COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Efficacy and Mechanisms of Naltrexone + Bupropion for Obesity and Binge Eating
Contact Principal Investigator: Carlos M. Grilo
Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to look at the effectiveness of a medication, naltrexone/ bupropion combination, relative to placebo for reducing binge eating. This medication is not approved by the FDA for the treatment of binge eating. You have been asked to take part because you experience binge eating, you have a body mass index between 21.5 and 50 kg/m^2, and you are between 18 and 70 years old. We expect that approximately 200 patients will participate in this study.

To decide whether or not you wish to be part of this research study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion will go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to take part in this study, you will be asked to do an initial evaluation. If you are eligible, you will be enrolled in a 12-week (3 month) treatment.

Initial Evaluation
Your first appointment will be with a research-clinician at our clinic (the Program for Obesity, Weight, and Eating Research on the Yale School of Medicine campus). During this visit, we will ask questions about your health, eating behaviors, any alcohol or drug use, and any other psychological and physical problems that you may have now or may have had in the past. We will also measure your weight, height, and blood pressure. We will also ask you to do online surveys at home.

If you had a physical by your own doctor within the past year, we will ask you to give us permission to get information about that physical. This information will include any medical conditions (including heart or liver problems) you may have had, blood pressure, and results of any blood tests you may have had. If you had not had a physical in the past year, we will ask you to get a

physical with a healthcare provider of your choice to help determine whether you are eligible to participate. If you are unable to obtain a physical from your provider, you will receive a physical as part of the study. The cost of a physical obtained at the Yale Church Street Research Unit would be covered by the study.

For your safety, we will ask you to have your blood drawn for routine blood tests and tests measuring your liver function. We will also ask you to have a test to ensure you are not currently taking drugs or medications that include opiates. If indicated at any time during treatment, we will also ask you to have a pregnancy test. There is no cost for these tests that are for your safety. If you are pregnant, you will not be allowed to participate in the study. We also ask that you agree to use a reliable form of birth control while you are in the study. The study medication should not be taken during pregnancy because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. Additionally, the safety of these medications to fetal health is not known. Bupropion is used as an antidepressant but is not a first-choice drug in pregnancy. Research has shown a possible connection between exposure to bupropion in early pregnancy and 1) cardiac abnormalities in the baby and 2) a risk of miscarriage. Therefore, using reliable birth control is required while on the study medication.

Once it is determined that you are eligible for the study and you are interested in participating, you will have a pre-treatment laboratory session at the Hospital Research Unit (HRU) of Yale New Haven Hospital or at the Church Street Research Unit (CSRU) at 2 Church Street South. You will not be excluded from the treatment study if you choose not to do the lab sessions. If scheduling is difficult for this appointment, you may be asked to complete the first laboratory session four to six weeks after you start the treatment. You must fast (no food, only water) starting at 10:00pm the night before your scheduled lab session and remain fasting until after you arrive at the HRU/CSRU. The lab session will begin at 7:30am and you will be discharged at 3:30pm. If you are a smoker, you are allowed to smoke as you normally would prior to coming to the HRU/CSRU. You will not be allowed to smoke during the lab session. In addition, gum, candy, etc. are not allowed during the lab session.

Upon arrival at the HRU/CSRU, you will meet with a member of the research team who will verify that you have fasted since at least 10:00pm the night before. If you have not fasted, we may have to reschedule your lab session. A research nurse will then insert a normal saline lock IV in one of your arms so that we can draw blood at regular intervals. There are multiple blood draws throughout the day, but they will all be drawn from the same IV so you will not be stuck multiple times throughout the day. Once all the baseline blood samples have been obtained, you will be provided with a standardized breakfast so all participants receive the same breakfast. You will be filling out questionnaires and have your vitals (blood pressure, pulse) taken throughout the day.

After you are settled in your room, you will have a 3-hour rest period during which time you can watch TV or read. There will be some questionnaires for you to complete during the 3-hour rest period and you will have your blood drawn. You may not eat during this time.

