Department of Veterans Affairs

Research Consent Form and Authorization for Use and Release of Individually Identifiable Health Information Collected for Research

Date: (Page **1** of **12**)

Subject Name: **SSN (last 4 only):**

Title of Study: MERIT: Mindfulness-Based Stress Reduction to Improve Neuropsychological Functioning in Acquired Brain Injury

Principal Investigator: Juliana Baldo, Ph.D. **VAMC:** VANCHCS

California Experimental Subject's Bill of Rights

The rights below are the rights of every person who is asked to be in a medical research study. As an experimental subject, you have the following rights:

1. To be told what the study is trying to determine.
2. To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes.
4. To be told if you can expect any benefit from participating and, if so, what the benefit might be.
5. To be told the other choices you have and how they may be better or worse than being in the study.
6. To be allowed to ask any questions concerning the study, both before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise.
8. To refuse to participate or to change your mind about participating after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether you wish to agree to be in the study.

If you have other questions, please ask the researcher or research assistant. You may also ask the VA Northern California Health Care System (VANCHCS) Human Research Protection Program (HRPP). The HRPP protects volunteers in research projects. You may call the HRPP at (916) 366-5359 from 8:00 a.m. to 4:30 p.m. Monday through Friday. You may also write to the HRPP. The address is: VANCHCS HRPP (151), 10535 Hospital Way, Mather, CA 95655. You may also call VA Chief Counsel at (415)750-2288.

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Principal Investigator: Juliana Baldo, Ph.D. **VAMC:** VANCHCS

Purpose of the Study

This is a research study. Research studies only include subjects who choose to take part. You do not have to be in this research study. You should read the information that follows. Please ask questions about anything you do not understand before deciding if you want to be in this research study. Please take your time to make your decision.

You qualify to take part in this project because you are between the ages of 20-80 and have had a stroke. We hope to learn more about different educational programs that may be beneficial to individuals who are recovering from a stroke.

The purpose of this study is to conduct a randomized study to test the degree to which two different health and wellness classes can improve cognitive and psychological functioning after stroke. We are particularly interested in whether such classes can reduce stress and anxiety and improve cognitive functioning such as attention and working memory. Two different brain health and wellness programs will be investigated. The classes provide information and strategies for improving cognitive function and brain health. Currently, we do not know which of these two treatments is better.

There will be about 120 subjects taking part in this study at VANCHCS.

Study Length (How long will I be in the study and how long will the study last?)

An initial session is required within 2 weeks prior to the start of the class. The class meets once a week for 8 weeks. Then there will be 2 research appointments after the class has been completed, the last one taking place six months after completion of the class. Thus, your involvement in the study will be spread out over a 9-month period. All of these sessions will either take place in person on our VA campus or online from your home, depending on a number of factors.

Researchers will conduct this study for 5 years.

1. Researcher's Financial Disclosure

The study investigator and staff are conducting this study entirely for research. They have no personal and no financial interest in this study.

2. Study Procedures

This is a Randomized trial: You will be randomly assigned to one health and wellness class or the other. You will not be told how the two classes differ. Randomization means that researchers put you in a group by chance. It is like flipping a coin. In this case, the group you are assigned to is done by a computer program that attempts to match the two classes for age, gender and education level of the participants.

Researchers will ask you to do the following things:

The health and wellness class will meet once a week, for 2.5 hours, for 8 consecutive weeks Within the 8-week period, there will also be one all-day class (approximately 9am-4pm). It is requested that you try not to miss more than one or two classes. Prior to beginning the class, you will be asked to complete a "pre-class" research testing session. Within two weeks of completing the class, you will be asked to participate in a similar "post-class" research testing session. A final follow-up will be conducted 6 months after class completion. If there are not already MRI brain images on file for you at the VA, you may also be asked to participate in one brain imaging MRI session. All of these activities will
either take place in person on our VA campus or online from your home, depending on a number of factors.

Study Procedures - Standard procedures being done because you are in this study. You will be asked to come to do the following study related activities:

- Medical History & Information. Researchers will ask you about your medical history and medications. Your blood pressure and heart rate may be taken if testing is done in person.

