NYU Langone Health

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NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	Transcranial near infrared radiation and cerebral blood flow in depression (TRIADE) i20-00217
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

For NYU Employees and Students: Your academic status or grades, or employment will not be affected by your decision to participate in this study. Record of the participation cannot be linked to an academic record.

2. What is the purpose of this study?

The purpose of this research study is to determine if application of near infrared energy to the forehead can change blood flow in the brains of people with depression. Near infrared energy is like light but is not visible to the human eye.

We are asking you to take part in this research study because you have depression.

This research study will compare near infrared exposure with a placebo or sham procedure. The sham procedure will look and feel just like the near infrared procedure but won’t include near infrared exposure.

Will I undergo the near infrared or the sham procedure?

Both. You will undergo both the sham procedure and the near infrared procedure on different days. At three study visits you will undergo a near infrared procedure. At each visit, you will be exposed to a different

dose of near infrared energy. At another visit, you will undergo the sham procedure. This is to compare your reaction to the near infrared procedures with your reaction to the sham procedure. A sham is used in research studies to compare the results and side effects of the procedure being studied to the results and side effects of having no procedure. This allows us to see if the procedure being studied works and what side effects it may cause.

When will I undergo the near infrared procedure and when will I undergo the sham procedure?
When you undergo the near infrared procedures and when you undergo sham procedure will be randomized. This means, like flipping a coin, the order of your procedures will be decided by chance.

This study is called "single blind" because you will not know when you will undergo the near infrared procedures or when you will undergo the sham procedure. The purpose of the single blind is to prevent you from having any expectations for a given treatment session, and therefore maintain data integrity. The study team will know which treatment you are receiving. A statistician also keeps records of which procedure you are undergoing.

Is the near infrared procedure approved to treat depression?
No. The device that delivers the near infrared energy is FDA approved for treating muscle aches and joint pains. It is not, however, FDA approved to treat depression. For this reason, the near infrared procedures you will undergo in this study are experimental.

3. How long will I be in the study? How many other people will be in the study?

This study will last 6-12 weeks and will involve five visits and one phone call.

About 30 people will take part in this study.

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you undergo any procedures with the study staff that are part of the study.

Visit 1: Screening Visit @ Nathan Kline Institute and Remote Video Conferencing

This study will be an out-patient study. Your first screening visit will occur in two parts. The first part is a remote visit held over video conference (via WebEx or Zoom) during which we will ask you questions about your medical and mental health history to determine your eligibility for the study. If you appear eligible, we will invite you to the second part of the screen visit at the Nathan Kline Institute (NKI) in Orangeburg, NY where we will collect a urine sample for safety labs and, if deemed necessary by a study physician, a blood sample for additional safety labs. We will also ask you to try on the study device and receive a small amount of the infrared light at its highest dose to make sure that you are able to tolerate the treatment comfortably. The next four treatment visits will also take place at NKI, approximately 20 miles north of Manhattan. We will provide round-trip transportation through a car service for you to travel between Manhattan and Orangeburg should you wish.

The remote part of this visit takes about 2 hours. During the remote visit, we will:

- Ask you about your medical history.
- Ask you what medications you take – including over-the-counter and prescription medications, vitamins or herbal supplements.

- Ask you to complete some forms and answer questions about your general health and well-being, quality of life (i.e., if you are happy about your life), mental health, mood and memory.

If you meet the requirements of the study based on the remote part of the screen visit, we will then invite you to come for the second part of the screen visit at the NKI. At the second part of the screen visit, we will do some tests to see if you meet the requirements to take part in the study. The second part of the screen visit will last about 2 hours.

During the second part of the screen visit, we will:

- Give you a physical exam, including recording your height, weight and "vital signs" (blood pressure, temperature, heart and breathing rates).
- Take a blood sample, if the study physician deems it necessary: if it is deemed necessary, we will insert a needle into your arm and take a small tube or vial of your blood (about 3 teaspoons).
- Ask you for a urine sample; We will test your urine for:
  -Certain drugs including illegal drugs (see next section called Urine Drug Screen).
  -Pregnancy; you may not take part in this study if you are pregnant.
- Ask you to try on the study device and to wear it inside of the MRI machine (we will do no imaging at this visit, we just want to make sure that both you and the device can fit inside the scanner comfortably)

<u>Urine Drug Screen</u>
During the screen we will test your urine for drugs, including illegal drugs like cocaine, amphetamines and others. If your urine shows you have taken any of these drugs, you cannot be in the study. The results of the urine test will NOT become part of your medical record.

