Department of Veterans Affairs	INFORMED CONSENT FORM
Subject Name:	**Date:**
Title of Study: Improving Mind/Body Health and Functioning with Integrative Exercise	
Principal Investigator: Thomas Neylan, M.D.	**San Francisco VAMC**

CONSENT TO PARTICIPATE IN RESEARCH

The purpose of this research study is to compare two types of treatment for symptoms of post-traumatic stress disorder (PTSD): Integrative Exercise (a combination of aerobic exercise and controlled breathing/strength training exercises) and PTSD Recovery Classes. The study researchers are from the San Francisco Veterans Affairs Medical Center, the UCSF Department of Psychiatry, and the Osher Center for Integrative Medicine and include Thomas Neylan, M.D., Margaret Chesney, Ph.D., Wolf Mehling, M.D., Jennifer Boyd, Ph.D. and Beth Cohen, M.D. A member of the Stress and Health research team will explain this study to you.

Participating in research studies is completely voluntary. Please take your time to make your decision about participating. You can discuss your decision with your family, friends, or health care provider if you wish. If you have any questions, you may ask someone from the study team.

You are being asked to take part in this study because you have symptoms of post-traumatic stress disorder.

Why is this study being done?

The purpose of this study is to compare the effectiveness of Integrative Exercise classes to PTSD Recovery Classes, to determine which can best improve quality of life and reduce symptoms of post-traumatic stress disorder (PTSD).

This study is funded by the Department of Veterans Affairs. The investigators do not have any financial interests in relation to this study.

How many people will take part in this study?

104 people will take part in this study. Participants will be randomly assigned (by chance selection) to one of two study groups: half of the participants (52 participants) will be randomly assigned Integrative Exercise Classes and the other half (52 participants) will be randomly assigned to PTSD Recovery Classes.

What will happen if I take part in this research study?

If you agree to participate in this study, you agree that you will not start up any new mental health treatment services/medications/procedures throughout the study, except emergency treatment. If you agree, the following procedures will occur:

Screening and Eligibility Assessments

First, you will need to complete the following "screening" tests or procedures to determine if you are eligible to participate in the main portion of the study (all screening assessments will take place at the San Francisco VA Medical Center):

- **Clinical Assessment & Questionnaires:** You will meet with a research mental health clinician who will ask you questions about your mental health history as well as your alcohol and drug use. **This assessment will last approximately 3 hours and will be audio-recorded** to ensure consistency across all clinical interviews. All audio recordings are encrypted, stored on a secure server, and identified only by a unique study ID number. We take our commitment to protect your privacy very seriously.

- **Medical Screen:** You will meet with a nurse who will ask you questions about your medical history, current health, and any medications you are taking. The nurse will also take your blood pressure, pulse, temperature, and record your height and weight. A brief physical exam will be performed to ensure that you are healthy and eligible to participate in the study. If you are a woman able to bear children, you will be asked to report if you are pregnant or suspect you are pregnant. If you become pregnant while enrolled in this study, please contact the study coordinator immediately. One of the study physicians will then discuss possible alternatives with you. If you have a medical record at the VA, we may review your medical record to confirm your eligibility for this study.

- **Blood Draw (Venipuncture):** You will be asked to provide a blood sample. Approximately 61.5 ccs (around 12 teaspoons) of blood will be drawn by inserting a needle into a vein in your arm. The blood will be stored at the San Francisco VA Medical Center. The blood will be used for the following:

  Routine lab tests: This will include a serum chemistry panel, liver function tests, thyroid functions, complete blood count, and differential, total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, glucose, hemoglobin A1c, and a urine toxicology screen. Depending on your medical history, additional tests may be ordered to confirm that you are healthy and eligible to participate in the study. If additional tests are ordered, you may be asked to have an additional 2.8 ccs (around ½ teaspoon) of blood drawn.

  Research analyses: The blood will also be used for future research to study chemicals, enzymes, and genes related to PTSD. This blood banking is required for participation in the research study, and the results of these research analyses will not be released to you. The blood will be stored at the San Francisco VA Medical Center. If you decide later that you do not want your samples used for future research you can notify the Principal Investigator and any remaining samples will be destroyed.

  An open medical chart will be created for you at the San Francisco VA Medical Center (if you do not already have one) as a result of your participation in these eligibility assessments. The following information will become part of your official VA medical record: documentation of your participation in this research study, documentation that you've been medically cleared to exercise, and the results of your routine lab tests.

The Medical Screen, Urine Sample and Blood Draw will take approximately 1 hour.

