Study Title: Kappa-PET imaging and naltrexone in alcohol drinking behaviors

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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Kappa-PET imaging and naltrexone in alcohol drinking behaviors
Principal Investigator: Suchitra Krishnan-Sarin, Ph.D., Associate Professor of Psychiatry
Funding Source: NIAAA

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to help identify important new targets for the development of new pharmacotherapies to treat alcohol dependence. We are recruiting individuals who are heavy drinkers, as well as individuals who are social drinkers for age- and gender-matched controls. The primary purpose of the study is to increase our knowledge of receptor function in the brains of people who are heavy drinkers and taking naltrexone, a medication that has been approved for the treatment of alcohol dependence. Receptors are special molecules in the brain to which other molecules (neurotransmitters) attach during the normal every-day workings of the brain. Drugs can bind to those receptor molecules as well. Recent evidence suggests that kappa opioid receptors (KOR's) may play an important role in alcohol drinking behavior. This study will try to determine if naltrexone's ability to attach to these receptors is related to its effectiveness. We will use PET (positron emission tomography) for this study. PET is a type of imaging device found in nuclear medicine. It is used for tracking the presence of injected radioactive materials in the body.

You have been chosen to participate because you report not being a heavy alcohol user and are not regularly using street drugs, are you may or may not have a family history of alcohol-related problems. Since this is not a treatment study, you should not participate in this project if you are seeking treatment for your drinking.

In order to decide whether or not you wish to be a 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 research study. A member of the research team will discuss the study with you. This discussion will go over all aspects of our research: the goals, the procedures that will be performed, the risks, and the possible benefits. 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

The study contains three parts: *1) Evaluation*: We will obtain informed consent and evaluate your eligibility for the study using clinical assessments, a physical exam, and a Magnetic Resonance Imaging (MRI) scan. If you are eligible, you will be scheduled for the rest of the study; *2) Practice PET: You may or may not participate in a mock (practice) PET (Positron Emission Tomography) scan; 3) PET Scan*

1) Evaluation

At the Substance Abuse Center (SAC) in Connecticut Mental Health Center (CMHC) (34 Park Street, New Haven), we will check whether or not you are eligible to participate in the study.

APPROVED BY THE YALE UNIVERSITY IRB 1/10/2018 VALID THROUGH 1/9/2019

This will require two to four hours of your time. You will be asked to not use any drugs while you are participating in this study. If you test positive for any drugs or alcohol, you may not be paid for your appointment and may be asked to reschedule. Females will have a pregnancy test and will only be allowed to participate if the result is negative. You will be interviewed and asked to fill out questionnaires. Following this, at your convenience, we will schedule you for a complete physical examination that will include an electrocardiogram, and blood and urine tests, which will require about 1½ hours of your time. You will also get a psychiatric evaluation to confirm your eligibility and may be scheduled to meet with the study physician.

On a different day, you will be asked to go to the MR center at The Anlyan Center for Medical Research & Education at Yale University (TAC, 300 Cedar Street, New Haven) to have an MRI scan of your brain. The MRI scan is a routine way to get pictures of the inside of the body. MRI scans are painless, do not involve the use of radiation, and are used routinely to diagnose neurological problems. You will be asked to lie still on your back, on a comfortable mattress, in the MRI scanner for about 20 minutes. Your head will be held still in a cushioned head rest, and you will wear earplugs to reduce the level of noise. You will not be able to see out of it, but you will be able to hear us and be heard if you wish to say anything. You will hear a drumming noise when the camera is taking pictures of your brain. Some people feel mildly anxious in the scanner. If it is too difficult for you to be in the scanner, we can end the scan. However, if you cannot complete the MRI scan, you will not be able to continue your participation in the study.

If for some reason more than six months elapses between the MRI scan and PET scan, we will ask you to come back and complete a second MRI for a current scan of your brain.

2) Practice PET

You may undergo a mock (dry-run) in the PET scanner. This means that you will just be walked through the steps to get familiar with the process. During the mock PET scan, you will lie in a real PET scanner or a replica of the PET scanner, be told when the scanner is being "turned on" and when blood samples are "being drawn".