After the second part of the screen visit, the study doctors will review the results of these tests and procedures. If you do not meet the requirements, the study doctors will tell you why.

Visits 2, 3, 4, & 5: Scans and Near Infrared or Sham Procedures @ NKI in Orangeburg, NY

Each visit will take about 3 hours.

At each visit, you will:

- Report any medications you are taking or side effects that you experience.
- Have your "vital signs" (blood pressure, temperature, heart and breathing rates) recorded.
- Complete some forms and answer questions about your general health and well-being, quality of life (i.e., if you are happy about your life), mental health, and mood.
- Have an MRI **brain scan**.
- Undergo either a **near infrared or a sham procedure** during the brain scan.

Brain Scan:
After ensuring that you have no metal on or in your body, you will lie on your back on a table in a Magnetic Resonance Imaging (MRI) machine for about one hour. During scanning, it will be necessary for you to lie very still and to stay as still as possible. At times there will be a loud banging noise. This is a normal part of scanner functioning, but it may cause slight discomfort if you are sensitive to loud noises. You will be given noise-cancelling headphones and/or foam earplugs to help reduce the noise. During the entire scan you will be able to communicate with the person operating the scanner by intercom. If you feel uncomfortable, you may choose to stop the scan at any time.

During the scan, we will take a picture of your brain's anatomy (structure) and gather information about the temperature of your brain. We will also record your brain activity using functional MRI, which is a method for monitoring the flow of blood. These MRI scans use a powerful magnet but do not involve exposure to radiation or contrast dye.

A radiologist or neurologist will review at least one of your brain scans.

Near Infrared or Sham Procedure:
The procedure will happen during the brain scan. For that reason, before you enter the scanner, we will examine your forehead for any possible skin lesions (for example, any cuts or signs of swelling). If you have any lesions on your forehead, you cannot undergo the near infrared or sham procedure. While you are in the scanner, you will wear a special cap on your head as well as protective goggles. The cap will be connected, with a wire, to a laser device located in another room. The laser device is programmed to automatically deliver either near infrared energy or sham. If it is programmed to deliver near infrared energy, the cap will administer the near infrared energy to your forehead, through your skull, and into your brain. If it is programmed to deliver sham, the cap will NOT administer near infrared energy. Both the near infrared and sham treatment procedures may leave your forehead feeling warm. Therefore, because near infrared energy cannot be seen by the human eye, you will not know whether or not you are being exposed to the near infrared energy.

After all of your study visits, we will remove any details from the information we collect that could be used to identify you (such as your name, date of birth, etc.). Instead, we will label everything with an identification number. After we remove such details, the information may be used for future research studies or shared with other researchers and we will not request additional informed consent from you.

Follow-up Phone Call and Questionnaire Completion:
About one week after your last near infrared or sham procedure, we will need to speak to you on the phone. During the call we will:

- Ask you about any medications you are taking or side effects you have experienced; and
- Ask you questions about your general health and well-being, quality of life (i.e., if you are happy about your life), mental health, and mood.

We will also ask you to complete some questionnaires online. The questionnaires will also include questions about your general health and well-being, quality of life (i.e., if you are happy about your life), mental health, and mood.

Altogether, the phone call and questionnaires should take about one hour.

5. What are the possible risks or discomforts?

The near infrared and sham procedures may cause you to have one or more of the side effects listed below. Because the near infrared procedure is experimental, not all side effects are known. There may be rare and unknown side effects.

It is important for you to tell the study staff about any changes you notice from the study procedures. You can tell the study staff at your scheduled visits or by calling the staff and telling them how you are feeling different from before the study procedures. If you are not honest with the study staff during this study, it may not be safe for you to stay in the study.

The **most common side effects** of the near infrared procedure are:

- Disturbed sleep, including restless or erratic sleep, or early morning awakenings

- Irritability
- Seeing vivid colors

Rare side effects of the near infrared procedure are:

- Abdominal bloating
- Amnesia
- Reddening of the skin at the application site
- Skin peeling and chafing at the application site
- Application Site Pain
- Application Site Reactions such as warming sensations and thermal pain
- Abnormal taste
- Decreased heart rate
- Abnormal hair growth
- Blood may clot at the location of a previous stroke in the brain causing the brain to become oxygen deprived. This oxygen deprivation may cause cell damage or death, and swelling or bleeding in the brain.
- Nausea
- Neck Pain
- "Out-of-body" experiences
- Itchy Skin
- Rash
- Skin Laceration
- Skin Lesion
- Skin burn if the device is not used as intended
- Vivid dreams
- Vomiting, and
- Word finding difficulties.

