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The objectives of this infrastructure enhancement project are to establish a population-based biological specimen and companion risk-factor data bank on 225 invasive breast cancer cases, ages 35 and under. These breast cancer cases have been enrolled through the tumor incidence registries in Connecticut, Massachusetts and 7 regions in California with a total population of 21 million (8% of U.S. women). Demographic, epidemiologic and family history data have been collected on 225 cancer cases, and fresh blood specimens have been processed to produce a lymphoblastoid cell line, cDNA and plasma in years 1-3. A computerized file of the epidemiologic data and specimen data has been generated. Despite a series of initial obstacles, we have completed on schedule all activities outlined in our Statement of Work. We have announced the availability of the resource to researchers on the internet with additional data available via the email link on this site. An Outside Advisory Committee will prioritize requests for tissues and risk factor data. This resource is available to multiple investigators for detection of *p53*, *BRCA1/2* and other inherited breast cancer susceptibility genes, and studies of gene-environment interactions.

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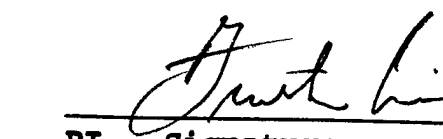

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## INTRODUCTION

Our purpose is to develop a biological specimen bank and epidemiological database of 225 early onset invasive breast cancer cases (ages 35 and under) enrolled in the population-based cancer incidence registry in Connecticut, Massachusetts and 7 regions of California (Santa Clara region, Central Valley, Sacramento, Inland Empire, San Diego, Bay Area, and Orange regions). Approximately one-third of breast cancer cases under age 35 are estimated to be carriers of an inherited gene: estimated carrier rates are 36% at ages 20-29; 29% at age 30; 28% age 31; and 24% at 35 years. The cut-off at age 35 is based on sample-size considerations. This resource will provide an infrastructure for the identification and studies of inherited breast cancer susceptibility genes, and their interactions with hormonal and environmental risk factors. The cases will be generated from a population base of 21 million (8% of entire US population) that is of special interest to breast cancer researchers. Age-adjusted cancer mortality rates, 1985-89, in Massachusetts ranks 6th highest nationwide, and Connecticut ranks 13th [1,2]. Both States are in the high breast cancer-mortality belt that spans the Middle Atlantic and New England regions. California, the most populace state in the nation, has substantial minority populations, including Asian-Americans (9.9%), Hispanic-Americans (20.9%), and Black-Americans (6.1%) in the study regions. The racial composition of Massachusetts is 88% Whites, 5% Hispanics, 5% Blacks, 2% Asians, and 0.6% others. In Connecticut, there are 83% Whites, 8% Blacks, 7% Hispanics and 2% Asians and 0.1% others.

## BODY

The objectives of the proposal are to identify all incident invasive breast cancer cases, ages 35 and under in a 3-year period, using rapid ascertainment systems available for the population covered by the cancer incidence registries of the State of Connecticut, Commonwealth of Massachusetts, and 7 regions in California that encompass 8% of the entire US population. With permission of the treating physician and patient, we planned to collect a completed questionnaire for 225 subjects, as well as peripheral blood. We proposed to use the blood sample to establish a lymphoblastoid line, produce cDNA, a plasma specimen, and store viably frozen cells along with paraffin blocks in laboratories of the PI and co-PIs in California and Massachusetts. At the end of year 3, we would make available to approved investigators all questionnaire and specimen summary data. An Outside Advisory Committee of leading scientists will prioritize requests from any breast cancer investigator for biologic specimens.

Methods were defined to uniformly collect blood specimens and questionnaire data from incident invasive breast cancer cases (age 35 and under) ascertained in Years 1-3 through the population-based cancer registries for Massachusetts and Connecticut, and 7 participating regions of California. Processing of specimens and establishment of a tissue repository and epidemiologic database for at least 225 cases was targeted. In total 499 eligible subjects were identified and physician permission was granted to contact 456 of these subjects. With physician permission, a total of 291 patients completed the risk factor questionnaire, and 261 lymphoblastoid samples were attained. Summary risk factor data for the 261 subjects who donated blood is attached (Appendix 1). From these blood samples, 211 cell lines were established (Appendix 2). Reasons for line

failures include low blood count, shipment delays and small blood volume from treated cancer patients with poor vein access, as well as technical laboratory problems. An announcement of the database has been on-line for e-mail accession, and specimens can be distributed to investigators with high priority studies. Despite initial obstacles, the project has been completed as described and later modified with DOD approval.

We had established mechanisms for rapid case ascertainment of all incident breast cancer cases within the initial 24 months of the project; obtaining informed consent from subjects; administering a standardized interview; performing a phlebotomy and processing the specimen [3-10]. Rapid case ascertainment systems differ slightly in California, Massachusetts and Connecticut. The approach in each region has been determined by cost considerations, and established resources.

In California, the project was conducted through the Cancer Surveillance Program for all 7 population-based California cancer registry regions [3-5]. In addition to the fact that cancer reporting is mandatory throughout the State of California, the Cancer Surveillance Program has long maintained a close working relationship with health care facilities and physicians throughout the region. Many hospitals participate in joint cooperative clinical research protocols. The Cancer Surveillance Program also circulates a newsletter that is used to inform local healthcare facilities and physicians of the study and ensure prompt enrollment of all patients. The rapid case ascertainment systems previously developed for this region have been used in all 7 population-based California cancer registry regions. The Cancer Surveillance Program staff contacted all health care facilities in the region that diagnose breast cancer cases. The Cancer Committee Chair and Tumor Registrar of each hospital of these regions were informed of the study. One individual from each facility was designated as the contact person with the Cancer Surveillance Program staff for rapid identification. The Cancer Surveillance Program staff worked with them to examine pathology reports and surgery logs on a regular basis.

