

Finding a cure now... so our daughters won't have to.

Pat Halpin-Murphy, President & Founder, PA Breast Cancer Coalition

Request for Application (RFA)

PA Breast Cancer Coalition
Breast and Cervical Cancer Research Initiative
RFA: 2024

Date of Issuance: May 1, 2023 Letter of Intent due*: June 16, 2023 Application due*: July 21, 2023

Grant period: January 1, 2024- December 31, 2024

All Applicants will be notified of grant decision by: November 1, 2023

*Whether submitted by mail or delivered in person, materials must be received at the Pennsylvania Breast Cancer Coalition Issuing Office address by 4:00 pm EST.

Issuing Office:

Pennsylvania Breast Cancer Coalition 2397 Quentin Road, Suite B Lebanon, PA 17042 717-769-2300

researchgrants@pabreastcancer.org

RFA Project Officer:

Diane Funston
Program Coordinator
PA Breast Cancer Coalition
2397 Quentin Rd., Suite B
Lebanon, PA 17042
717-769-2306
diane@pabreastcancer.org

RFA Administrator/Grants Officer:

Tricia Grove
Director of Finance and Administration
PA Breast Cancer Coalition
2397 Quentin Rd., Suite B
Lebanon, PA 17042
717-769-2304
tricia@pabreastcancer.org

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Part One - General Information

A. Information for Applicants

Through this RFA process, the Pennsylvania Breast Cancer Coalition (PBCC) is soliciting research applications on breast or cervical cancer from Pennsylvania institutions and organizations. The PBCC is interested in funding research applications addressing a problem area in either breast or cervical cancer but is not limiting the type of research. The overall goal of this funding is to promote research directed toward reducing the incidence of and mortality associated with breast or cervical cancer. The grant agreement term is January 1, 2024 - December 31, 2024.

Only applications previously submitted to the National Cancer Institute (NCI). Department of Defense (DOD), the National Institutes of Health (NIH), Susan G. Komen for the Cure (Komen), the National Office of the American Cancer Society (ACS), the Breast Can earch Foundation (BCRF) or the Mary Kay Foundation (Mary Kay) sl ding. Applications b must be reviewed by one ning hree years prior to the th application deadling date of correspondence sent to researcher from b€ the organization stat Additionally, only those research applicati ve been beerreviewed and received a summary statement, reviewer co who submitted an scientific critique document, but er application for a calculat and aid not receive funding must include the cover letter from ide identrying the funding status of their application. Funds may only be used for one year. If an awardee receives additional funding from the NCI, DOD, Komen, NIH, ACS, fun ng stall be withdrawn. BCRF or Mary Kay for the same research, the

Applicants that have previously submitted to NCI, DOD, NIH, Komen, ACS, BCRF or Mary Kay for grants larger than the PBCC grant maximum of \$100,000 are not expected to complete the entirety of their scope of work with the PBCC funding. Applicants should select a portion of their original project that is feasible to complete with a maximum budget of \$100,000.

Applications are welcomed from Pennsylvania-based for-profit and nonprofit institutions and organizations in either the public or private sector, such as universities, colleges, hospitals, and laboratories whose application and background show them to be qualified, responsible, and capable of conducting the activities described. Additional information about how to apply, relevant and specific restrictions, and stated preferences regarding applicants are noted and outlined in Section C, Application Procedures, beginning on page 6 below.

This RFA provides interested institutions, organizations, and persons with information to prepare and submit applications to the PBCC. Questions about this RFA can be directed to Diane Funston, RFA Project Officer, PA Breast Cancer Coalition at Diane@PABreastCancer.org.

B. Letter of Intent

The applicant must submit a Letter of Intent, using the form Attachment A, stating that they intend to apply for the grant. Letters of Intent must be received at researchgrants@pabreastcancer.org by 4:00 pm EST on June 16, 2023.

Any agreement resulting from this RFA will include certain standard general terms and conditions. Please have your facility's legal counsel review ATTACHMENT F: RESEARCH GRANT AGREEMENT which is included with this application PRIOR TO APPLYING. These terms are non-negotiable. If your facility cannot comply with these terms DO NOT APPLY.

Please fill out the following form and return it by email to researchgrants@PABreastCancer.org.

ATTACHMENT A: Letter of Intent

PA Breast Cancer Coalition Breast and Cervical Cancer Research Initiative RFA: 2024 *Due Date: June 16, 2023**

Topic Area (please selec	ct):() Breast Cancer or () Ce	rvical Cancer
Title of Project:		
Mailing Address (The ad	ddress where you would like	notification about this application to be sent):
Collaborator 1 (if applic	cable)	
PI Organization or Inst	itution Name:	
Type of Legal Entity: _		
If tax-exempt please ind	licate IRC Section (i.e., 501	(c) (3):
Federal I.D. #:		
Address:		
City:	St	ate:Zip Code:
Grant Office Contact P	erson:	
Title:		
Telephone #:	Fax:	Email:
		ndard terms and conditions. Our facility and legal counsel have EEMENT and agree to the contract terms.
BY:		DATE:
Signatur	re of Researcher	
Print/7	Гуре Name	Print/Type Title
	rom the Facility's Grant Departmer	DATE:
Print/T	Type Name	Print/Type Title

