Study Title:

Improving Outcomes for Patients With Sleep-Disordered Breathing and Insufficient Sleep (RESTORE)

ClinicalTrials.gov Identifier (NCT):

NCT04279834

Document Date:

December 12th, 2022

Participant Name (Last, First, MI, suffix): _____ Date: _____

Title of Study: Improving Outcomes for Patients with Sleep-Disordered Breathing and Insufficient Sleep

Principal Investigator: M. Safwan Badr, M.D., M.B.A VA Facility: John D. Dingell VAMC

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study to look at how mild to moderate sleep apnea and not getting enough sleep contribute to daytime sleepiness and also to determine the treatment that works best for improving daytime sleepiness. This information is to help you decide whether to participate. We have included detailed information about this research study on the following pages. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of the study is to look at how mild to moderate sleep apnea and not getting enough sleep each night contribute to daytime sleepiness. Your participation in this research will last about 5-6 months. The purpose of this research is to find out the best treatment for daytime sleepiness

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer for this study because you have been diagnosed with sleep apnea or are at a high risk of having the condition. The possible benefits to you for taking part in this research study are the diagnosis and treatment of sleep disorders, and learning information about healthy sleep habits for adults, which could lead to improvement in sleep quality and a decrease in daytime sleepiness. Additionally, information from this study may benefit other people with similar health issues now or in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might choose not to volunteer for this study because you may experience discomfort with the study devices used. The possible risks for taking part in this research study are discomfort with the equipment. For a complete list of risks refer to the Risks/Discomforts section of this form.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is M. Safwan Badr, MD, MBA of the John D. Dingell VA Medical Center (JDDVAMC). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information at JDDVAMC, 4646 John R. Detroit Rm C3411, MI 48201. Phone #313-745-8244 or (313) – 520 2766.

Participant Name (Last, First, MI, suffix): _____ Date: _____

Title of Study: Improving Outcomes for Patients with Sleep-Disordered Breathing and Insufficient Sleep

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RESEARCH DETAILS

COVID-19 PRECAUTIONS:

In lieu of in-person visits, we may conduct the consent appointment and study sessions remotely using VA approved telehealth services. If you agree to participate in the study, you may receive and return the study documents and devices by prepaid mail. We may also adjust the sequence and number of study activities based on your preferences and public health recommendations.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the study is to look at how mild to moderate sleep apnea and not getting enough sleep contribute to daytime sleepiness. We also want to determine the treatment that works best for improving daytime sleepiness. You qualify to participate because you have or you are at risk for mild to moderate sleep apnea.

If you have mild to moderate sleep apnea, we will determine whether or not you get enough sleep most nights and if you have symptoms of daytime sleepiness. If you don't get enough sleep most nights and show symptoms of daytime sleepiness, you may be asked to continue in the study. In this study we are comparing 2 programs that may improve symptoms of daytime sleepiness. The equipment and education programs that are part of this study will be provided at no cost to you.

HOW LONG WILL I BE IN THE STUDY?

We anticipate to enroll 500 people to take part in this study. This research study is expected to take approximately 5 years. Your individual participation in the project will take about 5-6 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you agree to take part in this research study, you will begin with an enrollment visit. After the enrollment visit we may schedule a time that is convenient for you to have an overnight sleep study. If you are eligible to continue in the study you will receive one of two sleep education and treatment programs. Which one you receive will be randomly assigned. You will come to the office once a week for four weeks to meet with one of the study team members to receive programs. After the program, you will be asked to return to the office for one month and three month follow up evaluation.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

If you agree to take part in this research study, you will begin with an enrollment visit.

Visit 1-3 (Enrollment and Baseline Visits): At the beginning of your first visit, we will review this consent form, answer all your questions, and have you sign this form. You will be asked to fast for eight hours, refrain from caffeine, alcohol and tobacco, and avoid exercise for eight hours prior to one of the visits..

If you agree to participate, we will conduct the study evaluations over 3 visits. We will schedule these visits based on what is most convenient for you. The total time for this evaluation will be 1-2 weeks. Between the visits, you will be asked to wear monitoring devices at home (described below).

