The Ohio State University Consent to Participate in Research

Study Title: **The Heart Study: Heart Health in Breast Cancer Survivors**

Principal Investigator: Janice Kiecolt-Glaser, PhD

Sponsor: **National Cancer Institute**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

Chemotherapy treatment can increase the longer-term risk for heart disease in some breast cancer survivors. This study tests how chemotherapy and other cancer treatments may affect the way your body metabolizes (processes) a high-fat meal. Additional factors related to heart health will also be measured. The researchers will study your body's response to a fast-food-type meal by measuring triglyceride levels (fat in the blood), immune responses (certain kinds of white blood cells), heart rate, and blood pressure. The goal is to see if responses before cancer treatment differ from those after cancer treatment. Specifically, the researchers want to know if these meal responses are related to the type of treatment you receive, your level of physical fitness and any changes in fitness following cancer treatment, emotional distress, and/or the buildup of calcium deposits in the blood vessels surrounding your heart, a risk factor for heart disease. In doing so, our study will contribute to knowledge about the long-term health of breast cancer survivors.

2. How many people will take part in this study?

180 breast cancer survivors will take part in the study, including both women who receive chemotherapy treatment as well as women who will not receive chemotherapy treatment.

3. What will happen if I take part in this study?

You will be scheduled for two visits after you have had your breast cancer surgery. If you are being treated with chemotherapy, the two visits will occur before you start chemotherapy or radiation treatment. If you are not being treated with chemotherapy, the visits will occur within one to two months after your surgery but before any radiation treatment. The first visit is a full-day visit that will take place at the Clinical Research Center (CRC), a hospital research unit located at the OSU Wexner Medical Center. The second visit will last 2.5 to 3 hours and take place in two locations, the Davis Heart and Lung Research Institute and the OSU Ross Heart Hospital; we will provide transportation between the two if needed. All visits will occur on weekdays.

You will then be scheduled for two more visits approximately two years after the completion of your cancer treatment. If you did not receive chemotherapy treatment the visits will occur about two years after your surgery and any radiation treatment.

Informed Consent will be obtained prior to CRC Visit #1, during pre-visit meal delivery					
Visit	CRC Visit #1	Exercise test/ Cardiac CT #1	1 Year Follow up	CRC Visit #2	Exercise test/ Cardiac CT #2
Length	9.5 hours	2.5-3 hours	1-1.5 hours	9.5 hours	2.5-3 hours
Timing	About 4-8 weeks post-surgery , but before starting any chemotherapy or radiation	After CRC Visit #1, before starting any chemotherapy or radiation	About 1 year after completion of cancer treatment (except hormonal therapies)	About 2 years after completion of cancer treatment (except hormonal therapies)	Ideally within about a week before or after CRC Visit #2
Activity	Blood draws Fast-food-type meal Questionnaires Metabolic Measurements Computer tasks Heart Rate/blood pressures	VO2 max test (exercise bike) Cardiac CT for calcium scoring	2 food recall interviews, telephone questions about memory and concentration Diet History Questionnaire	Blood draws Fast-food-type meal Questionnaires Metabolic Measurements Computer tasks Heart Rate/blood pressures	VO2 max test (exercise bike) Cardiac CT for calcium scoring

In preparation for the full-day visits:

Before your first full-day visit, you will be tested for anemia (a condition characterized by too few red blood cells, usually resulting in tiredness), indicated by your level of hemoglobin (an iron-rich protein that helps red blood cells carry oxygen throughout the body). You will not be tested if you have already tested negative for anemia in the past 12 weeks according to your electronic medical records. Otherwise, we test your hemoglobin levels using a drop of blood from a small finger prick. If we are not able to obtain an accurate hemoglobin reading from the finger stick, you will have 5ml (less than a tablespoon) of blood drawn from a vein in your arm. If you are anemic before CRC Visit 1, you will not be able to participate in the study; you will be compensated $5 for your time and you will be advised to consult with your physician.

Prior meals, recent exercise, and recent alcohol use can affect your body's responses to subsequent meals. To limit differences related to these factors, you will be given three standard meals prepared by the Clinical Research Center to eat the day before each of your two full-day visits. You will be asked to eat these prepared meals and nothing else on those days. You will also be asked to refrain from consuming alcohol for 24 hours before each full-day visit, and you will be asked to avoid any strenuous physical activity for the two days before each full-day visit. If you have been instructed by your physician to take aspirin daily, you can continue to take it; otherwise, you should refrain from taking aspirin for the 7 days prior to each admission.

