IRB Protocol# 2000030601
NCT05418608

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: Novel in vivo synaptic imaging in experienced meditators
Principal Investigator (the person responsible for this research): David Matuskey, MD
Phone Number: (203) 737-6316

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate synaptic density in experienced meditators (EM) and non-meditating subjects using Positron Emission Tomography (PET) scans. We will use a radioactive compound (or radiotracer) called [^{11}C]APP311, which attaches to the SV2A protein in the brain, a marker of synaptic density.
- Improvement of synaptic function and synaptic gain may be one of the biological mechanisms in meditation. Using [^{11}C]APP311 to measure synaptic density differences in EM has the potential to be used as a tool to track the benefits of meditation.
- Study procedures will include a screening appointment, a magnetic resonance imaging (MRI) scan, and one positron emission tomography (PET) scanning session.
- You will be scheduled to complete one PET scan session, but may be scheduled for two. In situations where one PET scan is not successful following tracer administration (e.g., problems with the PET scanner), you may receive one additional tracer administration for a total of up to 2 PET scans. *The total number of PET scans you may complete during this study will not exceed 2.*
- This consent form details the procedures for the study including screening and PET day.
- Two to three visits are required, with additional visits possible if cancellations occur.
- The screening visit will take 2-4 hours and the PET scanning session will take approximately 5-7 hours.
- There are some risks from participating in this study. This includes risks associated with blood drawing/IV Insertion, and radiation exposure.
- The study may have no benefits to you.
- 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 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 are in good physical health, you are not addicted to drugs or alcohol, and you do not have any psychiatric illnesses. We are looking for a total of up to 20 participants to be part of this research study.

Who is paying for the study?
National Institutes of Health

What is the study about?
The purpose of this study is to evaluate synaptic density in EM using the PET radiotracer [^{11}C]APP311. A radiotracer is a low dose of a drug that has a radioactive marker attached to it.

We will be using an imaging technique called PET (Positron Emission Tomography), which can track the movement of the radiotracer in the brain. After injection of a very low (micro) dose of the radiotracer into a vein in your arm, it will move through the blood, attach to the SV2A proteins in the brain, and give off energy (gamma-rays) that can be detected by the PET scanner. This allows us to measure the gamma rays and produce an image or picture of the brain areas where the proteins are located. We will look at how well [^{11}C]APP311 measures the synaptic vesicle glycoprotein 2 (SV2A) receptors in your brain.

What are you asking me to do and how long will it take?
If you agree to take part in this study, you will be invited to participate in one PET scan session. The study will be discussed with you during the screening visit. Approximately 1 week prior to your scheduled PET scanning session, a study coordinator will call to confirm your scan date,

You will complete the following:

- A screening visit
- MRI Scan (this scan may occur at the screening visit)
- PET scan Visit
    - You will be scheduled for one PET scan session..

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Your participation is expected to last approximately 2 months. Your participation may be extended in the event of unexpected cancellations.

Visit Details

Visit 1: Screening
You will report to the Yale University PET Center for your screening visit. The purpose of this visit is to find out if you meet all of the requirements to take part in this research study, and it will take approximately 2-4 hours to complete.

During this visit, you will be asked whether you are interested in joining the study. If you agree to participate in this study, you will complete a few brief questionnaires and complete a medical evaluation including the following:

- A review of your medical and psychiatric history, which may include any electronic health records (EHRs).
- Review of any current or past medications
- Demographic information
- Physical examination, including measurements of height and weight

- Neurological examination
- measurement of vital signs, which includes temperature, pulse, blood pressure, pulse oximetry (oxygen level in your blood), and respiration rate (the number of breaths you take per minute)
- Electrocardiography (ECG – a test that measures the electrical activity of your heart)
- Laboratory tests to ensure you are able to participate in the study
- Drug testing for drugs of abuse including but not limited to cocaine, amphetamine, PCP. You will not be allowed to participate in this study if you test positive for illegal drugs
- If you are a woman capable of having children, you will be required to have a pregnancy test prior to make sure you are not pregnant.

During the physical examination, a small amount (less than 4 tablespoons) of blood will be drawn from a vein in your arm for laboratory tests. Results of these tests are confidential. You will be notified if there are any clinically important results. You may be asked to return to complete additional blood tests and ECGs if your test results are out of range. All laboratory and ECG results will be made available to you, if requested.

You may be asked a series of questions about potential psychiatric or medical symptoms that you may have experienced during your lifetime. We will also ask if you have any family history of mental, emotional or drug abuse problems. These questions help us determine whether you can participate in the study.

