

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

37 study; if both you and your partner appear to be eligible for the study and you both agree to
38 participate, you will participate in an in-person screening appointment that will last 45-60
39 minutes to determine if you are eligible to take part in the full study; this appointment will
40 take place in the OSU Medical Center in the Institute for Behavioral Medicine Research.
41 Couples do not need to attend the initial screening visit together, but all other appointments
42 must be scheduled together.

43
44 You will have a finger stick blood test at this screening appointment. These blood samples
45 will be used to determine your hemoglobin A1C (a test related to your risk for diabetes). If
46 your blood test shows you may have diabetes, then you and your partner will not be able to
47 participate further in the screening session; however, you will each be given \$5 and asked to
48 see your physician. If you do not have a personal physician, you will be given contact
49 information for OSU physicians who can treat these medical conditions.

50
51 During this screening visit you will also complete psychological questionnaires with questions
52 of a personal nature regarding your mood, health behaviors, health, and relationship with your
53 partner. Your picture will be taken, so it can be used in one of your partner's computer tasks
54 during the 7-hour visits. You will also be asked to provide a saliva sample, which will be used
55 to look at the relationship between energy expenditure, mood and your relationship. At the
56 end of the screening appointment, as part of standard procedures, you will be provided with a
57 list of psychological counseling services should you wish to talk with someone at that time or
58 in the future about any problems you are having.

59
60 If you and your partner are eligible for the rest of the study, you will be scheduled for two 7-
61 hour visits to the Clinical Research Center (CRC), a hospital research unit in the OSU
62 Medical Center. All visits will occur on a weekday between 7:30 AM and 2:30 PM. These
63 visits will be scheduled about 2 years apart.

64
65 Because this research is designed in part to understand how your life with your partner is
66 related to the functioning of your immune, cardiovascular, and digestive systems, both
67 partners must be willing to participate; you cannot take part in the study if your partner does
68 not participate at the same time.

69
70 At the beginning of each of the 7-hour visits, a nurse will measure your weight, height, blood
71 pressure, and the amount of fat present in your abdominal area. Ideally, the measurements are
72 taken on bare skin or over underwear. If you are uncomfortable with removing your lower
73 body clothing, the measurements will be taken over your clothes. This information is of
74 interest because it is related to risk for heart disease.

75
76 A nurse will place sensors on your chest and wrist to assess your heart rate and perspiration
77 throughout the visit. Your blood pressure will also be measured at regular intervals
78 throughout each 7-hour visit.

79
80 A catheter (a small, hollow plastic tube, about the size of a small plastic sewing needle) will
81 be inserted into a vein in your arm so that small amounts of blood can be drawn at different

82 times across the visit. The catheter will be removed at the end of each visit. You will have a
83 total of 235 ml (1 cup) of blood drawn during each of the 7 hour visits; this is 1/2 of the
84 amount that you would give if you were donating blood. A total of 2 cups will be drawn in the
85 2 sessions that are 2 years apart. These samples will be used to examine the blood levels of
86 hormones and immune function indicators.

87

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

91

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

98

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

108

109 After you are given lunch, you will be asked to complete a series of physical performance
110 tasks. To assess grip strength, you will be asked to squeeze a handheld device. You will also
111 be asked to walk a 14-foot distance at your usual walking speed. Your balance will be tested
112 by having you stand with one foot in front of the other. Then, you will be asked to rise from a
113 chair as quickly as possible with your arms across your chest. A short task will measure
114 aspects of your memory. For example, you might be asked to memorize several words, and
115 then you would be asked which of the words you remember several minutes later. Near the
116 end of the visit, you will be asked about depression and anxiety symptoms that you have
117 experienced over your lifetime, and this interview will be audiotaped; all audiotapes (and the
118 videotapes made during your discussions with your partner) will be kept in locked file
119 cabinets and erased once they have been coded and/or transcribed (typed). You will also be
120 asked to sign a separate form regarding the use of these recordings.

