

Time Line and Collaboration Strategy – Form 13

Complete the table provided. A copy of Form 13 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 Grant Contract). Include frequency and methods of communications. Include strategies to overcome potential problems with communication and/or data and resource sharing.

Human Subjects – Form 14

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

Appropriate oversight and management of human subject research projects are essential to the ethical conduct of research. Certification of Institutional Review Board (IRB) review and approval is not required prior to application review; however, an appropriate standard IRB approval form or signed exemption will be required prior to contract award.

Complete the information requested on the form. If the Protocol Status is Approved or Pending, provide a complete narrative to address the eight points listed on the form.

APPLICATIONS THAT FAIL TO ADDRESS ANY ONE OR MORE OF THE EIGHT POINTS BELOW IN ACCORDANCE WITH THESE INSTRUCTIONS WILL BE PENALIZED (see Attachment 2 for details).

1) Involvement of Human Subjects and Population Characteristics

Describe the involvement of human subjects as outlined in the Workplan. Include descriptions of the subject population, e.g., number of subjects, age range and health status. Provide inclusion or exclusion criteria of any subpopulation (including women or minorities), and explain why such inclusion or exclusion is necessary to accomplish the research goals. Explain the rationale for the involvement of special classes of subjects, such as minors, mentally disabled adults, inmates, institutionalized individuals or others

likely to be vulnerable. Discuss proposed outreach programs for recruiting women and minorities as participants in clinical research.

2) Sources of Materials - Confidentiality

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

3) Risks

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

4) Recruitment and Consent

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

5) Protection From Risk

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

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

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

7) Importance of the Knowledge to Be Gained

Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

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

8) Education of Key Personnel

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

Vertebrate Animals – Form 15

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

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

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

If the applicant organizations does not have an approved Animal Welfare Assurance form on file with the Office of Laboratory Animal Welfare or a U.S. Department of Agriculture (USDA) registration number, if required, must insert "NONE" in the space provided on Form 14. In this case, the applicant organization, by the official's signature on the Face Page, is declaring that it will comply with U.S. Public Health Service policy on the care and use of animals by establishing an IACUC, and submitting an Animal Welfare Assurance form and verification of IACUC approval whenever requested to do so. If required, the applicant organization must also register its facility with the USDA.

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

- 1) Description of Proposed Animal Use
 Provide a detailed description of the animal use proposed in the Workplan, identifying
 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 number, and include power calculations as justification.
- 3) Description of Procedures to Ensure the Discomfort, Distress, Pain and Injury will be Limited Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. As appropriate, describe the use of analgesic, anesthetic and tranquilizing drugs, and comfortable restraining devices to minimize discomfort, distress, pain and injury.

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

VI. Application Review and Award Process

A. Application Acceptance

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

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. The Review Panel will evaluate and score each proposal according to the criteria specified in Section VI.D. and will score each criterion except Budget, which will be scored by three representatives from the Panel.

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

Numerical Score	Adjectival Score
1.0 – 1.5	Outstanding
1.6 – 2.0	Excellent
2.1 – 2.5	Very Good
2.6 – 3.5	Good
3.6 – 5.0	Fair

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

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

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

C. Application Penalties

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

D. Review Criteria

The following evaluation criteria are considered by the Review Panel:

Impact (20%)

- To what extent is the project one or more of the following?
 - high risk/high reward
 - o addressing an important under- or unexplored area of breast cancer research
- To what extent will the project, if successfully completed, do one or more of the following?
 - o open a new area of investigation
 - satisfactorily test a novel or innovative hypothesis
 - o make an original and important contribution to prevention, treatment (including treatment of its effects), survivorship or cure for breast cancer
 - produce viable data for preparation of a full-scale research application to another organization
- To what extent will the project lead to a useful outcome, even if the central hypothesis is disproved?

Innovation (20%)

- To what extent is the project innovative, based on one or more of the following?
 - o basic concepts and hypotheses are speculative or exploratory
 - o applies or develops state-of-the-art technologies, methods, tools or resources to breast cancer research or clinical practice
 - develops new paradigms or challenges existing paradigms of current research or clinical practice

Workplan (40%)

- To what extent are the overall strategy, proposed methods and analyses well-reasoned and the most appropriate to accomplish the specific aims of the project?
- Are potential problems discussed and alternative strategies provided?
- Are the knowledge, skills, research tools and experiences of the researcher(s) well-suited to the proposed work?
 - o For Early Stage Investigators, do they have appropriate training and experience?
 - For established investigators, have they demonstrated a track record of achievements advancing the field?
- Does the Pl's/Co-Pl's commitment and the overall research environment contribute to the likelihood of success?
- To what extent are the scientific resources, equipment and institutional support available to investigators adequate for the proposed work?

Budget (20%)

- To what extent are the items for each budget line explained? Are they adequately justified as necessary for completion of the project?
- Are the budget allocations sufficient to accomplish the research aims?
- Are the budgeted amounts reasonable and cost effective?
- Are there specific excessive or unnecessary budget items?
 (Note: the entire Panel will review and comment on, but not score the budget.
 Budget scores will be given by three designated representatives of the Panel).

E. Health Research Science Board Review

Only applications with a score ranging from 1.0 to 2.5 will be considered for funding. Applications with a score ranging from 2.6 to 5.0 will not be considered.

The HRSB will discuss the applications' strengths and weaknesses, and budget recommendations. The HRSB will consider responsiveness to the mission of the HRSB, responsiveness to the RFA, programmatic balance, and availability of funds, but is not obligated to recommend funding. Scoring ties will be resolved on the basis of the above and with consideration of the scores of review criteria in the following order: Impact, Innovation and Workplan.

The HRSB will vote on each selected application in compliance with HRSB bylaws as well as applicable laws and regulations. If an application for which there are available funds is not recommended for funding, the HRSB will fully justify in writing why the application was not approved. The HRSB will then 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 approval by the Commissioner, applicant organizations and PIs recommended for support 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 the Contract Policy Statements and Conditions (Contract Appendix A-2)
- Approved Facilities and Administrative Cost Rate

Once an award has been made, applicants may request a debriefing of their application. Please note the debriefing will be limited only to the strengths and weaknesses of the subject application and will not include any discussion of other applications. Requests must be received

no later than ten (10) business days from date of award or non-award announcement.

In the event unsuccessful applicants wish to protest the award resulting from this RFA, applicants should follow the protest procedures established by the Office of the State Comptroller (OSC). These procedures can be found on the OSC website at http://www.osc.state.ny.us/agencies/gbull/g 232.htm.

