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2 **The Ohio State University Consent to Participate in Research**  
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**Study Title:** The IMPACT Study: Inflammatory Responses, Mood, and Physical Fitness after Cancer Treatment

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

**Sponsor:** National Cancer Institute

- 5  
6 • **This is a consent form for research participation.** It contains important information  
7 about this study and what to expect if you decide to participate. Please consider the  
8 information carefully. Feel free to discuss the study with your friends and family and  
9 to ask questions before making your decision whether or not to participate.
- 10 • **Your participation is voluntary.** You may refuse to participate in this study. If you  
11 decide to take part in the study, you may leave the study at any time. No matter what  
12 decision you make, there will be no penalty to you and you will not lose any of your  
13 usual benefits. Your decision will not affect your future relationship with The Ohio  
14 State University. If you are a student or employee at Ohio State, your decision will  
15 not affect your grades or employment status.
- 16 • **You may or may not benefit as a result of participating in this study.** Also, as  
17 explained below, your participation may result in unintended or harmful effects for  
18 you that may be minor or may be serious depending on the nature of the research.
- 19 • **You will be provided with any new information that develops during the study**  
20 **that may affect your decision whether or not to continue to participate.** If you  
21 decide to participate, you will be asked to sign this form and will receive a copy of the  
22 form. You are being asked to consider participating in this study for the reasons  
23 explained below.  
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26 **1. Why is this study being done?**  
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28 Cardiovascular fitness often declines during and following cancer treatment. This study  
29 addresses how your cardiovascular fitness affects your body's immune response (certain kinds  
30 of white blood cells) in ways that may be related to risks for fatigue (tiredness), negative  
31 mood, pain sensitivity, memory, and concentration, which are all particularly relevant for  
32 cancer survivors. The researchers will use a typhoid vaccine to stimulate brief changes in your  
33 immune response to see how your responses to the vaccine compare with responses to a  
34 placebo (saline or salt water). They will also measure certain hormone responses and your  
35 heart rate and blood pressure and metabolic rate to see how they respond to the vaccine  
36 compared to the placebo. The researchers also want to know if your age and/or feeling blue or  
37 depressed may affect your body's responses to the vaccine.

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

240 breast cancer survivors will take part in the study.

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

You will be scheduled for two screening appointments and two nonconsecutive full-day visits. The first screening visit and the full-day visits will take place at the Clinical Research Center (CRC), a hospital research unit located at the OSU Wexner Medical Center. The second screening visit will take place at the Davis Heart and Lung Research Institute. All visits will occur on weekdays.

Visit	CRC Screen #1	VO2max Screen #2		Visit 1	Visit 2
Length	2 hours	2 hours		9.5 hours	9.5 hours
Activity	Consenting  Anemia/Diabetes blood draw  Questionnaires  Body measurements	VO2 max test (exercise bike)  Questionnaires	Eligibility Determined	Blood draws  Questionnaires  Metabolic Measurements  Computer tasks  Heart Rate/blood pressures/temp  <i>Condition:</i> Typhoid vaccine or Placebo/saline	Blood draws  Questionnaires  Metabolic Measurements  Computer tasks  Heart Rate/blood pressures/temp  <i>Condition:</i> Typhoid vaccine or Placebo/saline

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**Screening visit #1:** You will first participate in two screening appointments, which will last approximately 2 hours each, to determine if you are eligible to take part in the full study. At the first screening appointment, a nurse will measure your weight, height, blood pressure, and the distance around your hips and waist. A measurement will also 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 removing the clothing on your lower body, the measurements will be taken over your clothes.

Early in the first 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 indicates that you may have diabetes, then you will not be able to participate further in the screening session; however, you will be compensated \$5 for your time and asked to see your physician. If your blood test indicates that you may be anemic, you can complete the first screening appointment and will be compensated \$25 for your time.

67 However, you will not be able to participate in the study at that time, and you will be asked to  
68 see your physician. You have the option of being retested for anemia in 6 weeks; if you are  
69 no longer anemic, then you may be eligible to participate in the remainder of the study. If you  
70 are still anemic, you will not be able to participate in the second screening session or the two  
71 all-day sessions. If you do not have a personal physician, you will be given contact  
72 information for OSU physicians who can treat these medical conditions.