- Will review your medical history and ask you to complete questionnaires about your health, sleep, mood, and quality of life.
- We will play a short game that tests how alert you are.
- We will measure your blood pressure while you are here in our office.
- We will give you a blood pressure machine to take home with you that you will wear for 24 hours. We will show you how to use this machine before you take it home, and you will keep a log of activities that you do while you are wearing the machine. We will schedule a time for the blood pressure machine to be returned to us.
- Using a device called an EndoPAT we will measure changes in blood volume. You will be asked to have a sensor placed on your finger as well as a blood pressure cuff around your arm that will inflate for about 5 minutes. This procedure will take about 30 minutes.
- We will also give you a device similar to a watch (actigraphy) to wear for one week. The watch is like an activity tracker and it will measure your level of activity. During the week that you wear the watch, you will be asked to fill out a sleep diary about when you go to bed and when you get up in the morning. We will schedule a time for the watch to be returned to us.
- Each visit will take approximately 1 hour. You will receive $60 per completed visit.
- We may also schedule an evening for you to have a sleep study (described below). We will show you the equipment, and perform the appropriate hookup for the night study. The purpose of the night study is to determine whether or not you have sleep disordered breathing. If you had a sleep study in the past this may not be required.

Sleep Study Visit (if required):

We will schedule a time that is convenient for you to have a sleep study, either in the lab or at home. Monitoring devices will be used during the study, which include bands placed around the chest and abdomen to measure motion, wires taped to the skin to measure brain waves, eye movements, and body movement, and an instrument placed on your ear, finger, or forehead to measure oxygen levels in your blood. Another instrument will be placed on your finger to measure your heart rate and blood pressure through the night. The sleep study will take approximately 7-10 hours and you will be receive $75 for your time.

After you finish your sleep study, we will review the data from the sleep study and you will be informed of the results. If we find that you have mild to moderate sleep apnea, you don't get enough sleep at night, and you have symptoms of daytime sleepiness, you will be asked to continue in the study. If you are eligible to continue with the study you will receive one of two sleep education and treatment programs. Each program provides education on sleep, but the content and format of each program will vary. Which education program you will receive will

be determined randomly (like flipping a coin). In one of the treatment arms, you will also receive some equipment called "PAP" (positive airway pressure) that is used to treat sleep apnea. You may be asked to change your sleep habits and routines by spending more time in bed.You will not know in advance which group you will be assigned to.

Visits 4-7 (Sleep Education and Treatment Program): After you have been randomly assigned to one of the two sleep education and treatment programs, you will come to the office once a week for the next four weeks to meet with one of the study team members. The purpose of these visits is to provide you with information about sleep apnea and sleep habits. You may be asked to wear the sleep watch between these visits as well. Each visit will take approximately one hour. You will not be paid for these visits.

One or more of the education sessions you attend might be audio-recorded. This recording will only be heard by Dr. Badr and his research team members for the purpose of monitoring the quality of the education sessions and for training future staff. The recordings will not be transcribed and will not be shared with anyone outside project staff. Your full name will not be recorded on the session recordings to protect your identity. You do not have to agree to be recorded during the education sessions. Your refusal will not impact or affect your participation in other aspects of the research.

PAP Equipment (if applicable) : If you are given a PAP machine as part of this study, the study team will monitor whether or not you are using your PAP machine using a remote tele-monitoring system. The PAP machine you will be given will be compatible with the monitoring program. Nightly usage data will be available to the study team. The study team will make sure that the PAP machine has been set up and is transmitting data. We may ask you to bring the SD card when you come in for one or more of your visits. PAP treatment uses a mask that will cover the nose/mouth and will be attached by a flexible tube to a small machine the size of a shoebox that will sit on the table or floor next to the bed. It blows air into the throat at different pressures to help keep someone with sleep apnea breathing regularly at night. This device is approved by the FDA (the Food and Drug Administration, a government department that oversees drugs and medical devices). This means that if you have sleep apnea, your doctor could give you a prescription for this device whether or not you participate in this study. The device and education program that are part of this study will be provided at no cost to you.