- Neuropsychological testing and Surveys. You will be given neuropsychological tests and questionnaires that examine how well you can focus and pay attention or remember things. You will also be asked questions about your health, feelings of depression and/or anxiety/nervousness, and sleep. This testing will take approximately 60-90 minutes to complete.

- MRI Scan: If you do not already have brain imaging MRI scans available, you may be asked to participate in one research MRI brain imaging session, depending on a number of factors.

- This study does not use any experimental drugs.

MRI Procedure

- Magnetic Resonance Imaging (MRI) Scan:
  You may be asked to participate in one brain MRI session, depending on a number of factors. This is a medical imaging technique used in radiology to form pictures of the structures of the brain. For the MRI exam, you will be asked to change into hospital scrubs for your safety (to prevent metal jewelry or parts of clothing from entering the magnetic field). Next, you will lie down on a narrow bed that will move into a tunnel that is 6 feet long by 28 inches wide and open at each end. You will need to lie there quietly for about one hour, during which time there will be a loud banging noise. You may feel warm during this procedure.

  Researchers and a VA MRI technologist will be present for your MRI scan. An image of your brain will be taken using an MRI (magnetic resonance image) scanner.

  The MRI scan of your brain is for research and is not meant to evaluate your health. The pictures will not receive any routine clinical review. Instead, the pictures will be reviewed by the researchers involved in the study for the limited purpose of the study. Researchers may not notice all abnormal findings.

  However, if the researchers find a problem when they review your MRI scan, they will notify the researcher in charge of the study. This researcher will consult a physician (radiologist) about the problem. Researchers will cover your name when the physician checks your MRI pictures. The researcher in charge of this study will discuss these possible problems with you and will help you obtain a more complete review of your MRI scan by a specially trained physician. This physician can find out if any clinical health condition is present. If the physician thinks a health problem is present, we will give you a copy of the MRI picture. You can take the MRI picture to take to the physician of your choosing, at your expense. If you prefer, we can send the pictures electronically; there is a small risk that someone else could view electronically sent files.

3. Potential Risks and Discomforts

This research has no expected health risks. However, risks and side effects related to the study procedures may include:

Physical Risks:

The physical risks associated with neuropsychological testing are very small but could include fatigue. Every precaution will be taken to ensure your comfort during these tests, including adjustable seating and frequent breaks if testing is in person. You can also take breaks during the testing to help reduce fatigue.

- MRI risks:
  The MRI machine acts like a large magnet. It could move iron-containing objects in the MRI room. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocketknives or key chains, are not allowed in the MRI room. Researchers will not allow you into the MRI room and have an MRI if you have a piece of ferrous metal in your body. Examples would be a fragment in your eye, aneurysm clips, ear implants, or a pacemaker. If you have magnetic implants (e.g. pacemakers, brain surgical clips), you will not be able to participate in the MRI. A careful screening procedure will be conducted 3 times that includes a standard MRI screening form. For safety, participants will need to undress and change into hospital scrubs (in a private dressing room) prior to entering the MRI scanner room. This is to ensure that no metallic items (e.g., jewelry, pocket change, metallic buttons on clothing) will enter the MRI scanning environment.

  Having an MRI may mean some discomfort for you. At times during the test, researchers may ask you to hold still, which can be uncomfortable. The scanning procedure involves a loud banging noise. Temporary hearing loss has been reported from this loud noise. This is why researchers will ask you to wear earplugs. The study will be stopped at any time if you do not feel comfortable.

  The radio frequency waves used in MRI can produce local heating of biological tissues. However, FDA regulations on radio frequency deposition will be followed to avoid this problem. The magnetic field can sometimes also produce a sensation of disequilibrium, dizziness or nausea when you go in or out of the scanner. This sensation generally disappears after a few seconds. The study will be stopped if you feel these sensations for more than 5 minutes.

Because the risks to a fetus from MRI are unknown, pregnant women cannot participate in the MRI procedure.

- Randomization risks:
  Researchers will assign you to one of two health and brain wellness classes by chance. It is possible that the class you are assigned to may prove to be less effective or to have fewer benefits than the other class.

