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Award Number: W81XWH-07-1-0329

TITLE: Breast Cancer Epidemiology in Puerto Rico

PRINCIPAL INVESTIGATOR: Cruz Maria Nazario, Ph.D.

CONTRACTING ORGANIZATION: University of Puerto Rico Medical Science Center
San Juan, PR 00936

REPORT DATE: June 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE

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1. REPORT DATE *(DD-MM-YYYY)*
June 2013

2. REPORT TYPE
Annual

3. DATES COVERED *(From - To)*
1 June 2012 - 31 May 2013

4. TITLE AND SUBTITLE
Breast Cancer Epidemiology in Puerto Rico

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-07-1-0329

5c. PROGRAM ELEMENT NUMBER

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

6. AUTHOR(S)
Cruz Maria Nazario, Ph.D.

E-Mail: cruz.nazario@upr.edu

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Puerto Rico Medical Science Center
San Juan, PR 00936

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This report provides evidence that the recruitment and data collection phase has been developing successfully. The work between mentor institution, minority institution, physician and the project agency sponsoring has been effective. The project staff has participated in several scientific activities to presented preliminary data of the Breast Cancer Epidemiology Study (ATABEY). Also the project staff has written and submitted letters of intent, a pre-proposals and a full proposal to different funding agencies.

15. SUBJECT TERMS
Breast cancer; population-based study, epidemiology,

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
U	U	U	UU	38	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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Annual Report, 06 July 1, 2012 – June 30, 2013
Breast Cancer Epidemiology in Puerto Rico
BCRP HBCU/MI Partnership Training Award BC060131
CDMRP Grant W81XWH-07-1-0329

Cruz María Nazario, Ph.D.
Department of Biostatistics and Epidemiology, Office A-463
School of Public Health
University of Puerto Rico; Medical Sciences Campus
PO Box 365067, San Juan, Puerto Rico 00936-5067
(787) 758-2525 ext. 1429; cruz.nazario@upr.edu

Cruz María Nazario, Ph.D.; Principal Investigador
Jo Freudenheim, PhD; Principal Investigator, Mentor

Date of Publication: June 30, 2013

Grants Officer's Representative: Theresa J. Miller, Ph.D.

INTRODUCTION:

This project has two mayor goals: (1) to design and conduct a pilot case-control breast cancer study among Puerto Rican women and (2) to train and develop researchers in breast cancer at the minority institution. The case control study proposed to enroll women 30-79 years of age residents of the following municipalities in the San Juan metropolitan area: San Juan, Bayamón and Guaynabo. Cases are women with incident, primary, and pathologically confirmed breast cancer with no history of previous cancer other than non-melanoma skin cancer. Controls are randomly selected from females living in the same geographical area as of the breast cancer cases. We will examine adult and childhood factors in relation to risk of breast cancer in this understudied population of Puerto Rican women. The specific aims are: to examine dietary risk factors in relation to breast cancer; to examine other established risk factors such as lifetime weight gain, physical activity, alcohol consumption, and reproductive history among Puerto Ricans in relation to breast cancer risk; and to examine factors related to early life exposure including birth weight, adult height, childhood diet, physical activity, environmental factors and residential history as a proxy for environmental exposure. The overall training goal is to develop a team of independent investigators with the necessary skills to build up a program of breast cancer research in Puerto Rico and to obtain funds to support research. To accomplish this goal, researchers from the University of Puerto Rico obtained formal training in cancer epidemiology and participated in the design and conduct of the population-based case control study of breast cancer in Puerto Rico.

BODY:

STATEMENT OF WORK

Task 1: Training researchers from the University of Puerto Rico

The training of investigators from the minority institution has been an important goal in this project. Investigators have been involved in activities directed toward achieving the following goals: 1) to develop expertise in breast cancer epidemiology, especially in the areas of interest of this study, 2) to understand cutting edge developments in breast cancer in order to design future studies to test new hypothesis and 3) to develop needed expertise particularly for this study as well as for future studies. In order to meet the training goals, during the sixth year of the award, the project staff has participated in the following scientific activities.

Dr. Rosa Rosario attended the 13thRCMI International Symposium on Health Disparities in San Juan, Puerto Rico from December 10-13, 2012. She attended sessions on: Cancer and Health Disparities and Breast Cancer Research. Mentoring of researchers from Puerto Rico is ongoing in the discussions regarding abstract and publication submissions.

Johan Hernandez, the Program Coordinator attended the American Public Health Association's 140th Annual Meeting & Exposition in San Francisco from October 27-31, 2012. She attended sessions on: Cancer Epidemiology; Latino Cancer Research jointly (presented by the Cancer Forum and the Latino Caucus); Impact of Social Determinants on Cancer Morbidity and Mortality and other conferences.

Dr. Cruz M. Nazario, Dr. Rosa Rosario, Dr. Imar Mansilla and Johan Hernández atended *IV Conferencia Puertorriqueña de Salud Pública* (Fourth Puerto Rican Public Health Conference) on San Juan Puerto Rico, March 2013. The Project staff attended sessions on Public Health and also presented preliminary data of the Breast Cancer Epidemiology Study (ATABEY).

Dr. Michele Santos, Dr. Farah Ramirez and Dr. Jo Freudenheim attended the American Society for Nutrition at the Experimental Biology (EB) 2013 meeting in Boston, April 2013.

The project staff presented preliminary data of the Diet of Women in Puerto Rico in the Atabey Study.

Task 2: Develop and maintain communications among participating investigators.

During the sixth year of the award, the minority and the mentoring institutions have been in close communication to discuss relevant issues regarding the study protocol such as recruitment, interview process, analysis, publication and other. This communication has included weekly teleconference calls as well as frequent communications by email.

Task 3: Participate in summer courses.

The funds allocated for summer courses concluded in July 2009. The information related to the researchers' participation in summer courses was described in past reports.

Task 4: To design, implement and analyze a case control study of breast cancer in Puerto Rico.

Approval of the study informed consent continued review was obtained from all study institutions (University of Puerto Rico and University at Buffalo) and submitted to Human Subjects Protection Scientist of the CDMRP IRB in July 2012. Also the Continuing Review report was completed and submitted to USAMRMC Human Research Protection Office in December 2012. All questionnaires and protocols were developed as part of conducted work as reported previously.

Task5: Study participants' recruitment and data collection to conduct a breast cancer case-control study in Puerto Rico.

The recruitment of human subjects for the breast cancer study is ongoing.

Cases ascertainment and recruitment

The Principal Investigator (Dr. Nazario) and the Project Coordinator (J. Hernandez) continue establishing links of collaboration with hospitals and physicians to identify breast cancer cases. Twenty eight primary physicians (or referring physicians) and five hospitals (hospitals with oncology departments) have been contacted and accepted to identify and coordinate the recruitment of breast cancer cases. At the time of this report we have received 1,656 referrals of potential cancer cases.

The project staff has contacted 1,521 cases and evaluated their eligibility to participate in the study. Of these, 414 are eligible; that is they are incident, primary, pathologically confirmed breast cancer with no history of previous cancer that meet the age and residency inclusion criteria for the study. Of those, 298 (72%) have agreed to participate. The project staff schedules the appointments for the interview.

Control ascertainment and recruitment

The community outreach contacted 512 potential controls that are eligible to participate in the study. Of these 512 potential controls, 337(66%) have agreed to participate in the study and the project staff has schedule an appointment for the study.

For both cases and controls, we are monitoring ascertainment and recruitment procedures to optimize response rates and to maintain the population-based format of the study. During some months of the sixth year, recruitment was somewhat slow, because the Community Outreach worker was on sick leave for several months. In addition, the Puerto Rico Cancer Registry which is the primary source of this study to identify the breast cancer cases has undergone an administrative restructuring process during the past months. This process caused a delay in the evaluation of the pathology reports to identify the cases eligible for the study halting the recruitment process and the scheduling of interviews. However the recruitment and interviewing have accelerated in the last two months. In order to reach the proposed sample size of 500 cases and 500 controls we requested an additional one year no-cost extension. At the time of this report the U.S. Army Medical Research Acquisition Activity office is working to formalize the no cost extension process.

The electronic data collection phase is ongoing. At the end of this report, 635 interviews had been coordinated. The following table describes the interview process until June 30, 2013.

Interview	Control	Cases	Total
Completed	324	293	617
In process	13	5	18
Total of Coordinated Interviews	337	298	635
Completed Interviews (%)	**96%**	**98%**	**97%**

Task 6: Final analysis and report writing.

The final analysis has not yet begun but preliminary analysis of the data has been conducted and some posters have been presented in several scientific conferences:

1. Association between lifetime sun exposure and breast cancer: Preliminary data from the Atabey Study. This poster was presented in San Juan in March 2013 as part of the *IV Conferencia Puertorriqueña de Salud Pública* (Fourth Puerto Rican Public Health Conference), will present findings on sun exposure and breast cancer risk among Puerto Rican women.

2. Recruitment Challenges in the Atabey Study. The purpose of this presentation is to describe the challenges met in the recruitment of participants. The poster presentation was presented as part of the *IV Conferencia Puertorriqueña de Salud Pública* (Fourth Puerto Rican Public Health Conference) on San Juan Puerto Rico March 2013.

3. The Hispanic Dietary Mosaic: Assessing the Diet of Women in Puerto Rico in the Atabey Study. The poster was presented in Boston Massachusetts on April 2013 as part of the annual meeting of the American Society for Nutrition will provide a description of the study, particularly the methods to distinguish traditional dietary patterns from more acculturated diets.

Task 7: Proposal and manuscripts preparation.

Several manuscripts are in preparation. They include an examination of the foods which contribute to intake of nutrients of interest in the Puerto Rican diet. Another paper is in preparation examining body mass index, body fat distribution and other factors related to body fatness in the healthy control group. Understanding of BMI and possible differences in BMI in breast cancer among Puerto Rican women is of considerable public health impact. Finally, preparation is also underway of the manuscript for findings related to sun exposure and breast cancer risk. In addition project staff has written and submitted letters of intent, a pre-proposals and a full proposal to different funding agencies.

At this moment, we do not anticipate problems that could impede the progress of this project.

