Informed Consent for Participation in a Research Study

Title of Research Study: Prospective observational study of associations between diet, hepcidin, and relative dose intensity among women receiving chemotherapy for breast and gynecological cancer

Investigator: Kim Robien, PhD, RD, Associate Professor, Department of Exercise and Nutrition Sciences, Milken Institute School of Public Health, George Washington University

Key Information:

You are being asked to take part in a research study about diet, blood cell counts, and chemotherapy tolerance during treatment for cancer. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to understand how what people usually eat before starting cancer treatment is related to proteins in the blood and an individual's ability to tolerate chemotherapy. The study will also evaluate whether any of these blood proteins are related to risk of anemia during chemotherapy.

If you decide to participate in this study, you will be asked to complete a 45-60 minute baseline questionnaire during one of your office visits. You will also have some extra blood drawn at the same time that you will be having blood drawn for your regular cancer care. After you begin receiving chemotherapy, our study staff will collect information from your medical record about your prescribed chemotherapy and how your body responds to the treatment. All of the study activities will occur during your regular clinic visits, and you will not need to make any additional trips to the Cancer Center. Participation in this research study should require less than one hour of your time.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

In this study, we will simply be observing and recording your experiences during chemotherapy, so your participation in this study will not change anything about the treatment you will receive. However, by participating in this study, you may help to improve care for people who will be receiving the same treatment in the future. For a complete description of benefits of participating in this study, please refer to the Detailed Consent.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The potential risks associated with this study include being inconvenienced by the time required to complete the study survey, pain or discomfort with collecting samples of your blood, and the potential for disclosure of confidential data from your medical record. For a complete description of risks of participating in this study, please refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

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WHAT IF YOU HAVE QUESTIONS OR CONCERNS?
The person in charge of this study is Dr. Kim Robien, PhD, RD. If you have questions, suggestions, or concerns regarding this study, or if you decide that you want to withdraw from the study after starting in the study, you can talk to her at 202-994-2574 or via email at krobien@gwu.edu.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Detailed Consent Form:

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are female, 21 years of age or older, have been diagnosed with breast, ovarian, fallopian tube, primary peritoneal or endometrial/uterine cancer, and you are scheduled to receive chemotherapy.

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GW. If you decide not to take part, you can still receive medical care from GW.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator, Dr. Kim Robien, at 202-994-2574 or by e-mail at: krobien@gwu.edu.
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Why is this research being done?

The purpose of this study is to determine how your diet affects proteins in your blood, and how those proteins affect your ability to receive all of the chemotherapy you are prescribed. The study will also evaluate whether any of these changes are related to blood cell counts during chemotherapy.

How long will I be in the study?

We expect that you will be in this research study for the duration of your chemotherapy plus one month.

How many people will take part in this research study?

We expect about 100 people will take part in the entire study.

What happens if I agree to be in this research?

If you agree to participate in this study, you will be asked to complete an initial 45-60 minute baseline study visit. This visit will occur during one of your regularly scheduled clinic visits before chemotherapy begins. During this visit, you will be given one short questionnaire that asks you about yourself, and one longer questionnaire that asks you about what you ate during the previous month. You will use an iPad supplied by the clinic to complete the questionnaires. When the nurse draws your blood for your doctor's labs, she will draw two extra tubes for research use.

After the first visit, you do not need to do anything else for the study. Research staff will review your medical record to record your blood cell counts and chemotherapy records for the study until one month after you finish your chemotherapy course.

What other choices do I have besides taking part in the research?

Instead of being in this research study, you can choose not to participate in the study. This will not affect the clinical care you receive for your breast or gynecological cancer.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you decide to leave the study before completing all the study visits, please notify Dr. Robien of your decision in writing, either by e-mail: krobien@gwu.edu, or by mail:

Kim Robien, PhD, RD
Department of Exercise and Nutrition Sciences
Milken Institute School of Public Health
George Washington University
950 New Hampshire Ave, NW
Washington, DC 20052

The investigators will be allowed to use the data that has already been collected, but will not collect any additional data from you after receiving your written request to leave the study.

Is there any way being in this study could be bad for me?

The risks and discomforts associated with participation in this study are not greater than those ordinarily encountered during the performance of routine blood draws or surveys. Potential risks associated with participation in this study include:

1. You may find the time needed to complete this research study to be an inconvenience.
2. This study will require additional blood to be collected during a regularly scheduled blood draw. Blood draws may result in pain at the site of the blood draw, bleeding, bruising, fainting,

anemia, infection and/or hematoma (blood clot) at the site. We will not conduct blood draws solely for research purposes and will only collect additional blood when you are already having one done. Clinical staff collecting the blood are trained in blood draw procedures to minimize risks of adverse events during the blood draw.