G. Award Announcements

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

ATTACHMENT 1

APPLICATION FORMS 1 - 15

Applicant Face Page

Project Title:							
FAU # 1003251030 Application Type: Peter T. Rowley Breast Cancer Scientific Research Projects							
PRINCIPAL INVESTIGATOR Last Name, First Name, Mid	CO-PRINCIPAL INVESTIGATOR Last Name, First Name, Middle Initial Degree(s) (If different institution, do not complete this section – requires sub-applicant face page)						
Institution			Institution				
Department			Departmen	ıt			
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Phone	Fax		Phone		Fax		
E-mail			E-mail				
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Form 1

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

Face Page for Subcontracting Entities

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_	No 🗌	Verteb Yes □	rate Ar No		Human Pl Yes □	uripo No			Yes □		t DNA ⊃ □	
Project S	Start/End			Yr. One Total Co					Grand T Cost	otal		
Sub- App	olicant Orga	anizatio	n				Research Performance Sites					
Mailing Address (Street, MS, P.O. Box, City, State, Zip)												
Contract	s and Gran	ts Offic	ial				Official	Signing fo	or Orgai	nizatio	n	
Mailing A (Street, MS	Address S, P.O. Box, C	ity, State	, Zip)			Mailing Address (Title & Organization, Street, MS, P.O. Box, City, State, Zip)					ate, Zip)	
Phone			Fax				Phone			Fax		
E-mail							E-mail					
Institution name and address where reimbursement should be sent if contract is awarded (Street, MS, P.O. Box, City, NY, Zip):												
CERTIFICATION AND ASSURANCE: I certify that the statements herein are true and complete to the best of my knowledge. I agree to accept responsibility for the scientific conduct and integrity of the research, and to provide the required progress reports if a contract is awarded as a result of this application.												
SIGNATU	JRES OF SU	JB-APPL	ICANT	PRINCIP	AL INVEST	IGA1	ΓOR and	CO-PI				
#1 X										DATE		
#2 X	#17X											
ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and I accept the obligation to comply with the terms and conditions if a contract is awarded as a result of this application.												
	JRE OF THE	OFFIC	AL SIGN	NING FOR	R THE SUB-	-APF	PLICANT	ORGANIZ	ATION			
V										DATE		

Form 1-S

Submit a signed Face Page for each applicant and sub-applicant in a single PDF file.

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, including the PI and all Co-PIs and subapplicants. 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.

Name	Title	Institutional Affiliation	Role on Project
			PI

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

Acronyms and Abbreviations Used in Application

Provide a list of all acronyms and abbreviations used in the application. Also include the full text/definition/description as used in the application. This will allow the Peer Review Panel to fully comprehend the proposed experimental design and may be particularly important for the identification of specific protein cascades, for example.

Acronym/Abbreviation	Full Text/Definition/Description

Form 3

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

Lay Abstract

Provide a summary of the application, in non-technical terms; limit to 300 words (perform 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. Specifically, provide a brief background and description of the Workplan, emphasizing the significance of the study and its expected impact on the field of breast cancer.

Background:	
Description of the Workplan:	
Significance:	
Impact:	

Form 4

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

Scientific Abstract

Provide a one page scientific summary of the proposed project. The abstract should be written so that persons from diverse scientific backgrounds may easily understand the work proposed. Do not include confidential information in the scientific abstract. List key words that best describe the areas addressed in the application. **NOTE**: Applicants proposing the use of human pluripotent stem cells should clearly indicate the specific cell line planned for use, as well as its source, in the box provided.

Headings may be moved to allow use of available space to your best advantage; comply with font guidelines.

Also list any human pluripotent stem cell lines and the source of such lines:	
Research Areas: List key words that best describe the research areas addressed in the application.	
Background:	
Hypothesis:	
Objectives/Aims:	
Methods:	
Innovative Elements:	

Form 5

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

Table of Contents

Form 1	Form Name Applicant Face Page	Page 1
1-S	Sub-Applicant Face Page(s)*	
2	Staff, Collaborators, Consultants and Contributors	
3	Acronyms and Abbreviations Used in Application	
4	Lay Abstract	
5	Scientific Abstract	
6	Table of Contents	
7	Budget	
7	Budget – Sub-Applicant Organization(s)*	
8	Personnel Effort and Budget Justification	
8	Personnel Effort and Budget Justification – Sub-Applicant Organization(s)*	
9	Biographical Sketch(es)	
10	Facilities and Resources	
11	Other Support	
12	Workplan (do not exceed 15 pages for sections A-D) A. Specific Aims B. Significance C. Background and Preliminary Results D. Research Design and Methods E. Literature Cited - Not included in page limitations	
13	Time Line and Collaboration Strategy	
14	Human Subjects	
15	Vertebrate Animals	
	Appendix Material	

Form 6

Additional table rows may be added to identify specific appendix material or additional sub-applicant information. Submit Forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

Indicate "N/A" if not applicable.

BUDGET Name of Applicant or Sub-Applicant

BUDGET CATEGORY		Year One	Year Two	TOTAL (all years)
PEF	RSONAL SERVICE (PS)			
1	SALARY AND STIPENDS			
	Position – (separately list each position	to be funded, in	dicating if position	on is vacant)
	SUBTOTAL Salary & Stipends			
2	FRINGE BENEFITS			
3	SUBTOTAL PS (sum of lines 1 + 2)			

Form 7

Attach subcontractor budgets as additional copies of Form 7. Submit Forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

ОТІ	HER THAN PERSONAL SERVICE		
4	SUPPLIES		
	LAB SUPPLIES		
	OFFICE SUPPLIES		
	SUBTOTAL SUPPLIES		
5	EQUIPMENT		
6	TRAVEL		
7	SUBCONTRACTOR AND CONSULTANT COSTS		
8	OTHER EXPENSES		
	HUMAN SUBJECTS AND RELATED RESEARCH COSTS		
	ANIMALS AND CARE		
	CORE FACILITY USAGE FEES		
	COMMUNICATION COSTS		
	MEETING COSTS		
	PUBLICATION EXPENSES		
	MISCELLANEOUS		
	SUBTOTAL OTHER EXPENSES		
9	SUBTOTAL OTPS (sum of lines 4 - 8)		
10	TOTAL PS and OTPS (sum of lines 3 + 9)		
11	TOTAL SUBCONTRACT COST (sum of line 14 of all subcontractor budgets)		
12	TOTAL DIRECT COST (sum of lines 10 + 11)		
13	FACILITIES AND ADMINISTRATIVE COSTS		
14	GRAND TOTAL COST (sum of lines 12 + 13)		

Form 7

Attach subcontractor budgets as additional copies of Form 7. Submit Forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

Personnel Effort and Budget Justification

Key Personnel *			Dollar Amount Requested (Year One)			
Name	Role in Project	% of Total Professional Effort**	Total Salary at Institution	Salary Requested	Fringe Requested	Total \$
	PI					
	Co-PI					
					A 4 D	
•	Support Perso	onnei		Dollar	Amount Req (Year One)	juesteu
Name	Role in Project	% of Total Professional Effort**	Total Salary at Institution	Salary Requested	Fringe Requested	Total \$
					·	
J Colomy + Eringo	Requested - s	hould equal Vea	r One line 3 E	orm 7		

^{*} Insert additional lines as necessary under Key Personnel or Support Personnel.

