Neurobiological Mediators of Self-Regulatory and Reward-Based Motivational Predictors of Exercise Maintenance in Chronic Pain and PTSD

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Informed Consent Form

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1. Purpose of study: You are invited to be in a research study in order to evaluate the impact of an exercise program on stress hormone responses. Such responses may help to alleviate symptoms of chronic low back pain (cLBP), a common chronic pain condition that often co-occurs with psychiatric disorders such as posttraumatic stress disorder (PTSD) and depression, as well as other chronic pain conditions comorbid with cLBP. PTSD commonly co-occurs with chronic pain and previous research indicates that those with both diagnoses tend to suffer greater levels of pain sensitivity, sleep problems, overall distress and disability than those with either condition alone. The sponsor of this study is the National Institute of Health: Science of Behavior Change and the Common Fund. More specifically the National Center for Complementary and Integrative Health (NCCIH).

We expect ~210 participants will be consented and 70 participants take part in the active exercise phase of the study. However, participants will be randomly assigned to a **Wait-List Control Condition (n=35)** versus the **Immediate Active Exercise Testing/Training Condition (n=35)**. If you are randomized to the wait list control condition, you will perform all baseline blood draws and ratings (but not exercise testing or training). However, at the conclusion of the three-month wait list condition, you will be invited to engage in a **Delayed Active Exercise Testing/Training Condition** where you will receive the same exercise testing and training intervention as the Immediate Active Exercise Testing/Training condition. *You are eligible to participate in this study because you have been diagnosed with both chronic low back pain and PTSD. Additionally, you may have a qualifying chronic musculoskeletal pain condition co-occurring with your chronic low back pain.*

2. Description of the study, procedures to be used, and how long it will last:
Location: This study will take place at VA Boston Healthcare System (VABHS), Jamaica Plain campus, located at 150 South Huntington Avenue, Boston, MA, 02130. You will be given specific instructions about where to meet the study researchers for each part of the study.

Duration: Your participation will require 35 visits over 14 weeks.

a) **Phase I**: The first two sessions (approximately 6 hours total) will be an initial screening examination.

b) **Phase II**: If you are found to be eligible to participate and are randomized to the **Immediate Active Exercise Testing/Training Condition**, we will schedule you for a "cardiopulmonary exercise (CPX) and cold pressor testing session (CPX/CPT)" (4-5 hours). (Note that two more "CPX/CPT" sessions will be repeated at the midpoint of the study, about six weeks after your first CPX/CPT session, and

again after you complete the exercise training program, about 13-14 weeks after the first exercise test session).

c) The study also involves approximately 36 hours of regular exercise -- all of which will be performed in the clinic at VABHS and supervised by an exercise physiologist (36visits, up to 1.5 hours in length). You will be given an "actigraph" to record exercise training sessions you perform in the clinic and to wear at home throughout the study period. ***After completion of the final exercise test, two follow-up phone calls will be made to you at 1-month and 3-months post-study. Please refer to the Table below:***

Session	Session Type	Length of Time
Session 1: Phase I	**Screen for eligibility-**	**2 hours**
Session 2	**Screen for eligibility-**	**3-4 hours**
Session 3: Phase II	**Cold Pressor/Cardiopulmonary Exercise Test**	**4-5 hours**
Sessions 4-22	**In Clinic Exercise Training Sessions 3X/wee for 6 weeks**	**1-1.5 hours per session**
Session 23	**Week7 Midpoint Cold Pressor Test/ Cardiopulmonary Exercise Test**	**4-5 hours**
Sessions 24-42	**Exercise Training Sessions 3x/week for 6 weeks**	**1-1.5 hours per session**
Session 43	**Endpoint Cold Pressor/Cardiopulmonary Exercise Test**	**4-5 hours**
Session 44: phase III	**1-month Follow-up Phone Call**	**20 minutes**
Session 45	**3-month Follow-up Phone Call**	**20 minutes**

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NOTE: At these sessions, your actigraph will be worn and downloaded (1x/month) so it is required that you bring it with you to each visit.