Other risks of the study procedure: In addition to the side effects listed above, you may experience physical, emotional, financial, social and legal risks and discomforts.

Risk of Eye Damage: There is a risk of damage to your eyes (retina) due to accidental exposure to the laser. For instance, direct laser exposure to an open eye could cause blindness. There are multiple precautions made to prevent such an accident. You will need to wear protective goggles at all times during the procedure.

Risk of Allergic Reaction: As with any treatment, an allergic reaction can occur. Allergic reactions can be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away at the phone number at the top of page 1 of this consent form. If you are having trouble breathing, call 911 immediately.

Other Risks

The amount of time you have to spend with the research team may make you uncomfortable due to the long study visits (about 3 hours each).

In addition, there always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. For instance, MRI data, questionnaire responses, and health and symptom information obtained from this research are stored with a code number and not your name. A tracking file

will link the codes with identifying information, such as your name and contact information, but this file will be password-protected and located on a computer that can only be accessed with a password. Paper consent forms and payment forms that contain subject names will be kept in a locked cabinet located in a locked room, to which only authorized research personnel have access.

Delay in Treatment Changes: While you are taking part in this study, you will be allowed to continue treatments for depression that you started before the study screening. But you will not be allowed to change your treatments for depression until you complete the study. For that reason, you may have to delay starting a new treatment or changing your current treatments. You will also have to wait until the screening phase is complete before you start the near infrared procedures.

Risk of Worsening Depression: There is a risk that your depression could get worse while you are taking part in the study.

If you feel your depression is getting worse or if you have any thoughts of hurting or killing yourself, you should call the PI on page 1 of this form, or call 911.

Side Effects of Having Blood Taken include fainting or feeling faint. Tell the study staff right away if you feel faint. Redness, pain, bruising, bleeding or infection at the needle site may occur.

Magnetic Field Risk
MRI uses strong magnetic fields and radiowaves to make images of the inside of your body. MRI does NOT involve high-energy radiation (like x-rays). For most people MRI is very safe. However, if you have anything made of metal on your skin or inside your body, MRI may not be safe for you, and you must tell study personnel before your scan. Also, if you have any electronic devices on the outside or inside of your body, you must tell study personnel about those too. Some things, like tattoos, may have metal materials in them even though you might not realize it. For this reason, study personnel will give you a checklist of things that have metal or electronic parts in them. You must read the list carefully before your scan and put a checkmark next to everything that applies to you.

The following paragraphs will describe the possible risks of MRI. To reduce many of these risks, you will be given an emergency squeeze ball to hold in your hand during the scan. If you feel any discomfort you should squeeze the ball. This sets off an alarm that the technologist can hear. The technologist will then talk to you and will stop the scan if you want. There is a microphone in the scanner so that you can communicate with the technologist. However, the scanner makes a lot of noise when it is running and the technologist may not always hear what you say. If you need to get the technologist's attention, you should squeeze the ball.

Remember, if at any point you feel uncomfortable and want to stop the scan, just squeeze the ball and tell the technologist.

Risks from metal
The strong magnetic field in the scanner will pull on things that contain certain types of metal. If someone takes a metal object into the scan room, it might fly towards the scanner and hurt you. For this reason, everyone (including you) must remove everything metal from their clothes and pockets before going into the scan room. Also, the door to the scan room will be kept closed during the scan to prevent unauthorized people from walking in.

If you have something metal inside your body, the scanner might pull on it and make it move. You must tell study personnel before your scan if you have anything metal inside your body. Some types of metal

might heat up when the scanner is running. If you feel any burning sensation during the scan, you should squeeze the emergency ball and the technologist will stop the scan.

Risks from electronic devices
If you have any electronic devices on the inside or outside of your body, the scanner might make them stop working properly. For this reason, you must tell study personnel before your scan if you have anything electronic on or in your body.

Burns
Metal is not the only thing that can cause burns in MRI. It's possible (although very rare) to get burned by touching the inside walls of the scanner or by making skin-to-skin contact. The technologist will give you a blanket or cushions so that you don't touch the inside walls of the scanner. You should also avoid letting your hands or legs touch each other. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the technologist will stop the scan.

Tinnitus (ringing in the ears) and hearing loss
The scanner makes very loud sounds while it is running. You will be given earplugs or headphones to wear during the scan. Make sure you roll the earplugs tightly and let them expand in your ears so that they work properly. If the sound of the scanner is still so loud that it causes you discomfort, squeeze the emergency ball and tell the technologist. This is important because very loud sounds can cause ringing in the ears or even hearing loss.

