

**UNIVERSITY OF MICHIGAN  
CONSENT TO BE PART OF A RESEARCH STUDY**

**1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY**

**Study title:** Ultra Crave: An Investigation of Ultra Processed Food

**Principal Investigator:** Ashley Gearhardt, PhD, University of Michigan, Department of Psychology

**Co-Investigator(s):** Stuart Ferguson, University of Tasmania; Corby Martin, PhD, Pennington Biomedical Research Center, Louisiana State University; Lindsey Parnarouskis, University of Michigan; Caroline Richardson, Department of Family Medicine, University of Michigan Medical School; Kendrin Sonneville, ScD, RD, University of Michigan School of Public Health; Sonja Yokum, PhD, Oregon Research Institute

**Study Sponsor:** National Institute of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

**1.1 Key Information**

Things you should know:

- The purpose of the study is to investigate how eating different foods impacts the way that you feel.
- If you chose to participate in the main period of data collection you will be asked to:
  - Attend 3 in-person lab visits
  - Follow dietary instructions
  - Complete one fMRI Scan (if you are eligible)
  - Complete daily remote data collection
  - Wear a blood glucose monitor and a FitBit
  - Complete remote questionnaire batteries
  - Complete 4 20-30 minute phone interviews about what you have eaten (24 hour dietary recalls)
  - Complete a 1-month follow up questionnaire
  - Complete a 3-month follow up questionnaire
- The main portion of the study will include approximately 15 days of active data collection.
- Risks or discomforts from this research include:

- Breach of confidentiality – you may become upset when answering some of the survey questions or completing other research-related tasks
- There is a risk of skin infection with the placement of a glucose monitor and irritation with use of the FitBit.
- A food allergy could become apparent during the study
- If you are eligible, there are risks associated with the fMRI scan. Please see the fMRI consent form for more information.
- The direct benefits of your participation are:
  - Contributing knowledge about how eating different food impacts how you feel.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

## **2. PURPOSE OF THIS STUDY**

The purpose of the study is to investigate how different foods impact the way that you feel. The study team will provide you with dietary instructions while assessing your affect, behaviors, and physical functioning.

## **3. WHO CAN PARTICIPATE IN THE STUDY**

Participants in the current study must meet the following criteria:

- Between the age of 22-60
- English speaking
- Own an iPhone or Android smartphone
- Live within a 1-hour radius of the University of Michigan in Ann Arbor, MI
- Willing and able to follow specific dietary instructions provided by the study team
- Willing and able to attend 3 in-person lab visits on a Friday, Saturday, or Sunday over the course of the study
- Willing to complete 4 phone interviews about what you have eaten in the past 24 hours
- Willing to report daily intake of food
- Like the taste of chocolate milkshake (for fMRI scan eligibility only).

You are not eligible for the current study if:

- BMI is outside a range of 18.5 to 40 (above 18.5 if ineligible for fMRI)
- Current diagnosis of disorder that may impact study results or the ability to safely complete study tasks (hypothyroidism (uncontrolled by medication), diabetes, etc.)
- History of food allergies
- Unable to respond to brief questionnaires within 90-minutes during the day
- Work night shifts or irregular shifts
- Restrictive dietary requirements (e.g., vegan) or high levels of picky eating

- Medications (e.g., insulin, antipsychotic medications) that may impact study results or safe completion of study tasks
- Diagnosis of severe mental illness (e.g., schizophrenia, bipolar disorder)
- Diagnosis of a restrictive eating disorder (e.g., Anorexia Nervosa, Bulimia Nervosa, purging disorder) within the last 5 years
- Current diagnoses of disorders that can impact reward/metabolic functioning
- 20+ pound weight fluctuation in the last 3-months
- Prior weight loss surgery (e.g., bariatric surgery)
- Currently pregnant, breastfeeding, trying to get pregnant, or within 6-months of having given birth
- High levels or high-risk intake of alcohol or caffeine
- Use of tobacco or nicotine in the past month
- Use of THC cannabis within the past week
- Unwillingness to abstain from THC cannabis, tobacco or nicotine during the main portion of the study (~22 days)
- fMRI contraindications (e.g., claustrophobia, metal implants; for fMRI scan portion of the study only).