121

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

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

128
129 Everyone has bacteria in their gut (intestines), and these bacteria typically help the body to
130 digest food and synthesize vitamins. Studies have also linked differences in the gut
131 microbiome (the bacteria in your gut) to moods and to a person's typical daily diet, as well as
132 gut health and metabolic disorders. In order to help understand how your gut bacteria may be
133 related to aspects of your immune system and to any stress you may be experiencing, you and
134 your partner will each provide a stool sample for your gut microbiome analysis, and you will
135 be asked about bowel-related problems like constipation and diarrhea. You will receive a kit
136 at the visit that contains a cotton swab and a tube with a liquid preservative. You will collect
137 the sample at your home after the visit by swabbing a soiled place on your toilet paper after
138 you have had a bowel movement, then swishing the swab (a sterile Q-tip) in the tube with the
139 preservative liquid for two minutes before capping the tube and throwing away the swab. The
140 amount of sample needed is quite small, and the cotton swab goes immediately into the liquid
141 preservative, so there is no smell from the sample. You will return the sample in a special
142 envelope that will be provided.

143
144 At several times during both visits you will be asked to talk out loud into a tape recorder for a
145 minute or two about your thoughts about your partner, your health, the study, the setting, the
146 experimenter, or completely irrelevant things you may have been thinking about during the
147 study. Neither the researchers nor your partner will be present while you record your
148 thoughts. These tapes will be used to assess your reactions to different parts of the study and
149 your thoughts about your partner and your health.

150
151 No medical report will be added to your medical records based on any part of your research
152 participation. Neither you nor your doctor will receive the results of your blood analyses.
153 Your samples will not have identifying information such as your name, initials, or address on
154 it, only a code number. The specimens for testing will be stored with the same code number
155 that is used on all the questionnaires and other forms you have completed; the results of the
156 testing will be kept confidential and will not be released. Names and other identifying
157 information will be kept separate from the samples. No identifying information will be in any
158 publication or reports, only group results, with no personal code number or other identifiers,
159 will be reported.

160
161 You provided information about any medications and current physical problems on the online
162 screen and also when you were scheduled for this study. If you have started taking any new
163 medications or have developed any significant health problems, you must inform the
164 researchers immediately.

165
166 If you are pregnant, nursing, or become pregnant, you cannot participate in this study. If you
167 think there is a chance that you are pregnant, you must inform the researchers immediately
168 and you will be asked to provide a urine sample for a pregnancy test prior to any further
169 participation.

170

171 **4. How long will I be in the study?** Your participation will be complete in about 2 years,
172 depending on the availability of our study personnel, your own schedule, and your partner's
173 schedule. In addition to the 45-60 minute screening appointment, there are two 7 hour
174 appointments, all at The Ohio State University Wexner Medical Center. In addition, collecting
175 your gut microbiome stool samples at home will take 5 minutes each time, and the two over-
176 the-phone food recall interviews that follow each visit will take 15-25 minutes. The total
177 anticipated participation time for all visits and all the interviews over the two year period is
178 15.5-16 hours.

179
180 **5. Can I stop being in the study?** You may leave the study at any time. If you decide to
181 stop participating in the study, there will be no penalty to you, and you will not lose any
182 benefits to which you are otherwise entitled. Your decision will not affect your future
183 relationship with The Ohio State University.

184
185 In addition, your study participation can be stopped without your consent if we cannot obtain
186 blood samples from you or your partner, or if your partner decides not to participate or to
187 discontinue participation. Any results obtained prior to your withdrawal from the study will
188 be part of the overall study results.

189
190 **6. What risks, side effects or discomforts can I expect from being in the study?**

191 For questionnaires and interviews: Personal questions may make you uncomfortable or could
192 produce stress. When asked to discuss a problem or a disagreement with your partner, you
193 may experience distress similar to that experienced during a fight at home. Should you reveal
194 intent to harm yourself or others, the researchers are required to evaluate risk and may contact
195 appropriate authorities if you appear to be at imminent risk for harm to yourself or others.
196 Investigators are required by law to report child abuse.

197
198 For the blood draws and the catheter: You may experience bruising at the draw site, infection,
199 pain, fainting, and redness. These are risks that occur whenever blood is drawn. There is a
200 minor risk of an allergic response to the tape used to hold the catheter in place that may
201 include redness or a rash, swelling, small blisters, itching, and discomfort on the arm where
202 the skin was covered by the tape. There is also a minor risk of anemia associated with having
203 your blood drawn.

204
205 For blood pressure and heart rate: You may experience mild discomfort from the blood
206 pressure cuff that will be used at regular intervals.

