HIC#: **2000022480**
NCT03924193

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

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Cognitive-Behavioral and Pharmacologic (LDX) Treatment of Binge Eating Disorder and Obesity
Principal Investigator: Carlos M. Grilo, Ph.D., 301 Cedar Street, New Haven, CT 06520
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 two different treatment approaches for the combined problems of binge eating and overweight. There are two stages of the study. You will be randomly assigned to receive one of three treatments/combinations in Stage 1, and treatment in Stage 2 will depend upon your response in phase 1. During Stage 1, you will receive a cognitive behavioral treatment and/or medication treatment. The medication during Stage 1 is lisdexamfetamine dimesylate (LDX). During Stage 2, you may receive a medication treatment, either LDX or naltrexone/bupropion or placebo (an inactive pill). If you are randomized to the cognitive behavioral treatment during Stage 1, you will not participate in Stage 2 treatment.

You have been asked to take part because you experience binge eating, you have a body mass index between 27 and 50 kg/m^2, and you are between 18 and 64 years old. We expect that approximately 180 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 randomly assigned to treatment in stage 1 which will last 3 months. Assignment and treatment in stage 1 will determine participation in stage 2 which is also 3 months.

Initial Evaluation
Your first appointment will be with a research-clinician at our clinic (the Program for Obesity,

APPROVED BY THE YALE UNIVERSITY IRB 6/13/2022

Weight, and Eating Research on the Yale School of Medicine campus). During this visit, we will ask questions about your health, your 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, blood pressure, and attention. 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, an EKG, 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. An EKG is required to participate in this study. If you are unable to obtain an EKG or physical from your provider, you will receive an EKG and/or physical as part of the study. The cost of an EKG and physical obtained at the Yale Hospital Research Unit or Yale Church Street Research Unit would be covered by the study.

We will also ask you to go to Quest Diagnostics to have your blood drawn for routine blood tests and tests measuring your liver function and amphetamine levels (for safety). If you have used opioid-based pain medication during the past six months, we will ask you to have a test to ensure you are not currently taking these drugs or medications, for your own safety. There is no cost for these tests.

Treatment: Stage 1

If you qualify for treatment, and if you decide to participate, you will be assigned to treatment in stage 1 randomly (by chance, like flipping coins). The possible groups of treatment conditions are: (Group 1) cognitive behavioral therapy only, (Group 2) medication (LDX) only and (Group 3) cognitive behavioral therapy and medication (LDX). All treatment conditions last 3 months. You have a 33% chance (1 out of 3) of being assigned to each condition. You will be assigned randomly (by chance), not because of any special characteristics or problems you may have.

Cognitive Behavioral Therapy: If you are in group (1) or group (3), you will receive cognitive behavioral therapy. You will meet with a clinician weekly during this treatment. The treatment will focus on normalizing your eating pattern, decreasing your binge eating, building coping skills, and changing some things about how you think about binge eating and about your weight/shape.

Medication: If you are in group (2) or group (3), you will receive lisdexamfetamine dimesylate (LDX) medication. 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. During the treatment, people in the medication groups will be able to call the doctor if they have any concerns about the medication. You will meet with a research clinician monthly (for approximately 15 minutes) to talk about whether you are taking the medication (and count the pills you have left), and if you have any side effects.

At each monthly visit, we will measure your weight, blood pressure, and heart rate. We will also ask you to complete online surveys monthly.

Stage 1 Evaluation

At the end of Stage 1 Treatment (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, liver tests, and amphetamine levels, and measure your weight, blood pressure, heart rate, and attention. We will also ask you about your eating behaviors, including how frequently you are binge eating, and how you are doing psychosocially.

- If you were in group 1 (received only cognitive behavioral therapy - without active LDX), you will not be re-randomized to treatment in Stage 2. You will be asked to come in for the Stage 2 and follow-up evaluations described below.
- If you were in group 2 or group 3 during Stage 1 (both which involve LDX medication), you will be re-randomized to treatment. If Stage 1 Treatment reduced your binge eating substantially, we will give you a Stage 2 Treatment designed for "responders." If Stage 1 Treatment did not work to reduce your binge eating, we will give you a Stage 2 Treatment designed for "non-responders."