KEY RESEARCH ACCOMPLISHMENTS:

- Training of study investigators in basic epidemiology and nutrition epidemiology (Appendix A).

REPORTABLE OUTCOMES:

- Continue Review Informed Consent fully approved (approval letter) in UPR-Medical Sciences Campus (Appendix B).
- Poster presentation (Appendix C).

CONCLUSION:

This sixth year report provides evidence that the second phase of the study has been developing successfully (recruitment and data collection). The work, communication and coordination between mentor institution, minority institution, physician and the project agency sponsoring has been effective.

REFERENCES: N/A

APPENDIX:

- Progress and Training Report of study investigators in basic epidemiology and nutrition epidemiology (Appendix A)
- Continue Review Informed Consent fully approved (Approval letter) in local (UPR-Medical Sciences Campus) (Appendix B).
- Poster presentation (Appendix C)

Breast Cancer Epidemiology in Puerto Rico
Annual Report (6)
July 2012 to June 2013

Appendix A
Progress and training report of study investigators

Dr. Cruz M. Nazario (Principal Investigator)

1. Weekly conference call with investigators from Puerto Rico and Dr. Jo Freudenheim from the University at Buffalo.

2. Weekly meeting with project coordinator.

3. Workshop and meeting
    a. Attendance to the IV Conferencia Puertorriqueña de Salud Pública (Fourth Puerto Rican Public Health Conference) on San Juan Puerto Rico March 2013.
        i. Participate in panel and roundtable of discussions relating to public health issue such cancer, environmental pollution and other.

Co-investigators:

Dr. Michelle Schelske-Santos

1. Weekly conference call with investigators from Puerto Rico and Dr. Jo Freudenheim from the University at Buffalo.
2. Workshop and meeting
    a. American Society for Nutrition at the Experimental Biology (EB) 2013 meeting in Boston, April 2013.
        i. Presenter a poster with preliminary data of the Breast Cancer Epidemiology Study (ATABEY).

Dr. Imar Mansilla-Rivera

1. Weekly conference call with investigators from Puerto Rico and Dr. Jo Freudenheim from the University at Buffalo.

2. Workshop and meeting
    a. IV Conferencia Puertorriqueña de Salud Pública (Fourth Puerto Rican Public Health Conference) on San Juan Puerto Rico March 2013.
        i. Participate in roundtable of discussions relating to public health issue such cancer and environmental pollution.
        ii. Co-Presenter a poster with preliminary data of the Breast Cancer Epidemiology Study (ATABEY).

Dr. Farah Ramirez

1. Weekly conference call with investigators from Puerto Rico and Dr. Jo Freudenheim from the University at Buffalo.

2. Workshop and meeting

    b. American Society for Nutrition at the Experimental Biology (EB) 2013 meeting in Boston, April 2013.
        i. Co- presenter a poster with preliminary data of the Breast Cancer Epidemiology Study (ATABEY).

Dr. Rosa Rosario

1. Weekly conference call with Dr. Jo Freudenheim (University at Buffalo) and Puerto Rico investigators team.
2. Workshop and meeting

    a. 13thRCMI International Symposium on Health Disparities in San Juan, Puerto Rico from December 10-13, 2012.

    b. IV Conferencia Puertorriqueña de Salud Pública (Fourth Puerto Rican Public Health Conference) on San Juan Puerto Rico March 2013.
        i. Presenter a poster with preliminary data of the Breast Cancer Epidemiology Study (ATABEY).

Johan Hernandez, MPH (Project Coordinator)

1. Weekly meeting with principal investigator and other staff project.

2. Workshop and meeting

    a. Attendance to the American Public Health Association's 140th Annual Meeting & Exposition in San Francisco from October 29-31, 2012.
        i. *A*ttended several conferences and workshop on cancer:
            a. Cancer Epidemiology
            b. Latino Cancer Research jointly (presented by the Cancer Forum and the Latino Caucus)
            c. Impact of Social Determinants on Cancer Morbidity and Mortality
            d. Cancer and Health Disparities and Breast Cancer Research.
            e. Poster presentations

    b. Attendance to the IV Conferencia Puertorriqueña de Salud Pública (Fourth Puerto Rican Public Health Conference) on San Juan Puerto Rico March 2013.
        i. Attended conferences and workshop on Public Health
        ii. Presenter a poster with preliminary data of the Breast Cancer Epidemiology Study (ATABEY) Recruitment Process.

UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MÉDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE OF THE CHANCELLOR

COMITE DE DERECHOS HUMANOS (IRB)
INSTITUTIONAL REVIEW BOARD

Date: October 25, 2012

Protocol Number: 0750108

Principal Investigator: Cruz M. Nazario Delgado

Department / Division: School of Public Health - Epidemiology

Sponsor:

Title: ***Breast Cancer Epidemiology in Puerto Rico***

This is to certify that this continuing review #5 was evaluated on October 25, 2012 and meets **expedite** IRB review category #9. The research proposal was **approved.** A progress report (continuing review) is due on **October 25, 2013**.

The following documents were reviewed under this submission:
☒ Informed Consent Document
English and Spanish Version

For additional information please contact Human Research Subjects Protection Office at 787-758-2525 exts. 2510 to 2515; e-mail opphi.rcm@upr.edu.

Cordially,

Luz A. Muñiz, EdD
Chairperson IRB 2

bcg

1. Research must be conducted according to the proposal that was approved by the IRB.
2. Changes to the protocol or its related consent document must be approved by the IRB prior to implementation.
3. All serious or unexpected adverse events/drug reactions should be reported.
4. Each subject should receive a copy of the consent document, if appropriate.
5. Records must be retained for at least three years.
6. Any future correspondence should include the IRB identification number provided and the study title.

Universidad de Puerto Rico
Recinto de Ciencias Médicas
Escuela Graduada de Salud Pública
Apartado postal 365067, San Juan, Puerto Rico 00936-5067

CONSENTIMIENTO PARA PARTICIPAR EN ESTUDIOS DE INVESTIGACIÓN

TÍTULO: **Epidemiología de cáncer de mama en Puerto Rico**

NÚMERO DE PROTOCOLO: 0750108

PATROCINADOR:
Programa de investigación médica dirigido por el Congreso de los Estados Unidos para cáncer de mama, Departamento de Defensa CDMRP #BC060131USAMRMC-DOD

INVESTIGADORES: Cruz María Nazario-Delgado, Ph.D. (PI) Universidad de Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

Esta hoja de consentimiento puede contener palabras que usted no entienda. Por favor, pídale al investigador o a cualquier miembro del personal del estudio que le explique cualquier palabra o información que usted no entienda claramente. Usted puede llevarse a su casa una copia sin firmar de este consentimiento para pensar sobre este estudio o para discutirlo con su familia o amigos antes de tomar su decisión.

I - INTRODUCCIÓN

Usted ha sido invitada a participar en un estudio de investigación conducido por la Universidad de Puerto Rico, Recinto de Ciencias Médicas. Este proyecto recibe fondos del Programa de Investigación de Cáncer de Mama, bajo el mecanismo de Donativo para Adiestramiento en Colaboración con Universidades, Colegios e Instituciones de Grupos Minoritarios del Departamento de la Defensa. Sin embargo, antes de que usted decida participar en el estudio, por favor, lea este consentimiento cuidadosamente y haga todas las preguntas necesarias para asegurarse de que entienda los procedimientos del estudio, los riesgos y los beneficios.

II – PROPÓSITO DEL ESTUDIO

Estamos conduciendo un estudio para entender cómo la dieta, la actividad física, el historial familiar y las exposiciones tempranas, además de otros factores, están relacionados con el riesgo de cáncer del seno. Otros investigadores han estudiado estos factores en otras poblaciones. Nosotros queremos examinar la relación de esos factores de riesgo de cáncer del seno en mujeres que viven en Puerto Rico. Estos factores incluyen el consumo de alimentos que son ricos en vitaminas y antioxidantes. Los investigadores creen que estos alimentos pueden protegernos.

Hay indicios de que algunas exposiciones a través de nuestra vida son factores de riesgo importantes para el cáncer del seno. Por eso, necesitamos entender mejor las exposiciones que a través de la vida de la mujer pueden protegernos o aumentar el riesgo de cáncer del seno. Al igual que la gente se ve diferente, también hay diferencias en la forma que nuestro cuerpo maneja la exposición a lo que comemos, tomamos, fumamos y a los medicamentos que usamos. Un estudio en nuestra población puede proveernos mejor información sobre los factores que protegen o aumentan el riesgo de cáncer del seno en las mujeres en Puerto Rico.

III – PARTICIPANTES DEL ESTUDIO

En este estudio podrán participar 500 mujeres con cáncer de seno que hayan tenido un diagnóstico reciente (hace un año o menos) confirmado por pruebas y por el médico, que tengan entre 30 y 79 años y residan en alguno de los siguientes municipios: San Juan, Bayamón Guaynabo y Carolina. También podrán participar 500 mujeres que no tengan cáncer, a menos que haya sido cáncer de piel (no-melanoma) y que tengan entre 30 y 79 años y residan en alguno de los municipios mencionados anteriormente. Las mujeres menores de 30 o mayores de 79 años o que vivan en otros municipios fuera del área de estudio no podrán participar. La participación en este estudio es voluntaria y usted puede negarse a participar. Puede decidir no continuar en el estudio en cualquier momento, sin que implique alguna penalidad y no perderá los beneficios que le corresponden.

IV - PROCEDIMIENTOS

Si acepta a participar en este estudio, necesitamos que consienta y nos permita recoger información por medio de un cuestionario y tomar y analizar una muestra de tres tubitos de sangre (tubitos de 0.5 ml) en ayunas (siempre que sea posible). Si no puede donar una muestra de sangre, podemos tomarle una muestra de saliva para el análisis.

El procedimiento de tomar la muestra de sangre o de saliva es simple y el riesgo a su salud es mínimo. Una enfermera adiestrada del Consorcio de Investigación Clínica y Traslacional del Recinto de Ciencias Médicas (PRCTRC) tomará estas muestras. La enfermera también le tomará las medidas siguientes: peso, estatura, medida de la cintura y caderas, medidas de pliegues de piel (tríceps, subescapular, supra- ilíaco, vientre y muslo) y medidas del color de piel en la mano y el brazo.