#### 4. INFORMATION ABOUT STUDY PARTICIPATION

##### 4.1 What will happen to me in this study?

The study will include a combination of in-person, at-home, and virtual activities. For in-person activities, you will be asked to come to the University of Michigan in Ann Arbor 3 times.

In total, the study consists of 9 segments:

1. Remote Consent Visit
2. Remote Questionnaire Battery
3. In-Lab Visit #1
4. Week 1 Remote Data Collection
5. In-Lab Visit #2
6. Week 2 Remote Data Collection
7. In-Lab Visit #3
8. 1-Month Remote Follow Up
9. 3-Month Remote Follow Up

Additional information about study phases and study task as well as a chart summarizing study participation are provided below.

##### Additional Information about Study Segments

**Remote Consent Visit:** We will set up an initial call with you (via phone or secure video call) to discuss the study and a trained member of our team will be available to answer any questions that you have. You can choose to electronically sign the main study consent form during this visit if you would like to participate in the study. If it has been 3 or more months since your original screening questionnaire, we will re-screen some

criteria (e.g., medications, medical conditions) to confirm you are still eligible during this visit.

**Remote Questionnaire Battery:** We will send you questionnaires to complete at home on your own prior to In-Lab Visit #1. We estimate these questionnaires will take up to 2 hours. You can take breaks and complete these questionnaires over multiple days.

**In-Lab Visit #1:** We will discuss the study schedule with you, and ask you to complete study questionnaires, interviews, behavioral tasks. We will also complete body composition measurements (height, weight, Inbody scan), a brief mock fMRI scan (if eligible), set up and provide instructions for week 1 remote data collection tasks, set up a continuous blood glucose monitor, and provide you with a Fitbit watch to use during the main study segment. We will review and sign the fMRI consent form during this visit if you are eligible for the scan. You will also complete a computer task where you can earn money to be loaded onto different types of gift certificates.

**Week 1 Remote Data Collection:** We will ask you to eat your typical diet for 1 week and complete short check-ins and surveys throughout the day on your phone using an app called the RealLife App. Throughout the week, we will monitor your blood glucose levels, ask you to wear the provided Fitbit. Twice during the week you will be called by a trained staff member to complete a 24 hour dietary recall of everything you have eaten during a 20-30 minute phone call.

**In-Lab Visit #2:** We will ask you complete questionnaires, interviews, a full mock fMRI scan (if eligible) and body composition measurements (height, weight, InBody scan). We will provide you with dietary instructions during week 2 of remote data collection. We will also replace the continuous blood glucose monitor sensor and review instructions for week 2 tasks.

**Week 2 Remote Data Collection:** We will ask you follow dietary instructions provided by the study team for 1 week and complete short check-ins and surveys throughout the day on your phone using an app called the RealLife App. Throughout the week, we will monitor your blood glucose levels and ask you to wear the provided Fitbit. Twice during the week you will be called to complete a 24 hour dietary recall phone call about what you have eaten.

**In-Lab Visit #3:** We will ask you to complete questionnaires, behavioral tasks, body composition measurements (height, weight, InBody scan), and an fMRI scan (if you are eligible). We will ask you to complete an interview about your experience with the study and we will ask you to return your continuous blood glucose monitor sensor and the provided Fitbit.

**1-Month Remote Follow Up:** We will contact you approximately 1-month after your participation in this study. At this follow up, we will ask you to complete a short follow up survey and provide information about your current diet.

**3-Month Remote Follow Up:** We will contact you approximately 3-months after your participation in this study. At this follow up, we will ask you to complete a short follow up survey and provide information about your current diet.

### **Additional Information about Study Activities**

**Questionnaires:** Questionnaires will ask about a variety of topics including eating and dieting, weight history, emotions, depression and anxiety, family history, substance use, trauma, personality traits and impulsivity. We will also ask about demographic information such as your age, education level and race/ethnicity.

**Body Composition Measurements:** We will have a trained member of our team measure your height in person at our lab. We will also use an InBody 570 body impedance scanner to obtain body composition measurements. During this scan, we will ask you to stand on footplates and hold handles for less than a minute while a low level, undetectable electrical current passes through your body. Because the scan is not currently recommended for those with a pacemaker or those who are pregnant a pregnancy test will be available and participants unable to complete the scan will have their weight measured using a standard scale.