C. Application Procedures

1. General

- a) Letters of Intent due June 16, 2023*.
- b) Full applications due July 21, 2023*.
 - *Materials must be received by the PBCC at <u>researchgrants@pabreastcancer.org</u> by 4:00 pm EST.
- c) If it becomes necessary to revise any part of the application guidelines, an amendment will be posted on the PBCC website, www.PABreastCancer.org.
- d) The decision of the PBCC with regard to selection of applicants is final. The PBCC reserves the right to reject any and all applications received as a result of this request and to negotiate separately with competing applicants.
- e) Contractors whose applications are selected are not permitted to issue news releases pertaining to this project prior to official written notification of the award by the PBCC. Any subsequent publication or media release issued by the Contractor throughout the life of the grant using funding from this grant must acknowledge the PBCC as the granting agency.
- f) Applicants may submit more than one research application; however, only one award per principal investigator shall be made during any funding cycle.
- g) Applications are initiated by individuals but must be formally submitted by their institutions. Awards shall be made to institutions and organizations, not individuals.
- h) Any agreement resulting from this RFA will include certain standard general terms and conditions. Please have your facility's legal counsel review ATTACHMENT F: RESEARCH GRANT AGREEMENT which is included with this application PRIOR TO APPLYING. These terms are non-negotiable. If your facility cannot comply with all of these terms DO NOT APPLY.

2. Review of Applications

Process and Evaluation of Applications:

- a) All applications meeting stated requirements in this RFA and received by the designated date and time will be reviewed.
- b) The applications will be reviewed by the PA Breast and Cervical Cancer Research Initiative Review Committee (Review Committee), consisting of qualified personnel selected by the PBCC.
- c) The Review Committee will recommend applications for funding that most closely meet the evaluation criteria developed by the PBCC.
- d) If the Review Committee needs additional clarification of an application, PBCC staff may schedule an oral presentation and/or request written clarification and assign a due date for the submission of such written clarification.

e) Evaluation criteria used by the Review Committee include:

Scientific Relevance, Impact, and Innovation: The application must address a critical problem or innovative issue in breast or cervical cancer research. The study should, if successful, advance knowledge toward the goal of reducing breast or cervical cancer incidence and mortality. The proposed research should add to current knowledge in breast or cervical cancer. The application should address the likelihood that funding from the PA Breast and Cervical Cancer Research Initiative would lead to subsequent success in achieving funding from a national organization.

<u>Principal Investigator (PI):</u> The application must address the representation from all the areas of expertise needed to conduct the study successfully. The application shall show that the PI and other researchers (if any) are appropriately trained and well suited to carry out this work.

Feasibility and Timelines: The applicant must articulate a clear plan for what shall be accomplished, including a step-by-step plan with timelines for accomplishing the specific tasks. The application should indicate that the objectives shall be met within the time frame.

Budget: The budget must be reasonable for the work proposed.

3. Awards

Grants will be administered through the PBCC. The maximum grant award per research application is \$100,000. Indirect costs (overhead, general, administrative, and other) may not be billed.

All applicants will receive official written notification of the status of their application from the PBCC. All applicants may request a final report showing the strengths and weaknesses of their application. This request must be in writing and must be received by the PBCC within 30 calendar days of the date of the PBCC's written notification of the status of the application. A comparison of applications will not be provided.

4. Deliverables

- a) The Contractor may be required to present an oral report to the PBCC or the PA Breast and Cervical Cancer Research Initiative Review Committee at any time between the end of the grant period and six months following.
- b) The Contractor is encouraged to publish their results in scientific literature. The Contractor will submit a copy of any manuscript or publications resulting from their research to the PBCC. The Contractor will include the following statement on printed materials resulting from funded research: "This project is funded, in part, by the Pennsylvania Breast Cancer Coalition. The PBCC takes no part in and is in no way responsible for any analyses, interpretations, or conclusions."

5. Reporting Requirements

- a) The Contractor must request and receive written approval from the PBCC prior to making any changes in key project personnel.
- b) Any changes to the budget, scope, or methodology of the research during the term of the grant agreement must be requested in writing and approved in writing by the PBCC prior to implementation.
- A. The Contractor will submit the following reports:
 - 1. A Midterm Report on or before the 6th month after the beginning of the grant period which shall be a narrative, not to exceed two (2) pages, summarizing the results of the research to that date.
 - 2. A Final Report on or before the 13th month after the beginning of the grant period which shall be in the following form:

Part #1: A narrative, not to exceed three (3) pages, summarizing the results of the research, specify plans for Scholarly Publications or presentations, and provide answers to the following questions:

- (i) Was the research successful?
- (ii) What are the next steps?
- (iii)Where does the researcher stand with previous grant applications or any other application(s) that would be relevant?

Part #2: Summary and copies of scholarly publications or presentations resulting from or related to this research grant.

6. Additional Grant Requirements

a) The Contractor will not make any announcement(s) about PBCC research grant funding prior to the official grant announcement from the PBCC.

b) The Contractor will agree to hold a publicity event at their facility between February 15, 2024 and June 30, 2024 with the support of the PBCC to publicize the grant and publicly recognize the researcher. PBCC staff will work with key facility staff to organize the event.