NOTE: Please note that any of the scheduled sessions (listed in table above) can be rescheduled if unforeseen circumstances occur on your part or that of the participant or study staff (i.e. medical illness, travel, holiday, inclement weather, etc.). If the cancellation occurs based on an unforeseen circumstance on the part of study staff, you will still be compensated the full amount of the session.

NOTE: For women who are still menstruating, the cold pressor test and the CPX/CPT sessions need to be scheduled during the follicular phase of your menstrual cycle which could be up to a month delay in scheduling these sessions. Women who are peri/post-menopausal will be scheduled according to the standard study timeline.

NOTE: If you are randomized into the waitlist control group, you will not complete any exercise training for the 12-week duration of the study. You will instead come in for sessions 1, 2, 3, 23, and 43 listed above. During sessions 2, 23, and 43, you will come in for routine blood and urine testing. After the 12 weeks, you will be offered the opportunity to participate in the full exercise program as part of the **Delayed Active Exercise Testing/Training Condition.**

As part of this research study, you will participate in several tests during the procedures mentioned above. The tests include:
a) a screening psychiatric exam and physical-- completed during the screening sessions
b) blood measurements of stress hormones and fuels used by your body for energy-completed at both the cold pressor and cold pressor/exercise testing sessions

d) a test of how long you can tolerate having your hand in very cold water completed during the cold pressor test session, and cold pressor/exercise testing sessions.
e) ratings of stress, mood, pain, self regulation, reward sensitivity and exercise behavior/motivation-- completed at the screening and cold pressor/exercise testing sessions.

Screening Exam (Visits 1 and 2)

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Phase 1. The results of the in-person screening examination (about 4-6 hours; over 1-2 weeks described below will determine whether you meet preliminary eligibility requirements for the study. If you do not meet eligibility requirements, you cannot participate.

1. If you are on medication for pain, you must be willing to be off of the pain medication long enough for it to be out of your blood during the three cold pressor/ cardiopulmonary exercise test sessions (one before, one at the midpoint, and one after the 12 week exercise training program. For most pain medications, that would be about 24 hours).
2. You will be provided details about medications that will be allowed. In addition, you must check with the study researchers about any medications you wish to take or do take during this study to make sure that they will not interfere with the study results or your safety. You will not be asked to stop medication for the purpose of participating in this study if it is not clinically advisable. If you, your providers, or the study investigator feels that staying off of medication for this period of time is clinically undesirable or unsafe, you will not be enrolled in the study.
3. You must be free of other substances with central nervous system effects (legal and illegal), including alcohol and marijuana for 2-4 weeks (depending on the substance) prior to participation in exercise testing. If you have been dependent on alcohol or illicit, unprescribed drugs in the past 3 months you will not be enrolled in the study. You will receive a urine test for illegal drugs. A urine drug screen will be repeated before each procedure described below (A-C). If positive, you will not be able to continue in the study. In addition, if you have a positive urine toxicology screen for an unapproved drug you are not prescribed for pain (e.g., cocaine, heroin, etc), you will not be able to continue in the study and will not receive financial compensation for the screening visit.

NOTE: You may also be excluded from further participation in the study at any point if you are unable to provide reliable study data, for example, altering your urine sample (in which case you would not be paid for the session), providing misinformation during an interview, or misinforming study staff of conditions that would exclude you from the study.

4. You must not be currently enrolled in any structured psychotherapy for your cLBP or PTSD at the time of your enrollment and for the duration of your participation in this study.
5. To ensure that you are generally physically healthy and able to safely participate in the study procedures, you will receive a physical exam, an electrocardiogram (EKG), a urinalysis, and a urine test for nicotine use. In addition, 2 tubes of blood will be drawn for routine medical

laboratory tests. Parts of the physical examination, lab tests, or the EKG may be repeated in order to clarify results, or to track or evaluate possible medical problems during the study. To do this, you may be asked to return for an extra visit for which you will be compensated.