3) PET Scan

You will participate in a PET scan. You will be asked to arrive at the Yale University PET Center (801 Howard Ave, New Haven) for your PET scan by no later than 7:00 am. We will check your vital signs and have you complete some questionnaires. We will measure your breath alcohol level by asking you to blow into a meter. If you arrive with a positive breath alcohol level, indicating recent alcohol consumption, then the session will have to be rescheduled. A urine drug screen will also be done and if you are female, we will conduct a urine pregnancy test. If you test positive for either, you will be discharged from the study.

Before your PET scan, the research nurse or technologist will help get you settled and check your vital signs. A trained nurse or CNMT (Certified Nuclear Medicine Technologist) will place an IV line in your arm to inject the radiotracer. The radiotracer is injected as a bolus only (over a minute) and the scan is 90 minutes long. You will feel little, if any, pain during this process.

An experienced physician will insert an arterial catheter in your wrist area. The arterial catheter is about 2 inches long and looks like a regular IV tube, but it is inserted into an artery, not a vein. The blood flow in the arteries can tell us about your blood pressure. If an arterial catheter is in place, we can measure your blood pressure continuously. The other main reason to put in an arterial catheter is to be able to draw blood samples rapidly, repeatedly, and without causing you pain. Here is what happens when an arterial line in placed. First, the skin is cleaned with betadine solution (contains iodine) so that it is sterile and protected against infection. Second, the insertion area is numbed with a local anesthetic, so that you feel less pain when the catheter is inserted. You will probably just feel pressure but may also feel pain. This pain is usually like the pain you feel when an IV is placed and only rarely is it worse. Third, the catheter will be flushed regularly during your scan with a salt solution, which prevents clogging of the catheter with a blood clot. The arterial line will remain in palce for the whole scanning period. After the catheter is removed, local pressure is applied for a minimum of 15 minutes to prevent bleeding under the skin. A pressure dressing (coban) and a clear dressing (tegaderm) will then be applied and you will be asked to keep it clean and dry, refrain from lifting objects weighing more than 5 pounds, and to avoid repetitive movements for 48 hours. You may remove the pressure dressing at bedtime and the clear dressing after 48 hours, but do not submerge your hand in water for a full 72 hours. Strenuous activity is prohibited for at least 48 hours after removal of the arterial catheter. After this time, mild physical activity can be resumed.Since the catheter is in for a minimal period, there is a low risk of infection.

If for some reason, an arterial catheter cannot be inserted, after no more than three attempts per arm are made, the scan will be rescheduled for another day. You will still be paid $50 for your time. At the rescheduled scan, the physician will try to insert an arterial catheter again and the scan will be conducted regardless of whether or not the catheter was inserted.

As part of the PET scanning, you will be asked to lie very still on a table. At the beginning of the scan, you are positioned in the scanner and will undergo a “transmission scan” to calibrate the PET scanner. The radiotracer will then be injected into the catheter in your wrist. Following the injection, the PET scanner camera will detect the radiotracer present in brain areas. This information will be used to create pictures of the receptors in your brain. Each PET scan will take about two hours. If you ask, we can stop the scan at any time. However, if you can’t complete the PET scan, you may not be able to complete this study. You will be asked to drink several glasses of water at the close of the PET scanning session to wash out the radiotracer. We will monitor your vital signs throughout the study to see how you are feeling, before, during and after scanning. You will also have several electrocardiograms (ECG's). We will also draw blood for routine blood tests to measure levels of substances found naturally in your blood, the levels of the radiotracer and its metabolites, and to measure the same chemical in your blood that we will measure in your brain.

After the PET scan, you will be provided with a light meal, discharged and allowed to go back home. Depending on the start time of the PET scan, you may be at the PET Center until at least the early afternoon. You will be provided with a telephone number you can call anytime after the study if you need assistance for problems related to the study procedures.

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.

