New York State Health Research Science Board

Breast Cancer Research and Education Program

Award Year 2004

Guidelines, Instructions and Application Forms for Postdoctoral Fellowships

Administered by the
New York State Department of Health
Wadsworth Center
Office of Extramural Funding
Room C675
Empire State Plaza
Albany, NY 12201-0509

"Under Governor Pataki's leadership, New York has taken major steps to protect and ensure that the special health care needs of women with breast cancer are met. Ongoing research plays a vital role in New York's efforts to not only find a cure but to help prevent and treat women who are already coping with the devastating effects of breast cancer."

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
New York State Commissioner of Health

Letter of Intent Deadline: January 17, 2005

DEADLINE FOR SUBMISSION: APRIL 11, 2005

The NYS Breast Cancer Research and Education Program Postdoctoral Fellowships Request for Applications are also available at: http://www.wadsworth.org/new/rfa/hrsb/index.htm. Application forms may be completed on-line and then printed for submission with the rest of the mailed application.

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Breast Cancer Research and Education Program

I. Program Information

A. Background

Each year more than 12,000 women are diagnosed with breast cancer in New York State, and nearly 3,000 women die from this disease. In response to this crisis, Governor George E. Pataki authorized legislation in 1996 creating the Breast Cancer Research and Education Fund (the Fund). The Fund is financed by donations made on New York State income tax forms, direct gifts to the Fund, and proceeds from sales of "Drive for the Cure" specialty license plates. In October 2000, Governor Pataki signed legislation authorizing State funds to match dollar-for-dollar check-off donations and specialty plate proceeds. The Health Research Science Board (the Board), whose membership roster appears on page 19, administers the Fund. Among the Board's main duties are to solicit, review and recommend to the Commissioner of Health creative and innovative research or education projects for support by the Fund. At least $2 million is expected to be available to support this competition cycle.

B. Program Objectives

The intent of the Postdoctoral Fellowships awards is to support the continued training of basic or clinical investigators with exceptional potential for making significant contributions to the battle against breast cancer. For this round of competitions, our goal is to fund postdoctoral fellowships. We anticipate a separate mechanism for community-based organizations (CBO) to be announced later.

The Board expects that outcomes of supported activities will benefit subsequent research or education efforts, breast cancer policy or the continuum of breast cancer care – from prevention to treatment. To fulfill this vision, applications may address any topic or issue related to breast cancer causation, prevention, detection, treatment or cure. Any investigative approach appropriate to the application topic may be used, including, but not limited to, basic, behavioral, clinical, environmental, epidemiological or psychosocial research. Award recipients and project titles from earlier competition cycles are listed on pages 20 - 22.

C. Eligibility

The proposed research project must be formulated and agreed upon by the fellowship sponsor (or mentor) and the postdoctoral candidate, and described in detail in the application.

1. Citizenship

There are no citizenship restrictions for either candidate or sponsor.

2. Degree Requirements

Candidates and sponsors must have doctoral-level degrees (e.g., Ph.D., M.D., D.V.M, Psy.D., Ed.D., etc.) by the award start date of October 1, 2005.

3. Applicant Organization

Eligible applicant organizations include academic or medical institutions, State or local government agencies, or any other institution within the State of New York. Unaffiliated individuals are ineligible for awards.

No more than one award will be made to the same laboratory, although more than one may be made to the same institution.

Organizations awarded funds must have the ability to monitor funds, maintain individual accounts and fulfill other fiscal management criteria.

4. Additional Eligibility Requirements

a) Sponsors/Mentors

To encourage new or cross-disciplinary approaches to breast cancer research, fellowship sponsors need not be well established in the breast cancer field, although they should be

highly qualified to supervise the proposed project. Sponsors who are five years or less into their first permanent position are encouraged to identify a more senior collaborator to co-sponsor the fellow. Sponsors may submit more than one fellowship application; however, only one award will be made per sponsor.

b) Candidates

Fellowship nominees may have no more than two years of prior postdoctoral training under the sponsor's supervision by the expected start date of the award. Candidates may have more than one sponsor to enhance training, but only one sponsor of record is permitted.

D. Award Size and Duration

Total support requested may be up to $60,000 per year for a two-year period, beginning no earlier than October 1, 2005.

E. Stipend and Allowances

Fellowship funding is provided to the host institution, except where otherwise noted. A Postdoctoral Fellowship consists of a stipend, a travel allowance, and research related expenses.

1. Fellow's Stipend

For each fellow's stipend, $35,000 is to be allocated for year-one and $37,000 for year two. Support for fringe benefits may be requested in accordance with institutional guidelines for postdoctoral fellows, provided that such support is administered consistently by the applicant organization as a direct cost to all sponsors. The stipend may be supplemented by other sources to offset the cost of living; however, in such case additional effort may not be required from the fellow.

Basic and clinical research fellows are to be involved in their proposed training full-time. Research clinicians must restrict clinical duties to those activities that are directly related to the research training experience.

2. Additional Allowance

Funds must be budgeted for:

a) **If required**, travel to New York City to present project results to the Board; and

b) **If required**, travel for the fellow to participate at one national scientific meeting.

Remaining funds may be applied to other allowable costs, e.g., fringe benefits and purchase of research supplies. Note: the Board expects the sponsor, the institution or other external funding sources to contribute to the cost of supplies and other expenses for each fellow's research project.

3. Facilities and Administration Costs

Facilities and administration costs are limited to 8 percent of total project costs and, if waived, may be used to supplement the fellow's stipend.

F. Application Information – Questions and Answers

To clarify any questions concerning the request for applications (RFA), program administrators will accept questions from potential applicants through January 28, 2005.

Questions must be submitted in writing and should be mailed or faxed to Martin D. Sorin, Ph. D. at

Breast Cancer Research and Education Program
New York State Department of Health
Wadsworth Center
Office of Extramural Funding, Rm. C675
Empire State Plaza
Albany, N Y 12201-0509
Fax: 518-486-2798

All questions and answers will automatically be made available to those applicants who submit a Letter of Intent (refer to next section). The questions and answers will also be posted by February 8, 2005 on our website at:
http://www.wadsworth.org/new/rfa/hrsb/index.htm.

G. Letter of Intent

The submission of a non-binding letter of intent to submit application is strongly recommended so that an adequate number of reviewers is reserved. Please fax your letter to (518) 486-2798 by January 17, 2005.

H. Application Selection Process

1. Pass/Fail

Applications will first be examined for completeness by program administrators. Incomplete applications, such as those that do not include the fellow's three signed sealed references (refer to page 4, bullet 6) will not be considered for review.

Complete applications will be reviewed for scientific, technical and training merit and relevance, as determined by panels of scientific/technical experts and lay breast cancer survivors. Panels will be comprised of a Board member, at least one breast cancer survivor, and a sufficient number of individuals qualified to provide scientific, technical and educational review of the applications. Survivor and scientific merit reviewers will be recruited from outside New York State.

The second review will be by the Board. Those applications approved by the Board will be recommended for funding to the Commissioner of Health, who will make the final determinations.

Applications that encourage the training of young breast cancer researchers or those whose potential project results will lead to future funding or will have an impact on breast cancer policy or practice in New York State are preferred.

2. Scoring Criteria

For the first level review, a panel of scientific/technical experts will review complete applications using criteria described below. All applicants will receive unedited, anonymous copies of reviewers' critiques.

The review criteria focus on six main components:

Candidate. The candidate's previous academic and research performance and his/her potential to become an important contributor to the biomedical, behavioral or clinical sciences related to breast cancer. (15% of total score.)

Sponsor and Training Environment. The quality of the training environment and the qualifications of the sponsor(s) as mentor(s) to facilitate the proposed research training experience. (15%)

Training Potential. The value of the proposed fellowship experience as it relates to the candidate's needs in preparation for a career as an independent researcher in the field of breast cancer research. (15%)

Research Application. The scientific merit of the application. (20%)

Significance Review Criteria. Does the project address an area of importance to breast cancer? What is the likelihood the project will lead to further funding, or be translated into practice, or impact policy? (15%)

Budget. Reviewers may also recommend modifications to an application's scope of work or budget. (20%)

3. Other Review Criteria

Before research may begin, all applications will be reviewed for adequacy of protection of human subjects or vertebrate animals.

I. Notification of Results

Fellowship sponsors will receive formal notification of the competition's outcome. Applicant organizations will be notified of applications awarded funding by the Commissioner of Health. Contracts will be negotiated between the New York State Department of Health and the applicant organization, with input from the fellowship sponsor.

II. Application Instructions

A. Application Materials

The fellowship application consists of thirteen forms (enclosed in this document), research application, supporting materials and three letters of reference. Application instructions are provided in the next section (Section III. Application Components).

The application forms are also available at http://www.wadsworth.org/new/rfa/hrsb/index.htm or may be requested from program administrators.

Questions about application procedures may be submitted to program administrators via e-mail (hrsb@wadsworth.org) or fax at (518) 486-2798. Responses to such inquiries will be made within one week of receipt, and will be made available to all applicants at http://www.wadsworth.org/new/rfa/hrsb/index.htm.

B. Formatting the Application

The entire application including continuation pages should be submitted on white 8 ½" X 11" paper.

1. *Type size.* The entire text of the application should be in a readable font. Use standard 12 point type (no more than 15 cpi).

2. *Page Margins.* Margins in all directions should be at least ½ inch.

3. *Line Spacing*. No more than 6 lines of type within a vertical inch.

4. *Headers and Footers.* The fellowship sponsor's name (last name, first name, middle initial) should appear at the top right-hand corner of each page. Pages should be numbered consecutively at the center of the page, bottom edge.

5. *Page Limitations.* Do not exceed the page limits stated for each section. Figures and illustrations referenced in the research plan are included in the ten-page research plan limit. The pages that exceed the stated page limits will receive a lower score.

6. *Appendices.* Postdoctoral candidates must include three signed, sealed references with the original copy of the application (see page 11, Appendices). Two, three-hole-punched, collated and stapled sets of other supplementary materials or appendices may be submitted for use by primary scientific/technical reviewers. Limit appendices to 20 pages. Other allowable materials include: **Informed Consent Documents for Human Subjects (if applicable)**; Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approvals; memoranda of understanding or contractual agreements; letters of collaboration or support; or one highly relevant manuscript. Appendices **must** not serve to circumvent page limitations. All material crucial to the application **must** be incorporated within the ten pages of the research plan.

Guides to Application Preparation. Applicants new to grant writing or unfamiliar with research oversight regulations are encouraged to obtain advice from their institution's sponsored programs office (or equivalent). An excellent article on grant writing can be found at the Human Frontier Science Program Web site: http://www.hfsp.org/how/content.htm – (The Art of Grantsmanship, by Jacob Kraicer.) Grant writing tip sheets from the National Institutes of Health can be found at http://grants.nih.gov/grants/grant_tips.htm. Especially helpful is the link, "How to Write a Research Grant." Applicants without Web access are invited to request these documents from program administrators. General information presented in the National Science Foundation's "Guide for Application Writing" may also be useful and can be found at http://www.nsf.gov/pubsys/ods/getpub.cfm?ods_key=nsf04016.