D. Application Instructions and Required Format

1. Application Instructions

- a) The applicant must complete and submit the attached Letter of Intent form stating that they intend to apply for the grant. Letters of Intent must be received by the PBCC at researchgrants@pabreastcancer.org by 4:00 pm EST on June 16, 2023.
- b) The application must be received by the PBCC at <u>researchgrants@pabreastcancer.org</u> by 4:00 pm EST on July 21, 2023. (Late applications will be rejected, regardless of the reason).
- c) The application must be submitted using the format described in Subsection 2, below Application Format.
- d) The Certifications Form must be completed and signed by an official authorized to bind the organization to the application.

Applicants are to be brief and clear in the presentation of ideas.

2. Application Format

Applicants must follow the format as described below to complete the application. Applications must be typewritten on 8 ½" by 11" paper, with a font size no smaller than 12 point and margins of at least .5 inch. Please use Times New Roman font.

- a) Cover Page Complete the form on pages 12-13.
- b) Certification for the Protection of Human Subjects, Human Anatomical Substances, Human Cadavers All Applications involving human subjects, human anatomical substances, and human cadavers must be reviewed and approved by the applicant's appropriate institutional review board (IRB) or biosafety committee prior to the initiation of any research. Applications will be rejected if the Certification, found in this RFA at page 14, is not completed, signed by the authorized institutional official, and included with the grant application.
- c) Containment of Recombinant DNA Research, and the Care and Treatment of Laboratory Animals All Applications involving laboratory animals or recombinant DNA must be reviewed and approved by the applicant's appropriate institutional review board, biosafety committee, or animal care and use committee prior to the initiation of any research. Specific documents will be required relating to the use of animals in the proposed research. Applications will be rejected if the Certification, found in this RFA at page 15, is not completed, signed by the authorized institutional health official, and included with the grant application.
- d) **Notice and Payment Provisions** Applicants must provide contact information for the person within their institution who is authorized to receive Notices from PBCC regarding the grant and contact information for the person authorized to receive periodic grant payments. The Notice and Payment Provision form, found in this RFA at page 16, must be completed and attached to the application.

- e) **Research Description**—Provide a narrative description of the proposed methodology addressing the following topics:
 - i. Summary: The Application Summary should not exceed two (2) pages and must include the following:
 - Title of project
 - Objectives
 - Brief summary of experimental or research design
 - Outline of anticipated results
 - Relevance and impact of project
 - ii. Work Statement: The work statement should not exceed eight (8) pages and must include the following:
 - Background statement of problem, including hypothesis to be tested, aims and objectives
 - Public/lay abstract
 - Technical abstract
 - Research or experimental design
 - Anticipated results
 - Steps to be taken to address concerns raised in initial peer review
 - Statement of work, including lists of tasks to be performed and timeline associated
- f) **Researcher Qualifications** Provide a narrative description of the staff (including qualifications, classifications, whether they are professional, technical, consultant, subcontractor, volunteer, etc.), and identify key personnel who shall be engaged in the research. Include a biographical sketch or curriculum vitae of each staff person, with the exception of support staff. These pages are not counted in the page limit of this application.
- g) **Budget** Use the downloadable format to present the budget request. The budget forms can be found at **pbcc.me/RFA**. The anticipated grant agreement term is January 1, 2024 December 31, 2024. The overall 12-month budget for the application shall not exceed \$100,000. The budget must contain an overall summary and details for each budget category. Please see budget worksheets and definitions for more information.
- h) **Original Research Proposal** Provide a copy of the proposal as originally submitted to NCI, NIH, DOD, ACS, or Komen.
- i) Scientific Critique Place (Courty of the summary statement, reviewer comments, peer review panel report or other scientific critique document, existent for the original application. Include the critique document, existent for the original application. Include the court of the period of the department of Defense and did not receive funding must include the cover letter from the organization identifying the funding status of their application.
- j) **Completed W-9 form** Provide a copy of the completed Internal Revenue Service form W-9. The W-9 form and instructions for completing the form are available at the website http://www.irs.gov.

ATTACHMENT B: APPLICATION COVER PAGE

PA Breast Cancer Coalition Breast and Cervical Cancer Research Initiative RFA: 2024

Principal Investigator (PI):			
Telephone #:			
E-mail:			
Mailing Address: (The address where you we	ould like notification	about this application to be sent	.)
Title of Project:			
Topic Area (please select): Breast Cance	er or Cervical Ca	ancer	
Short Project Summary:			
PI Organization or Institution Name:			
Type of Legal Entity:			
If tax-exempt please list IRC Section (i.e. 50			
Federal I.D.#:			
Address:			
City:	State:	Zip Code:	
Grant Office Contact Person:			
Title:			
Telephone #:			
E-mail:			

ATTACHMENT B: APPLICATION COVER PAGE- Page 2

PA Breast Cancer Coalition Breast and Cervical Cancer Research Initiative RFA: 2024

Application Checklist

- In order to be reviewed, applications must contain all items, including certifications and agreements that are required in the Request for Application (RFA).
- Submit all application files electronically to <u>researchgrants@pabreastcancer.org</u> by 4:00 pm EST on July 21, 2023.