Risks and Inconveniences

1) *Magnetic resonance (MR):* Magnetic resonance is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of various parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.

   You will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time and we will take you out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them.

   There are some risks with an MR study for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MR scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet.

   We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important. This MR study is for research purposes only and is not in any way a clinical examination.

   The scans performed in this study are not designed to find abnormalities. The primary investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a diagnostic evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the primary investigator or consulting physician will contact you, inform you of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie solely with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a clinical MR exam and for that reason, they will not be made available for diagnostic purposes.

If you become uncomfortable for any reason or at any time, you should inform the MRI technician or research assistant immediately.

2) *PET Scan*

a) Risks Associated with Use of an Arterial Catheter

Putting in the plastic tube into the artery in the wrist area may cause bruising, and potentially infection. The arterial puncture may also cause spasm or clotting of the artery with a temporary decrease in blood flow, this may cause tingling or numbness at the injection site and/or in the hand/fingers. In rare instances blocking of the artery, poor healing, infection, hematoma (a solid swelling of blood within the tissues), or inflammation at the catheter insertion site may occur. Insertion of arterial catheters for giving drugs or sampling blood may be associated with mild-to-moderate pain or bruising at the puncture site. To minimize these risks, an experienced physician will insert the arterial line and a trained nurse will oversee subject care.

For two days following the placement of the arterial line, you should check your wrist/arm daily. The study team will also be in touch with you daily either via phone, or in person, during this two-day period. If you experience any excessive pain, tenderness, swelling, redness, drainage, skin color changes, numbness, pins and needles, or decreased strength in the arm that had the catheter, you should immediately call the study team (203-464-6015). You can also contact the study PI Dr. Krishnan-Sarin (860-575-9895), or the PET center physician, Dr, David Matuskey (203-370-1403), or the study physician, Dr. Julia Shi (203-781-4640).

You may experience a rare allergic reaction to the medicine used to numb your skin prior to placement of the arterial catheter. If you have had a bad reaction to lidocaine or other anesthetic agents used to numb the skin in the past, please tell us about this experience before you go through the arterial line placement. Severe allergic reactions can be life threatening. Important: If you have a history of a bleeding disorder or are taking medication to thin your blood, you will not be allowed to participate in this study. You will also be asked to abstain from using aspirin and other anti-inflammatory drugs (such as Motrin or Aleve) for 7-10 days before arterial line placement and 7-10 days after arterial line removal.

b) Risks Associated with Radiation

This research study involves exposure to radiation from positron emission tomography (PET). Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only. The radiation you will receive in this study is from **[11C]LY2975050** scan(s) and from transmission scans of your head used to help obtain the PET images.

The total amount of radiation you will receive during the PET scan session in this study is from **1** injection(s) of the tracer, **[^{11}C]LY2795050,** and from transmission scans of your head.

Although each organ will receive a different dose, the amount of radiation exposure you will receive from this study is equal to a uniform whole-body exposure of **.72** rem, which is the equivalent of approximately **2** years of natural environmental exposure. This value is known as the "effective dose" and is used to relate the dose received by each organ to a single value. This amount of radiation exposure is below the annual limit of 5 rem set by the federal government for research subjects.
The effects of radiation exposure on humans have been studied for over 60 years. In fact, these studies are the most extensive ever done of any potentially harmful agent that could affect humans. In all these studies, no harmful effect to humans has been observed from the levels of radiation you will receive by taking part in this research study. However, scientists disagree on whether radiation doses at these levels are harmful. Even though no effects have been observed, some scientists believe that radiation can be harmful and may cause cancer at any dose- even low doses such as those received during this research.

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.

If you are pregnant or breast feeding, you may not participate in this research study. We will perform urine pregnancy tests prior to your participation on your PET and MRI scan days.

3) *Risks Associated with Blood Drawing and Urine Collection*
Urine samples will be used for drug and pregnancy tests and there is no risk. Drug tests will be done at the initial appointment, the PE, and the PET session.

