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Approval Date: November 30, 2016
Expiration Date: November 30, 2017

Department of Veterans Affairs

RESEARCH CONSENT FORM

Title of Study: Breathing Meditation Intervention for Posttraumatic Stress Disorder	
Principal Investigator: **Dr Peter J. Bayley**	VAMC: VA Palo Alto HCS

Breathing Meditation Intervention for Posttraumatic Stress Disorder

Informed Consent

Are you participating in other research studies? ___Yes ___No

PURPOSE OF RESEARCH

You are invited to participate in a research study to compare the efficacy of a breathing meditation to Cognitive Processing Therapy in treating symptoms of Posttraumatic Stress Disorder (PTSD). You were selected as a possible participant in this study because: 1) you are a Veteran; and 2) you have symptoms of PTSD.

This study is being done by researchers at VA Palo Alto, and is sponsored by the Department of Veterans Affairs (VA).

This research study is looking for 76 Veterans who exhibit symptoms of PTSD.

The primary aim for this study is to compare two different ways of treating PTSD in Veterans. One way involves treatment with a breathing-based meditation in a group setting. The other involves a therapy commonly used by the VA to treat PTSD called Cognitive Processing Therapy. Apart from changes in your symptoms of PTSD, we will also be assessing whether there are related changes to your memory, attention, mood, sleep, medication and heart rate.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but you may withdraw your consent later and stop being in the study without any loss of benefits or medical care you are entitled to.

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DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 4 years. Participants will be assigned to either a meditation treatment group or a one-on-one Cognitive Processing Therapy treatment. Participants in the meditation group will undergo a treatment program consisting of a 5-day group class (3 hours/day) followed by five weeks of sessions twice per week (1hr/session). Participants given Cognitive Processing Therapy treatment will be given 12 one-hour sessions twice per week over the course of 6 weeks. At the end of treatment all participants will be tested again. Follow up tests will be given at one-month and 12-months post-treatment.

PROCEDURES

Patients who sign this informed consent and meet the study eligibility criteria will be enrolled into the study and will be randomized to one of two treatment groups: a meditation treatment group or a one-on-one Cognitive Processing Therapy treatment.

If you choose to participate, Dr. Bayley and his research staff will ask you to participate in the activities described below. All study procedures will be completed by trained professionals and research staff. This study has 4 phases: baseline and randomization (1 day), intervention (6 weeks), end of treatment (1 day), 4) follow-up at one month (one hour) and one year (one hour).

1. BASELINE AND RANDOMIZATION PHASE

If you agree to be in this study, you will complete a number of tests to make sure that you are eligible. You will read and sign this informed consent form before you begin the baseline phase. The baseline phase will take place over two half-days (an afternoon and a morning) and will involve overnight measurements of memory, heart rate and sleep. To conveniently undergo the afternoon and morning assessments you will be accommodated overnight in a local hotel.

During the baseline phase and before you are given any treatments, the following will happen:

- We will ask for some general information, and give you questionnaires about your mental health, mood, and sleep.
- You will be given computerized tests of cognition to measure your memory and attention.
- Study staff will review with you any drugs (prescriptions, "natural food products" and "over the counter" supplements) that you are taking. During the study, you will be able to take medications. You will also be given a questionnaire about any non-medical use of drugs over the past year.
- You will complete self-report questionnaires about the symptoms of PTSD which will be reviewed by study staff in an interview.
- On the overnight visit, you be asked to wear a heart rate monitoring device and an actigraph motion logger on your wrist. The heart rate monitor and motion logger will be fitted in the evening and you will be asked to keep wearing them for the next 12 hours. You will also be assessed to see how well you remember some information overnight using computer-based tests. For these you will be trained in the afternoon and retested the next morning.

If you agree and are eligible to participate in this research study, you will be randomized to either the breathing meditation treatment or to the Cognitive Processing Therapy treatment. Randomization is a process that is similar to flipping a coin where one side of the coin is breathing meditation and the other side is the Cognitive Processing Therapy. There is a 50:50 chance of being randomized to either treatment. Both groups will receive all the same measurements and tests.

