The Ohio State University Consent to Participate in Research

**Study Title:** Marriage, Fast Food, Stress, and Inflammation. The COUPLES FOOD Study  
**Principal Investigator:** Janice Kiecolt-Glaser, PhD  
**Sponsor:** National Institutes of Health

- **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?

Fast food meals often have high levels of saturated fats (from meats, dairy products, chips, and pastries). This study is designed to help understand important differences in your body's responses when you eat a fast-food-type meal compared to a healthier meal. The researchers will measure certain stress hormone responses, aspects of your immune system, your heart rate and blood pressure, cholesterol, and triglycerides to see if your responses to the two meals differ in ways that could promote obesity and heart disease. In addition, the researchers want to know if involvement in a marital problem discussion, as well as mood and weight contribute to these changes.

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

100 couples, for a total of 200 participants.

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

Couples will be scheduled for a screening appointment and two nonconsecutive full-day visits to the Clinical Research Center (CRC), a hospital research unit. All visits will occur on a weekday between 7:30am and
5:00pm. In order to assess your typical food intake, you and your spouse will have two telephone interviews between the two full-day visits and be asked to list all the foods you ate in the last 24 hours. These interviews will last 15-30 minutes each.

You will first participate in a screening appointment which will last approximately 2 hours to determine if you are eligible to take part in the full study. Couples do not need to attend the initial screening visit together, but all other appointments must be scheduled together. At this appointment, a nurse will measure your weight, height, blood pressure, and the distance around your hips and waist. A measurement will also be performed to assess the amount of fat present in your abdominal area. Ideally, the measurements are taken on bare skin or over underwear. If you are uncomfortable with removing your lower body clothing, the measurements will be taken over your clothes. This information is of interest because it is related to risk for heart disease. Also, in order to assess your typical food intake, you will be asked to list all the foods you ate in the last 24 hours.

During the screening session you will complete psychological questionnaires with questions of a personal nature regarding mood, feelings, health behaviors, health, and personality. You will be asked about depression and anxiety symptoms that you have experienced over your lifetime, and this interview will be audiotaped; all audiotapes (and the videotapes made during the two all-day study visits) will be kept in locked file cabinets and erased once they have been coded and/or transcribed (typed). At the end of the screening 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.

Early in the screening session, you will have 5 ml (less than a tablespoon) of blood drawn from a vein in your arm, as well as a finger stick blood test. These blood samples will be used to determine your hemoglobin A1C (a test related to your risk for diabetes), as well as a test for anemia (a condition characterized by too few red blood cells, usually resulting in tiredness). If your blood test shows you may have diabetes, then you will not be able to participate further in the screening session; however, you will be given $5 and asked to see your physician. If your blood test shows you may be anemic, you can participate in the screening session and receive $10 for your time, but you will not be able to participate in the two all-day sessions and you will be asked to see your physician. You can ask to be retested for anemia in 6 weeks; if you are no longer anemic, then you may be eligible to participate in the remainder of the study. If you do not have a personal physician, you will be given contact information for OSU physicians who can treat these medical conditions.

If you and your spouse are eligible for the rest of the study, you will be scheduled for two full-day visits to the CRC. These visits will be scheduled 1-3 weeks apart.

In order to assess your typical food intake, you will be called twice between the two full-day visits and asked to list all the foods you ate in the last 24 hours. These interviews will last 15-30 minutes each.
Prior meals, exercise, and recent alcohol use can affect your body’s responses to subsequent meals. To limit differences across participants, you will be given three standard meals prepared by the CRC to eat the day prior to 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 avoid any strenuous physical activity for the two days before each full-day visit. You will not be able to take vitamins, aspirin, antioxidants, or other dietary supplements for the 7 days prior to each admission.

You cannot eat anything after 7:30 PM on the nights before the two full-day visits. On the day of each visit, you will be given a full meal as soon as your first blood sample has been drawn. You will receive two different kinds of meals during the study, one at each full-day visit. One type will be high in saturated fat resembling a typical fast-food meal in terms of its nutritional content. The other meal will be low in saturated fat. The two types of meals will appear identical. Neither you nor the research staff will know the meal type. You will need to eat the entire meal within 20 minutes each time. You will receive water but no other food or drink during the next 7 hours after you finish the meal.

Following the meal, you and your spouse will be asked to discuss and try to resolve an area of disagreement. This discussion will last 30 minutes and the topics will be chosen based on your ratings of common areas of marital disagreement. The research team will remain out of sight during the discussion. These discussions will be videotaped, and you will be asked about your reactions afterward.