At 11:00am, you will be seated in your room at the HRU/CSRU and you will participate in an eating self-serve session, which you will choose to begin at any time between 11:00 am and 2:00

pm. You are not allowed to watch TV, read, use your cellphone or any electronics during the eating self-serve session. Cellphones will be locked away. The eating self-serve session will be videotaped and you will wear a wristwatch that is paired with a smartphone that will track eating behavior/movement. You will be presented with 6 of your preferred food/snack options. You must remain seated throughout the self-serve session. During the next three hours, you can choose to eat as much of these foods you like, but for each minute that you can wait to start the eating the snacks, you will earn money. You start by earning $0.35 per minute for each minute you wait. The amount of money you earn per minute decreases by $0.01 every 5 minutes. To be clear, for the first 5 minutes you wait (1-5 minutes), you are earning $0.35 each minute, for the 5 minutes after that (6-10 minutes), you are earning $0.34 each minute, and for the 5 minutes after that (11-15 minutes), you are earning $0.33 each minute. This continues to decrease by $0.01 every 5 minutes until it reaches $0.00 at 180 minutes. You can earn a maximum of $31.50 if you wait all 180 minutes. There will be some questionnaires to fill out during this waiting period along with vitals and blood draws. Once you decide to start the eating session, you can eat as much as you would like until the end of the eating session, which is 2:00pm. You will be filling out questionnaires, having vitals taken and getting your blood drawn at regular intervals throughout the eating self-serve session. At the end of the eating session the food will be removed and you will remain in the lab room until discharge at 3:30pm.

Treatment: If you qualify for treatment, and if you decide to participate, you will be assigned randomly (by chance, like flipping coins) to one of two medication treatments: (1) active medication (naltrexone/bupropion combination), (2) inactive placebo pill. Both last 3 months. You have a 50% chance (1 out of 2) of being assigned to each group. You will be assigned randomly (by chance), not because of any special characteristics or problems you may have.

This is a "double blind" study, which means that neither you nor the research team will know what medication you will be taking. The study doctor will meet with you before you start the medication, and will talk to you about how to take it, when to take it, and how you might feel when you take it. You will also be given a card to keep in your wallet that has information to use if you have an emergency. This card identifies you as a participant in this research study and has phone numbers to call in case of emergency. At the end of treatment, or if you stop the study before it is over, we will ask you to return any extra medication and take a smaller dose of the medication to avoid side effects that could come from stopping the medication too suddenly.

During the treatment, people in both groups will be able to call the doctor if they have any concerns about the medication. You will meet with a research clinician twice during the first month, and then monthly, for the time you are taking the study medication. (for approximately 15 minutes) to talk about whether you are taking the medication, if you have any side effects, and to measure your weight and blood pressure. We will also ask you to complete online surveys. For safety, at the first monthly visit and at the end of treatment we will also ask you to get your blood drawn so that we can make sure your liver tests are still normal or healthy.

Biosensor

A small group of participants (n=60) will be asked to use a wearable biosensor system for the first 6-weeks of the medication/treatment period to remotely monitor stress and eating behavior. There are a limited number of biosensor units, so participants will be invited to participate as units are available. If equipment is available, we will provide you with a Garmin wristband and an Android cell phone. You must wear the Garmin wristband daily and carry the cell phone with you at all times. Each evening at 10:00PM (or when you initiate "End of the Day"), we ask that you complete the Daily Diary, which is located in an app on the cell phone. You'll be asked questions regarding your eating behavior and stress for that specific day. Throughout the day, you'll receive random prompts on the cell phone asking you various questions such as: What is your stress level right now? What is your urge to binge right now? How long has it been since you last finished eating something? You'll receive up to 4 of these prompts per day. These are brief prompts that should take no more than 1 minute to respond to. It is important that you respond to all prompts throughout the day, but you should never respond to a prompt while you are driving a car. The prompt can be answered once you have safely reached your location and no longer driving. In addition, if you do binge eat, we ask that you open the app on the Android cell phone and answer a few brief questions. These questions can be about stress relief, craving relief, stimulation and sedation. We ask that you interact with the app before and after you binge eat. We will be using GPS data to look at how stress and eating behavior varies across locations. The GPS data will be collected through the app and will be collected every 5 minutes during waking hours. The proposed GPS device will allow the research team to determine your location throughout the day unless you actively disable the device. It is important that you wear the Garmin band daily, carry the cell phone with you at all times, and make sure both the Garmin band and cell phone are properly charged.

The Android cell phone provided to you will have the app already loaded and ready for use. The information that you enter into the app is de-identified because it will be set up using a Subject ID and not your real name. UMass will be collecting the data from the phone, but will not receive a "key" to identify anyone enrolled in the study. This application does not qualify under the FDA definition as a medical device, and more specifically Software as a medical device (' FDA Software as a Medical Device (SAMD): Clinical Evaluation, Guidance for Industry and Food and Drug Administration Staff, issued on December 8, 2017'). Data collected from the app and the Garmin device will allow use to understand how stress affects your eating, and how the medication might affect this.