2. INTERVENTION PHASE

BREATHING MEDITATION GROUP

This treatment will be given in a group setting at VA Palo Alto and will last 6 weeks. The class meets 3 hours per day for the first five days, followed by five weeks of sessions given twice per week (one hour per session). There will be a maximum class size of ten..The meditation will include several types of breathing exercises involving arousal and attentional control. Initial breathing exercises are designed to be calming and focusing. Subsequent breathing exercises are more fully energizing, allowing you to focus more fully. All are soothing and present-focused. You will be encouraged to learn all the breathing exercises, and to utilize the ones that seem most appropriate to your needs. During the six weeks of treatment, you will be encouraged to engage in optional home practice. This will consist of seeking venues that you have been avoiding in order to practice the meditation techniques in those environments. You will be encouraged to start with situations that are less arousing, and progress to more difficult situations. At each class you will have the opportunity to share your experiences, and discuss ways to continue to incorporate the exercises into your daily lives. You will also be asked to keep a daily log to record whether you practiced the intervention, your estimated hours of sleep, and any changes to medications.

COGNITIVE PROCESSING THERAPY

This treatment will be given individually as a series of office visits at VA Palo Alto and will last for six weeks. Each session will last around forty-five minutes and there will be two sessions per week. Sessions will include reviewing homework from the previous session, focusing on specific issues, learning new therapeutic techniques and setting up homework for the following session including real-life application of learned techniques.

In the first few sessions you will be told more about the theory behind the treatment. You will be taught the connection between events, thoughts, and

feelings and begin to identify places where you can focus on thinking about past emotionally traumatic events. Later, skills will be taught, including looking at the evidence for and against some of your beliefs, and examining the context from which the belief was formed. You will be asked to focus on five key areas, including safety, trust, power/control, esteem, and intimacy. Finally, you will be asked to look to the future and identify areas that may be problematic and discuss ways that you can manage these issues. You will also be asked to keep a daily log to record whether you practiced the intervention, your estimated hours of sleep, and any changes to medications.

3. END OF TREATMENT PHASE

When you finish treatment, you will be given most of the same tests and questionnaires as you received during the baseline phase:

- We will give you questionnaires about your mental health, mood, and sleep.
- You will be given computerized tests of cognition to measure your memory and attention.
- Study staff will review with you any drugs (prescriptions, “natural food products” and “over the counter” supplements) that you are taking. You will also be given a questionnaire about any non-medical use of drugs over the past year.
- You will complete self-report questionnaires about the symptoms of PTSD which will be reviewed by study staff in an interview.
- On the overnight visit, you will be asked to wear a heart rate monitoring device and an actigraph motion logger on your wrist. The heart rate monitor and motion logger will be fitted in the evening and you will be asked to keep wearing them for the next 12 hours. You will also be assessed to see how well you remember some information using

computer-based tests. For these you will be trained in the afternoon and retested the next morning.

4. FOLLOW-UP PHASE

Two follow-ups visits are scheduled following treatment at 1) one month, and 2) one year. The amount of time required to complete each follow-up should be around 1 hour. During the follow-up, study staff will ask you to complete three self-assessments about your mood and current PTSD symptoms.

5. FOR ALL STUDY PHASES

- It is important for study staff to be aware of any changes in your medications during your participation in the study.
- You will interact with members of the entire study team. The study takes place at the VA Palo Alto Health Care System (VAPAHCS). If asked, we will provide a note for your employer that you were receiving medical treatment. We will not compensate for missed work time.
- You will be asked about adverse events whenever you are seen by study staff for treatment, evaluation, and follow-up visits. An adverse event is anything bad that happens with you and may or may not be related to your participation in this study. An independent committee will be told about all adverse events at least once every six months. If they believe that any aspect of this study is unsafe, they will recommend that changes be made to eliminate the safety problem.

6. OPTIONAL STUDY PHASES

If you agree to take part in the study described above, you will be offered the option to participate in the additional (optional) study phases described below. These will occur during Baseline, End of Treatment, and Follow-Up.

☐ Magnetic Resonance Imaging (MRI) scans of the head:

The MRI phase will be done at the Stanford Center for Cognitive and Neurobiological Imaging (CNI) and will take 1 hour.

The MRI scan uses a strong magnet and radiofrequency magnetic fields to create pictures of the structure and function of the brain. The scanning procedure is like an X-ray or CT scan but you will not be exposed to x-rays. You will not feel anything. The hardest part of the scan is the need to lie still for the duration. You will lie on a table and be slid into a tunnel. Your head and shoulders lie in a plastic rounded tray which makes it more comfortable and easier to lie still. You will hear repetitive tapping noises from the scanner as it collects data to make the pictures of the brain. You will be required to wear earplugs. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the “claustrophobic” feeling.

