The Ohio State University Consent to Participate in Research

Study Title: **Marriage and Gut Feelings**

Principal Investigator: **Janice Kiecolt-Glaser, PhD**

Sponsor: **National Institutes of Health; Gut microbiome kits/analysis provided by uBiome.com**

- **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? On average, people who are married or in a marriage-like relationship have better health than people who do not have a partner, but people's interactions with their partner also been related to health. This study is designed to help understand how people's feelings about their partner may be related to their immune, cardiovascular, and digestive systems in ways that might influence health. The researchers will measure aspects of your immune system, your heart rate and blood pressure, and your gut microbiome (the bacteria in your gut) to see if these are related to your relationship with your partner in ways that could affect longer-term health.

2. How many people will take part in this study? 110 couples, or a total of at least 220 participants will be recruited for the study.

3. What will happen if I take part in this study? You and your partner will each complete an online screening form to determine if you are eligible to take part in the full

study; if both you and your partner appear to be eligible for the study and you both agree to participate, you will participate in an in-person screening appointment that will last 45-90 minutes to determine if you are eligible to take part in the full study; this appointment will take place in the OSU Medical Center in the Institute for Behavioral Medicine Research. Couples do not need to attend the initial screening visit together, but all other appointments must be scheduled together.

You will have a finger stick blood test at this screening appointment. These blood samples will be used to determine your hemoglobin A1C (a test related to your risk for diabetes). If your blood test shows you may have diabetes, then you and your partner will not be able to participate further in the screening session; however, you will each be given $5 and asked to see your physician. If you do not have a personal physician, you will be given contact information for OSU physicians who can treat these medical conditions.

During this screening visit you will also complete psychological questionnaires with questions of a personal nature regarding your mood, health behaviors, health, and relationship with your partner. Your picture will be taken, so it can be used in one of your partner's computer tasks during the 7-hour visits. You will also be asked to provide a saliva sample, which will be used to look at the relationship between energy expenditure, mood and your relationship. 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.

If you and your partner are eligible for the rest of the study, you will be scheduled for two 7-hour visits to the Clinical Research Center (CRC), a hospital research unit in the OSU Medical Center. All visits will occur on a weekday between 7:30 AM and 2:30 PM. These visits will be scheduled about 2 years apart.

Because this research is designed in part to understand how your life with your partner is related to the functioning of your immune, cardiovascular, and digestive systems, both partners must be willing to participate; you cannot take part in the study if your partner does not participate at the same time.

At the beginning of each of the 7-hour visits, a nurse will measure your weight, height, blood pressure, and 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.

A nurse will place sensors on your chest and wrist to assess your heart rate and perspiration throughout the visit. Your blood pressure will also be measured at regular intervals throughout each 7-hour visit.

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 235 ml (1 cup) of blood drawn during each of the 7 hour visits; this is 1/2 of the amount that you would give if you were donating blood. A total of 2 cups will be drawn in the 2 sessions that are 2 years apart. These samples will be used to examine the blood levels of hormones and immune function indicators.

You cannot eat anything after 7:30 PM on the nights before the two 7-hour visits. On the day of each visit, you will be given a breakfast as soon as your first blood sample has been drawn, and a lunch at midday.

In order to assess your typical food intake, you will be asked to list all the foods you ate in the last 24 hours before the visit. In addition, because people eat different foods on different days, you and your partner will each have two telephone interviews after each of the two 7-hour visits and will be asked to list all the foods you ate in the last 24 hours. These interviews will last 15-25 minutes each. We collect this information because your diet affects your immune system and your gut microbiome.

Following breakfast, you and your partner will be asked to have several conversations. In the first conversation, each of you will be asked to discuss 2-3 positive events that have happened in your own personal life. Next, each of you will have 10 minutes to talk about something you would like to change about yourself. Then, each of you will be asked to recount a past memory while the other partner listens for 10 minutes. In the last discussion, you and your partner will be asked to discuss and try to resolve an area of disagreement. This discussion will last 20 minutes and the topics will be chosen based on your ratings of common areas of disagreement. The research team will remain out of sight during these discussions. These conversations will be videotaped, and you will be asked about your reactions afterward.

After you are given lunch, you will be asked to complete a series of physical performance tasks. To assess grip strength, you will be asked to squeeze a handheld device. You will also be asked to walk a 14-foot distance at your usual walking speed. Your balance will be tested by having you stand with one foot in front of the other. Then, you will be asked to rise from a chair as quickly as possible with your arms across your chest. A short task will measure aspects of your memory. For example, you might be asked to memorize several words, and then you would be asked which of the words you remember several minutes later. Near the end of the visit, 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 your discussions with your partner) will be kept in locked file cabinets and erased once they have been coded and/or transcribed (typed). You will also be asked to sign a separate form regarding the use of these recordings.

During the visit you will complete survey questions of a personal nature regarding your medications, health conditions, mood, feelings, memory and concentration, health behaviors, personality, your relationship with your partner, as well as aspects of your current living environment (for example, pets) that may be related to your immune system and your gut

microbiome. You will also be asked to perform several tasks on the computer, including tasks that measure aspects of attention.