Form 8

Attach sub-applicant justifications using additional copies of Form 8. Submit Forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

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

Describe and justify the key personnel and technical staff.
Describe the items to be included in <i>Other than Personal Service</i> Costs.
Supplies
<u>Equipment</u>
<u>Travel</u>
Subcontractors and Consultants
<u>Other Expenses</u> (human subjects, animals and their care, core facility usage, communication costs, meeting costs, publication cost, and miscellaneous)

Form 8

Attach sub-applicant justifications using additional copies of Form 8. Submit Forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

Biographical Sketch

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

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

Form 9

Not to exceed two pages per individual. Present the PI first, followed by Co-PI(s) and then remaining key personnel in alphabetical order using additional copies of Form 9. Submit forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

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Biographical Sketch

Page 2

Form 9

Not to exceed two pages per individual. Present the PI first, followed by Co-PI/mentor(s) and then remaining key personnel in alphabetical order using additional copies of Form 9. Submit forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

Facilities and Resources

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.

Laboratory:
Clinical:
Animal:
Computer:
Office:
Other: Identify support services such as machine shop and electronics shop, and specify the extent to which

Form 10

such services will be available to the project.

Not to exceed two pages per collaborating institution. Attach sub-applicant information using additional copies of Form 10. Submit forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

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

Form 10

Not to exceed two pages per collaborating institution. Attach sub-applicant information using additional copies of Form 10. Submit forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

Other Research Support

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

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

Name of Key Personnel:			_
Check if no other support is available for the individual listed	d: 🗆		
TITLE OF PROJECT:	□PENDING	□ACTIVE	
BRIEF PROJECT DESCRIPTION:			
PROJECT PI:			
FUNDING AGENCY/GRANT ID NO.:			
PERIOD OF SUPPORT: %	PROFESSIONAL EF	FORT :	_
THIS PROJECT INVOLVES BREAST CANCER-RELATED	RESEARCH?	□YES	□NO
THIS PROJECT OVERLAPS A RESEARCH AIM IN THIS A	APPLICATION?	□YES*	□NO
For any "Yes" answer, explain the distinction between the p Indicate a possible resolution, if this application is funded.	roject noted here and	this applicatio	n.

Form 11

Form 11

Workplan

Form 12

Follow all page limitations, and font and margin requirements. Submit forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

- A. Specific Aims
- B. Significance
- C. Background and Preliminary Results
- D. Research Design and Methods
- E. Literature Cited

Timeline and Collaboration Strategy Form 13

Complete the table provided. A copy of Form 13 will be included 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 Grant Contract). Include frequency and methods of communications. Include strategies to overcome potential problems with communication and/or data and resource sharing.

Submit Forms 6-15 and all appendix material in a single .pdf file of not greater than 12MB.

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

Human Subjects

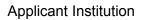
Each applicant and sub-applicant will complete this form. Where multiple protocols will be followed in completion of the proposed research project, **complete a separate form for each protocol**. It is the responsibility of the applicant organization to ensure that all performance sites comply with the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

Applicant/Sub-applicant Institution:				
Institutional OHRP Federal-wide Assurance of Compliance Number:				
IRB Protocol Status:				
☐ Approved(Date) ☐ Pending ☐ Exempt # ☐ Not required for this research				
*If 'Not required for this research project,' do not complete the remainder of the form. If Protocol Status (above) is Approved, Pending or Exempt, also complete the box below.				
Protocol Number: Principal Investigator:				
Project Title:				
Are all appropriate staff listed on this protocol? Yes No				
Does the IRB require annual (or more frequent) reviews of this protocol? ☐ Yes ☐No				
If "Yes", date of next review:				
☐ Ethnically/Racially diverse populations included.☐ Ethnically/Racially diverse populations excluded.				

If Protocol Status (above) is Approved or Pending, also address the eight points listed below in narrative (see Section V., Instructions for Completing the Application).

- 1. Involvement of human subjects and population characteristics
- 2. Sources of materials confidentiality
- 3. Risks
- 4. Recruitment and consent
- 5. Protection from risk
- 6. Potential benefits of the proposed research to the subjects and others
- 7. Importance of the knowledge to be gained
- 8. Education of key personnel

Form 14



PI Last Name, First Name

Form 14

Vertebrate Animals

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

Applicant/Sub-appli	cant Institu	ition:		
Institutional Animal	Care & Use	e Number:		
NYS DOH Animal Ca	are & Use C	Certificate Number	r:	
USDA Registration Number (if applicable to species):				
Vertebrate Animal P	rotocol Sta	itus:		
☐ Approved	(Date)	□Pending	☐ Notrequired for this research project	
If Protocol Status (above) is Approved or Pending, also complete the box below.				
			vestigator:	
Are all appropriate	staff listed	on this protocol?	☐ Yes ☐ No	
Does the IACUC red	quire annua	I (or more freque	nt) reviews of this protocol? ☐ Yes ☐No	
If " <u>Yes</u> ", date of nex	kt review: _			

If Protocol Status (above) is Approved or Pending, also address the four points listed below in narrative (see Section V., Instructions for Completing the Application).