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74 During the first screening session you will complete psychological questionnaires that include  
75 questions of a personal nature regarding your mood, feelings, health behaviors, health, and  
76 personality. In order to assess your typical food intake, you will be asked to list all the foods  
77 you ate in the last 24 hours. You will be asked about depression and anxiety symptoms that  
78 you have experienced over your lifetime and this interview will be audio-recorded so that  
79 interview responses can be formally coded; all digital recordings will be kept in our  
80 password-protected computer system. At the end of the screening appointment, as part of  
81 standard procedures, you will be provided with a list of psychological counseling services  
82 should you wish to talk with someone at that time or in the future about any problems you are  
83 having. Finally, in order to measure hand strength, you will be asked to squeeze an instrument  
84 that measures your grip strength.

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87 **Screening visit #2:** You will complete a brief (6-10 minute) exercise test on a bicycle. This  
88 test will help researchers measure your fitness level. If you choose not to participate in the  
89 exercise test, you will not be able to participate in the rest of the study.

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

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

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113 If you are eligible for the rest of the study, you will be scheduled for two full-day visits to the  
114 CRC. These visits will be scheduled 14-30 days apart.

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116 *In preparation for the visits:* Recent exercise and alcohol use can affect your body's immune  
117 responses. For the two days before each full-day visit, you will be asked to refrain from  
118 consuming alcohol and to avoid any strenuous physical activity. If you have been instructed  
119 by your physician to take aspirin daily, you can continue to take it; otherwise, you should  
120 refrain from taking aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) for the 7 days  
121 prior to each visit. You should not change your diet or start taking any new dietary  
122 supplements or vitamins because this could influence the immune and hormone measures that  
123 the study is examining. If you make any important changes to your diet or if you begin taking  
124 dietary supplements during the course of the study, you must inform the researchers.

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126 You cannot eat anything after 7:30 PM on the nights before the two full-day visits, but you  
127 can drink as much water as you want, and you should take any prescription medications as  
128 scheduled. On the day of each visit, you will be given a standardized breakfast as soon as you  
129 receive either the vaccine or saline (placebo) injection. You will also receive a standardized  
130 lunch later in the day.

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

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137 **Full-day visits 1 and 2:** Recent illness can affect your body's immune response. If you have  
138 a temperature greater than 99.7°F when you arrive to the CRC, we will cancel the session and  
139 reschedule for a later date.

140  
141 At the beginning of each of your full-day visits, a catheter (a small, hollow plastic tube) will  
142 be inserted into a vein in your arm so that small amounts of blood can be drawn at different  
143 times across the visit. The catheter will be removed at the end of each visit. You will have a  
144 total of 250 ml (1 cup + 1 tablespoon) of blood drawn during each of the 9½ hour visits. At  
145 the end of the research day a final teaspoon of blood will be drawn from your arm which does  
146 not have the catheter inserted; this is to confirm that immune changes are not just reflecting  
147 local changes at the catheter site. A total of 510 ml of blood (just under 2 1/4 cups) will be  
148 drawn across the screening visit and both study visits that are ideally scheduled over the span  
149 of 3-4 weeks. These samples will be used to examine the blood levels of hormones and  
150 immune function indicators.

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152 The nurse will administer an injection into your upper arm that contains either saline (salt  
153 water) or a typhoid vaccine. Neither you nor the research staff will know the injection type for  
154 the day. This is because a person's expectations can sometimes influence the way that she  
155 feels throughout the day. If you are not willing to receive the injections, you will not be able  
156 to participate in the study.

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

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164 During both of the full-day visits you will complete questionnaires and interviews that include  
165 personal questions about mood, feelings, health behaviors, health, and personality; the  
166 interviews will be audio-recorded. In order to assess your typical food intake, you will be  
167 asked to list all the foods you ate in the last 24 hours. You will also be asked to perform  
168 several tasks on the computer and with the research assistant, including tests that measure  
169 aspects of concentration and memory.

170  
171 At your first full-day visit, body composition (fat tissue mass and lean tissue mass) will be  
172 assessed using a DEXA (dual x-ray absorptiometry) machine. You will be asked to wear  
173 clothing with minimal metal, remove all jewelry, empty your pockets, and take off your  
174 glasses and shoes before lying down on the DEXA table. You will be instructed to remain still  
175 in position on the DEXA table while being scanned for 15-20 minutes. If you have any doubt  
176 about whether you are postmenopausal, we will ask for a urine sample to make sure you are  
177 not pregnant prior to the test.