Después de estos procedimientos, le daremos una merienda y la entrevistadora le hará las preguntas del cuestionario. La entrevista dura aproximadamente 30 minutos y las preguntas están relacionadas a la dieta, la actividad física, el historial de peso, los hábitos de fumar, la exposición al sol, su información demográfica, su historial personal y familiar de enfermedades crónicas, su historial residencial, el uso de vitaminas y medicinas, información sobre la menstruación y los hijos que ha tenido, al igual que algunas preguntas sobre diagnóstico y tratamiento de cáncer.

Una vez que terminemos la entrevista, usted habrá completado su participación en el estudio. El procedimiento completo no debe tardar más de una (1) hora.

Para este estudio usaremos muestras de sangre o saliva para estudiar cómo el cuerpo de una mujer procesa y elimina de forma diferente los nutrientes, las hormonas y otras sustancias que pueden afectar el riesgo de cáncer. Estas diferencias pueden ser el resultado de los genes, que son las características que heredamos de nuestros padres. Es poco probable que las diferentes formas de esos genes causen enfermedades por si mismas. Es más probable que estos genes afecten la manera en que el cuerpo maneja las exposiciones y otros factores de riesgo. Debido a que la ciencia médica no conoce si estas diferencias afectan y tampoco conocen de qué forma afectan el riesgo de cáncer, usted no recibirá los resultados de estas pruebas ni los hallazgos que pudieran resultar. Los datos de este estudio serán analizados y presentados en forma de comparación de los grupos de mujeres con cáncer y las mujeres sin cáncer para estudiar el riesgo asociado a la exposición a diferentes genes. Además, estudiaremos otros compuestos en la sangre (nutrientes, hormonas, entre otros) para entender mejor estos procesos en las mujeres que viven en Puerto Rico. Su sangre será analizada en el laboratorio del Roswell Park Cancer Institute por científicos que colaboran con este estudio. La sangre y la saliva, no tendrá información personal que pudiera identificarla, y sólo estará identificada con un código numérico.

V – RIESGOS O INCOMODIDADES

Usted debe entender que este estudio no es para probar nuevos medicamentos o tratamientos. Los procedimientos para tomar una muestra de sangre o una muestra de saliva son sencillos y el riesgo es mínimo. Estos son procedimientos rutinarios en la clínica del Consorcio de Investigación Clínica y Traslacional del Recinto de Ciencias Médicas. Usted debe entender que la muestra de sangre debe ser en ayunas (siempre que sea posible) y que la tomará una enfermera adiestrada para estos procedimientos. La extracción de sangre de las venas puede causar dolor, moretones, mareos y en raras ocasiones, infección. Las medidas de los pliegues de la piel pueden causar dolor, moretones o alguna incomodidad. Si siente alguna molestia o incomodidad habrá un área de descanso disponible y se le dará una merienda luego de que se le tome la muestra.

Usted debe entender que las preguntas del cuestionario no son sensitivas u ofensivas, pero algunas preguntas podrían considerarse moderadamente sensitivas (por ejemplo: el historial reproductivo). Una mujer profesional y adiestrada en estudios en salud pública le hará la entrevista. Hemos puesto mucho énfasis en adiestrar y supervisar a la entrevistadora para que la incomodidad de la entrevista sea mínima. Usted puede rehusar a contestar cualquier pregunta que le resulte incomoda. No habrá consecuencias negativas si usted se niega a contestar alguna de esas preguntas.

VI – BENEFICIOS

Es probable que usted no reciba ningún beneficio personal de este estudio. Este estudio no fue diseñado para tratar sus problemas de salud. Sin embargo, su participación en este estudio es muy importante porque nos ayudará a conocer los factores que afectan el riesgo de desarrollar cáncer en las mujeres que viven en Puerto Rico. Los resultados del estudio pueden aumentar nuestro conocimiento de cómo la dieta, la actividad física y el metabolismo hormonal están relacionados con el cáncer del seno en las mujeres en Puerto Rico. El número de mujeres en Puerto Rico que desarrollan cáncer del seno continúa en aumento.

VII – COSTOS

No hay ningún costo por las visitas del estudio.

VIII – INCENTIVO PARA EL PARTICIPANTE

Usted recibirá $25 por su participación en el estudio una vez que haya terminado de contestar el cuestionario para cubrir los gastos de transportación.

Durante este estudio, se le pedirá que done una muestra de sangre o saliva. Si usted lo autoriza, esa muestra puede ser usada en el futuro para otros estudios sobre los genes que regulan las hormonas y los procesos que afectan el riesgo de enfermar. Existe una posibilidad de que la sangre que usted done se use en otros estudios que puedan tener algún valor comercial. Si esta muestra que usted ha donado llegara a ser usada junto con la de otras personas para el desarrollo de un producto comercial, la Dra. Cruz M. Nazario y la Dra. Jo Freudenheim serán las dueñas y podrán patentizar el producto. Las doctoras Nazario y Freudenheim no la compensaran en este estudio ni en los estudios futuros por el uso de su muestra de sangre. No recibirá notificación sobre el uso futuro de la muestra.

IX - ALTERNATIVAS DE PARTICIPACIÓN

Este estudio no conlleva tratamiento médico. Usted puede rehusar a contestar cualquier pregunta del cuestionario si lo desea. Esto no tiene ningún efecto en los tratamientos que está recibiendo. Su participación es voluntaria.

X – PRIVACIDAD Y CONFIDENCIALIDAD (HIPAA)

Si elige participar, el investigador obtendrá información personal sobre usted y su salud en este estudio. Esto puede incluir información que puede identificarle. El investigador también puede conseguir, mediante el cuestionario, información sobre su salud que incluye: dieta, actividad física, historial de peso, uso de cigarrillos, exposición al sol, información demográfica, número de seguro social, historial personal y familiar de enfermedades crónicas, dirección actual e historial residencial, uso de vitaminas y medicinas, información sobre la menstruación y los

embarazos y alguna información sobre el diagnóstico y tratamiento del cáncer. Si usted ha tenido un diagnóstico de cáncer de seno, obtendremos la información de la patología del Registro Central de Cáncer de Puerto Rico.

La información sobre usted y su salud que podría identificarla puede ser brindada a otros que colaboran en este estudio de investigación. El patrocinador analizará y evaluará los resultados del estudio. El personal del patrocinador y de sus consultores podrán visitarnos para observar cómo se hace el estudio.

Sin embargo, los datos con su información personal estarán guardados y custodiados en un archivo con llave y solamente el personal del estudio autorizado (las investigadoras principales, la coordinadora del estudio, la tecnóloga médica y la enfermera del estudio) tendrá acceso a ellos, según la reglamentación de HIPAA.

La información obtenida en este estudio será guardada sin la información personal en archivos electrónicos que sólo pueden ser usados con una clave. La información podrá ser revisada por el Comité de Derechos Humanos (IRB, por sus siglas en inglés) del Recinto de Ciencias Médicas de la Universidad de Puerto Rico, el Comité de Revisión Institucional del Hospital Español Auxilio Mutuo, el Comité de Derechos Humanos del Hospital Oncológico Isaac González Martínez y por la Oficina de Protección de los Derechos Humanos del Departamento de la Defensa (HRPO-USAMRMC, por sus siglas en inglés). Estas personas revisan, de forma independiente, la investigación según ha sido reglamentado. Su información será mantenida tan confidencial como sea posible bajo la ley. Está información no podrá ser protegida por las reglas de privacidad una vez que se divulgue a nuestros asociados y puede ser compartida con otros. Sin embargo, nuestros asociados en esta investigación también están acogidos a las leyes de protección de información personal de los participantes en la investigación.

Los resultados de esta investigación pueden ser publicados en revistas científicas o ser presentados en reuniones médicas pero su identidad no será divulgada.

Esta autorización estará vigente hasta el final del estudio, a menos que usted la cancele antes. Usted puede cancelar esta autorización en cualquier momento mediante un aviso escrito que debe enviar a la Investigadora Principal en la dirección siguiente:
Dra. Cruz María Nazario
Departamento de Bioestadística y Epidemiología
Escuela Graduada de Salud Pública
Recinto de Ciencias Médicas, UPR
PO Box 365067 San Juan, PR, 00936-5067

Si usted cancela esta autorización, el Investigador Principal no usará ni divulgará su información personal ni de su salud bajo la autorización de este estudio. Esta información sólo se divulgará en caso de que se necesite la información personal de su salud para preservar la integridad científica del estudio. La información sometida antes de que usted cancele esta autorización puede ser utilizada por los asociados.

La autorización para el uso y el acceso de la información protegida de la salud para los propósitos de la investigación es totalmente voluntaria. Sin embargo, de no firmar este documento no podrá participar en este estudio.

XI – COMPENSACIÓN EN CASO DE DAÑO

En el caso de lesión física o mental como resultado de este estudio de investigación usted recibirá tratamiento médico sin costo alguno en el Hospital Universitario de la Universidad o en cualquier otro hospital designado por el Rector del Recinto de Ciencias Médicas de la Universidad de Puerto Rico. La Universidad de Puerto Rico no ofrecerá ninguna forma de renumeración directamente a usted. Sin embargo, al firmar está hoja de consentimiento, usted no renuncia a ningún derecho legal.

XII – PARTICIPACIÓN Y RETIRO VOLUNTARIOS

Su participación en este estudio es voluntaria. Usted puede decidir no participar o retirarse del estudio en cualquier momento. Su decisión no resultará en ninguna penalidad o pérdida de beneficios para los cuales tenga derecho. De ser necesario, su participación en este estudio puede ser detenida en cualquier momento por el investigador del estudio o por el patrocinador sin su conocimiento. Usted puede estar de acuerdo en donar una muestra de sangre o una muestra de saliva y de completar el cuestionario además de que se le tomen las medidas del cuerpo. Si decide participar, también puede en cualquier momento retirar su consentimiento y descontinuar su participación sin ningún perjuicio para usted y no se usarán los datos y las muestras serán descartadas de acuerdo al protocolo del laboratorio.