In Connecticut, the rapid case ascertainment system has been used for many studies over the last decade [6]. For this project, rapid case ascertainment was used to identify cases in the 9 hospitals found in a preliminary study to have reported two-thirds of the incident early-onset breast cancers. Other patients were identified through the usual reporting mechanisms of reporting cancer incidence to the Connecticut Tumor Registry.

In Massachusetts, pilot data show that the majority of very young breast cancer cases are referred to a few specialty centers for consultation and treatment. These cases can be efficiently ascertained at lowest cost by directly approaching clinicians and hospital tumor registries of the Dana-Farber Cancer Institute (the Regional Comprehensive Cancer Center), its sister institutions in Harvard Medical School (Brigham and Women's, Massachusetts General, Beth Israel, Deaconess, and Mount Auburn Hospitals), and Dana-Farber Affiliate community hospitals. Nearly 2/3 of all incident breast cancers of early onset in Massachusetts can be rapidly ascertained through these institutions[7]. Recruitment from more than 100 community hospitals statewide proved problematic, largely because each of their Institution Review Boards (IRBs) had to be approached individually. Some had no previous experience with cancer genetic studies, and others required changes that would destroy uniformity of the study.

Recruitment of subjects, informed consent and questionnaire administration for California cases were handled through UC Irvine, and Massachusetts and Connecticut cases were through Dana-Farber. Consent to participate in this study is a 2-step process. Initially, the physician of the subject was contacted for permission to inform the patient of the study and request voluntary participation. With physician consent, the patient was sent a letter that explained the study, and subsequently telephoned. After verbal consent was obtained a telephone questionnaire was administered. In addition, arrangements were made for collection of up to 50 ml of peripheral blood by venipuncture at a facility specified by the patient.

Arrangements were made for collection and shipment of blood specimens to Boston. We have extensive experience in collecting, shipping and processing freshly collected blood samples from study subjects within the United States [3-5, 8-11]. Cases had their blood drawn at either one of the collaborating centers, by their family doctor, oncologist or local health care facility or at a home by a member of the visiting nurse association. The physician or clinic designated by the patient was contacted, and the purpose and procedures explained. A package with consent form, blood collection and handling instructions, Leukoprep tubes, and a pre-paid shipping invoice was sent prior to the date of collection. No medical complications were encountered. These specimens were delivered to the laboratory in Boston by express mail (or by taxi for specimens collected locally). Cells were used to generate EBV immortalized lymphoblastoid cells. This process involves culturing cells over a period of 6-8 weeks before stable immortalized cells are established. A test of cell-viability was performed before the immortalized cells are considered properly frozen and stored. Requests from researchers for a cell line can either be filled directly from these frozen vials or by thawing out samples and regenerating more frozen sample vials. If available, primary lymphocytes have also been viably frozen in 10% DMSO as a reserve source of cells in case there is ever a need to regenerate a new lymphoblastoid cell line, as well as produce genomic DNA.

During the study, however, we had to modify our proposal regarding collection of breast tumor blocks. Hospitals are refusing to send us the blocks, a departure from past standard of practice. Alternatively, they were willing to cut slides, but often at charges of over $100. A supplemental request to our award could not be made and the Project Officer agreed to drop this aspect of the project. We have met all other study objectives within the time specified in our proposal. To ensure equal access to the resources, the Outside Advisory Committee will prioritize requests. The following breast cancer researchers have agreed in writing to serve on the Committee:

Dr. Bruce Ponder, Director, CRC Human Cancer Genetics Research Group, Cambridge University, England;
Dr. Barbara Weber, Director, Breast Oncology Program, University of Michigan Medical and Genome Center; and
Dr. Anne Bowcock, University of Texas, Southwestern Medical Center.

A group of leading epidemiologists, clinical investigators, molecular biologists and geneticists has been contacted regarding their personal use of the resource to be developed under this proposal. Availability of the database and specimens has been announced on the Internet (see Appendix 3; http:/wwwicic.nci.nih.gov/breastdata/sc9dana.htm.) Detailed information about our risk factor database and specimen availability may be provided via the e-mail link on this web site. We have

received a number of inquiries about the specimen bank through the e-mail link on this Internet site. However, no written requests to use this resource have been received to date.

## CONCLUSIONS

All aspects of our study have been completed on time. Specifically, we have collected risk factor data from 291 patients under age 35, as stated in our Statement of Work. We have collected bloods from of these 261 patients. Lymphoblastoid cell lines have been successfully established when adequate volume of blood has been obtained. We have already placed an announcement on the Internet regarding the availability of the specimen resource (see attached notice). Our External Advisory Committee is prepared to review our request for utilization of the materials and data. The work has been accomplished despite multiple early problems with hospital IRBs who questioned various aspects of the DOD requirements for informed consent. This is an infrastructure grant, so no publications were expected. However, we are preparing a paper to describe the resource, and to compare risk factor data in our population based series with published data of the Cancer and Steroid Hormone (CASH) Study.

