1. OVERVIEW OF THE RESEARCH STUDY:

We are asking you to be in a research study that will be conducted online or in person, between you and members of the Translational Research Center for TBI and Stress Disorders (TRACTS) study staff. This research is being supported by the Department of Veteran Affairs Rehabilitation Research and Development Service. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to better understand traumatic brain injury (TBI) and stress disorders in Veterans who have served in the military after the attacks on America on 9/11. This study will assess your medical history, current health status, and your psychological well-being. If you agree, you will be asked to complete online questionnaires and participate in a clinical interview. From there, you will receive feedback conveying the findings from the assessment and may be provided with a number of choices of follow-up research and/or clinical options that you may or may not wish to participate in. These referral options include:

- A Brief Assessment of Thinking, which is a neuropsychological/cognitive assessment that will be conducted to gather information about your functioning in the areas of memory, attention, and thinking.
- STEP-Home-Brief, which is a 1-3 session, skills-based rehabilitation workshop that targets potential area(s) of weakness identified by the assessment, and will help you with the transition from military to civilian life.
- At-Home Exercise program will provide you with an at-home, 5-week program targeting cardiovascular health and endurance.
- Referrals to existing VA research and clinical programs as appropriate. These referrals may include, but are not limited to, the 12-week STEP-Home workshop research study (VABHS IRB# 3210), Polytrauma, Center for Returning Veterans, Whole Health, PTSD, Mental Health, Vocational Rehabilitation, and Neurology.

Additional assessment or treatment options that best meet your needs will be informed by a consensus of the V-TRACTS clinical team. It will be your choice whether you want to participate in any one or more of the cognitive assessment or rehabilitation options.

When you complete the program(s) that you choose, you will be asked to complete a number of online assessments to see whether the program was helpful to you.

We expect there will be a minimum of four visits for you to complete this study. The first visit will be conducted online where you will complete questionnaires that will take 45-60 minutes to complete. The second visit will be a clinical interview with a TRACTS Psychologist or Clinical Research Fellow that will take 45-60 minutes. The third visit will be a feedback appointment that includes discussion of possible options for further assessment and/or treatments that differ in time commitment as described below that will take 15-30 minutes. The fourth visit will include brief, online follow-up questionnaires to assess your daily functioning that will take 15 minutes to complete. We will describe each of these visits in more detail later in this form.

You might choose to volunteer in the study to learn more about your health status or because you can choose your treatment plan to best help your situation. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study if you may become anxious or fatigued from the online assessments or clinical interview. You will find more information about these risks later in this form.

Alternate treatments/procedures include treatment as usual at VA Boston and will be under the supervision of your doctor or caregiver. You will find more information about alternate treatment/procedures later in this form.

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

2. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to test the feasibility and acceptability of a wholistic, research-informed targeted assessment, feedback, and treatment for post-9/11 Veterans. More specifically, we will combine assessment, feedback, and intervention options to provide precision treatment to you. Depending on the results of the initial assessments and clinical interview in this study, you may then be offered supplemental assessment and/or different treatment modules, such as STEP-Home-Brief, At-home Exercise program, or other VA Boston clinics, including STEP-Home 12-week research study.

This research study is funded as a Development Project within the TBI National Network Research Center by the Department of Veterans Affairs Rehabilitation Research and Development Service called the Translational Research Center for TBI and Stress Disorders or TRACTS. If you agree, the data collected from your participation will be made available to other investigators who are conducting research studies that are approved by the VABHS Institutional Review Board and who have the written consent of the TRACTS Director or Associate Director**.**

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

The general requirements of the study include:

- Visit 1: Brief Online Self-Report Assessments (Questionnaires: 45-60 minutes)
- Visit 2: Clinical Interview (one-on-one with TRACTS Psychologist/Clinical Research fellow: 45-60 minutes; online or in person)
- Visit 3: Feedback Visit by the Psychologist conveying findings from the assessment (15-30 minutes; online or in person) and targeted referral options with a feedback report
- Visit 4: Brief Follow-Up Assessment (Questionnaires: 15 minutes)

Visit 1/Visit 2 Overview: This assessment will target the domains of head injury, psychological trauma, depression, suicidality, anxiety, chronic pain and sleep, substance use, and physical activity level.

Background and Health Portion

The collection of background and health information will be done through questionnaires. You will be asked general questions about your background and medical history (e.g., educational level, smoking history, past surgeries/illnesses).