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

Form 15

1	Applicant Institution	

PI Last Name, First Name

Form 15

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. 4)
The Institution is a New York State not-for-profit organization or a governmental organization (see pg. 2).
If the electronic files are damaged, a paper copy has been submitted (see pg. 10)

The following items are not mandatory. Appendices may include items such as:
Vendor Responsibility Attestation (Attachment 3)
Completed Vendor Responsibility Questionnaire
Protocol approval notices for human subjects and vertebrate animals
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

APPLICATION PENALTIES:

Equipment quotes

All application completion instructions found in Section V. should be followed. A total penalty of 0.1 point will be assessed to an application if:

essential to document the investigator's capability to undertake the work proposed

Application is not submitted electronically on a CD or DVD;

☐ Facilities and Administrative rate agreements

- Electronic submission is password protected:
- Submission does not include:
 - Applicant Forms 1 5 in a single Microsoft Word (DOC or DOCX) file;
 - Applicant Forms 1 5 in a single Portable Document Format (PDF) file;
 - o Forms 6 15 and all appendix material in a single PDF file;
 - Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned into a separate PDF file;
 - Budget Form 7 one for the applicant and each sub-applicant institution;
 - Personnel Effort and Budget Justification Form 8 one for the applicant and each subapplicant institution;
 - o Biographical Sketch Form 9 one for each key personnel listed on each Form 8;
 - Facilities and Resources Form 10 one for each collaborating or sub-applicant institution;
 - Other Support Form 11 one for each key personnel listed on each Form 8;
 - o Form 12 Workplan limited to 15 pages for sections A-D;
 - Form 14 Human Subjects at least one per applicant and sub-applicant, and one for each protocol used for this research project; and
 - Form 15 Vertebrate Animals at least one per applicant and sub-applicant, and one for each protocol used for this research project.

An additional penalty of 0.2 point will be assessed if the narrative on either Form 14 or 15 is incomplete or does not conform to the instructions for completion. In no case will more than a 0.3 point penalty be assessed to any single application.

Vendor Responsibility Attestation

Peter T. Rowley Breast Cancer Scientific Research Awards

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

Choose	e one:
	An on-line Vender 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.
Signatu	re of Organization Official:
•	pe Name:
Title:	
Organiz	ation:
Date Sig	gned:

Letter of Intent

New York State Department of Health and the Health Research Science Board

Peter T. Rowley Breast Cancer Scientific Research Awards

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.

I. Investigator Information (please print or type)

Principal Investigator:			
Sponsoring Institution:			
Address:			
City:		State:	ZIP Code:
E-Mail:			
II. Collaborator Informati	ion (please print or type)		
Primary Contact:			
Collaborating Institution:			
Address:			
City:		State:	ZIP Code:
E-Mail:			
Primary Contact:			
Collaborating Institution:			
Address:			
City:		State:	ZIP Code:
E-Mail:			

Collaborator Information	า (continued)			
Primary Contact:				
Collaborating Institution:				
Address:				
City:		State:	ZIP Code:	
E-Mail:				
Primary Contact:				
Collaborating Institution:				
Address:				
City:		State:	ZIP Code:	
E-Mail:				
Primary Contact:				
Collaborating Institution:				
Address:				
City:		State:	ZIP Code:	
E-Mail:				
SIGNATURE OF PRINCIPA	L INVESTIGATOR			
х			DATE:	
ORGANIZATION CERTIFICATION OF THE OFFICE SIGNATURE OF THE OFFICE SIGNATURE OF THE OFFICE OFFICE OF THE OFFICE OF THE OFFICE OFFICE OFFICE OF THE OFFICE OFFI		-		omplete
Y			DATE:	

Sample Contract*

2/10

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

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

DO NOT COMPLETE THEM AT THIS TIME.

GRANT CONTRACT (MULTI YEAR)

STATE AGENCY (Name and Address):		Address):	. NYS COMPTROLLER'S NUMBER:	
			ORIGINATING AGENCY CODE:	
CONTR	ACTOR (Name and A	address):	TYPE OF PROGRAM(S)	
FEDER	AL TAX IDENTIFICAT	TION NUMBER:	: INITIAL CONTRACT PERIOD	
MUNICIPALITY NO. (if applicable):		able):	. FROM: . TO:	
CHARIT	TIES REGISTRATION	NUMBER: or ()EXEMPT:	. FUNDING AMOUNT FOR INITIAL PERIOD:	
CONTR FILED V	ACTOR HAS() HA	S NOT() TIMELY Y GENERAL'S	MULTI-YEAR TERM (if applicable): FROM: TO:	
OR ANN	NUAL WRITTEN REP	ORTS.		
SEC [*] CONTR	ACTOR IS() IS NO TARIAN ENTITY ACTOR IS() IS NO FOR-PROFIT ORGAI	T() A		
APPEND	DICES ATTACHED AND	PART OF THIS AGREEM	IENT	
X _X_ _X_ _X_ _X_	APPENDIX A APPENDIX A-1 APPENDIX B APPENDIX C APPENDIX D APPENDIX X	Standard clauses as required by the Attorney General for all State contracts. Agency-Specific Clauses (Rev 2/10) Budget Payment and Reporting Schedule Program Workplan Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)		
OTHER A	APPENDICES			
X _X_ _X_ _X_	APPENDIX A-2 APPENDIX E-1 APPENDIX E-2 APPENDIX H	Program-Specific Clauses Proof of Workers' Compensation Coverage Proof of Disability Insurance Coverage Federal Health Insurance Portability and Accountability Act Business Associate Agreement Request for Applications		
	APPENDIX			

below their signatures.	
	Contract No.
CONTRACTOR	STATE AGENCY
By:(Print Name)	By:(Print Name)
Title:	. Title: Date:
	 State Agency Certification: "In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."
STATE OF NEW YORK)	•
satisfactory evidence to be the individual(s) whose na acknowledged to me that he/she/they executed the	before me, the undersigned, personally appeared ly known to me or proved to me on the basis of ame(s) is(are) subscribed to the within instrument and ne same in his/her/their/ capacity(ies), and that by dividual(s), or the person upon behalf of which the
(Signature and office of the individual taking acknowledgement)	
ATTORNEY GENERAL'S SIGNATURE .	STATE COMPTROLLER'S SIGNATURE
	·
Title:	. Title:
Date:	Date:

IN WITNESS THEREOF, the parties hereto have executed or approved this AGREEMENT on the dates

STATE OF NEW YORK

AGREEMENT

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

WITNESSETH:

