COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE- YALE-NEW HAVEN HOSPITAL

Study Title: **Sympathetic activation in obesity**
Principal Investigator (the person who is responsible for this research): Renata Belfort De Aguiar, MD. and 300 Cedar Street, TAC S-135, New Haven, CT, 06510
Phone Number: **203-785-2440**

Research Study Summary:

- We are asking you to join a research study. The purpose of this research study is to investigate whether obesity is associated with increased activity of the sympathetic nervous system (SNS).
- Study procedures will include: physical examination, electrocardiogram (EKG), an oral glucose tolerance test, blood work, a DXA scan (described in more detail on the following pages), 2 positron emission tomography – computed tomography(PET-CT) scans, mixed meal test (MMT), and microneurography.
- Five visits are required.
- The screening visit will last approximately 150 minutes and visits 2-5 will last up to 4 hours.
- There are some risks from participating in this study. The main risks are associated with the IV placement that is required for the blood work, oral glucose tolerance test, PET scans, microneurography, MMT, and DXA. These procedures are routinely performed by our experienced research staff. The most common risk is bruising or soreness at the site. The total amount of blood drawn for this study is 160 mL, and people who are in good health are not usually affected by this kind of blood loss.
- The study may have no benefits to you. However, knowledge gained from the study will help us to better understand the role of the SNS in obesity and whether increased SNS activity is important for the development of obesity-associated cardiometabolic disorders.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because **you have normal body mass index (BMI between 18-25 kg/m^2) or have obesity (BMI 30-40 kg/m^2)**. We are looking for **20 women and 20 men** to be part of this research study. All research activities are experimental and not standard of care.

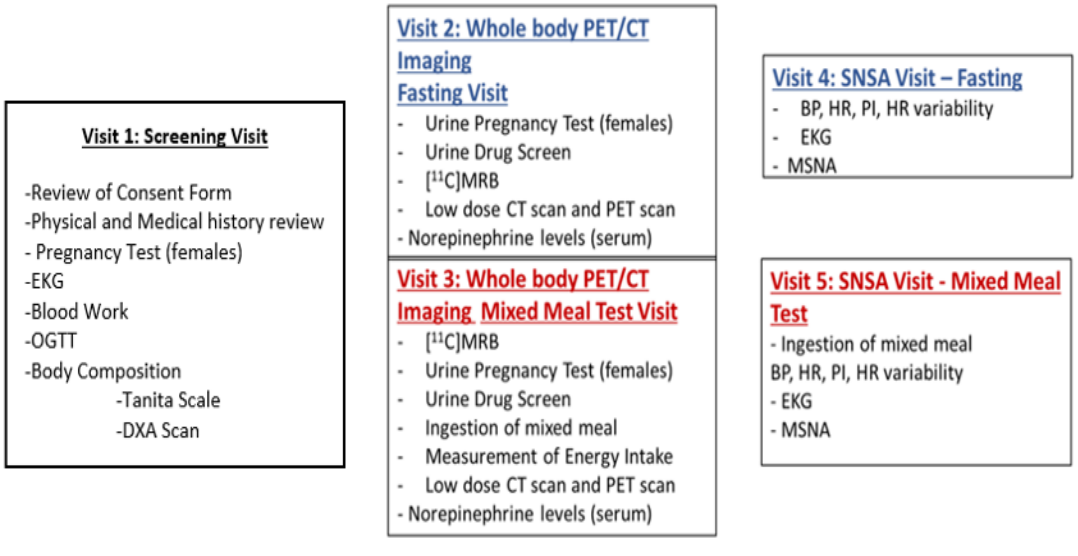
Who is paying for the study?

The NIH/NIDDK is sponsoring the study

What is the study about?

The purpose of this study is to quantify whether sympathetic nervous system (SNS) activity in adipose tissue, muscle and brain is altered in individuals with obesity in comparison to individuals with normal weight.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen:



Abbreviations: BP=blood pressure,EKG=electrocardiogram, HR=heart rate, MSNA=Muscle sympathetic nerve activity, SNSA=Sympathetic Nervous System Activity

Please note: PET and MSNA visits do not need to occur in sequence, i.e. PET scans can occur before or after the MSNA.