Functional Outcome & Health Assessment

Questionnaires will be used to assess any cognitive or behavioral symptoms associated with military service, general functioning with regard to cognition and activities of daily living and physical disability.

Mood/Emotional Assessment

An evaluation will be conducted to assess your mood, emotions, and psychological status. Questionnaires and interviews will be used to assess any lifetime exposure to traumatic events, depression, anxiety, sleep, pain, alcohol/substance use, combat and blast-specific events, and psychiatric symptoms.

Visit 3: A 1:1 conversation with a TRACTS psychologist or Clinical Research Fellow to review in detail the results of your assessment from Visit 1 and Visit 2. This will consist of a discussion regarding your strengths and weaknesses determined by these questionnaires and clinical interview. At this visit, the psychologist or clinical research fellow will provide you with the opportunity to continue your participation in one of these additional research modules as part of this study. We will also let you know about clinical programs that may be of interest to you, and other research studies that you may wish to participate in. These referral options include:

1) Brief Assessment of Thinking: An assessment will be conducted to gather information about your functioning in the areas of memory, attention, and thinking. Testing will be conducted in a single session, and it will take approximately 45-90 minutes to complete (conducted online or in person at the VA). This is a module of this research study.
2) STEP-Home-Brief workshops: (1-3, 90-minute sessions conducted online or in person at the VA) designed to help you reintegrate/adjust to civilian life. This is a program that will teach you 4 core skills (problem solving, emotional regulation, attention training, and health and wellness) using examples from your life that we have identified that you may benefit from. These workshops may be conducted in group format (minimum of 3 and a maximum of 10 participants) or individually. This is a module of this research study.
3) At-home Exercise Program: This is a 5-week, full-body exercise program that can be done in the convenience of your home, using only your bodyweight as resistance and with household items as equipment. During your initial meeting, you will be guided through a brief muscular fitness assessment by the TRACTS Exercise Physiologist or study staff member to assist in the development of an exercise prescription appropriate for your fitness level. A 1-minute push-up test and a 1-minute repeated-squat test will be used to measure your upper and lower-body muscular fitness. You can expect this session to last about 20-30 minutes. You will be asked to perform as many proper form push-ups as you can in one minute, and then after a rest you will be asked to perform as many proper form bodyweight squats as you can in one minute. At the end of this program, you will complete this same brief muscular fitness assessment again. These fitness data will be used to assess changes in your muscular fitness over the course of the study. The program will encourage you to complete three exercise sessions per week on nonconsecutive days (e.g. Monday/Wednesday/Friday). The exercise sessions will follow a circuit training format, where you will complete a series of upper and lower-body exercises in succession, alternating between periods of exercise and rest. The goal is to increase fitness levels and meet the recommended level of weekly physical activity. Given the online delivery of this program, you will receive access to instructional videos and materials that demonstrate how to perform each exercise safely and correctly, you will be asked to record the number of exercise sessions completed each week. You will be contacted by a staff member weekly via

phone to encourage you and see if you have any questions about the program. This is a module of this research study.

4) Referral to 12-week STEP-Home workshop (a TRACTS-affiliated research study funded by VA). This research study teaches the same skills as "STEP-Home-Brief" from above; however, over the span of 12 weeks, you will have one, 90-minute session per week. This is a referral to a separate research study.
5) Clinical referrals to VABHS clinical services based on assessment and patient-directed primary problem/complaint. This is a referral to a separate clinical service.

Visit 4 Brief Follow-Up Assessment:

You will be asked to complete online questionnaires on daily functioning and asked how satisfied you are with the program. You will be asked to do this after you participate in one of the research programs or after your clinical referral.

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There may be some discomfort in the form of boredom and fatigue when completing assessments and questionnaires. You may take rest breaks as needed. There is also a chance you may become fatigued during the workshop sessions or exercise; if so, you may take a rest break.

Overall, this study poses low risks to you. During the screening questionnaires and the intervention, you may become anxious or fatigued. While the questionnaires and the intervention can be associated with emotional distress, every effort will be made by the evaluators to make the process as comfortable as possible; distressed participants will be referred to either the Principal Investigator (PI) or staff psychologist, who are both clinical psychologists, to assist with possible treatment or referral. You are free to discontinue your participation at any time.

Self-Report Questionnaires/Clinical Interview: Some people may become mildly uncomfortable about being asked about their medical, psychological, or vocational history.
STEP-Home-Brief Workshops: Discussing psychological symptoms, vocational, and life stressors can increase anxiety for some people. Furthermore, confidentiality cannot be guaranteed in a group setting.
At-home Exercise Program: Some people may risk physical injury when doing home-based exercise.