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**PERSONNEL**

| Name | Role on Project | effort |
|---|---|---|
| Frederick Li, M.D. | Principal Investigator | 20% 9/30/94-9/29/97<br>5% 9/30/97-9/29/98 |
| Anastasia Satterfield | Data Manager | 25% 9/30/94-9/29/95 |
| Christine Henault | Data Manager | 45% 9/30/96-5/31/97 |
| Katherine Nicholls | Data Manager | 25% 9/30/97-9/30/98 |
| Nina Cardoza | Data Manager | 10% 3/1/98-8/1/98 |

# Appendix 1

# SUMMARY RISK FACTOR DATA
# FOR ALL SUBJECTS WHO DONATED A BLOOD SAMPLE

DOD/EARLY BREAST CANCER STUDY SUMMARY OF RESULTS

| DEMOGRAPHIC INFORMATION | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| EDUCATION | TOTAL | <8 YEARS | 8-11 YEARS | 12 YEARS | SOME COLLEGE | COLLEGE GRAD | MASTERS | MD, PHD, JD | OTHER | | |
| | 261 | 0 | 8 | 52 | 82 | 79 | 14 | 3 | 23 | | |
| % | 100 | 0.0 | 3.1 | 19.9 | 31.4 | 30.3 | 5.4 | 1.1 | 8.8 | | |
| MARITAL | | SINGLE | MARRIED | SEPARATED | DIVORCED | WIDOWED | LIVING AS MARRIED | | | | |
| | 261 | 45 | 181 | 5 | 19 | 0 | 11 | | | | |
| % | 100 | 17.2 | 69.3 | 1.9 | 7.3 | 0.0 | 4.2 | | | | |
| RELIGION | | BAPTIST | EPISCOPOLIAN | JEWISH | METHODIST | MORMAN | PRESBYTERIAN | PROTESTANT | CATHOLIC | UNITARIAN | OTHER |
| | 251 | 12 | 10 | 8 | 11 | 1 | 5 | 28 | 126 | 1 | 49 |
| % | 100 | 4.8 | 4.0 | 3.2 | 4.4 | 0.4 | 2.0 | 11.2 | 50.2 | 0.4 | 19.5 |
| ETHNIC | | WHITE | BLACK | HISPANIC | ASIAN | NATIVE AMERICAN | OTHER | | | | |
| | 261 | 204 | 13 | 28 | 3 | 1 | 12 | | | | |
| % | 100 | 78.2 | 5.0 | 10.7 | 1.1 | 0.4 | 4.6 | | | | |
| SPOUSE EDU | | <8 YEARS | 8-11 YEARS | 12 YEARS | SOME COLLEGE | COLLEGE GRAD | MASTERS | MD, PHD, JD | OTHER | | |
| | 213 | 2 | 5 | 81 | 53 | 41 | 10 | 8 | 13 | | |
| % | 100 | 0.9 | 2.3 | 38.0 | 24.9 | 19.2 | 4.7 | 3.8 | 6.1 | | |

