

CONSENT FORM

BODY ACCEPTANCE PROJECT VALIDITY SUB-STUDY

My name is Eric Stice, and I am a scientist at Oregon Research Institute here in Eugene, Oregon. I would like to invite you to participate in a separate study that is part of the larger research study evaluating two programs designed to increase body satisfaction among female college freshman. The purpose of this sub-study is to collect more detailed information about a person's weight, diet, and exercise levels, in order to assess the validity of self-report information. You were randomly selected from the young women who are participating in the main research study.

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 in the study.

What You Will Be Asked to Do

If you decide to participate, you will be asked to take part in two lab assessments conducted at the Oregon Research Institute. These lab visits will occur during the last two weeks of the time when you are attending the group intervention sessions. Alternatively, if you received the brochure (instead of attending the group intervention), your 1st lab assessment will be completed within one month of your baseline assessment for the main study.

For the 1st lab visit, which takes about 5 hours, you will arrive at the Oregon Research Institute in the morning after an overnight fast (no caloric food or caloric beverage intake after 11:59 pm the previous evening). You will be asked to drink a solution of water containing 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. This solution, called "doubly labeled water" can be analyzed to measure your caloric expenditure. You will be asked to drink less than a 1/2 cup of the doubly labeled water. You will be asked to provide a urine sample before drinking the solution and then at three additional time points within 4 hours after drinking the solution, during which time you will remain in the lab.

At the 2nd lab visit 14 days later, 2 additional urine samples will be collected for the doubly labeled water analysis. You will also be asked to complete a short survey during this visit. The second visit takes about 1.5 hours. Urine samples are not being collected for diagnostic purposes. The results will not be reviewed by a physician and no action will be taken if a laboratory value falls outside of the normal range. The urine samples will be shipped to a lab at the University of Wisconsin-Madison for analysis.

There are no known risks of doubly labeled water to a developing fetus; however, it is possible that risks may be discovered in the future. For this reason, women who are pregnant will not be able to participate in the sub-study. A pregnancy test will be completed at both of your lab visits, using a portion of your 1st urine sample. We will use commercially available pregnancy tests that produce results within a few minutes. If your pregnancy test is positive, a female research assistant will inform you of this and you will not be able to participate in the sub-study. However, you may continue participation in the main study. In the case that you have a positive pregnancy test, we ask that you see your physician or a provider at the University of Oregon Health Center. There is no cost for the pregnancy test.

In addition, individuals who use insulin for diabetes mellitus will not be able to participate in the sub-study. The reason for this is that subjects will be asked to come into the lab fasted, and for those who take morning insulin might become hypoglycemic and faint.

In order to obtain an accurate value for the doubly labeled water procedure, the following is required:

- During the week prior to the sub-study and throughout the sub-study, you should not travel more than 200 miles with an overnight stay (unless drinking the same bottled water as usual);
- During the week prior to the sub-study and throughout the sub-study, you should not have a blood transfusion, use bottled oxygen, or be administered intravenous fluids;
- During the 3 days prior to the sub-study and throughout the sub-study, you should not give blood.

Also during this 1st lab visit, your resting metabolic rate (RMR) will be measured using indirect calorimetry and a ventilated hood. For this procedure, you will lie down (on your back) on a bed in a quiet, dimly lit room. For the 1st 20 minutes you will be asked to rest. After this time has elapsed, a clear plastic canopy will be placed over your head to measure the amount of oxygen consumed and the amount of carbon dioxide produced by your body for 25-30 minutes. While the canopy is over your head, a staff member will always remain in the room with you.

In order to obtain an accurate RMR at your 1st lab visit, it is necessary to abstain from the following:

- Food and beverages (besides water) for at least 5 hours;
- Caffeine (e.g. coffee, tea, diet soda) for at least 5 hours;
- Alcohol for at least 13 hours;
- Smoking, nicotine products and narcotics for at least 13 hours;
- Exhaustive exercise for at least 24 hours;
- Vigorous exercise that day (prior to the lab visit)

Because of the intensive nature of this data collection, you will be paid \$80 in cash or check upon completion of your 1st lab visit, and \$100 in cash or check after you have completed your 2nd lab visit. This is in addition to your compensation for participating in the main study.

Risks and What Will Be Done to Reduce the Risks

Although the sub-study contains additional demands to the participants and involves a broader range of assessment procedures, risks are minimal. Staff will be carefully trained in all assessment procedures. Potential risks associated with the doubly labeled water and the RMR procedures are discussed below:

1. Measuring energy expenditure with doubly labeled water carries no physical risk. All of the tracers used in these studies are stable isotopes – there is no radiation hazard. The two natural atoms given in the water are not dangerous at all and are often given to small children and pregnant women. Of these stable isotope tracers, only deuterium has a known biological toxicity. Behavioral effects are noted when 10-15% of body water is replaced with deuterium oxide and death occurs at 50% replacement. The highest level reached in this study will be less than 0.1%.

2. Regarding the assessment of RMR with a ventilated hood, this procedure carries no risk, however, some participants may experience a feeling of claustrophobia. Lab staff will monitor this procedure carefully to ensure that you are comfortable. In addition, the procedure will be described to you before it begins and, if you are concerned, the lab staff will give you an opportunity to become accustomed to the ventilated hood prior to the procedure. If necessary, the hood can quickly and easily be removed during the procedure. People rarely experience claustrophobic symptoms, and when they do, these actions are effective.

3. As with the main study, we will be getting personal information from you. There is always the possibility that someone who is not authorized might see it. Any information you give us will be kept strictly confidential, even from other members of your own family and friends. We have a "Certificate of Confidentiality"¹ which is a legal paper from the federal government, which will help us protect your privacy even if the records are subpoenaed. We will not give information to anyone unless you provide a signed release or we have reason to suspect:

- Abuse, neglect, or endangerment of a child or elder; or
- That anyone is in immediate danger of seriously hurting himself/herself or someone else.

Such reports will be made to the appropriate authorities. 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. The urine samples shipped to the University of Wisconsin-Madison lab will only be identified by an ID number, and will be destroyed immediately after their assessment is completed. Your name will never be mentioned in any publications resulting from the study.

4. Since we are conducting a pregnancy test at both of your lab visits, it is possible that you may discover that you are pregnant after one of these tests. Our experience indicates that this situation is extremely rare; however, our female research assistants will be trained to deliver this information thoughtfully, and to be sensitive to your feelings. We will also provide referrals for university and community resources to support you in this situation.

5. Another possible risk is that you may be embarrassed by some of the assessments. You have the right to refuse any of the procedures. In addition, the lab staff are carefully trained and supervised to be sensitive to your feelings.

Benefit to You for Your Participation

Participants often derive a sense of altruism and accomplishment in knowing that they are contributing to understanding how we can better help other women overcome body image problems.

Your Right to Withdraw from the Project

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits you might otherwise receive. If you do decide to participate, you can stop participating at any time without penalty. For example, if you decide to withdraw from the project, it will not affect your grade at school.

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 Sheri Foster (Project Manager) at 541-484-2123. If you have questions about your rights as a research participant, call the Office for the Protection of Human Subjects, Oregon Research Institute, 541-484-2123. To contact Sheri Foster 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 understand 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.

Signature of Participant

Date

Printed Name

Signature of Investigator (or Designee)

Date

¹ *If the U. S. Department of Health and Human Services (DHHS) audits our research project, they can have access to information about you. However, they cannot report it to the police or use it for any reason besides the audit. Even though a Confidentiality Certificate was issued, it does not mean that the Secretary of DHHS supports this research project.*