6. If you are taking any medications that could put you at additional cardiac risk during the exercise test sessions (baseline, midpoint and endpoint), you will receive an additional EKG prior to each exercise test; the EKG will be reviewed by the covering cardiologist immediately. Should the EKG indicate that undergoing the exercise test will put you at any additional cardiac risk, you will be withdrawn from the study; however you still will be paid in full for the session.

During the first screening session, blood tests will include a complete blood count, other red blood cell or iron indices if indicated, B12 or possibly folate levels, electrolytes, glucose measure(s), liver function tests, a hepatitis screen if indicated, cholesterol or other lipids if indicated, thyroid function tests, or other tests that may be needed to evaluate a specific medical problem you might have. Women may receive a follicular stimulating hormone (FSH) level test to determine if they are perimenopausal. If you are found to be anemic, you will be excluded from the study until this condition has been resolved through treatment with your own medical provider.

Additional blood tests will be performed during the baseline cold pressor, mid-point and endpoint cold pressor assessment sessions. These tests will measure vitamin D3, sedimentation rate, CBC, C-reactive protein, and a lipid profile in order to explore the potential association of changes among these labs over time with potential improvements in chronic pain symptomatology over time.

7. You will be screened for current and past psychiatric and substance abuse disorders, as well as past exposure to traumatic incidents in a clinical interview setting. This is the only part of the screening exam that will be audio recorded and the recording will be used to help the researchers make more accurate psychiatric diagnoses. IF YOU DO NOT AGREE TO BEING RECORDED YOU CANNOT PARTICPIATE IN THIS STUDY.

**Please note that if scheduling difficulties (e.g. staff or participant availability, holidays, inclement weather) occur between the screening session and the baseline cold pressor and exercise testing sessions, we may ask you to return for another screening session to evaluate your eligibility as the medical and psychiatric assessments discussed in items 5 and 6 above

expire between one to three months post-administration. If you need to return for another screening session, you will be compensated an additional $30 for your time.

If we need to repeat the psychiatric portion of the screening procedure (item #5), we will administer that assessment at the baseline cold pressor and exercise assessment session, prior to any cold pressor assessment procedures, but after the routine urine testing. Regardless of the outcome of these assessments (i.e. should your eligibility status change), we will still compensate you $50 for the session.

8. If any of your screening examinations are abnormal, you will be referred for appropriate medical care.
9. For women with child-bearing potential: Since this research could result in harm to a fetus and should not be done during pregnancy, women enrolling in this study must (i) have a negative pregnancy test at screening and before each exercise test, and (ii) agree to use an effective form of contraception for the duration of the study. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. Nursing mothers may not participate in this study because the hormones to be studied are influenced by nursing.

If you are not currently enrolled in VA healthcare, you must sign a Release of Information form so that we can communicate with your medical and/or psychiatric providers in the event that we have any clinical concerns. If you are a veteran whose medical or psychiatric providers are at this VA, we will inform you of any information we wish to share with your treaters in order to provide you with the best possible care.

Phase 2. Baseline Testing (visit 3):

A. Test Before the 12-Week Exercise Training Program (Visit 3)

(Note that women will be scheduled for these tests between 2 and 7 days after the onset of menses).

Visit 3: Cardiopulmonary Exercise Test (CPX Test) and Cold Pressor (CPT) Session (about 4-5 hours)