III. Application Components

A. Application-Specific Guidelines

1. Face Page (Form Page 1)

1. *Project Title.* Describe the focus or purpose of the proposed project in up to 60 characters and spaces; longer titles will be truncated.

2. *Fellow Candidate and Fellowship Sponsor*. Provide information requested; insert "N/A" in lines that are not applicable.

   For items 2e-2m provide the fellowship sponsor's institutional affiliation and requested contact information.

3. *Applicant Organization*. The legal name of the entity to whom payment will be made in the event of an award. Provide information requested; insert "N/A" in lines that are not applicable.

4. *Type of Organization.* Check appropriate box(es). A small business is an independently owned and operated entity not dominant in the field in which research is proposed, and employing 500 or fewer persons. A "WMO" is a woman- or minority-owned business.

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

6. *Legislative District Numbers.* Enter the New York State Senate and Assembly district numbers corresponding to the address provided in item 15, Face Page (Form Page 1). Senate district information may be found at: www.senate.state.ny.us and Assembly district information obtained by calling (518) 455-4100.

7. *Charities Registration Number.* In the space provided, enter the applicant organization's registration number or if exempt, indicate the exemption category. For information on registration numbers or exemption status, contact the Office of the Attorney General, Charities Registration Bureau at 518-486-9797 or 212-416-8430.

8. *Entire Project Period.* Enter the proposed project period (i.e., the start and end dates of the entire project). In the event an award is recommended, no fiscal commitment or obligations should be incurred until the actual start date is confirmed by the New York State Department of Health.

9. *Year-One Total Costs Requested.* Enter Year-One total costs (line 10, Year One, Form Page 4). All amounts requested in items 9 and 10 on Form Page 1 and on the budget page(s) must be in U.S. dollars, not to exceed $60,000 per year.

10. *Total Project Costs for All Years.* Not to exceed $120,000.

11. *11a. Application History*. Check the appropriate box. Applicants who are resubmitting applications that were not funded in previous cycles **must** check "Resubmission of Application No." and record the previous cycle's application number.

    11b. Subcontract. Check whether the application includes a subcontract to another entity or institution.

12. *Human Subjects.* If human subjects will not be involved in any activity during the proposed project period, check "NO" in item 12. The remaining parts of item 12 are then not applicable and should be left blank. If human subjects will be involved in any activity during the proposed project period, either at the applicant organization, subcontractor organization, or at any other performance site or collaborating institution, check "YES." Any research conducted using human subjects shall comply with the human research conditions described on page 13, Article B of the *Contract Policy Statement and Conditions*. Compliance is demonstrated, in part, by submission of a New York State Health Research Science Board Human Subjects Research Certification, signed by the organization's Institutional Review Board (IRB) chair or other authorized individual (see Form Page 9, Human Subjects). This certification will also be required of

collaborating or subcontracting organizations, prior to contract execution.

Exempt Activities: If the human subjects activities are exempt from applicable regulations, insert in item 12a the exemption number(s) corresponding to one or more of the six exemption categories. The remaining parts of item 12 are then not applicable and should be left blank. The New York State Department of Health will make all final determinations as to whether the proposed activities are covered by applicable regulations or qualify for an exempt category, based on the information provided in the application. A current exemption certification form signed by the organization's IRB will be required for contract execution.

Non-exempt Activities: If the human subject activities are not exempt, complete the remaining parts of item 12. Report in 12b the IRB approval date, and check whether IRB review was expedited or full. The approval date must be no earlier than one year prior to the application due date. If the applicant organization has an approved Multiple Project Assurance of Compliance form on file with the federal Office for Human Research Protection (OHRP), formerly the Office for Protection from Research Risks (OPRR), that covers the specific activity, insert the Assurance number in 12c.

If IRB review has begun but is not completed by the time the application is submitted, enter "Pending" in item 12b. Informed consent documents must be provided in the application's appendix for application review, even if IRB review is pending. The organization's certification of IRB approval, the NYS Health Research Science Board Breast Cancer Program Human Subjects Certification form (Form Page 9), and approved informed consent documents will be required for contract execution.

13. *Vertebrate Animals.* If vertebrate animals will not be used in any activities during the proposed project period, check "NO" in item 13. The remaining parts of item 13 are then not applicable and should be left blank. If vertebrate animals are involved in any activities during the project period, either at the applicant organization, subcontractor organization, or at any other performance site or collaborating institution, check "YES." The table regarding Vertebrate Animals must be completed (see Form Page 9, Vertebrate Animals). In item 13a, provide the date of Institutional Animal Care and Use Committee (IACUC) approval. If IACUC review is not completed by the time the application is submitted, enter "Pending" in 13a. IACUC review is required prior to contract execution. If the applicant organization has an approved Animal Welfare Assurance form on file with the Office of Laboratory Animal Welfare (OLAW), formerly OPRR, insert in item 13b the Assurance number, and if required for the species under investigation, the U.S. Department of Agriculture (USDA) registration number.

    If the applicant organization does not have an approved Animal Welfare Assurance form on file with OLAW or a USDA registration number, and these are required, insert "NONE" in 13b. 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.

14. *Official to Be Notified if an Award Is Made.* Provide information requested; leave blank those lines that are not applicable.

15. *Official Signing for Applicant Organization.* Provide the name and contact information for the individual authorized to act for the applicant organization. This individual will assume the obligations imposed by applicable federal and State laws, regulations, requirements, and conditions for the application or contract, and will be responsible for administration and fiscal management of the research program should an award be made. Provide information requested; leave blank those lines that are not applicable.

    Note: This individual typically is not the fellowship sponsor or the fellowship candidate.

16. *Fellowship Sponsor and Candidate Assurance.* The fellowship sponsor and fellowship candidate must sign and date, in blue ink, the Face Page. Persons signing the application Face Page certify to the truthfulness, completeness and accuracy of the information provided. The fellowship sponsor is responsible for planning, coordinating and implementing the research program in the event an award is made. The fellowship sponsor will also act as liaison with program administrators, and be required to fulfill technical reporting requirements and submit any revised budgets co-signed by an authorized organizational representative.

17. *Applicant Organization Certification and Acceptance.* The official signing for the applicant organization must sign and date, in blue ink, the Face Page. In signing the application Face Page, the duly authorized organizational representative certifies that the organization will comply with all applicable assurances, and certifications referenced in these application guidelines and accompanying *Contract Policy Statement and Conditions* (page 13). The applicant organization is responsible for verifying the accuracy, validity and conformity with the latest institutional guidelines of all administrative, fiscal and scientific information in the application. Deliberate withholding, falsification or misrepresentation of information may result in administrative actions, such as withdrawal of an application, suspension or termination of an award, debarment of individuals, and/or possible criminal penalties. The signer further certifies that the applicant organization will be accountable for both appropriate use of any funds awarded, and for performance of the grant contract-supported project or resulting activities. The contracting institution may be liable for reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

    Applications that include sub-contractual arrangements are to insert additional Face Pages signed by the lead co-investigator and official signing for the subcontract organization.

2. Scientific Abstract/Performance Sites/Key Personnel (Form Page 2)

Follow the instructions provided on Form Page 2. Do not include proprietary/confidential information. The scientific abstract should be composed so that persons from diverse scientific backgrounds can easily understand the work proposed. A lay abstract describing the project and its expected outcomes is requested in *Research Categories and Lay Abstract* (section 11, page 10).

3. Table of Contents (Form Page 3)

Complete the table of contents, entering page numbers as appropriate. Insert "N/A" for sections that are not applicable. Please flag with asterisks (*) all page numbers containing information that, if released, would put the applicant at a competitive disadvantage (e.g., financial or commercial confidential information, including trade secrets). Information submitted to the Board is subject to the Freedom of Information Law (New York State Public Officers' Law, Article 6, Sections 84 to 90).

4. Proposed Budget (Form Page 4)

Follow instructions provided on the form. Report in U.S. dollars the amount requested for each category, as well as subtotals and totals requested.

5. Budget Justification (Form Page 5)

Justify amounts requested in each budget category, starting with personnel (i.e., candidate). Regardless whether financial support is requested; describe briefly the roles of the candidate, the fellowship sponsor, and all key personnel listed on Form Page 2, and the percent-effort devoted to the project. For the fellow to be supported, also report the corresponding dollar value of stipend plus fringe benefits. The sum of the stipend plus fringe benefits amounts requested should correspond to "Subtotal Personal Service" for Year One (line 3, Form Page 4).

6. Biographical Sketch (Forms Page 6 and 6a)

Biographical sketches are required for both fellow and sponsor (Forms Page 6 and Page 6a) and are limited to four pages each.

Biographical sketches are also required for all key personnel, other than the fellow and sponsor, listed on Form Page 2. For other key personnel, biographical sketches (Forms Page 6 and 6a) are limited to two pages each.

7. Facilities and Resources (Form Page 7)

Describe the facilities and resources available to support the performance of the proposed project. Also describe any support the applicant organization is providing for the conduct of the project, including any additional facilities or equipment requested in support of the project or available for use at no cost to the project.

8. Project Plan (Form Page 8)

Text and figures are limited to 12 pages total; figure captions may be under 12 cpi, but must be clearly legible.

The project plan should present the application in sufficient detail to convey clearly and concisely to the reviewer(s) that: (i) the application's basis, while innovative and potentially high-risk, is conceptually well-founded and substantiated by the literature; (ii) the approach proposed is the most appropriate strategy; (iii) the applicants (candidate and sponsor) will successfully manage expected or unexpected methodological challenges; (iv) successful completion of the project will aid the Board's mission; and, (v) how successful completion of the project will contribute to the fellow's pursuit of a career in basic or clinical breast cancer research, and generate high quality data that will enable the fellow to secure future funding from other sources.

a) Background and Preliminary Results

Review the literature that underlies the proposed project. Preliminary data, although not required, are strongly encouraged.

b) Specific Aims

List the objectives, hypotheses to be tested, gaps in knowledge to be filled, education or outreach strategies to be developed and evaluated, or technologies/tools to be developed or tested. A description of training to be obtained during the fellowship should also be included.

c) Relevance

Describe briefly the application's broad relevance to breast cancer and provide for each proposed aim a succinct description of how its attainment will advance our understanding of some aspect of breast cancer. This section should also convey the applicant's plans for future studies and possible funding sources, considering results that either support or refute predictions, or future efforts to translate to practice or disseminate project results or outcomes to appropriate target populations or groups. This section should not exceed one page.

d) Research Design and Methods

Describe the plan that will be followed to achieve the specific aims proposed, including descriptions of how data will be interpreted and conclusions drawn (i.e., describe the experimental design, methodological approaches, statistical analyses and interpretation to be used to accomplish the specific aims). Information provided should convey the applicants' understanding of the strengths and limitations of the proposed project design (as evidenced by consideration of alternatives), methodologies, and breast cancer models. Ensure that important unpublished information is presented in sufficient detail to enable reviewers to assess its quality and relevance.

e) Timeline (not included in ten-page application limit)

Include a timeline for project completion.

f) Literature Cited

References are not included in project plan page limitations, nor is the number of references restricted. However, applicants are urged to select references that comprehensively reflect both current and historic literature. Provide complete citations to references (i.e., include titles).