XIII – FONDOS PARA PAGAR EL ESTUDIO

Este estudio es subvencionado por un donativo del "*Congressionally Directed Medical Research Program's Breast Cancer Research Program*" (BCRP), del Departamento de la Defensa bajo el mecanismo de acuerdo para el adiestramiento en los Colegios y Universidades con estudiantes de grupos minoritarios en asociación con universidades en los Estados Unidos.

XIV – PREGUNTAS

Si tiene alguna pregunta sobre este estudio o sobre su participación en el mismo, o si piensa que ha sufrido alguna lesión asociada al estudio, usted puede contactar a la Dra. Cruz M Nazario en el siguiente número de teléfono 787-758-2525 extensión 1-1429 o a Johan Hernández (Coordinadora del Proyecto) en el número 787-758-2525, extensión 1-1936.

Si tiene alguna pregunta sobre sus derechos como participante del estudio, puede contactar a la:
Oficina de Protección de Participantes Humanos en Investigación
Teléfono 787-758-2525, extensión 1-2510, 2511, 2512, 2513,2514 o 2515.
Correo electrónico (E-mail): opphi.rcm@upr.edu

Si usted es paciente del Hospital Auxilio Mutuo, también se puede comunicar con el Dr. Jorge Bertrán, presidente del Comité de Revisión Institucional (IRB) al teléfono: (787) 645-8074.

O si usted es paciente del Hospital Oncológico Isaac González Martínez se puede comunicar con la Dra. Cristina Nery, Presidenta del Comité de Derechos Humanos del Hospital al (787) 763-4149 x 1050 o con la Dra. Hilda Rivera, Coordinadora de Investigación al teléfono (787) 753-8433(Oficina del director medico).

No firme este consentimiento a menos que haya tenido la oportunidad de hacer preguntas y recibir contestaciones satisfactorias para todas sus preguntas. Si firma y acepta participar en este estudio, recibirá una copia firmada, con el sello de aprobación de IRB y con la fecha de esta hoja de consentimiento para usted.

XV - CONSENTIMIENTO

He leído la información de esta hoja de consentimiento o se me ha leído de manera adecuada. He tenido la oportunidad de formular preguntas y todas mis preguntas sobre el estudio y mi participación han sido atendidas.

Yo autorizo el uso y la divulgación de mi información de salud a las entidades antes mencionadas en este consentimiento para los propósitos descritos anteriormente.

Al firmar esta hoja de consentimiento, no he renunciado a ninguno de mis derechos legales.

_____
Nombre del Sujeto/Paciente

_____ _____
Firma del Sujeto/Paciente (o marca) Fecha

_____
Nombre del Testigo (Si aplica)

_____ _____
Firma del Testigo (Si aplica) Fecha

_____ _____
Dra. Cruz María Nazario, Fecha
Firma de la Investigadora Principal

Las muestras pueden ser guardadas para estudios futuros

□ Sí (Iniciales del Sujeto/Paciente _____)
□ No, las muestras sólo pueden usarse en este estudio (Iniciales del Sujeto/Paciente __)

Universidad de Puerto Rico
Recinto de Ciencias Médicas
Escuela Graduada de Salud Pública
Apartado postal 365067, San Juan, Puerto Rico 00936-5067

CONSENTIMIENTO PARA DONAR MUESTRA DE TEJIDO O DE BLOQUE DEL TUMOR PARA INVESTIGACIÓN (PARTE 2)

TÍTULO: **Epidemiología de cáncer de mama en Puerto Rico**

NÚMERO DE PROTOCOLO: 0750108

PATROCINADOR:
Programa de investigación médica dirigido por el Congreso de los Estados Unidos para cáncer de mama, Departamento de Defensa CDMRP #BC060131USAMRMC-DOD

INVESTIGADORES: Cruz María Nazario-Delgado, Ph.D. (PI), Universidad de Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

Esta hoja de consentimiento puede tener palabras que usted no entienda. Por favor, pídale al investigador o a cualquier miembro del personal del estudio que le explique cualquier palabra o información que no entienda claramente. Usted puede llevarse a su casa una copia sin firmar de este consentimiento para pensar sobre este estudio o para discutirlo con su familia o amigos antes de tomar su decisión.

I. INTRODUCCIÓN:

Durante el proceso de confirmación y tratamiento del cáncer de seno, a usted le hicieron varios procedimientos que incluyeron biopsias (muestra pequeña del seno) y cirugía (extracción del cáncer). Usualmente, el hospital o el laboratorio guarda dentro de un bloque de parafina, el tumor que ha sobrado después de la cirugía.

II. PROPÓSITO:

Este estudio es parte de la investigación *Epidemiología de cáncer de mama en Puerto Rico* a la cual usted consintió en participar. Nos gustaría que nos permita sacar una muestra pequeña del bloque de tumor que ha sido guardado. La muestra de tejido podría ser usada en el futuro para estudiar las características y los cambios que ocurren dentro de ese tejido. La investigación con estas muestras de tejido puede ayudarnos a entender si esos cambios tienen relación con algunos alimentos, el cigarrillo, las hormonas y con otras exposiciones dañinas.

APPROVED *Consent Formed Approved by the UPR-MSC IRB October 25, 2012 - October 25, 2013*

III. PROCEDIMIENTO:

Si usted autoriza, tomaremos una muestra de aproximadamente 25 pedacitos pequeños y finos del tumor (tan finos que se puede ver a través de ellos) para analizar en el laboratorio de Roswell Park Cancer Institute las características internas del tumor. Si su muestra llegara a ser usada junto con la de las otras personas para el desarrollo de un producto comercial, la Dra. Cruz M. Nazario y Dra. Jo Freudenheim serán dueñas de este producto y podrán patentizarlo. En ese caso, las doctoras Nazario y Freudenheim no la compensarán por el uso de la muestra de tejido. No recibirá notificación sobre el uso futuro de la muestra.

IV. PRIVACIDAD Y CONFIDENCIALIDAD:

La información sobre la privacidad y confidencialidad es igual a la que leyó en el consentimiento para el estudio. Usted puede rehusar a participar en esta parte del estudio.

V. PREGUNTAS:

Si tiene alguna pregunta sobre este estudio, puede contactar a la Dra. Cruz M. Nazario en el número de teléfono 787-758-2525 extensión 1-1429 o a Johan Hernández (Coordinadora del Proyecto) en el número 787-758-2525, extensión 1-1936.

Si tiene alguna pregunta sobre sus derechos como participante del estudio, puede contactar a la:
Oficina de Protección de Participantes Humanos en Investigación
Teléfono 787-758-2525, extensión 1-2510, 2511, 2512, 2513,2514 o 2515.
Correo electrónico (E-mail): opphi.rcm@upr.edu

Si usted es paciente del Hospital Auxilio Mutuo, también se puede comunicar con el Dr. Jorge Bertrán, presidente del Comité de Revisión Institucional (IRB) al teléfono: (787) 645-8074.

O si usted es paciente del Hospital Oncológico Isaac González Martínez se puede comunicar con la Dra. Cristina Nery, Presidenta del Comité de Derechos Humanos del Hospital al (787) 763-4149 x 1050 o con la Dra. Hilda Rivera, Coordinadora de Investigación al teléfono (787) 753-8433(Oficina del director medico).

No firme este consentimiento a menos que haya tenido la oportunidad de hacer preguntas y recibir contestaciones satisfactorias para todas sus preguntas. Si firma y acepta participar en este estudio, recibirá una copia firmada, con el sello de aprobación de IRB y con la fecha de esta hoja de consentimiento para sus archivos.

VI. CONSENTIMIENTO

He leído la información en esta hoja de consentimiento o se me ha leído de manera adecuada. He tenido la oportunidad de hacer preguntas y todas mis preguntas sobre el estudio y mi participación han sido atendidas.

Yo autorizo el uso y la divulgación de mi información de salud a las entidades antes mencionadas en este consentimiento para los propósitos descritos anteriormente.

Al firmar esta hoja de consentimiento, no se ha renunciado a ninguno de los derechos legales.

_____
Nombre del Sujeto/Paciente (Nombre, Inicial, Apellidos)

_____ _____
Firma Sujeto/Paciente (o marca) Fecha (día/mes/año)

_____ _____
Hospital que divulga el tejido Fecha de hospitalización

_____
Dra. Cruz María Nazario, Investigadora Principal

Las muestras de tejido del bloque del tumor pueden ser utilizadas y guardadas para estudios futuros.

□ Sí, (Iniciales del Sujeto/Paciente _____)
□ No, (Iniciales del Sujeto/Paciente _____)

University of Puerto Rico
Medical Sciences Campus
Graduate School of Public Health
P.O. Box 365067, San Juan, Puerto Rico 00936-5067

CONSENT TO PARTICIPATE IN RESEARCH STUDIES

TITLE: **Breast Cancer Epidemiology in Puerto Rico**

PROTOCOL NUMBER: 0750108

SPONSOR: **Congressionally Directed Medical Research Program's Breast Cancer Research Program, Department of Defense, USAMRMC-DOD.**

CDMRP #BC060131

INVESTIGATORS: Cruz María Nazario-Delgado, Ph.D. (PI) University of Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about it or to discuss it with family or friends before making your decision.

I - INTRODUCTION

You have been invited to participate in a research study conducted at the University of Puerto Rico-Medical Sciences Campus. This project is funded by a grant from the Congressionally Directed Medical Research Program's Breast Cancer Research Program (BCRP) under the Historically Black Colleges and Universities/Minority Institutions Partnership Training Award mechanism, Department of Defense. However, before you agree to take part in this study, please read this consent form carefully and ask as many questions as you need in order to be sure you understand the study procedures, including risks and benefits.

II - PURPOSE OF THE STUDY

We are conducting a project to examine how our diet, physical activity, family history, early life exposures, and other factors are related to breast cancer. Other researchers have studied these factors in other populations. We want to examine the relation of these factors to breast cancer risk among women living in Puerto Rico. These factors include the consumption of foods that are rich in vitamins and antioxidants. Investigators think that these could protect us.