You must return the smartwatch and smartphone to the Research Team at the end of the 6-weeks. If you do not return the smartwatch and smartphone, you will not receive additional compensation for completing the 6-weeks.

During the final week of the 12-week medication period, you will complete a second lab session at the HRU of Yale New Haven Hospital or CSRU at 2 Church Street South. The lab session is held from 7:30am to 3:30pm and the procedures are the same as the lab session previously completed before you started taking the medication. We will ask you to take your medication dose right before you come to the lab session.

<u>Post-Treatment Evaluation</u>

At the end of the treatment stage (3 months into the study), you will meet with a research clinician for approximately 2 hours. We will ask you to do online surveys, have your blood drawn for routine blood work and liver tests, and measure your weight and blood pressure. We will also ask you about your eating behaviors, including how frequently you are binge eating, and how you are doing psychosocially.

Follow-up Evaluations

We will ask you to come back to do an evaluation 6 months after treatment is over and again 12 months after treatment is over. You will meet with a research clinician for approximately 2 hours. We will ask you to do online surveys, have your blood drawn, and measure your weight and blood pressure. We will also ask you about your health and eating behaviors. These evaluations help us know how long the effects of the treatments may last. You will find out what medications you received after your last visit.

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.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

Risks and Inconveniences

Since you will have had a thorough physical examination and will discuss your current medications and health problems with research clinicians and a study doctor, potential risks will be minimized.

1. *Medication Side Effects.* Naltrexone/bupropion medication has certain side effects that are mostly gastrointestinal. The most common side effects include nausea (32.5%), constipation (19.2%), headache (17.6%), vomiting (10.7%), dizziness (9.9%), insomnia (9.2%), dry mouth (8.1%), and diarrhea (7.1%).

   The U.S. Food and Drug Administration (FDA) has issued an Advisory cautioning health care providers, patients, and families to closely watch individuals taking bupropion medication for signs of their depression getting worse and for thoughts of killing or harming themselves, especially during the first several weeks that the medication is being taken. Patients and their families should watch for and promptly report new symptoms. For example, report to the study doctor as soon as possible any signs of impulsivity (taking action or saying something without thinking first), agitation (feeling nervous or finding sitting still very difficult), and panic attacks (extreme fear without apparent reason).

   We will ask you about depression twice during the first month, and then monthly, for the time you are taking the study medication.

   One of the study medications, naltrexone, can cause withdrawal symptoms in someone who is taking certain types of pain medications or drugs. If you are taking

any of these medications or drugs you should not participate in the study. If you would like to participate in the study you should tell us about all the medications or drugs you are taking, or have taken recently, so we can let you know whether you can safely qualify for the study. *If you are dependent on opiate drugs, such as heroin, morphine, codeine, Demerol, Percocet, or Percodan, naltrexone can cause significant opiate withdrawal.* You should not participate and we will not include you in the study if we know or suspect you are using opiate-containing drugs. For your safety, we will ask you to have a urine test to ensure you are not currently taking drugs or medications that include opiates.

You will be asked to carry a medication card that will let medical personnel treating you know that you may be taking naltrexone. You should show this card to any medical provider who is treating you. This card, which should be kept on you at all times, will include appropriate medication information and precautions. In an emergency, the medication being taken (naltrexone/bupropion combination or placebo) may be identified by calling the telephone number listed on the card.

You should not stop taking the study medication without talking to the study doctor. If you choose to drop out of the study, you will be asked to return all the medication you have not used, and you may be given a smaller dose of the medication to take for one week so that you do not experience the side effects that could come from stopping the medication too suddenly.