At the beginning of each of the full-day visits, a catheter (a small, hollow plastic tube, about the size of a small plastic sewing needle) will be inserted into a vein in your arm so that small amounts of blood can be drawn at different times across the visit. The catheter will be removed at the end of each visit. You will have a total of 320 ml (1 1/3 cup) of blood drawn during each of the 9 1/2 hour visits; this is 2/3 of the amount that you would give if you were donating blood. 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 645 ml of blood (just under 2 2/3 cups) will be drawn in the 3 sessions that are ideally scheduled over the span of 3-4 weeks. These samples will be used to examine the blood levels of fats, sugars, and certain other nutrients, as well as stress and appetite hormones and immune function indicators.

A nurse will place a Polar™ band that wraps around your chest to assess your heart rate. At both visits 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. Your blood pressure will also be measured at regular intervals throughout each full-day visit.

During both of the full-day visits you will complete questionnaires and interviews that include questions of a personal nature that will ask about mood, feelings, health behaviors, health, and personality; the interviews will be tape recorded. You will also be asked to perform several tasks on the computer, including tasks that measure aspects of attention.
At the first full-day visit, body composition (fat tissue mass and lean tissue mass) will be assessed using a DEXA (dual x-ray absorptiometry) machine. You will be asked to wear clothing with minimal metal, remove all jewelry, empty pockets, and take off 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. A full body DEXA scan will last between 15-20 minutes.

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 completely irrelevant 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 (15-18) saliva samples to measure how stress hormones 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.

Your calorie needs and metabolic responses to the meals will be measured 12-15 times during each full-day visit. For this purpose you will lay in a hospital bed with a facemask that either covers your nose and mouth or rests under your chin for about 45 minutes the first time, and thereafter 10-20 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.

The study will also investigate how differences in genetic material (DNA and RNA) may be related to an individual’s response to high-fat meals and stress. The researchers are trying to determine if particular genetic markers (certain characteristics of a person’s DNA) among those who also eat high-fat meals and/or have recent stressful experiences are associated with certain kinds of changes in the immune response, stress and appetite hormones, and heart disease risk 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. 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

You should not change your diet or start taking any new dietary supplements or vitamins because this could influence the immune and hormone measures that the study is examining. If you make any important changes to your diet or if you begin taking dietary supplements during the course of the study, you must inform the researchers.

You provided information about any 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.

If you are pregnant, nursing, or become pregnant, you cannot participate in this study. If you think there is a chance that you are pregnant, you must inform the researchers immediately and you will be asked to provide a urine sample for a pregnancy test prior to any further participation. Regardless, if you have not gone through menopause, you will be asked to provide a urine specimen at the first visit to confirm that you are not pregnant.

4. **How long will I be in the study?** Your participation will be complete in about 1-3 weeks, depending on scheduling availability in the Clinical Research Center and your personal schedule. There are a total of 3 sessions at the CRC, a screening session and 2 all-day visits. The screening visit will last approximately 2 hours. The full-day visits will take 9½ hours each, and will be scheduled 1-3 weeks apart. Between the full-day visits 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. The total anticipated participation time for all visits and the interviews is 22-23 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 withdrawal 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 and interviews: Personal questions may make you uncomfortable or could produce stress. When asked to discuss problem areas in marriages, you may experience distress similar to that experienced during a fight at home. Should you reveal intent to harm yourself or others, 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. Investigators are required by law to report child abuse.

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 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 at regular intervals. You may experience mild discomfort from the polar heart monitor strap around your chest.

Incidental findings from routine hospital blood analyses: Any potentially abnormal results from the hospital lab data will be first discussed with Dr. Malarkey 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 day-long CRC visits: You will receive a meal near the beginning of each of the full-day visits, 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. You may also feel weak because you have not eaten for several hours and have had 1 1/3 cups of blood drawn. We will offer you a choice of several snacks at the end of your visit.

For the meals: On the visit you are randomly assigned to receive the fast-food-type meal, 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. If you receive the fast-food-type meal on your first visit, you will receive the other meal option at your second visit, and vice versa.

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 4 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. Any potentially abnormal results discovered from the DEXA scan will be shared with you, and you will be asked to see your primary physician.

For genetic testing: Because neither you nor your doctor will receive the results of your DNA testing, 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).

7. What benefits can I expect from being in the study? You will receive a report based on your answers to the food recall 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.

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

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. At all visits, you will receive free parking. You will receive $10 for completing the screening session. You will receive $200 for completing Visit 1 (the first full-day visit), and $240 for completing Visit 2 (the second full-day visit). Therefore, you will have an opportunity to receive a total of $450. Payment will be sent after completing all visits that will ideally be scheduled within about a month; if your visits are more than a month apart, a check in the appropriate amount will be mailed to you within 2-4 weeks of each phase of study completion. If you do not receive your check within 4 weeks 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.

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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.

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