Pre-Treatment Assessments

If the screening assessments indicate that you are eligible to participate in this study, and you choose to take part, the following tests, questionnaires, and study procedures will be completed (at the San Francisco VA Medical Center) before you are randomly assigned to a study group:

- **Self-Report Questionnaires:** You will be asked to complete a set of questionnaires, which will include questions about your health, mood, sleeping patterns, social relationships, possible life trauma experiences, exercise habits, and PTSD symptoms. You will complete these questionnaires using an online survey application called Qualtrics. **This set of questionnaires will take about approximately 1 hour to complete.**

- **Neurocognitive Testing:** You will be asked to complete a set of neurocognitive tests administered by study staff. These are tests of memory and thinking. **This set of tests will take about approximately 30 minutes to complete.**

- **Brachial flow-mediated dilation (FMD) test:** A flow-mediated dilation (FMD) test is an ultrasound measurement of the blood vessels in your arm. For the FMD test, a blood pressure cuff will be placed around your arm and inflated for five minutes then released. Ultrasound will be used to take pictures of the blood vessels in your arm during the test. There is no radiation involved (as when you get an X-ray). The ultrasound probe looks like a microphone and will be moved back and forth over your arm to take pictures. You will be asked to fast on the morning of the procedure and to avoid nicotine and caffeine for at least 4 hours prior to the test. You may be asked to hold certain blood pressure medications until after you complete the test. **The FMD test takes approximately 1 hour.**

Randomization

After completing the above procedures, you will then be "randomized" into one of the study groups described below.

Randomization means that you are placed into a study group by chance, and group assignments are determined by an automated computer system. Neither you nor the study researchers can choose the group you will be in. In this study, you have an equal chance of being assigned to Integrative Exercise Classes or PTSD Recovery Classes.

Every participant at the end of the first treatment period will have the chance to receive the alternate treatment if they so choose.

Treatment

Depending on which study group you have been assigned to, your participation will involve the following:

Integrative Exercise Classes – 12 weeks

You will attend 3 classes weekly (for 12 weeks), with each class lasting approximately 60 minutes. Integrative Exercise incorporates elements of strength training, flexibility, cardiovascular training, and controlled breathing exercises. Exercises are adapted to your level of fitness.

PTSD Recovery Classes – 12 weeks

You will attend 3 classes weekly (for 12 weeks), with each class lasting approximately 60 minutes. PTSD Recovery classes include several topics: recovery, practical facts about PTSD, stress-

vulnerability, building social support, medications for PTSD, drug and alcohol use, coping with stress, coping with persistent symptoms, getting needs met in the VA healthcare system, and living a healthy lifestyle.

For both groups: AFTER completion of the post-treatment assessments, you will have the chance to attend classes in the alternate treatment condition if you so choose.

Within-Treatment Assessments
Both groups will complete the following procedures during the treatment phase of the study:

- At week 4: **Self- Report Questionnaires (30 minutes)**
- At week 8: **Self- Report Questionnaires (30 minutes)**
- Every week you will receive a check-in call from the study coordinator.

Post-Treatment Assessments
Following 12 weeks of Integrative Exercise or PTSD Recovery Classes, you will repeat the following study procedures that were conducted during Eligibility and Pre-Treatment:

- **Clinical Assessment & Questionnaires (1-2 hours)**
- **Blood Draw (Venipuncture): The same amount of blood will be drawn at baseline: 61.5 ccs, or 12 teaspoons. (20 minutes)**
- **Self- Report Questionnaires (1 hour)**
- **Neurocognitive Testing (30 minutes)**
- **Brachial flow-mediated dilation (FMD) test (45 minutes)**

6 Month Follow-up Assessments
6 months after the end of treatment, you will repeat the following study procedures that were conducted during Eligibility and Pre-Treatment:

- **Clinical Assessment & Questionnaires (1-2 hours)**
- **Self- Report Questionnaires (1 hour)**
- **Neurocognitive Testing (30 minutes)**

Study location
All eligibility assessments, laboratory tests, medical screen, and FMD tests will take place at the San Francisco VA Medical Center. Self-report questionnaires can be completed on the premises of the VA or offsite. PTSD Recovery Classes will take place at the San Francisco VA Medical Center. Integrative Exercise Classes will take place at the Embarcadero YMCA in San Francisco. Other exercise class sites may need to be considered based on space availability/scheduling; however, unexpected changes to the location of the exercise sessions are unlikely.

How long will I be in the study?

After completing the eligibility assessments and screening assessments to determine if you're a match for the study, you will be asked to be in the study for approximately 14-18 weeks, and then, six months later, an additional 1-2 days:

- 1-3 Weeks: Pre-treatment Assessments

- 12 Weeks: Integrative Exercise Classes or PTSD Recovery Classes
- 1-3 Weeks: Post-treatment Assessments
- 1-2 days: 6 Month Follow-Up Assessments

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study researcher may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped. Should your participation in the study be terminated, you will be paid for any interviews or procedures that you have completed.