Please check to confirm that you have submitted the following:

AGREEMENT and agree to the contract terms.

Letter of Intent Submitted to the PBCC by 4:00 pm EST on June 16, 2023 **Application** Cover Page (2-page document) Research Description Public/Lay Abstract **Technical Abstract** Researcher Qualifications and Key Personnel List Budget REQUIREMENT SUSPENDED FOR 2024
Scientific Critique **Required Attachments** Attachment B: Cover Page Attachment C: Certification for the Protection of Human Subjects, Human Anatomical Substances, **Human Cadavers** Attachment D: Certification for the Containment of Recombinant DNA Research, and the Care and Treatment of Vertebrate Laboratory Animals Attachment E: Notice and Payment Provisions

Our facility and legal counsel have reviewed ATTACHMENT F: RESEARCH GRANT

If this grant application is awarded and if PBCC requests, the Applicant Organization/Institution agrees to hold an event at their facility with the PBCC between the 1st month and 6th month of the grant period to publicize the grant and publicly recognize the researcher. PBCC staff will work

with key organization/institution staff to organize and publicize this event.

ATTACHMENT C: CERTIFICATION FOR THE PROTECTION OF HUMAN SUBJECTS, HUMAN ANATOMICAL SUBSTANCES, HUMAN CADAVERS

PRINCIPAL INVES	TIGATOR NAME	PRINCIPAL INVESTIGATOR TITLE
TITLE OF RESEAR	RCH PROJECT	INSTITUTION
CERTIFI		HUMAN SUBJECTS, HUMAN ANATOMICAL
Ta : 41	SUBSTANCES, HUI	
PA Breast Cance	•	at the rights and welfare of all human subjects used in any Any research involving human subjects must be reviewed
agrees that all expapproval of its Inbut not limited to participants) and be obtained. If guardian shall be result in the los	perimentation with human subjects shall be pastitutional Review Board (IRB) is obtained a 42 U.S.C. Section 3515 (b) (relating to prothe regulations there under. Further, the prior the subject is a minor, or incompetent, the required. The applicant shall inform each	ividuals who participate in research activities. The applicant prohibited unless the applicant certifies that the prior written or is not required, subject to all applicable laws, including chibitions on funding certain experiments involving humans, written, voluntary, informed consent of each subject must prior, written, voluntary, informed consent of their legal potential subject prior to their consent that refusal shall not is otherwise entitled from the federal government, the cant, or any third party insurer.
	-	or human cadavers will be used in any of the proposed
to certify (IRB) on	that the proposed activities on human sub	man cadavers will be used in the proposed research. This is jects have been reviewed by an institutional review board accordance with current Department of Health and Human
certify the review be funds to proposed	nat the proposed activities involving human oard (IRB), and that prior to the initiation pay for any of the research expenses, the	aman anatomical substances or human cadavers. This is to subjects have NOT yet been reviewed by an institutional of research involving human subjects and the use of grant applicant will send documentation to the PBCC that the ational review board (IRB) and have been found to be in uman Services (DHHS) policy.
NAME O	F AUTHORIZED INSTITUTIONAL OFFICIAL	TITLE
SIGNATU	JRE	DATE

ATTACHMENT D: CERTIFICATION FOR THE CONTAINMENT OF RECOMBINANT DNA RESEARCH, AND THE CARE AND TREATMENT OF VERTEBRATE LABORATORY ANIMALS

PRINCIPAL INVESTIGATOR NAME	TITLE OF PRINCIPAL INVESTIGATOR
TITLE OF RESEARCH PROJECT	INSTITUTION

CERTIFICATION FOR CONTAINMENT OF RECOMBINANT DNA RESEARCH

It is the responsibility of the research institution to assure that the physical and biological containment needed for research involving any recombinant DNA molecules is within policies set out in the current "National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules."

Please check the appropriate statement:	
This research does not involve any use of recombinant DN	NA molecules as defined by current NIH guidelines.
	ecules as defined by current NIH guidelines. This is to certify that cules have been reviewed by an institutional biosafety committee on with current NIH guidelines.
the proposed activities involving recombinant DNA mol committee, and that prior to the initiation of research involving	ecules as defined by current NIH guidelines. This is to certify that lecules have NOT yet been reviewed by an institutional biosafety lving recombinant DNA and the use of grant funds to pay for any of ion to the PBCC that the proposed activities have been reviewed by nee with current NIH guidelines.
	CARE AND TREATMENT OF ORATORY ANIMALS
· · · · · · · · · · · · · · · · · · ·	care and treatment of all vertebrate laboratory animals used in any nvolving laboratory animals must be reviewed and approved by an JC).
Please check the appropriate statement:	
No vertebrate laboratory animals will be used in any of	the proposed research.
Vertebrate laboratory animals will be used in the proposal laboratory animals have been approved by an institution be in accordance with current Public Health Service poles.	; ;
laboratory animals have NOT yet been approved by a involving vertebrate animals and the use of grant fund	sed research. This is to certify that the proposed activities involving an appropriate IACUC, and that prior to the initiation of research is to pay for any of the research expenses, the applicant will send a have been reviewed by an appropriate IACUC, and found to be in
NAME OF AUTHORIZED INSTITUTIONAL OFFICIAL	TITLE
SIGNATURE	DATE

ATTACHMENT E: NOTICE AND PAYMENT PROVISIONS

The following individual is authorized to receive all Notices from PBCC pertaining to this grant:

Name
Title
Address
Address
City
State
Zip Code
Phone
Fax
Count assessments of could be used at a the following.
Grant payments should be made to the following:
Name
Title
Address
Address
City
State
Zip Code
Phone
Fax

ATTACHMENT F: SAMPLE RESEARCH GRANT AGREEMENT

WHEREAS, The Pennsylvania Breast Cancer Coalition (PBCC) has solicited applications for research grants to fund research relating to breast or cervical cancer from institutions and organizations based in Pennsylvania.