Feeling warm or hot
The radiowaves used in MRI are like those your cellphone uses, but much stronger. Sometimes they are strong enough to make you feel warm (just like standing in bright sunshine makes you feel warm). MRI scanners are designed to try to avoid you getting too hot. However, if you start to feel uncomfortable, squeeze the ball.

Peripheral nerve stimulation (tingling or twitching)
The magnetic field inside the scanner changes very quickly while the scanner is running. If it changes too quickly, it can give you tingling sensations or make you twitch. MRI scanners are designed to try to avoid this. However, if you experience tingling or twitching, squeeze the emergency ball and tell the technologist.

Claustrophobia (discomfort in enclosed spaces)
Some people get panic attacks inside enclosed spaces. This is called 'claustrophobia', which means 'fear of confined spaces'. If you know that you are claustrophobic, tell study personnel before your scan. Some people only find out they are claustrophobic when they have an MRI for the first time. If you feel anxious or panicky inside the scanner, squeeze the emergency ball and the technologist will get you out.

Quench
In very rare circumstances, the scanner can lose its magnetic field. This happens very suddenly and is known as a 'quench'. The helium that helps keep the magnetic field strong will then escape from the scanner. The scanner is connected to a vent so that the helium will go outside the building. However, if for some reason the vent doesn't work properly, helium might fill the scan room, making it difficult to breathe. In the very unlikely event of a quench, the technologists will get you out of the scanner immediately.

6. Can I be in the study if I am pregnant or breastfeeding?

We do not know how taking part in this study would affect an embryo, fetus, or breastfeeding baby. Therefore, you should not become pregnant, breastfeed a baby, or father a child while participating in this study. Other risks may not yet be known.

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use a medically accepted method of birth control while you participate in the study:

- Hormonal methods like birth control pills, patches, vaginal rings or implants
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

7. What if new information becomes available?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

In some cases, an imaging scan of will reveal an abnormality with (or without) a clinical significance. Every scan performed in this study is saved and handled under the standard PHI confidentiality restrictions and regulations employed for patients' information. Each scan is additionally reviewed by a radiologist, who might then detect an abnormality. If clinically useful information is uncovered, either the Principal Investigator or another clinician on the study will speak to you in person or on the telephone regarding the new information. A copy of the original image report will also be provided to you in person and you will be encouraged to follow up on the discovery with your treating physician.

8. What are the possible benefits of the study?

It is possible that some study subjects may experience an improvement in their depression after the near infrared procedures during the study. However, if you receive such benefit, because near infrared exposure is not FDA-approved for depression, your doctor cannot prescribe it after you finish the study. Also, you may not get any benefit from being in this research study. Others with depression may benefit in the future from what we learn in this study.

9. What other choices do I have if I do not participate?

You do not have to take part in this research study. If you decide not to participate, your decision will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Other treatments that are available to treat depression include:

- Medications such as fluoxetine (Prozac®) or escitalopram (Lexapro®),
- Procedures such as transcranial magnetic stimulation (TMS) or electroconvulsive therapy (ECT),
- Psychotherapy.

You may discuss these other treatment options with your personal doctor or therapist.

10. Will I be paid for being in this study?

You will be paid for your participation in each of the study visits as follows:

- Screening Visit, $50
  - Screen Visit Part 1: $25
  - Screen Visit Part 2: $25
- Scan and Treatment Visits, $75 per visit (4 visits total), and
- Follow-up phone call and questionnaires, $50.

If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid only for the visits you already completed.

If you do complete all the study visits, you will receive $400 for being in this study.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check,), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

We will also pay you back for travel costs of up to $50 per visit once you give us receipts and/or, if you use your own car, a record of the number of miles your drove. For the scan and treatment visits in Orangeburg, NY, we can arrange for a car service to transport you (instead of paying you back).

11. Will I have to pay for anything?

You will not have to pay for any tests or procedures as they are all covered by the study.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by the study doctors, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates

to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
    - Anonymized MRI data will be shared with our collaborator and co-investigator, Jacek Dmochowski, PhD, of CUNY, such that he will analyze the imaging data we collect
- The study sponsor: National Institutes of Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA)
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study
- Other study sites involved in the research (Nathan Kline Institute and Massachusetts General Hospital)
- Data and Safety Monitoring Board

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form.

You can also call the research coordinator if you have any questions about the study or the study visit scheduling: Ellen Krotow, 646-754-2211.

If a member of the research team cannot be reached, or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date