Visit 1 - Screening procedures:

You will be asked to complete a pre-screening questionnaire over the telephone for approximately 10 minutes to determine preliminary eligibility based on inclusion/exclusion criteria and basic socio-demographic information. Potentially qualifying participants will be screened at the YNHH Hospital Research Unit (HRU) or Church Street Research Unit (CSRU) with a medical history and exam, an electrocardiogram (EKG), and a urine pregnancy test will be administered for women at childbearing age. Oral glucose tolerance tests (OGTT) will be performed after an overnight fast.A nurse will insert an intravenous (IV) catheter and you will be

asked to ingest 7.5 oz of glucola,which contains 75 g of glucose in flavored water. Blood samples obtained from the catheter willbe taken at certain time points before and after glucola ingestion. Blood will be collected from the catheter to check for anemia, kidney and liver function and thyroid test and diabetes. The visit will last approximately 150 min. Approximately 40 mL of blood will be drawn at this visit.

Body Composition, Percent Body Fat & Percent Body Water: will be assessed using bioelectrical impedance analysis Tanita® scale (FDA cleared); which is a special multi frequency seg-mental body composition analyzer that delivers a very mild electrical current through your feet that allows measurement of fat mass, percent body fat, fat free mass, total body water, and percent body water. This test will be performed at screening visit.

For better accuracy, measurements of percent fat and percent body water will be obtained with whole body Dual X-Ray Absorptiometry (DXA) scan (Hologic®), which is located in the hospital research unit (HRU) and will be performed during the screening-OGTT visit. The scanner arm will move over the participant's body from feet to head. The machine uses a small amount of radiation (0.0001 rem) to measure body fat, muscle and bone density.

If you fail any of the screening procedures, you will be informed and excluded from participating in the study. You will be allowed to be re-screened at a later time,

Visit 2 – Whole body PET/CT Imaging Visit – FASTING:
After 2 weeks from the screening visit, participants who qualified for the study will be asked to come to the PET Center to undergo the whole-body positron emission tomography (PET) and low dose computed tomography (CT) scan. Participants will be asked to maintain their regular exercise routine.

You will be asked to participate in two PET-CT scanning sessions. The scans will be conducted at the Yale University Positron Emission Tomography (PET) Center at 801 Howard Avenue in New Haven. You will be asked to fast prior to the PET scan. At the PET Center, female subjects will have a urine pregnancy test and all subjects will have a urine drug screen to determine current illicit drug use (for all potential subjects). You cannot participate in this study if you are pregnant or taking illicit drugs. To participate, you must use an acceptable form of birth control (birth control pills, diaphragm, or condoms with spermicide) throughout the study period.

A trained nurse or CNMT (Certified Nuclear Medicine Technologist) will place plastic catheters (tubes) in your arms (for the radiotracer injection and to take venous blood samples). After the catheter is inserted, you will receive the radiotracer [^{11}C]MRB drug (which is limited by Federal Law for investigational use only), during the PET scan. This radiotracer, which is a minimal amount of a drug that is labeled with a very small amount of a radioactive substance, binds to a protein located in the brain and nervous cells in the adipose tissue and skeletal muscle and can be detected by a special camera in the PET scanner. As part of the PET scanning session, you will be asked to lie very still on a table. The radiotracer will then be injected into the tube in your vein. Following this injection, the PET scanner camera will detect the radiotracer presentin the brain and upper body. This information will be used to create pictures of your brain. A low dose computed tomography (CT) scan will be completed immediately before or after each PET scan. This information is used to increase the accuracy of the PET data. Blood samples during the PET scanning sessions will be used to measure the amount of radiotracer in your blood. We may also collect blood samples for measurement of certain substances in the blood such as glucose, fat and hormones. You will be asked to drink several glasses of water at the close of the PET scanning session to wash out the radiotracer. A light meal will be provided. After the PET scanning session, you will be free to leave. You will be provided with a telephone number you can call any time after the study if you need assistance for problems related to the study procedures.

Occasionally there are problems making the [^{11}C]MRB and there is not enough to perform the PET scan. If this happens, we will offer to reschedule your PET scan on another day within a few weeks.
The maximum number of attempts for each failed/incomplete imaging and test is 2 times.