9. Human Subjects (Form Page 9)

Appropriate oversight and administration of human subjects research are essential to the ethical conduct of clinical and preclinical research. In addition to the information requested below, applicants are asked to include in the appendix pending or approved informed consent document(s). As applicable, a New York State Breast Cancer Research and Education Research Program Human Subjects Research Certification (Form Page 9), the institution's standard IRB approval form, a final, approved informed consent document or a signed exemption form from the applicant organization's IRB will be required for contract execution.

If you marked "Yes" on item 12 of the Face Page and did not designate exemptions from the regulations, or plan to include minors, mentally disabled adults or prisoners in your research, succinctly address the following seven points. In addition, if research involving human subjects is to take place at collaborating site(s) or other performance site(s), provide this information before discussing the seven points.

1) *Involvement of Human Subjects.* Describe the involvement of human subjects as outlined in the research plan. Include descriptions of the subject population, e.g., number of subjects, age range, race, gender and health status. Provide inclusion or exclusion criteria for any subpopulation. Explain the rationale for involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals or others who are likely to be vulnerable.

2) *Sources-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 use will be made of existing specimens, records or data. Discuss the system that will maintain subjects' confidentiality.

3) *Recruitment and Consent.* Describe recruitment plans for subjects and the consent procedures to be followed. Describe when consent will be requested and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the methods of documenting consent. State whether the IRB has authorized a modification or waiver of the elements of consent or the requirement for consent documentation.

4) *Risks.* Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. As appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5) *Protection from Risk.* Describe the procedures for protecting against or minimizing potential risks, including risk to confidentiality, and assess their likely effectiveness. As appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, as appropriate, describe provisions for monitoring the data collected to ensure the safety and confidentiality of subjects.

6) *Benefits.* Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

7) *Education.* Individuals who are identified as key personnel and who are involved with human subject research are to indicate their education in the protection of human research participants. For each individual, provide the title and date of the education program completed, and a one-sentence description of the program.

10. Vertebrate Animals (Form Page 10)

If you marked "Yes" on item 13 on the Face Page of the application, succinctly address the five points listed **below**. In addition, if research involving vertebrate animals is to take place at collaborating site(s) or other performance site(s); provide this information before discussing the five points. Acquisition and use of animals must comply with New York State Public Health

Law, Article 5, Title I, Sections 504 and 505-a. **Experiments must** not be **initiated** until IACUC approval is obtained.

1) Provide a detailed description of the proposed use of animals in the work outlined in the research plan. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

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

3) Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, as appropriate, to minimize discomfort, distress, pain and/or injury.

4) 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 the recommendations.

11. Research Categories and Lay Abstract (Form Page 11)

a) Research Categories

1) Specify which aspect of breast cancer is addressed: (1) cancer biology, (2) prevention, (3) detection and diagnosis, (4) therapeutic treatment, (5) chronic disease management/quality of life, or (6) education.

2) Indicate whether the project is most appropriately considered to be basic or clinical research, or education/outreach.

3) Indicate an appropriate sub-discipline: behavioral, environmental, epidemiological, psychosocial or other (describe).

4) Provide up to five specific keywords and descriptive technical terms that would best explain the technical aspects of your project. Please be sure to include terms that reflect the research topic and methodologies used (e.g., cell signaling, apoptosis, angiogenesis, drug delivery systems, gene therapy, X-ray crystallography, genetic counseling, quality of life, nuclear medicine, immunology, clinical oncology, pesticide exposure, peer support network and nutrition).

b) Lay Abstract

In approximately 200 words, describe the purpose and expected outcomes of your application. Please use everyday language, easily understandable to all readers; avoid jargon, and highly technical "scientific" terms or words. In the event of an award, this summary would be made available to the public.

12. Conflict of Interest (Form Page 12)

The following information will be used by program staff to avoid real and apparent conflicts of interest during the review process.

1) Scientific Collaborations. For each person indicated on Form Page 2, list alphabetically any individuals from Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont or New Hampshire, and their organizational affiliation, who have been collaborators on a project, book, article, report or paper within the last 48 months. If there are no collaborators for a person listed, please so indicate.

2) Training Relationships. For each person indicated on Form Page 2, list alphabetically any individuals from Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont or New Hampshire and their organizational affiliation, with whom the person has had an association during the last

five years as thesis advisor or postdoctoral sponsor.

3) *Financial or Other Conflicts.* For each person listed on Form Page 2, list the businesses in which the person has a financial interest relevant to the proposed project; also list other potential conflicts that do not fall into previous categories.

13. Checklist (Form Page 13)

For the applicant organization and all subcontracting organizations, provide: *Assurances/Certifications.* Each application to the New York State Department of Health requires that the assurances and certifications listed on the Checklist be verified by the official signing for the applicant organization on the Face Page (Form Page 1) of the application. **All application participants and applicant organizations must comply with the terms and conditions set forth in the *Contract Policy Statement and Conditions* (page 13). Regulations governing these assurances and certifications are provided in the *Contract Policy Statement and Conditions*** (see pages 13 - 18).

14. Appendices (no form provided)

Applications proposing non-exempt human subjects research must include *a copy of the protocol's informed consent document(s)* in the Appendix. Other items that may be included are: IRB certification of exemption; IRB approval; the New York State Breast Cancer Research and Education Research Program Human Subjects Certification (Form Page 9); IACUC approval; documentation of contractual/consortium agreements; or letters of support from collaborators. Reprints of one highly relevant peer-reviewed manuscript may be included.

Fellowship candidates must include *three signed, sealed references.* They may also include up to two representative publications or abstracts, if available.

Limit appendices to 20 pages (excluding fellow's sealed references). Submit two, three-hole-punched, collated and stapled sets of Appendices.

Candidate's References. References are to comment on the fellow's potential for significant contributions to cancer research as indicated by intellectual creativity, written and oral communication skills, commitment and drive and quality of work produced. References are strongly encouraged to provide a relative comparison (i.e., candidate is within the top five percent of all candidates, top 15 percent, etc.).

The fellowship sponsor of the application **must** be counted as a reference.

To ensure the confidentiality of information, the envelopes **must** not be opened. The sealed envelopes should be attached to the original application. Applications submitted without sealed references will not be considered for review.

IV. Application Mailing Instructions

Applications submitted for review are to contain the items below. Do not send items in binders or pressboards. The application package should contain:

- one original – signed, single-sided copy of the application
- 2 double-sided, three-hole punched, copies of the application, paper-clipped or stapled
- 2 double-sided, three-hole punched, copies of the appendices, paper-clipped or stapled
- three signed, sealed references to be included with the original copy of the application

Applications should be sent to the address appropriate to the mail service used as listed below. The exterior of the package should be clearly labeled with the applicant's name and address. A 3" x 5"-postcard labeled "Breast Cancer Application" should be affixed to the outside of the package. Applications sent by fax or e-mail will not be accepted.

A. Express Mail Services

Breast Cancer Research and Education Program
Office of Extramural Funding
New York State Department of Health
Wadsworth Center, Room C675
Empire State Plaza
Dock J – P1 Level
Albany, New York 12237

Tel: (518) 474-8543

B. Regular Mail Services

Breast Cancer Research and Education Program
Office of Extramural Funding
New York State Department of Health
Wadsworth Center, Room C675
Empire State Plaza
P.O. Box 509
Albany, New York 12201-0509

The application package must be received no later than **5:00 p.m., Monday, April 11, 2005.**

V. Anticipated Timeline

RFA Distribution	December 8, 2004
Letter of Intent Deadline	January 17, 2005
End Date for Questions	January 28, 2005
Answers to Questions Posted	February 8, 2005
Application Deadline	April 11, 2005
Notification of Awards	July 11, 2005
Earliest Contract Start Date	October 1, 2005

VI. Contract Policy Statement and Conditions

A. Ethical Considerations

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

In accepting an award from the New York State Department of Health for support from the Breast Cancer Research and Education Fund, each project investigator agrees to conform strictly to the codes of practice, regulations and laws governing ethical conduct of scientific research in her/his own laboratory/institution. She/he is solely responsible if any of these regulations are infringed. If experimental procedures conducted pursuant to this application 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 (see Section I. (d), page 18).

B. Human Subjects Research

Human subjects research is essential to 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, research applications that fail to include required documentation for human subjects research (see pages 5-6) will not be considered for review. 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.

- The research study will comply with 45 CFR Part 46 (unless exempt from the requirements of this Part) and, if applicable, 21 CFR Parts 50 and 56; 21 CFR 312; 21 CFR 361; and 21 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 informed consent will be obtained from all study participants, or their legally authorized representatives, unless the study is exempt from the requirements of 45 CFR Part 46 and is not human research as defined by PHL Section 2441 (2).

- The IRB has determined that the risks of the research study, including pain or discomfort, are minimized consistent with sound research design and that procedures proposed by the research do not unnecessarily expose research participants to risk or discomfort.

- The IRB has determined that any use of race, ethnicity or gender as an inclusion or exclusion criterion for the research study, other than use of such criterion to reflect the racial, ethnic or gender composition of the general population of New York State or the United States, is necessary to accomplish the goals of the research.

- 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

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.

- The IRB has determined that all research participants have suffered breast cancer.

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 her/his capacity to consent to research is under consideration; notice to a prospective subject of a determination that she/he 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 shall 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).

D. Tissue Use

HRSB will support research using human tissue, other than human pluripotent stem cells, and requires 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, PHL 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 42 USC Section 289g, et seq. Research proposing to use pluripotent stem cells requires appropriate, and rigorous legal and ethical oversight. Applications will not be considered until federal oversight guidelines have been fully implemented and Breast Cancer Research and Education Research Program policy is developed.

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

E. Publication and Intellectual Property Rights

1) It is HRSB's intent that the results of research it supports as well as the resources created through its sponsorship be disseminated and made easily available to the research community. Manuscript submission for publication of research funded by the Breast Cancer Research and Education Fund cannot 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, and not delayed for more than such time period for commercial reasons, or any other reasons unconnected with editorial delays to ensure scientific accuracy and presentation.