There are indications that exposures throughout our life are important risk factors for breast cancer. That is why we need to better understand the exposures that could protect or increase the risk for breast cancer. Just as people differ from one another in how they look, they also differ in what goes on inside their bodies and in how their bodies handle exposures to the things we eat, drink, or smoke, and to the medications that we take. A study in our population will provide a better insight into the factors that protect or increase the risk of breast cancer in Puerto Rico.

III - STUDY PARTICIPANTS

In this study, 500 women aged 30-79, with newly diagnosed (within a year) and confirmed breast cancer, who are residents of San Juan, Bayamón, Guaynabo and Carolina will be eligible to participate. Also, 500 women aged 30-79, without breast cancer, other than skin cancer, who are residents in one of the municipalities mentioned above will also be eligible to participate. Women less than 30 years or over 79 years of age, as well as those women that live in other geographical areas of Puerto Rico are not eligible to participate. Your participation is voluntary and you may refuse to participate. You may also decline to continue participating at any moment during the study. Your decision will not result in any penalty or loss of benefits to which you are entitled.

IV - PROCEDURES

If you agree to participate in the study, we need your consent for us to collect information through a questionnaire and to collect and process a fasting (whenever possible) blood sample, about 3 tubes (0.5 ml tubes). If you can not give a blood sample, we ask you to provide a saliva sample for the analysis.

The procedure to collect the blood or the saliva sample is simple and the risk to your health is minimal. A trained research nurse from the Puerto Rico Clinical and Translational Research Consortium (PRCTRC) will do this procedure. A nurse will measure your weight, height, waist, hips, skin folds (triceps, sub-scapular, supra-iliac, abdomen, and thigh), and underarm and hand skin color.

After these procedures, we will provide a snack, and the study interviewer will ask you some questions. The interview will take approximately 30 minutes and the questions are related to your diet, physical activity, weight history, smoking, sun exposure, demographic characteristics, personal and familial history of chronic diseases, residential history, vitamin and medication use, menstrual and reproductive information, as well as some questions about cancer diagnosis and treatment. Once the interview is over, you will have completed your participation in this study. The complete process should be over in less than 1 hour.

For this study, we will use samples of blood or saliva to study how a woman's body differently processes and eliminates nutrients, hormones, or other substances that may affect the risk of breast cancer. These differences may be due to the genes, which are the characteristics that we inherit from our parents. It is unlikely that the presence of these different forms of a gene would cause diseases alone. It is more likely that they will affect the way that the body reacts to exposures or risk factors. Because medical science does not know whether or not or how these gene variants affect the health and risk for cancer, you will not receive the results of these tests nor any incidental finding from such tests. The data from this study will be analyzed and presented in groups, comparing women with cancer and women without, to study the risk associated with different forms of genes. We will also examine other compounds in the blood (nutrients, hormones, etc) to better understand the process of these substances in women that live in Puerto Rico. Your biological samples will be analyzed in Roswell Park Cancer Institute Laboratory by scientists collaborating in this study. The blood or saliva samples will not have your name or any other information that could identify you, as they will be identified by a numeric code.

V - RISKS AND DISCOMFORTS

You understand that this study will not test any new drug or clinical treatment. The procedures to collect the blood or saliva samples are simple and the risk to your health is minimal. These are standard medical procedures in the Puerto Rico Clinical and Translational Research Consortium. You understand that the blood will be drawn while you are fasting (whenever possible) and it will be done by a trained nurse. Drawing blood from your arm may cause pain, bruising, lightheadedness and, on rare occasions, infection. Skin fold measurements could cause pain, bruising, and some discomfort. If you feel any discomfort, a rest area will be available, and after the blood draw, a snack will be provided.

You also understand that most questions in the questionnaire are not sensitive, but there are a few questions that could be considered as moderately sensitive (i.e., reproductive history). A professional woman, with training in conducting public health studies, will conduct the interview. Particular emphasis has been placed in the training and supervision of the interviewer in order to minimize the potential risks during the administration of the questionnaire. You can refuse to answer any question that makes you uncomfortable. There will be no negative consequence should you refuse to answer those questions.

VI - BENEFITS TO SUBJECTS

You may not receive any personal benefits from being in this study. This study is not being done to treat your health problems. Nevertheless, your participation in this study is very important because it will help us understand the factors that affect the risk of developing breast cancer among women living in Puerto Rico. The results of this study may improve our

knowledge about how diet, physical activity, and hormone metabolism are related to breast cancer in Puerto Rico. The number of women getting breast cancer in Puerto Rico continues to increase.

VII – COSTS There are no charges for the study visits.

VIII - COMPENSATION FOR PARTICIPATION

You will be paid $25 for your participation in the study after the questionnaire is completed to compensate for traveling expenses.

During this study, you will be asked to provide a blood or a saliva sample. If you consent, this sample may be used for future analysis of genes that may influence disease risk. There is a chance that the samples that you are donating under this study may be used in other research studies and may have some commercial value. Should your donated sample lead to the development of a commercial product, Dr. Cruz M. Nazario and Dr. Jo Freudenheim will own it and may take action to patent and license the product. In such case, Drs. Nazario and Freudenheim will not compensate you for your participation in this study or for any future use of the sample you have given. You will not receive any notice of future uses of your samples.

IX – PARTICIPATION ALTERNATIVES

This study does not involve medical treatment. You may refuse to answer any question in the questionnaire. Your refusal will not impact the treatment you may be receiving. Your participation is voluntary.

X - PRIVACY AND CONFIDENTIALITY (HIPAA)

If you choose to participate in this study, the investigator will get personal information about you. This may include information that might identify you. The investigator may also get information about your health using a questionnaire including questions related to your diet, physical activity, weight history, smoking, sun exposure, demographic characteristics, social security number, personal and familial history of chronic diseases, actual address and residential history, vitamin and medication use, menstrual and reproductive information, as well as some questions about cancer diagnosis and treatment. If you had a breast cancer diagnosis, the pathological information will be obtained from the Puerto Rico Central Cancer Registry.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done. Data with your identifying information will be kept in a locked file cabinet and only authorized study personnel (Principal Investigators, Project Coordinator, Lab

technician, and the clinical nurse) will have access to it according to the Health Insurance Portability and Accountability Act (HIPAA) according to the Health Insurance Portability and Accountability Act (HIPAA). The information obtained in this study will be collected and stored without personal identifiers and will be stored in password protected electronic data file. The records will be safeguarded following HIPAA regulations.

The information may be reviewed by the UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB), Hospital Auxilio Mutuo Institutional Review Board, Isaac González Martinez Oncology Hospital Human Rights Committee and the Human Research Protection Office of the Department of Defense (HRPO USAMRMC -DOD). They are a group of people who perform independent review of research as required by regulations. Your personal health information will be kept as confidential as possible under the law. However, your personal health information is no longer protected by the privacy rule once it is disclosed to our associates, and may be shared with others. Nonetheless, our research associate must also comply with the laws that protect the personal information of study participants.

The results of this research may be published in scientific journals or presented at medical meetings, but no information will be included that will reveal your identity.

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel this authorization at any time by sending a written notice to the principal investigator at the following address:

Dr. Cruz María Nazario
Biostatistics and Epidemiology Department
Graduate School of Public Health
Medical Sciences Campus, UPR
PO Box 365067 San Juan, PR, 00936-5067

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study.

XI – COMPENSATION FOR INJURY

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of change at the University Hospital or any other hospital designated by the Chancellor or the Medical Sciences Campus of the University of Puerto Rico. The University of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

XII – VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. You can agree to donate blood or a saliva sample and to complete a questionnaire that collects personal information, as well as your body measures are taken. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice, any collected data will not be included in the study, and blood will be discarded according to the laboratory procedure. The investigator may withdraw you from participating in this study if it is necessary. The decision may be made either to protect your health and safety by the investigator without your consent.

XIII – SOURCE OF FUNDING

This project is funded by the Congressionally Directed Medical Research Program's Breast Cancer Research Program (BCRP) under the Historically Black Colleges and Universities/Minority Institutions Partnership Training Award mechanism of the Department of Defense.

XIV – QUESTIONS

If you have questions regarding this study or your participation in this study or if at any time you feel you have experienced a research related injury, you may contact Dr. Cruz M. Nazario at this number: 787-758-2525 extension 1-1429 or Johan Hernández (Project Coordinator) at the 787-758-2525, extension 1-1936. If you have any questions about your rights as a research subject you may contact the

Human Research Subjects Protection Office
University of Puerto Rico
Medical Sciences Campus
Telephone 787-758-2525, extensión 1-2510, 2511, 2512, 2513, 2514 o 2515
E-mail: opphi.rcm@upr.edu

If you are patient of the Hospital Auxilio Mutuo, also, you can communicate with Dr. Jorge Bertrán, President of the Institutional Review Board (IRB) at the phone (787) 645-8074

Or if you are patient of the Isaac González Martinez Oncology Hospital, you can communicate with Dr. Cristina Nery, President of the Human Rights Committee of the Oncology Hospital at this number: (787) 763-4149 x 1050 or with Dr. Hilda Rivera, Coordinator of Investigation at the phone 787-753-8433 (Office of the medical director).

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of the IRB approval for your records.

XV - CONSENT

I have read the information provided above or the information has been read to me. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.
By signing this consent form, I have not given up any of my legal rights.

_____
Printed Name of Subject/Patient

_____ _____
Signature of Subject/Patient Date

_____
Printed name of Witness (if applicable)

_____ _____
Signature of Witness (if applicable) Date

_____ _____
Cruz Maria Nazario, PhD
Signature of Principal Investigator Date

Samples can be stored for future use

☐ Yes (Subject/Patient initials, _____)

☐ No, samples can only be used in the current study. (Subject/Patient initials, _____)

University of Puerto Rico
Medical Sciences Campus
Graduate School of Public Health
Box 365067, San Juan, Puerto Rico 00936-5067

CONSENT TO DONATE TISSUE OR TUMOR BLOCK SAMPLE FOR RESEARCH (PART 2)

TITLE: **Breast Cancer Epidemiology in Puerto Rico**

PROTOCOL NUMBER: 0750108

SPONSOR: **Congressionally Directed Medical Research Program's Breast Cancer Research Program, Department of Defense, USAMRMC-DOD.**

CDMRP #BC060131

INVESTIGATORS: Cruz María Nazario-Delgado, Ph.D. (PI), University of Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about it or to discuss it with family or friends before making your decision.