| PREGNANCY AND FERTILITY | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No | Yes | | | | | | | | | | | |
| EVER PREG | | 71 | 190 | | | | | | | | | | | |
| | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | | | | |
| TOTAL TIMES PREG | 190 | | 35 | 73 | 45 | 19 | 14 | 2 | 2 | | | | | |
| LIVE PREG | 326 | | 54 | 86 | 23 | 5 | 1 | 1 | 0 | | | | | |
| MISCAR | 69 | | 32 | 13 | 2 | 0 | 1 | 0 | 0 | | | | | |
| STILL BIRTH | 3 | | 3 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| ABORTION | 94 | | 37 | 21 | 2 | 1 | 1 | 0 | 0 | | | | | |
| | | | | | | | | | | | | | | |
| Out Come | | | Live | Still birth | Miscar | Abort | Multiple | Preg now | | | | | | |
| PREG 1 | 190 | | 115 | 0 | 26 | 47 | 2 | 0 | | | | | | |
| PREG 2 | 155 | | 106 | 3 | 22 | 23 | 1 | 0 | | | | | | |
| PREG 3 | 82 | | 57 | 1 | 8 | 13 | 2 | 1 | | | | | | |
| PREG 4 | 37 | | 26 | 0 | 6 | 5 | 0 | 0 | | | | | | |
| PREG 5 | 17 | | 8 | 0 | 1 | 6 | 1 | 1 | | | | | | |
| PREG 6 | 2 | | 1 | 0 | 0 | 0 | 1 | 0 | | | | | | |
| | 483 | 0 | 313 | 4 | 63 | 94 | 7 | 2 | | | | | | |
| | | | | | | | Early→ | | full term→ | late → | | | | |
| Duration of Pregnancy | | don't know | <8 | 8-15 | 16-23 | 24-31 | 32-35 | 36-39 | 40-43 | 44-47 | | don't know | | |
| PREG WKS 1 | | 1 | 32 | 33 | 2 | 2 | 3 | 32 | 77 | 4 | | 5 | | |
| PREG WKS 2 | | 3 | 16 | 25 | 2 | 3 | 10 | 33 | 63 | 1 | | 2 | | |
| PREG WKS 3 | | 0 | 5 | 15 | 1 | 2 | 5 | 16 | 34 | 2 | | 1 | | |
| PREG WKS 4 | | 1 | 4 | 4 | 0 | 1 | 1 | 7 | 18 | 0 | | 2 | | |
| PREG WKS 5 | | 0 | 1 | 4 | 0 | 0 | 0 | 2 | 7 | 0 | | 2 | | |
| PREG WKS 6 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | 1 | | |
| | | | | | | | | | | | | | | |
| Live born | | | Boy | Girl | Twin Girls | Twin Boys | Twin boy & girl | | | | | | | |
| BIRTH 1 | 117 | | 63 | 52 | 1 | 0 | 1 | | | | | | | |
| BIRTH 2 | 107 | | 50 | 56 | 0 | 1 | 0 | | | | | | | |
| BIRTH 3 | 58 | | 29 | 28 | 0 | 2 | 0 | | | | | | | |
| BIRTH 4 | 26 | | 13 | 13 | 0 | 0 | 0 | | | | | | | |
| BIRTH 5 | 8 | | 5 | 3 | 1 | 0 | 0 | | | | | | | |
| BIRTH 6 | 2 | | 1 | 0 | 0 | 1 | 0 | | | | | | | |
| | 320 | | | | | | | | | | | | | |
| Birth Weight Oz. | | <80 | 80-88 | 89-96 | 97-104 | 105-112 | 113-120 | 121-128 | 129-136 | 137-144 | 145-152 | 153-160 | >160 | |
| OZ 1 | | 2 | 5 | 4 | 10 | 19 | 12 | 27 | 12 | 11 | 8 | 4 | 3 | |
| OZ 2 | | 3 | 2 | 3 | 6 | 15 | 20 | 18 | 24 | 11 | 6 | 4 | 1 | |
| OZ 3 | | 1 | 0 | 8 | 2 | 9 | 10 | 12 | 12 | 5 | 4 | 0 | 0 | |
| OZ 4 | | 0 | 0 | 0 | 2 | 1 | 9 | 6 | 4 | 3 | 2 | 0 | 0 | |
| OZ 5 | | 0 | 0 | 1 | 1 | 2 | 1 | 0 | 0 | 3 | 0 | 0 | 1 | |
| OZ 6 | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | |
| | | | | | | | | | | | | | | |
| Birth Weight Oz. | | <88 | 89-104 | 105-120 | 121-136 | 137-152 | >152 | | | | | | | |
| OZ 1 | | 7 | 14 | 31 | 39 | 19 | 10 | | | | | | | |
| OZ 2 | | 5 | 9 | 35 | 42 | 17 | 6 | | | | | | | |
| OZ 3 | | 1 | 10 | 18 | 24 | 9 | 0 | | | | | | | |
| OZ 4 | | 0 | 2 | 10 | 10 | 5 | 0 | | | | | | | |
| OZ 5 | | 0 | 2 | 3 | 0 | 3 | 2 | | | | | | | |
| OZ 6 | | 0 | 0 | 1 | 0 | 0 | 2 | | | | | | | |
| | | | | | | | | | | | | | | |
| | | No | Yes | | | | | | | | | | | |
| BRFEED 1 | 117 | 43 | 74 | | | | | | | | | | | |
| BRFEED 2 | 107 | 39 | 68 | | | | | | | | | | | |
| BRFEED 3 | 59 | 26 | 33 | | | | | | | | | | | |
| BRFEED 4 | 26 | 11 | 15 | | | | | | | | | | | |
| BRFEED 5 | 9 | 4 | 5 | | | | | | | | | | | |
| BRFEED 6 | 2 | 1 | 1 | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| Weeks breast fed | | 1 to 9 | 10 to 19 | 20 to 29 | 30 to 39 | 40 to 49 | 50 to 59 | 60 to 69 | 70 to 139 | | | | | |
| NURSE 1 | | 20 | 16 | 11 | 11 | 5 | 8 | 0 | 3 | | | | | |
| NURSE 2 | | 14 | 21 | 12 | 7 | 2 | 3 | 5 | 4 | | | | | |
| NURSE 3 | | 7 | 7 | 6 | 6 | 3 | 1 | 3 | 0 | | | | | |
| NURSE 4 | | 4 | 5 | 2 | 1 | 0 | 1 | 1 | 1 | | | | | |
| NURSE 5 | | 2 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | | | | | |
| NURSE 6 | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| | | 48 | 50 | 33 | 25 | 10 | 13 | 9 | 11 | | | | | |
| | | | | | | | | | | | | | | |
| | | No | Yes | | | | | | | | | | | |
| PREG MED | | 179 | 11 | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| Birth No. | | | 1 | 2 | 3 | 4 | 5 | 6 | | | | | | |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MED PREG 1 | 7 | | 4 | 2 | 1 | 0 | 0 | 0 | | | | | |
| MED PREG 2 | 4 | | 2 | 1 | 1 | 0 | 0 | 0 | | | | | |
| MED PREG 3 | 2 | | 0 | 0 | 1 | 1 | 0 | 0 | | | | | |
| Medication taken to hold preg | | | Other | Pills | Shots | Yutapar | brethine & MGH | Macadan sen | Progestero ne | | | | |
| PMED 1 | 7 | | 0 | 2 | 2 | 1 | 0 | 1 | 1 | | | | |
| PMED 2 | 4 | | 0 | 1 | 2 | 0 | 1 | 0 | 0 | | | | |
| PMED 3 | 2 | | 0 | 0 | 1 | 0 | 1 | 0 | 0 | | | | |
| | | | | | | | | | | | | | |
| | | | <10 | 10to19 | 20to29 | 30to39 | | | | | | | |
| ST PMED WKS 1 | | | 3 | 0 | 2 | 2 | | | | | | | |
| ST PMED WKS 2 | | | 2 | 0 | 2 | 0 | | | | | | | |
| ST PMED WKS 3 | | | 0 | 0 | 1 | 1 | | | | | | | |
| | | | | | | | | | | | | | |
| Weeks taken During pregnancy | | | <10 | 10to19 | 20to29 | 30to39 | Don't know | | | | | | |
| PMED WKS 1 | | | 4 | 2 | 0 | 1 | 0 | | | | | | |
| PMED WKS 2 | | | 2 | 0 | 0 | 1 | 1 | | | | | | |
| PMED WKS 3 | | | 1 | 0 | 0 | 0 | 1 | | | | | | |
| | | No | Yes | | | | | | | | | | |
| TRY PREG | 260 | 227 | 33 | | | | | | | | | | |
| FERT TEST | 34 | 21 | 13 | | | | | | | | | | |
| Problem due to: | | | Self | Husband | Both | None | | | | know | | | |
| FERT PROB | 13 | | 4 | 2 | 2 | 3 | | | | 2 | | | |
| | | No | Yes | | | | | | | | | | |
| FERT DRUG | 261 | 255 | 6 | | | | | | | | | | |
| | | | | | | | | | | | | | |
| Birth Control Pills | | | | | | | | | | | | | |
| | | No | Yes | | | | | | | | | | |
| BCP | 261 | 31 | 230 | | | | | | | | | | |
| Months taken | Don't know | <1 | 1 to 11 | 12 to 23 | 24 to 35 | 36 to 47 | 48 to 59 | 60 to 71 | 72 to 83 | 84 to 95 | 96 to 107 | 108 to 119 | >=120 |
| BCP MOS 1 | 7 | 1 | 45 | 34 | 28 | 23 | 19 | 20 | 6 | 6 | 8 | 8 | 25 |
| BCP MOS 2 | 5 | 0 | 28 | 34 | 26 | 15 | 10 | 6 | 3 | 2 | 4 | 2 | 5 |
| BCP MOS 3 | 14 | 0 | 14 | 6 | 7 | 7 | 5 | 1 | 0 | 2 | 2 | 1 | 1 |
| | | | | | | | | | | | | | |
| Reason not used BCP | | | Yes | | | | | | | | | | |
| BCP Dr. | | | 2 | | | | | | | | | | |
| BCP FAMHX | | | 1 | | | | | | | | | | |
| BCP SAFE | | | 6 | | | | | | | | | | |
| BCP CHOICE | | | 23 | | | | | | | | | | |
| | | No | Yes | | | | | | | | | | |
| OTH HORM USE | 261 | 231 | 30 | | | | | | | | | | |
| HORM NAME | | | | | | | | | | | | | |
| HORM REASON | | | | | | | | | | | | | |
| HORM ST | | | | | | | | | | | | | |
| | Months | | 0 to 11 | 12 to 23 | 24 to 35 | 36 to 47 | >100 | | | | | | |
| HORM MOS | 30 | | 20 | 6 | 1 | 2 | 2 | | | | | | |