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

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

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

I. Conditions of Agreement

- A. The period of this AGREEMENT shall be as specified on the face page hereof. Should funding become unavailable, this AGREEMENT may be suspended until funding becomes available. In such event the STATE shall notify the CONTRACTOR immediately of learning of such unavailability of funds, however, any such suspension shall not be deemed to extend the term of this AGREEMENT beyond the end date specified on the face page hereof.
- B. Funding for the entire contract period shall not exceed the amount specified as "Funding Amount for Initial Period" on the face page hereof.
- C. This AGREEMENT incorporates the face pages attached and all of the marked appendices identified on the face page hereof.
- D. To modify the AGREEMENT, the parties shall revise or complete the appropriate appendix form(s). Any change in the amount of consideration to be paid, change in scope, or change in the term, is subject to the approval of the Office of the State Comptroller. Any other modifications shall be processed in accordance with agency guidelines as stated in Appendix A-1.
- E. The CONTRACTOR shall perform all services to the satisfaction of the STATE. The CONTRACTOR shall provide services and meet the program objectives summarized in the Program Workplan (Appendix D) in accordance with: provisions of the AGREEMENT; relevant laws, rules and regulations, administrative and fiscal guidelines; and where applicable, operating certificates for facilities or licenses for an activity or program.
- F. If the CONTRACTOR enters into subcontracts for the performance of work pursuant to this AGREEMENT, the CONTRACTOR shall take full responsibility for the acts and omissions of its subcontractors. Nothing in the subcontract shall impair the rights of the STATE under this AGREEMENT. No contractual relationship shall be deemed to exist between the subcontractor and the STATE.
- G. Appendix A (Standard Clauses as required by the Attorney General for all State contracts) takes precedence over all other parts of the AGREEMENT.

II. Payment and Reporting

- A. The CONTRACTOR, to be eligible for payment, shall submit to the STATE's designated payment office (identified in Appendix C) any appropriate documentation as required by the Payment and Reporting Schedule (Appendix C) and by agency fiscal guidelines, in a manner acceptable to the STATE.
- B. The STATE shall make payments and any reconciliations in accordance with the Payment and Reporting Schedule (Appendix C). The STATE shall pay the CONTRACTOR, in consideration of contract services for a given PERIOD, a sum not to exceed the amount noted on the face page hereof or in the respective Appendix designating the payment amount for that given PERIOD. This sum shall not duplicate reimbursement from other sources for CONTRACTOR costs and services provided pursuant to this AGREEMENT.
- C. The CONTRACTOR shall meet the audit requirements specified by the STATE.
- D. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epunit@osc.state.ny.us or by telephone at 518-486-1255. CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

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

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

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

III. Terminations

- A. This AGREEMENT may be terminated at any time upon mutual written consent of the STATE and the CONTRACTOR.
- B. The STATE may terminate the AGREEMENT immediately, upon written notice of termination to the CONTRACTOR, if the CONTRACTOR fails to comply with the terms and conditions of this AGREEMENT and/or with any laws, rules and regulations, policies or procedures affecting this AGREEMENT.

- C. The STATE may also terminate this AGREEMENT for any reason in accordance with provisions set forth in Appendix A-1.
- D. Written notice of termination, where required, shall be sent by personal messenger service or by certified mail, return receipt requested. The termination shall be effective in accordance with the terms of the notice.
- E. Upon receipt of notice of termination, the CONTRACTOR agrees to cancel, prior to the effective date of any prospective termination, as many outstanding obligations as possible, and agrees not to incur any new obligations after receipt of the notice without approval by the STATE.
- F. The STATE shall be responsible for payment on claims pursuant to services provided and costs incurred pursuant to terms of the AGREEMENT. In no event shall the STATE be liable for expenses and obligations arising from the program(s) in this AGREEMENT after the termination date.

IV. Indemnification

- A. The CONTRACTOR shall be solely responsible and answerable in damages for any and all accidents and/or injuries to persons (including death) or property arising out of or related to the services to be rendered by the CONTRACTOR or its subcontractors pursuant to this AGREEMENT. The CONTRACTOR shall indemnify and hold harmless the STATE and its officers and employees from claims, suits, actions, damages and costs of every nature arising out of the provision of services pursuant to this AGREEMENT.
- B. The CONTRACTOR is an independent contractor and may neither hold itself out nor claim to be an officer, employee or subdivision of the STATE nor make any claims, demand or application to or for any right based upon any different status.

V. Property

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

VI. Safeguards for Services and Confidentiality

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

STANDARD CLAUSES FOR NYS CONTRACTS

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

- 1. <u>EXECUTORY CLAUSE</u>. 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.
- 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.
- COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds \$50,000 (or the minimum thresholds agreed to by the Office of the State Comptroller for certain S.U.N.Y. and C.U.N.Y. contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount, or if, by this contract, the State agrees to give something other than money when the value or reasonably estimated value of such consideration exceeds \$10,000, it shall not be valid, effective or binding upon the State until it has been approved by the State Comptroller and filed in his office. Comptroller's approval of contracts let by the Office of General Services is required when such contracts exceed \$85,000 (State Finance Law Section 163.6.a).
- 4. WORKERS' COMPENSATION BENEFITS. In accordance with Section 142 of the State Finance Law, this contract shall be void and of no force and effect unless the Contractor shall provide and maintain coverage during the life of this contract for the benefit of such employees as are required to be covered by the provisions of the Workers' Compensation Law.
- 5. <u>NON-DISCRIMINATION REQUIREMENTS</u>. 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.

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. <u>NON-COLLUSIVE BIDDING CERTIFICATION</u>.

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. <u>INTERNATIONAL BOYCOTT PROHIBITION</u>. 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

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

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

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(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. <u>CONFLICTING TERMS</u>. 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. <u>GOVERNING LAW</u>. 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. <u>NO ARBITRATION</u>. 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. <u>SERVICE OF PROCESS</u>. 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 30 South Pearl St -- 7th Floor Albany, New York 12245 Telephone: 518-292-5220 Fax: 518-292-5884

http://www.empire.state.ny.us

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

NYS Department of Economic Development Division of Minority and Women's Business Development 30 South Pearl St -- 2nd Floor Albany, New York 12245 Telephone: 518-292-5250

Fax: 518-292-5803

http://www.empire.state.ny.us

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

(a) The Contractor has made reasonable efforts to encourage the participation of New York State Business

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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. <u>RECIPROCITY AND SANCTIONS PROVISIONS.</u>

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. <u>COMPLIANCE WITH NEWYORK STATE</u>

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. <u>COMPLIANCE</u> <u>WITH</u> <u>CONSULTANT</u> <u>DISCLOSURE LAW</u>. 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. <u>CERTIFICATION OF REGISTRATION TO</u> 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.

