Are you participating in any other research studies? ___Yes ___No

Your consent is being sought for participation in an eating disorders treatment research study. This is a brief, group-based intervention that attempts to reduce eating disorder symptoms, and decrease binge food cravings. Participation in the research study will include attending one-hour weekly group meetings that will take place for 8 weeks. You will also come to Stanford for three assessment visits (for surveys and measurement) over the course of the study: one visit at the beginning of the study; one visit following the 8-week group intervention; and one 6 months after the end of the group intervention. As part of this research study you will complete structured interviews with trained research assistants, computer tasks, and engage in a variety of treatment specific activities including participation in the group intervention where you will be asked to complete verbal, written, and behavioral exercises about eating habits.

Your participation in this study is completely voluntary. Some possible risks and inconveniences of the study include, travel to the study location, psychological discomfort during interviews and group treatment sessions. Some possible benefits of participating in this research are an improvement in body satisfaction and eating disturbances, as well as a contribution to the further understanding of eating difficulties.

PURPOSE OF RESEARCH

You are invited to participate in a research study of two group-based eating disorders treatment programs. We hope to learn about the effectiveness of these treatments in reducing eating disorder symptoms. You were selected as a possible participant in this study because your responses to our online and phone surveys indicate that you are a woman who might have an eating disorder.

If you decide to terminate your participation in this study, you should notify Dr. Cara Bohon at (650) 721-6960.

This research study plans to recruit 60 women between the ages of 18 – 34 who might have an eating disorder. Stanford University expects to enroll 60 research study participants.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take three years. Your participation will only occur over the course of approximately nine months. Each participant will complete:

1. One pre-treatment assessment, for about 2 hours
2. Eight one-hour weekly group interventions that will take place for eight consecutive weeks.
3. One post-treatment assessment, for about 2 hours
4. One six-month follow-up assessment, for about 1 hour
5. Two fMRI scans, one at pre-treatment and another at post-treatment for about 30 minutes each

PROCEDURES

If you choose to participate, Dr. Cara Bohon and her research study staff will coordinate a time with you to complete the various steps of the study.
After completion of the online and phone screener, a baseline interview will take place to confirm eligibility for participation in the study. The interview asks about eating and exercise habits, body image, and mood.

We require that all participants have a primary care physician in order to enroll. We will measure your body mass index (BMI) in the initial interview. Potential participants who have a BMI value less than 18 or who report more than weekly vomiting or laxative use will be required to visit their physician prior to enrollment. We will require that the physician provide a letter indicating that he or she approves your participation in our research activities.

Following enrollment in the study, you will be randomly assigned to one of two group interventions. These are one-hour weekly groups that will take place for eight consecutive weeks. Following the end of the intervention, participants are asked to complete a post-treatment assessment and fMRI scan. A final assessment visit will take place six months after completion of treatment. These activities are further outlined below.

<u>Assessment Visits to Stanford for Surveys and Measurement:</u>

You will come to Stanford University for three assessment visits over the course of the study: one visit at beginning of the study; one visit following the 8-week group intervention; and one six months after your post-intervention visit. Each of these visits will include:

1. A diagnostic interview assessing eating behaviors and attitudes.
2. A written survey that will address eating and exercise habits, body image, and mood.
3. An assortment of computer task involving the rating of images of different foods.

A small number of the participants will be randomly selected (by chance) to repeat the interview to make sure the research assistants are all asking the questions in the same manner. If you are chosen, you will be compensated for your time.
In the event of illness or travel, interviews can take place over the phone and survey completion can take place via Qualtrics if necessary. In rare cases (such as a global pandemic), participants may be admitted into the study without collection of in-person data (i.e. height and weight, computer tasks, and fMRI), but will still need to meet all other eligibility requirements.

fMRI Scans:

Participants will be asked to complete two fMRI brain scans. For both scans, participants will complete three tasks while in the scanner where they will be exposed to pictures of thin women, pictures of different types of foods, and action words. Each of the two scans will take approximately 30 minutes. Once positioned in the scanner, it will take anatomical images of your brain. It is important that you stay completely still while the scan is running. These scans will take place at the Lewis Center for Neuroimaging (LCNI) at the University of Oregon. The first scan will be scheduled after your baseline assessment is completed. The second scan will take place 8 weeks after the first scan and can be completed during the same visit as your interview and survey. Following the first scan, participants are asked to complete two brief computer tasks that involve rating images models and assessing the valuation of different foods. Following the second scan, participants will be asked to complete three brief computer tasks that involve rating images of different foods and models, and assessing valuation of different foods. Completing the scans is not required to participate in the study.

