UNIVERSITY OF MASSACHUSETTS AMHERST
HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD

Informed Consent Document

Study title: Role of Pregnancy and Lactation in Inhibiting Age-Induced Promoter Hypermethylation

Introduction to the study: You are being invited to participate in a research study conducted by Dr. Kathleen Arcaro and her research assistants, Ms. Melissa Greven and Ms. Megan Wing, from the University of Massachusetts Amherst. The purpose of this study is to attempt to understand how first full-term pregnancy at different ages may alter the risk of breast cancer. Although we will not actually be studying breast cancer, some of the results of our study may be relevant to breast cancer risk.

Early pregnancy and lactation decrease a woman's lifetime risk of developing breast cancer. Little is known about the molecular mechanisms responsible for the protective effect of early pregnancy and lactation. Knowledge of the changes in the breast underlying this protection will help in developing preventative and therapeutic strategies for all women.

What will happen during the study: You will be asked to complete this consent form, a questionnaire, and to donate a fresh breast milk sample. The milk sample should include all the milk in at least one breast. You may pump all the milk from both breasts if you like, but this is not required. We will come to your home to pick up the milk sample which you may pump before we arrive (up to 12 hours in advance) or while we are there. We will then transfer the fresh breast milk to a sterile bottle and return to our laboratory to study both the milk and the cells in the milk. Ideally we would like to collect 100 milliliters (or about 3.4 ounces) of fresh breast milk from each participant. From our experience we have found that some women can provide 100 milliliters of fresh breast milk while other women can provide much less. Regardless of the amount of fresh breast milk you can provide, we will be able to use your breast milk sample and are grateful for your participation.

Who to go to with questions: If you have any questions or concerns about being in this study you should contact Dr. Kathleen Arcaro at 413 577-1823 or at 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); Telephone ((413) 545-3428); or Mail (Office of Research Affairs, Research Administration Building, University of Massachusetts Amherst, 70 Butterfield Terrace, Amherst, MA 01003-9242).

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 publication 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. When the study is finished the code that can link information to you personally will be destroyed.

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.

Compensation: You will receive $20.00 to thank you for participating in the study.

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).

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 to Dr. Kathleen Arcaro or her research assistants, Ms. Melissa Greven and Ms. Megan Wing.

_____
Street Address

_____
Town State Zip code

_____ _____
Signature Date

_____
Print Name

_____
email address

_____ _____
Signature of Witness* Date

*Witness signature is required only when the capacity of the subject to understand the description of the project and its associated risks is in question or when otherwise required by the Institutional Review Board.