178  
179 At several times during both visits you will be asked to talk out loud into a tape recorder for a  
180 minute or two about your thoughts about your health, the study, the setting, the experimenter,  
181 or other things you may have been thinking about during the study. Researchers will not be  
182 present while you record your thoughts. These tapes will be used to assess your reactions to  
183 different parts of the study and your thoughts about your health.

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185 You will be asked to perform a temperature sensitivity test, to study how the vaccine-related  
186 changes affect your sensitivity to heat and cold. During this task, you will be asked to place  
187 your non-dominant hand on a thermal plate (a device that changes temperature). The  
188 temperature of the plate will gradually increase and decrease. You will be asked to rate how  
189 painful the temperatures feel, and to remove your hand if the temperature becomes too  
190 painful.

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192 In order to measure hand strength, you will be asked to squeeze an instrument that measures  
193 your grip strength.

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195 You will provide 15 saliva samples to measure how hormones related to the immune response  
196 may have changed during each of the full-day visits. For this purpose, you will put a piece of  
197 dental cotton in your mouth for 1-2 minutes each time to saturate the cotton.

198  
199 During both visits your metabolic response to the vaccine and placebo will be measured 6-8  
200 times. For this purpose you will lay in a hospital bed with a facemask that covers your nose

201 and mouth for about 20 minutes each time. During these times, you will be asked to lay still  
202 and breathe normally.

203  
204 To provide a uniform experience during parts of the visits, you will be asked to watch DVDs  
205 of nature shows or documentaries. During the time you are in the CRC, you will only be able  
206 to use your cell phone to make or receive calls or e-mails at set times. In the case of an  
207 emergency, however, your family will be able to reach you at 614-293-8750.

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209 You will be called the day following each of your long visits, and asked to answer questions  
210 which should take 5 to 10 minutes about your sleep, fatigue, pain, and thinking since your  
211 visit.

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213 We will get information from your doctor's treatment records about the tests you have had for  
214 your breast cancer, as well as information on the type of breast cancer, the stage, and the  
215 treatment you received, any current medications, and other health conditions so we can see if  
216 these are related to your immune responses. If you have already participated in one of our  
217 ongoing studies, such as THRIVE or Yoga for Breast Cancer Survivors Research Program,  
218 we will also use the health information that you shared at that time, as well as collecting any  
219 new updated information on medications or health conditions.

220  
221 **Genetic studies:** The study will also investigate how differences in genetic material (DNA  
222 and RNA) may be related to an individual's vaccine responses. The researchers are trying to  
223 determine if particular genetic markers (certain characteristics of a person's DNA) among  
224 those who also have certain immune responses and/or have recent stressful experiences are  
225 associated with changes in the immune response, and stress and appetite hormones in  
226 comparison to individuals who do not have the same genetic markers. The researchers will  
227 use frozen samples of your white blood cells as one source of DNA, as well as saliva samples.

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229 No medical report will be added to your medical records based on this testing or any other  
230 part of your research participation. Your sample will not have identifying information such as  
231 your name, initials, or address on it, only a code number. The specimens for testing will be  
232 stored with the same code number that is used on all the questionnaires and other forms you  
233 have completed; the results of the testing will be kept confidential and will not be released.  
234 Names and other identifying information will be kept separate from the samples. No  
235 identifying information will be in any publication or reports; only group results, with no  
236 personal code number or other identifiers, will be reported. Scientists working with your  
237 DNA samples will not have access to any identifying information. The researchers for this  
238 study will store your DNA samples in a secure room with limited access.

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240 Neither you nor your doctor will receive the results of your DNA testing. If you decide that  
241 you want to pursue genetic testing in the future based on results reported for this study, it will  
242 be at your expense and you will be referred to the genetic testing and counseling services in  
243 the OSU Medical Center. It may be a long time (months or years) before results from this  
244 study are available. In the unlikely event that any profitable discoveries are made using your  
245 biological material, you will not receive any personal financial benefit. If there are any patent

246 or commercial uses of your DNA data, any identifiable information linking the data to you  
247 will be destroyed (e.g. your name, address, phone number, and social security number).  
248

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

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

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

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#### 256 **4. How long will I be in the study?**

257 Your participation will be complete in about 3-5 weeks, depending on scheduling availability  
258 in the Clinical Research Center and your personal schedule. There are a total of 4 sessions at  
259 the CRC, 2 screening sessions and 2 all-day visits. Each screening visit will last  
260 approximately 2 hours. The full-day visits will take 9½ hours each, and will be scheduled 14-  
261 30 days apart. The total anticipated participation time for all visits and the interviews is 23-24  
262 hours.  
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#### 264 **5. Can I stop being in the study?**