**Interviews:** You will be asked to complete short interviews with a trained member of our study team. Interviews will include questions on a variety of topics including your typical activity level, eating behaviors, relationship with food, your experience in the study, and past non-traumatic stressful events you've experienced. Information from non-traumatic stressful events will be used in a behavioral task (see behavioral tasks below for additional information). We will also ask to audio-record information shared during some interviews. You will also be asked to complete 20-30 minute phone interviews at 4 points during the study where you will be asked to recall everything you have eaten in the past 24 hours.

**Mock Neuroimaging Scans:** During screening, we will assess whether you are eligible for the fMRI portion of our study. If you are eligible, then during visit 1 and visit 2 you will be asked to complete mock neuroimaging scans. At visit 1, you will enter the mock scanner to screen for comfort and contraindications (e.g., claustrophobia). At visit 2, we will familiarize you with the full fMRI procedure and practice with the mock scanner.

**Neuroimaging:** During screening, we will assess whether you are eligible for the fMRI portion of our study. You will be asked to complete an fMRI scan during In-Lab Visit 3. During the fMRI scan, you will be asked to view pictures on a screen and will be given small amounts of liquid (water, chocolate milkshake) to drink. At In-Lab Visit 1, we will discuss the fMRI scan in additional detail and complete a mock fMRI scan to practice what the scan will be like. The fMRI scan will take approximately 45 minutes. You can participate in the other study tasks even if you are not eligible for the fMRI scan.

**Behavioral Tasks:** You will be asked to complete several behavioral tasks during in-lab visits including 1) entering a simulated fast-food restaurant environment to complete questionnaires, 2) completing a computer task to earn money to be loaded onto gift certificates you will receive, 3) filling out a brief task about preferences for different financial amounts at different times, and 4) listening to pre-recorded scripts based on your own non-traumatic past stressful experiences.

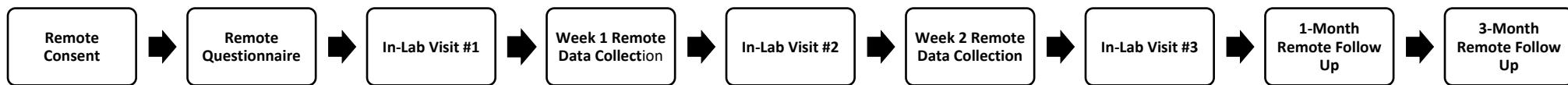
**24-Hour Dietary Recall:** Twice per week of remote data collection you will receive a phone call for an interview where you are asked to report on anything you ate or drank that day (total of 4 times over the study).

**Remote Check-Ins and Surveys (RealLife App):** You will be asked to download an app called RealLife App on your phone. Approximately 4-5 times per day you will receive alerts from the app to complete a brief set of questions on various topics including your current physical, cognitive, and affective state. You will also be asked to fill out brief surveys when you first wake up to assess your sleep and how you are feeling in the morning and each evening to assess your day overall. These reports will include questions about your overall physical, cognitive, and affective state. You will also be asked to provide photos of your grocery receipts through the RealLife app (or you may bring physical receipts to in-lab appointment if preferred).

**Continuous Blood Glucose Monitoring:** We will ask you to wear a small, minimally invasive technology (approximately the size of two stacked quarters) inserted subcutaneously (just under the skin) with a sensor that detects blood glucose levels using electrochemical assessment. The sensor can be discretely placed on the back of your arm and can be worn at all times (including when bathing). The sensor will provide the study team with real-time glucose readings to a receiver accessible only by the study team. You will not be able to see your blood glucose levels while wearing the sensor and you will be asked to return the continuous blood glucose monitoring system (using a pre-paid mailing envelope) after week 3.

**Fitbit Watch:** We will ask you to wear a small Fitbit smart watch that will track your activity level, sleep patterns and heart rate. You will not be able to see your Fitbit data while wearing the watch and you will be asked to return the Fitbit (using a pre-paid mailing envelope) after week 3.

**Diet ID:** We will ask you to complete a short online assessment of your typical weekday diet and your typical weekend diet.