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1. Within one month following the screening sessions, you will come to the CSU laboratory again for a cardiopulmonary exercise test (CPX Test) followed by a repeat Cold Pressor Test (CPT).
2. Your urine will again be checked for the presence of illegal drugs; women will receive a urine pregnancy test, and your height, weight, blood pressure, and pulse will be recorded.
3. If you are currently taking any prescribed psychotropic or other medications, an additional EKG will be done as an extra safety precaution, prior to participating in the CPX test. Should the EKG indicate that participating in the CPX test puts you at any additional risk for a cardiac event, you will be withdrawn from the study; however you still will be paid for the full amount of the session.
4. An IV (or butterfly) needle will be placed in your arm and the breakfast of power bars will be provided.
5. During the next 2 hours, you will complete ratings of mood, self regulation, reward sensitivity and exercise behavior/motivation.
6. Just prior to exercise testing, electrodes will be placed on your chest for performance of a continuous EKG (measurement of your heart performance) during exercise. For men, we may have to shave your chest to ensure the electrodes adhere correctly. A blood pressure cuff will be placed on one arm.
7. If you are currently taking any prescribed psychotropic or other medications, an additional EKG will be done as an extra safety precaution, prior to participating in the CPX test. Should the EKG indicate that participating in the CPX test puts you at any additional risk for a cardiac event, you will be withdrawn from the study; however you still will be paid for the full amount of the session.
8. A sterilized breathing facemask will be fitted into your face, through which you will breathe room air. This will allow us to measure the amount of oxygen you use and carbon dioxide you produce during the exercise test.
9. Exercise test: You will be instructed to walk on the treadmill in time with a metronome for about twenty minutes while the walking difficulty is gradually increased. You will continue walking/running until either you: a) feel you cannot continue, b) fall behind the walking/running pace, c) or are otherwise judged by the medical personnel present to have reached your maximum exercise load. AFTER REACHING YOUR MAXIMUM EXERCISE LOAD, YOU WILL BE ASKED TO WALK STEADILY FOR ANOTHER FEW MINUTES UNTIL YOUR HEART RATE RETURNS TO NEAR BASELINE.
10. Blood samples will be taken through your IV before you start walking/running, after each increase in the walking difficulty, and twice after you are done exercising. Your blood

pressure will be taken and you will be asked to give a rating of how strenuous the exercise feels before each blood draw. In the case of difficulty placing the IV, a butterfly needle will be used instead to draw blood samples before you start pedaling and twice after you are done exercising.

Safety precautions during exercise testing: If at any time you feel sick, faint, or otherwise too uncomfortable, you can and should stop exercising. The cardiologist or other qualified medical professional present during testing will stop the test if you develop any changes in your EKG or blood pressure that cause concern for your safety.

9. Thirty minutes after exercise testing, you will again complete questionnaires about your mood, pain, and/or psychiatric symptoms. You then will complete the cold-pressor test. During this test, you will be instructed to place your right hand into temperature controlled ice water and state when you first experience pain. You will then be instructed to keep your hand in the ice water until you can no longer tolerate it. A maximum time limit will be imposed so you will not be at risk for freezing your hand.
10. Upon completion of the cold pressor test session, a study staff member will program, explain, and show you how to wear an activity monitoring device called an Actigraph that is worn around the waist, under your clothes. As part of the study, you will wear the device throughout the 12 weeks of exercise training to evaluate your physical activity.

B. 12-Week Progressive Exercise Training Program (Visits 4--22, 24-42)

The next phase of the study is the exercise training phase. This will take place over 12 weeks. The training program (e.g., walking, running) will be individualized, based on your performance during the CPX test. You will come to the VABHS exercise clinic at Jamaica Plain campus three times a week to be trained and guided by an exercise physiologist to help you perform the exercise program properly. During these visits the exercise physiologist will be present during your exercise sessions to offer assistance so you can maintain proper exercise technique. The exercise program will progressively increase your target heart rate range over the course of the 12 weeks. During exercise, you will wear a heart rate monitor and actigraph device to ensure you are exercising properly in accordance with your individualized prescription and meeting the prescribed heart rate range.

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A qualified staff member will call you approximately weekly, beginning at Week 3 of your exercise prescription while you are exercising primarily at home, to review any barriers you may encounter for exercising and problem solve with you to help you stay on track with your exercise prescription.

