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Protocol Title: A Randomized Controlled Trial of Liraglutide 3.0 mg/d for Binge Eating Disorder

Principal Investigator: Kelly C. Allison, Ph.D.

University of Pennsylvania
Research Subject Informed Consent and HIPAA Authorization Form

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Principal Investigator: Kelly C. Allison, Ph.D.

Co-investigators: Robert Berkowitz, M.D.
Thomas A. Wadden, Ph.D.

University of Pennsylvania School of Medicine
Center for Weight and Eating Disorders
3535 Market Street, 3rd Floor
Philadelphia, PA 19104
215-898-7314

Principal Investigator Contact Information:

Kelly C. Allison, Ph.D.
215-898-2823

24-Hour Emergency #: 215-662-6059
Ask for the Psychiatric Resident on call

Why am I being asked to volunteer?

You are being invited to participate in the 20-week research study because you have indicated that you are interested in reducing your binge episodes and potentially are agreeable to using a medication. The medication is currently FDA-approved for weight loss, but not BED, which is why we are testing it in this study. You may choose not to participate in the study at any time. All participants will be provided with one of the two interventions which will be administered in the form of an injection, either liraglutide 3.0mg/day (Saxenda®) or a placebo. A placebo is an inactive substance (has no medical effect) that looks like the study drug, but contains no medication. This consent form discusses the two interventions in detail. Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of participating in the study, and what will be required of you during the study. The research team is going to talk with you about the study, and a staff member will give you this consent form to read. You may wish to discuss it with your family, friends, or primary care provider. You may find some of the medical language difficult to understand. Please ask the study staff if you have any questions. If you decide to participate, you will be asked to sign this form.

What is liraglutide?

Liraglutide 3.0 mg (Saxenda[®]) belongs to a class of medications called glucagon-like peptide-1 (GLP-1) receptor agonists. When activated by liraglutide, the GLP-1 receptor stimulates the release of insulin into the bloodstream. Liraglutide is a once-daily self-administered, subcutaneous (beneath the skin) injection that evidence shows may reduce appetite and reduce the urge to engage in binge eating. Liraglutide is approved by the U.S. Food and Drug Administration (FDA) for chronic weight management and diabetes management when combined with a reduced-calorie diet and increased physical activity. The present study aims to examine the effectiveness of the drug in treating BED as compared to placebo. The placebo, as mentioned previously, is an inactive substance and is designed to look like the study drug, but contains no medication. The placebo's ingredients include: disodium phosphate dihydrate, 1.42 mg; propylene glycol, 14 mg; phenol, 5.5 mg; and water for injection. Please see below for more specific goals of the present study.

What is the purpose of this research study?

This study has several goals. They include examining the effectiveness of liraglutide 3.0mg/day as compared to placebo in reducing the number of binge episodes per week during a 17-week, randomized, placebo-controlled trial. The study will also examine the proportion of participants on liraglutide 3.0 mg/day as compared to placebo who achieve a change in binge episodes from the start of the study compared to week 17. Additionally, the study will compare differences between the liraglutide 3.0 mg/day and placebo groups in changes in body weight, global BED symptom improvement, and other eating and mood related measures at treatment end. Approximately one half of the participants will be randomly assigned to receive liraglutide and one half will be randomly assigned to receive the placebo. Researchers at the University of Pennsylvania do not know whether the use of liraglutide 3.0 mg/day will lead to fewer binge episodes per week. This study is designed to answer this question.

How long will I be in the study? How many other people will be in the study?

A total of 152 participants will be enrolled in this study, and the total duration of the study for each participant will be about 20 weeks (from initial assessment through the end of treatment). The entire study, with all participants, will be completed in about 3 years.

What am I being asked to do?

You are being asked to participate in this study because you have indicated that you are interested in reducing your binge episodes and potentially are agreeable to using liraglutide 3.0 mg/day, which is an FDA-approved drug for weight loss, for the treatment of BED.

Procedures

Screening Evaluation

Behavioral screening visit. Persons who are interested in the study first will attend a behavioral screening visit. You will meet with a psychologist (or other qualified staff member) who will inform you about the study, review this consent form with you, and obtain your written informed consent. The study staff will assess your behavioral eligibility for the study, which includes evaluating your willingness to participate in the research procedures, as well as determining whether you meet the study criteria. The study staff will assess your BED symptoms, your mood, and possible psychiatric illness. With your permission, you may be asked to be audio recorded the administration of one of the interviews that assesses eating behaviors. The purpose of recording this section is to confirm reliability across interviewers and ensuring accurate diagnosis of binge episodes, when necessary. The recordings will be taken using recording devices and stored in a locked office. The recordings will be downloaded to a password protected and institutionally secured and managed network drive on University of Pennsylvania secured and managed computers. The recordings will be deleted from both the recorder and the network drive once study analysis has concluded.