WHEREAS, Contractor, named below, a qualifying Pennsylvania institution or organization, has submitted a research application to the PBCC that addresses these research areas.

NOW, THEREFORE, in consideration of the covenants, warranties and representations set forth below, the PBCC and _______, Contractor, intending to be legally bound agrees as follows:

SECTION 1: DEFINITIONS

Unless otherwise noted in this Agreement the terms shall have the following meanings:

Agreement: the terms and conditions of this document, any subsequent grant contracts awarded by the PBCC to Contractor that are solely related to the Scope of Work, the Statement of Work and the Research Application of Contractor.

Background Material: original work papers, notes and drafts prepared by or for Contractor to support conclusions in any final report or product delivered under this Agreement, including but not limited to completed questionnaires and material in electronic data processing form, computer programs and other tangible materials produced by or for Contractor during the term of this Agreement and directly related to the services being rendered. It does not include Contractor's financial reports or other information incidental to the administration of this Agreement.

Contractor:	

Data: includes, but is not limited to, written reports and analyses, diagrams, maps, system designs, computer programs, flow charts, punched card decks, magnetic tapes, diskettes, drawings, studies, manuals, brochures, advertisements, documents, sketches, papers, files, information, computer documentation, other tangible materials and work of any similar nature which is required to be performed by or for Contractor under this Agreement or which is incidentally prepared by or for Contractor in the performance of this Agreement. Data also includes Background Material prepared by or for Contractor incidental to the performance of this Agreement.

Grant: the award of funds made by the PBCC as in this Agreement.

Grant Period: the duration of this Agreement, which shall commence on January 1, 2024 and end December 31, 2024 or as extended in accordance to this Agreement.

Grant Proposal: the proposal submitted by Contractor attached hereto as Exhibit A and incorporated as if fully set forth herein.

Key Personnel: the primary investigator or other participants as set forth in Exhibit A who are considered essential to the research being performed under this Agreement.

Pre-Existing Material: intellectual property that Contractor, prior to the grant period, had developed independently or developed with or obtained from third Parties, including but not limited to, background material, proprietary materials, data, software and methodologies.

Printed Material: includes, but is not limited to, notices, informational pamphlets, press releases, research reports, brochures, manuals, newsletters, artwork and print advertisements.

Project or Contracting Officer: PBCC personnel as identified by the PBCC.

Records: books, documents, sub-contracts and other evidence pertaining to Contractor's costs and expenses in performance of this Agreement.

Research or Research application: the work, investigation, and/or scientific study, to be conducted in accordance with the grant proposal, Exhibit A, and this Agreement.

Researcher: the person designated in the grant proposal and Exhibit A as the primary investigator responsible for conduct of the research subject to this grant.

Scholarly Publication or Presentation: any academic article, abstract, research report, manuscript or presentation that is submitted for peer-review or review by other scholars, experts, or researchers or in any academic or professional meeting or setting resulting from or related to this Grant.

Scope or Statement of Work: any and all research and obligations undertaken or to be performed by Contractor pursuant to this Agreement as set forth in Contractor's research application or as subsequently modified upon prior approval of PBCC and in agreement with the Contractor.

SECTION 2: CONTRACTOR, CONTRACTOR'S OBLIGATIONS

2.1 INDEPENDENT CONTRACTOR: Contractor shall perform its services under this Agreement as an independent Contractor and shall provide insurance for public liability and for property damage coverage insuring the interests of all Parties to the Agreement against any and all claims which may arise out of Contractor's performance under the terms of this Agreement. Contractor shall be responsible for workers' compensation; social security; income tax deductions; and any other taxes or payroll deductions required by law for its employees who are performing services under this Agreement.

2.2 KEY PERSONNEL AND PROJECT CHANGES

- A. No diversion or removal of Key Personnel shall be made by Contractor without the prior written consent of the Project Officer.
- B. Contractor shall provide written notice to the PBCC within 30 (thirty) days of any Key Personnel dissociating or being disassociated from Contractor, whether permanently or temporarily. The PBCC reserves the right upon such event to terminate this Agreement at the PBCC's sole discretion.
- C. No Key Personnel performing research funded pursuant to this Agreement, nor any officer, member or employee of Contractor who exercises any functions or responsibilities under this Agreement, shall participate in any decision relating to this Agreement which affects that person's personal interest or the interest of any corporation, partnership, or association in which that person is, directly or indirectly, interested. Contractor further covenants that in the performance of this Agreement, it shall not knowingly employ any person having such interest.
- D. In addition to the notice relating to Key Personnel above Contractor will notify the PBCC 30 days in advance of and must receive prior written approval for any other proposed changes to the personnel, design, budget, content or specific aims of the Research.
- E. The PBCC will be provided a minimum of 14 days to review and accept or reject any such proposed changes and will provide Contractor with a decision in writing after review.
- F. Notwithstanding the above, Contractor may modify the budget or this research without prior approval of the PBCC if the modification does not (i) change any budget expense subcategory by more than 5%; (ii) increase the amount of any cost above the maximum allowable for a subcategory item; or (iii) result in an expenditure beyond the Grant.