Summary of Study Participation

	Remote Consent	Remote Questionnaires	In-Lab Visit #1	Week 1	In-Lab Visit #2	Week 2	In-Lab Visit #3	1-Month Follow Up	3-Month Follow Up
<b>Study Consent</b>	✓								
<b>fMRI Consent*</b>			✓						
<b>Questionnaires</b>		✓	✓		✓		✓		
<b>Body Composition (height, weight, Inbody)</b>			✓		✓		✓		
<b>Interviews</b>			✓		✓		✓		
<b>Mock Neuroimaging Scan*</b>			✓		✓				
<b>Behavioral Tasks</b>			✓				✓		
<b>Consume Typical Diet</b>				✓					
<b>24-Hour Dietary Recall</b>				✓		✓			
<b>RealLife App</b>				✓		✓			
<b>Continuous Glucose Monitoring</b>				✓		✓			
<b>Fitbit</b>				✓		✓			
<b>Follow Dietary Guidelines</b>						✓			
<b>Neuroimaging Scan*</b>							✓		
<b>Follow Up Survey</b>								✓	✓
<b>Diet ID</b>			✓		✓		✓	✓	✓

\* indicates only applicable to fMRI eligible participants.

**4.2 How much of my time will be needed to take part in this study?** The main portion of the study entails ~15 days of active participation beginning with in-lab visit 1. Including In-Lab Visit #1, you will be asked to come to the University of Michigan for in-person lab visits 3 times. After the main portion of the study, we will also contact approximately 1-month and approximately 3-months after study completion for a short follow up survey assessment that can be done on your own at home.

**4.2.1 When will my participation in the study be over?**

Your participation will end after the 3-month follow up period. If you are non-compliant with study protocols (e.g., non-responsive to RealLife App daily check-in and survey prompts, failing to complete 24 hour dietary recalls, not showing up to in-lab visits), you will be withdrawn from the study and be compensated for the study activities you have completed.

**4.3 If I decide not to take part in this study, what other options do I have?**

Your participation in this study is completely voluntary. You may refuse to enroll in this study, or withdrawal at any time without penalty or loss of benefits to which you may be otherwise entitled.

**5. INFORMATION ABOUT STUDY RISKS AND BENEFITS**

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

There are some risks to study participation that you should be aware of. The table below outlines potential risks of involvement with this study as well as steps the study team will take to minimize these risks.

Potential Study Risk	Protections Against Risks
<ul style="list-style-type: none"> <li>It is possible you may feel uncomfortable answering some questions or completing some tasks included in this study.</li> </ul>	<ul style="list-style-type: none"> <li>You do not have to answer any question or complete any study task that you do not want to. If you feel uncomfortable at any time you can let a member of the study team know and we will immediately stop the task. Study team members are trained to be sensitive to your feelings.</li> </ul>
<ul style="list-style-type: none"> <li>We will ask you to share personal information with trained research staff as part of your participation in this study. There is always the possibility that someone who is not authorized might see it.</li> </ul>	<ul style="list-style-type: none"> <li>We take the following precautions to prevent unauthorized persons from having access to your information: <ul style="list-style-type: none"> <li>Any information you give to us will be kept strictly confidential. All information will be kept in locked files or kept on password-</li> </ul> </li> </ul>

	<p>protected documents on secure research servers.</p> <ul style="list-style-type: none"> <li>- An ID number will be assigned to your information and only authorized staff will have access to the link between your name and your ID.</li> <li>- All research protocols are conducted in a quiet, private laboratory environment, so your responses will be confidential.</li> <li>- We will not give out information about you to anyone unless you provide a signed release or we suspect 1) that you have a medical condition requiring immediate care 2) abuse, neglect, or endangerment of a child or elder, or 3) that you or anyone else is in immediate danger or seriously hurting themselves or someone else</li> <li>- See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.</li> </ul>
<ul style="list-style-type: none"> <li>• The InBody system that will be used to assess weight and body composition has not been tested for safety in pregnant women and is not recommended for those with a pacemaker. While we will ask about this to confirm safe use of the device, it is possible to be unknowingly pregnant.</li> </ul>	<ul style="list-style-type: none"> <li>• Prior to using the InBody system, a pregnancy test will be available.</li> <li>• If participants would prefer, they can use a standard scale to assess body weight.</li> </ul>
<ul style="list-style-type: none"> <li>• Although you have been asked questions to ensure that you do not have a known allergy to foods involved in this study, it is possible that you could have an unknown food allergy that could become apparent during the study.</li> </ul>	<ul style="list-style-type: none"> <li>• Dietary instructions consist of common foods in the Western and constitute no more risk than standard dietary decisions.</li> </ul>