Medical screening visit. Following successful completion of the behavioral assessment, you will:

- Undergo a complete medical history and physical examination.
- Your height, weight, blood pressure, pulse, and waist circumference will be measured.
- You will have an electrocardiogram (EKG) to assess your heart functioning.
- Several blood tests will be performed and approximately 1 tablespoon of blood will be collected.
- For women of childbearing potential, a urine pregnancy test also will be performed.

These labs will also be repeated at week 17 (treatment end). Results of these tests and evaluations will be reviewed by the study's physician to determine whether you have any contraindications to the treatment or to the use of liraglutide. Those who have recently used any other investigational drug and those who have previously participated in this trial will be ineligible to participate in the study. You will be referred to seek medical attention if the tests reveal any health concerns that require attention.

In order to participate in this study, you must have a primary care provider (PCP) who is responsible for providing routine medical care. If you do not have a PCP, you may ask the study team to provide you with a referral. You will not, however, be eligible to participate in the study until you have met with your new PCP.

Run-In Period

Upon successful completion of the screening visit, you will be asked to not change anything and eat normally for 2 weeks. Once per week over the next two weeks you will receive a brief survey to assess your binge eating episodes over the past week. If you do not have internet access, study staff will ask you these questions over the phone. You will be trained at the screening visit on general guidelines for the definition of a binge episode.

Randomization Visit

After the 2 week run-in period, the principal investigator will review all materials and further assess eligibility criteria based on the information gathered up to this point. If you meet all eligibility criteria assessed at the screening visit and during the 2 week run-in period, you will be scheduled for a randomization screening visit. If the criteria are not met, your participation would end at this point.

At the randomization visit, your weight, blood pressure, and pulse will be measured. You will then be randomly assigned by chance to one of the two intervention groups (i.e., liraglutide 3.0 mg/day or placebo). You will not be able to choose the group that you prefer (if you have a preference), and you must be willing to participate in either of the two groups to which you are randomly assigned. If you are not willing to participate in either of the two groups, then this research study is not appropriate for you, and you should not proceed to give your informed consent. The study team will provide other recommendations for treating BED.

Because the study is double-blind, this means that neither you, Dr. Allison, the study physician, or the study staff are aware of what condition you will have been randomized to. A randomization code will be created by Penn's Investigational Drug Service (IDS). At the conclusion of the study, the randomization code will be opened and the conditions of each participant will be revealed. In the case of a medical emergency, the code may be broken if the identity of the treatment would influence your treatment. You are not permitted to participate in any other treatments for BED, including medications or psychotherapy, while you are participating in this study.

During this first treatment visit, you will have a medical visit with the study physician who will instruct you in the use of the medication. You will be provided with the first month's supply of medication or placebo, which will be provided as pre-filled, disposable, personal injectors.

Ongoing Medical and Safety Measures

After randomization, you will return at week 1 to assess your eating and any other effects of the medication. You will return for study visits every two weeks thereafter, at weeks 3, 5, 7, 9, 11, 13, 15, and 17. At these visits, there will be brief (5-10 minutes) medical visits with a physician or nurse practitioner (total of 9 visits). Weight and vital signs (blood pressure and pulse) will be measured at each of the visits. At each medical visit, your response to the treatment will be assessed. You will be asked whether there has been any change in your health or medications.

At these visits, you will also meet with the study staff to assess binge eating episodes and will be asked about your mood or any thoughts of harming yourself, as assessed by clinical interviews and questionnaires. You will be referred to your PCP if your mood significantly disrupts your normal function (as reflected by symptoms that include feeling blue, not enjoying usual activities, trouble sleeping or concentrating, or having thoughts of dying or harming oneself). In the event of reports of suicidal ideation or disturbances in mood, you will be referred to the study's psychologist or psychiatrist for further evaluation, as appropriate. You will be referred to

your own PCP for all non-study-related medical events and asked to follow up with the study team with any medical events. You will be asked to report all study-related medical events to the study staff who will closely monitor them.