**Please note that at each in-clinic exercise training session, your urine will again be checked for the presence of illegal drugs as well as cotinine (a byproduct of nicotine). Women will receive a urine pregnancy test.

At the midpoint of your training (at about 6 weeks), you will return to VABHS for a "check in" with the exercise physiologist and the principal investigator. At this time, you will bring in your actigraph device for downloading of your exercise activity data. You will repeat the cardiopulmonary exercise test and cold pressor task (session A above) and you will receive a modified exercise prescription, based on your performance over the first 6 weeks of your training. You will also complete questionnaires of mood, pain, distress and exercise motivation.

The entire exercise training program will involve up to 36 in-clinic exercise training/check-in sessions, each lasting up to 1.5 hours (including warmup and cool down) over the course of the twelve weeks. You will be paid $10.00 for each in-clinic training/check-in session.

C. Tests After the 12-Week Exercise Training Program (Visit 43, about 4-5 hours)

Once you have completed the 12 weeks of exercise training, you will return to the clinic at Jamaica Plain campus of VABHS during weeks 14 or 15 and repeat the cold pressor/CPX test session as described under Section A above. This will allow us to see whether your exercise capacity, stress hormone system, and pain, mood, or PTSD symptoms have changed in response to the progressive exercise training. Finally, we will call you one month and three months after the final exercise test session. During these calls, we will conduct a brief check-in and ask you questions related to any mood, pain or PTSD symptoms you may be experiencing as well as your current exercise behavior and associated motivation.

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3. Reasonably foreseeable discomforts or inconveniences of the study:

1. Participation in the exercise test itself may feel physically uncomfortable. However, you will only be instructed to exercise for as long as you feel reasonably comfortable. At any point that you feel too uncomfortable, you are free to stop the exercise.
2. Placement of the IV or butterfly needle for the blood drawing may initially feel uncomfortable.
3. Pain is an expected part of the cold-pressor test. You are asked to remove your hand from the cold water when you can no longer tolerate the pain. It can then take several minutes for the pain to subside. Again, there is a limit to the amount of time that you are allowed to leave your hand in the cold water; you are therefore not at risk of freezing your hand.
4. If you take pain medication, you will be required to be off of pain medication for about 24 hours prior to the exercise testing session.
5. Women Only: Scheduling the exercise test to coincide with the desired phase of the menstrual cycle can be a challenge and may lead to a delay in scheduling until the next month.
6. Men may need to have parts of their chest hair shaved in order to properly attach electrodes for the EKG procedures during the screening session as well as the cold pressor/exercise test sessions.

4. Reasonably foreseeable risks of study:

1. There are some medications and psychological treatments that have been found to be effective for at least some of the symptoms of PTSD and chronic pain. Participating in this study could delay initiation of such treatment.
2. Going over your trauma history during the screening for this study can be stressful and sometimes can increase anxiety or PTSD symptoms. Please let the person conducting this interview know if you become too uncomfortable, or contact the researchers (see the phone numbers on the last pages this consent form) if your symptoms bother you after you go home. They or another licensed mental health professional will be contacted to evaluate you by phone or in person, if necessary, to see if any further treatment is needed.
3. If, in the opinion of study personnel, any of your symptoms (e.g., depression, PTSD, chronic pain), seriously threaten your ability to function or your safety, your participation in the study will be ended and you will be referred for appropriate treatment. You will be asked to sign a form for release of information so that your provider can be informed, whether or not you are a

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VA patient. If such a situation is emergent, your confidentiality may be violated to the extent necessary to ensure your safety. You may be referred to a psychiatric emergency room for further evaluation, against your will, if necessary.