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. Some people feel lightheaded but this effect is temporary. The total volume of blood collected during this study will be about **8** tablespoons (1 tablespoon at the physical exam for safety labs and 7 tablespoons at the PET scan). This amount of blood loss is safe for healthy persons.

4) *Risks Associated with Pregnancy and Breastfeeding*
You may not participate in this study if you are currently pregnant, might become pregnant during the study, or you are breastfeeding an infant. Acceptable levels of radioactivity are lower for pregnant individuals. It is best to avoid radiation exposure to unborn or nursing children since they are more sensitive to radiation than adults. You will be tested for pregnancy as part of the routine lab tests. 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 you 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 to tell us immediately. You will be

given one pregnancy blood test during the initial physical evaluation, and you will also be given a urine pregnancy test on the day of the MRI and on the day of the PET scan.

Benefits

There are no direct benefits to you for your participation. We expect that the results of the study, however, will benefit science and others through increasing our knowledge about the use of naltrexone as a treatment for alcohol drinking and its efficacy through the use of PET.

Compensation

You will be paid:
$50 for the initial interview
$50 for the physical examination
$250 for the PET scan
$50 for each arterial catheter insertion
$50 for the MRI scan

Subjects **may** also earn:
$50 to show up for additional PET scan
$50 for an additional MRI scan
Compensation could total $575 for attending and participating in all appointments.

Appointment	Cash	Check
Intake	$50	
Physical Exam	$50	
MRI Scan	$50	
PET scan		$250
Arterial Catheter insertion		$50
Repeat Arterial Catheter insertion		$50*
Extra Lab Appointment	$25**	
Standby for PET scan	$50***	

*In the case that the first arterial line cannot be placed at the PET scan, you will be paid $50 and rescheduled to try again.

**If you are asked to come back in for a repeat lab appointment (bloodwork or EKG), we will compensate you $25 in cash for your time.

***You may be asked to come to our office as a standby participant in case the primary scheduled participant has a conflict for the PET scan. If the scheduled participant arrives, you

will be paid $50 for your time and be asked to come back at a later date to complete your scheduled appointment. However, if the scheduled participant does not arrive, you will still be paid $50 and will be invited to complete the appointment of the original participant.

You will receive up to a total of $350.00 in the form of a check after completing the study. This check can take 4-6 weeks to process. All other payments will be given in cash.

Subject Obligation

The only way you might be dismissed from the study is if you repeatedly do not show up or lie about your alcohol and drug use. We will be monitoring your urine periodically for alcohol and other drugs and will also check your breath alcohol level. If your drug test is positive, the session will have to be rescheduled if possible.

Confidentiality and Privacy

There are two separate statutes which provide the means to protect your confidential information related to your health information. One statute of protection is called HIPAA and the second is called a Certificate of Confidentiality (CoC).

A Personal Health Information (PHI) record is routinely created whenever you see a physician or go to the hospital or you are seen in an outpatient clinic. Personal health information is also called a medical record. Your medical record is considered confidential under the privacy statutes referred to as HIPAA. However, there are certain circumstances when medical records can be demanded without your written permission. In some cases, medical records can be requested, for example, by an insurance company, the government, or an attorney representing another person. HIPAA allows the court to order such information to be provided to them for good reasons.

When you participate in a research study, your identity as a research participant—and all the identifiers that could lead to your identity will be held confidentially. The investigator cannot be forced to release your identifiers to anyone outside of the research team if a Certificate of Confidentiality is issued. Thus, to protect your sensitive information, we have obtained a Certificate of Confidentiality (CoC) from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) which is part of the National Institutes of Health (NIH).
The CoC protects the identity of individuals in a study and protects the investigators from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. This protection, however, is not absolute. 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 subject'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. Individuals who participate as research subjects (i.e., about whom the investigator maintains identifying information) in the specified research project during any time the Certificate is in effect are protected permanentlyAlso, because this research is sponsored by NIAAA, staff from NIAAA and other DHHS agencies may review records that identify you but only for the purposes of audit for quality and accuracy or program evaluation.