Everyone has bacteria in their gut (intestines), and these bacteria typically help the body to digest food and synthesize vitamins. Studies have also linked differences in the gut microbiome (the bacteria in your gut) to moods and to a person's typical daily diet, as well as gut health and metabolic disorders. In order to help understand how your gut bacteria may be related to aspects of your immune system and to any stress you may be experiencing, you and your partner will each provide a stool sample for your gut microbiome analysis, and you will be asked about bowel-related problems like constipation and diarrhea. You will receive a kit at the visit that contains a cotton swab and a tube with a liquid preservative. You will collect the sample at your home after the visit by swabbing a soiled place on your toilet paper after you have had a bowel movement, then swishing the swab (a sterile Q-tip) in the tube with the preservative liquid for two minutes before capping the tube and throwing away the swab. The amount of sample needed is quite small, and the cotton swab goes immediately into the liquid preservative, so there is no smell from the sample. You will return the sample in a special envelope that will be provided.

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 partner, your health, the study, the setting, the experimenter, or completely irrelevant things you may have been thinking about during the study. Neither the researchers nor your partner will 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 partner and your health.

No medical report will be added to your medical records based on any part of your research participation. Neither you nor your doctor will receive the results of your blood analyses. Your samples 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.

You provided information about any medications and current physical problems on the online screen and also 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.

4. How long will I be in the study? Your participation will be complete in about 2 years, depending on the availability of our study personnel, your own schedule, and your partner's schedule. In addition to the 45-90 minute screening appointment, there are two 7 hour appointments, all at The Ohio State University Wexner Medical Center. In addition, collecting your gut microbiome stool samples at home will take 5 minutes each time, and the two over-the-phone food recall interviews that follow each visit will take 15-25 minutes. The total anticipated participation time for all visits and all the interviews over the two year period is 15.5-16.5 (15.5-16.5) 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 we cannot obtain blood samples from you or your partner, or if your partner decides not to participate or to discontinue participation. 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 a problem or a disagreement with your partner, 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.

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 blood tests unless the results appear potentially abnormal.

For stool sample collection: Inconvenience.

7. What benefits can I expect from being in the study? You will receive the results of your gut microbiome test. You will be better able to understand your microbiome, how you compare to others, and even how you compare to yourself over time, from the first to the second sample. At the www.uBiome.com website, your bacteria is compared to all samples of the same type using the largest microbiome database in the world, and the website provides many tools for understanding and interpreting your results. For example, you will be given a diversity score; greater microbiome diversity has been correlated with good health. The website also allows you to compare your microbiome to groups like vegans, smokers, or people on antibiotics at the website.

It usually takes the uBiome company 4-6 weeks to process a microbiome sample and compile the results. Note that your microbiome test is not a diagnostic test and cannot predict your future health. If you are concerned about a medical issue, please see your doctor.

You will receive a report based on your answers to the three food recall interviews after you have finished all 3 interviews for each visit; all three are necessary to provide valid feedback. You will receive a report based on your answers to your answers in the dietary recall interviews. The report will tell you about your eating patterns, such as how closely your intake of calories, fats, fiber, protein and carbohydrates compares to the Dietary References Intakes, a set of federal standards for nutrient amounts that should be present in a healthy 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. uBiome kits may be purchased apart from the study via the uBiome website.

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.

In order for you to see your microbiome test results, we will create an account on the uBiome website where you will be asked to provide identifiable information as well as the number of the test kit with which you have been provided. You will log into this account in order to see your results. The researchers will have access to the data from your stool sample, but it will only be identifiable by the test kit number. They will not have access to your personal information or your account on this website.

The National Institutes of Health (NIH) issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if NIH requests the information, or if the FDA tells us to release this information.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

Please visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

10. What are the costs of taking part in this study? There is no cost to you for participating 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 and your partner will each receive $10 for completing the screening visit, $200 for completing the first of the 7-hour visits, and $225 for completing Visit 2 (the second 7-hour visit two years later). You will also receive $10 for completing each of the food recalls following the visit, and $30 for mailing your microbiome sample (after uBiome confirms it has received your stool sample). Therefore, you will each have an opportunity to receive a total of $535 for all research activities across the two years. Payment will be sent after completing each of the visits 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 completing the visit, food recalls, and the microbiome sample, please notify the researchers. By law, payments to subjects are considered taxable income.

Activity	Complete screening session	Complete each of the 7-hour visits	Each 24-hour food recall after each of the 7-hour visits	Microbiome sample mailed to uBiome after each of the 7-hour visits
Payment/each person	$10	$200 first visit $225 second visit, two years later	$10 for each of the two recalls completed ($20 total)	$30

If you choose not to complete the 2 food recalls and/or to not send your uBiome sample, you will still be compensated for the study activities you do complete. 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 Wexner 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 614-366-5029.

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 the study coordinator at 614-366-5029.

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