2.3 ASSIGNABILITY

- A. Contractor may not assign whole or in part or its rights, duties, obligations or responsibilities under this Agreement without the prior written consent of PBCC, which consent may be withheld at the sole and absolute discretion of PBCC.
- B. Any assignment consented to by PBCC shall be in writing executed by Contractor and its assignee in which the assignee agrees to be legally bound by all of the terms and conditions of this Agreement and to assume the duties, obligations, and responsibilities being assigned.
- C. Notwithstanding the foregoing, Contractor may, without the consent of the PBCC, assign its rights to payments to be received under this Agreement, provided that Contractor provides written notice of such assignment to the PBCC together with a written acknowledgment from the assignee that any such payments are subject to all of the terms and conditions of this Agreement.

2.4 SUB-CONTRACTS

- A. Except for sub-contracts specifically authorized by this Agreement, Contractor shall not enter into sub-contracts for any of the work contemplated under this Agreement without obtaining prior written approval of the PBCC, which shall be attached to this Agreement, subject to such conditions and provisions as the PBCC may deem necessary.
- B. Notwithstanding the foregoing, unless otherwise provided herein, such prior written approval shall not be required for the purchase by Contractor of articles, supplies, equipment and services which are both necessary for and merely incidental to the performance of the Research required under this Agreement.
- C. Approval by the PBCC of any sub-contract, shall not be deemed to provide for the incurrence of any obligation or liability on the part of the PBCC with regard to any sub-contract entered into by Contractor.

2.5 DATA, COPYRIGHTS, AND DISCLOSURE

- A. The PBCC shall have no ownership rights to Contractor's Pre-Existing Material.
- B. Contractor shall retain all copyright interests, proprietary rights, trade secrets and other right, title and interest in and to all Data resulting from the performance of this Agreement, provided, however, that Contractor shall, and hereby effectively does grant to the PBCC a non-exclusive, non-transferable license to use, modify, prepare derivative works and to grant to third parties engaged by the PBCC, the right to use, modify and prepare derivative works, from all or any portion of the Data solely for PBCC's internal research and educational purposes.
- C. To Contractor's knowledge and without the obligation to conduct any searches, Contractor represents that the Data is original and does not infringe the rights of any other work.

2.6 EQUIPMENT AND OTHER MATERIAL

- A. Contractor retains ownership and title to all supplies and equipment obtained by Contractor in performance of this Agreement. Contractor shall be solely responsible for all maintenance, repair, protection, preservation, and insurance of such supplies and equipment.
- B. The PBCC shall have no ownership interest in any supplies or equipment obtained by Contractor. Contractor remains liable for any loss, destruction of or damage to such supplies or equipment or any injury or damage to any person or property as a result of the use of such supplies or equipment by Contractor.

2.7 NON-EXCLUSIVE AGREEMENT, OTHER CONTRACTORS

- A. Contractor understands that this Agreement is non-exclusive and the PBCC may undertake or award other contracts for additional, related, or similar research to other Contractors.
- B. Contractor shall not interfere with the performance of work or research by any other Contractor or by PBCC employees.
- C. Nothing in this Agreement shall be construed to limit the freedom of Contractor or of the Key Personnel under this Agreement from engaging in research similar to this grant made under other grants, contracts or agreements with Parties other than the PBCC. However, during the period of this Agreement, the Key Personnel shall not undertake any obligations that would prevent the researcher from fulfilling their obligations under this Agreement.

2.8 INVOICES

- A. Contractor shall submit quarterly invoices within thirty (30) days from the last day of the quarter within which the work is performed. The invoice must include a detailed accounting itemized in accordance with any budget approved in writing by the PBCC and any other relevant supporting documentation.
- B. Contractor's final invoice shall be submitted within forty-five (45) days of the expiration of the Grant Period. The PBCC will neither honor nor be liable for invoices not submitted in compliance with the requirements of this paragraph unless the PBCC agrees in advance and in writing to an extension or modification to these requirements.
- C. Indirect costs (overhead, general and administrative) and travel or subsistence costs may not be billed.
- D. Invoices should be sent to <u>researchgrants@pabreastcancer.org</u>.