Visit 8-10 (One-Month Follow-Up): After the four-week education and treatment sessions, you will be asked to return to our office for a follow-up visit, which will involve up to 3 visits scheduled at your convenience. You will complete questionnaires about your health, sleep, mood, and quality of life similar to the ones you completed at the baseline visit. We will also play a short game that tests how alert you are and we will measure your blood pressure while you are here in our office. You will also be asked to wear the blood pressure machine for 24 hours and the activity watch for one week, as well as, keep a log of your activity and sleep while wearing the devices. We will schedule a time for you to return these devices to us. In addition, using a device called an EndoPAT we will measure changes in blood volume. You will be asked to have a sensor placed on your finger as well as a blood pressure cuff around your arm that will inflate for about 5 minutes. To perform this you will be asked to

fast for eight hours, refrain from caffeine, alcohol and tobacco, and avoid exercise for eight hours prior to testing. This procedure will take about 30 minutes. This visit will take about two hours and you will receive $60 per completed visit.

Visit 11-13 (Three Month Follow-Up/End of Study): About two months after the one-month follow up visit you will be asked to return to our office for the three-month follow-up, which will involve up to 3 visits, scheduled at your convenience. You will complete questionnaires about your health, sleep, mood, and quality of life similar to the ones you completed at the enrollment and one-month visits. We will also play a short game that tests how alert you are and we will measure your blood pressure while you are here in our office. You will also be asked to wear the blood pressure machine for 24 hours and the activity watch for one week, as well as, keep a log of your activity and sleep while wearing the devices. We will schedule a time for you to return the devices to us. In addition, using a device called an EndoPAT we will measure changes in blood volume. You will be asked to have a sensor placed on your finger as well as a blood pressure cuff around your arm that will inflate for about 5 minutes. To perform this you will be asked to fast for eight hours, refrain from caffeine, alcohol and tobacco, and avoid exercise for eight hours prior to testing. This procedure will take about 30 minutes. This visit will take about two hours and you will receive $60 per completed visit.

Transition to the Sleep Clinic: After the three-month follow-up visit, you will be scheduled for a face-to-face visit in the sleep clinic. During that visit, you will discuss all available and appropriate treatment options for your sleep apnea with a healthcare provider. Your sleep medicine provider will be notified when your participation in the study has ended, and they will provide any needed follow-up care.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
By taking part in this study, you may experience the following risks:

COVID-19:
There is a possibility that study participation may increase the risk of exposure to COVID-19. In order to help prevent this, careful precautions will be taken to ensure the work environment is clean, PPE is worn at all times, and social distancing is maintained.

Polysomnography (Sleep Study): In rare cases the tape or paste used to affix the EEG/EMG electrodes to the head and chin for the purposes of the sleep study may cause redness or irritation. This normally goes away within several hours of removal of contact with the electrodes.

Untreated Sleep Apnea: Possible effects from untreated sleep apnea include daytime sleepiness. The major concern related to daytime sleepiness is risk of motor vehicle accidents. The risk is rather minimal in patients with mild to moderate sleep apnea and the length of time in the study where participants may have untreated sleep apnea

is within the range that is experienced in clinical care. Given the short time frame of this study, long-term sleep apnea should not be impacted negatively by participation in this study.

Untreated Insufficient Sleep: Short-term consequences include daytime sleepiness. The major concern related to daytime sleepiness is risk of motor vehicle accidents. Given the short time you will be in the study, severe consequences are unlikely.

PAP Treatment: You may experience discomfort with the PAP mask. Occasionally, the mask may leave a rash or redness on the face. Participants may experience some dry mouth when using the PAP machine or feel air blowing from around the mask towards their eyes if the mask is not properly fitted or moves during sleep. The research team will work with you to resolve these problems. Participants may report poor sleep or difficulty falling asleep while using the mask and PAP machine during the first week of therapy. This usually improves with education and encouragement and requires that the subject get used to sleeping with mask and PAP.