Health

| | | No | Yes | <10 | 10to14 | 15to19 | 20to24 | 25to29 | 30to35 | |
|---|---|---|---|---|---|---|---|---|---|---|
| GALL BLADDER | 261 | 245 | 16 | | | | | | | |
| AGE GALL | | | | 0 | 0 | 0 | 4 | 6 | 6 | |
| ACNE | 261 | 241 | 20 | | | | | | | |
| AGE ACNE | | | | 0 | 10 | 4 | 2 | 2 | 2 | |
| DIABETES | 261 | 257 | 4 | | | | | | | |
| AGE DIABETES | | | | 0 | 1 | 0 | 0 | 2 | 1 | |
| POLYPS | 261 | 259 | 2 | | | | | | | |
| AGE POLYPS | | | | 0 | 1 | 0 | 0 | 0 | 1 | |
| HIRSUTISM | 261 | 251 | 10 | | | | | | | |
| AGE HIRSUT | | | | 0 | 1 | 3 | 1 | 1 | 1 | |
| OV CYST | 261 | 209 | 52 | | | | | | | |
| AGE CYST | | | | 1 | 1 | 10 | 4 | 15 | 18 | |
| HBP | 261 | 253 | 8 | | | | | | | |
| AGE HBP | | | | 0 | 0 | 2 | 2 | 2 | 2 | |
| HI CHOL | 261 | 234 | 27 | | | | | | | |
| AGE CHOL | | | | 0 | 0 | 2 | 6 | 6 | 11 | |
| PELVIC SURG | 261 | 243 | 18 | | | | | | | |
| | | | | 1 | 0 | 6 | 2 | 5 | 4 | |
| EST | | 17 | 1 | | | | | | | |
| FIBROCYSTIC | 261 | 207 | 54 | | | | | | | |
| AGE FIBRO | | | | 0 | 0 | 9 | 12 | 22 | 10 | |
| PRIOR BX | 261 | 232 | 29 | | | | | | | |
| REASON BX | | | 28 | 0 | 1 | | | | | |
| PRIOR BX AGE | | | | 0 | 1 | 6 | 6 | 4 | 8 | |
| | | | Benign Cyst | Malignancy | Unkn | | | | | |
| BX FIND | | | 26 | 2 | 1 | | | | | |
| BR SURG | 261 | 249 | 12 | | | | | | | |
| BR SIZE | | 3 | 9 | | | | | | | |
| BR SURG AGE | | | | 0 | 0 | 2 | 3 | 6 | 1 | |
| | | | Augmentation | Reduction | Other | | | | | |
| BR PROCED | | | 8 | 2 | 2 | | | | | |
| | | | Self | Mamogam | MD | Other | | | | |
| BR FOUND | 261 | | 208 | 17 | 22 | 14 | | | | |
| | | | | | | | | | | |
| SMOKING HISTORY | | | | | | | | | | |
| | | No | Yes | | | | | | | |
| SMOKE 100 | | 153 | 108 | | | | | | | |
| SMOKE NOW | | 74 | 34 | | | | | | | |
| | | 0 | 1 to 9 | 10 to 14 | 15 to 19 | 20 to 24 | 25 to 29 | 30 to 34 | | |
| SMOKE START | | | 1 | 25 | 67 | 14 | 1 | 1 | | |
| SMOKE END | | | 0 | 0 | 9 | 27 | 27 | 12 | | |
| DUR_SMOKE years | | 2 | 22 | 24 | 27 | 13 | 1 | 0 | | |
| | | 1 to 4 | 5 to 9 | 10 to 19 | 20 to 29 | 30 to 39 | 40 to 49 | 50 to 59 | 60 to 69 | Don't Know |
| CIG DAY | | 24 | 13 | 32 | 27 | 3 | 4 | 0 | 1 | 4 |