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APPENDIX A-1

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

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

- If the CONTRACTOR is a tax-exempt organization under Section 501 (c)(4) of the Internal Revenue Code, the CONTRACTOR certifies that it will not engage in lobbying activities of any kind regardless of how funded.
- 2) The CONTRACTOR acknowledges that as a recipient of federal appropriated funds, it is subject to the limitations on the use of such funds to influence certain Federal contracting and financial transactions, as specified in Public Law 101-121, section 319, and codified in section 1352 of Title 31 of the United States Code. In accordance with P.L. 101-121, section 319, 31 U.S.C. 1352 and implementing regulations, the CONTRACTOR affirmatively acknowledges and represents that it is prohibited and shall refrain from using Federal funds received under this AGREEMENT for the purposes of lobbying; provided, however, that such prohibition does not apply in the case of a payment of reasonable compensation made to an officer or employee of the CONTRACTOR to the extent that the payment is for agency and legislative liaison activities not directly related to the awarding of any Federal contract, the making of any Federal grant or loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan or cooperative agreement. Nor does such prohibition prohibit any reasonable payment to a person in connection with, or any payment of reasonable compensation to an officer or employee of the CONTRACTOR if the payment is for professional or technical services rendered directly in the preparation, submission or negotiation of any bid, proposal, or application for a Federal contract, grant, loan, or cooperative agreement, or an extension, continuation, renewal, amendment, or modification thereof, or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan or cooperative agreement.
- 3) This section shall be applicable to this AGREEMENT only if federal funds allotted exceed \$100,000.
 - a) The CONTRACTOR certifies, to the best of his or her knowledge and belief, that:
 - No federal appropriated funds have been paid or will be paid, by or on behalf of the CONTRACTOR, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal amendment or modification of any federal contract, grant, loan, or cooperative agreement.
 - If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the CONTRACTOR shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying" in accordance with its instructions.
 - b) The CONTRACTOR shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including

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

- c) The CONTRACTOR shall disclose specified information on any agreement with lobbyists whom the CONTRACTOR will pay with other Federal appropriated funds by completion and submission to the STATE of the Federal Standard Form-LLL, "Disclosure Form to Report Lobbying", in accordance with its instructions. This form may be obtained by contacting either the Office of Management and Budget Fax Information Line at (202) 395-9068 or the Bureau of Accounts Management at (518) 474-1208. Completed forms should be submitted to the New York State Department of Health, Bureau of Accounts Management, Empire State Plaza, Corning Tower Building, Room 1315, Albany, 12237-0016.
- d) The CONTRACTOR shall file quarterly updates on the use of lobbyists if material changes occur, using the same standard disclosure form identified in (c) above to report such updated information.
- 4) The reporting requirements enumerated in subsection (3) of this paragraph shall not apply to the CONTRACTOR with respect to:
 - 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 Budget line interchanges; Any proposed modification to the contract which results in a change of greater than 10 percent to any budget category, must be submitted to OSC for approval;
 - Appendix C Section II, Progress and Final Reports;
 - ◆ Appendix D Program Workplan will require OSC approval.
- b. To make any other modification of this AGREEMENT within an existing PERIOD, the parties shall revise or complete the appropriate appendix form(s), and a Modification Agreement (Appendix X is the blank form to be used), which shall be effective only upon approval by the Office of the State Comptroller.

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

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

- CE-200 Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- **C-105.2** -- Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the **U-26.3**; OR
- **SI-12** -- Certificate of Workers' Compensation Self-Insurance, OR **GSI-105.2** -- Certificate of Participation in Workers' Compensation Group Self-Insurance

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

- CE-200 Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- DB-120.1 -- Certificate of Disability Benefits Insurance OR
- DB-155 -- Certificate of Disability Benefits Self-Insurance
- 14. Contractor shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208). Contractor shall be liable for the costs associated with such breach if caused by Contractor's negligent or willful acts or omissions, or the negligent or willful acts or omissions of Contractor's agents, officers, employees or subcontractors.
- 15. All products supplied pursuant to this agreement shall meet local, state and federal regulations, guidelines and action levels for lead as they exist at the time of the State's acceptance of this contract.
- 16. Additional clauses as may be required under this AGREEMENT are annexed hereto as appendices and are made a part hereof if so indicated on the face page of this AGREEMENT.

APPENDIX A-2 New York State Health Research Science Board

Contract Policy Statement and Conditions

Rev. approved 3/09

A. Ethical Considerations

The Health Research Science Board (HRSB) stipulates that each awarded contract satisfy the following requirements:

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

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning breast cancer. In carrying out such research, the rights and welfare of all individual research participants are of critical importance. Furthermore, additional safeguards must protect especially vulnerable research subjects, including minors, mentally disabled adults who lack capacity to provide informed consent to research participation, and prisoners.

Accordingly, no research study shall be approved for funding recommendation by HRSB unless it is demonstrated that all the following requirements are satisfied:

- The research study will comply with New York State Public Health Law (PHL) Article 24-A, Sections 2440 to 2446, unless the research is subject to, and in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.
- The research study will comply with 45 CFR Part 46 (unless exempt from the requirements of this Part) and, if applicable, 21 CFR Parts 50 and 56; 21 CFR 312; 21 CFR 361; 21 CRF 812.
- The research study will comply with all other applicable federal and New York State laws, regulations and guidelines.
- The research study has been approved by an Institutional Review Board (IRB).
- If applicable, the applicant organization's IRB has received and reviewed written approval from an authorized representative of each site where the study will take place.

- The IRB has determined that the investigator will immediately withdraw a subject from the research study if continued participation would be detrimental to the subject's well-being.
- The IRB will communicate to HRSB program administrators (i) any unanticipated problems involving risks to subjects, (ii) any serious or continuing noncompliance with IRB policy or requirements; and (iii) any suspension or termination of IRB approval.

Vulnerable Populations

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

- The IRB has determined that the research study constitutes either: research with a prospect of direct benefit to research participants; or research with no prospect of direct benefit to research participants that presents minimal risk.
- If the research involves one or more mentally disabled adults, each investigator must use IRB approved methodologies and procedures for initial capacity assessment, including: procedures for notice to a prospective subject that his/her capacity to consent to research is under consideration; notice to a prospective subject of a determination that he/she lacks the capacity to consent to research; and the opportunity for a prospective subject to contest such a determination of incapacity through a second opinion and a judicial proceeding prior to enrollment in the research.
- The IRB has determined that, prior to involving in a research study a minor, a mentally disabled adult who lacks the capacity to provide informed consent to research participation, or a prisoner, each investigator will obtain such individual's assent to research participation. ¹

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

C. Animal Use

HRSB requires that all individuals and institutions that conduct research using animals supported by the Breast Cancer Research and Education Fund adhere to all federal, state and local laws pertaining to humane care and use of animals for research purposes. Research applications submitted to the Board for consideration are expected to be reviewed by an Institutional Animal Care and Use Committee (IACUC) whose guidelines are in compliance with the U.S. Public Health Service's *Policy on Humane Care and Use of Laboratory Animals*, and *Guide for the Care and Use of Laboratory Animals*, as well as any other federal, state and local laws or regulations (e.g., the federal Animal Welfare Act and its implementing regulations; and PHL Article 5, Title I, Sections 504 and 505-a).