If we see a worrisome finding on your scan or on another test performed as part of this protocol, a radiologist or another doctor will look at the scan/results and may recommend you seek medical advice to be safe. We will not provide the scan/results to your doctor. You can decide with your doctor whether you should have another scan for healthcare or diagnostic purposes. If you have another scan, you or your insurance company may have to pay for the scan. We are not responsible for whatever decisions you and your doctor make.

Visit 3 – Whole body PET/CT Imaging Visit - High-Carbohydrate Mixed Meal Test (MMT)
High Carbohydrate Mixed Meal Test (MMT):

Two weeks after the first scan, you will be asked to return to the PET Center. You will be asked to fast prior to the PET-CT scan. Female subjects will have a urine pregnancy test and all subjects will have a urine drug screen to determine current illicit drug use (for all potential subjects). A nurse or CNMT place plastic catheters (tubes) in your arms (for the radiotracer injection and to take venous blood samples). After that, you will be asked to ingest a liquid meal containing 65% carbohydrate, 20% fat, and 15% protein, equal to 40% of daily energy expenditure (~16 ounces) that will be prepared by the YNHH Metabolic Kitchen. Blood samples will be collected at several time points for measurements of glucose, lipids, and hormone levels.

After drinking the high carbohydrate meal, you will again participate in PET-CT scan as described in visit 2.

Method of Assignment/Randomization- The order of the PET scan visits 2 (PET-CT Fasting) and 3 (PET/CT-MMT) will be randomly assigned (with a 50% chance of being assigned to each visit). SNSA visits 4 (fasting) and 5 (MMT) will be also be also be randomized (with a 50% chance of being assigned to each visit).

Measurement of Energy Intake: Hunger and fullness will be determined immediately before, during and after the PET scans with Visual Analog Scales (VAS).

PET and MSNA visits do not need to occur in sequence, i.e. PET scans can occur before or after the MSNA.

Visit 4 – Sympathetic Nervous System Activity (SNSA) measurement Visit - Fasting

Two weeks from visit 3, you will be asked to return for a separated visit for measurements of SNS activity at rest and fasting. This visit will be performed at the Pierce Laboratory (located at 290 Congress Ave. New Haven, CT). You will be asked to fast for 10-hour and to maintain your regular exercise routine. The following measurements will be obtained during this visit: microneurography, blood pressure (BP) and heart rate (HR) measurements and electrocardiogram (EKG). The visit will be approximately 4 hours.

1) You will come to the lab at 8 a.m. and change into a sports bra and exercise shorts (women). Men will be asked change into exercise shorts and remain shirtless throughout the study assessment. You will be asked to provide a urine sample and you will be weighed.

2) You will go into a room that will be 82 degrees. We will attach EKG electrodes to your chest.

3) You will lie down, and we will put an IV in each of your arms. We will be using the IVs to draw your blood, for a total of about 1 tablespoon (20ml). We will be testing your blood for levels of hormones related to blood pressure and norepinephrine levels. We will attach one blood pressure cuff to your arm and another to your middle finger. We will put 2 small sensors on your skin on your forearm to measure skin blood flow.

4) We will look for the path of the peroneal nerve, which runs along the outside of your knee and lower leg. You will need to lie very still for about an hour while we do this. We will apply small electrical pulses to the skin over the nerve and use an ultrasound on your leg. This might cause some tingling but will not be painful. Then we will place two small sterile metal microelectrode needles under the skin. The electrodes record nerve activity. You will feel tingling or pressure in the nerve area during the electrode placement. This is called microneurography. We will record your nerve activity, heart rate, blood pressure and skin blood flow during several

activities: breathing at a normal rate to the beat of a metronome; doing a Valsalva maneuver, which involves exhaling forcefully with your mouth closed.

Visit 5 – Sympathetic Nervous System Activity (SNSA) measurement Visit - MMT

You will be asked to return to the Pierce Laboratory 2 weeks after visit 4 for the same experiments described in Visit 4. However, prior to collecting the measurements of SNSA, you will be asked to ingest a high carbohydrate drink (as described in Visit 3).