2. *Placebo Pill*. Placebo is an inactive substance in pill form. You have a chance (by random) of receiving inactive placebo pill. The major risk associated with placebo is failure to improve, although some persons do improve solely on placebo. Although the placebo is inactive, some persons who take the pill placebo report that they experience some of the side-effects listed above. You should not start or end the use of any medications during this treatment without consulting the study doctor.
3. *Blood Draws*. For each lab session we will draw about 1/2 cup of blood, for a total of 1 cup over both laboratory sessions. This is a minimal risk in healthy subjects. Some people feel "lightheaded" while having blood drawn, but this effect is temporary. Other possible, but less common risks include pain, bruising at the withdrawal site, and fainting. You should not have donated blood in the last 6 weeks or plan to donate blood in the 8 weeks following the study. The amount of blood drawn for routine blood work and liver tests is minimal.
4. *Assessments and Interviews*. There is the possibility that some of the questions during the interviews or in the questionnaires may make you mildly uncomfortable. There is the possibility that drawing blood might cause a small bruise or cause mild discomfort.
5. *Physical discomfort from wristband.* As part of the study, you will wear a smartwatch and carry your smartphone for the collection of data, the purpose of which will be to predict future smoking lapse, and deliver a just-in-time intervention. While there is potential physical discomfort associated with regular wearing of a wristband, our experience in the pilot study suggests that this has been minimal and subjects have been comfortable wearing the device for extended periods.
6. *Failure to Improve.* There is a chance that your binge eating or obesity may not improve or may worsen during the study. You will be withdrawn from the study if your clinical condition becomes significantly worse.

7. *Breach of Confidentiality*. There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.
8. *Garmin Wristband Android Cell Phone App.* All information collected from both the Garmin wristband and the Android cell phone app will be de-identified. The data from the bands is continuously transmitted to the mHealth Core Facility at UMass through the Garmin service for Academic Researchers. The data from the Android cell phone app will be collected, transmitted, and stored by the mHealth Core Facility at UMass and provided to Yale.
9. *Loss of Confidentiality and Privacy***.** At Yale, the risk will be minimized by the use of code numbers on all research material with a locked master file maintained by the principal investigator. No reports will identify specific subjects, and only aggregate data will be used. Individually identifiable health information will be protected in accordance with the Health Insurance Portability and Accountability Act of 1996. Data/information collected by wristband and smartphone will be logged at servers at mHealth Core Facility at UMass, in order to analyze the data. You will be asked to specify privacy zones where you do not wish GPS information to be recorded at any point during the study by contacting study organizers or you can explicitly turn on or off GPS logging by using the Settings screen on the app. During periods when location logging is enabled, our system will automatically upload location data to a secure backend database, but logging is turned off at other times.
10. *Data Security***.** Security of your information is of paramount importance to us. We work to protect security of sensitive information during transmission by using Secure Socket Layer (SSL) software, which encrypts information that is input. Our servers are behind a firewall, and we secure it using the best available methods. This data will not be associated with any personal information about you; rather, it will only be associated with a random key associated with the phone. The study organizers at Yale will keep a mapping between the random key and the identity of the individual.

Benefits

There may be no direct benefit to you from your participation in this study. We cannot determine ahead of time whether you will personally benefit or how much you will benefit.

You will be provided comprehensive evaluations and leading treatments by experienced clinicians free of charge. The bloodwork will also be free of charge. The interviews and surveys may help you to better understand your problems. We will discuss findings with you.

We anticipate that some of the knowledge from this study will be used to improve treatments and to increase our understanding of binge eating and obesity.

Economic Considerations

You will be compensated each time you meet with a researcher to do assessments post-treatment and at the follow-up appointment. The specific amounts are as follows: $100 at the post-treatment assessment (approximately 3 months after you start treatment); $100 six months after you finish both treatment stages (approximately 9 months after starting); and $100 twelve months after you finish both treatment stages (approximately 15 months after starting).

Payment for each of the lab sessions is $200. If you do not complete a lab session (for example, if you decide to withdraw from the study in the middle of a lab session), your payment will be prorated on an hourly basis.

You may earn up to an additional $31.50 for each of the laboratory sessions if you choose to delay eating for the full 3-hour period.

If equipment is available, you will receive up to $300 for wearing the Garmin band and responding to the prompts daily for the 6-week treatment phase (42 days). You will earn $6 per day if you respond to all prompts. If you do not respond to all of the prompts on a particular day, you will earn $0.50 for each prompt that you did respond to that day.

The Garmin band and Android phone must be returned to the Research Team at the end of the 6-weeks. Once you have completed the 6-weeks and returned the equipment, you will earn a $48 Completion/Return Bonus. If you do not return the Garmin band and/or the phone, you will not receive payment as you will have received the items in place of any additional compensation.

Payment for the blood draw after 1 month of treatment is $10.

Parking will be compensated for research study appointments at the HRU/CSRU. You must show your parking ticket to the Research Staff for verification. Parking tickets will be returned to you so you are able to exit the parking lots and you will sign a Parking Voucher for the money received.

You can earn up to $1,073 for completing all parts of the study.

According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a participant in a study may be considered taxable income.