I. INTRODUCTION

During the process to confirm or treat cancer you received various procedures including biopsies (small samples from breast) and surgery (remove cancer). Usually, the hospital or lab keeps the remaining tumor within a paraffin block.

II. PURPOSE

This study is part of the study *Breast Cancer Epidemiology in Puerto Rico* to which you have already consented to participate. We would like to obtain a small sample of the saved tumor block. The tissue sample could be used in the future to study the characteristics and changes that occur within that tissue. Research with tissue samples could help us understand if those changes are related to the food, cigarettes, hormones, or other harmful exposures.

III. PROCEDURE

If you authorize us, we will take a sample of approximately 25 very small and thin (so thin you can see thru them) samples of tissue and, in the Roswell Park Cancer Institute's lab, analyze the internal characteristics of the tumor. If your sample, along with the sample of other persons, is used to develop a commercial product, Dr. Cruz M. Nazario and Dr. Jo Freudenheim will own it and may patent the product. In such case, Drs. Nazario and Freudenheim will not compensate you for your tissue sample. You will not receive any notice of future uses of your samples.

IV. PRIVACY AND CONFIDENTIALITY

The information about the privacy and confidentiality is the same as the one you read in the previous consent for the study. You may refuse to participate in this part of the study.

V. QUESTIONS

If you have questions regarding this study or your participation in this study, or if at any time you feel you have experienced a research related injury, you may contact Dr. Cruz M. Nazario at this number: 787-758-2525 extension 1-1429 or Johan Hernández (Project Coordinator) at the 787-758-2525, extension 1-1936.

If you have any questions about your rights as a research subject you may contact:
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Telephone 787-758-2525, extension 1-2510, 2511, 2512, 2513, 2514 o 2515
E-mail: opphi.rcm@upr.edu

If you are patient of the Hospital Auxilio Mutuo, also, you can communicate with Dr. Jorge Bertrán, President of the Institutional Review Board (IRB) at the phone (787) 645-8074

Or if you are patient of the Isaac González Martinez Oncology Hospital, you can communicate with Dr. Cristina Nery, President of the Human Rights Committee of the Oncology Hospital at this number: (787) 763-4149 x 1050 or with Dr. Hilda Rivera, Coordinator of Investigation at the phone 787-753-8433 (Office of the medical director).

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of the IRB approval for your records.

VI. CONSENT

I have read the information provided above or the information has been read to me. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Printed Name of Subject/Patient (First, middle, and last name)

_____ _____
Signature of Subject/Patient (or mark) Date (day/month/year)

_____ _____
Hospital or lab releasing the tumor block Date (day/month/year)

_____
Cruz María Nazario, Principal Investigator

Tissue samples can be obtained and stored for future use.

☐ Yes (Subject/Patient initials, _____)

☐ No (Subject/Patient initials _____)

Appendix C

Recruitment Challenges in the Atabey Study

Johan Hernández M.P.H[1], Ivonne Calderon MD (MPH candidate) [1], Rosa Rosario Dr PH[1], Cruz M. Nazario PhD[1], Imar Mansilla-Rivera PhD[1], Michelle Schelske-Santos PhD[2], Farah Ramírez-Marrero PhD[2], Gilberto Ramos DrPH[1], Lydia Robles MPL[1], Jo Freudenheim, PhD[3]. (1) Graduate School of Public Health, University of Puerto Rico; Medical Sciences Campus; (2) University of Puerto Rico, Río Piedras Campus; (3) Department of Social and Preventive Medicine, University at Buffalo.

INTRODUCTION

Breast cancer incidence in Puerto Rico is about half the incidence in USA, but the risk of this disease in Puerto Rico is increasing at a faster rate than in the USA.

This increasing trend most likely correlates with environmental and lifestyles changes in Puerto Rico.

Atabey is a population-based, case-control study that investigates female breast cancer risk factors, including Hispanic health disparities, in women who are current residents of Puerto Rico. The purpose of this presentation is to describe the challenges met in the recruitment of participants.

METHODS

Atabey is a population-based, case-control study that proposes to recruit 500 incident breast cancer cases and 500 controls from 3 municipalities (San Juan, Bayamón and Guaynabo) in Puerto Rico (Figure 1).

•Cases are women aged 30 to 79 years with incident, primary, pathologically confirmed breast cancer and no history of previous cancer other than non-melanoma skin cancer.

•Controls are randomly selected women residing in the same geographical areas as the breast cancer cases.

•Personal information is collected through a face to face structured interview (electronic questionnaire). The anthropometric measurements, biological (blood or saliva) samples and skinfold measurements are collected by a trained nurse in the clinic or at the participant's home.

•The sources of cases are the Puerto Rico Central Cancer Registry and the log books of hospitals or physician offices in the Metropolitan San Juan Area (Figures 2 and 3).

•Controls are selected from a population sample of women in the same age group, who are residents of the same municipalities as the cases. The source of controls is the *Estudio Continuo de Salud* (ECS), a National Health Survey in Puerto Rico, conducted by the Graduate School of Public Health, University of Puerto Rico for the Puerto Rico Department of Health. (Figure 4).

Figure 1 Municipality of Residence of the Study Population

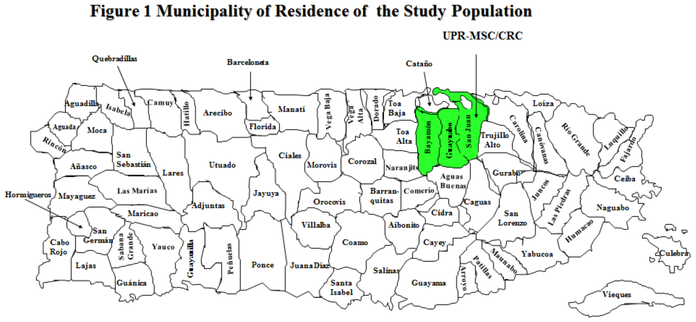

Figure 2. Identification of cases

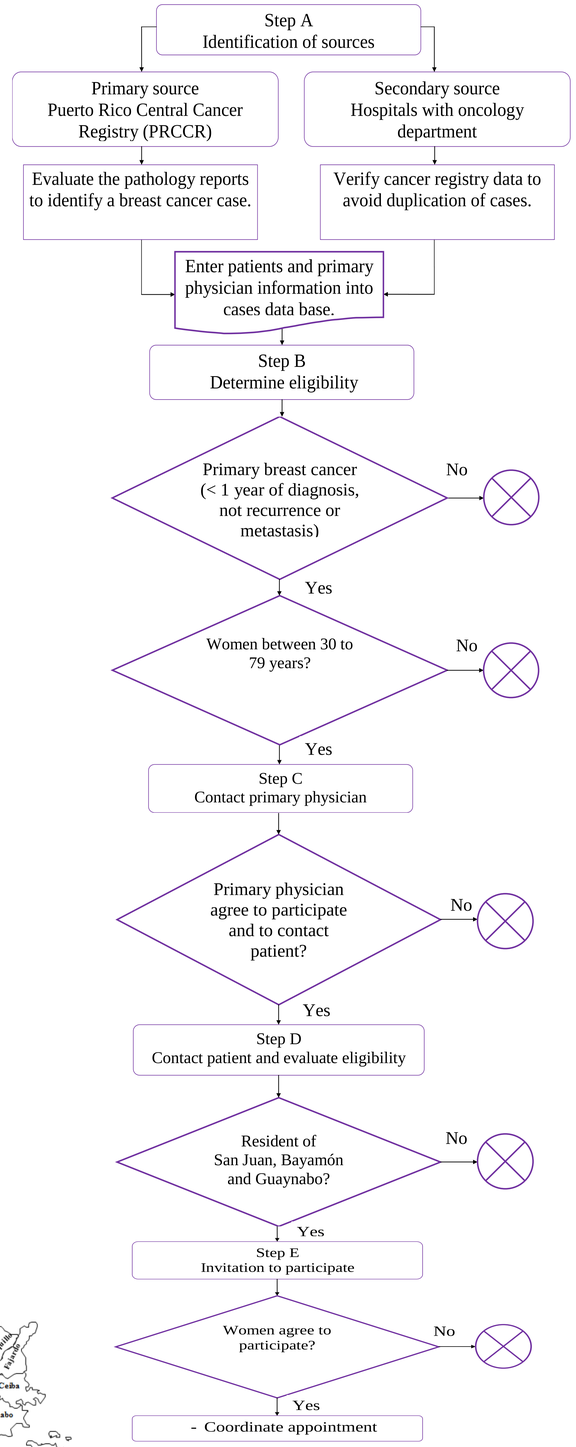

Figure 3. Recruitment of cases

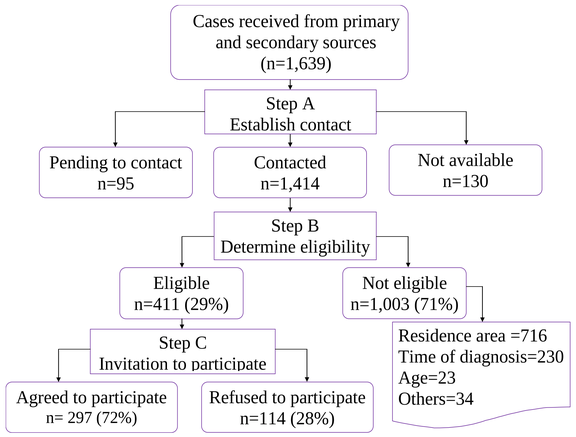

Figure 4. Identification of controls

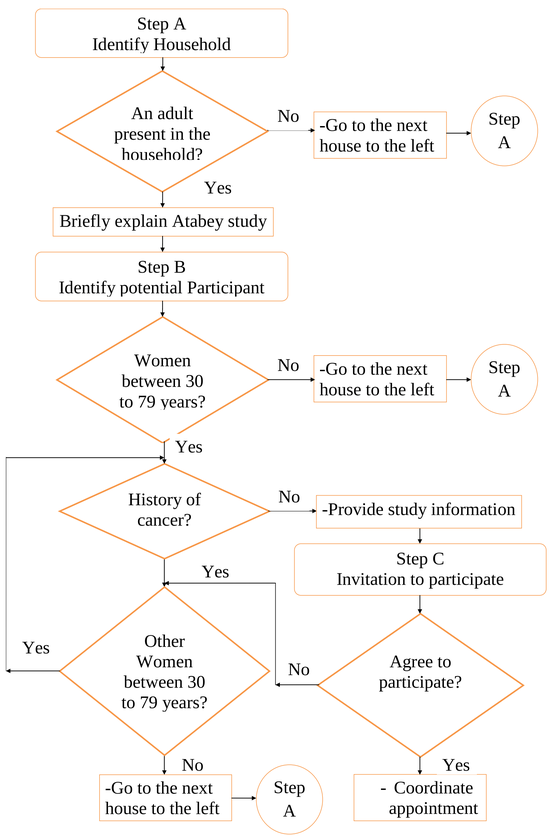

Table 1 Distribution of visits to households during recruitment of controls

Housing Status	Guaynabo	Bayamón	San Juan	Total
Total of Households Visited	**185**	**382**	**375**	**942**
Contact with a resident	138	304	293	735
Vacant	30	21	38	89
No contact with a resident (after 3 visits or more)	17	48	34	99
Pending for the next visit	0	9	10	19