The MRI in this study is not harmful. The scanner and associated equipment are approved by the FDA. However, the scanner uses a strong magnet that will attract metals and affect some electronic devices. If you have a cardiac pacemaker, any other biomedical device (surgical clips, devices, or implants) in or on your body, a history of head or eye injury involving metal fragments, have ever worked in a metal shop, if you could be pregnant, or have kidney trouble, you must you tell the MRI operator/investigator before entering the MRI room, as it may be decided that should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be given a secure place to store such objects prior to the MRI scan. There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is expected and should not be painful. There is a small risk the scanner will heat up, so tell the operator if

you start to feel heat. Dizziness or nausea may occur if you move your head rapidly within the scanner.

If you feel discomfort at any time, notify the operator and the exam will be stopped.

The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. Our research scans do not qualify as a clinical diagnostic scan. The investigators for this project may not be trained to perform medical diagnosis. The investigators are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. If this occurs, we will follow CNI's protocol for incidental findings. In this case, the research scans are referred to an approximately qualified individual (neuroradiologist) designated by the CNI Board for further review. The reviewer will determine if the potential abnormality merits further investigation and will inform the Principal Investigator of the action to be taken. The CNI operations team promptly provides a DVD with the scans in question or in another way that makes the images available to the reviewer to be read "as is". If follow-up is recommended, the investigator will contact you with the appropriate information. Because the images are taken using research settings, they will not be made available for clinical purposes. Finding out that you may have a medical abnormality that you had not been aware of before could cause psychological stress to you or your family and possibly affect your health insurance coverage in the future.

The safety protocol for the Stanford CNI does not require a pregnancy test because MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA, such as with x-rays used in CT scans). There are currently no known harmful side-effects associated with temporary exposure to the strong magnetic field used by MRI scanners. However, because MRI may

involve risks to the subject (or the embryo, fetus, or nursing infant if the subject is or may become pregnant), which are currently unknown and unforeseeable, if you are pregnant, or suspect you might be, or there is a chance you are, or you are currently breast feeding, you may not participate in this part of the study.

☐ Electroencephalography (EEG) and psychophysiological assessment:

The EEG phase will be done at the Palo Alto VA and will take 1.5 hours, including time spent setting-up the cap and removing it/washing hair.

EEG is a test that measures and records the electrical activity of the brain. To collect this information we will ask you to wear a cap on your head similar to a swimming cap. The cap has special sensors attached to it and is hooked by wires to a computer. Sensors will also be attached to your face and hands with a sticky paste to record facial movements, eye-blinks, heart rate, and skin conductance. The sensors only record activity, they do not produce any sensation. The hardest part of the EEG assessment is the need to minimize any movement including jaw movements, coughing, sneezing, yawning.

A computer will be set up to provide visual stimulation while you are in a shielded EEG room. Simple sounds or pictures will be projected onto a computer and headphones. You will be asked simple questions relating to these sounds or pictures. Your responses to these questions will be recorded using EEG specific equipment such as a computer-amplifier interface system. You will be given a hand-held control box or joystick to manually respond to the questions. Some pictures or words may provoke emotional responses such as fear, disgust, or sadness.

If you choose to undergo the optional phases, you will be asked to complete each of these assessments three times: before treatment, after treatment, and at 1-year follow-up.

The EEG performed in this study is for specific research purposes and is not optimized to find medical abnormalities. Our research tests do not qualify as clinical diagnostic tests. The investigators for this project may not be trained to perform medical diagnosis. The investigators are not responsible for failure to find existing abnormalities with these EEG data. However, on occasion the investigator may notice a finding on an EEG wave that seems abnormal. If this occurs, a doctor will be asked to look at the raw EEG to see if any medical follow-up is needed. If so, the investigator will contact you and recommend you inform your doctor about the findings. Because the wave signals are collected using research settings, they will not be made available for clinical purposes.

PARTICIPANT'S RESPONSIBILITIES

You should:

- Follow the instructions of the investigators and study staff.
- Complete your questionnaires as instructed. You are free to skip any questions that you prefer not to answer.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research study without approval from the investigators. Taking part in other research studies without approval from the investigators may invalidate the results of this research, as well as that of the other studies.

