

## Adolescent and Parent Consent Form

### **PROJECT MILKSHAKE**

My name is Eric Stice, and I am a scientist at Oregon Research Institute here in Eugene. I would like to invite you to participate in a research study funded by the National Institute of Health. The purpose of the study is to determine whether people are different in the way that their brains respond to food, and to investigate potential causes of eating and weight gain. You were selected as a possible participant in this study because you are between the ages of 14-17 or because you are the parent of a 14-17 year-old.

We want everyone to understand what this research study is about. Please read this form and ask any questions you may have before agreeing to participate. You can also find more information about the project on our website: [www.ori.org/milkshake](http://www.ori.org/milkshake).

#### **What Parents Will Be Asked to Do**

If you consent to your child's participation in this study, you will be asked to provide us with your height and weight. We will also be sending your child home with a food environment questionnaire that asks about the foods in your house, and you may need to help him/her complete the form. In addition, you will be responsible for transporting your child to and from all appointments associated with this study. There will be six to seven visits over the course of the study, and visits will range from one to five hours, depending on which activities are scheduled. Finally, we will ask you a couple of questions about your and/or the other biological parent's use of intoxicating substances. You will be able to choose to conduct the interview in person at Oregon Research Institute or by phone. The interview can take up to 15 minutes of your time.

#### **What Teens Will Be Asked to Do**

If you are eligible and decide to participate, you will be asked to complete several activities over a three-year period. These activities are outlined below. You will receive a specified amount after each visit to Oregon Research Institute, and you have the potential to receive up to \$365 over the course of the study.

All activities, with the exception of the fMRI scan (see details below), will take place at the Oregon Research Institute in Eugene.

#### Questionnaires

You will be asked to complete several questionnaires over the course of the study that ask about your body image, development, eating habits, and exercise routine. Most of these questions will be presented in paper-and-pencil format; however, there are some questions that will be asked by trained interviewers.

#### Measuring Height & Weight

We will be measuring your height and weight during most of your visits.

### Measuring Body Composition

We can determine your body composition (percentage of muscle and fat) by using an FDA approved device called the Bod Pod. For this procedure, you will be asked to put on your swimsuit and a swim cap that we will provide (wearing the swimsuit and cap will allow for the best possible test results). You will then be asked to sit inside the egg-shaped Bod Pod while it measures changes in air volume to calculate your body composition. The total time spent in the Bod Pod is approximately 3 minutes. For the study visits that involve the Bod Pod, you will be asked to not exercise, eat food, or drink anything (except water) for at least 2 hours before your visit to ensure that the results are accurate.

### Measuring Energy Use

In order to determine how much energy you use, we will conduct a test at Oregon Research Institute that specifically measures this. The test requires that you participate in an overnight fast (no food or drink, except water) before you come to Oregon Research Institute. Once here, you will be asked to provide a urine sample. Afterward, you will drink a water solution (less than 1/2 cup) that contains two stable isotopic tracers that are safe for use in humans. These are harmless, heavy water molecules, small amounts of which are found in tap water.

After drinking the water, we will need you to provide three additional urine samples within four hours of drinking the water. This test also requires a measurement of your resting metabolic rate, which is how much energy your body uses while resting. To measure this, we will have you wear a plastic hood over your head while you lie down and rest. The hood is fully ventilated, which means it will be easy for you to breathe. The hood makes it possible to measure the amount of oxygen you are using. While the hood is over your head, a staff member will always be in the room with you.

To complete the energy use test, we will need you to return to the lab approximately two weeks later so that we can collect additional urine samples.

### Saliva Sample

To determine the possible genetic influences on eating behavior and weight gain, we will ask you to provide us with a saliva sample. With this saliva sample we are able to collect these genes.

### Measuring Reward

You will play a game in which you try to earn points toward your favorite snack food. The game will be repeated, only this time you can earn points toward money.

### Measuring Brain Activity

As part of the study, we will ask you to participate in an fMRI brain scan. The scanning procedure will be conducted at the Lewis Center for Neuroimaging (LCNI) located in Straub Hall at the University of Oregon. Once you are positioned in the scanner, it will take anatomical images of your brain. You will see pictures of a chocolate milkshake or a glass of water. At certain time points you will receive very small amounts (2-3 drops) of chocolate milkshake or a tasteless solution (similar to water). While in the scanner, you will also play another game in which you try to earn a reward. In addition, you may be asked to participate in a second scan at the end of the study.