Treatment: Stage 2

For those randomized to Stage 2 treatment

Groups 2 or 3 from Stage 1: assignment to treatment is based upon response in stage 1 and will also last 3 months, and start approximately 1 week after Stage 1 Treatment ends.

> **Responders from Stage 1 group 2 or 3:** If you are in this category, you will be randomly (like flipping a coin) assigned to (1) lisdexamfetamine dimesylate (LDX) only, or (2) inactive placebo pill only. The study doctor will meet with you to explain the medication again. Stage 2 is "double blind", which means that neither you nor the research team will know what medication (LDX or placebo) you will be taking.
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> **Non-Responders from Stage 1 group 2 or 3:** If you are in this category, you will be randomly (like flipping a coin) assigned to (1) naltrexone/bupropion medication only, or (2) inactive placebo pill only. The study doctor will meet with you to explain this medication. Stage 2 is "double blind", which means that neither you nor the research team will know what medication (naltrexone/bupropion or placebo) you will be taking. We will check your safety by asking you to go to Quest Diagnostics again so that we make sure your liver tests are still healthy at the first monthly visit.

During the treatment, people in the medication groups (active or placebo) will be able to call the doctor if they have any concerns about the medication. We will also ask you to complete online surveys monthly. You will meet with a research clinician monthly (for approximately 15 minutes) to talk about whether you are taking the medication, if you have any side effects, and to measure your weight, blood pressure, and heart rate.

Stage 2 Evaluation

At the end of Stage 2 Treatment (6 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 amphetamine levels, and measure your weight, blood pressure, and attention. We will also ask you about your eating behaviors and how you are doing psychosocially.

Follow-up Evaluations

After the Stage 2 evaluation, we will ask you to come back for an evaluation 6 and 12 months after the stage 2 evaluation. 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, blood pressure, and heart rate. 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 during Stage 2 at 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

Given that you will have had a 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.

a. Lisdexamfetamine Dimesylate (LDX) medication side effects include dry mouth (36%), insomnia (20%), decreased appetite (8%), increased heart rate (7%), feeling jittery (6%), anxiety (5%), diarrhea (4%), decreased weight (4%), hyperhidrosis (excessive sweating) (4%), vomiting (2%), gastroenteritis (2%), paresthesia (burning or prickling sensation) (2%), pruritis (itching) (2%), upper abdominal pain (2%), increased energy (2%), urinary tract infection (2%), nightmares (2%), restlessness (2%), and oropharyngeal pain (2%). Even more rarely, it is possible that individuals taking LDX may also experience circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon) and bruxism (excessive grinding of the teeth or clenching of the jaw).

   Serious potential risks of LDX include psychiatric problems and heart complications, including sudden death in people who have heart problems or heart defects, and stroke and heart attack in adults. Central nervous system stimulants, including LDX, may cause psychotic or manic symptoms, such as hallucinations, delusional thinking, or mania, even in individuals without a history of psychotic illness. If you notice any of these symptoms, please contact the study team immediately.

Also, combining LDX and serotonergic drugs increases the risk of serotonin syndrome, which is a potentially life-threatening syndrome.

Warning: LDX is a federally controlled substance (CII) because it can be abused or lead to dependence. You may become addicted to LDX. Keep LDX in a safe place to prevent misuse and abuse. Selling or giving away LDX may harm others and is against the law. Misuse of this medication can result in overdose and death.

If you have ever abused stimulants (or other drugs or alcohol), you will not be eligible for this study (for your safety). You should not participate and we will not include you in the study if we know or suspect you had problems with stimulants (or drugs or alcohol).

b. 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%). Risk of seizure may be minimized by adhering to the recommended dosing schedule and avoiding co-administration with high-fat meal. Increase in Blood Pressure and Heart Rate: Monitor blood pressure and heart rate in all patients, especially those with cardiac or cerebrovascular disease. Hepatotoxicity: Cases of hepatitis and clinically significant liver dysfunction observed with naltrexone exposure. Angle-closure glaucoma: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Monitor blood glucose.

