The Ohio State University Consent to Participate in Research

Study Title:	**The Gut Feelings Study: Marriage, Mood, and the Gut Microbiome**
Principal Investigator:	**Janice Kiecolt-Glaser, PhD**
Sponsor:	**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? 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.

This study is designed to help understand how your mood, your diet, and your life with your partner affect your gut microbiome and your immune system, and to assess the degree of similarity in your partner's microbiome and your own microbiome. The researchers will measure certain aspects of your immune system to see if your microbiome, your mood, your diet, and your relationship with your partner are related to your immune system in ways that could affect long-term health.

2. How many people will take part in this study? 425 couples, for a total of at least 850 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 you and your spouse are both eligible for the study and you both agree to participate, you will be scheduled for two 1.5 hour in-person appointments at either your home/workplace or at Ohio State, depending on your preference and availability of our study personnel. These visits will be scheduled about 2-4 months apart. All visits will occur on a weekday between 7:30 AM and 11:45 AM.

You will be asked to attend the visit together with your partner, although we may be able to schedule you separately in some cases. Because this research is designed in part to understand how your life with your partner affects your gut microbiome and your immune system, both partners must be willing to participate; you cannot take part in the study if your partner does not participate.

During each session, you will have 65 ml (2.2 ounces, or just over 1/4 cup) of blood drawn from a vein in your arm by a trained study staff member or OSUWMC phlebotomy lab.

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 that contains a cotton swab and a tube with a liquid preservative. You will collect the sample at your home 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 by mailing it with the special pre-paid envelope provided in the kit then email us when uBiome has confirmed receipt of the sample. We will register your kit with uBiome before each visit using the information you provide in the online screen. You will have access to this online uBiome account so that you can get your own results.

You will complete survey questions of a personal nature regarding your medications, health conditions, mood, feelings, 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 gut microbiome. As part of our standard procedures, you will be given a list of local psychological counseling services should you wish to talk with someone at that time or in the future about any problems you are having.

In order to assess the typical foods you eat that are related to your microbiome, you and your partner will be interviewed separately and asked to list all the foods you ate in the last 24 hours three times: once during each of the two visits, and once on the phone between visits. These interviews will last 15-25 minutes each.

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.

4. How long will I be in the study? Your participation will be complete in about 2-4 months, depending on the availability of our study personnel, your own schedule, and your partner's schedule. There are a total of two 1.5 hour in-person appointments at either your home/workplace or at The Ohio State University Wexner Medical Center. In addition, collecting your gut microbiome stool samples at home will take 5 minutes each, and the over-the-phone food recall interview will take 15-25 minutes. The total anticipated participation time for all visits and the interviews is 3 hours and 35 minutes.

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 if you do not return your microbiome sample, 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 the blood draws: You may experience bruising at the blood draw site, infection, pain, fainting, and redness. These are risks that occur whenever blood is drawn.

For questionnaires and interviews: Personal questions may make you uncomfortable or be stressful. Should you reveal suicidal intent, we are required to evaluate risk and may contact appropriate authorities if you appear to be at imminent risk for harm to yourself or others. We are required by law to report child abuse. Some questions ask about psychological and physical partner abuse in the past year. Researchers will provide a list of mental health counseling resources, including domestic violence agencies.

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 interviews; 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 for $89 per kit.

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 to see your microbiome test results, you will need to 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.

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 either receive Amazon gift cards or a check (depending on the researchers' funding at the time) to compensate you for your time. If you come to OSU for the study, you will receive free parking. For each of the two visits you and your partner will each receive $5 for completing the questionnaires, $10 for the blood draw, and $15 for the gut microbiome (stool) sample; you can receive an additional $10 for completing all components of each visit, which, for the first visit, also includes the second food recall interview. Therefore, you each will have an opportunity to receive a total of $80 (up to $160/couple) for participating in the whole study. You and your partner will both be paid once uBiome confirms it has received your stool samples and the second food recall interviews have been completed; and a check or gift cards in the appropriate amount will be mailed to you within 2-4 weeks of uBiome confirmation. If you do not receive your payment within 4 weeks of sending your uBiome sample, please notify the researchers. If you or your partner chooses 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 614-685-2249

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 614-685-2249.

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)**
Relationship to the subject	**AM/PM** **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