4. It is possible that it may take up to 2 hours from the time of your urine test to the time when we may receive the results of the test, although the study staff will try to obtain the results more quickly. Therefore, it is possible that you may complete certain study procedures before we know whether your test is positive for illegal drug use in which case you will not be compensated for the time already spent completing study procedures.
5. Cardiopulmonary exercise testing is generally associated with a 1 in 10,000 chance of a bad reaction (heart attack or dying). In unselected populations, which include persons referred for exercise testing because of cardiac symptoms, the risk of myocardial infarction or death from exercise testing is approximately 1 in 2,500. Specifically, the risk of death has been estimated at less than one hundredth of one percent. In a non-symptomatic population, selected to have no history, signs, or symptoms of coronary artery disease (as in this study), the risk of harm would be expected to be even lower. There will be a cardiologist or qualified nurse directly supervising the performance of the exercise test to be sure that you are maximally safe and well cared for if any problems develop. Other problems that might develop from a CPX test include heart rhythm abnormalities and skin reactions to the electrode leads. The cardiologist or nurse will administer care for any problem that may arise and will coordinate any needed further care with your doctors.
6. Some PTSD patients report increases in anxiety, intrusive thoughts, or other re-experiencing symptoms of PTSD during exercise. If this occurs during exercise testing, you may stop exercising. In addition, a psychiatrist or psychologist present at the test will talk with you to determine whether any additional treatment should be offered to help with such symptoms. If an increase in PTSD or anxiety symptoms persists or occurs after you leave the VA, you should call the phone numbers on the last page of this consent for assistance.
7. Blood drawing and placement of an IV or butterfly needle may cause pain, minor bruising, infection, or rare fainting. Having you lie down for the IV or butterfly needle placement will minimize the risk of fainting and use of sterile techniques by an experienced clinician minimizes the risks of pain, bruising and infection.
8. The amount of blood sampled during this study over 4 months will be about 300 cc (or about 16 tablespoons which is equal to a little more than 1/2 of a standard blood donation).

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9. There may be circumstances in which your participation may be terminated by the investigator without your consent (e.g. safety concerns, no longer meet eligibility criteria, or administrative issues that may interfere with continuation of the study).
10. The treatment or procedure may involve risks that are currently unforeseeable. In addition to the risks listed above, you may experience a previously unknown risk or side effect.
11. Since some medications can increase your risk for cardiac abnormalities, as an extra safety precaution, we will do an additional EKG prior to any exercise testing (baseline and endpoint) and will have it reviewed/approved by the on call cardiologist immediately. Should the EKG indicate that you are at any additional cardiac risk when undergoing the exercise test, you will be withdrawn from the study and paid in full for the session.

5. Expected benefits of study:
There are no direct benefits to you from participating in this study. The results of your screening physical examination, laboratory testing, and cardiac stress testing will be made available to you if you wish.

6. Other treatment available:
This study is not intended to provide treatment for your PTSD symptoms but could benefit your chronic pain symptoms. As an alternative to participating in this study, the researchers can provide you with information about available treatment programs for PTSD and/or chronic pain. You are free to withdraw from this study at any time.

Use of research results and Confidentiality: Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

a) Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way.

Subject's Name: _____ (Last) , _____ (First) **Date:** _____

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained. If research does not require documentation in the medical record the SSN should not be obtained)

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b) Only the research team will have access to the information collected from you for this study. The paper data collected from this study will be kept in a locked cabinet in a locked office, while the electronic data will be coded and stored without personal identifiers on secure VA servers. The digital audiotape from your psychiatric screening evaluation will only have a code without personal identifiers as a label. Only members of the research team will have access to the digital recording, which will be used to monitor diagnostic accuracy and destroyed at the end of the study. Any personally identifiable information (i.e. this signed Informed Consent Form) and the file that links your personal identifying information to your research code will be kept on a separate drive of the server with password protection or in a locked cabinet in a different locked office from the other information collected in this study.

c) Because you will be providing some information on illegal activities, such as drug use, there is a slight risk that your records could be subpoenaed. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences. The researchers will use the Certificate to resist ant demands for information that would identify you, except as explained below:

The Certificate cannot be used to resist a demand by personnel of the United States Government for information used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: in the event that you report engaging in behavior that constitutes child abuse or elder abuse as defined by the Commonwealth of Massachusetts; or, if you are deemed at immediate risk of suicide; or, if you are deemed to be at risk for doing bodily harm to a specifically identifiable individual.