<ul style="list-style-type: none"> <li>Completing interview questions about past stressful experiences and/or listening to pre-recorded scripts about these experiences could result in some distress.</li> </ul>	<ul style="list-style-type: none"> <li>Interview questions about stressful experiences and the pre-recorded stressful scripts are expected to only invoke a short-lived experience of stress and safeguards are in place to reduce any distress you may experience. For example, we instruct you not to discuss any past traumatic experiences you may have had and will ask you to view a relaxing recording following the task. A list of resources and consultation with a licensed clinical psychologist will also be available if you or the study team determines these are necessary.</li> </ul>
<ul style="list-style-type: none"> <li>There is a risk of local skin infection at the point of insertion of the continuous glucose monitoring system which could include itchiness, redness, bruising, skin agitation. This is a rare occurrence, particularly in healthy individuals. It is also possible that the blood glucose monitoring could indicate a blood glucose level that indicates a condition such as pre-diabetes, diabetes, or hypoglycemia.</li> </ul>	<ul style="list-style-type: none"> <li>Removal of the continuous glucose monitoring system and time are typically sufficient to resolve risks of skin infection as well as associated symptoms.</li> <li>The blood glucose data in the study will not be viewed by a medical professional with the aim of providing a diagnosis. We encourage you to discuss any potential health concerns related to blood glucose with a primary care physician.</li> </ul>
<ul style="list-style-type: none"> <li>It is possible that wearing the Fitbit watch may cause skin irritation.</li> </ul>	<ul style="list-style-type: none"> <li>Removal of the Fitbit is typically sufficient to resolve skin irritation.</li> </ul>
<ul style="list-style-type: none"> <li>There are risks associated with the fMRI scan if you are eligible to complete the scan. These risks will be discussed in the fMRI consent form.</li> </ul>	<ul style="list-style-type: none"> <li>For additional information please see the fMRI consent form.</li> </ul>

## 5.2 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You will also be adding to the knowledge about how eating certain foods impacts the way you feel and may feel a sense of altruism and accomplishment in knowing this.

## 5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

## 6. ENDING THE STUDY

### **6.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

## 7. FINANCIAL INFORMATION

### **7.1 Will I be paid or given anything for taking part in this study?**

You will receive compensation at multiple points throughout the study for completing study visits and tasks.

After completing the remote questionnaire battery, we will mail you a \$20 reloadable gift card. All future compensation will be loaded onto this gift card after confirming the completion of study tasks for each segment of the study. A maximum of \$385 of compensation may be earned during the study if all study tasks at all study segments are completed.

You will not receive compensation for tasks that are not completed. If, for any reason, your study participation is discontinued you will receive compensation only for completed tasks up to that point and will not continue with the study or receive further compensation.

The breakdown of study compensation is described in the following table:

<b>Study Task / Segment</b>	<b>Description of Compensation</b>	<b>Total</b>
Remote Questionnaire Battery	\$20 for completing the remote questionnaire battery	<b>\$20</b>
In-Lab Visit 1	\$40 for completing in-lab visit	<b>\$40</b>
In-Lab Visit 2	\$40 for completing in-lab visit	<b>\$40</b>
In-Lab Visit 3	\$40 for completing in-lab visit	<b>\$40</b>
RealLife App (Check-ins and surveys)	\$5 per day completed for 14 days	<b>\$70</b>
24-hour dietary recalls (Food Intake)	\$10 per interview completed on 4 days	<b>\$40</b>
fMRI Scan	Completion of all components of the fMRI protocol (mock scans, actual scan, etc.)	<b>\$60</b>

RealLife App Bonus	\$10 for 80% completion of RealLifeTasks, \$15 for 100% completion of RealLife Tasks	<b>\$25</b>
24-Hour Dietary Recall Bonus	\$10 for completing all four 24-hour dietary recall interviews	<b>\$10</b>
Continuous Blood Glucose Monitoring and Fitbit Bonus	\$10 for returning the sensor and Fitbit system in the prepaid envelope	<b>\$10</b>
1month follow up	\$15 compensation for completion of follow up	<b>\$15</b>
3-month follow up	\$15 compensation for completion of follow up	<b>\$15</b>
<b>Maximum Compensation (eligible for fMRI Scan)</b>	Maximum possible compensation including bonuses and follow up periods if eligible	<b>\$385</b>

In addition to the above compensation, you will have an opportunity to earn money for a gift card to specific store locations (e.g., dairy queen, lowes) at visit 1 and visit 3. You will receive a giftcard with the earned compensation for those locations following the completion of visit 3.