Figure 5. Recruitment of controls

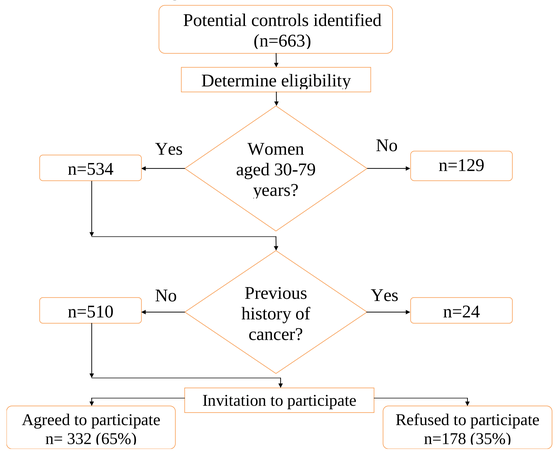

Table 2 Reasons for non-participation

Reasons	Controls (n=178)	Cases (n=114)	Total (n=292)
Working	40 (23%)	12 (11%)	52 (18%)
Lack of time	28 (16%)	23 (20%)	51 (17%)
Not interested	37 (21%)	34 (30%)	71 (24%)
Too sick to participate	30 (17%)	26 (22%)	56 (20%)
Caregiver	15 (8%)	4 (4%)	19 (7%)
A family member did not allow her to participate	11 (6%)	4 (4%)	15 (5%)
Have a private physician	4 (2%)	0 (0%)	4 (1%)
Other reasons	13 (7%)	11 (9%)	24 (8%)
Total	**178 (100%)**	**114 (100%)**	**292 (100%)**

RESULTS

Results: From the 1,639 breast cancer cases referred by their primary physician or by the cancer registry of the hospital, 1,414 were contacted and 411 met eligibility criteria (Figure 3). Of those, 28% refused to participate, most of them (30%) expressing a lack of interest and 22% expressing that they did not want to talk about cancer or were too sick to participate. Our community outreach personnel visited 942 households to identify and recruit potential controls. She contacted a resident in 735 households (Table 1). 663 potential controls were identified. Of these 534 were women between 30 and 79 years (Figure 5). A total of 510 women fulfilled the eligibility criteria; however, 35% refused to participate, with 23% of them citing their job as the major conflict (Table 2).

CONCLUSION

The percentage of cases that refused to participate was unexpected, since persons with diseases are usually willing to participate in health studies. One inclusion criteria for the cases was a recent diagnosis. These observations give us the opportunity to evaluate the challenges faced, and to explore alternative recruitment plans for future population-based cancer studies in Puerto Rico.

Supported by CDMRP Grant W81XWH-07-1-0329
BCRP HBCU/MI Partnership Training Award
Acknowledge: Puerto Rico Clinical and Translational Research Consortium

For more information: cruz.nazario@upr.edu

Association between lifetime sun exposure and breast cancer: Preliminary data from the Atabey Study

Paola Piovanetti MS[1], Rosa Rosario-Rosado DrPH[2], Heidi L. Venegas-Ríos DrPH[2], Michelle Schelske-Santos PhD[3], Johan Hernández MPH[2], Imar Mansilla-Rivera PhD[2], Farah Ramírez PhD[3], Cruz M. Nazario PhD[2], Jo L. Freudenheim, PhD[4]. (1) University of Texas Southwestern Medical Center; (2) University of Puerto Rico Graduate School of Public Health; (3) University of Puerto Rico, Río Piedras Campus; (4) Department of Social and Preventive Medicine, University at Buffalo.

INTRODUCTION

Breast cancer is the most common cancer type and the most common cause of cancer death among women in Puerto Rico (Torres-Cintrón et al., 2010).

- 31.9% of all diagnosed female cancers in the period 2000-2004.
- 17.8% of all female cancer deaths in the period 2000-2004.

Recent epidemiologic studies have suggested that sun exposure can reduce the risk and improve outcomes of cancer, especially breast cancer (Grant, 2009 & Kricker & Armstrong, 2006). Yet the potential benefit of sun exposure has been controversial due to the fact that high dosages and long term exposure has been associated with the risk of skin cancer (Freedman et al., 2002).

The positive effect is presumed to be related to the synthesis of Vitamin D from ultraviolet rays absorbed through the skin (Cui & Rohan, 2006 & Garland et al., 2007). Several studies suggest that 80% to 90% of all Vitamin D utilized by the human body is obtained from sun exposure (Holick, 2008; Moan et al., 2008). There are other sources of Vitamin D intake including consumption of supplements and foods rich in vitamin D.

Puerto Rico's geographic location (proximity to the equator) makes it an ideal place to study sun exposure as a potential protective factor for breast cancer. In Puerto Rico, the ultra-violet index (UVI) varies from 7 to 13 throughout the year (NOAA, n.d.).

OBJECTIVE

To examine the association between lifetime sun exposure and the risk of breast cancer among women (30-79 years living in the San Juan Metropolitan Area) that participated in the *Atabey* study.

METHODS

The *Epidemiology of Breast Cancer in Puerto Rico (Atabey Study)* is a population-based case-control study designed to examine established and potential risk factors for breast cancer. Participants are women aged 30 to 79 years living in the metropolitan area of Puerto Rico (San Juan, Bayamón, Carolina and Guaynabo). The study was approved by the Institutional Review Board (IRB) . of the University of Puerto Rico Medical Science Campus (Protocol number A8330111). This report presents the preliminary analysis of the first 100 cases and 100 controls.

- Cases: women with primary, incident, histologically confirmed breast cancer.
- Controls: women without a history of breast or other cancers, except non-melanoma skin cancer, recruited through a probabilistic sampling of the population living in the target area (*Puerto Rico Health Interview Survey*).

Data collection instruments:

- Structured questionnaire.
- Chromameter (Minolta CR-400) to quantify skin color. The numerical values range from 0 (black) to 100 (white).

Skin color measured in two different areas of the body:

- Facultative: area exposed to sunlight measured as skin color at the dorsal area of the left hand.
- Constitutive: area unexposed to sunlight measured at the interior area of the left arm.

CHROMA METER CR-400 Konica Minolta

Facultative skin pigmentation

Constitutive skin pigmentation

The Sun Exposure Index (SEI) was estimated by the standardized difference in the average of three measurements of the facultative and the average of three measurements of the constitutive skin pigmentations. The distribution of the Sun Exposure Index among the controls was used to determine quartile cut-off levels.

Statistical analyses were performed using descriptive statistics and logistic regression using STATA v.8.2.

RESULTS

Table 1. Percent distribution of constitutive and facultative pigmentation for the sample (n=200)

Pigmentation	Constitutive pigmentation	Facultative pigmentation
0 "very dark"	16.5%	16.5%
1 "dark"	21.5%	24.5%
2 "light"	26.5%	25.0%
3 "very light "	35.5%	34.0%

Cases were significantly older than controls, with a mean age of 58 and 51 years, respectively. Most of the breast cancer cases were between 60 to 69 years of age. There were no significant differences between cases and controls in the distributions by body mass index, use of hormone replacement therapy, frequency of sun block use, tanning lotion use, tanning bed use, reported amount of sun exposure throughout different stages across the life, multivitamin use, nor in consumption of selected foods high in vitamin D content: sardines, milk and yogurt [See Table 2].

Nevertheless, cases and controls showed important differences in the distributions of the following variables: education, presence of menopause, history of benign breast disease, family history of breast cancer, ever-use of sun screen, consumption of vitamin D supplements and consumption of salmon and tuna, which are high in vitamin D content. Potential confounders identified by stratified analysis were age, education, ever use of sun screen and presence of menopause. However, the variable "presence of menopause" was excluded from the logistic regression analysis due to its collinearity with the age of the participant [Table 2].

Table 2. Socio-demographic and clinical variables

	Cases %	Controls %	Total %	p-value*
Age (yrs.)	(n=100)	(n=100)	(n=200)	0.001†
30-39	5.00	24.0	14.5	
40-49	24.0	27.0	24.5	
50-59	25.0	20.0	22.5	
60-69	29.0	15.0	22.0	
70-79	17.0	14.0	15.5	
Education	(n=100)	(n=97)	(n=197)	0.032
Less than high school	15.0	29.9	22.3	
HS diploma/associated degree	46.0	42.5	44.2	
College/post graduate degree	39.0	27.6	33.5	
Marital Status	(n=100)	(n=100)	(n=200)	0.119
Never married	11.0	12.0	11.5	
Separated or divorced	19.0	31.0	25.0	
Married or living with partner	51.0	47.0	49.0	
Widow	19.0	10.0	14.5	
Menopause	(n=98)	(n=93)	(n=191)	<0.001
Artificial	41.9	22.6	32.5	
Natural	45.9	34.4	40.3	
No menopause	12.2	43.0	27.2	
History of benign breast disease	(n=94)	(n=97)	(n=191)	<0.001
Yes	53.2	23.7	38.2	
No	46.8	76.3	61.8	
Family history of breast cancer	(n=91)	(n=92)	(n=183)	<0.001
Yes	33.0	12.0	22.4	
No	67.0	88.0	77.6	
Sun screen use (ever)	(n=100)	(n=100)	(n=200)	0.002
Yes	72.0	51.0	61.5	
No	28.0	49.0	38.5	
Vitamin D supplements (past year)	(n=100)	(n=100)	(n=200)	0.036
Yes	22.0	11.0	16.5	
No	78.0	89.0	83.5	
"calcium+vit. D" supplements (past year)	(n=100)	(n=99)	(n=199)	<0.001
Yes	39.0	14.1	26.6	
No	61.0	85.9	73.4	
Salmon or tuna intake	(n=99)	(n=99)	(n=198)	0.032
Frequent	35.4	41.4	38.4	
Not frequent	19.2	30.3	24.7	
Not at all	45.4	28.3	36.9	

*Chi-square test. †Fisher's exact test.