Subject's Name: _____ (Last) , _____ (First) **Date:** _____

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained. If research does not require documentation in the medical record the SSN should not be obtained)

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d) Your research records will be kept indefinitely or until the law allows their destruction in accordance with the VA Record Control Schedule (wwwl.va.gov/NHAPUBLICATIONS/RCSlO/rcsl0-1.pdf).
Records will be destroyed, when allowed, in the following manner:

- Paper records will be shredded.
- Electronic records will be destroyed in a manner in which they cannot be retrieved
- Digital images (i.e. audio recordings) will be destroyed in a manner in which they cannot be retrieved.
- Tissue samples will be discarded - five years after the end of the study - with biological laboratory waste or pick-up and disposal by VABHS Environmental Management Service.

e) Your research records and the information within them will not be used for any purpose other than that which is described in the study as approved by the IRB.

8. New Findings: You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

9. Special circumstances: A veteran subject will not be required to pay for medical care and services received as a subject in an approved VA research study. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

1) *Economic Considerations:* Specifically, participants will be compensated $90 for participation in the full screening evaluation, $100 for participation in each CPX-CPT session (3 total), $10 for in clinic exercise training sessions (up to 36 total) and, $5.00 for each telephone call (during weeks 3 through 12 (up to 10 total). If the participant participates in all of the study procedures over the ~6-month study, he/she will be compensated up to $800.00.

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You may stop your participation in the study at any point. The only risk is that you would forfeit payment for any parts of the study that you have not yet started. For instance, if you started an exercise test and then decided to stop the procedure, you still would be paid the full $100.

You consent to the release of personally identifying information about you including your name, address, and the last 4 of your social security number to the Fiscal Office of the VA Boston Healthcare System so that we may provide compensation to you. If payment is made to you by the VA (by cash voucher), an IRS Form 1099 will be generated regardless of the amount you are paid. 2) *If you must travel more than 2 hours to participate* in this study, overnight accommodations can be provided to you free of charge. If you require financial support for transportation, it can be provided.

3) *Based on your home address on file,* if you reside at a distance of 50 miles or greater (round trip) from VABHS, you are eligible to receive $5 for each 10 miles of travel above 50 miles, for a maximum of $50 (or 100 miles) per visit.

10. Rights of Recourse: In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

11. Study Monitoring: You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Human Studies Subcommittee and Research Oversight Committees of this hospital, the VA, federal agencies, the Office for Human Research Protection (OHRP), the Government Accountability Office (GAO), and other national research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff.

12. RESEARCH SUBJECT'S RIGHTS:
I have read or have had read to me all of the above. The study person named below has explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained. If research does not require documentation in the medical record the SSN should not be obtained)

VA Boston IRB # _____
Approval Period: _____

Principal Investigator: Erica Scioli, PhD

Title: Neurobiological Mediators of Self-Regulatory and Reward-Based Motivational Predictors of Exercise Maintenance in Chronic Pain and PTSD

I understand that if I have any medical questions about this research study, I can call **Dr. Erica Scioli** at ***(857) 364-5696*** during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. Erica Scioli** at ***(857) 364-5696*** during normal working hours.

I understand that if I have any medical problems that might be related to this study that I can call **Dr. Erica Scioli at 857-364-5696** during the day. I can also call the **VA Medical Center operator at 617-323-7700** and ask for the fellow on call for the Psychiatry or Medical Service after hours.

I understand that, if at any point during or after this study I have any questions about my rights as a research subject or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Subject's Signature	**Month Day Year**	**Name (print)**
Signature of Person Obtaining Consent	**Month Day Year**	**Name (print)**
Signature of Witness	**Month Day Year**	**Name (print)**

Subject's Name: _____ , _____ **Date:** _____
Last First

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