Outcome Assessment Measures

Study visits will assess the primary and secondary outcome measures used to judge the effectiveness of the treatments for BED.

Binge episodes. Reported binge episodes will be assessed by an interviewer-based questionnaire to measure the change in binge episodes per week from week 0 (randomization) to week 17. With your consent, you may be audio recorded during this portion of the study for the purpose of confirming reliability across interviewers and ensuring accurate diagnosis of binge episodes, when necessary

Questionnaires. You will be asked to complete several questionnaires at each of the assessment visits. These questionnaires are designed to assess your mood, quality of life, hunger, and attitudes towards food. You will have the opportunity to examine the questionnaires before you complete them. Your answers to these questionnaires will provide data for the secondary outcomes.

Blood tests. You will undergo fasting blood tests at your screening visit and week 17, as described previously. Approximately 1 tablespoon (i.e., 15 ml) of blood will be needed at these two visits. The results of these assessments will be used by the study physician to monitor your health, in addition to providing research data.

Vital signs and weight measurement. Vital signs, such as blood pressure and pulse, and weight will be measured at each of the study visits to monitor your health, in addition to providing research data.

What are the possible risks or discomforts?

Risks of the 17-Week Treatment – Liraglutide 3.0mg/d or Placebo

Blood draw. Risks of drawing blood include pain or discomfort, bruising at the puncture site, swelling, feeling faint or lightheaded, and rarely infection.

Subcutaneous Injection. Risks of subcutaneous injection of the study medication include pain or discomfort, bruising at the puncture site, swelling, feeling faint or lightheaded, and rarely infection.

Risks of Liraglutide

All drugs carry some risk of side effects. In order to prevent harm, you must inform the study team if you experience any side effects from the study medication.

In several clinical trials of at least 1-year duration, the following side effects were reported in greater than 5% of persons taking liraglutide and more frequently than in placebo-treated patients:

- Nausea
- Low blood sugar
- diarrhea
- constipation
- vomiting
- increased lipase (an indicator of liver and pancreas abnormalities)
- abdominal pain
- indigestion
- headache
- dizziness
- decreased appetite
- fatigue

Adverse reactions reported in greater than or equal to 2% of liraglutide-treated patients and more frequently than in placebo-treated patients included:

- gastroesophageal reflux disease
- bloating
- belching
- flatulence
- hypoglycemia
- dry mouth
- injection site erythema (redness)
- injection site reaction
- asthenia (weakness)
- gastroenteritis (stomach flu)
- urinary tract infection
- insomnia
- anxiety

Liver enzyme elevation. Blood test abnormalities that have been reported with the use of liraglutide include increases in alanine amino transferase (ALT), a liver enzyme. During this study, you will have your blood tested regularly to monitor for any changes.

Thyroid C-Cell Tumors. Liraglutide causes both cancerous and non-cancerous thyroid C-cell tumors in mice and rats; the relevance of this finding to humans has not been determined. Persons with a personal or family history of thyroid tumors are not eligible for this study. If you experience any signs or symptoms of thyroid tumors (e.g., a lump in the neck, hoarseness, difficulty swallowing, or shortness of breath) you should contact your primary care provider (PCP) or the study staff.

Acute pancreatitis. Acute pancreatitis (inflammation of the pancreas) has been observed in patients treated with liraglutide. Contact your PCP or the study staff if you experience severe pain in your stomach area (abdomen) that is persistent.

Acute gallbladder disease. Gallbladder problems, including gallstones, have been reported in patients taking liraglutide. Contact your PCP or the study staff if you experience pain in your stomach area (abdomen), fever, yellowing of your skin and eyes (jaundice), or clay-colored stools.

Increased heart rate. Liraglutide may increase heart rate. During this study, you will have your heart rate measured regularly to monitor for any changes.

Kidney impairment. In patients treated with GLP-1 receptor agonists, including liraglutide, there have been reports of acute kidney failure and worsening chronic kidney (renal) failure, sometimes requiring dialysis. Persons with clinically significant kidney disease are not eligible for this study. During this study, you will have your blood tested regularly to monitor for any changes in kidney function.

Suicidal behavior and ideation. Suicidal behavior and thoughts were reported in liraglutide-treated patients. Persons who are at risk for suicide attempts or those with active suicidal thoughts should not take liraglutide. (That is why study staff will ask you questions about these issues at your screening visit.) Your mood will be assessed throughout the program. If you experience a change in mood, or have thoughts of harming yourself, you should contact your primary care provider and the study staff.