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.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Veterans may learn about their health status by completing the assessments and feedback. Although direct clinical benefit to the participants remains theoretical, participants have often enjoyed participating in medical research in general in the past and have enjoyed the opportunity for contact with other post-9/11 Veterans and research staff members. Veterans participating in the At-home Exercise program may experience improvements in muscular strength and endurance. Regular exercise is also known to reduce the risk of chronic disease, disability and mortality. Veterans participating in other referrals, such as STEP-Home, may gain other knowledge and/or skills.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress. You may withdraw and still receive the same standard of care that you would otherwise have received. If you decide to withdraw, we do not expect any adverse effects on your health or welfare. For data already collected prior to your withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information.

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

Other treatment in addition to that described above may include treatment as usual at VA Boston and will be under the supervision of your doctor or caregiver. The study researchers will discuss these other treatment options with you and refer you to other treatment providers not connected with this research study, if you wish.

8. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

If the study staff determines that you are experiencing mental health issues that interfere with your participation in this study and that you may require more intensive mental health treatment, your participation may be terminated. In the event that this occurs, the PI or staff psychologist will meet individually with you to discuss his/her decision to end your participation and to offer appropriate

referrals. The investigator may continue to use the data already collected prior to your termination, but cannot collect further information.

9. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

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: We will store your information in ways we think are secure. Information collected for the purpose of this research study will be kept confidential. The results of this study may be published for scientific purposes, but your records or identity will not be revealed. Only trained research personnel directly involved in this study will have access to information gathered in this study. Data from this study will be shared with subprojects that are a part of TRACTS. Additionally, other studies under the approval of the VABHS Institutional Review Board who have received specific approval to use data from TRACTS, via the TRACTS data repository, may also have access, but only if you agree to share your data. All shared data will be de-identified.

_____ Please initial here if you **agree** to have your data shared with the TRACTS data repository.

Identifiers might be removed from the identifiable private information. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

To help protect your privacy, we have applied for a Certificate of Confidentiality (CoC) from the National Institutes or Health. With this CoC, we cannot be forced, even by a court subpoena from any Federal, state, or local civil, criminal, administrative, legislative, or other proceeding, to disclose information that may identify you. We will use this CoC to resist any demands for information that would identify you, except as explaiend below.

The CoC cannot be used to resist a demand for information from personnel of the United States Government that is used for audting or evaluting Federally funded projects, or for information that must be disclosed to meet the requirements of the Federal Food and Drug Adminsitration (FDA).

You should understand that this CoC does not prevent you from voluntarily releasing information about you or your involvement in this research. If an insurer, employer, or other person obtains your

written consent to receive research information, then the researchers cannot use the CoC to withhold that information.

The CoC does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a research participant under the following circumstances: in the event that you report engaging in behavior that constitutes child 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 of doing bodily harm to a specifically identifiable individual.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.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.

To comply with laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to self or others.

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

10. WHO ELSE MIGHT SEE MY DATA?

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 Institutional Review Board and Research & Development Committees of VABHS, the VA, Federal agencies, or national research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and her research staff.

11. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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.

12. WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants 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.

You may be compensated up to $115 for your time and effort taking part in this study.

- ***You will be compensated $20 for completing online questionnaires***
- ***You will be compensated $20 for completing the clinical interview***
- ***You will be compensated $10 for completing the feedback session***
- ***You will be compensated $20 for completing the brief assessment of thinking and cognition***
- ***You will be compensated $15 each for completing the pre-exercise fitness assessment and post-intervention assessment (STEP-Home-Brief and/or At-home Exercise Program).***

You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. You can expect to receive a check within 2-6 weeks. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

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 (whether by check or cash voucher), an IRS Form 1099 will be generated regardless of the amount you are paid.

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

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.

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

I understand that if I have any medical questions about this research study, I can call **Dr. Regina McGlinchey** at ***(857) 248-0091*** during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. Regina McGlinchey** at ***(857) 248-0091*** during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Regina McGlinchey** at ***(857) 248-0091*** and **after hours** I can call ***the Medical Center operator at (617) 323-7700 and ask to speak to the psychiatrist on call.***

I understand that, if at any point during or after this study I have any questions about my rights as a research participant 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.

15. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have 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.

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.

Participant's Signature	**Month**	**Day**	**Year**	**Name (print)**