2.9 RECORDS, RECORD ACCESS AND RECORD RETENTION

- A. Contractor agrees to maintain records in such detail as will properly reflect all net costs, direct and indirect, of labor, materials, equipment, supplies and services and other costs and expenses for which reimbursement is claimed under the provisions of this Agreement.
- B. Contractor agrees to maintain financial Records in accordance with accounting procedures and practices which meet Generally Accepted Accounting Principles (GAAP).
- C. During the grant period Contractor agrees to make Records available at Contractor's address during normal business hours and at mutually agreed upon times, for inspection, audit or reproduction by any authorized designee of the PBCC, subject to reasonable safeguards to ensure confidentiality of such Records.
- D. Records which relate to litigation or the settlement of claims arising out of the performance of this Agreement, or costs and expenses of this Agreement as to which exception has been taken by any auditor, shall be retained by Contractor until such litigation, claims or exceptions have been disposed of.

2.10 REPORTS REQUIRED WITH RESPECT TO THIS RESEARCH

- B. With respect to this research Contractor shall submit the following:
 - 3. A Midterm Report on or before the 6th month after the beginning of the grant period which shall be a narrative, not to exceed two (2) pages, summarizing the results of the research to that date.
 - 4. A Final Report on or before the 13th month after the beginning of the grant period which shall be in the following form:
 - Part #1: A narrative, not to exceed three (3) pages, summarizing the results of the research, specify plans for Scholarly Publications or presentations, and provide answers to the following questions:
 - (iv) Was the research successful?

- (v) What are the next steps?
- (vi) Where does the researcher stand with previous grant applications or any other application(s) that would be relevant?
- **Part #2:** Summary and copies of scholarly publications or presentations resulting from or related to this research grant.

Part #3: Describe how this grant impacted your work.

- 5. The reports required by this section:
 - a. Shall be sent to researchgrants@pabreastcancer.org.
 - b. The above reports will not be treated as confidential, and may be reviewed and evaluated by third Parties. The PBCC will not be responsible for any damages resulting from the disclosure of the reports to third Parties.
 - c. The grant information may be shared with donors of the PBCC or with members of the general public.
- C. In addition to the reports required by this section during the grant period information such as the progress, results or status of the research project may be requested by the PBCC and shall be made available to the PBCC within ten (10) days after such request.

2.11 CONFIDENTIALITY, SENSITIVE DOCUMENTS AND INFORMATION

- A. Contractor shall not publish or otherwise disclose to the PBCC or anyone else, except as to matters of public record, any information or data obtained hereunder from private individuals, organizations or public agencies, where the information or data furnished by or about any particular person or establishment can be identified, except with the prior, voluntary, written and informed consent of such person or establishment.
- B. In addition to the above:
 - 1. Contractor agrees that all human subject research, including but not limited to research which obtains personally identifiable information or data through intervention or interaction with an individual, shall be prohibited unless Contractor also certifies that prior written approval of its own or another institutional review board (IRB) has been obtained or the research has been exempted. This provision is subject to all applicable laws, including but not limited to, 42 U.S.C. §3515(b) (relating to prohibitions on funding certain experiments involving human participants) and the regulations thereunder.
 - 2. Contractor shall obtain prior, voluntary, written and informed consent of each subject. If the subject is a minor or incompetent, the prior, voluntary, written and informed consent of their legal guardian shall be required.
 - 3. Contractor shall inform each potential subject prior to their consent that refusal will not result in the loss of any benefits to which the subject might otherwise be entitled to from the federal government, the Commonwealth, Contractor, any sub-Contractor, or any third party insurer.
 - 4. Contractor agrees that any research involving human subjects, human anatomical substance, and/or human cadavers must be reviewed and approved by Contractor's appropriate IRB or biosafety committee prior to the initiation of any research.

2.12 PUBLICITY

- A. Contractor will not make any announcement(s) with regard to the Grant prior to the official grant announcement by the PBCC.
- B. Contractor agrees to hold a publicity event at their facility with the support of the PBCC between the 1st month and 6th month of the grant period or at a date designated by the PBCC to publicize the grant and publicly recognize the researcher. PBCC staff will work with Contractor to organize, conduct and participate in this event.

C. Neither Party to this Agreement will use the names, images, logos, or trademarks of the other Party in any publicity, advertising, promotional, securities, sales literature or press release without the prior written approval of the authorized representative of the other Party.

2.13 ACKNOWLEDGEMENT & ATTRIBUTION

- A. Contractor will acknowledge and will cause any of its subcontractors and Contractors involved in this research project to acknowledge the PBCC's grant by including an attribution on all material produced from this grant, including but not limited to Scholarly Publication or Presentations; on Contractor's website; and in Contractor's annual report and other donor listings.
- B. The attribution as required by "A." above shall state: "This research is funded, in part, by a contract with the Pennsylvania Breast Cancer Coalition (PBCC). The PBCC takes no part in and is in no way responsible for any analyses, interpretations, or conclusions contained herein."
- **2.14 COMPLIANCE WITH LAWS:** Contractor will comply with all laws and regulations applicable to its activities associated with this Agreement and Grant, including but not limited to:
 - A. Health Insurance Portability & Accountability Act of 1996
 - B. Equal Employment Laws
 - C. Affirmative Action Laws
 - D. American with Disabilities Act requirements
 - E. Corporate Practice of Medicine Doctrine
 - F. anti-terrorist financing and asset control laws, statutes and executive orders
 - G. if Contractor prescribes or dispenses drugs to consumers, it shall do so in accordance with Act 259 of November 24, 1976, P.L. 1163, 35 P.S. §960.1 et seq., as amended, and prescribe and dispense generically equivalent drugs rather than brand name drugs whenever possible.