Important differences were observed when constitutive and facultative mean values were compared between cases and controls. The range of values of the Sun Exposure Index was wider among cases than among controls, as can be observed in Table 3.

Table 3. Constitutive and Facultative Skin Pigmentation and Sun Exposure Index.

	Cases	Controls	P value
Constitutive pigmentation			
Mean (SD)	63.75 (4.27)	60.88 (5.64)	
Median	64.49	61.94	0.001†
Min–Max	52.00 - 70.40	57.25 - 72.21	
Facultative pigmentation			
Mean (SD)	56.81(4.52)	54.13(6.11)	<0.001‡
Median	57.23	54.55	
Min–Max	43.11 - 66.94	39.40 - 67.07	
Sun exposure index			
Mean (SD)	10.80 (5.60)	11.82(6.08)	
Median	10.76	11.41	0.273†
Min–Max	0.04 - 31.32	0.68 - 29.72	

†Wilcoxon-Mann Whitney test. ‡t-test.

A dose-response effect (p-value for trend =0.014) was observed in the adjusted Odds Ratio after controlling for age, education and ever use of sun screen, as shown in Table 4. High SEI showed a protective benefit against breast cancer (OR = 0.20; 95% CI: 0.06, 0.63) in this analysis.

Table 4. Association between lifetime Sun Exposure Index and breast cancer

	OR	95% CI	Adjusted OR*	95% CI
Sun Exposure Index				
No sun exposure	Reference	-	Reference	-
Low sun exposure	1.29	0.60 - 2.79	1.03	0.43 - 2.47
Moderate sun exposure	1.42	0.66 - 3.03	0.98	0.39 - 2.45
High sun index exposure	0.46	0.19 - 1.13	0.20	0.06 - 0.63

*Controlling by age, education and ever use of sun block.

LIMITATION

Due to the sample size, caution in the interpretation of the study results is recommended.

CONCLUSIONS

High sun exposure was associated with a protective benefit against breast cancer after controlling for age, education, and sun screen use at some point in the lifetime. The decreasing trend of the estimated risk of breast cancer was statistically associated with the increase of sun exposure index in this population.

This preliminary analysis supports the hypothesis that high cumulative sun exposure may contribute to a reduction in the risk of breast cancer. Other studies also have found an association between sun exposure and a reduction in the risk of breast cancer (Engel et al., 2010; John et al., 2007; Knight et al., 2007 & Yang et al., 2011). Further analytic studies evaluating this association are recommended, considering the concentration and the level of 25-hydroxyvitamin D in the blood serum as well as the potential polymorphisms associated to the metabolism of vitamin D.

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Supported by CDMRP Grant W81XWH-07-1-0329
BCRP HBCU/MI Partnership Training Award
Acknowledge: Puerto Rico Clinical and Translational Research Consortium

Program No. 1061.1

Hispanics represent a variety of cultures with roots in Europe, Africa, the Americas, and the Caribbean. Important differences exist in ancestry, disease patterns, health behaviors, and even in language. Appropriate vocabulary and visual aids are essential for dietary assessment, for defining specific food items and portion sizes. Careful distinctions must be made between foods with the same Spanish name, yet different nutrient composition. Incomplete or misclassified dietary data may mask or severely limit the possibilities of demonstrating true correlations between diet and disease, and understanding health disparities. Objective: In the Atabey Study, we are developing techniques for obtaining culturally-specific dietary data for women living in Puerto Rico, in order to assess dietary exposures in relation to risk of breast cancer and other co-morbidities. Methods: A booklet of photographs was constructed to define portion sizes for key beverages and foods. Questions were designed to distinguish traditional dietary patterns from more acculturated diets both in childhood and adulthood. The nutrient database includes culturally-specific recipes. Conclusion: Development of culturally-specific dietary assessment tools requires in-depth understanding of the specific population being studied in order to provide insight into underlying health disparities.
Funded in part by DOD CDMRP, BC060131 [Abstract No. 8588]

The Hispanic Dietary Mosaic: Assessing the Diet of Women in Puerto Rico in the Atabey Study

Michelle Schelske-Santos[1], Cruz María Nazario[2], Rosa V. Rosario Rosado[2], Imar Mansilla-Rivera[2], Johan Hernández[2], Farah A. Ramírez Marrero[1], Susan McCann[3], Jo L. Freudenheim[4]. [1]UPR-Río Piedras, San Juan, PR 00931, [2]UPR-Medical Sciences, San Juan, PR 00936, [3]Roswell Park Cancer Institute, Buffalo, NY 14263, [4]University at Buffalo, NY 14214

INTRODUCTION

The Atabey Study is a population-based breast cancer epidemiology project with a goal of recruiting 500 incident breast cancer cases and 500 controls from the Greater San Juan Area on the island of Puerto Rico. Cases are women with incident, primary, pathologically confirmed breast cancer with no history of previous cancer other than non-melanoma skin cancer; controls are frequency-matched on age and randomly selected from women who reside in the same geographical area.

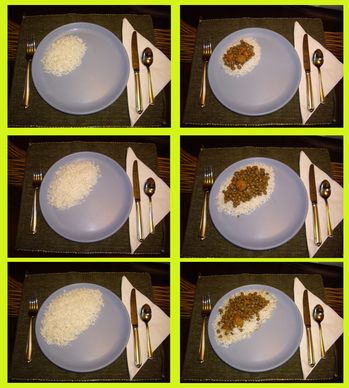
Puerto Rico is a particularly interesting place for breast cancer research, because the incidence rate of breast cancer in Puerto Rico is about half that in the United States. Nonetheless, the risk of this disease among women in Puerto Rico is increasing at a faster rate compared to the United States. The rapidly increasing rate likely reflects changes in environmental and lifestyle exposures over time, including diet. Variability in the Puerto Rican diet could help us identify protective factors, as well as risk factors, for breast cancer and other co-morbidities that affect this population of Hispanic women, and may help explain health disparities.

Hispanics represent a variety of cultures with roots in Europe, Africa, South America, Central America, North America, and the Caribbean. Each culture brings with it differences in dietary consumption, as well as food description or vocabulary. The ability to communicate efficiently and effectively with all Hispanics is key to defining and understanding health disparities. Appropriate vocabulary and visual aids are essential for dietary assessment particularly for defining specific food items and portion sizes. Incomplete or misclassified dietary data may mask or severely limit the possibilities of demonstrating true correlations between diet and disease.

METHODS

A booklet of photographs was constructed to define portion sizes for key foods, beverages and condiments, and to accompany dietary assessment by a semi-quantitative food frequency questionnaire. Questions were designed to distinguish traditional dietary patterns from more acculturated diets both in childhood and adulthood. The nutrient database includes culturally-specific recipes which reflect traditional Puerto Rican cooking practices.

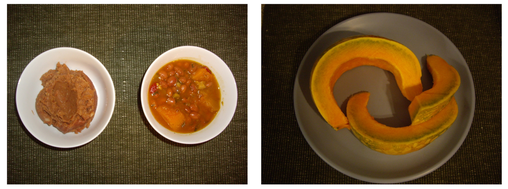
Three portion sizes of rice alone, or topped with pigeon peas (*gandules*, a typical legume of Puerto Rico and the Caribbean) from Food Booklet (to scale)



Three portion sizes of hot beverages from the Food Booklet (to scale). Coffee as espresso is frequently consumed in a demitasse (3 – 4 fl. oz.)

Unique Puerto Rican/Caribbean Condiments (not to scale)

Comparison of Refried Beans and Puerto Rican/Caribbean Beans (not to scale)



Puerto Rican beans include tropical squash (left, *calabaza*) and traditional condiments (above, *sofrito*: garlic, onion, sweet peppers (*ajíes dulces*), fresh corriander (*cilantrillo, recao*), and the red/orange pigment, annato (*achiote*).

Apio	*Ñame*
Yuca (cassave)	*Yautia* (tannier)

Traditional Puerto Rican / Caribbean cuisine also includes frequent use of starchy tubers boiled in soups (*sopón, guiso, sancocho*), or used as a side dish, either mashed or in pieces.

Spanish Language Homonyms 1: *Pastel*

Pastel (near right): Cake, (in PR, *bizcocho)* *Pastel* (far right): green banana – based mass with chunks of pork, chick peas or potato and *sofrito,* wrapped in a plantain leaf and paper and boiled (not to be confused with *tamale*, which has a cornmeal base)

Spanish Language Homonyms 2: *Tortilla*

Tortilla (far left): Cornmeal – based flat bread used in Mexican and Central American cuisine
Tortilla (near left): Egg – based Spanish omelet with potatoes and onion (Spain and PR)

CONCLUSIONS

Development of culturally-specific dietary assessment tools requires in-depth understanding of: 1) dietary practices (Ex. common portion sizes), 2) use of particular food items (Ex. inclusion of unique recipes and specific nutrient content), and 3) variations in vocabulary within the language (Ex. homonyms within *Spanish*) of the specific population being studied. These tools will allow investigators to more accurately reflect nutrient intake, avoid misclassification, and increase detection of potential positive and negative correlations to disease, while providing insight into underlying health disparities.

Funded in part by DOD CDMRP, BC060131

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