- Keep your study appointments. If it is necessary to miss an appointment, please contact the investigator or study staff to reschedule as soon as you know you will miss the appointment.
- It is important that you not give false, incomplete, or misleading information about your medical history, including past and present drug use.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled and your decision will not affect your ability to receive medical care for your condition.

The investigators may also withdraw you from the study without your consent for one or more of the following reasons:

o Failure to follow the instructions of the investigators and/or study staff.

o The investigators decide that continuing your participation could be harmful to you.

o Pregnancy

o The study is cancelled.

o Other administrative reasons.

o Unanticipated circumstances.

If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Dr. Bayley at (650) 493-5000 x68653, or the Study Coordinator at (650) 785-6661

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POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Study Director if you have any questions. This study involves the following risks, discomforts, and possible inconveniences:

There are few risks involved in the treatments. However, because the treatments deal with painful feelings, emotions and experiences you may feel emotionally uncomfortable at times. You may even experience a temporary increase in your symptoms of PTSD during treatment which usually resolves as treatment progresses. Risks of the behavioral testing and measurements include possible anxiety that can be associated with any test. It is possible that you might also become tired or frustrated by some of our testing. You may find answering the questionnaires annoying, boring, or repetitive. If this happens, please tell us and we will take a break or skip a particularly difficult test.

For the heart rate monitor and the actigraph motion logger there is the possibility of developing a skin rash where they touch the skin. If this were to occur, the devices can be moved to a different location and lotion can be applied to the rash. We may request to remove obstructive chest hair with an electric razor in order to ensure a proper heart-rate reading.There are no other known risks associated with wearing the devices, other than the inconvenience of wearing them

All breathing meditation classes will be given in a group setting. As a consequence you should keep in mind that anonymity is not possible. However, all tests and assessments will be given individually and your results will not be shared with the group.

Risks of the usual care you receive are not risks of the research. They are not included in this consent form. You should talk with your health care providers about risks of usual care.

Optional phases:

MRI Risks. There are no known significant risks with this procedure at this time because the radiofrequency magnetic field(s) and magnetic fields, at the strengths used, are thought to be without harm. However, metallic objects may experience a strong attraction to the magnet, so it is very important that you notify the researcher of any metal objects, devices, or implants that are in or on your body before entering the magnet room. This includes biomedical devices such as pacemakers and aneurysm clips, prostheses, and any other metallic objects embedded in the body such as bullets, buckshot, shrapnel, and any metal fragments from working around metal.

If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, if you have some type of implanted electrical device (such as a cardiac pacemaker), if you have severe heart disease (including susceptibility to arrhythmias), if you are wearing metal braces on your teeth, or (for women) if you could be pregnant or are breast feeding, you should not have an MRI scan.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. Please report any heating sensation immediately. Dizziness and nausea may occur if the head is moved rapidly within the bore of the magnet.

If you feel discomfort at any time, notify the operator and the exam will be stopped.

EEG Risks. EEG experiments are non-invasive and painless. However, some people do experience mild and temporary skin irritation from: i) skin preparation where skin debris (dead skin cells) is removed from the area directly on the outer area of the eyes with a pad, or ii) slight itchiness from conductive paste that is used during application of the cap and sensors.

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If you feel discomfort at any time, notify the operator and the exam will be stopped.

VIDEO RECORDING

Video recording will be used to monitor treatment delivery. Recordings will be made of treatment providers, and not the participants. All recordings will be stored indefinitely in accordance with VA guidelines.

POTENTIAL BENEFITS

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may include being able to deal better with thoughts and memories associated with PTSD. The information that is obtained during this study may be scientifically useful and may lead to greater knowledge about the treatment of PTSD.

The testing done in this study could reveal a condition that you might not have previously been aware of and for which you may need treatment. Study staff will refer you for additional treatment if such problems are identified but the study will not pay for the treatment of any such identified problems.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY DIRECT BENEFITS FROM THIS STUDY.

ALTERNATIVES

You may choose not to participate in this study. If this is your decision, there are other choices including the standard treatments provided by a local clinic. Your study investigator will discuss any alternatives with you before you agree to participate in this study. Alternative treatments include medication and behavioral therapy.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not

include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PARTICIPANT'S RIGHTS

Your participation is voluntary. You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. You have the right to refuse to answer particular questions.