2) The State of New York shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, any published or otherwise reproducible material, device, invention, technique, 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. Use by those other than the State of New York under this license shall be limited to research and governmental purposes.

3) The State of New York shall be provided 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 consistent with; the license rights granted the State pursuant to the above paragraph.

4) Support by the New York State Breast Cancer Research and Education Fund **must** be acknowledged **and accurately stated** in all publications, presentations and products of research in a form consistent with the publication's guidelines, e.g.:
"…supported by the New York State Breast Cancer Research and Education Fund through Department of Health Contract # <<>>. Opinions expressed 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."

   The minimum acknowledgement is "NYS Breast Cancer Research and Education Fund".

5) 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 Chapters 647 and 229.

F. Reporting Requirements

1. Scientific/Technical

a) Progress Reports

The fellowship sponsor's scientific/technical reporting obligations will include:

1. submitting two brief (two-page) scientific progress reports covering consecutive nine-month periods from the start date of the contract;

2. participating in an annual or biennial scientific meeting sponsored or co-sponsored by HRSB; and

3. submitting a detailed scientific report within 60 days of project termination.

Progress reports will describe:

- project participants, including the fellow;
- activities and findings corresponding to research or education/outreach aims; and
- products resulting during the reporting period (e.g., abstracts, publications, presentations, or invention disclosures). Copies of published abstracts, publications and other products resulting from Fund support should be

submitted to HRSB program staff as soon as available.

b) Other Activities

Awardees shall participate with program staff in meetings, conference calls, site visits, or other reasonable activities as frequently as deemed necessary, for the monitoring, evaluation and scientific exchange of the project results/outcomes.

2. Financial

The Department of Health reimburses contractors for approved, allowable expenditures incurred under the awarded contract. After successful contract negotiation and execution, and at the start of the project period, up to 25 percent of the total annual award amount may be advanced to not-for-profit contracting organizations upon submission of a standard New York State voucher (available by written request from the Office of the State Comptroller, Supply Room, Alfred E. Smith State Office Building, Albany, New York 12236). The contracting organization will be responsible for disbursing funds to any subcontractors in accordance with the amounts approved for their research. If facilities and administration costs are charged by a sub-contractor, the same limits as for fellowships apply to the subcontractor. The New York State Department of Health will not establish contracts for the HRSB with entities outside of New York State.

The contracting organization will submit quarterly vouchers within 60 days of the end date of the period for which reimbursement is being claimed, accompanied by a budget statement that reports expenditures corresponding to approved budget categories. Prior approval by HRSB program staff will be required for all budget line interchanges exceeding 10 percent of the grand total of the budgeted amount. A request for budget line interchanges must be made in writing and include a justification for the proposed changes. A statement to the effect that the proposed changes will not negatively affect the scope of work as defined in the Research Plan must also be included. Budget line interchanges which (on the most recent in a series of budget line interchanges which cumulatively) exceed $12,000 or 10 percent of the grand total of the budget amount require Office of the State Comptroller notification.

G. The Department of Health Reserves the Right to

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

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

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

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

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

6) Modify the detail specifications should no applications be received that meet all these requirements.

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

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

H. Other Information

Documents submitted to the Department of Health on behalf of the HRSB program will not be returned to the applicant.

1) The initial budgetary plan incorporated into a contract between the New York State Department of Health and the contracting organization may be reviewed and revised each year, depending on research progress and the availability of funds.

2) 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. In the event that the funded postdoctoral fellow leaves the funded institution, all unexpended funds shall be returned to the Department of Health and the fellow shall submit a final report of all work performed.

3) The New York State Department of Health will assume no responsibility for any damage or injuries caused in relation to research conducted with the support of the Breast Cancer Research and Education Fund.

4) Detailed arrangements for starting the research program (e.g., start date, award amount and work plan) will be negotiated by the contracting organization and HRSB program staff.

5) Recipient entities accept auditing of their expenditures by an appointed representative of the HRSB at any time.

6) Incorporated into all contracts between the contracting organization and the New York State Department of Health will be Appendix A, "Standard Clauses for all New York State Contracts" and Appendix A-1, "Agency-Specific Clauses for all Department of Health Contracts." These and other NYS appendices are located at the end of this document.

7) A contract may not be entered into for any work involving "employment of employees in employment" without satisfactory evidence, as described below, that the payment of Workers' Compensation and disability benefits has been secured for all employees (Workers' Compensation Law Sections 57 and 220, as amended by Chapter 213, L.1993).

a) Workers' Compensation Insurance

- Certificate of Workers' Compensation Insurance, on Workers' Compensation Board form C-105.2 or State Insurance Fund form U-26.3 (naming Department of Health, Wadsworth Center, Room C675, Albany, NY 12237); OR
- affidavit certifying that compensation has been secured (Form SI-12); OR
- statement that applicant does not require Workers' Compensation or disability benefits coverage (Form **WC/DB 100 or WC/DB 101**, completed for Workers' Compensation).

b) Disability Insurance

- Certificate of Insurance (Form DB-120.1); OR
- Notice of Qualification as self-insurer under Disability Benefits Law (Form DB-155); OR
- statement that applicant does not require Workers' Compensation or disability benefits coverage (Form **WC/DB 100 or WC/DB 101**, completed for disability benefits insurance).

9) Additional State Procurement Disclosure (For-Profit Entities Only)
Executive Order 127 provides for increased disclosure regarding persons and organizations contacting state government regarding procurement transactions in order to enhance public confidence in the procurement process. If the applicant organization is a for-profit entity, the forms included at the end of this document must be completed.
1. The CONTRACTOR certifies that all information provided to the STATE with respect to New York State Executive Order Number 127, signed by Governor Pataki on June 16, 2003, is complete, true, and accurate.
2. The STATE reserves the right to terminate this AGREEMENT in the event it is found that the certification filed by the CONTRACTOR, in accordance with New York State Executive Order Number 127, was intentionally false or intentionally incomplete. Upon such finding, the STATE may exercise its termination right by providing written notification to the CONTRACTOR in accordance with the written notification terms of this AGREEMENT.

I. Assurances and Certifications

The New York State Health Research Science Board has adopted the following federal regulatory mechanisms to ensure responsible administration of its awards and preserve the integrity of the research enterprise it supports. By signing the Face Page of the application, the authorized representative of the applicant 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) Human Subjects

- Protection of Human Subjects: 45 CFR 46.

b) Vertebrate Animals

- U.S. Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*
- PHS *Guide for the Care and Use of Laboratory 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.
-

c) Debarment and Suspension/Drug Free Workplace

- 45 CFR 76, "Government-wide debarment and suspension (nonprocurement) and Government-wide requirements for drug-free workplace (Grants)," Appendix A.
- Contractors will be required to obtain a similar certification from subawardees, or lower tier participants (45 CFR 76, Appendices A and B).

Even if unable to certify to these statements, the applicant organization must, nonetheless, submit the certification and attach an explanation.

d) 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 staff upon request.

e) Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)

The institution has filed with the U.S. Department of Health and Human Services (DHHS) Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (PL 88352, as amended), which prohibits discrimination on the basis of race, color or national origin; Section 504 of the Rehabilitation Act of 1973 (PL 93-112, as amended) which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (PL 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (PL 94-135), which prohibits discrimination on the basis of age.

Implementing regulations:

- 45 CFR 80: Civil Rights
- 45 CFR 84 and 85: Handicapped Individuals
- 45 CFR 86: Sex Discrimination
- 45 CFR 91: Age Discrimination

f) Conflict of Interest

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

g) Other Documentation

The Department of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight, as part of the negotiation of any contract arising from this request for applications.

New York State Health Research Science Board

Santo M. DiFino, M.D., Chair
Hematology-Oncology Associates of Central New York, P.C.

Christine Ambrosone, Ph.D.
Roswell Park Cancer Institute

Geri Barish*
1 in 9, Long Island Breast Cancer Coalition

Alexander P. Gross*, P.E.
Man-to-Man

Russell Hilf, Ph.D.
University of Rochester School of Medicine

Carl Johnson*, M.S.
New York State Department of Environmental Conservation

Philip J. Landrigan, M.D., M.Sc.
Mount Sinai School of Medicine

Thomas J. Lester, M.D.
Katonah Medical Group

Alexander Y. Nikitin*, M.D., Ph.D.
Cornell University

Arun Puranik, M.D.
Capital District Radiation Oncology, P.C.

Peter T. Rowley, M.D.
University of Rochester Medical Center

Lawrence Sturman*, M.D., Ph.D.
New York State Department of Health

Jean Wactawski-Wende, Ph.D.
University at Buffalo

Marc Wilkenfeld, M.D.
Columbia University Medical Center

*ex officio member

Breast Cancer Research and Education Program Award Recipients

A. 1998 Award Recipients

EMPIRE, Pilot Grants

Albany Medical College
Thomas T. Andersen, Ph.D.
AFP-Derived Peptides which Stop Breast Cancer Growth

Albert Einstein Medical Center-Yeshiva University
John Condeelis, Ph.D.
Isolation of Motile Tumor Cells from Live Breast Tumors

Benedictine Health Foundation
Barbara Sarah, M.S.W.
Nurturing Neighborhood Networks

Canisius College
Susan M. Aronica, Ph.D.
Hormonal Regulation of Mammary Chemokine Expression

Long Island Jewish Medical Center-Albert Einstein
Eliot M. Rosen, Ph.D.
BRCA1 Modulates Estrogen Receptor Response in Breast Cancer

Medical and Health Research Association of New York
Dorothy J. Jessop, Ph.D.
Preparing for Prevention Breast Cancer: MIC-FPP/MHRA

Memorial Sloan Kettering Institute for Cancer Research
Laura Liberman, M.D.
Cost-Effectiveness of Stereotactic Vacuum Breast Biopsy

New York University Medical Center
Pamela Cowin, Ph.D.
The Role of beta-Catenin in Breast Cancer

New York University Medical Center
Elissa L. Kramer, M.D.
Combined Radioimmunotherapy/Chemotherapy for Breast Cancer

New York University Medical Center
Herbert H. Samuels, M.D.
Inhibition of Breast Cancer Cell Growth by Retinoids

New York University Medical Center
William F. Symmans, M.D.
Cellular Responses during Neoadjuvant Paclitaxel Therapy

Population Council
Milan K. Bagchi, Ph.D.
Role of Steroid Receptor Coactivators in Breast Cancer

Rensselaer Polytechnic Institute
Jonathan C. Newell, Ph.D.
Breast Tumor Diagnosis by Electrical Impedance Imaging

Samuel Stranton VA Medical Center
William J. Hrushesky, M.D.
Fertility Cycles and Breast Cancer Outcome

State University of New York at Buffalo
Marilyn E. Morris, Ph.D.
Dietary Modulators of Multidrug Resistance