Actigraphy: You may experience skin irritation under the device or may find the device slightly uncomfortable to wear. You will be asked to keep the skin under the device clean and dry in order to prevent irritation.

24-Hour Blood Pressure Monitoring: Wearing the blood pressure monitor for 24 hours may be inconvenient, uncomfortable, and may disturb sleep on the night it is worn. We have made the recording time as short as possible to minimize the inconvenience. Likewise, the EndoPAT may also cause some discomfort while the blood pressure cuff inflates.

Questionnaires: Answering some of the questions about your sleep habits, mood, health, or quality of life may make you feel sad or uncomfortable. You are free to not answer any question that makes you feel uncomfortable. You may find responding to the questionnaires emotionally tiring.

Privacy: It is possible that there may be a breach of privacy regarding your study participation. In order to help prevent this, you will be assigned a study code that will be used instead of your name on all study documents. Your personal information will kept in a different place than data collected for the study. All paper documents are kept in a locked cabinet inside a locked office and all electronic data is kept on password protected computers. Only approved study staff have access to the study documents. If you participate in telehealth visit, there may be possible for others to see you. Reasonable and appropriate efforts will be made to eliminate any issues with the telehealth visits.

Photographs, audiotaping, or videotaping: As part of standard care, a polysomnogram in a sleep laboratory includes audio and video recordings. Any recordings obtained during the course of your sleep study will remain confidential and will only be accessed by the study physician and designated personnel. The photographs and recordings will hide your identity as much as possible, including a black box over the eyes. However, there is a risk a photograph may not protect participant's identity. The study team has also explained that you will not

receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used. The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize video recordings and/or audio recording(s) to be made of you by the research team in the VA Sleep Research Lab or via telehealth while you are participating in this study. Upon termination of this study, all data will be maintained and disposed according to RCS-10-1 or current VA policy.

Pregnancy: There may be unknown risks to women who are or may become pregnant, to unborn babies, and to nursing infants. Therefore, to take part in this study, a medically acceptable form of birth control is required for female participants. Medically acceptable birth control may include the following methods: barrier protection such as condoms, intrauterine devices (IUD), abstinence (not having sex), etc. Oral contraceptives may be used but should not be the only means of protection. No birth control method completely eliminates the risk of pregnancy. You should inform the study doctor (PI) immediately if you intend to get pregnant or if you should become pregnant while participating in this research study, so that your choices and options can be explored and discussed. If you are a woman, a urine pregnancy test will be performed at the enrollment visit to make sure that you are not pregnant.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The possible benefits to you for taking part in this research study are the diagnosis and treatment of sleep apnea, and information about healthy sleep habits for adults, which could lead to improvement in sleep quality and a decrease in daytime sleepiness. Additionally, information from this study may benefit other people with similar health issues now or in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

The alternative to participating in this study is not participating in this study. You are still free to see your healthcare provider for any sleep issues that you have.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

All records identifying you as a subject of this study will be kept confidential to the extent permitted by law. Photographs, videos, or audiotape recording of participants will be used for research or educational purposes and participants' identity will be protected or disguised. The record will be filed in a locked area of the Sleep Research Laboratory and will be accessible only to the Principal Investigator and his associates on this project. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. Federal agencies including, but not limited to, the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Research Oversight (ORO),

and the Veterans affairs (VA) Office of the Inspector General (OIG) may have access to the records. If the results are published, you will not be identified in any way. You may take as much time as you wish to think this over before you sign this form. Please ask any questions you may have before, during, or after this study. Research records will be kept in accordance with the VA record retention policy. Until that time your research records will be kept in a secure location. The results of this study may be published, but your records will not be revealed unless required by law. 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.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA will be responsible to study eligible veterans who qualify for the study pursuant to federal law for diagnostic procedures and medical treatment necessary to treat physical injury that such study subject would not have received if he or she had not participated in the study.