You cannot eat anything after 7:30 PM on the night before the two visits. However, you are free to drink as much water as you want, and you should take any prescription medications as scheduled. You will be given a full meal as soon as your first blood sample has been drawn on each visit. At both visits, you will receive a meal that resembles a typical fast-food meal in terms of its nutritional content (it is high in saturated fat). You will need to eat the entire meal within 20 minutes each time. If you are not willing to eat the required food, or are unable to eat the required food due to food allergies, you will not be able to participate in the study. You will receive water but not any other food or drink during the next 7.5 hours after you finish the meal.

You provided information about medications and current physical problems when you were scheduled for this study. If you have started taking any new medications or have developed any significant health problems, you must inform the researchers immediately.

Full-day visits:

Recent illness can affect your body's immune response. If you have a temperature greater than 99.7°F when you arrive to the CRC, we will cancel the session and reschedule for a later date.

At the beginning of each of your full-day visits, a catheter (a small, hollow plastic tube) will be inserted into a vein in your arm so that small amounts of blood can be drawn at different times across the visit, unless you already have a central line or mediport that can be used

instead. If a catheter is used, it will be removed at the end of each visit. You will have a total of 240 ml (1 cup) of blood drawn during each of the 9½ hour visits. At the end of the research day a final teaspoon of blood will be drawn from your arm which does not have the catheter inserted; this is to confirm that immune changes are not just reflecting local changes at the catheter site. A total of 480 ml of blood (2 cups) will be drawn across both study visits. These samples will be used to examine the blood levels of hormones and immune function indicators.

At each visit, a nurse will place a Polar™ band or similar sensor that wraps around your chest to assess your heart rate. You will be asked to time your breathing to a pre-recorded tape for five minutes in order to help us better understand how your normal breathing affects your heart rate. Throughout your full-day visits, nurses will monitor your blood pressure, heart rate, and body temperature.

During both of the full-day visits you will complete questionnaires and interviews that include personal questions about mood, feelings, health behaviors, health, and personality; the interviews will be audio-recorded. You will also be asked to perform several tasks on the computer and with the research assistant, including tests that measure aspects of concentration and memory. You will be asked about depression and anxiety symptoms that you have experienced over your lifetime and this interview will be audio-recorded so that interview responses can be formally coded; all digital recordings will be kept in our password-protected computer system. At the end of the first appointment, as part of standard procedures, you will be provided with a list of psychological counseling services should you wish to talk with someone at that time or in the future about any problems you are having.

Body composition (fat tissue mass and lean tissue mass) will be assessed using a DEXA (dual x-ray absorptiometry) machine at each full-day visit. You will be asked to wear clothing with minimal metal, remove all jewelry, empty your pockets, and take off your glasses and shoes before lying down on the DEXA table. You will be instructed to remain still in position on the DEXA table while being scanned for 15-20 minutes. If you are a woman of childbearing age, you will be asked to provide a urine sample for a pregnancy test prior to participation in the study. If you are pregnant or nursing or you become pregnant, you will not be able to participate.

At several times during both visits you will be asked to talk out loud into a tape recorder for a minute or two about your thoughts about your health, the study, the setting, the experimenter, or other things you may have been thinking about during the study. Researchers will not be present while you record your thoughts. These tapes will be used to assess your reactions to different parts of the study, and your thoughts about your health.

You will provide 16 saliva samples to measure how hormones related to the immune response may have changed during each of the full-day visits. For this purpose, you will put a piece of dental cotton in your mouth for 1-2 minutes each time to saturate the cotton.

During both visits your metabolic responses to the fast-food-type meal will be measured 6-8 times. For this purpose you will lay in a hospital bed with a facemask that covers your nose and mouth for about 20 minutes each time. During these times, you will be asked to lay still and breathe normally.

To provide a uniform experience during parts of the visits, you will be asked to watch DVDs of nature shows or documentaries. During the time you are in the CRC, you will only be able to use your cell phone to make or receive calls or e-mails at set times. In the case of an emergency, however, your family will be able to reach you at 614-293-8750.

We will get information from your doctor's treatment records about the tests you have had for your breast cancer, as well as information on the type of breast cancer, the stage, and the treatment you received, any current medications, and other health conditions so we can see if these are related to your immune responses.

Before or after your second full-day visit, in order to assess your typical food intake, you will be called three times within a 2 week period by our research assistant and asked to list all the foods you ate in the last 24 hours. These interviews will last 15-30 minutes.