State University of New York at Stony Brook
Lisa A. Mueller, M.D.
Dendritic Cell Infusion to Treat Metastatic Breast Cancer

State University of New York at Stony Brook
Jacqueline E. Testa, Ph.D.
Identification and Cloning of a Breast Cancer Metastasis Gene

Wadsworth Center, New York State Department of Health
Andrew A. Reilly, Ph.D.
Improving Diagnostic Accuracy of Mammography by Image Analysis

Postdoctoral Fellowships

Albert Einstein Medical Center-Yeshiva University
Mark D'Amico, Ph.D.
Mechanisms of CK1 Tumor Suppression in Breast

Albert Einstein Medical Center-Yeshiva University
Sang-hoon Kim, Ph.D.
Role of Spindel Checkpoint in Preventing Breast Cancer

Long Island Jewish Medical Center-Albert Einstein
Mingsheng Wang, M.D.
Prevention of Breast Cancer by Pregnancy-and Lactation-induced Mammary Gland Differentiation: The role of mammary-derived growth inhibitor-related gene MRG

Memorial Sloan Kettering Institute for Cancer Research
Shawn J. Stachel, Ph.D.
Total Synthesis of Salicylihalamide A

New York University Medical Center
Ajita A. Bhat, Ph.D.
Structural Determinants of Estrogen Receptor Isoforms

New York University Medical Center
Alexandra Imbert, Ph.D.
The Role of Plakoglobin in Breast Cancer

State University of New York at Stony Brook
Deborah S. Black, Ph.D.
Dissection of Integrin Signaling Using Yersinia YopE

University of Rochester
Shannon Hilchey, Ph.D.
A Novel Model for Xenoantigen-Targeted Tumor Immunotherapy

Weill Medical College of Cornell University
Xiaojia Guo, Ph.D.
Retinyl Esterification In Human Breast Cancer Cells

B. 2001 Award Recipients

EMPIRE, Pilot Grants

Binghamton University
Walker Land, Ph.D.
Computer-Aided Classification for Breast Cancer Screening

Columbia University Mailman School of Public Health
Victoria Raveis, Ph.D.
Breast Cancer and the Family Caring Unit: Psychosocial Issues

Hamilton College
George Shields, Ph.D.
Design of Molecules that Inhibit Human Breast Cancer

Medical & Health Research Association of New York City, Inc.
Mary Ann Chiasson, Dr. PH.
Informal Networks and Breast Cancer Screening in Black Women

Mid Hudson Options Project
Hope Nemiroff
Companion/Advocate for Breast Cancer Patient Medical Visit

Mount Sinai School of Medicine
Barry Rosenstein, Ph.D.
Screening for ATM Mutations in an African-American Population

Mount Sinai School of Medicine
Toru Ouchi, Ph.D.
DNA Damage and BRCA1-Interacting Protein

Our Lady of Mercy Medical Center
Polly Etkind, Ph.D.
A Viral Etiology for a Subset of Human Breast Cancers

Roswell Park Cancer Institute
William Kraybill, M.D.
Hyperthermia and DOXIL: Laboratory to Breast Cancer Clinic

Roswell Park Cancer Institute
John Subjeck, Ph.D.
Immunotherapy of Breast Cancer using HSP110-HER-2/neu Vaccine

Roswell Park Cancer Institute
Xinhui Wang, M.D., Ph.D.
Anti-angiogenesis and Immunotherapy of Breast Carcinoma

State University of New York at Buffalo
Michael Detty, Ph.D.
New Sensitizers for Photodynamic Therapy of Breast Cancer

State University of New York at Stony Brook
Ute Moll, M.D.
Role of the p53/p73 Interference Network in Breast Cancer

State University of New York at Stony Brook
Dafna Bar-Sagi, Ph.D.
Human Sprouty, A Novel Antagonist of EGF Receptor Signaling

State University of New York at Upstate Medical University
Matthew Allen, Vet. M.B., Ph.D.
Radiation Therapy for Skeletal Metastases of Breast Cancer

University of Rochester Medical Center
Kishan Pandya, M.D.
Treatment of Hot Flashes due to Tamoxifen in Women with Breast Cancer

University of Rochester Medical Center
Shuyuan Yeh, Ph.D.
Androgen Receptor Knockout in Breast and Breast Cancer Cell

Wadsworth Center, New York State Department of Health
Donald Carl Porter, Ph.D.
Thymidylate Synthase Proteiolysis to Improve Drug Sensitivity

Wadsworth Center, New York State Department of Health
Erasmus Schneider, Ph.D.
The Role of the Lysosome in Methotrexate Resistance

Postdoctoral Fellowships

Cornell University
Bendicht Paulie, D.V.M., Ph.D.
Fibronectin's DPP IV Binding Site(s) and Lung Metastasis

Mount Sinai School of Medicine
Stuart Aaronson, M.D.
BRCA2: Identification of Binding Proteins and Domain Mapping

New York University School of Medicine
Pamela Cowin, Ph.D.
Role of Beta-Catenin in Mammary Stem Cells and Breast Cancer

New York University School of Medicine
Michele Pagano, M.D.
The Role of the F-Box Protein Skp2 in Breast Cancer

New York University School of Medicine
Mark Phillips, M.D.
Characterization of TPR1 as a Ras Binding Protein

State University of New York at Upstate Medical University
David Gilbert, Ph.D.
Promoter Shut-off System of ORC1 in Cultured Mammalian Cells

Strang Cancer Research Laboratory
Alvaro Monteiro, Ph.D.
Functional Assay for BRCA1

Weill Medical College of Cornell University
Lorraine Gudas, Ph.D.
Retinoid and Hox-A Target Genes in Human Breast Cancer Cells

C. 2002 Award Recipients

The Maurer Foundation
Stephanie Kassebaum
Breast Health Educator Certification Program

South Fork Breast Health Coalition
Susan Barry Roden
Breast Health Education-A Tailoring Approach

St. John Baptist Church at Buffalo
Rev. Michael Chapman
The Fruitbelt Community Witness Project

To Life! Inc.,
Lauren Ayers
Medical Caregivers – Treating the Whole Breast Cancer Patient

New York State Department of Health

Health Research Science Board

Breast Cancer Research and Education Program

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Focus | Date Received | Appl. Number

1. PROJECT TITLE *(Do not exceed 60 characters, including spaces and punctuation.)*

2. FELLOW CANDIDATE AND FELLOWSHIP SPONSOR	**3. APPLICANT ORGANIZATION**
2a. Fellow's Name (Last, First, Middle) Degree(s) ,	3a. Legal Name (Entity to which payment will be sent, i.e. Payee)
2b. Sponsor's Name (Last, First, Middle) Degree(s) ,	3b. Street Address/Suite (Address where payment is to be sent)
2c. Sponsor's Professional Title Relevant to Application	3c. P.O. Box
2d. Sponsor's Institutional Affiliation	3d. City
2e. Department, Service, Laboratory or Equivalent Unit	3e. Zip Code
2f. Institutional Subdivision (College, Division or Equivalent Unit)	**4. TYPE OF ORGANIZATION** Public ☐ Federal ☐ State ☐ Local Private ☐ Private Nonprofit For profit ☐ General ☐ Small Business ☐ WMO
2g. Street Address/Suite	
2h. P.O. Box	**5. FEDERAL IDENTIFICATION NUMBER** (nine digits)
2i. City	**6. LEGISLATIVE DISTRICT NUMBERS** (for address in Item 15) Senate Assembly
2j. Zip Code	**7. CHARITIES REGISTRATION NO**. **EXEMPT**
2k. Telephone	**8. ENTIRE PROJECT PERIOD**
2l. Fax	**9. YEAR ONE TOTAL COSTS REQUESTED**
2m.E-mail	**10. TOTAL PROJECT COSTS FOR ALL YEARS**

11a. APPLICATION HISTORY	**11b. SUBCONTRACT**
☐ New ☐ Resubmission of Application No.	☐ No ☐ Yes*

12. HUMAN SUBJECTS ☐ No ☐ Yes	12a. Exemption No.	12b. IRB Approval Date ☐ Expedited IRB Review ☐ Full IRB Review	12c. Assurance of Compliance No.
13. VERTEBRATE ANIMALS ☐ No ☐ Yes	13a. If "Yes," IACUC Approval Date	13b. Animal Welfare Assurance No.	13c. USDA Registration No.

14. OFFICIAL TO BE NOTIFIED IF AWARD IS MADE	**15. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION**
Name Title Address Telephone FAX E-mail	Name Title Address Telephone FAX E-mail

16. PRINCIPAL INVESTIGATOR or FELLOWSHIP SPONSOR AND CANDIDATE ASSURANCE

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to fulfill the technical reporting requirements if a contract is awarded as a result of this application.

_____

SIGNATURE OF SPONSOR NAMED IN 2b. ***(In blue ink)*** **DATE**

_____

SIGNATURE OF FELLOWSHIP CANDIDATE ***(In blue ink)*** **DATE**

17. APPLICANT ORGANIZATION CERTIFICATION/ ACCEPTANCE

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I certify compliance with all applicable assurances and certifications pertaining to: human subjects, vertebrate animals, research misconduct, debarment and suspension, drug free workplace, financial conflict of interest, and civil rights. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil or administrative penalties.

_____

SIGNATURE OF OFFICIAL NAMED IN 15. ***(In blue ink)*** **DATE**

*If yes, insert signed copies for subcontracting organizations behind the applicant organization face page.

Fellowship Sponsor *(Last, First, Middle):* _____

Proposal Title _____

SCIENTIFIC ABSTRACT: Summarize concisely your proposed research, outlining objectives, methods, and relevance to the breast cancer problem. Compose the abstract so that persons from diverse scientific backgrounds can easily understand the work proposed. Do not include proprietary/confidential information.

DO NOT EXCEED THE SPACE PROVIDED. Abstract type density may not be less than 10 cpi and may not exceed 6 vertical lines per inch.

PERFORMANCE SITE(S) *(Organization, City, State)*. List the applicant organization first, followed alphabetically by other sites.

KEY PERSONNEL. Provide the information requested; list the fellowship sponsor first, the fellowship candidate second, and then other key personnel alphabetically.

Name	**Organization**	**Role in Project and Percent Effort**

TABLE OF CONTENTS

Number pages consecutively, enter "N/A" if not applicable

N. Appendix – *Two three-hole-punched, collated and stapled sets. Appropriately assemble, secure and label with fellowship sponsor's name, PI, institution, etc.)*

☐ Check if Appendix is included

Other items (list):

Sealed References original copy of the application must include three signed, sealed references

☐ Check if 3 sealed references are included

PROPOSED BUDGET

	BUDGET CATEGORY	Year One	Year Two	Total
	PERSONAL SERVICE (PS)			
1	FELLOW'S STIPEND[1]			
2	FRINGE BENEFITS			
3	SUBTOTAL PS			
	OTHER THAN PERSONAL SERVICE (OTPS)			
4	SUPPLIES			
5	TRAVEL[2]			
6	SUBTOTAL OTPS			
7	**TOTAL PS AND OTPS**			
8	Facilities and Administration[3]			
9	Total Sub-Contractual Costs[4]			
10	**TOTAL PROJECT COSTS**[5] Sum of lines 7 + 8 + 9 may not exceed $60,000/year			

1 Recommended Stipends:
Year One: $35,000
Year Two: $37,000

2 Applicants are to budget for travel annually to New York City to present their results to the Health Research Science Board and for candidate's participation at a national scientific meeting.