Psychological Risks:

- Participants may find the neuropsychological tests boring or frustrating, but there are no other foreseeable mental risks. Participants doing the testing in person will be accompanied by a member of the project team throughout the testing session. Each session has breaks programmed in, and additional breaks can be taken as necessary. Participants may terminate the study at any time.

- MRI Risks: Some participants can experience feelings of claustrophobia while lying in the MRI scanner. All participants are screened for claustrophobia prior to participation in the MRI scanning. Prism glasses will be provided so you can see out of the MRI scanner into the main room. Finally, a two-way intercom allows the participants and research team members to communicate during the scanning procedure. Participants may terminate the MRI at any time.

Privacy Risks:

- Legal Risks: There are no known legal risks associated with this study.
- Employment or Economic Risks: To avoid any economic hardship, we can schedule appointments during day or evening hours if you are doing the testing in person. For online testing, you can complete the testing during times that work best for you.

- Social Risks: There are no social risks associated with this study.

Unforeseeable Risk:
The researcher does not know all the side effects that may happen. You may experience a side effect or new risk that the researchers do not know about at this time.

4. Expected Benefits to Subjects

You may not benefit from taking part in this research. However, you may learn more about your cognitive abilities from participating in this research. It is possible that you may experience some psychological or cognitive benefit from taking part in the health and wellness class, but we cannot guarantee this.

5. Expected Benefits to Others

We hope to learn whether different types of health and wellness classes can be beneficial to stroke patients as a low-cost rehabilitation option. The information we get from this study may help us treat future stroke patients.

6. Other Options to Taking Part in this Study

Your alternative is not to take part in this study.

7. Right to Withdrawal from the Study

Your taking part in this research is voluntary. You can stop taking part at any time. If you choose not to take part in this study, you will not be penalized or lose any benefits to which you are entitled. Please tell the researcher if you are thinking about stopping or decide to stop. Your decision will not affect your relationship with the researcher. If you choose to withdraw from the study, any data that has already been collected may continue to be reviewed, but no further data will be collected.

The investigators may terminate your taking part in the study if an intervening health event makes you ineligible to participate, or if it is believed that taking part in research is detrimental to your health or safety in some way.

8. Confidentiality

We will do our best to keep your medical records and personal information private. However, we cannot guarantee absolute confidentiality. We will disclose your personal information if required by law. We will disclose your information to protect your rights or welfare. We will disclose your information if the researcher becomes aware that you may be a danger to yourself or to others. We will disclose your information if the researcher becomes aware that acts of child, elder, or dependent adult abuse or neglect may have occurred.

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If you are a Veteran registered at VANCHCS, VA policy requires that a note be placed in the medical record that identifies you as taking part in this research study. If you are not a registered patient at VANCHCS and participate in an MRI scan for the study, VA Policy requires that an entry be created for you in the VANCHCS computerized medical record system. To do so, your name, gender, and a unique 9-digit identification number (that will be created upon enrollment in this study) will be entered into the computerized medical record system. All authorized VA personnel with approved access to this medical record system would be able to see your name and gender, but no other data.

Researchers may publish or present the results of this study, but they will not reveal your name or identity. Your research data will always be stored with a research code (number) rather than your name. Only the research team will have access to the link between individuals and their assigned research code. Paper-based study data will be kept in a locked filing cabinet in private research offices, accessible only to the research team. Electronic/digital study data files will be kept on encrypted, password-protected VA research servers that are accessible only to approved research staff.

When the research is completed, the data will be backed up and archived in a secure filing cabinet or stored electronically on secure VA computer servers. These data will eventually be deleted or shredded when the study is complete, as deemed allowable by the VA record retention schedule. While this study is being conducted, you will not have access to your research related health records. Participation in this study will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care.

The research sponsor, Department of Veterans Affairs, may also look at your research files and medical record. Organizations may inspect and/or copy your research records for quality assurance and data analysis. One of these is the VANCHCS Institutional Review Board (otherwise known as the Human Subjects Subcommittee). The Institutional Review Board is a committee whose purpose is to review and monitor research studies that involve human subjects.