3. We will ask you questions about the foods you have eaten during the month prior to your diagnosis. We will also ask questions about your race/ethnicity, level of education, stress, smoking, exercise, and who lives in your household. Finally, we will ask what times you eat and sleep, and whether you have had difficulty affording food or other household bills. If you find the questions emotionally distressing, you can skip that particular question and continue the survey.
4. The researchers will need to collect additional data from your medical record. This information will be recorded using a study identification number, rather than using your name or other identifying information (such as social security number or birth date). The data will be stored in secure, password protected electronic files, and only study staff who need the information in order to conduct the study will be allowed to access your information. While every effort will be made to secure your data, we cannot guarantee that the data will not be accidently released.

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the risks involved in participating in this study, and the blood draw and surveys you will be asked to complete are unlikely to result in injuries or illness. However, if you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

You will not receive any financial payments from GWU and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. By participating in this study, you will be contributing important information for improving care for people who will be receiving the same chemotherapy treatment in the future.

What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who need to review it in order to conduct the study. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information.

Specimen collection for Research

Research using blood samples is an important way to try to understand human disease. You have been given this information because the investigators want to include your blood samples in a research project, and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your blood samples will be stored in a locked freezer in the GW Science and Engineering Hall for up to 6 years after completion of this study. The samples will be labeled with a study identification number, and will not be labeled with any identifying information, such as your name or birthdate. Only the members of the research team will have access to the link between the study identification

number and any of your identifying information, and that file will be kept in a secured, password protected electronic file. The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

Allowing researchers to save your blood for additional analysis is optional. You can choose whether or not you want to allow your specimens to be used in future studies. You may withdraw from this portion of the study at any time.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

Tissue Sampling for Genetic Testing

As part of the future analysis on your samples, the investigators may do genetic testing to evaluate whether a person's genes alter how the body produces proteins in the blood, and whether genes alter an individuals' ability to tolerate chemotherapy. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

The researchers can extract DNA from the blood sample that you will provide for the main portion of the study; no additional blood draw is required for this portion of the study. Allowing the researchers to extract DNA from your stored blood sample for these additional analyses is optional. You can choose whether or not you want to allow your specimens to be used for these genetic studies, and you may withdraw from this portion of the study at any time.

_____ I consent to my samples being used for genetic research

_____ I do not consent to my samples being used for genetic research

May we contact you about future studies that may be of interest to you? ____ Yes ____ No

How will my privacy and health information be protected?

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The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form.

The use and release of protected health information is for the purpose of collecting data for this study. Protected Health Information to be shared: *age, height, weight, diagnosis, other health conditions you may be experiencing, the treatment that you received, whether you experienced infections, disease status, and laboratory data.*

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from the GW Medical Faculty Associates and GW Cancer Center

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team
- Institutional officials who are responsible for compliance

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

This Authorization does not have an expiration date.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.

To cancel your permission, you will need to send a letter to Dr. Kim Robien stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

Kim Robien, PhD, RD
Department of Exercise and Nutrition Sciences
Milken Institute School of Public Health
George Washington University
950 New Hampshire Ave, NW
Washington, DC 20052

Are there any costs for participating in this research?

There are no costs associated with participating in this study. The costs for all tests will be paid by the researchers and will not be charged to your insurance.

Will I be paid for my participation in this research?

You will receive $50 to compensate you for the time it takes to participate in this study.

The research team will use a system called Forte Participant Payments to manage payments to research participants. The system offers 3 payment options:

1. Reloadable debit / credit cards. When selected, funds are available on the same business day. If you choose to receive a reloadable debit/credit card, as per the cardholder agreement, there are some restrictions on the use of the card.
2. Electronic deposits into your bank account. You define your bank account via a banking portal provided to you via email. When selected and appropriately defined, the funds are available within 3 business days. To use this method you will need to provide your bank account information to Forte.
3. Paper check mailed to you. You define this method via a banking portal provided to you via email. When selected and appropriately defined, a paper checks require 3 days to process plus delivery time.

All three options require the collection of your name, date of birth and gender. If you choose payment option 2 or 3 you will need to provide your email address to the research team.

The payment method selected will be associated with your participant record. If you enroll in other studies at the university (or the GW Medical Faculty Associates) that use the Forte Participant Payment system, payments from those other studies will be made using the same payment method (same card, bank account information or paper check mailing address) that you choose.

If you choose to use a reloadable card, Forte Participant Payments may disclose information to third parties about the card or the transactions you make:

(1) Where it is necessary for completing transactions;

(2) In order to verify the existence and condition of the card for a third party, such as a merchant;

(3) In order to comply with government agency, court order, or other legal or administrative reporting requirements;

(4) If you consent by giving us your written permission;

(5) To our employees, auditors, affiliates, service providers, or attorneys as needed; or

(6) Otherwise as necessary to fulfill our obligations under the card holder agreement (provided separately)

Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____

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Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of person obtaining consent Date