3 Facilities and Administration Costs not to exceed 8.7% of Line 7. (This corresponds to 8 percent of total project costs.)

4 Provide additional copies of Form Page 4 for each subcontractor, completing lines 1 - 10.

5 Total project costs requested may not exceed $60,000 per year; Year Two may not exceed Year One.

Personnel Effort and Budget Justification

Key Personnel *		Percent FTE			Dollar Amount Requested (Year One)		
Name	**Role in Project**	**Appt.**	**On project**	**For Salary Requested**	**Salary**	**Fringe**	**Total**
Support Personnel *		**Percent FTE**			**Dollar Amount Requested (Year One)**		
Total Salary + Fringe Requested – should equal Year One, line 3, Form 6							

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

Briefly describe the items that will be included in *Other than Personal Service* Costs.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel listed on Form Page 2.

Do not exceed four pages each for sponsor and candidate. Follow instructions provided on both Form Page 6 and Form Page 6a.

NAME	**POSITION/TITLE**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, and include postdoctoral training.)*

INSTITUTION AND LOCATION	**DEGREE** *(if applicable)*	**YEAR(S)**	**FIELD OF STUDY**

EXPERIENCE/QUALIFICATIONS/AVAILABLE FUNDING: I. In chronological order, list employment experience, concluding with present position. II. List professional activities and honors relevant to the application. Include present membership on federal, state or local government public advisory committee(s). III. In chronological order, list complete references for all publications during the past three years and relevant earlier publications. If the publication list exceeds the page limit, select the most pertinent publications. Mark with an asterisk (*) the five publications most relevant to the proposed project. IV. List all current or pending funding available. Include funding source, award number, project title, principal investigator, total project period, and direct costs for the current budget period. Fellowship candidates who have or will be applying for support that would run concurrently with the period covered by this application, should mark such support with an asterisk (*).

Place fellowship sponsor biosketch first, then fellow, followed in alphabetical order by the remaining key personnel biosketches.

Additional Biographical Information Required

For Forms Page 6 and Page 6a limit four pages each for sponsor and candidate, and two pages each for all other key personnel listed on Form Page 2. Sponsors who are five years or less into their first permanent position are encouraged to identify a more senior collaborator to co-sponsor the fellow.

1) Sponsor

(a) Summary of Training Experience

Report the number of pre- and post-doctoral fellows who have completed training under your supervision. In a table, list up to five representative trainees and indicate their name, degree/program completed (e.g., M.S., Ph.D. or postdoctoral), year training was completed and current position title and affiliation.

Also report the names for pre- and post-doctoral fellows who will be actively training under your supervision during the fellow's tenure.

2) Candidate

(a) Dissertation Summary

For Ph.D. candidates, list the title, advisor's name and a brief (up to ¾ page) summary of dissertation research. The summary should include the aims, approaches used and key research results. If the advisor has not provided a letter of support, please explain.

(b) Fellowship Goals

Explain the goals and outcomes expected from your fellowship training, and their relevance to your career goals in breast cancer basic or clinical research or education. Include a summary of your previous research or subspecialty training experience. Describe the skills, theories and scientific understanding that will be obtained during this fellowship. Indicate how this training will advance your professional development in the field of breast cancer research.

(c) Sponsor Selection

Describe the rationale for sponsor selection. If you have remained at your doctorate-awarding institution, explain how this will not compromise, but rather will benefit your professional development.

(d) Research Training and Other Activities

In a table, list the percent effort devoted to research training and other activities (e.g., teaching, clinical duties, course work). The total must equal 100 percent. All activities must clearly relate to the training proposed and your future plans as an investigator in the field of breast cancer. If applicable, list the titles of courses to be taken or taught.

FACILITIES and RESOURCES

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

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

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

Project Plan

A. Background and Preliminary Results
B. Specific Aims.
C. Relevance
D. Research Design and Methods.
E. Timeline
F. Literature Cited.

New York State Breast Cancer Research and Education Program

Human Subjects Certification

The project entitled, _____, has been reviewed and approved by the Institutional Review Board (IRB) of _____.

The review process, protocol and informed consent document(s) have been determined to be in compliance with New York State Public Health Law (PHL) Article 24-A,; 45 CFR Part 46, unless exempt from the provisions of that Part; and, if applicable, 21 CFR Parts 50, 56, 312, 361 and 812.

In addition, the IRB has determined that:

- informed consent will be obtained from all study participants, or their legally authorized representatives, unless the study is exempt from the requirements of 45 CFR Part 46 and is not human research as defined by PHL Section 2441 (2);
- if applicable, the IRB has received and reviewed written approval from an authorized representative of each site where the study will take place;
- the risks of the research study, including pain or discomfort, have been minimized consistent with sound research design, and proposed research procedures do not unnecessarily expose research participants to risk or discomfort;
- any use of race, ethnicity or gender as a research study inclusion or exclusion criterion, other than use of such criterion to reflect the racial, ethnic or gender composition of the general population of New York State or the United States, is necessary to accomplish the research goals;
- the investigator will immediately withdraw a subject from the research study if continued participation would be detrimental to a subject's well-being; and
- the IRB will communicate to Health Research Science Board (HRSB) program administrators at the Department of Health: (i) any unanticipated problems at any site(s) involving risks to subjects; or (ii) any serious or continuing noncompliance with the IRB's policy or requirements; or (iii) any suspension or termination of IRB approval;

In addition to the above, for research involving participants who are minors, mentally disabled adults who lack capacity to provide informed consent to research participation, or prisoners, the IRB has also determined that:

- the research study constitutes either: (i) research with a prospect of direct benefit to participants; or (ii) research with no prospect of direct benefit to participants, but which presents minimal risk;
- the research study, involving one or more mentally disabled adults, uses IRB-approved methodologies and procedures for initial capacity assessment, including: (i) notice to a prospective subject that his/her capacity to consent to research is under consideration; (ii) notice to a prospective subject of a determination that he/she lacks the capacity to consent to research; and (iii) the opportunity for a prospective subject to contest such a determination of incapacity prior to enrollment in the research through a second opinion and a judicial proceeding; and
- 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, the investigator will obtain such individual's assent to research participation[1].

_____
Signature and Date

_____
Typed Name

_____
Title

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

Vertebrate Animals

This form is required only for applications that checked "**Yes**" for vertebrate animals on the face page.

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

Institution: _____

Institutional Animal Care & Use Number: _____

NYS DOH Animal Care & Use Certificate Number: _____

USDA Registration Number (if applicable to species): _____

Vertebrate Animal Approval Status ☐ Approved ☐ Pending

Protocol Number: _____ Principal Investigator: _____

Project Title: _____

_____

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

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

If "Yes", when is the next review: _____

Repeat table as often as necessary.

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

1. Provide a detailed description of the animal use proposed in the research work plan, including identification of the species, strains, ages, sex, and number of animals to be used.

2. Justify the use of animals, the choice of species and the number to be used; provide power calculations to justify your application.

3. 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. 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 the recommendations.

Research Categories and Lay Abstract

Present the information requested below in non-technical terms. Failure to do so could adversely affect the application's Programmatic Review. Use available space to your best advantage; comply with font guidelines (e.g. Arial 11 or Times Roman 12).

Introduction/Background to the research topic:

The question(s) or central hypothesis of the research:

The general methodology to be used:

Innovative elements of the project:

Impact on Treatments or Cures

Conflict of Interest

The following information will be used by program staff to avoid real and apparent conflicts of interest during the review process.

1) *Scientific Collaborations.* For each person indicated on Form Page 2, list alphabetically any individuals from Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont or New Hampshire, and their organizational affiliation, who have been collaborators on a project, book, article, report or paper within the last 48 months. If there are no collaborators for a person listed, please so indicate.

2) *Training Relationships.* For each person indicated on Form Page 2, list alphabetically any individuals from Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont or New Hampshire and their organizational affiliation, with whom the person has had an association during the last five years as thesis advisor or postdoctoral sponsor.

3) *Financial or Other Conflicts*. For each person listed on Form Page 2, list the businesses in which the person has a financial interest relevant to the proposed project; also list other potential conflicts that do not fall into previous categories.

CHECKLIST

ASSURANCES/CERTIFICATIONS

The following assurances/certifications are verified by the signature of the official signing for the applicant organization on the Face Page of the application. Descriptions of individual assurances/certifications begin on page 13 (Section VI) of the *Contract Policy Statement and Conditions*. If unable to certify compliance as applicable, provide an explanation, and place it after this page.

- Human Subjects
- Vertebrate Animals
- Debarment and Suspension
- Drug-Free Workplace
- Research Misconduct
- Assurances of Compliance
  - __ Civil Rights (Form HHS 441 or HHS 690)
  - __ Handicapped Individuals (Form HHS 641 or HHS 690)
  - __ Sex Discrimination (Form HHS 639-A or HHS 690)
  - __ Age Discrimination (Form HHS 680 or HHS 690)
- Conflict of Interest
- Publication and Intellectual Property Rights

GRANT CONTRACT

STATE AGENCY (Name and Address):

_____

CONTRACTOR (Name and Address):

_____

FEDERAL TAX IDENTIFICATION NUMBER:

MUNICIPALITY NO. (if applicable):

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

_____

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

_____

CONTRACTOR IS( ) IS NOT( ) A SECTARIAN ENTITY

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

NYS COMPTROLLER'S NUMBER: _____

ORIGINATING AGENCY CODE:

_____

TYPE OF PROGRAM(S)

_____

INITIAL CONTRACT PERIOD

FROM:

TO:

FUNDING AMOUNT FOR INITIAL PERIOD:

_____

MULTI-YEAR TERM (if applicable):

FROM:

TO:

APPENDICES ATTACHED AND PART OF THIS AGREEMENT

_____	APPENDIX A	Standard clauses as required by the Attorney General for all State contracts.
_____	APPENDIX A-1	Agency-Specific Clauses (Rev 02/03)
_____	APPENDIX B	Budget
_____	APPENDIX C	Payment and Reporting Schedule
_____	APPENDIX D	Program Workplan
_____	APPENDIX X	Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)

OTHER APPENDICES

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

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

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

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

On the ____ day of _____20__, before me personally appeared _____ __, to me known, who being by me duly sworn, did depose and say that he/she resides at _____ _____, that he/she is the _____ of the _____ _____, the corporation described herein which executed the foregoing instrument; and that he/she signed his/her name thereto by order of the board of directors of said corporation.