If you decide not to participate, tell the Protocol Director. You will still receive care for any disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of the VA, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel. The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement of the consent, we do not intend to disclose this information.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Federal agencies as required, including the Department of Defense, the VA Office of Research Oversight or the VA Office of the Inspector General may have access to your information and research records.

FINANCIAL CONSIDERATIONS

Payments

You will receive a payment of $400.00 for successful completion of the study.

- $200 will be paid after the completion of the Treatment Phase.
- $200 will be paid after the completion of the Follow-Up Phase.
- $50 will be paid for each session (Baseline, End of Treatment) of the optional study phase (MRI, EEG), after completion of the Treatment Phase.
- $50 will be paid for each session of the optional study phase (MRI, EEG), after completion of the Follow-Up Phase.
- If you withdraw from the study early, your payment will be prorated for the proportion of the study completed.

These payments will be mailed in the form of a personal check. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work-eligible visa. You may need to provide your social security number to receive payment.

Costs

You will not have to pay anything to be in this study.

Sponsor

The Department of Veterans Affairs is providing financial support and/or material for this study.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study you should ask the Principal Investigator, Peter Bayley, Ph.D. You can call him at 650-493-5000 ext. 68653. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

Appointment Contact: If you need to change your appointment, please contact the Study Coordinator at (650) 785-6661.

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Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak with a person who is independent of the research, call the Stanford Institutional Review Board (IRB) at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

May we contact you (by phone or letter) about related studies that may be of interest to you?

_____ Yes. I would like to be contacted for future research opportunities.

_____ No. Do not contact me about future research opportunities.

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____

Signature of Participant Date

_____

Print Name of Participant

Person Obtaining Consent:

_____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent

This page separates the

Informed Consent Document *(above)*

from the

HIPAA Authorization document

(below)

To preserve formatting, please

DO NOT DELETE this page

Authorization To Use and Share Your Health Information For Research Purposes

HIPAA (Health Insurance Portability & Accountability Act) is a federal privacy law that protects the confidentiality of health information collected about you. The following explains how health information collected about you will be used by the investigators and who they may share your health information with as part of this research.

What is the purpose of the research study, and how will my health information be utilized in the study?

The study is to compare the effectiveness of treating posttraumatic stress disorder (PTSD) using two different methods; breathing meditation or a standard Cognitive Processing Therapy. Health information will be used in the study to monitor your progress and to evaluate the effectiveness of the treatment.

What Personal Health Information Will Be Used or Shared?

The following health information, linked to you by your name, SSN, Date of Birth, Address, email address, telephone number, will be used for this research:

- Date of visit
- Demographic information
- Physiological and Cognitive test data
- Medical history information
- Survey/questionnaire responses

Who May Use or Share Your Health Information?

By signing this document, you allow the following individuals and entities to obtain, use and share your health information for this research study:

- The Principal Investigator (Dr Bayley) and members of the VA research team.
- Departments within the VA Health Care System responsible for the oversight, administration, or conduct of research.

- The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of research.

Who May Receive and Use Your Health Information

The investigators may share your health information with the following individuals as part of this research study.

- Stanford University collaborating investigators and research staff.
- The Office for Human Research Protections in the U.S. Department of Health and Human Services

We will protect your health information as required by all laws, however health information shared with others may no longer be protected by Federal laws or regulations and might be shared by the parties above.

Do I have to sign this form?

No. Signing this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on signing this form. If you decide not to sign the form, you will not be able to take part in this study or receive any research-related treatment.

If I sign now, can I decide later not to continue in the study?

Yes. You are free to take back your permission and stop being in the study. The investigators will not collect any more information about you after you take back your permission, but they can continue to use your information that was collected before you took back your permission.

Your request to take back your permission must be done in writing. Either give your written request to the investigator or send it by mail to: Dr Peter Bayley, War Related Illness and Injury Study Center (WRIISC), 3801 Miranda Avenue, MC 151Y, Palo Alto, CA 94304-1290

Does My Permission for the use my Personal Health Information expire?

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your health information expires when this research study is completed.

HIPAA regulations require you to give separate written permission (signature) for the use of your protected health information.

Signature of Participant Date

Printed Name of Participant