Exercise Test/Cardiac CT visits:

On one of the days before or after your full-day visit, you will complete a brief (6-10 minute) exercise test on a bicycle. This test will help researchers measure your fitness level. The test will be completed at the Ohio State Davis Heart and Lung Research Institute.

The test (a graded cycle ergometry exercise test) will be supervised by an exercise physiologist (an expert trained to determine your fitness level). You will be asked to get permission from your primary care physician or surgeon or oncologist before participating in this activity. Sensors will be attached to your chest for heart rate measurements. You will rest quietly for 15 minutes before and after the test. Then, you will sit on an electronically braked bicycle. The speed and workload (strength needed to pedal) will begin at a level that can be easily accomplished, and will gradually increase depending upon your abilities. The speed and workload will be increased until your heart rate is within 85% of your age-predicted maximal heart rate, or until you cannot continue the exercise. It is *not* desired that you exercise at a level that is abnormally uncomfortable; however, you should exercise as long as is reasonably comfortable. You may stop the test at any time. While exercising, you will wear a snorkel-like mouthpiece with a breathing valve. This mask collects the gas that you are breathing out, and helps researchers to measure your level of cardiorespiratory fitness. Your heart rate and blood pressure will also be monitored before, during, and after the test. You can signal the exercise physiologist to stop the test if you become too fatigued or decide to stop, or if other symptoms prevent you from exercising further

You should not have any caffeine on the day you have the exercise test. You may eat a light meal up to 2 hours before the exercise test, but you should not eat within 2 hours before the test.

In order to measure hand strength, you will be asked to squeeze an instrument that measures your grip strength during the same appointment in which you will complete your exercise test.

On the same day as the exercise test, you will have a computerized tomography (CT) scan to measure the amount of calcium in the blood vessels surrounding your heart. This test measures the amount of calcium in the blood vessels surrounding your heart, which can help determine risk for coronary ("heart") artery disease. The cardiac CT scan procedure will take place at the Ohio State Ross Heart Hospital.

The scan is similar to an x-ray of the heart, which uses radiation to produce the images. A multi-slice computed tomography (MSCT) scan of your heart- generally known as a cardiac CT- involves lying flat on a table that slides into a short round CT scanner. To get ready for the procedure, you will be asked to remove jewelry (especially necklaces). You will also be asked to remove your bra due to metal fasteners, and you may be asked to slip into a gown. Before undergoing the actual scan, the technician will clean areas of your chest and apply sticky patches with sensors called electrodes. The patches are connected to an EKG (electrocardiogram) machine. Contrast agent/medium, a type of dye sometimes used to clarify the scan, will not be administered. The technician will give you instructions through speakers, including asking you to hold your breath for a few seconds at a time. While the scan itself only takes a few minutes, the visit may involve up to 30 minutes of your time including registration and setup.

<u>If you are pre-menopausal and there is any chance you might be pregnant</u>, we need to be sure that you are not pregnant before you have the CT scan. Directly before your scheduled cardiac CT, you will come to the Clinical Research Center to provide a urine sample for a pregnancy test. The sample will be processed immediately. This test is performed to protect pregnant women from being exposed to radiation from the CT scan. The test detects hormone levels in the body that are associated with pregnancy. You will be informed of the results of the pregnancy test immediately. If you are pregnant you will be encouraged to follow-up with your physician and will not be able to complete the cardiac CT scan at this time and you will be compensated $5 for your time (as well as free parking for all participant visits).

<u>If you are post-menopausal</u>, you will not have a pregnancy test.

Genetic studies: The study will also investigate how differences in genetic material (DNA and RNA) may be related to a woman's cardiovascular (heart), immune, and metabolic responses. The researchers are trying to determine if particular genetic markers (certain characteristics of a person's DNA) are associated with changes in cardiovascular, immune, and metabolic responses in comparison to individuals who do not have the same genetic markers. The researchers will use frozen samples of your white blood cells as one source of DNA, as well as saliva samples.

No medical report will be added to your medical records based on this testing or any other part of your research participation. Your sample will not have identifying information such as your name, initials, or address on it, only a code number. The specimens for testing will be

stored with the same code number that is used on all the questionnaires and other forms you have completed; the results of the testing will be kept confidential and will not be released. Names and other identifying information will be kept separate from the samples. The samples that do not have any identifying information other than your subject number may be sent to UCLA or another institution for analysis. No identifying information will be in any publication or reports; only group results, with no personal code number or other identifiers, will be reported. Scientists working with your DNA samples will not have access to any identifying information. The researchers for this study will store your DNA samples in a secure room with limited access.