(Notary) _____

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

STATE OF NEW YORK

AGREEMENT

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

WITNESSETH:

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

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

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

I. Conditions of Agreement

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

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

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

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

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

E. The CONTRACTOR shall perform all services to the satisfaction of the STATE. The CONTRACTOR shall provide services and meet the program objectives

summarized in the Program Workplan (Appendix D) in accordance with: provisions of the AGREEMENT; relevant laws, rules and regulations, administrative and fiscal guidelines; and where applicable, operating certificates for facilities or licenses for an activity or program.

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

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

II. Payment and Reporting

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

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

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

III. Terminations

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

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

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

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

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

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

IV. Indemnification

A. The CONTRACTOR shall be solely responsible and answerable in damages for any and all accidents and/or injuries to persons (including death) or property arising out of or related to the services to be rendered by the CONTRACTOR or its subcontractors pursuant to this AGREMENT. 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-1.

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.

APPENDIX A
STANDARD CLAUSES FOR NYS CONTRACTS

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

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

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

3. COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds $15,000 (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 $30,000 (State Finance Law Section 163.6.a).

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

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

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

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

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

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

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

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

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

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

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

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

(c) the Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status. Contractor will include the provisions of "a", "b", and "c" above, in every subcontract over $25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (the "Work") except where the Work is for the beneficial use of the Contractor. Section 312 does not apply to: (i) work, goods or services unrelated to this contract; or (ii) employment outside New York State; or (iii) banking services, insurance policies or the sale of securities. The State shall consider compliance by a contractor or subcontractor with the requirements of any federal law concerning equal employment opportunity which effectuates the purpose of this section. The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall waive the applicability of Section 312 to the extent of such duplication or conflict. Contractor will comply with all duly promulgated and lawful rules and regulations of the Governor's Office of Minority and Women's Business Development pertaining hereto.

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

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

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

16. NO ARBITRATION. Disputes involving this contract, including the breach or alleged breach thereof, may not be submitted to binding arbitration (except where statutorily authorized), but

must, instead, be heard in a court of competent jurisdiction of the State of New York.

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

18. PROHIBITION ON PURCHASE OF TROPICAL HARDWOODS. The Contractor certifies and warrants that all wood products to be used under this contract award will be in accordance with, but not limited to, the specifications and provisions of State Finance Law §165. (Use of Tropical Hardwoods) which prohibits purchase and use of tropical hardwoods, unless specifically exempted, by the State or any governmental agency or political subdivision or public benefit corporation. Qualification for an exemption under this law will be the responsibility of the contractor to establish to meet with the approval of the State. In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

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

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

NYS Department of Economic Development
Division for Small Business
30 South Pearl St -- 7 th Floor
Albany, New York 12245
Telephone: 518-292-5220

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

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

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

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

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

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

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

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

APPENDIX A-1
(REV 02/03)

AGENCY SPECIFIC CLAUSES FOR ALL
DEPARTMENT OF HEALTH CONTRACTS

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

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

3. Administrative Rules and Audits:

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

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

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

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

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

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

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

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

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

a. LOBBYING CERTIFICATION

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

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

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

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

- No federal appropriated funds have been paid or will be paid, by or on behalf of the CONTRACTOR, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal amendment or modification of any federal contract, grant, loan, or cooperative agreement.

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

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

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

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

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

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

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

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

b. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE:

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by federal programs whether 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 $1,000 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 an 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 transactions, 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 Transactions,” 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 a 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. 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;
        - Appendix C – Section 11, Progress and Final Reports;
        - Appendix D – Program Workplan

    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.

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

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

        - Certificate of Workers' Compensation Insurance, on the Workers' Compensation Board form C-105.2 or the State Insurance Fund Form U-26.3 (naming the Department of Health, Corning Tower, Room 1315, Albany, 12237-0016), or

        - Affidavit Certifying That Compensation Has Been Secured, form SI-12 or form GSI 105.2, or

        - Statement That Applicant Does Not Require Workers' Compensation or Disability Benefits Coverage, form 105.21, completed for workers' compensation; and

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

- υ Certificate of Disability Benefits Insurance, form DB-120.1, or

- υ Notice of Qualification as Self Insurer Under Disability Benefits Law, form DB-155, or

- υ Statement That Applicant Does Not Require Workers' Compensation or Disability Benefits Coverage, form 105.21, completed for disability benefits insurance.

13. 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

Contract Policy Statement and Conditions

A. Ethical Considerations

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

In accepting an award from the New York State Department of Health for support from the Breast Cancer Research and Education Fund, each project investigator agrees to conform strictly to the codes of practice, regulations and laws governing ethical conduct of scientific research in her/his own laboratory/institution. She/he is solely responsible if any of these regulations are infringed. If experimental procedures conducted pursuant to this proposal 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 (see Section H.(d)).

B. Human Subjects Research

Human subjects research is essential to 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.
- The research study will comply with 45 CFR Part 46 (unless exempt from the requirements of this Part) and, if applicable, 21 CFR Parts 50 and 56; 21 CFR 312; 21 CFR 361; and 21 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 informed consent will be obtained from all study participants, or their legally authorized representatives, unless the study is exempt from the requirements of 45 CFR Part 46 and is not human research as defined by PHL Section 2441 (2).

- The IRB has determined that the risks of the research study, including pain or discomfort, are minimized consistent with sound research design and that procedures proposed by the research do not unnecessarily expose research participants to risk or discomfort.

- The IRB has determined that any use of race, ethnicity or gender as an inclusion or exclusion criterion for the research study, other than use of such criterion to reflect the racial, ethnic or gender composition of the general population of New York State or the United States, is necessary to accomplish the goals of the research.

- 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

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.

- The IRB has determined that all research participants have suffered breast cancer.

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 her/his capacity to consent to research is under consideration; notice to a prospective subject of a determination that she/he 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 shall 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 proposals.

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 proposals 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).

D. Tissue

HRSB will support research using human tissue, other than human pluripotent stem cells, and requires 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, PHL 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 42 USC Section 289g, et seq. Research proposing to use pluripotent stem cells requires appropriate, and rigorous legal and ethical oversight. Proposals will not be considered until federal oversight guidelines have been fully implemented and Breast Cancer Research and Education Research Program policy is developed.

E. Publication and Intellectual Property Rights

1. It is HRSB's intent that the results of research it supports as well as the resources created through its sponsorship be disseminated and made easily available to the research community. Manuscript submission for publication of research funded by the Breast Cancer Research and Education Fund cannot 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, and not delayed for more than such time period for commercial reasons, or any other reasons unconnected with editorial delays to ensure scientific accuracy and presentation.

2. The State of New York shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, any published or otherwise reproducible material, device, invention, technique, or methodology developed under or in the

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

course of performing this funded research, dealing with any aspect of the research activity, or of the results and accomplishments attained from the research. Use by those other than the State of New York under this license shall be limited to research and governmental purposes.

3. The State of New York shall be provided 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 consistent with, the license rights granted the State pursuant to the above paragraph.

4. Support by the New York State Breast Cancer Research and Education Fund should be acknowledged in all publications, presentations and products of research in a form consistent with the publication's guidelines, e.g.:

   "…supported by the New York State Breast Cancer Research and Education Fund through Department of Health Contract # <<>>. Opinions expressed 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."

   The minimum acknowledgement is "NYS Breast Cancer Research and Education Fund".

5. 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 Chapters 647 and 229.

F. Reporting Requirements

1. Scientific/Technical

Progress Reports

The principal investigator's scientific/technical reporting obligations will include:

1. submitting two brief (two-page) scientific progress reports during the contract period;
2. participating in an annual or biennial scientific meeting sponsored or co-sponsored by HRSB; and
3. submitting a detailed scientific report within 60 days of project termination.

Progress reports will describe:

- project participants, including trainees and/or fellows;
- activities and findings corresponding to research or education/outreach aims; and
- products resulting during the reporting period (e.g., abstracts, publications, presentations, or invention disclosures). Copies of published abstracts, publications and other products resulting from Fund support should be submitted to HRSB program staff as soon as available.

Other Activities

Awardees shall participate with program staff in meetings, conference calls, site visits, or other reasonable activities as frequently as deemed necessary, for the monitoring, evaluation and scientific exchange of the project results/outcomes.

Financial

The Department of Health reimburses contractors for approved, allowable expenditures incurred under the awarded contract. After successful contract negotiation and execution, and at the start of the project period, up to 25 percent of the total annual award amount may be advanced to not-for-profit contracting organizations upon submission of a standard New York State voucher (available by written request from the Office of the State Comptroller, Supply Room, 110 State Street, Albany, New York 12236). The contracting organization will be responsible for disbursing funds to any sub-contractors in accordance with the amounts approved for their research. If facilities and administration costs are charged by a sub-contractor, the same limits as for EMPIRE and fellowships apply to the subcontractor. The New York State Department of Health will not establish contracts for the HRSB with entities outside of New York State.

The contracting organization will submit quarterly vouchers within 60 days of the end date of the period for which reimbursement is being claimed, accompanied by a budget statement that reports expenditures corresponding to approved budget categories. Prior approval by HRSB program staff will be required for all budget line interchanges. A request for budget line interchanges must be made in writing and include a justification for the proposed changes. A statement to the effect that the proposed changes will not negatively affect the scope of work as defined in the Research Plan must also be included. Budget line interchanges which (on the most recent in a series of budget line interchanges which cumulatively) exceed $12,000 or 10 percent of the grand total of the budget amount require Office of the State Comptroller notification.

G. Other Information

1. Documents submitted to the Department of Health on behalf of the HRSB program will not be returned to the applicant.

2. The initial budgetary plan incorporated into a contract between the New York State Department of Health and the contracting organization 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. The Department of Health or the State of New York will assume no responsibility for any damage or injuries caused in relation to research conducted with the support of the Breast Cancer Research and Education Fund.

5. Detailed arrangements for starting the research program (e.g., start date, award amount and work plan) will be negotiated by the contracting organization and HRSB program staff.

6. Equipment may not be purchased within 90 days of contract termination.

7. Recipient entities accept auditing of their expenditures by an appointed representative of the HRSB at any time within three days prior notice to the Director, Office of Sponsored Programs.

8. Incorporated into all contracts between the contracting organization and the New York State Department of Health will be Appendix A, "Standard Clauses for all New York State Contracts"; Appendix A-1, "Agency-Specific Clauses for All Department of Health Contracts"; and Appendix A-2, "Program-Specific Terms and Conditions".

