

**UNIVERSITY OF MASSACHUSETTS AMHERST  
HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD**

**Informed Consent Document**

**Study title:** Molecular Biomarkers for Assessing Breast-Cancer Risk

**Introduction to the study:** You are being invited to participate in a research study conducted by Dr. Kathleen Arcaro and supported by funding from the Congressionally Directed Medical Research Program. The purpose of this study is to attempt to understand what kinds of genetic changes are associated with various breast lesions including breast cancer. Some of the results of our study may be relevant to breast cancer risk. You have been asked to participate in this study because you are age 18 or older, nursing a baby and you have either had a breast biopsy **OR** your doctor may be considering a breast biopsy for a lesion identified on palpation, mammography, ultrasound or MRI. The study will continue until samples have been obtained from 250 women who have undergone breast biopsy. Since not all women who participate will ultimately have a biopsy, in order to meet our sample size goal, we may collect milk from as many as 500 women.

No accurate methods currently exist that will give women information about their personal risk of developing breast cancer risk. Knowledge of the changes associated with both breast cancer and other non-cancerous breast lesions will help in developing risk assessment information useful for all women.

We will use the cells naturally present in breastmilk to examine changes in DNA that occur in association with benign and cancerous breast lesions. In addition, we will save a portion of your milk for use in future studies aimed at understanding how other genetic changes and environmental exposures may affect breast-cancer risk.

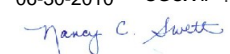
**What will happen during the study:** You will receive a box containing sterile bottles for milk collection, this Informed Consent Document, a Patient Eligibility form, a Questionnaire, and a prepaid return delivery label. You will be asked to complete this Consent Document and Eligibility forms and Questionnaire. The fresh milk samples should NOT have been previously frozen. You will donate two fresh breastmilk samples (one from each breast). The breastmilk samples, this Informed Consent Document, the Patient Eligibility form and the Questionnaire should then be placed back in the shipping container. You will then call the telephone number on the shipping label, ask for the milk box to be picked up at your home or another location convenient to you (work etc.). The shipping company will return your samples to our laboratory to study both the milk and the cells in the milk. Ideally we would like to collect at least 75 milliliters (or about 2.5 ounces) of fresh breastmilk from each breast. However, regardless of the amount of fresh breastmilk you can provide, we will be able to use your breastmilk sample and are grateful for your participation in the study.

After we have received your breastmilk sample, you will be contacted by one of the study researchers and asked if you have indeed had a breast biopsy. If you have had a biopsy you will contact your physician and ask for a copy of the biopsy report. We will be happy to assist you with this process.

Finally we will contact you approximately one year from the date on this Consent document to inquire whether you have been diagnosed with breast cancer in the intervening year. After that we will contact you annually with the same question. At any time you can ask to be removed for our contact list.

We will retain your milk sample for use in future research projects. If you prefer not to have your sample used for further research, you may notify Dr Arcaro (see e-mail below) and your milk sample will not be included in any future research.

**Who to go to with questions:** If you have any questions or concerns about being in this study you should contact Dr Sarah Lenington at 413 545-1037 ([slenington@sglbiiconsult.com](mailto:slenington@sglbiiconsult.com)) or Dr. Kathleen Arcaro at 413 577-1823 or at [karcaro@nre.umass.edu](mailto:karcaro@nre.umass.edu). If you would like to speak with someone not directly involved in the research study, you may contact the Office of Research Affairs at the University of Massachusetts Amherst via email ([humansubjects@ora.umass.edu](mailto:humansubjects@ora.umass.edu)); Telephone (413) 545-3428); or Mail (Office of Research Affairs, Research Administration Building, University of Massachusetts Amherst, 70 Butterfield Terrace, Amherst, MA 01003-9242).

<b>University of Massachusetts Amherst-IRB</b> (413) 545-3428	
<b>Approval Date:</b> 11-02-2009	<b>IRB #:</b> 08-41
<b>Valid Through:</b> 06-30-2010	<b>OGCA #</b> 108-1083
<b>IRB Signature:</b>	

Last Modified November 1, 2009

**How your privacy is protected:** Every effort will be made to protect your privacy. Your name will not be used in any of the research reports or publications prepared with results obtained from this study. All information obtained in the study that identifies who you are will be recorded with a code number. During the study the key identifying which code number goes with your information will be kept in a locked drawer. The only people other than the principal researchers who may have access to your medical information that is part of this study are members of the Institutional Review Board at the University of Massachusetts, and Representatives of the U.S. Army Medical Research and Materiel Command as part of their responsibility to protect human subjects.

**Risks and discomforts:** There are no known personal risks or discomforts associated with participating in this study. There is no way you will personally benefit from participating in this study. It is hoped that results from this study will benefit others in the future, particularly those at risk of developing breast cancer.

**Expenses:** There will be no expenses to you for participation in this study.

**Compensation:** You will receive \$25.00 to thank you for participating in the study when we receive the breastmilk sample. In addition, if we receive a biopsy report you will receive an additional \$25.00 to thank you for your assistance in providing this document.

**Your rights:** You should decide on your own whether or not you want to be in this study. You will not be treated any differently if you decide not to be in the study. If you do decide to be in the study, you have the right to tell me you do not want to continue with the study and stop being in the study at any time.

**Follow-up:** We ask that you kindly inform us should there be any significant change in your health or that of a family member (e.g. diagnosis of breast cancer).

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**PLEASE READ THE FOLLOWING STATEMENT AND SIGN BELOW IF YOU AGREE**

I have had the chance to ask any question I have about this study and my questions have been answered. I have read the information in this consent form and I agree to be in the study. There are two copies of this form. I will keep one copy and return the other in the package with my milk sample to Dr. Kathleen Arcaro.

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Signature

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Date

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Print Name

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Street Address

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Town

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State

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Zip code

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email address

<b>University of Massachusetts Amherst-IRB</b>	
(413) 545-3428	
Approval Date: 11-02-2009	IRB #: 08-41
Valid Through: 06-30-2010	OGCA # 108-1083
IRB Signature:	<i>Nancy C. Swett</i>

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