Even when a CoC is in place, you must still continue to actively protect your own privacy. If you voluntarily give your written consent to anyone to receive information about your participation in the research or freely volunteer information to anyone other than the study staff that you are a research participant in this study, then we may not use the CoC to withhold this information.

Further details about the limitations and protections of your medical records and the information you provide as a research participant are provided below.

Use and Protection of Collected Medical Record information

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the Yale University Privacy Notice. If you have not received this notice, please request a copy from the investigator. At Yale University, your medical record information will only be used or shared as explained and authorized in this consent form or when required by law.

We ask anyone who gets your health information from us to protect your privacy. However, there may be some cases beyond our control where we cannot protect your privacy but we expect that those instances will be rare and accidental disclosures.

To participate in this research you must allow the study team to use your health information. If you do not want us to use your medical record information, you may not participate in this study.

Documents that contain your name, such as this consent form signed by you, will be securely stored separately from your research data. All research data will be coded in a way that does not identify you by name or initials and will be kept in a secure place that allows only selected study personnel to have access to this information. The research data collected will be kept separate and distinct from the medical record.

You should understand that there is a risk that you will be recognized by other patients or staff involved in the laboratory or hospital ward and it could be known that you are participating in this study. If you find this to be an unacceptable condition you should not sign this consent form.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

Withdrawing Your Authorization to Use and Disclose Your Health Information

The use and disclosure of your information has no time limit. Any research information in your research record will be kept indefinitely. If you wish to revoke permission for the use and sharing of your health information, you may do so by notifying the study doctor, Dr. Krishnan-Sarin, but in doing so; you will no longer be able to participate in this research study.

If you withdraw your permission:

- No new health information identifying you will be gathered after that date.

- We will no longer use or share medical information about you for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

MEDICAL RECORD INFORMATION COLLECTED DURING THIS STUDY

The investigator and staff involved with the study will keep your medical record information collected for the study strictly confidential. Medical record information covered by HIPAA, including your name, initials, and other identifying information will not be released or published without your permission unless required by law. The following medical record information will be collected and used for research:

- *Name*
- *Address*
- *Telephone number*
- *Information from a brief psychiatric examination*
- *Emergency contact information*
- *Initial telephone screening information*
- *Allergies*
- *Current and past medications and therapies*
- *Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature*
- *Electrocardiogram*
- *Breath Alcohol Tests*
- *Urine Drug Screens*
- *Urine Pregnancy Tests if you are female*
- *Clinical laboratory Tests*
- *Healthcare, Social Functioning, and Addiction Questionnaires/Forms*

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
• Representatives from Yale University and the Human Investigation Committee, who are responsible for insuring research compliance. These individuals are required to keep all information confidential.
• Those providers who are participants in the Electronic Medical Record (EMR) system. Members of the research team who are participants in the EMR system, including the study physicians and study psychologist, will have access to your medical information in the EMR to ensure eligibility and safety for research participation.
• Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
• The Principal Investigator and selected members of the research team

• Collaborating research groups and research centers where research personnel from this study are also involved.
• Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

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 and Yale New Haven Hospital is 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.

In Case of Injury

If you develop any mental or physical problems as a direct result of being in this study, we will refer you for treatment. 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. Your legal rights are not waived by signing this consent 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. It will not harm your relationship with your own doctors or with the researchers, YNHH, the PET Center, or the Connecticut Mental Health Center.

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. 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. You will also be paid for your participation up until the moment you withdraw from the study.

When you withdraw from the study, 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.

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 the researchers, YNHH, the PET Center, or the Connecticut Mental Health Center.

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 Dr. Suchitra Krishnan-Sarin at Yale University, CMHC, 34 Park Street, New Haven, CT 06519.

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

When 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 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 Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem/injury, you may contact the Principal Investigator, Suchitra Krishnan-Sarin, PhD at (203)974-7595 or the study physician, Julia Shi, M.D, at (203)781-4640. 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. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/436-3650.