

CONSENT FORM

BODY ACCEPTANCE PROJECT

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 research study evaluating two programs designed to increase body satisfaction among female college freshman. The current research study is funded by the National Institute of Diabetes and Digestive and Kidney Disease. Because many young women are dissatisfied with their bodies, and body dissatisfaction is a risk factor for eating problems and depression, we developed body acceptance programs for this age group. You were selected as a possible participant in this study because you are a female freshman at the University of Oregon in Eugene (all have been invited).

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 are interested in participating, you will call the lab and engage in a brief phone interview with a female staff member. If you report body dissatisfaction during your phone interview, you are potentially eligible to participate in the study. If you do not report body dissatisfaction during this interview, the programs involved in this project probably will not be helpful to you, and you will not be invited to participate. In addition, if you are already very slender (i.e., weigh in the lowest 5% for your age and gender), you will not be invited to participate since it might be medically hazardous for you to be in a program (that could result in further weight loss). If you are not eligible to participate, your consent forms and other information will be destroyed in order to protect your privacy.

If you are eligible and you decide to participate, you will be asked to take part in one of two programs that research suggests will promote body image acceptance. You will first take part in a brief survey and interview regarding your eating and exercise habits, body image, and mood. The initial interview will take place at Oregon Research Institute, which is located across the street from the University of Oregon campus. The interview will include measuring your height and weight. If you report a medically dangerous eating disturbance, which is rare, you will not be able to participate in this study and we will provide a treatment referral. If you report serious depression, we will provide a treatment referral, but you can still participate in this study.

In addition to the baseline assessments you will be asked to complete surveys and interviews regarding your eating and exercise habits, body image, and mood approximately 1 to 1.5 months after your baseline assessment and at 3 additional time points (6, 12, and 24 months after the baseline assessment). Furthermore, at 3 of your assessments, we would like to measure your body composition at baseline and at 12 and 24 months after your baseline assessment.

We can determine your body composition 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. We ask that you bring and wear your swimsuit and we will provide a swim cap to ensure the most accurate results. You will be asked to sit inside the BOD POD and remain still while the machine calculates changes in air volume to assess your body composition. This part of your visit will take about 15 minutes. You may feel slightly claustrophobic while sitting in the BOD POD. There is a window in the machine so you can see out and there is also a 'panic' button for you to push if you want to stop the procedure immediately. The BOD POD is kept clean between each use with a disinfectant.

For the study visits that involve the BOD POD, you will be asked to abstain from several activities to insure that accurate results are obtained. These activities include abstaining from: exercise, food, and drink for at least 2 hours prior to your scheduled assessment. The total assessment (including the BOD POD) should take about 1 hour and 45 minutes. You may participate in the study even if you do not want to have your body composition assessed via the BOD POD procedure.

If the baseline assessments indicate that you are eligible for the project, you will be randomly assigned to one of two programs designed to improve body satisfaction. In one group, called the Healthy Weight program, you will be encouraged to reduce fat and sugar intake and to increase physical activity as a way of improving body satisfaction. The program will consist of four 1-hour group meetings. The other group will participate in a psycho-educational brochure control condition. You will receive the brochure through post-mail and no additional follow-up will be completed for this intervention.

The group meetings will be audiotaped. The use of audiotapes will be limited to research and training of project staff under the supervision of the project directors. ORI may at any time copy, erase, or destroy these tapes. You may review the audiotape, and can request that any or all of the information contained on these tapes be destroyed. You can also request that the taping be stopped at any time during the group.

You will be given compensation for your participation in this study. You will be paid \$30 in cash or check for each assessment: baseline and 1 to 1.5 months, 6-months, 12-months, and 24-months after your initial baseline assessment. In addition, you will be given an additional \$30 upon completion of all assessments at the end of the study, for a total of \$180 over the course of two years. To make sure that our interviewers are asking the questions in the same manner, you may be selected to repeat some of the assessments with the same or different interviewer. If you are selected, you will receive an additional \$20. In addition, you may be selected to participate in a more detailed assessment of your weight, diet, and exercise levels. If you are randomly selected for that “add-on” study, you will be asked to complete a separate consent form describing that project.

Risks and What Will Be Done to Reduce the Risks

There are some possible risks involved for participants. These are:

1. 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 will request information about your alcohol and/or illegal drug use in some of the surveys. We have a “Certificate of Confidentiality¹” 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. Your name will never be mentioned in any publications resulting from the study.

2. Another possible risk is that you may be embarrassed by some of the questions on the assessments. You have the right to refuse to answer any question. In addition, the interviewers are closely trained and supervised to be sensitive to your feelings.
3. The BOD POD poses no physical risk because it uses changes in air volume within the chamber to assess body composition. However, some subjects may feel embarrassed when asked to wear only a swimsuit and cap during the procedure. Trained lab staff will be sensitive to your feelings to make you as comfortable as possible. 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 BOD POD prior to the procedure. If necessary, the chamber can be quickly and easily opened during the procedure. People rarely experience claustrophobic symptoms, and when they do, these actions are effective.
4. Finally, you may be worried that others will find out what you have told us. Only people who work on this project will have access to your personal information, and they are trained in keeping that information confidential. Also, we will ask that no participants in the program use names, refer to other people by name, or tell anyone else what they hear during the group sessions. This is an important aspect of group confidentiality, and anyone who is unable to honor this will be asked to leave the group in order to protect all group members’ privacy and to create a trusting environment. However, researchers cannot guarantee the confidentiality of what is said in the group setting.

Benefits to You for Your Participation

There are also some benefits to you for taking part in this research project:

1. The primary potential benefit from being in the study is an improvement in body satisfaction.
2. You will receive repeated assessments and be provided with referrals to treatment, if that should become necessary.
3. 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.
4. Monetary compensation as described above.

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, this 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 at 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.