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 depressed mood, suicidal thoughts, 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 Tramadol or opiate-containing drugs including, but not limited to, codeine, hydrocodone, oxycodone, or phenacetin. For your safety, if you have ever had problems with drugs or medications that include opiates, you will not be eligible for the study. You will be asked to carry a medication card that will, in case of emergency, alert medical personnel treating you that you may be taking naltrexone. 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 people do improve solely on placebo. Although the placebo is inactive, some people 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. *Cognitive Behavioral Therapy*. This treatment ("talk therapy") involves few foreseeable risks, but you may feel uncomfortable when thinking about or discussing your eating and weight.

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. *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.

The Committee recognizes that because this study contains sensitive information and drug testing and is funded by the NIH, per the Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality (NOT-OD-17-109), effective October 1, 2017, this study is assumed to now have a Certificate of Confidentiality, subjects are anticipated to be protected, and the consent form Privacy and Confidentiality section needs to be modified to include related template language addressing this. The following language, altered to include needed information specific to this study, must be added:

If you decide to take part in this research study, you will be required to give us information about your substance use. We have been issued a Certificate of Confidentiality (CoC) by the NIH. The researchers 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. When the CoC is obtained, we will inform all active study participants.

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.

Because this study is working with the pharmacy at the Connecticut Mental Health Center (CMHC), you will be required to complete CMHC admissions paperwork, which will involve protected health information, to receive the study medications. Discharge paperwork will be completed when you stop taking the study medications; however, your information will be retained in the CMHC medical record system. This will include research test results. Your health care providers will be able to see these test results. Other people or groups such as a health insurance company who have access to your EMR may see this information.

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. ***Unknown Effects of Medication on Pregnancy.*** **If you are a woman of reproductive age who is sexually active: 1) you will be asked to have a pregnancy test before Stage 1 and before Stage 2 (if you were in groups 2 or 3 during Stage 1), 2) you will be required to use a reliable method of birth control while you are in the study and to alert the research team if you depart from your birth control plans or if, in spite of these plans, you think you might be pregnant, and 3) if you become pregnant after study entry, you will notify the team immediately and the medication will be discontinued.**

Benefits

There may be no direct benefit to you from your participation in this study. The behavioral, cognitive-behavioral, and medication treatments may be helpful for some but not all people with binge-eating disorder. 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 after the Stage 1 post assessment (approximately 3 months after you start treatment); $100 after the Stage 2 post assessment (approximately 6 months after starting); $100 six months after both stages end (approximately 12 months after starting); and $100 twelve months after both stages end (approximately 18 months after starting).

We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. We will have to share your name, address, and telephone number with Bank of America for ePayments. You will receive a card in the mail with the first payment. You will need to activate the card over the phone. Each additional payment will be automatically added to your card.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

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, both behavioral and medication, 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 available to you without enrolling in the study. The *Lisdexamfetamine Dimesylate* medication that is also part of this study is FDA-approved for binge-eating disorder but not for weight loss.
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> **Therapy:** The *Cognitive Behavioral Therapy* treatment that is part of this study is an evidence-based treatment, and available to you without enrolling in the study. Two alternative treatments are *Behavioral Weight Loss* counseling and *Interpersonal Psychotherapy.*

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.

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.

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
- The Principal Investigator (Carlos M. Grilo, Ph.D.)
- Health care providers who provide services to you in connection with this study.
- 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 sign 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.

Audio-Recording

If you are willing, the interviews and treatment sessions will be recorded. This is not required for you to participate. If you are willing and agree to the recording, we will ask you to sign a separate section below. If you do agree to recording, all audio records will be erased after the completion of this study (five years) or at any time at your request.

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.

> Principal Investigator: Carlos M. Grilo, Ph.D., (203) 785-2792
> Study Physician: Cenk Tek, MD., (203) 974-7484
> 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 naltrexone/bupropion medication for one week to avoid side effects that can happen if you stop this 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 06519 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 [and give out] 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

Consent to Audio-Record Interviews/Sessions:
I have read (or someone has read to me) this form and have decided to allow my research interviews and/or treatment sessions to be audio-recorded.

_____ _____
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.