| HEIGHT, WEIGHT & ACTIVITY | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 to 24 | 25to 29 | 30+ | dk |
| MEN 1ST | | 8 | 12 | 40 | 74 | 69 | 35 | 12 | 6 | 2 | | | | | | 3 |
| MEN REG AGE | | 2 | 10 | 20 | 46 | 36 | 39 | 25 | 19 | 9 | 15 | 4 | 9 | 0 | 3 | 15 |
| | | | Natural | BC Pills | Other | Never reg | | | | | | | | | | |
| MEN REG | | | 210 | 40 | 2 | 9 | | | | | | | | | | |
| | | | Much lower | Some what | Averag e | some what | much higher | | | | | | | | | |
| HEIGHT 12 | | | 18 | 38 | 100 | 57 | 48 | | | | | | | | | |
| WEIGHT 12 | | | 43 | 59 | 114 | 39 | 6 | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| | | no | yes | | | | | | | | | | | | | |
| VIG PHY 12 | | 110 | 151 | | 104 to | 156 to | 208 to | 260 to | 312 to | 364 to | | | | | | |
| times per year | | | <52 | 52 to 103 | 155 | 207 | 259 | 311 | 363 | 415 | | | | | | |
| VIG FREQ 12 | | | 1 | 4 | 18 | 31 | 13 | 42 | 5 | 35 | | | | | | |
| Req to keep wt low? | | no | yes | | | | | | | | | | | | | |
| VIG WEIGHT 12 | | 148 | 3 | | | | | | | | | | | | | |
| MOD PHY 12 | | 24 | 237 | | 104 to | 156 to | 208 to | 260 to | 312 to | 364 to | | | | | | |
| times per year | | | <52 | 52 to 103 | 155 | 207 | 259 | 311 | 363 | 415 | | | | | | |
| MOD FREQ 12 | | | 1 | 12 | 30 | 47 | 16 | 55 | 1 | 69 | | | | | | |
| Req to keep wt low? | | no | yes | | | | | | | | | | | | | |
| MOD WEIGHT 12 | | 235 | 2 | | | | | | | | | | | | | |
| | | | very slender | average | a little over weight | very over weight | | | | | Don't know | | | | | |
| BUILD 20 | | | 90 | 115 | 50 | 5 | | | | | 1 | | | | | |

| *Height* | Inches | <60 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 | >69 | dont know | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| HEIGHT 20 | | 7 | 14 | 13 | 24 | 26 | 36 | 32 | 28 | 24 | 22 | 12 | 23 | 0 | | | | |
| *WEIGHT* | pounds | <90 | 90-99 | 100 to 109 | 110 to 119 | 120 to 129 | 130 to 139 | 140 to 149 | 150 to 159 | 160 to 169 | 170 to 179 | 180 to 189 | 190 to 199 | 200+ | dont know | | | |
| WEIGHT 20 | | 1 | 11 | 35 | 43 | 69 | 39 | 23 | 11 | 8 | 8 | 4 | 0 | 5 | 4 | | | |
| | | no | yes | | | | | | | | | | | | | | | |
| VIG PHY 20 | | 174 | 87 | | 104 to | 156 to | 208 to | 260 to | 312 to | 364 to | | | | | | | | |
| times per year | | | <52 | 52 to 103 | 155 | 207 | 259 | 311 | 363 | 415 | | | | | | | | |
| VIG FREQ 20 | | | 5 | 6 | 8 | 19 | 15 | 16 | 5 | 11 | | | | | | | | |
| | | no | yes | | | | | | | | | | | | | | | |
| VIG WEIGHT 20 | | 80 | 4 | | | | | | | | | | | | | | | |
| MOD PHY 20 | | 75 | 186 | | | | | | | | | | | | | | | |
| | | | <52 | 52 to 103 | 104 to 155 | 156 to 207 | 208 to 259 | 260 to 311 | 312 to 363 | 364 to 415 | | | | | | | | |
| MOD FREQ 20 | | | 8 | 14 | 42 | 49 | 23 | 24 | 1 | 23 | | | | | | | | |
| | | no | yes | | | | | | | | | | | | | | | |
| MOD WEIGHT 20 | | 182 | 4 | | | | | | | | 0 | | | | | | | |
| | | <100 | 100 to 109 | 110 to 119 | 120 to 129 | 130 to 139 | 140 to 149 | 150 to 159 | 160 to 169 | 170+ | | | | | | | | |
| WEIGHT LO | | 16 | 42 | 58 | 62 | 36 | 14 | 13 | 10 | 6 | | | | | | | | |
| WEIGHT HI | | 0 | 6 | 16 | 30 | 50 | 33 | 31 | 25 | 61 | | | | | | | | |
| | | <20 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 |
| WEIGHT LO AGE | | | 94 | 38 | 19 | 20 | 14 | 22 | 10 | 8 | 8 | 6 | 10 | 3 | 2 | 2 | 0 | 0 |
| WEIGHT HI AGE | | 10 | 10 | 8 | 4 | 5 | 12 | 20 | 12 | 11 | 16 | 17 | 32 | 13 | 17 | 30 | 27 | 12 |
| | | Never over weight | below waist | around above waist | equal | | | | | | | | | | | | | |
| WEIGHT GAIN | 261 | 4 | 142 | 46 | 69 | | | | | | | | | | | | | |

| Alcohol | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | No | Yes | | | | | | |
| ALCOH 16 | 261 | 169 | 92 | | | | | | |
| BEER 16 | 92 | 18 | 74 | | | | | | |
| WINE 16 | 92 | 65 | 27 | | | | | | |
| LIQ 16 | 92 | 58 | 34 | | | | | | |
| | | | 1 to 5 | 6to10 | 11to15 | 15to20 | 20+ | Dont know | |
| BEER WK 16 | 74 | | 46 | 19 | 3 | 0 | 1 | 5 | |
| WINE WEEK 16 | 27 | | 25 | 2 | 0 | 0 | 0 | 0 | |
| LIQ WK 16 | 34 | | 25 | 2 | 3 | 1 | 3 | 0 | |
| | | No | Yes | | | | | | |
| ALCOH 20 | 261 | 101 | 160 | | | | | | |
| BEER 20 | 160 | 56 | 104 | | | | | | |
| WINE 20 | 104 | 95 | 63 | | | | | | |
| LIQ 20 | 62 | 83 | 78 | | | | | | |
| | | | 1 to 5 | 6to10 | 11to15 | 15to20 | 20+ | Dont know | |
| BEER WK 20 | 104 | | 58 | 32 | 10 | 3 | 1 | 0 | |
| WINE WK 20 | 62 | | 56 | 5 | 1 | 0 | 0 | 0 | |
| LIQ WK 20 | 76 | | 59 | 9 | 3 | 5 | 0 | 0 | |
| | | | | | | | | | |

## Appendix 2

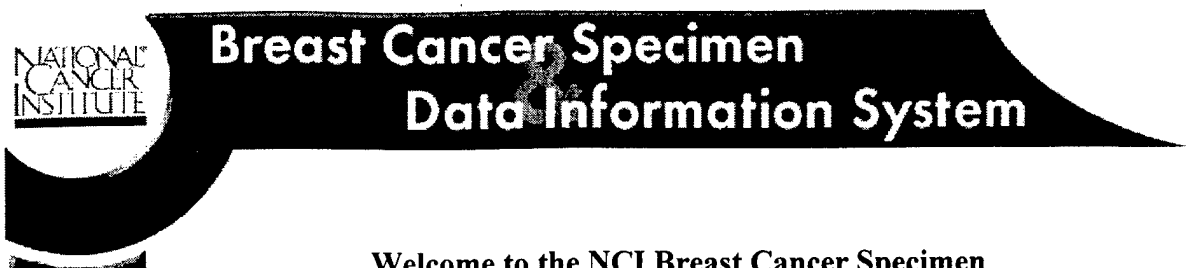
### DOD - Early Breast Cancer Study
### Summary of Responses

| | |
|---|---|
| Eligible Subjects | 499 |
| Physician Permission | 456 |
| Interview Completed | 291 |
| Blood Received | 261 |
| | |
| Specimens Available* | 235 |
| Cell Lines Established | 211 |

* Either frozen cell line, plasma, blood or DNA

# Appendix 3

# INTERNET SITE ANNOUNCING AVAILABILITY OF THE BIOLOGICAL SPECIMEN BANK AND EPIDEMIOLOGICAL DATABASE




what's new
database
about
suggest
resources

## Welcome to the NCI Breast Cancer Specimen and Data Information System

This database was developed by the National Cancer Institute (NCI) to help breast cancer researchers identify sources of biological specimens needed for their research. Breast cancer researchers can use this database to identify biological specimen banks or distribution systems where they can obtain specimens from patients diagnosed with breast cancer, individuals at high risk, and unaffected individuals. Specimens in these resources include breast tissue (normal and malignant), serum, urine, cells, and DNA.

The database is not intended as an exhaustive national listing of all facilities with access to breast tissue. It is limited to resources with the capability and desire to provide breast cancer specimens to the scientific community at large, generally with cost reimbursement or a requirement for scientific collaboration. Many holders of specimens, such as community hospitals and private pathology laboratories, are not able to make tissue available on request and these resources are not listed.

Cancer researchers who need additional help identifying sources of breast tissue specimens, or specimens from other tumor sites should contact the NCI Tissue Expediter.

Information about breast cancer clinical trials can be found on the NCI Cancer Trials website. The CancerNet contains a wealth of other information for cancer patients and the public, and also for health professionals.

disclaimer

NATIONAL CANCER INSTITUTE

# Current Database Contents

| RESOURCE | TISSUE TYPE(S) | OTHER DATA |
|---|---|---|
| **Dana Farber Cancer Institute**, Boston, MA | Frozen<br>Cell lines | Demographic<br>Clinical<br>Other |
| **Duke University**, Durham, NC | Fresh<br>Frozen | Demographic<br>Clinical<br>Outcome |
| **Georgetown University Medical Center and Lombardi Cancer Center and SPORE**, Washington, DC | Fresh<br>Frozen<br>Paraffin-embedded | Demographic<br>Clinical<br>Outcome |
| **National Cancer Institute of Canada - Manitoba Breast Tumor Bank**, Winnipeg, Manitoba, Canada | Frozen<br>Paraffin-embedded | Demographic<br>Clinical<br>Outcome |
| **National Surgical Adjuvant Breast and Bowel Project (NSABP)** | Paraffin-embedded | Demographic<br>Clinical<br>Outcome |
| **NCI Cooperative Breast Cancer Tissue Resource (CBCTR)** | Paraffin-embedded | Demographic<br>Clinical<br>Outcome<br>Other |
| **NCI Cooperative Human Tissue Network (CHTN)** | Fresh<br>Frozen<br>Paraffin-embedded | Demographic<br>Clinical<br>Outcome |
| **NCI Surveillance, Epidemiology, and End Results Program (SEER)** | N/A | Demographic<br>Clinical<br>Outcome |
| **New York University**, New York, NY | Frozen<br>Paraffin-embedded | Demographic<br>Clinical |
| **North Central Cancer Treatment Group Research Base at Mayo Clinic**, Rochester, MN | Paraffin-embedded | Demographic<br>Clinical<br>Outcome |
| **San Antonio SPORE - Familial Breast Cancer Registry and Gene Bank**, San Antonio, TX | Frozen<br>Paraffin-embedded | Demographic<br>Clinical<br>Outcome |
| **San Antonio SPORE - National Breast Cancer Tissue Resource**, San Antonio, TX | Frozen | Demographic<br>Clinical<br>Outcome |

| | | |
|---|---|---|
| **University of Michigan**, Ann Arbor, MI | Fresh<br>Frozen<br>Paraffin-embedded<br>Cell lines | Demographic<br>Clinical<br>Outcome |
| **University of Pennsylvania**, Philadelphia, PA | Fresh<br>Frozen<br>Paraffin-embedded<br>Cell lines | Demographic<br>Clinical<br>Outcome |

NEW DATA INFO MAIL OTHER MAIN
what's new database about suggest. resources home

NATIONAL CANCER INSTITUTE

# Breast Cancer Specimen / Data Resource

**Name:**
Dana Farber Cancer Institute

**Address:**
44 Binney Street
Boston, MA 02115

**Description:**
The Dana Farber Cancer Institute has established a population-based biological specimen and risk factor data bank on 225 invasive breast cancer cases, who were aged 34 and under. One-third of these exceptionally young study subjects are estimated by statistical analysis to be carriers of a susceptibility gene. These 225 women have been ascertained over 3 years through the tumor incidence registries in Connecticut, Massachusetts, and 7 regions in California, with a total population of 21 million (8% of U.S. women). This work was supported by the U.S. Army Medical Research and Material Command under DAMD-17-94-J-4450.

## CONTACT INFORMATION

**Type(s) of Specimens Available:**
Fresh blood specimens have been processed to produce:
- a lymphoblastoid cell line
- genomic DNA
- plasma
- viably frozen cells.

**Number of Specimens Held:**
225 cell lines and frozen blood specimens

**Other Available Data:**
- **Demographic:** Age, sex, race, ethnicity
- **Clinical:** Laterality (right, left, both breasts)
- **Other:** Age at diagnosis, medical history, family history, pregnancy and fertility, smoking, alcohol, prenatal

NOTE: All questionnaire data at this stage are unconfirmed.

**Researcher Requirements for Obtaining Specimens/Data:**
Breast cancer-related specimens/data are available or procured for distribution to outside researchers without restrictions related to collaboration. An outside advisory committee will

prioritize requests for specimens and risk factor data. All specimens sent to outside investigators
will remain stripped of identifiers.

**Procedures to Obtain Access to Specimens/Data:**
Contact Dr. Frederick Li or Katie Nicholls for further information.

**Costs to Researchers:**
Approved researchers will be required to pay for the costs associated with generating and
delivering all specimens, such as cell lines.

**Limitations of Specimen Use:**
No information that identifies an individual subject will be provided.

**Consent:**
Not applicable. Data provided will be non-identified.

**Date of Last Update:**
July 31, 1997