265 You may leave the study at any time. If you decide to stop participating in the study there  
266 will be no penalty to you, and you will not lose any benefits to which you are otherwise  
267 entitled. Your decision will not affect your future relationship with The Ohio State  
268 University. In addition, your study participation can be stopped without your consent if we  
269 cannot obtain blood samples or exercise testing data, or if you refuse the vaccine or saline  
270 injections. Any results obtained prior to your withdrawal from the study will be part of the  
271 overall study results.  
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273 You can withdraw from this study at any time and withdraw your consent for the use of your  
274 white blood cells for genetic research. Upon withdrawing consent, your samples for genetic  
275 research will be destroyed (along with any study code number) if they have not already been  
276 used. Any results obtained prior to your withdrawing from the study will be part of the  
277 overall study results.  
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#### 279 **6. What risks, side effects or discomforts can I expect from being in the study?**

280 For the exercise test: You may feel tired or short of breath after the test. You may experience  
281 other physical changes associated with exercise, such as temporary muscle aches or joint pain.  
282 There is a remote risk that you may experience abnormally high blood pressure or heart  
283 rhythm disturbance during exercise, and in rare instances, heart attack, stroke, or death. An  
284 exercise physiologist will supervise the tests, and a physician will be available on-site; every  
285 effort will be made to minimize the occurrence of these problems (including stopping the test  
286 when necessary). Emergency equipment and trained personnel will be available to deal with  
287 any unusual situations that arise.  
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289 For the blood draws and the catheter: You may experience bruising at the blood draw site,  
290 infection, pain, fainting, and redness. These are risks that occur whenever blood is drawn.

291 There is a minor risk of an allergic response to the tape used to hold the catheter in place that  
292 may include redness, rash, swelling, small blisters, itching, and discomfort on the arm where  
293 the skin was covered by the tape. There is also a minor risk of anemia (a condition  
294 characterized by too few red blood cells, usually resulting in tiredness or light-headedness)  
295 associated with having your blood drawn. Therefore, you are advised not to donate blood  
296 within 8 week of study participation.

297

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

302

303 For the typhoid vaccine: If you take part in this research, you will receive a typhoid vaccine  
304 at one of your full-day visits. The vaccine has a well-established safety profile and is well-  
305 tolerated in adults. Side effects are mild and infrequent. You may experience local pain,  
306 redness, raised skin, or swelling at the injection site. About 1 in 10 people who receive the  
307 vaccine report feeling feverish or experience a headache; the likelihood that you will  
308 experience a clinical fever (as measured by a nurse) is about 1 in 100. Other side effects, such  
309 as a rash, muscle or joint pain, or gastrointestinal discomfort are also rare, and occur in about  
310 2 out of 100 people. There is a rare risk of severe allergic reaction that could require  
311 emergency medical treatment.

312

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

319

320 Everyone receives a small amount of unavoidable radiation each year. Some of this radiation  
321 comes from space and some from naturally-occurring radioactive forms of water and  
322 minerals. This research gives your body the equivalent of about 4 extra days' worth of this  
323 natural radiation. The radiation dose we have discussed is what you will receive from this  
324 study only and does not include any exposure you may have received or will receive from  
325 other tests.

326

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

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330 For questionnaires, interviews, and cognitive tests: Personal questions may make you  
331 uncomfortable or be stressful. Should you reveal suicidal intent, the researchers are required  
332 to evaluate risk and may contact appropriate authorities if you appear to be at imminent risk  
333 for harm to yourself or others.

334



335 For the temperature sensitivity test: You may experience short-term pain or discomfort  
336 associated with exposing your hand to hot or cold temperatures. You may remove your hand  
337 from the plate when the pain or discomfort becomes too great. The test will be stopped before  
338 reaching extreme temperatures (55° C or -4°C), therefore the temperatures used are not hot or  
339 cold enough for any lasting temperature effects to occur.

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341 For grip strength assessments: You may experience some slight hand and/or arm soreness.

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

349  
350 For genetic testing: Because you will not be receiving your personal results from this study,  
351 most of the usual psychological risks associated with genetic testing do not apply to you. If  
352 you decide, at your expense, to undergo clinical genetic testing in the future based on  
353 discoveries made as part of this study, the risks of receiving genetic test results will be  
354 discussed with you at that time.