This study is a registered Clinical Trial. 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, averaged across all participants. You can search this Web site at any time.

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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. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, diagnoses, radiology findings, and drug or alcohol abuse.

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 may include the study sponsor (VA Clinical Sciences & Research Development), the Institutional Review Board, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO). 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 Principal Investigator for this study at the following address.

Juliana Baldo, PhD
VA NCHCS (151)
150 Muir Road, Bldg.26
Martinez, CA 94553

Your request will be valid as soon as it is received by the study's Principal Investigator. If you revoke this authorization, you will not be able to continue to participate in this study. This will not affect your rights as a VHA patient to treatment or benefits outside of the study.

If you revoke this authorization, Dr. Juliana Baldo & and her 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.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time. Any study information that has been placed into a repository to be used for future research will not expire.

9. Research Related Injury

The procedures being conducted for this study are for research purposes only.

If you are injured as a result of being in this study, treatment will be available. If you are eligible for Veteran's benefits, the costs of such treatment will be covered by the Department of Veterans Affairs. If not, the costs of such treatment may be covered by the Department of Veterans Affairs depending on a number of factors. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form. For further information about this, you may call the V.A. Chief Counsel at (415)750-2288.

10. Costs to Study Subjects

As a research subject, you are not required to for care or services conducted for research purposes. Some veterans are required to pay co-payments for medical care and services specifically related to their medical care provided by the VA. These co-payments will continue to apply to medical care and services provided by VA that are not part of this study.

11. Payment for Taking Part in the Study

In return for your time, effort and travel expenses, you will be paid $25/hour for taking part in this study. You will be paid in cash or by gift card upon the completion of each research appointment (enrollment, testing, and brain imaging, if applicable). You will not be paid for the time you spend in the brain health and wellness classes. Payments will be pro-rated in 12-minute increments of time.

12. Questions About this Study

If you have any questions, concerns or complaints about this study, please contact Dr. Juliana Baldo at (925) 372-4649.

13. Questions About Research Subject Rights

You may have questions about your research subject rights, or you may want to obtain information or offer input. You may also have questions that you feel cannot be discussed with

the researchers. In this case, you may call the VANCHCS Human Research Protection Program. The phone number is (916) 366-5359. You may also call the VA Chief Counsel. The phone number is (415)750-2288.

14. Optional - Use of Existing Research Data

If you have participated in other research studies at VANCHCS, we ask that you give us permission to access prior imaging and behavioral data to prevent the need for re-acquiring the same data. By signing below, you are agreeing to let us use this existing data in the current study.

_____ _____
Signature of Participant Date

15. Optional - Re-Contact

You may also qualify for future studies at the VA. If we become aware of a research study that you would be eligible for, we can call you to ask you whether you would be interested in participating. Please initial here if you are willing to be contacted for future research that you may be eligible for. [_____]

16. Optional - Future Use of Data

We would like to save your data from this study in a data repository once the VANCHCS IRB approves such a VA Research Data Storage Bank. These data would be stored with a research code (no names) on a secure and firewall protected VA research data server. The key to this code will be kept by Dr. Baldo, Ph.D. in a locked filing cabinet in a private VA research office. If you agree to be re-contacted and re-consented to have your data included in an approved VA Research Data Bank, please check the appropriate box below. Your decision will not affect your medical care or your participation in the current study.

☐ YES. I agree to be re-contacted and re-consented to have my research data used for future research, once the IRB receives and approves a Research Data Bank specifically designed to be used for future research.

☐ NO. I do not want to be re-contacted and re-consented to have my research data used for future research.

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Principal Investigator: Juliana Baldo, Ph.D. **VAMC:** VANCHCS

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. _____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Juliana Baldo at (925) 372-4649 during the day, and at (909) 753-9704 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

I understand my rights as a research subject, and I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

_____	_____	_____
Participant's Name	Participant's Signature	Date
_____	_____	_____
Name of person obtaining consent	Signature of person obtaining consent	Date

Research Consent Version date: 08/192021

Subject's Initials _____

VANCHCS IRB
Effective Date: August 18, 2021