Unforeseen risks. People may have allergic reactions to medications. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include rash, difficulty breathing, wheezing, sudden drop in blood pressure, fast pulse, sweating, and swelling around the mouth, throat, or eyes. There may be other risks associated with liraglutide that have not been identified. If additional risks are identified during the study, you will be informed of them by the study team.

Reproductive risks. The use of liraglutide may pose risks to pregnancy and/or an unborn baby. Therefore, you should not become pregnant while you are in the study. If you are able to become pregnant, you will be required to follow a study-approved method of birth control while participating in the study. Adequate birth control in this study is the use of double barrier methods (condom with spermicide or diaphragm with spermicide), stable hormonal contraception, intrauterine device, abstinence, or tubal ligation.

Liraglutide also may have unknown risks to breast-fed babies. Therefore, you should not breastfeed while you are taking this drug.

If you are a male, there is no documented risk for males who reproduce while taking the study drug. Therefore, using birth control is not a requirement for participation in the study.

Although pregnancy testing will be performed, it is possible that the results could be wrong. If you do become pregnant during the study, you will be asked to immediately notify the study team, to discontinue the drug, and to consult an obstetrician or maternal-fetal specialist. You will be withdrawn from the study but the study physician or nurse practitioner will remain in contact with you to learn the outcome of your pregnancy. The study physician or nurse practitioner will confirm that you are consulting with an obstetrician or maternal-fetal medicine specialist, record any complications, and obtain information regarding the overall health of you and the baby via self-report measures each trimester and post-delivery. The study physician will share this information with the University of Pennsylvania Institutional Review Board and with Novo-Nordisk, who manufactures the medication.

Risks of Placebo

Because the placebo does not contain any active ingredients and is not intended to treat your symptoms, there is a risk that your binge-eating may get worse.

What if new information becomes available about the study?

During the course of the study, we may discover new information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

It is not known if the study drug will cause any reduction in binge episodes or any medical benefit. This study may benefit society at large by providing information about the effectiveness of liraglutide 3.0 mg/day.

What other choices do I have if I do not participate?

Your alternative is not to participate in this study. Should you choose not to participate in this research study, there are several ways to reduce binge episodes that do not require the methods used in this program. These include psychotherapies, specifically cognitive behavioral therapy. Additionally, other pharmacological treatments are sometimes used to treat BED including antidepressant medications, antiepileptic medications, weight loss medications, and stimulant (ADHD) medications. Lisdexamfetamine is the only currently approved drug by the U.S. Food and Drug Administration (FDA) for treating BED, which has been shown to reduce binge eating episodes, increase cessation of binge episodes, and increase weight loss compared to placebo. We do not know how lisdexamfetamine or other treatments compare in safety and effectiveness to liraglutide 3.0 mg (Saxenda[®]) as there have been no previous randomized controlled trials examining the effectiveness of liraglutide 3.0 mg in treating BED (or comparing liraglutide 3.0 mg to lisdexamfetamine or other treatments, for that matter). This present study is designed to collect data on efficacy and safety of use of liraglutide compared with placebo. We may then compare the results of the present study to studies published using lisdexamfetamine to examine effects on BED and on frequency of adverse events for the two different medications.

Will I be paid for being in this study?

You will receive travel funds of \$10 at the randomization visit and each of the study visits (weeks 1, 3, 5, 7, 9, 11, 13, and 15). You also will also receive \$30 for the first screening visit and week 17 visit. Additionally, you will receive a \$100 bonus for completing the study. This is a total of \$250.00. You will only receive payment for the visits you complete. Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of \$600 in a calendar year.

Will I have to pay for anything?

There is no cost or financial risk for participating in this study. All study medication and assessment measures will be provided free of charge.

This research is being sponsored by an Investigator Initiated Study grant (to Kelly Allison, Ph.D.) from Novo Nordisk, the pharmaceutical company that manufacturers and markets liraglutide 3.0 mg (Saxenda). Dr. Allison, with assistance from colleagues, designed the present research trial and is the principal investigator of the study at the University of Pennsylvania (which is the only site at which the study is being conducted). Novo Nordisk will not be involved in conducting this research trial but will receive periodic reports on the study's progress.

What happens if I am injured or hurt during the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator, Kelly Allison, Ph.D. (215-898-2823) or emergency contact (215-662-2121). You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

We will offer you the care needed to treat injuries directly resulting from taking part in this research study. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for an injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, you should contact the Principal Investigator listed on page 1 of this form.

When is the study over? Can I leave the study before it ends?

The study will end after all participants have completed all visits and all research information has been collected. The study may be stopped without your consent for the following reasons:

- The Principal Investigator or your physician believes it is necessary for your health or safety. You will be informed if such a decision is made and the reasons for the decision.
- You have not followed study instructions.
- The Principal Investigator or the Office of Regulatory Affairs at the University of Pennsylvania has decided to stop the study.

Your participation in this study is voluntary. You may withdraw from the study at any time without penalty or loss of any benefits to which you are otherwise entitled. Withdrawal will not affect your future care at the University of Pennsylvania Health System. If you wish to withdraw, you should contact the Principal Investigator listed on page 1 of this form.

How will confidentiality be maintained and my privacy be protected?

Personal information is anything that can be used to identify who you are. Examples include your name, address, telephone number, medical record number, social security number, or electronic mail address. We will do our best to make sure that the personal information obtained during the course of this research study will be kept confidential. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Where will study records and data collected at this site be stored?

- In a locked office
- In password protected and institutionally secured and managed computers
- In password protected and institutionally secured and managed network storage

What information about me may be collected, used, or shared with others?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this study:

- Name, address, telephone number, and date of birth
- Social security number
- Personal and family medical history
- Electronic mail address
- Medical record number
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, weight, height, and waist measurements
- Results of tests and procedures you will undergo during this research study as described in the informed consent form

What Is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Why is my personal health information being collected?

Your personal health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care.

How is my information being used?

Your information is used by the research team to contact you during the study via telephone or email. Your social security number is used to process any reimbursement payments. Your information and results of tests and procedures are used to:

- Conduct the research
- Oversee the research
- Determine if the research was executed properly

Who may use and share information about me?

The following individuals and organizations may use or disclose your personal health information for this research study:

- The Principal Investigator and the research team associated with the study
- The University of Pennsylvania Institutional Review Board (the committee responsible for overseeing research on human participants) and the University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.)
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Who, outside of the School of Medicine, might receive my personal health information?

- The Food and Drug Administration
- The OHR Protections
- Medical personnel from Novo Nordisk Inc. which manufactures, markets, and distributes liraglutide.
- Quest diagnostics

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations. The study team will inform you if there are any additions to the list above during your participation in the study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than the study unless:

- You have given written authorization
- The University of Pennsylvania Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my personal health information?

You may withdraw your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigator of the study. Even if you withdraw your permission, the Principal Investigator may still use your personal information that was collected prior to your written withdrawal request. If you withdraw your permission to use your personal health information, you will not be able to remain in the study.

Who can I call with questions or complaints, or if I'm concerned about my rights as a research participant?

If you have questions, complaints, or concerns regarding your participation in this study or your rights as a research participant, you should speak with the Principal Investigator listed on page 1 of this form. If a member of the study team cannot be reached or you want to talk with someone other than those working on the study, you may call the Office of Regulatory Affairs at the University of Pennsylvania at (215) 898-2614.

What if I decide not to give permission to use my personal health information?

You will not be able to participate in this study if you do not give permission to use your personal health information.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes, as described above.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

You will be given a copy of this consent form.

Name of Participant (Please Print) _____ Signature of Participant _____ Date _____

Name of Person Obtaining Consent (Please Print) _____ Signature _____ Date _____

Please indicate whether you agree to be audiotaped during an assessment of eating behavior:

Yes No Initials: _____

Schedule of Visits and Assessments

	Screening			RCT									
				Weeks									
	Screen	2-week run-in	Randomization/ Week 0	1	3	5	7	9	11	13	15	17	
Procedures													
Informed consent	x												
Adverse events actively collected	x	x	x	x	x	x	x	x	x	x	x	x	
Behavioral evaluation	x												
History and physical	x												
EKG	x												
Blood draw	x												x
Labs	x												x
Log of BED behaviors		x											
Self-reported outcomes			x	x	x	x	x	x	x	x	x	x	x
Medical visit			x	x	x	x	x	x	x	x	x	x	x
Psychological assessment of BED symptoms	x		x	x	x	x	x	x	x	x	x	x	x
Vital signs	x	x	x	x	x	x	x	x	x	x	x	x	x