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

D. Tissue

HRSB will support research using human tissue and require that such research adhere to all federal, state and local laws, regulations and guidelines pertaining to use of such tissue, including, but not limited to, 42 USC Section 289g et seq.; Public Health Law Article 5, Title V, sections 570 to 581; Article 24-A, sections 2440 to 2446; Article 43, sections 4301 to 4309; Article 43-B, sections 4360 to 4366; and 10 NYCRR Part 52. Research proposing to use pluripotent stem cells requires appropriate and rigorous legal and ethical oversight.

E. Publication and Intellectual Property Rights

- 1. It is HRSB's intent that the results of research it supports through its sponsorship be disseminated and made easily available to the research community and the lay public. Manuscript submission for publication of research funded by the Fund shall not be delayed by investigators or their research institutions for more than 60 days after the manuscript is completed. Research results are to be submitted promptly for publication in internationally recognized scientific journals. Publication should not be delayed for commercial or other reasons beyond the editorial period needed to ensure scientific accuracy and presentation.
 - a. All publications reporting research supported by HRSB funds published in peer reviewed journals must be deposited in the National Institutes of Health National Library of Medicine's PubMed Central (PMC). The HRSB 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 HRSB-funded research findings as "open access" publications, contract funds may be used to cover costs required for such "open access" publication.
 - b. An electronic copy of each such publication must be filed with the progress report pursuant to the contract.
 - c. Within 60 days of publication, the investigator must submit to HRSB program administrators a 500 word abstract of the publication suitable for the general public, highlighting the research findings. A full literature citation and a brief biographical sketch of the HRSBfunded Principal Investigator must also be submitted. This information will be made available to the public through the program's website.
 - d. Support by the Breast Cancer Research and Education 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 Breast Cancer Research and Education 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 Health Research Science Board, the New York State Department of Health, or the State of New York."
- 2. It is HRSB's intent that the resources, materials and methods created through its sponsorship be disseminated and made easily available to the research community. All such materials described in invention disclosures, publications, or other public forums shall be made available to requesting investigators. The contractor may collect reasonable costs for provision of such resources and may require execution of appropriate material transfer agreements, licenses, or confidentiality agreements (see paragraph #4, below).

- 3. With regard to HRSB funded research, where the grantee organization has not made reasonable efforts to protect the property interests or because the grantee has failed to share the research developments, the State shall retain march-in rights. The State shall have perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, for research and governmental purposes only, any published or otherwise reproducible material, device, invention, technique, material, or methodology developed under or in the course of performing this funded research, dealing with any aspect of the research activity, or of the results and accomplishments attained from the research.
- 4. The contractor must have written agreements with researchers requiring prompt disclosure of inventions made in the performance of HRSB-funded research. Within 60 days of such disclosure the contractor shall notify HRSB program administrators of the invention disclosure. The contractor shall notify HRSB program administrators upon the filing of any patent application in the progress report pursuant to the contract. The contractor shall provide HRSB program administrators with advance written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Fund. Any such assignment or transfer must acknowledge, and be subject to the rights retained by the State pursuant to the above paragraph 3, supra.

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

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

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

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

F. Reporting Requirements

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

G. Equipment

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

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

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

H. Other Information

- 1. Documents submitted to the Department of Health on behalf of the HRSB program will not be returned to the applicant.
- 2. Appendix B (Budget) may be reviewed and revised each year, depending on research progress and the availability of funds.
- 3. The New York State Department of Health may require reimbursement of all or a part of the award if ineligible expenses have been incurred or false accounting statements have been submitted.
- 4. Neither the Department of Health nor the State of New York will assume any responsibility for any damage or injuries caused or resulting from research conducted with the financial support of the Fund.
- 5. Recipient entities accept auditing of their expenditures by an appointed representative of the HRSB research program at any time.
- 6. Assurances and Certifications. The New York State HRSB has adopted the following federal regulatory mechanisms to ensure responsible administration of its awards and to preserve the integrity of the research enterprise it supports. By signing this Grant Contract, the authorized representative of the organization certifies that, in addition to all applicable state and local statutes and regulations, the applicant organization will comply with applicable federal regulations and statutes, including but not limited to:

a. Vertebrate Animals:

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

b. Research Misconduct:

- 42 CFR Part 50, Subpart A, "Responsibilities for PHS awardees and applicant institutions for dealing with and reporting possible misconduct in science."
- 42 CFR 94, "Public Health Service standards for the protection of research misconduct whistleblowers" (effective on the date set forth in the final rule).
- Each covered institution must certify that it will comply with the above policies and the requirements of the Final Rule.

 A copy of the institution's Annual Report on Possible Research Misconduct (Form 6349), routinely sent to all PHS awardees by the Office of Research Integrity, shall be forwarded to HRSB Program administrators.

c. Conflict of Interest

- 42 CFR 50, Subpart F, "Responsibility of applicants for promoting objectivity in research for which PHS funding is sought."
- 7. The Department of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight.
- 8. Fees related to patient care costs are not reimbursable expenses. Tuition reimbursement is not an allowable expense for the Peter T. Rowley Breast Cancer Research awards.

APPENDIX B

BUDGET (Sample Format)

Name of Contractor or Subcontractor

BUDGET CATEGORY		Year One	Year Two	TOTAL (all years)		
PEI	PERSONAL SERVICE (PS)					
1	SALARY AND STIPENDS					
	Position (separately list each position to be fund	ded, indicating i	f position is vaca	ant)		
	SUBTOTAL Salary & Stipends					
2	FRINGE BENEFITS					
3	SUBTOTAL PS					

OTHER THAN PERSONAL SERVICE (OTPS) SUPPLIES LAB SUPPLIES OFFICE SUPPLIES 4 **SUBTOTAL SUPPLIES EQUIPMENT** 5 6 TRAVEL 7 SUBCONTRATOR AND CONSULTANT COSTS OTHER EXPENSES 8 HUMAN SUBJECTS AND RELATED RESEARCH COSTS ANIMALS AND CARE **CORE FACILITY USAGE FEES** COMMUNICATION COSTS MEETING COSTS PUBLICATION EXPENSES MISCELLANEOUS **SUBTOTAL OTHER EXPENSES** 9 SUBTOTAL OTPS (sum of lines 4 - 8) **TOTAL PS & OTPS** 10 (lines 3 + 9)TOTAL SUBCONTRACT COST (sum of line 14 of 11 all subcontractor budgets) **TOTAL DIRECT COST** 12 (sum of lines 10 + 11) 13 FACILITIES AND ADMINISTRATIVE COSTS 14 GRAND TOTAL COST (sum of lines 12 + 13)