Neurocognitive and meditation assessments, including behavioral measures and computerized cognitive testing (e.g., CogState), may be obtained. The clinical ratings may take place during the screening session or on the same day as the MRI or PET scan(s).

Visit 1: Remote Screening

Some portions of the screening may be conducted remotely. This includes review of psychiatric or medical symptoms that you may have experienced during your lifetime. Review of any family history of mental, emotional or drug abuse problems, and completion of Neurocognitive and meditation assessments. This will reduce the overall time spent onsite at the PET Center for the in-person screening visit. The remote portion of the screening, including review of this consent form, may take up to 2 hours to complete.

Re-Screening

In the event that your PET scanning session is postponed and is scheduled to occur more than 60 days after your screening visit, you may be asked to return for re-screening visit. This is to ensure that you still meet all of the study criteria. This visit may include additional blood work and a physical exam.

MRI Scan

During the screening visit, or on a separate day, depending on scheduling and your availability, you may complete a Magnetic Resonance Imaging (MRI) session. The MRI image is important because it is often difficult to identify the brain structures in the PET image, especially when they are small. The MRI creates a very detailed picture of the brain. By overlaying the PET image onto the MRI image, we can measure the concentration of the SV2A proteins in the brain.

- The MRI (Magnetic Resonance Imaging) scan session will last about 60 minutes. The entire appointment may take up to 80 minutes, including scan preparation.
- You may complete the MRI on the day of your screening appointment. In this case, you will be escorted to the MR Center by PET Center staff. The research staff member will stay with you at the MR Center during your scan.
- If the MR is scheduled for a different day, you should report to the Magnetic Resonance Research Center (MRRC) at The Anlyan Center for Medical Research & Education (TAC), 300 Cedar Street, in New Haven. You will be contacted to schedule your arrival time. A research staff member will meet you there and stay with you at the MR Center during your scan.
- The MRI test involves lying inside the MRI scanner, which is a strong magnet. No metal can be on your body or in your body. In the MR Center you will be asked to fill out the Magnetic Resonance Safety Check list, which will help to make sure that it is safe for you to have the MRI scan. The technologist will escort you into the MRI room and ask you to lie on your back on the bed. When you are comfortable, the bed will slide into the scanner and the test will begin. You will be asked to lie still in the MRI scanner for about 60 minutes.
- You will hear a drumming noise when the camera is taking pictures of your brain. If you feel uncomfortable during the scan, we can end the scan at any time you wish to do so; however, if you cannot complete the MRI scan, you will not be able to participate in any more of these studies.
- If you have recently (within 1 year) completed an MRI scan, as part of another Yale approved research study, you may not be asked to complete an additional MRI scan for this study.

Visit 2: PET Scan Session
You will participate in one PET scanning session at the Yale University Positron Emission Tomography (PET) Center, 801 Howard Avenue, in New Haven.

You will be scheduled for one PET scan. In the event that a scan is unable to be completed, due to equipment issues, you will be asked to return on a separate day to complete the PET scan.

Arrival Procedures
If you are a female of child-bearing potential, we will conduct a urine pregnancy test. If you test positive your participation in this study may be cancelled. You will also be asked how you are feeling, if you have taken any medications, or if any changes have occurred in your medical history since the screening visit.

IV Lines
After the above procedures have been performed, a trained nurse or CNMT (Certified Nuclear Medicine Technologist) will place plastic up to 2 IV (intravenous) catheters (small plastic flexible tubes) in your arms (one for the radiotracer injection, and one to take venous blood samples, if necessary.

Radiotracer Injection and PET Scan
You will receive the radiotracer [^{11}C]APP311 (a drug which is limited by Federal Law for investigational use only), during the PET scanning sessions. The radiotracer, which has a minimal amount of a drug that is labeled with a very small amount of a radioactive substance, binds to proteins in the brain 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 the injection, the PET scanner camera will detect the radiotracer present in your organs. We will take several pictures during the scanning session that will last up to 120 minutes. Blood samples during the PET scanning session will be used to measure the amount of radiotracer in your blood.

A transmission scan will be completed before or after the PET scan. This information is used to increase the accuracy of the PET data.

The following will also occur during the PET scanning session:

- Your vital signs will be taken throughout your PET scan days
- In the unusual circumstance where there are some technical problems with the scanning equipment, if appropriate, the timing of one of your scans may be adjusted. You may also be asked to return on another day, and complete an additional radiotracer injection and PET scan.
- If you ask to stop the study, we can stop any aspect of the study, including the scan(s), at any time.
- Blood may be drawn throughout your PET scan

After scanning you will stay at the PET Center for an observation period that could last up to 60 minutes. During this time discharge instructions will be reviewed and you may have a light snack or meal.