Follow Up Procedures

A member of the study team will reach out to you 1-2 weeks upon study completion for a brief follow-up telephone call. During this phone call, you will asked how you are feeling since completing the study assessments and if you have any questions or concerns.

Please note the following anticipated circumstances under which your participation may be terminated by the investigator without regards to your consent: inability to tolerate or performstudy related procedures, inability to fast for study visits, and at the discretion of the principalinvestigator, Dr. Belfort De Aguiar.

What are the risks and discomforts of participating?

1) Risks Associated with Radiation

This research study involves exposure to radiation from PET imaging. If you take part in this research, you will be exposed to a small to moderate dose of radiation from the radiolabeled probes used for the PET scans and associated with the transmission scans. Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only. The Yale University Radiation Safety Committee (RSC) and Radioactive Drug Research Committee (RDRC) have both reviewed the use of radiation in this research study and have approved this use as involving slightly greater than minimal risk and necessary to obtain the research information desired.

The total amount of radiation you will receive in this study is from up to 3 low dose CT scans - used to optimize the PET scan – and up to 3 injections of radioactive material (20 mCi), [^{11}C]MRB and the DXA scan.

This radiation is in addition to what you may get as part of your regular medical care and what you receive from natural radiation in our environment. Everyone is exposed to low levels of natural radiation, called background radiation. This background radiation comes from outer space and from rocks and minerals in the soil, and is greater at higher altitudes. The average yearly background radiation in the United States is about 0.3 rem. The amount of additional radiation you will get from participating in this study is about 2.307 rem. This is equal to about 7.69 years worth of natural radiation.

The amount of radiation involved in this research is small, but may slightly increase your risk of getting cancer. Scientists are not certain about the actual cancer risk at these low doses, and there may be no risk at all, but to be conservative we assume that any amount of radiation may pose some increased cancer risk.

Should a scan session be canceled due to problems with the tracer or camera, an additional scan may be scheduled. Calculations for additional PET/CT scans in this situation are included in the possible scan radiation dose calculations above.

Please tell your study doctor if you have taken part in other research studies at Yale or other places/hospitals that used radiation. This way we can make sure that you will not receive too much radiation. You should consider x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body. Before you take part in any future studies that use radiation, you should also tell those study doctors about your participation in this study.

2) Risks associated with pregnancy and breastfeeding: WOMEN PLEASE NOTE: You should not participate in this study if you are currently pregnant, if you might become pregnant during the study or if you are breastfeeding, because we do not know how radiation may affect a fetus or whether it is present in breast milk. You will be tested for pregnancy as part of the routine lab tests and at the beginning of each PET scan day. If the test is positive, you will not be included in the study. Before starting the study, we will ask you to avoid becoming pregnant and ask what precautions you plan to take. If you change your mind about becoming pregnant or how you will avoid becoming pregnant, we ask that you tell us immediately.

3) Risks Associated with Blood Drawing and IV Line Insertion
Drawing blood and inserting an intravenous line (IV) into an arm vein are safe and standard medical procedures. Sometimes a bruise will occur at the puncture site and rarely a blood clot or infection will occur in the vein. You should not donate blood for at least 6 weeks after the study. The total volume of blood collected during this study will be up to 8 tablespoons (160ml), including screening laboratories and blood drawn from your vein and during your PET scan and SNSA day(s). This amount of blood is safe for study participants.

) Discomfort in scanner
It may be uncomfortable to lie motionless in the cameras (PET) and it may cause you to feel anxious. The PET scans can be up to four hours each. Lying still for that long may cause some back discomfort. A member of the research staff will be available to provide support and to make you as comfortable as possible.

5) Microneurography: Most people have no problems after microneurography. Near where the electrode is placed you might feel itching, tightness, burning, hypersensitivity to cold or touch, pain or tenderness, numbness or motor weakness. When these symptoms occur, they last about 10 days. There is a low risk of injuring the nerve while adjusting the position of the microelectrodes. The risk of microneurography is a peroneal paresthesia (numbness) for 2-10 days following the experiment. The incidence of

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paresthesias is reported to be less than 10%, in less than 1% of all subjects paresthesias can persist for up to two months. These paresthesias resolve spontaneously.