SECTION 3: PBCC'S OBLIGATIONS

3.1 PAYMENTS

- A. The PBCC agrees to award a research grant to Contractor in the amount of One Hundred Thousand and 00/100 Dollars (\$100,000.00) pursuant to the terms and conditions of this Agreement.
- B. Payments by the PBCC to Contractor shall be made as submitted in accordance to Section 2.8 and will be sent in accordance to the directions of Contractor.
- C. The PBCC will not be liable for payments of invoices not submitted in accordance with the requirements of this Agreement unless the PBCC agrees in advance to an extension or modification of these requirements.

3.2 NATURE OF AGREEMENT, SUFFICIENCY OF FUNDS

- A. This Agreement is a funding agreement, and no employment, partnership, joint venture or agency relationship is created, implied or deemed to be created by this Agreement.
- B. The PBCC is not obligated to provide Contractor or any Collaborating Organization any additional financial or other support, in connection with the Grant, this Agreement or the Research Project.
- C. The PBCC may terminate this Agreement at any time in the event funds become unavailable or are insufficient for PBCC program purposes.
- D. In the event of termination or suspension of this Agreement the PBCC shall provide Contractor with advance notice to the extent reasonable and possible under the circumstances to either terminate the Agreement completely, or suspend all or a portion of such Agreement as determined by the PBCC and as set forth in the PBCC's notice to Contractor.

- E. In the event of termination or suspension of this Agreement the PBCC will pay Contractor for satisfactory work completed up until such termination or outside such suspension period, but in no event shall Contractor be entitled to receive loss of profits.
- **3.3 EXTENSION OF GRANT PERIOD:** Any extension or modification of the Grant Period is at the sole discretion of the PBCC and must be approved in writing.
- 3.4 INTERESTS OF MEMBERS OF THE PBCC AND OTHERS: No officer, member or employee of the PBCC, who exercises any functions or responsibilities under this Agreement, shall participate in any decision relating to this Agreement which affects that person's personal interest or the interest of any corporation, partnership, or association in which that person is, directly or indirectly, interested; nor shall any such officer, member or employee of the PBCC have any interest, direct or indirect, in this Agreement or the proceeds thereof.

SECTION 4: JOINT RESPONSIBILITIES

4.1 LIABILITY

- A. Each Party (which shall include their employees, agents, officers and directors) agrees to be solely responsible for any and all claims, demands, costs, liabilities, losses, expenses and damages (including reasonable attorneys' fees, costs, and expert witnesses' fees) arising out of or in connection with the negligent or intentional acts or omissions of that Party.
- B. Contractor shall not be liable for any direct, indirect, consequential, punitive or other damages suffered by the PBCC or any other person as a result of PBCC's actions and responsibilities under this Agreement, including but not limited to, PBCC's provision of funds for Contractor to conduct research pursuant to the terms of this Agreement or PBCC's use of Contractor's intellectual property product.
- C. PBCC shall not be liable for any direct, indirect, consequential, punitive or other damages suffered by Contractor or any other person as a result of Contractor's actions and responsibilities under this Agreement, including but not limited to, Contractor's conducting of research as incorporated in this Agreement as Exhibit A.

4.2 **DEFAULT AND TERMINATION**

- A. If either Party fails to perform or is in breach of the terms, conditions, Agreements, covenants, representations or warranties contained in this Agreement the Party shall notify the other of the alleged breach or default. If the default is not curable, or if such default remains uncured for a period of 30 days after written notice thereof has been given to the defaulting Party, the non-defaulting Party, at its sole election, may immediately terminate this Agreement by written notice thereof to the defaulting Party.
- B. Either Party may terminate this Agreement prior to the expiration of the grant period or any extension there of for any cause upon 30-day written notice to the other Party.

SECTION 5: MISCELLANEOUS PROVISIONS

- 5.1 The Parties agree that this Agreement supersedes any prior oral or written understandings or communications between the Parties and constitutes the entire Agreement between the Parties with respect to the Agreement.
- 5.2 This Agreement may not be modified, altered, amended or revoked except in writing, duly executed by authorized representatives of each of the Parties.
- 5.3 The provisions of this Agreement are severable so that if any provision is found to be invalid or illegal, the unaffected provisions remain valid and enforceable.
- 5.4 Failure of either Party to enforce its rights under this Agreement will not constitute a waiver of such rights.

- 5.5 The provisions of this Agreement shall be construed in accordance with the provisions of the Laws of the Commonwealth of Pennsylvania; any dispute arising out of or in connection with this Agreement will be filed and heard in state or federal courts of Harrisburg, PA; and the Parties consent to the exclusive jurisdiction of such courts.
- 5.6 Contractor will promptly notify the PBCC of any potential or threatened litigation, claim, assessment or audit related to the Project and of any challenge that may prevent Contractor from fulfilling the objectives described in the grant proposal.
- 5.7 Any notices required or given under this Agreement shall be in writing and personally delivered, delivered by facsimile or sent via overnight courier or certified mail, postage prepaid and return receipt requested, addressed to the other Party at the addresses as set forth in RFA 2024 Attachment E.