To determine eligibility for the study, the urine sample provided for the energy use test will be tested for pregnancy and randomly on *current* substance use (we will use commercially available tests that produce results within minutes). **If you test positive for pregnancy or substance use, you will be informed of the results and you will not be able to continue participation in the study. If you are excluded from the study because of a positive pregnancy or substance use test, your parents will be informed that you are not eligible to participate, but they will *not* be told why.** In the case of pregnancy, we exclude people as an extra safety precaution; in the case of substance use, we exclude people because the presence of certain substances in the body can interfere with the results of several measures we use in the study. Additionally, if you report a medically dangerous eating disturbance during the first visit, you will not be able to participate in this study and we will provide a treatment referral.

### **Risks and What Will Be Done to Reduce the Risks**

There are some possible risks involved for participants.

- 1) One possible risk is that you may feel uncomfortable by some of the questions that are on the questionnaires or asked during the interviews. You have the right to refuse to answer any question. In addition, the interviewers are trained to be sensitive to your feelings.
- 2) 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, though this has not happened previously. We take the following precautions to prevent any unauthorized person from having access to the information you give us:
  - a) Any information you give us will be kept strictly confidential. All information will be kept in locked files. We will remove all names from all the information we get (except this consent form). An ID number will be assigned to the information you give us, and only authorized staff will have access to the locked file that links your name to your ID number. Your name will never be mentioned in any publications resulting from this study.
  - b) We will not give information about you to anyone unless you provide a signed release or we have reason to suspect: (1) abuse, neglect, or endangerment of a child or elder; (2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these cases, we may have to break confidentiality and report this information to our supervisors and/or the appropriate authorities.
- 3) Parents may be concerned that their children will learn of their current or past use of intoxicating substances. In addition to the precautions listed above, we will store parents' responses related to substance use separately from the rest of our data.
- 4) While participating in measurements associated with the Bod Pod, the hood used for the energy use test, and the fMRI, teens may experience a feeling of claustrophobia. Lab staff will monitor these procedures carefully to ensure that teens are comfortable. In addition, the

procedures will be described before they begin. If the adolescent is concerned, the lab staff will provide an opportunity to become accustomed to the procedures before beginning the measures. If necessary, any procedure can be immediately stopped if the participant feels uncomfortable.

- 5) The safety of fMRI has been evaluated over the past 20 years and no short-term effects have been observed. However, the long-term effects of fMRI on the body are not fully known. The fMRI scanner makes loud "beeping" and "thumping" sounds. Teens will be required to wear protective earplugs during scanning. In addition, teens will be asked several questions before the scan to ensure that they do not have any conditions that would make the procedure unsafe.
- 6) As part of this study, teens will supply us with a DNA sample. (a) You may be worried about the potential risk for detection of any carriers of a disease or other medical condition. However, we are not using the sample to look for these things; we will only gather data about the specific DNA variations that we are studying. (b) The DNA sample will not contain any identifying information (only a subject identification number will be associated with the sample). The DNA will be stored in a secure lab, and only authorized staff will have access to remove DNA samples for analysis. After six months, all DNA samples will be destroyed.

### **Benefits to You for Your Participation**

There is a benefit for taking part in this research project. By serving as a participant, you may contribute new information that may benefit people in the future. You will be adding to knowledge about a new method of evaluating the relation between genes and risk factors for weight gain. We hope this can help us eventually reduce the prevalence of obesity and eating disorders in adolescents.

### **Your Right to Withdraw from the Project**

Your participation is entirely voluntary and you can decide to stop participating at any time during the project without penalty.

### **Questions**

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call Dr. Eric Stice (541-484-2123). If you have questions about your rights as a research participant, call the Office for the Protection of Human Subjects at Oregon Research Institute (541-484-2123). To contact Eric Stice or the Office for the Protection of Human Subjects by TDD, call 1-800-735-2900. You will be given a copy of this form to keep.

Your signature below indicates that you (1) have read and understand the information provided above, (2) that you willingly agree to participate, (3) that you may withdraw your consent at any time and stop participating at any time without penalty, and (4) that you have received a copy of this consent form.

**I consent to my child's ( \_\_\_\_\_ ) participation in this study.**  
*Print First and Last Name*

\_\_\_\_\_  
Name of Parent or Legal Guardian (Please print)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

**I assent to participate in the study described above.**

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Adolescent

\_\_\_\_\_  
Date

OPTIONAL: I agree to be contacted about a related research study. I understand that I can decline participation when contacted.

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Adolescent

\_\_\_\_\_  
Date