6) DXA scanning: The DXA measurement poses no major risk to the subject. The amount of radiation you will be exposed to is one tenth of the amount of radiation for a chest X-ray.

7) Risks associated with IV contrast: We will use a contrast agent, which is like a dye, for the scan. It is called Gadolinium. It has been used in many patients and it is approved by FDA. You will feel a slight pin prick when the needle is inserted into your vein. You may have a warm, flushed feeling during the injection of the contrast. You can also feel a metallic taste in your mouth for a few minutes.

Some people feel dizzy or queasy or get a headache. These side effects usually go away themselves. There is also a small chance of having an allergic reaction to the dye such as hives, itching, or having a hard time breathing.

If you have severe or chronic kidney disease, there is a chance that the dye could cause nephrogenic systemic fibrosis (NSF). NSF is a disease in which too much scar tissue forms, leading to serious damage to skin, muscle, and internal organs, and, in some cases, death. If you have kidney disease or think your kidneys may not be functioning properly, you should discuss this with the investigator before any dye is injected. You will be asked to undergo blood work to make sure that your kidney function is normal. We will also check whether you are pregnant.

We know that tiny amount of gadolinium stays in your body, including within the brain. We do not know what effects it may have. There are no known harmful effects. There is still research being done on this topic.
It is important to tell the study doctor if you are pregnant or breast feeding, if you have had allergic reactions to MR or CT contrast agents before, if you have had seizures, asthma, or allergic respiratory disorders, and if you have anemia or disease that affects red blood cells.

8) Risks associated with the Mixed Meal Test (MMT): There is a risk of an allergic reaction. It can range from rashes to difficulty breathing, shock, and sudden death.

Possible Participation in Future Studies
We would like to be able to contact you in the future to offer you participation in other studies. Giving your permission for the research team to contact you does not obligate you to answer any future questions or to participate in any future research – you always have the right to decline further participation in research. If you agree to participate in another study, we would ask you to read and sign a new consent form. Please initial if you would like to be contacted to participate in other studies.

I agree to be contacted for future research studies:_____.

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How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

Any significant new findings developed during the course of the research that may relate to your willingness to continue participation will be provided to you.

How can the study possibly benefit me?
The study may have no benefits to you.

How can the study possibly benefit other people?

General advancement of scientific knowledge from this study may include a better understanding of the importance of SNS activation in obesity.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study. You will be compensated for those parts of the study that you have completed. You will be paid for taking part in this study as follows:

- $25 for the screening visit, regardless of the outcome,
- $200 for completion of each PET scan sessions, 2 in total = $400,
- $100 for completion of each SNSA visit, 2 in total = $200,
- $25 for each Mixed Meal Test, 2 in total = $50
-
- $100 bonus for completion of all 5 visits.

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.

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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.

You are free to stop the study at any time and will be paid for the parts of study that you have participated in and completed to that point. You will not be charged for any of the test or scans that are part of this research.

What are my choices if I decide not to take part in this study?

The alternative would be not to participate in the study.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by YNHH from the time your medical record was created until present
- Records about your study visits

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- Information obtained during this research regarding
    - Medical history and physical exams
    - Laboratory and x-ray test results
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Physical exams
    - Laboratory, DXA, PET and other test results
    - Use of illegal drugs or the study of illegal behavior

Clinically relevant research results, including individual research results, will be disclosed to you under the following conditions: research manuscript publications and ClincalTrials.gov results information upon study completion.

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The study sponsor.
- 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.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study
- Bank of America to process study payments

The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about the intervention involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. 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.

Your biospecimens (even if identifiers are removed) may be used for commercial profit and you will not share in this commercial profit.

Certificate of Confidentiality:

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

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

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to:

Renata Belfort De Aguiar
Department Internal Medicine / Section of Endocrinology
300 Cedar Street, TAC S-135
New Haven, CT, 06510

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctors as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital, do 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.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

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.

What will happen with my data if I stop participating?

Data and samples will be unable to be withdrawn once they are collected and they will remain de-identified.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-785-2440**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

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