Group Treatment Sessions:

Participants will be randomly assigned (by chance) to one of two interventions designed to improve functioning and reduce eating disorders. Groups of 8-10 women will meet weekly at Stanford University. Groups last one hour and you will be asked to complete verbal, written, and behavioral activities. There are eight weekly meetings. During weeks two, four, and six, you will be asked to complete a brief survey following the group session.

The group sessions will be video-recorded to provide supervision to the group leaders. The use of video-recordings will be limited to research and training of project staff under the

supervision of the project directors. The tapes will be stored in a HIPAA-compliant encrypted online server, and will be labeled by group and session number. You may also request that the recording be stopped at any time during the group sessions. Your permission to be video-recorded is not required to participate in the study. In the event you are unable to attend a group meeting due to illness or travel, we offer the option of virtually attending the group meeting via Zoom.

I give consent to be video recorded during this study:

Please initial: Yes_____ No_____

Occasionally we use segments of the video recordings to train staff external to the project or for presentations at professional conferences and we ask your permission to use tapes of your groups for those purposes. Your permission to be video-recorded is not required to participate in the study.

I give consent for videos of my group to be used externally, as described above:

Please initial: Yes_____ No_____

MRI (magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. During the scan you will be asked to lie on a long narrow couch for a certain amount of time (state how long) while the machine gathers information. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken steps to relieve the "claustrophobic" feeling.

Future Use of Private Information and/or Specimens:

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Your specimens will be stored in a secure lab and only authorized staff will have access to remove DNA samples for analysis. Because your specimens will not be linked to your name you cannot withdraw your consent to the use of the specimens after they are taken.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Genetic Testing and Future Research:

As part of the analysis on your specimens, the investigators will do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment.

Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

We will examine your DNA sample for specific DNA variations related to eating behavior. The DNA tests we do are not diagnostic.

Genetic Information:

Information from analyses of your coded specimens and your coded information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic information in our databases back to you.

For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr.

Cara Bohon at (650) 721-6960

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Your participation in this study may involve risks that are currently unforeseeable due to the investigational nature of the study. However you will be informed if any new risks become apparent. The following explains the possible risks involved and the precautions we are taking

You will need to travel to our offices for your appointments; for some people, this is an inconvenience.

You may feel uncomfortable by some of the questions in the interviews and surveys. 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.

Participants involved in the group sessions may feel uncomfortable with some of the activities; the exercises are designed to help participants practice new behaviors to improve functioning and reduce eating disorders. Your participation in all activities is completely voluntary. In addition, group facilitators are closely trained and supervised to be sensitive to your feelings.

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects

must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed, so it is very important that you notify the operator. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. There is also a possibility of tinnitus (ringing in the ears) after the MRI.

If you feel discomfort at any time, notify the operator and you can discontinue the exam at any time.

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

POTENTIAL BENEFITS

There are also some benefits to you for taking part in this research project. The primary benefits from being in the study are an improvement in body satisfaction and decrease in eating disturbances. In addition, 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 and eating problems. Participation will inform the widespread distribution of an effective evidence-based intervention.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this study is to not participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

We will strive to keep your information as confidential as possible. However if information is disclosed to us during this study regarding suspected child abuse or neglect, suspected elder abuse or neglect, or the intent to hurt oneself or others - we must report it for legal and ethical reasons.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of abuse and neglect of children or elders, harm to self, or harm to others.

FINANCIAL CONSIDERATIONS

Payment/Reimbursement:

You will be paid for your participation. Participants can receive up to $305 across the course of the study. The following amounts will be given at the following times:

- First (pre-treatment) interview & survey: $45
- Completion of a pre-treatment fMRI scan (if applicable): $50
- Surveys completed during weeks 2, 4, and 6 of treatment: $30 total ($10 per survey
- Second (post-treatment) interview & survey: $45
- Completion of a post-treatment fMRI scan (if applicable): $50
- Completion of a reliability interview (if applicable): $25
- Completion of a six-month assessment following the date of the post-treatment interview: $60

If six-month assessment is completed virtually, participants will be compensated $50 instead of $60 as they will not be asked to complete all portions of the visit.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs:

There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

Sponsor:

NIH is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol

Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Cara Bohon You may contact her now or later at (650) 721-6960.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Cara Bohon You may contact her now or later at (650) 721-6960..

Independent Contact: If you are not satisfied with how this study is being conducted, or if

you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900.

Appointment Contact: If you need to change your appointment, please contact Ayotola Onipede at (650) 723-7885

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment,
- and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?

_____Yes_____No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

Signature of Adult Participant	**Date**
Print Name of Adult Participant	**Date**
Signature of Person Obtaining Consent	**Date**
Print Name of Person Obtaining Consent	**Date**