University of Pittsburgh

School of Nursing

Addendum Consent
Genetic Variability and Postoperative Nausea Study

TITLE: Two year follow up to the Genetic Variability and Postoperative Nausea and Vomiting Study

PRINCIPAL INVESTIGATOR:

Susan W. Wesmiller, PhD, RN
Associate Professor
School of Nursing
440 Victoria Building
University of Pittsburgh
412-383-7270

STUDY COORDINATOR:

Caroline Harpel, MPH, CAPM
Research Manager
School of Nursing
440 Victoria Building
University of Pittsburgh
412-383-4707

SOURCE OF SUPPORT: National Institute of Nursing Research NR016695

Key Information

You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision. Your participation is completely voluntary.

The purpose of the Genetic Variability and Postoperative **research** study is to understand the trajectory of symptoms that are experienced by women following treatment for breast cancer, and determine if we are able to identify genetic predictors associated with the common symptoms of nausea and vomiting, and co-occurring symptoms such as fatigue, sleep disturbances, pain, and anxiety.

If you agree to participate, you will be called or emailed monthly and will be sent a saliva kit with instructions every six months for the next two years. We hope to have **200** women from the TINV study participate in the **two-year** follow up study.

Risks related to the study include those which are:

Less Likely: Risk of Breach of Confidentiality
Less Likely: Risk of Genetic Testing

There will be no direct benefit to you from participating in the study. However, this study will help doctors learn more about trajectory symptoms following breast cancer treatment and it is hoped that this information will help in the treatment of future patients with conditions like yours.

If you decide not to participate in this research, your other choices may include: Taking part in another study or doing nothing.
You are being invited to take part in this follow-up study because you participated or are currently a study participant in the GENETIC VARIABILITY AND POSTOPERATIVE NAUSEA AND VOMITING study. We found that many women continued to experience symptoms at the 12-month data

collection point; therefore, we would like to extend our data collection for two more years.

Overview of study procedures

1. Agree to be contacted every month for two years, either by email or by phone.

2. Complete short questionnaires (exactly like you have done for the TINV study) on nausea and vomiting and other symptoms such as sleep, fatigue, anxiety, and pain.

3. Send in a saliva sample every six months, just as you have done for the past year.

4. You will be paid $25.00 for each collection point.

The following rare, but foreseeable risks are associated with participation in this research study:

Risks of genomic testing:
There is a possibility that if the results of a research study involving genetic material were to become generally known, this information could affect one's ability to be insured, employed, affect future plans for children, or family relationships.

There is a risk of breach of confidentiality: that is, in very rare cases, people not associated with this research study may inadvertently see the identifiable research results.

Specimens and all other data will be stored to include unique code numbers. All identifiers are removed from study records. Biological specimens will be kept for an indefinite period of time in the genetics laboratory in the School of Nursing. The samples will not include any personal identifiers (for example name or social security number) and will include only the assigned code number. Information linking these code numbers to the corresponding subject identities will be kept in a separate secure location. Should you decide to withdraw from the study, (instructions on how to formally withdraw from the study are at the end of this consent) you can request that the specimens collected are destroyed. However, if you agree to the continual storage and testing of specimens, the code linking you to the specimens will be eventually destroyed.

Sharing Data and Samples
Your research data and samples may be shared with investigators conducting other research; this information will be shared without identifiable information, and may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize. Individual results from this pilot study will not be shared with study participants.

Genetic Information Nondiscrimination Act
In addition, there is a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), that generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This new Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

Foreseeable expected benefits
There are no individual benefits from participating in this study, except to know that you are contributing to our knowledge of symptoms experienced in the three years following original treatment for breast cancer. Because this study does not include treatment, there are no alternative treatment procedures.

VOLUNTARY CONSENT
Your participation in this research study is completely voluntary. Whether or not you participate will have no effect on your current or future relationship with the University of Pittsburgh, Magee Women's Hospital or its affiliated health care providers or health insurance providers, or your participation in the Genetic Variability and Postoperative Nausea and Vomiting study. If you decide you no longer wish to participate after you have signed the consent form, you should contact Dr. Wesmiller at 412-383-4707. You may also withdraw at any time your authorization to allow the research team to review your medical records, but if you do, you will no longer be able to participate in the study. Any information and samples obtained from you up to that point would, however, continue to be used by the research team. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh or with UPMC or its affiliate health care and insurance providers.

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by Dr. Wesmiller who is listed on the first page of this form.

Any questions, which I have about my rights as a research participant, will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____
Participant's Name

_____ _____
Participant's Signature Date

Please select one.

☐ I would like to complete my monthly surveys via **email.**

Email address: _____

☐ I would like to be **called** by a study team member to complete my monthly surveys.

Preferred phone number: _____

Best days/times to call: _____

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date