Except when you get a medical evaluation from a doctor of your own choosing, the evaluations and blood tests will involve no charge. The treatments will involve no charge.

Treatment Alternatives/Alternatives

There are certain available treatments for obesity, and other available treatments for binge-eating disorder.

Medication: The *Naltrexone/Bupropion* medication that is part of this study is FDA-approved for weight loss, and therefore may be available to you without enrolling in the study. An

alternative medication option might be *Lisdexamfetamine Dimesylate,* which is FDA-approved for binge-eating disorder.

Therapy: *Behavioral Weight Loss* and *Cognitive Behavioral Therapy* treatments are evidence-based treatments that can help improve binge eating. An alternative treatment is *Interpersonal Psychotherapy,* a "talk therapy" that may also help treat binge-eating disorder.

If you choose not to participate in this study, we can give you referrals for alternative treatments.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. Your records will be kept in locked files and research information entered into password-protected computers for analyses will use code numbers to help maintain your confidentiality. The results of your evaluations and treatment will be available to clinicians caring for you following discharge only with your signed written consent. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

If you decide to take part in this research study, you will be required to give us information about your substance use. *We have a Certificate of Confidentiality (CoC) issued by the NIH*. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

Because this research is sponsored by the Department of Health and Human Services through NIH, *staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation. They cannot report anything that would harm you or other research subjects.*

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the research team will get information that identifies you and your personal health

information. This may include information that might directly identify you, such as your name, address, telephone number, email address, and date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All records will be kept in locked cabinets separate from any identifying information, and all computer records will be password-protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

Information about your study participation will be entered into your Electronic Medical Record (EMR). This information includes that you might be taking a study medication, and some of the health information we collect (for example, your height, weight, and vital signs). Laboratory test results, interviews, and survey responses will not be entered into your EMR. Once placed in your EMR, information is accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g., health insurance company, disability provider).

The information about your health that will be collected in this study includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The following information:
  - Records about phone calls made as part of this research
  - Records about your study visits
  - Information obtained during this research regarding
    Physical exams
    Laboratory test results
    Diaries and questionnaires
    The diagnosis and treatment of a mental health condition
    Use of illegal drugs
  - Records about any study drug you received

Authorized representatives from the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) and the National Institutes of Diabetes and Digestive and Kidney Diseases may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity.

In addition, information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies

- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about the drug products involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- Contact Principal Investigator (Carlos M. Grilo, Ph.D.)
- Health care providers who provide services to you in connection with this study.
- Those providers who are participants in the Electronic Medical Record (EMR) system.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

The sponsor will see the research information we collect about you when they come to Yale to monitor the conduct of this research study. The "Sponsor" includes any persons that work for or are hired by the sponsor to conduct research activities related to this study. For this study the sponsor includes the National Institute of Diabetes and Digestive and Kidney Diseases. Yale researchers may also send the sponsor your health information during the study or at the end of the study. When Yale researchers send information about you to the sponsor, they will not send information that directly identifies you such as your name, address, telephone number, email address or birth date.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in a single- or double-blinded treatment study and signing this permission form, you will not be allowed to look at or copy your study-related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury

If you are injured while participating in this study, seek treatment and contact the study doctor as soon as you are able.

Contact Principal Investigator: Carlos M. Grilo, Ph.D., (203) 785-2792
Study Physician: Ania Jastreboff, M.D., Ph.D., (203) 785-4183
Yale New Haven Hospital Investigational Drug Service: (203) 688-4872 or (203) 688-2978 (nights and weekends)

Yale School of Medicine does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing from the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. We ask that you return for one final visit, and that you return any medications you have not used. You may be asked to take a smaller dose of the medication for one week to avoid side effects that can happen if you stop the medication too quickly.

The researchers may withdraw you from participating in the research if necessary. Such conditions would include adverse reactions that would suggest that it is contraindicated for you to proceed with treatment, or non-compliance with study treatments.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale School of Medicine, or with the Program for Obesity, Weight, and Eating Research in the Department of Psychiatry.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Carlos M. Grilo, Ph.D., 301 Cedar St., 2nd Floor, New Haven CT 06520 at the Yale University School of Medicine.

If you withdraw your permission, you will not be able to stay in this study.

If you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

_____

Name of Participant

_____ _____

Signature of Participant Date

_____ _____

Signature of Principal Investigator Date

or

_____ _____

Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Carlos M. Grilo, Ph.D. 203-785-2792. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.