Follow-up Phone Call
You will be contacted by phone 1-3 days after your PET scanning session for a follow-up assessment to assess how you are feeling. This will take about 5 minutes of your time.

Cancellations
In the event that your PET scan day gets cancelled for reasons outside of your control (such as radiotracer synthesis failure), you will receive a payment per cancelled scan. This amount will be based on your length of participation on the scan day prior to cancellation, and will be up to the discretion of the PI.

RESTRICTIONS/ YOUR RESPONSIBILITIES

- 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.
- Because the radiotracer [^{11}C]APP311 is in the early stage of investigation, the potential for interactions with other drugs is not presently known.
- Please tell your 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. You are encouraged to inform your family doctor and your other healthcare providers that you are taking part in this research study.
- You will be asked to drink 2 to 3 glasses of water the night prior to and after their PET scan(s).

- You will be asked to refrain from donating blood for at least 8 weeks after the study completion.
- Contact the study team if you are prescribed medications within 2 weeks of scanning, or antibiotics within 30 days of scanning, so they may determine if these medications could impact the study result.
- You will be asked to reschedule your study participation visits should you acquire a cold, upper respiratory tract infection, or fever, within 5 days prior to admission.
- You will be told of any significant new findings that develop during the course of your participation in this study that may affect your willingness to continue to participate.

What are the risks and discomforts of participating?

There may be side effects that are not known at this time. Your health and safety will always be the first concern of the doctors and staff performing this study. In the event of an unexpected outcome, all necessary medical action will be taken. Medication might be administered as needed, per the Yale PET Center standard operating procedure for medical emergencies, in order to treat complications.

Possible risks from participation in this study include:

- Risks associated with evaluation
- Risks associated with radiation
- Risks associated with blood drawing and IV line insertion
- Risks associated with MRI scanning

Risks Associated with Evaluation

Some of the questions in the interviews may be uncomfortable for you to answer. You may refuse to answer any specific questions or discontinue the interview at any time. The tasks and structured interviews may be tiring, but every effort will be made to avoid making you tired. Breaks will be offered frequently and you can quit at any time if you get tired. However, if you can't complete the evaluation process, you may be disqualified from the current study. During the evaluation we might uncover unanticipated psychiatric and medical information. In that case we will discuss with you the findings and will advise you of appropriate follow-up.

Risks Associated with Radiation

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, used to help obtain the PET images. 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 targeted amount of radiation you will receive from participating in this study is from one injection of [^{11}C]APP311, plus transmission scans. In situations where a PET scan is not successful following a radiotracer injection (e.g. problems with the PET camera), you may receive an additional injection of [11C]APP311, for a maximum of 2 injections, plus additional transmission scans.

The maximum radiation exposure you will receive from 2 radiotracer injections is 1.214 rem, plus up to 0.0056 rem from 4 transmission scans, for a total of 1.219 rem.

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 1.219 rem, which is about 4 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.

If you are pregnant or breast feeding, you may not participate in this research study. It is best to avoid radiation exposure to unborn or nursing children since they are more sensitive to radiation than adults. We will perform urine pregnancy tests, if you are a female of child-bearing potential, prior to your participation on your PET scan day(s).

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 8 weeks after completion of PET scanning.

The total volume of blood collected during this study will be up to 270 milliliters (approximately 19 tablespoons). This includes screening blood draws, repeat blood draws if needed, and blood drawn from your vein and/or artery during up to 2 PET scan day(s). This amount of blood is safe for research participants.

Risks Associated with MRI Scanning
Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of different 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 lower 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 complete healthcare imaging examination. The scans performed in this study are not designed to find abnormalities. The principal 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 healthcare 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 principal 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 only 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 healthcare MR exam and for that reason, they will not be made available for healthcare purposes.

Reporting: If you experience any side effects or unusual events during the course of the study, report them immediately to the study doctor or research staff. If, in the opinion of the study doctor, there are any problems possibly caused by the study drug that makes it unwise for you to continue, you will be withdrawn from the study.

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.

How can the study possibly benefit me?
There is no direct benefit other than contributing to the knowledge of [^{11}C]APP311.