355  
356 The results of the testing will be kept confidential to the fullest extent possible. Although the  
357 specimens will be stored with a code number, if this confidentiality were broken, a researcher  
358 could learn something about you that you do not want them to know (i.e., name, address, or  
359 other personal information you do not want them to have).

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

- 364
- 365 • Health insurance companies and group health plans may not request your genetic  
366 information from this research.
  - 367 • Health insurance companies and group health plans may not use your genetic  
368 information when making decisions about your eligibility or premiums.
  - 369 • Employers with 15 or more employees may not use your genetic information from this  
370 research when making a decision to hire, promote, or fire you or when setting the  
terms of your employment.

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

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

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

383  
384 You will receive a report based on your answers to the diet questionnaires and interviews.  
385 The report will tell you about your eating patterns, such as how closely your number of  
386 servings in each food group consumed daily matches USDA recommendations. In addition,  
387 this report will show your average daily intake of different nutrients and recommendations for  
388 improving your diet.

389  
390 You will receive the results of your DEXA scan. The results obtained from the DEXA scan  
391 will provide you with information about your muscle and fat composition, bone mineral  
392 density, and the amount of calories your body uses at rest in a 24 hour period.

393

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

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

397

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

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

402

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

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

411

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

416

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

420

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

422 There are no costs if you take part in this study. All procedures are paid by the study, and  
423 participants do not pay for any procedures.  
424

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

426 You will be compensated for your time. At all visits, you will receive free parking. You will  
427 receive \$25 for completing the first screening session. You will receive \$75 for completing  
428 the second screening session, which includes the exercise testing. You will receive \$250 for  
429 completing each full day visit. Therefore, you will have an opportunity to receive a total of  
430 \$600. If you are not able to complete the full day visit, your payment will be pro-rated based  
431 on the percentage of the visit that you actually completed. Payment will be sent after  
432 completing all visits that will ideally be scheduled within about a month; if your visits are  
433 more than a month apart, a check in the appropriate amount will be mailed to you within 2-4  
434 weeks of each phase of study completion. If you do not receive your check within 4 weeks of  
435 study completion, please notify the researchers. By law, payments to subjects are considered  
436 taxable income.  
437

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

439 If you suffer an injury from participating in this study, you should notify the researcher or  
440 study doctor immediately, who will determine if you should obtain medical treatment at The  
441 Ohio State University Medical Center.  
442

443 The cost for this treatment will be billed to you or your medical or hospital insurance. The  
444 Ohio State University has no funds set aside for the payment of health care expenses for this  
445 study.  
446  
447

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

449 If you choose to participate in the study, you may discontinue participation at any time  
450 without penalty or loss of benefits. By signing this form, you do not give up any personal  
451 legal rights you may have as a participant in this study.  
452

453 You will be provided with any new information that develops during the course of the  
454 research that may affect your decision whether or not to continue participation in the study.  
455

456 You may refuse to participate in this study without penalty or loss of benefits to which you  
457 are otherwise entitled.  
458

459 An Institutional Review Board responsible for human subjects research at The Ohio State  
460 University reviewed this research project and found it to be acceptable, according to  
461 applicable state and federal regulations and University policies designed to protect the rights  
462 and welfare of participants in research.  
463

464 **14. Who can answer my questions about the study?**

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

467  
468 For questions about your rights as a participant in this study or to discuss other study-related  
469 concerns or complaints with someone who is not part of the research team, you may contact  
470 Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

471  
472 If you are injured as a result of participating in this study or for questions about a study-  
473 related injury, you may contact Janice Kiecolt-Glaser, PhD at 614-293-3499 or William  
474 Malarkey, MD at 614-293-8775.

475  
476  
477

### 478 **Signing the consent form**

479  
480 I have read (or someone has read to me) this form and I am aware that I am being asked to  
481 participate in a research study. I have had the opportunity to ask questions and have had them  
482 answered to my satisfaction. I voluntarily agree to participate in this study.

483  
484 I am not giving up any legal rights by signing this form. I will be given a copy of this form.  
485

_____	_____
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

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### 496 **Investigator/Research Staff**

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

\_\_\_\_\_  
Printed name of person obtaining consent

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date and time AM/PM

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504

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

\_\_\_\_\_  
Printed name of witness

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date and time AM/PM

\_\_\_\_\_  
Printed name of witness

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date and time AM/PM

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