9. A contract may not be entered into for any work involving "employment of employees in employment" without satisfactory evidence, as described below, that the payment of Workers' Compensation and disability benefits has been secured for all employees (Workers' Compensation Law Sections 57 and 220, as amended by Chapter 213, L.1993).

   1.) Workers' Compensation Insurance:

   - Certificate of Workers' Compensation Insurance, on Workers' Compensation Board form C-105.2 or State Insurance Fund form U-26.3 (naming Department of Health, Wadsworth Center, Room E275, Albany, NY 12237); OR
   - affidavit certifying that compensation has been secured (Form SI-12); OR
   - statement that applicant does not require Workers' Compensation or disability benefits coverage (Form WC/DB 100 or WC/DB 101, completed for Workers' Compensation).

   2.) Disability Insurance:

   - Certificate of Insurance (Form DB-120.1); OR
   - Notice of Qualification as self-insurer under Disability Benefits Law (Form DB-153); OR
   - statement that applicant does not require Workers' Compensation or disability benefits coverage (Form WC/DB 100 or WC/DB 101, completed for disability benefits insurance).

H. Assurances and Certifications.

The New York State Health Research Science Board has adopted the following federal regulatory mechanisms to ensure responsible administration of its awards and preserve the integrity of the research enterprise it supports. By signing the Face Page of the proposal, the authorized representative of the applicant 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) Human Subjects:

- Protection of Human Subjects: 45 CFR 46.

(b) Vertebrate Animals:

- U.S. Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*

- PHS *Guide for the Care and Use of Laboratory 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

(c) Debarment and Suspension/Drug Free Workplace:

- 45 CFR 76, "Government-wide debarment and suspension (nonprocurement) and Government-wide requirements for drug-free workplace (Grants)," Appendix A.

- Contractors will be required to obtain a similar certification from subawardees, or lower tier participants (45 CFR 76, Appendices A and B).

Even if unable to certify to these statements, the applicant organization must, nonetheless, submit the certification and attach an explanation.

(d) 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 staff upon request.

(e) Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination):

The institution has filed with the U.S. Department of Health and Human Services (DHHS) Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (PL 88352, as amended), which prohibits discrimination on the basis of race, color or national origin; Section 504 of the Rehabilitation Act of 1973 (PL 93-112, as amended) which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (PL 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (PL 94-135), which prohibits discrimination on the basis of age.

Implementing regulations:

- 45 CFR 80: Civil Rights
- 45 CFR 84 and 85: Handicapped Individuals
- 45 CFR 86: Sex Discrimination
- 45 CFR 91: Age Discrimination

(f) Conflict of Interest

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

(g) Other Documentation

The Department of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight, as part of the negotiation of any contract arising from this request for proposals.

APPENDIX B

BUDGET
(sample format)

Organization Name: _____

Budget Period: Commencing on: _____ Ending on: _____

Personal Service

Number	Title	Annual Salary	% Time Devoted to This Project	Total Amount Budgeted From NYS

Total Salary _____
Fringe Benefits (specify rate) _____
TOTAL PERSONAL SERVICE: _____

Other Than Personal Service Amount

Category
- Supplies
- Travel
- Telephone
- Postage
- Photocopy
- Other Contractual Services (specify)
- Equipment (Defray Cost of Defibrillator) _____

TOTAL OTHER THAN PERSONAL SERVICE _____

GRAND TOTAL _____

APPENDIX C

PAYMENT AND REPORTING SCHEDULE

1. 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 _____ percent of the maximum amount indicated in the budget as set forth in the most recently approved Appendix B. If this payment is to be made, it will be due thirty calendar days, excluding legal holidays, after the later of either:

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

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

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

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

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

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

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

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

liability under this AGREEMENT to the CONTRACTOR, and this AGREEMENT shall be considered terminated and cancelled.

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

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 ____ 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 monthly/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 _____.

All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than _____ days after the end date of the period for which reimbursement is being claimed. 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.

II. Progress and Final Reports

Organization Name: _____

Report Type:

A. Narrative/Qualitative Report

_____ (Organization Name) will submit, on a quarterly basis, not later than _____ days from the end of the quarter, a report, in narrative form, summarizing the services rendered during the quarter. This report will detail how the _____ (Organization) _____ has progressed toward attaining the qualitative goals enumerated in the Program Workplan (Appendix D).

(Note: This report should address all goals and objectives of the project and include a discussion of problems encountered and steps taken to solve them.)

B. Statistical/Quantitative Report

_____ (Organization Name) will submit, on a quarterly basis, not later than _____ days from the end of the quarter, a detailed report analyzing the quantitative aspects of the program plan, as appropriate (e.g., number of meals served, clients transported, patient/client encounters, procedures performed, training sessions conducted, etc.)

C. Expenditure Report

_____ (Organization Name) _____ will submit, on a quarterly basis, not later than _____ days after the end date for which reimbursement is being claimed, a detailed expenditure report, by object of expense. This report will accompany the voucher submitted for such period.

D. Final Report

_____ (Organization Name) _____ will submit a final report, as required by the contract, reporting on all aspects of the program, detailing how the use of grant funds were utilized in achieving the goals set forth in the program Workplan.

APPENDIX D

PROGRAM WORKPLAN
(sample format)

A well written, concise workplan is required to ensure that the Department and the contractor are both clear about what the expectations under the contract are. When a contractor is selected through an RFP or receives continuing funding based on an application, the proposal submitted by the contractor may serve as the contract's work plan if the format is designed appropriately. The following are suggested elements of an RFP or application designed to ensure that the minimum necessary information is obtained. Program managers may require additional information if it is deemed necessary.

I. CORPORATE INFORMATION

Include the full corporate or business name of the organization as well as the address, federal employer identification number and the name and telephone number(s) of the person(s) responsible for the plan's development. An indication as to whether the contract is a not-for-profit or governmental organization should also be included. All not-for-profit organizations must include their New York State charity registration number; if the organization is exempt AN EXPLANATION OF THE EXEMPTION MUST BE ATTACHED.

II. SUMMARY STATEMENT

This section should include a narrative summary describing the project which will be funded by the contract. This overview should be concise and to the point. Further details can be included in the section which addresses specific deliverables.

III. PROGRAM GOALS

This section should include a listing, in an abbreviated format (i.e., bullets), of the goals to be accomplished under the contract. Project goals should be as quantifiable as possible, thereby providing a useful measure with which to judge the contractor's performance.

IV. SPECIFIC DELIVERABLES

A listing of specific services or work projects should be included. Deliverables should be broken down into discrete items which will be performed or delivered as a unit (i.e., a report, number of clients served, etc.) Whenever possible a specific date should be associated with each deliverable, thus making each expected completion date clear to both parties.

Language contained in Appendix C of the contract states that the contractor is not eligible for payment "unless proof of performance of required services or accomplishments is provided." The workplan as a whole should be structured around this concept to ensure that the Department does not pay for services that have not been rendered.

APPENDIX X

Agency Code _____

Contract No. _____
Period _____
Funding Amount for Period _____

This is an AGREEMENT between THE STATE OF NEW YORK, acting by and through _____, having its principal office at _____ (hereinafter referred to as the STATE), and _____ (hereinafter referred to as the CONTRACTOR), for modification of Contract Number as amended in attached Appendix(ices)_____.

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

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

_____
CONTRACTOR SIGNATURE

By: _____

_____
Printed Name

Title: _____

Date: _____

_____
STATE AGENCY SIGNATURE

By: _____

_____
Printed Name

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)
) SS:
County of _____)

On the ____ day of _____ 20__, before me personally appeared _____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, that he/she is the _____ of the _____, the corporation described herein which executed the foregoing instrument; and that he/she signed his/her name thereto by order of the board of directors of said corporation.
(Notary) _____

ATTORNEY GENERAL'S SIGNATURE

_____

Title: _____

Date: _____

STATE COMPTROLLER'S SIGNATURE

_____

Title: _____

Date: _____

NEW YORK STATE DEPARTMENT OF HEALTH

EXECUTIVE ORDER #127
CONTRACTOR DISCLOSURE OF CONTRACTS

This form shall be completed and submitted with your bid/proposal or offer. Failure to complete and submit this form shall result in a determination of non-responsiveness and disqualification of the bid, proposal or offer. If, at the time of submission of this form, the specific name of a person authorized to attempt to influence a decision on your behalf is unknown, you agree to provide the specific person's information when it is available. You also agree to update this information during the negotiation or evaluation process of this procurement, and throughout the term of any contract awarded to your company pursuant to this bid/proposal or offer.

Name of Contractor: _____

Address: _____

_____

Name and Title of Person Submitting this Form: _____

_____

Is this an initial filing in accordance with Section II, paragraph 1 of EO 127 or an updated filing in accordance with Section II, paragraph 2 of EO 127? (Please circle):

Initial filing Updated filing

The following person or organization was retained, employed or designated by or on behalf of the Contractor to attempt to influence the procurement process:

Name: _____

Address: _____

_____

Telephone Number: _____

Place of Principal Employment: _____

Occupation: _____

Does the above named person or organization have a financial interest in the procurement? (Please circle) Yes No

"Financial interest in the procurement" shall mean:

(a) owning or exercising direct or indirect control over, or owning a financial interest of more than one percent in, a contractor or other entity that stands to gain or benefit financially from the award of a procurement contract; or

(b) receiving, expecting or attempting to receive compensation, fees, remuneration or other financial gain or benefit from a contractor or other individual or entity that stands to benefit financially from a procurement contract; or

(c) being compensated by, or being a member of, an entity or organization which is receiving, expecting or attempting to receive compensation, fees, remuneration or other financial gain from a contractor or other individual or entity that stands to benefit financially from a procurement contract; or

(d) receiving, expecting or attempting to receive any other financial gain or benefit as a result of the procurement contract;

(e) being a relative of a person with a financial interest in the procurement, as set forth in paragraphs (a) though (d) above. For purposes of this paragraph, "relative" shall mean spouse, child, stepchild, stepparent, or any person who is a direct descendant of the grandparents of an individual listed in paragraphs (a) though (d) above or of the individual's spouse.

NEW YORK STATE DEPARTMENT OF HEALTH

EXECUTIVE ORDER #127
CONTRACTOR DISCLOSURE OF PRIOR NON-RESPONSIBILITY DETERMINATIONS

Name of Contractor: _____

Address: _____

_____

_____

Name and Title of Person Submitting this Form: _____

Has any covered agency or authority made a finding of non-responsibility regarding the Contractor in the last five years? Yes No If yes, was the basis for the finding of the Contractor's non-responsibility due to the intentional provision of false or incomplete information required by Executive Order Number 127? Yes No If yes, please provide details regarding the finding of non-responsibility below: COVERED AGENCY OR AUTHORITY: _____ YEAR OF FINDING OF NON-RESPONSIBILITY: _____ BASIS OR FINDING OF NON-RESPONSIBILITY: