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Studies of Inherited Breast Cancer Genes

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FOREWORD

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*Frank O. Li* 10/3/97  
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PI - Signature Date

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## INTRODUCTION

Our purpose was 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 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<sup>1,2</sup>. Both States are in the high breast cancer-mortality belt that spans the Middle Atlantic and New England regions. California, the most populous 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 be 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 would be completed by year 4. At year 4, the announcement of the database will be kept on-line for e-mail accession, and specimens will be distributed worldwide to investigators with high priority studies. Despite initial obstacles, we are on schedule and the project will be 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<sup>3-10</sup>. 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<sup>3-5</sup>. 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 through the region. Many hospitals participate in joint cooperative clinical research protocols. The Cancer Surveillance Program also circulates a newsletter which 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 <sup>6</sup>. 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 Womens, 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. The remaining 1/3 of all cases will be contacted after they are reported to the Massachusetts Tumor Registry <sup>7</sup>.

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 a signed 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 <sup>3-5, 8-11</sup>. Cases either came to Dana-Farber, UC Irvine or Yale for phlebotomy or blood was drawn by their family doctor, oncologist or local health care facility. 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, requests will be prioritized by the Outside Advisory Committee. 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 have been contacted regarding their personal use of the resource to be developed under this proposal. Availability of the database and specimens is being announced on the Internet.

## CONCLUSIONS

All aspects of our study have been completed on time. Specifically, we have collected risk factor data from 225 patients under age 36, as stated in our Statement of Work. We have collected bloods from each of these 225 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. 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. Since this is an infrastructure grant, no publications were expected or produced.

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## **APPENDIX A**

### **PRELIMINARY SUMMARY OF QUESTIONNAIRE RESULTS**

DOD/EARLY BREAST CANCER STUDY SUMMARY OF RESULTS

DEMOGRAPHIC INFORMATION												
		COLLEGE				LIVING AS				OTHER		
EDUCATION	TOTAL	<8 YEARS	8-11 YEARS	12 YEARS	SOME COLLEGE	COLLEGE GRAD	MARRIED	DIVORCED	WIDOWED	MASTERS	MD, PHD, JD	OTHER
	261	0	8	52	82	79	14	3	23	3	1.1	8.8
%	100	0.0	3.1	19.9	31.4	30.3	5.4	1.1	8.8	1.1	0.4	3.4
MARITAL	SINGLE	MARRIED	SEPARATED	DIVORCED	WIDOWED	MARRIED	DIVORCED	WIDOWED	MASTERS	MD, PHD, JD	OTHER	
	261	181	5	19	0	11	11	11	11	11	11	11
%	100	69.3	1.9	7.3	0.0	4.2	4.2	4.2	4.2	4.2	4.2	4.2
RELIGION	BAPTIST	EPISCOPOLIAN	JEWISH	METHODIST	MORMAN	PRESBYTERIAN	PROTESTANT	CATHOLIC	UNITARIAN	OTHER		
	251	12	8	11	1	5	28	126	1	49	1	19.5
%	100	4.8	3.2	4.4	0.4	2.0	11.2	50.2	0.4	19.5	0.4	7.6
ETHNIC	WHITE	BLACK	HISPANIC	ASIAN	AMERICAN	OTHER						
	261	13	28	3	1	12	12	12	12	12	12	12
%	100	5.0	10.7	1.1	0.4	4.6	4.6	4.6	4.6	4.6	4.6	4.6
SPOUSE EDU	<8 YEARS	8-11 YEARS	12 YEARS	SOME COLLEGE	COLLEGE GRAD	MASTERS	MD, PHD, JD	OTHER				
	213	5	81	53	41	10	8	13	13	13	13	13
%	100	2.3	38.0	24.9	19.2	4.7	3.8	6.1	6.1	6.1	6.1	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	69	29	28	0	2	0						
BIRTH 4	26	13	13	0	0	0						
BIRTH 5	9	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	19	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	69	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	brethline & MGH	Macadan sen	Progesterone										
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	5	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	8	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	
			Augmenta tion	Reduction	Other					
BR PROCED			8	2	2					
			Self	Mamogram	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		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													15	16	17	18	19	20 to 24	25 to 29	30+	dk
MEN 1ST	9	10	11	12	13	14	15	16	17	18	19	20 to 24	25 to 29	30+	dk						
MEN REG AGE	8	12	40	74	69	35	12	6	2						3						
	2	10	20	46	36	39	25	19	9	15	4	9	0	3	15						
MEN REG		Natural	BC Pills	Other	Never reg																
		210	40	2	9																
HEIGHT 12		Much lower	Some what	Average	some what	much higher															
WEIGHT 12		18	38	100	57	48															
		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											

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

Alcohol	No	Yes	1 to 5	6to10	11to15	15to20	20+	Dont know
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 B**

### **RESOURCE ON NIH WEBSITE**



NATIONAL ACTION PLAN ON BREAST CANCER  
A Public/Private Partnership

## Breast Cancer Specimen/Data Resource

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**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

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**Parent document** within information database hierarchy [*Returns user to first screen.*]

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*Breast Cancer Specimen/Data Resource/ September 17, 1997* □