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than \$400 for this study or 2) if you receive payments of greater than \$400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

## 8. PROTECTING AND SHARING RESEARCH INFORMATION

### 8.1 How will the researchers protect my information?

We take the following precautions to prevent any unauthorized individuals from having access to your information:

- Any information you give to us will be kept strictly confidential. All information will be kept in locked files or kept on password-protected documents on secure research servers.
- We will remove all names from all information we get (except the consent form). An ID number will be assigned to your information and only authorized staff will have access to the link between your name and your ID number. Your name will never be mentioned in any publication resulting from the study.
- All research protocols are conducted in a quiet, private laboratory environment, so your responses will be confidential. Further, we believe that the content of the questionnaires does not contain particularly sensitive information.
- We will not give out information about you to anyone unless a signed release. There are a few situations in which we would need to break confidentiality.

Outside of these reasons, we will not give out information about you to anyone else unless a signed release is provided. **Situations where we would need to share information with others would be if we suspect:**

- that you have a medical condition requiring immediate care
- abuse, neglect, or endangerment of a child or elder
- that you or anyone else is in immediate danger or seriously hurting themselves or someone else.

Your research information will be stored electronically on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

### 8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc/what-is.htm>

## **8.2 Who will have access to my research records?**

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

## **8.3 What will happen to the information collected in this study?**

We will keep the information we collect about you during the research for study record keeping and future research projects. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. We will retain identifying information for 10 years after which we will destroy all identifying information.

The researchers may contact you again as part of this project in the future.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

## **8.4 Will my information be used for future research or shared with others?**

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies. We would like to share your identifiable information with other researchers for future research. We will ask for your consent to do so at the end of this form. You can be a part of this current research project without agreeing to this future use of your identifiable information.

### **8.4.1 Special Requirements**

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We may put the information we collect from you into a repository. The repository would contain information about many people. Your information will be labeled with your study ID number instead of your name or other information that could identify you directly.

## **9. CONTACT INFORMATION**

## **Who can I contact about this study?**

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

**Study Coordinator:** Lindzey Hoover, MS

**Email:** [lindzeyh@umich.edu](mailto:lindzeyh@umich.edu)

**Phone:** (734)-763-5146

**Principal Investigator:** Dr. Ashley Gearhardt, PhD

**Email:** [agearhar@umich.edu](mailto:agearhar@umich.edu)

**Phone:** (734)-647-3920

**If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:**

University of Michigan

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)

2800 Plymouth Road

Building 520, Room 2144 Ann Arbor, MI 48109-2800

Telephone: 734-936-0933 or toll free (866) 936-0933 Fax: 734-936-1852

E-mail: [irbhsbs@umich.edu](mailto:irbhsbs@umich.edu)

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

## **10. YOUR CONSENT**

### **Consent to Participate in the Research Study**

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

## 11. OPTIONAL CONSENT

### **Consent to use audio-recording for purposes of this research.**

This study involves audio-recording. If you do not agree to be audio-recorded, you can still take part in the study.

Yes, I agree to be audio-recorded

No, I do not agree to be audio-recorded.

### **Consent to use and/or share your identifiable information for future research**

The researchers would like to use your identifiable information for future research that may be similar to or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future research. We may also share your identifiable information with other researchers. You can contact us at any time to ask us to stop using your information. However, we will not be able to take back your information from research projects that have already used it.

Yes, I agree to let the researcher(s) use or share my personally identifiable information for future research.

No, I do not agree to let the researcher(s) use or share my personally identifiable information for future research.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

### **Consent to be Contacted for Participation in Future Research**

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

Yes, I agree for the researchers to contact me for future research projects.

No, I do not agree for the researchers to contact me for future research projects.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (m/dd/yy): \_\_\_\_\_