APPENDIX C

Payment and Reporting Schedule Rev. approved 8/11

Peter T. Rowley Breast Cancer Scientific Research Awards

- 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 the initial or subsequent PERIODS. Should funds for subsequent PERIODS not be appropriated or budgeted by the STATE for the purpose herein specified, the STATE shall, in accordance with Section 41 of the State Finance Law, have no liability under this AGREEMENT to the CONTRACTOR, and this AGREEMENT shall be considered terminated and cancelled.
- D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the program workplan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's

designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epunit@osc.state.ny.us or by telephone at 518-486-1255. The CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

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

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

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

- E. The CONTRACTOR will provide the STATE with the reports of progress or other specific work products pursuant to this AGREEMENT as described in this Appendix below. In addition, a final report must be submitted by the CONTRACTOR no later than 60 days after the end of this AGREEMENT. All required reports or other work products developed under this AGREEMENT must be completed as provided by the agreed upon work schedule in a manner satisfactory and acceptable to the STATE in order for the CONTRACTOR to be eligible for payment.
- F. The CONTRACTOR shall submit to the STATE quarterly voucher claims and reports of expenditures on such forms and in such detail as the STATE shall require. The CONTRACTOR shall submit vouchers to the STATE's designated payment office located in the:

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

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

advances in excess of actual expenditures will be recouped by the STATE prior to the end of the applicable budget period.

G. If the CONTRACTOR is eligible for an annual cost of living adjustment (COLA), enacted in New York State Law, that is associated with this grant AGREEMENT, payment of such COLA, 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 the Program (found online at http://www.wadsworth.org/extramural/breastcancer.htm) which shall accompany the voucher submitted for each period (see Table I for annual schedule). Documentation of all expenses shall be available upon request. The STATE may require documentation of expenses before payment of any voucher. No vouchers shall be paid until the corresponding progress report is received and approved pursuant to this AGREEMENT.

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

The CONTRACTOR shall submit the final voucher for the 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 case shall the final voucher for the contract be paid prior to the submission of the final progress report.

TABLE I
Annual Voucher and Expenditure Reporting Schedule

Voucher and	Period Covered	Due Date*
Expenditure Report		
1 st Quarter	January 1 – March 31	April 30
2 nd Quarter	April 1 – June 30	July 30
3 rd Quarter	July 1 – September 30	October 30
4 th Quarter	October 1 – December 31	January 30
Final	October 1, 2014 –	March 2, 2015
	December 31, 2014	

^{*}This table assumes a 2 year contract with no extension. 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 the Program (found online at http://www.wadsworth.org/extramural/breastcancer.htm), summarizing the work performed during the period (see Table II for 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 hrsb@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).

<u>TABLE II</u> <u>Progress Reporting Schedule</u>

Progress Report #	Period Covered	<u>Due Date*</u>
1	January 1, 2013 – May 31, 2013	June 30, 2013
2	June 1, 2013 – November 30, 2013	December 30, 2013
3	December 1, 2013 – May 31, 2014	June 30, 2014
Final Progress Report	Entire Contract Period	March 2, 2015

^{*}This table assumes a 2 year contract with no extension. 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).

C. Final Progress Report

The CONTRACTOR shall submit a detailed comprehensive final progress report not later than 60 days from the end of the contract, summarizing the work performed during the entire contract period (i.e., a cumulative report), in the forms and formats as provided by the Program (found online at http://www.wadsworth.org/extramural/breastcancer.htm).

APPENDIX D

PROGRAM WORKPLAN

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

APPENDIX G

NOTICES

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

- (a) via certified or registered United States mail, return receipt requested;
- (b) by facsimile transmission;
- (c) by personal delivery;
- (d) by expedited delivery service; or
- (e) by e-mail.

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

State of New York Department of Health

Name: Title:

Address:

Telephone Number:

Facsimile Number:

E-Mail Address:

[Insert Contractor Name]

Name:

Title:

Address:

Telephone Number:

Facsimile Number:

E-Mail Address:

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

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

APPENDIX X

Agency Code 12000

Contract Number:	Contractor:
Amendment Number X-	_
Department of Health, having	veen THE STATE OF NEW YORK, acting by and through NYS its principal office at Albany, New York, (hereinafter referred to as the hent of this contract.
This amendment makes the fo	ollowing changes to the contract (check all that apply):
Modifies the contract	
Modifies the contract	
Modifies the budget of	r payment terms
Modifies the work pla	n or deliverables
Replaces appendix(e	s) with the attached appendix(es)
Adds the attached ap	pendix(es)
Other: (describe)	
This amendment is is not	a contract renewal as allowed for in the existing contract.
All other provisions of said AC	GREEMENT shall remain in full force and effect.
Prior to this amendment, the o	contract value and period were:
\$ (Value before amendment)	From / / to / / . (Initial start date)
This amendment provides the	following modification (complete only items being modified):
\$	From <u>/ /</u> to <u>/ /</u> .
This will result in new contract	t terms of:
\$(All years thus far combin Ver. 2/19/10	ed) From / / to / / . (Initial start date (Amendment end date)

Signature Page for:	
Contract Number: C	ontractor:
Amendment Number: <u>X-</u>	
	to have executed this AGREEMENT as of the dates appearing under
CONTRACTOR SIGNATURE:	
By: D (signature)	ate:
(signature) Printed Name:	
Title:	
STATE OF NEW YORK)) Si County of)	S:
	r before me, the undersigned, personally appeared, personally known to me or proved to me on the basis of satisfactory
me that he/she/they executed the same in instrument, the individual(s), or the person (Signature and off	ne(s) is(are) subscribed to the within instrument and acknowledged to his/her/their/ capacity(ies), and that by his/her/their signature(s) on the upon behalf of which the individual(s) acted, executed the instrument.
STATE AGENCY SIGNATURE	
"In addition to the acceptance of this cobe attached to all other exact copies of	ontract, I also certify that original copies of this signature page will this contract."
Ву:	Date:
(signature) Printed Name:	
Title:	
	 -
ATTORNEY GENERAL'S SIGNATURE _	
By:	Date:
STATE COMPTROLLER'S SIGNATUF	RE
Ву:	Date:

Ver. 2/19/10