What side effects or risks can I expect from being in the study?

You may have the following side effects or discomforts while in the study (described below). Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. You should talk to your study doctor about any side effects or discomforts you experience while taking part in the study.

Clinical Assessment & Questionnaires: The assessment and questionnaires may be distressing to some participants. You are free to decline to answer any questions or to stop the interviews at any time. The interviewer will be available to immediately assist with any problems that arise in the interview and will make a referral, if required.

- ***However, the assessment will be conducted by an experienced mental health professional and it is very likely that these feelings of upset or distress will be temporary***.

Audio Recording – Clinical Assessment: The clinical assessment will be audio recorded. The audio recording might make you somewhat more uncomfortable than you would be without the recording. Only research personnel will use the recordings to ensure consistency across all clinical interviews.

- ***All audio recordings will be maintained under secured conditions (they are encrypted, stored on a secure server, and identified only by a unique study ID number)***

Blood Draw: The risks of drawing blood include temporary discomfort from the needle stick, bruising, discomfort, and rarely, infection.

- ***To minimize these risks, experienced medical personnel will handle all the blood drawing procedures and sterile conditions will be maintained.***

Brachial artery flow-mediated dilation (FMD) test: Inflation of the cuff will cause a tingling sensation in your arm and hand and can cause discomfort.

- ***To minimize any risks, experienced medical personnel will handle all aspects of the procedure. You are free to discontinue the test if you wish.***

Self-Report Questionnaires*:* There are no physical risks from answering questionnaires. Some of the questions may be upsetting to you. You are free to decline to answer any question that you do not want to answer.

- ***You can always take a break from a questionnaire or contact study staff with any questions.***

Neurocognitive Testing*:* There are no physical risks from answering these tests. This may be slightly frustrating or produce fatigue and boredom.

- ***You can always take a break, skip a question, and/or ask study staff if you have any questions.***

Integrative Exercise Classes: As with any program involving new exercises, you may experience injuries including muscle strain or soreness. During the course of treatment, fatigue and/or sleepiness, and/or memory and concentration difficulties may occur (although these symptoms are usually limited to the first 1-2 weeks of treatment). To ensure that the program is safe and likely to be effective, our 12-week Integrative Exercise program was developed in consultation with experts worldwide who have extensive knowledge of stress reducing exercises.

- ***However, if side effects occur that are not controllable or are too bothersome, you are free to discontinue treatment and withdraw from the study.***

PTSD Recovery Classes: There are no physical risks from participating in the classes. Some of the topics covered in the classes may be emotionally upsetting to you. PTSD Recovery Classes have been developed for use with diverse veteran populations and is shown to be safe. The classes will be conducted by trained mental health professionals in meeting rooms at the San Francisco VA Medical Center Department of Mental Health.

- ***The classes will be conducted by experienced mental health professionals and it is very likely that these feelings of upset or distress will be temporary. However, if side effects occur that are not controllable or are too bothersome, you are free to take a break from class or discontinue treatment and withdraw from the study.***

Unknown Risks: The treatments may have side effects or discomforts that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

You will be offered 12 weeks of Integrative Exercise or PTSD Recovery Classes and a free 6-month YMCA of San Francisco gym membership after the trial (as a completion bonus).

Taking part in this study may or may not make your PTSD symptoms better. While doctors are hopeful that these two treatments will provide an exciting new therapy for PTSD symptoms, the very purpose of this study is to test this possibility.

What other choices do I have if I do not take part in this study?

You may choose to not take part in this study or choose to take part in another research study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and if you are a veteran you can still get your care from our institution the way you usually do.

Please talk to your doctor about your choices before deciding if you will take part in this study.

Will my medical information be kept private?

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Documentation of your involvement in this research study, documentation that you've been medically cleared to exercise, and the results of your routine lab tests will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

We will do our best to make sure that the personal information in your medical record is kept private; however, we cannot guarantee total privacy. Your personal information may be given out if required by law. For instance, if it were learned through the clinical assessment or treatment that you were a danger to yourself or others, that a child had been abused or neglected, or that an elder or dependent had been abused, the appropriate authorities would be notified, as required by law.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. All study information, such as the interviews and questionnaires, will be coded with an ID number unique to the study. Only research study personnel, with the permission of the principal investigator, will have access to the files with the name and ID codes.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- The University of California (a group of people who review the research to protect your rights)
- The Department of Veterans Affairs Regulatory Personnel (the group which protects research participants' rights at the VA)
- You will complete questionnaires online using Qualtrics. Only de-identified data will be used on this site and your name, birthday or any other identifying information will not be used.
- If you attend Integrative Exercise Classes the YMCA of San Francisco, they will be given your name so that you may be allowed to check in and participate in the study at their facility.