207
208 Incidental findings from routine hospital blood analyses: Any potentially abnormal results
209 from the hospital lab data will be first discussed with Dr. Malarkey to confirm the nature and
210 seriousness of the problem; if there appears to be reason for concern, you would be informed
211 of the abnormal value and advised to seek treatment from your personal physician. Neither
212 you nor your doctor will receive the results of the blood tests unless the results appear
213 potentially abnormal.

214
215 For stool sample collection: Inconvenience.

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

225
226 It usually takes the uBiome company 4-6 weeks to process a microbiome sample and compile
227 the results. Note that your microbiome test is not a diagnostic test and cannot predict your
228 future health. If you are concerned about a medical issue, please see your doctor.

229
230 You will receive a report based on your answers to the three food recall interviews after you
231 have finished all 3 interviews for each visit; all three are necessary to provide valid feedback.
232 You will receive a report based on your answers to your answers in the dietary recall
233 interviews. The report will tell you about your eating patterns, such as how closely your
234 intake of calories, fats, fiber, protein and carbohydrates compares to the Dietary References
235 Intakes, a set of federal standards for nutrient amounts that should be present in a healthy diet.

236
237 **8. What other choices do I have if I do not take part in the study?** You may choose
238 not to participate without penalty or loss of benefits to which you are otherwise entitled.
239 uBiome kits may be purchased apart from the study via the uBiome website.

240
241 **9. Will my study-related information be kept confidential?**

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

245
246 Also, your records may be reviewed by the following groups (as applicable to the
247 research):

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

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

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

264
265 In order for you to see your microbiome test results, we will create an account on the uBiome
266 website where you will be asked to provide identifiable information as well as the number of
267 the test kit with which you have been provided. You will log into this account in order to see
268 your results. The researchers will have access to the data from your stool sample, but it will
269 only be identifiable by the test kit number. They will not have access to your personal
270 information or your account on this website.

271
272 The National Institutes of Health (NIH) issues Certificates of Confidentiality for all NIH-
273 funded studies, including this study. This Certificate provides extra protection for you and
274 your study information, documents, or samples (blood, tissue, etc.). The Certificates are
275 issued so that we cannot be required to disclose any identifiable information collected about
276 you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over
277 and above the already existing protections in place for you and your information, documents,
278 or samples.

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

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284 Please talk to your study team, or contact the Office of Responsible Research Practices at
285 614-688-8641, if you have questions.

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

288
289 **10. What are the costs of taking part in this study?** There is no cost to you for
290 participating in this study. All procedures are paid by the study, and participants do not pay
291 for any procedures.

292
293 **11. Will I be paid for taking part in this study?** You will be compensated for your
294 time. At all visits, you will receive free parking. You and your partner will each receive \$10
295 for completing the screening visit, \$200 for completing the first of the 7-hour visits, and \$225
296 for completing Visit 2 (the second 7-hour visit two years later). You will also receive \$10 for
297 completing each of the food recalls following the visit, and \$30 for mailing your microbiome
298 sample (after uBiome confirms it has received your stool sample). Therefore, you will each
299 have an opportunity to receive a total of \$535 for all research activities across the two years.
300 Payment will be sent after completing each of the visits a check in the appropriate amount
301 will be mailed to you within 2-4 weeks of each phase of study completion. If you do not
302 receive your check within 4 weeks of completing the visit, food recalls, and the microbiome
303 sample, please notify the researchers. By law, payments to subjects are considered taxable
304 income.

305

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

306 If you choose not to complete the 2 food recalls and/or to not send your uBiome sample, you
307 will still be compensated for the study activities you do complete. By law, payments to
308 subjects are considered taxable income.

309

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

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

314

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

318

319 **13. What are my rights if I take part in this study?** If you choose to participate in the
320 study, you may discontinue participation at any time without penalty or loss of benefits. By
321 signing this form, you do not give up any personal legal rights you may have as a participant
322 in this study.

323

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

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

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

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335 **14. Who can answer my questions about the study?** For questions, concerns, or
336 complaints about the study you may contact the Principal Investigator at 614-293-3499.

337

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

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342 If you are injured as a result of participating in this study or for questions about a study-
343 related injury, you may contact the study coordinator at 614-366-5029.

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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
	Date and time

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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.

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

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362

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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