Wayne State University will be responsible for VA care of non-veterans as well as veterans who are not eligible to get the VA care for diagnostic procedures and medical treatment necessary to treat physical injury that such study subject would not have received if he or she had not participated in the study. If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: Available 24 hours: Dr. M.Safwan Badr at 313-745-8244 and
AFTER HOURS: Available 24 hours: Dr. M.Safwan Badr at 248-763-9795.
Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

The participation in this study is voluntary and refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled, if you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. You may discontinue taking part at any time without any penalty or loss of benefits. If you decide to withdraw from the study, you will still receive the same standard of care that would otherwise have received.

The investigator has the right to review the data collected for the study prior to your withdrawal. However, the investigator will not collect further information about you except from public records. Also, specimens already used cannot be withdrawn.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

If the Principal Investigator finds any reason why you would not be fit for the study, your participation would be terminated.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, concerns or complaints about this study now or in the future, you may contact Dr. Badr or one of his research team members at the following phone number (313) 576-3545 or 313-520-2766. If you have questions about your rights as a study participant or you want to make sure this is a valid study, you may contact the Wayne State University, Investigational Review Board at (313) 577-1628. This is the Board that is responsible for overseeing the safety of human participants in this study. If you are unable to contact the research staff, or if you want to talk to someone other than the research team, you may call the VA Research Compliance Officer at (313) 576-4467 to ask questions or voice concerns or complaints or you may call the VA Patient Advocate at (313) 576-1000, ext. 65158.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be informed if there are any new findings during the course of the research that may affect your willingness to continue participation. If we find that you have sleep apnea we will inform you of your results so that you are able to go to your primary care physician.

FUTURE USE OF DATA AND RE-CONTACT

Participants will be asked to sign a consent form giving the sleep lab permission to re-contact them and store their de-identified study data. Participants' names, phone numbers, addresses, age, gender, ethnicity, and email address will be stored securely on an electronic list. Participation in this is completely voluntary. In addition to being added to the VA network folder, we will also add it on a VA database called REDcap. The computer will be stored in a locked lab only accessible to key personnel and staff approved by the VA. The files will only be accessible by study staff approved by the IRB on the protocol. If you wish to be re-contacted in the future about participating in future research we will ask you this in the consent stated. If you change your mind at any time you can withdraw from being contacted in the future contact or having your de-identified study data stored you can withdraw at any time

Participant Name (Last, First, MI, suffix): _____Date:_____

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

Witness to the Consenting Process		
_____ Name of Witness	_____ Signature of Witness	_____ Date

Participant Name (Last, First, MI, suffix): _____ Date: _____

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Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. Information that might be collected includes: your name, which will be used as a form of identity, address which will be used as a form of identity, date of birth which will be used as a form of identity, phone number which will used as a form of contact, fax number and e-mail address, which will be used as a form of contact, lab results and mental health status may be collected as part of research, social security number which will be used as a form of identity, bank information which will be submitted to the fiscal department as required by VA if necessary for payment purposes. Voice and full face images will be collected while doing the polysomnography, to confirm position along with identifying respiratory events, and information from your medical records will be collected to help us locate participants' medical history. Information learned from your IRB approved questionnaires and forms will be shared on the platform known as OnCore CTMS.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others includes, Non-VA Institutional Review Board at Wayne State University who monitor the study, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), The Michigan Department of Health and Human Services (MDHHS) and other relevant public health agencies.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

Address to send Revocation of HIPAA Authorization:

John D. Dingell VA Medical Center
Attn: Release of Information Office
4646 John R Street
Detroit, MI 48201

Participant Name (Last, First, MI, suffix): _____ Date: _____

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If you revoke this authorization, **(M. Safwan Badr, M.D., M.B.A)** and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Signing this authorization will not affect your treatment, payment or enrollment/eligibility for benefits. This authorization will expire at the end of this research study unless revoked prior to that time.

AUTHORIZATION FOR USE AND DISCLOSURE OF INFORMATION PROTECTED BY HIPAA PRIVACY RULES

By signing this document below, you voluntarily authorize the use and disclosure of your health information for this study.

I authorize the use and disclosure of my individually identifiable health information as described above.		
_____ Participant's Name	_____ Participant's Signature	_____ Date