- If you attend the PTSD Recovery Classes, each class will be scheduled as an appointment in your VA medical record (CPRS). A progress note for each class attended will be added to your medical record. These are the same procedures that would be followed for a veteran enrolled in any group or class as a VA patient not in a research study.

What are the costs of taking part in this study?

You will not be charged for any of the study assessments and questionnaires. There may be parking/transportation costs associated with attending Integrative Exercise and PTSD Recovery classes. A travel stipend of $5 per class attended (based on attendance sheet records) will be provided which may or may not cover all of your travel expenses. Study staff may use text messaging to remind you of study appointments. Your phone company may charge you for message and data services when you receive or send a text.

Will I be paid for taking part in this study?

In return for your time, effort, and travel expenses, you will be paid for taking part in this study as described below:

Total possible compensation = $400

Screening/Eligibility Assessments:
- Clinician Assessment = $55
- Medical Exam and Urine/Blood Collection = $25

Pre-Treatment Assessments:
- Self-Report Questionnaires/Neurocognitive Testing = $25
- FMD test = $30 (in addition to free breakfast on the day of your appointment)

4 week Self-Report Questionnaires = $25
8 week Self-Report Questionnaires = $25

Post-Treatment Assessments:
- Follow-up Clinical Assessment = $25
- Follow-up Blood Draw = $20
- Self-Report Questionnaires/Neurocognitive Testing = $25
- FMD test = $30 (in addition to free breakfast on the day of your appointment)

Completion Bonus #1:
As a bonus for completing all assessments at Screening/Eligibility, Pre-Treatment, 4 Weeks, 8 Weeks and Post-Treatment, you may receive:
- A 6-month free YMCA of San Francisco gym membership will be provided after the trial.

6 Month Follow-Up Assessments:
- Clinician Assessment and Self-Report Questionnaires and Neurocognitive Tests = $55

Completion Bonus #2:
As a bonus for completing all assessments at Screening/Eligibility, Pre-Treatment, 4 Weeks, 8 Weeks, Post-Treatment and 6 Month Follow-up you may receive:

- Completion Bonus = $60

If you withdraw from the study prior to completion for any reason, you will be compensated for the procedures that have been completed. You will need to provide your social security number for payments to be processed.

What happens if I am injured because I took part in this study?

It is important that you tell the study doctor, Thomas Neylan, M.D., if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at (415) 750-6961.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, VA will ensure that treatment is made available at a VA medical facility. If you are eligible for veteran's benefits, the costs of such treatment will be covered by the Department of Veterans Affairs. If you are not eligible for veteran's benefits, the costs of treatment may be billed to you or your insurer just like any other medical costs, or covered by the Department of Veterans' Affairs or the University of California, depending on a number of factors. The Department of Veterans Affairs and the University do not normally provide any other form of compensation for injury. For further information about this, call the VA Regional Counsel at (415) 750-2288 or the office of the UCSF Committee on Human Research at (415) 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. If you are a veteran you can still get your medical care from our institution. The research team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. 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.

Who can answer my questions about the study?

You can talk to the study doctor about any questions or concerns you have about this study. Contact the study doctor, Thomas Neylan, M.D., at (415) 750-6961. **For questions about your rights while taking part in this study**, call the office of the **Committee on Human Research**, UCSF's Institutional Review Board (a group of people who review the research to protect your rights) at **(415) 476-1814.**

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. **PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to participate or

to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you wish to participate in this study, please sign below.

_____ _____
Date Subject's Printed Name

_____
Subject's Signature

_____ _____
Date Person Explaining and Obtaining the Consent (Printed)

_____
Person Explaining and Obtaining the Consent Signature

Future contact for other studies

You may be eligible to participate in future research studies conducted by the Stress & Health Research Program. If you would like to provide permission to be contacted by the Stress & Health Research Program about their studies, please check "yes" below and add your initials. If you would prefer not to be contacted by other researchers, please check "no." **You can still be a part of this study even if you say "no" to being contacted about other studies.**

Do you give your permission to be contacted by researchers within the Stress & Health Research Program about other or future research studies? Researchers conducting other studies within the Stress & Health Research Program may access data collected during this study. You are free to decline to participate in the other studies and may ask at any time to have your name removed from the contact list.

☐ Yes ☐ No _____ Subject initials

VETERANS ADMINISTRATION MEDICAL CENTER, SAN FRANCISCO
AND
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

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

1. To be told what the study is trying to find out,
2. To be told what will happen to me 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 me for research purposes,
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5. To be told of the other choices I 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 at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I 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 I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Call 476-1814 for information on translations.