Neither you nor your doctor will receive the results of your DNA testing. If you decide that you want to pursue genetic testing in the future based on results reported for this study, it will be at your expense and you will be referred to the genetic testing and counseling services in the OSU Medical Center. It may be a long time (months or years) before results from this study are available. In the unlikely event that any profitable discoveries are made using your biological material, you will not receive any personal financial benefit. If there are any patent or commercial uses of your DNA data, any identifiable information linking the data to you will be destroyed (e.g. your name, address, phone number, and social security number).

You can decide not to participate in the genetic portion of this research study but still be able to take part in the main research study.

____ I wish to participate in the genetic portion of this research study

____ I do NOT wish to participate in the genetic portion of this research study

One year followup:

At about one year after completion of cancer treatment except for hormonal therapies, you will be called twice and asked to recall the foods you ate in the past 24 hours and each interview will take 15-30 minutes. During one of the phone calls, you will also be asked questions to measure memory and concentration. You will also be asked to complete an online food frequency questionnaire that will take approximately one hour.

After data collection for this study is completed, the researchers may keep track of the people who participated in this study by using public vital statistics records for the next 15 years.

4. How long will I be in the study?

Your participation will be completed in about 2 – 3.5 years, depending on the length of your cancer treatment as well as the schedules of the CRC and project staff. After your breast cancer surgery but before any chemotherapy treatment, you will participate in a full-day visit at the CRC and a 2.5 hour visit that will include the exercise test and cardiac CT scan. Two years after your cancer treatment, you will participate in another full-day visit at the CRC and another 2.5 hour visit during which you will complete exercise test and cardiac CT scan. There are a total of 2 full-day sessions at the CRC and two sessions that include exercise testing and cardiac CT for calcium scan that will take 2.5 hours each. Before the second full-day visit you will be called three different times and asked to recall the foods you ate in the

past 24 hours and each interview will take 15-30 minutes. The one year follow up interviews and questionnaire will take approximately 1 – 1.5 hours to complete. The total anticipated participation time for all 4 visits and the interviews is 27.5 – 29.5 hours.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. In addition, your study participation can be stopped without your consent if you cannot eat the full meal within the time limit or if we cannot obtain blood samples.

You can withdraw from this study at any time and withdraw your consent for the use of your white blood cells for genetic research. Upon withdrawing consent, your samples for genetic research will be destroyed if they have not already been used; identifiers that would link it to you will be destroyed, that is, your name, address, phone number, and social security number. Any results obtained prior to your withdrawing from the study will be part of the overall study results.

6. What risks, side effects or discomforts can I expect from being in the study?

For questionnaires, interviews and computer tasks: Personal questions may make you uncomfortable or could produce stress. Should you reveal that you are feeling suicidal, the researchers are required to evaluate risk and may contact appropriate authorities if you appear to be at imminent risk for harm to yourself or others.

For the blood draws and the catheter: You may experience bruising at the draw site, infection, pain, fainting, and redness. These are risks that occur whenever blood is drawn. There is a minor risk of an allergic response to the tape used to hold the catheter in place that may include redness or a rash, swelling, small blisters, itching, and discomfort on the arm where the skin was covered by the tape. There is also a minor risk of anemia (a condition characterized by too few red blood cells, usually resulting in tiredness) associated with having your blood drawn.

For blood pressure and heart rate: You may experience mild discomfort from the blood pressure cuff that will be used approximately every hour. You may feel some skin irritation at the site where the adhesive sensors are removed, much like you experience when you pull off Band-Aids from your skin.

Incidental findings from routine hospital blood analyses: Any potentially abnormal results from the hospital lab data (blood cell count and triglycerides) will be first discussed with Dr. Malarkey, the Director of the CRC and a physician on the study, to confirm the nature and seriousness of the problem; if there appears to be reason for concern, you would be informed of the abnormal value and advised to seek treatment from your personal physician. Neither you nor your doctor will receive the results of the immune or hormone tests unless the results appear potentially abnormal.

For the full-day CRC visits: You will receive a meal near the beginning of Visit 1 and 2, but no food or drink except water over the next 7 hours; because most people typically eat every 4-5 hours, you will probably be hungry during the latter part of your visit. We will offer you a snack at the end of your visit.