How can the study possibly benefit other people?
It might lead to an imaging tool that help others in the future. Society may benefit from these insights, as this research information may have clinical application in the future.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation, which will be reimbursed if reasonable, 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 paid the following:

Study Days / Procedure	Payment	Payment Method
Screening Session	$50	Check or BOA pre-paid debit card
MRI Session	$50	Check or BOA pre-paid debit card
Repeat Screening Bloodwork and/or ECG (if needed)	$25	Check or BOA pre-paid debit card
PET Scans	$250 (per PET scan)	Check or BOA pre-paid debit card

- The total amount that you are expected to be compensated will be up to $350. This includes completion of screening, MRI, and 1 PET scan.
- In the event that you complete additional screening blood work, your total would increase.
- All study procedures will be provided free of charge
- Reasonable transportation costs will be reimbursed. Receipts must be submitted. You will be required to contact the study coordinator prior to your study date to discuss transportation plans and confirm that they will be appropriate for reimbursement
- You will receive compensation upon completion of each study visit, as described below in the method of payment section.
- If you withdraw or are withdrawn from the study early, you will only be compensated for the procedures that you have completed.
- According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income.
- You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study, if applicable (i.e. amount receive is taxable). Taxes are not withheld from your payments.

Method of Payment

For this study you may be paid by check or Bank of America (BOA) pre-paid debit card. Please allow 4-6 weeks for receipt of your check.

If you are paid via a BOA card, **please note that your name, address, and telephone number will be shared with Bank of America.** Upon completion of the first study visit, you will receive a card in the mail, which you will need to activate over the phone. Any subsequent payments, if remaining, will automatically add additional funds to your card. An information sheet indicating how to activate your BOA pre-paid debit Card will be provided to you.

In the event that you are unable to receive payment by check or Bank of America pre-paid card, payment may be issued in cash. This would need to be discussed with the study team and approved by the Principal Investigator of 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.

If you decide to take part in this research study, you will be required to give us information about any past substance abuse, and will also be required to take a drug test. These results will be kept confidential.

All data is securely stored in locked filing cabinets or on a password-protected computer server.

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 cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Neurological Disorders and Stroke which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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 researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name 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.
For the purposes of your participation in this study and the protection of your identity, your study doctor will assign you a unique code, such as a series of numbers and/or letters. The study doctor will record the study data collected from you in a report form that uses your assigned code, not your name. This is to protect your study data by making it anonymous for most study purposes.

The data that is recorded with your assigned code rather than your name is called "**key-coded data**". The key-coded data will be entered into the study's computer database. Your study doctor will keep a confidential list linking your name to your code and only authorized persons will have access to this list.

Some study data will identify you (such as medical records), and the ways in which this data may be used and shared is described below.

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. Information about your participation in this study is stored in locked file cabinets. The research team will only give this coded information to others to carry out this research study. De-identified data will be kept for a minimum of 7 years.

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
- Medical and laboratory records stored in EPIC for previous clinical or research visits.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Other reportable infectious diseases
    - Physical and neurological exams
    - ECG tracings
    - Questionnaires
    - Use of illegal drugs or the study of illegal behavior
    - Records about the radiotracer you received
    - PET and MRI data

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 Radiation Safety Committees that have reviewed and approved this study,

- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- 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
- National Center for Complementary and Integrative Health (NCCIH) (part of the National Institutes of Health, NIH)
- Food and Drug Administration (FDA)

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.

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 the Principal Investigator:

David Matuskey, MD
Department of Radiology and Biomedical Imaging
Yale University PET Center 137A
801 Howard Avenue
P.O. Box 208048
New Haven, CT 06520-8048
United States

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 believe you have been injured, please contact the Principal Investigator/Study Doctor, Dr. David Matuskey, (203) 370-1403 (voice mail pager), office: (203) 737-6316, as soon as you are able.

If you seek emergency care, or if hospitalization is required, please inform the treating doctor that you are participating in a clinical trial.

Medical care will be provided for any physical injury, complication, or illness that occurs as a direct result of your participation in this study. Medical care will be arranged through Yale-New Haven Hospital. 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.

The researchers may withdraw you from participating in the research if necessary. Conditions under which you might be withdrawn from the research include development of serious side effects, or non-compliance. Non-compliance means that you do not show up for study appointments as scheduled.

If you withdraw or are withdrawn from the study, you may be asked to have appropriate medical tests and follow-up to evaluate your health and safety. This could occur if you experience a serious side effect.

What will happen with my data if I stop participating?

We cannot discard or destroy data once it is collected. However, you can be assured that if you withdraw from the study, the information collected will be coded in such a manner that it cannot be traced back to you.

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 a research coordinator at 203-737-7496 or the Study Doctor/Principal Investigator, Dr. David Matuskey, at (203) 370-1403 (voice mail pager), or (203) 737-6316 (office).

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.

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: _____.
Participant's Initials

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