For the meals: During both full-day visits, you will eat an unhealthy meal high in saturated fat, similar to what you might receive nutritionally if you ordered a Big Mac cheeseburger, a medium-size French fries, and a medium chocolate milkshake from McDonald's.

For the DEXA scan: If you take part in this research, you will have two medical imaging procedure (DEXA) which uses radiation, in order to get a lean body mass measurement. To give you an idea about how much radiation you will receive, we will make a comparison with an every-day situation: A single DEXA scan produces a very small amount of radiation, approximately $1/10^{th}$ of that experienced during a cross-country air flight or $1/120^{th}$ of what you would experience during a dental scan.

Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 7 extra days' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests.

This procedure will not add to the risk of the research. However, if you have concerns about the total radiation exposure, you should discuss them with your physician.

Cardiac CT Calcium scan: You will be exposed to a small amount of radiation which occurs with any type of x-ray. The cardiac CT uses radiation to produce the images. The equipment and scanning techniques are perfected so as to ensure that exposure to x-rays is at a minimum. If you take part in this research, you will have 2 cardiac CT scans for calcium scoring which use radiation at least 2 years apart. To give you an idea about how much radiation you will get, we will compare it to the amounts that people encounter in daily life. There is radiation that naturally occurs from space and from rocks in the soil. This natural radiation is greater at higher altitudes. This research gives you about the same amount of radiation as you would get from living in a high altitude city such as Denver for 5 weeks, or taking 13 airplane flights from New York to Los Angeles. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may have received or will receive from other tests.

For the exercise test: You may feel tired or short of breath after the test. You may experience other physical changes associated with exercise, such as temporary muscle aches or joint pain. There is a remote risk that you may experience abnormally high blood pressure or heart rhythm disturbance during exercise, and in rare instances, heart attack, stroke, or death. An exercise physiologist will supervise the tests, and a physician will be available on-site; every

effort will be made to minimize the occurrence of these problems (including stopping the test when necessary). Emergency equipment and trained personnel will be available to deal with any unusual situations that arise.

For genetic testing: Because you will not be receiving your personal results from this study, most of the usual psychological risks associated with genetic testing do not apply to you. If you decide, at your expense, to undergo clinical genetic testing in the future based on discoveries made as part of this study, the risks of receiving genetic test results will be discussed with you at that time.

The results of the testing will be kept confidential to the fullest extent possible. Although the specimens will be stored with a code number, if this confidentiality were broken, a researcher could learn something about you that you do not want them to know (i.e., name, address, or other personal information you do not want them to have).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

•Health insurance companies and group health plans may not request your genetic information from this research.

•Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility or premiums.

•Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under Ohio law, health insurance companies cannot ask about the results of a genetic test or use any information obtained from genetic testing to make decisions about providing coverage or benefits for health care services.

7. What benefits can I expect from being in the study?

You will receive a report of the results of your CT scans. You are encouraged to share these results with your doctor, who may be helpful in determining your heart disease risk.

You will receive a report based on your answers to the diet questionnaires and interviews. The report will tell you about your eating patterns, such as how closely your number of servings in each food group consumed daily matches USDA recommendations. In addition,

this report will show your average daily intake of different nutrients and recommendations for improving your diet.

You will receive the results of your exercise tests. The results obtained from the exercise test will provide you with information about your physical fitness, cardiorespiratory endurance, and your ability to sustain prolonged exercise related to others in your age group.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

There are no costs if you take part in this study. All procedures are paid by the study, and participants do not pay for any procedures.

11. Will I be paid for taking part in this study?

You will be compensated for your time. You will receive $250 for completing the 1st full-day CRC visit, $50 for the follow up exercise test and $25 for the cardiac CT scan. Two years after your cancer treatment, you will again receive $250 for the full-day CRC visit, $50 for the follow up exercise test and $25 for the cardiac CT scan. You will receive $15 for completing the 1 year follow up questions. Therefore, you will have an opportunity to receive a total of $665. If you are not able to complete the full day visit, your payment will be pro-

rated based on the percentage of the visit that you actually completed. Payment will be sent after completing your 2 pre-treatment visits and again after completing your 2 post-treatment visits; a check in the appropriate amount will be mailed to you, usually within 2-4 weeks of each phase of study completion. If you do not receive your check within 4 weeks after each of these phases of study completion, please notify the researchers.

By law, payments to subjects are considered taxable income.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the study coordinator at 614-293-4736.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Janice Kiecolt-Glaser, PhD at 614-293-3499 or William Malarkey, MD at 614-293-8775.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time

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