CONSENT TO BE PART OF A RESEARCH STUDY

Participant Name: _____ **Date:** _____

Study Title: New Applications of Neuroplasticity Biomarkers in Veterans with Traumatic Brain Injury or Schizophrenia

Principal Investigator: Jonathan K. Wynn, Ph.D. Phone: [redacted]

INVITATION and KEY INFORMATION

We invite you to take part in a research study about your brain's ability to change its responses to visual and auditory stimuli in Veterans either with a traumatic brain injury (TBI), schizophrenia, or have no psychiatric or neurological diagnosis. We are inviting you because you are a Veteran with either TBI, schizophrenia, or neither.

You do not have to take part in this research; participation is completely voluntary. If you decide not to take part in this study there is no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. We anticipate that your participation will take approximately 8 hours, which you may split over two days if requested. The following information is provided to help you decide whether to participate in this study:

- This study is being done to obtain information on how your brain's electrical responses change over time in response to simple auditory and visual stimuli (this is called neuroplasticity), and how schizophrenia or TBI may impact this important process in your brain.
- This information will be collected by placing small electrodes on the surface of your scalp that are able to pick up the very small electrical signals generated by your brain. Your brain's electrical activity will be recorded while listening to simple auditory tones or viewing simple visual stimuli, such as a checkerboard pattern.
- You will also receive assessments of community integration using questionnaires and interviews, and cognition (for example, learning, memory, identifying social interactions) at a preliminary visit. We will ask you to refrain from taking any sedative or benzodiazepine at least 12 hours prior to these visits.
- You will be given a psychiatric interview that asks questions about any symptoms you may have experienced throughout your life or when and how your brain injury happened, and your history with alcohol and substance use. You may be uncomfortable answering some of these questions.
- The study has obtained a Certificate of Confidentiality as another level of protection for your data collected under this study.

CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: New Applications of Neuroplasticity Biomarkers in Veterans with Traumatic Brain Injury or Schizophrenia

Principal Investigator: Jonathan K. Wynn, Ph.D. [redacted]

BACKGROUND AND PURPOSE

We expect about 150 people at the VA Greater Los Angeles Healthcare System will participate in this research.

Veterans with schizophrenia or TBI often experience cognitive difficulties in such areas as attention, memory, learning, speed of processing, and processing of social information. These difficulties in turn make it difficult to integrate into the community (for example, obtaining work, making new friends, having contact with family). It is thought that *neuroplasticity*, a term that refers to how the brain can adapt its functioning and structure at the level of the neurons, in response to our experiences with the environment. We know that neuroplasticity is a fundamental brain process that underlies important non-social cognitive functions such as learning and memory, and social cognitive functions, such as emotion and facial affect processing. There is strong evidence that neuroplasticity is impaired in people with schizophrenia or TBI which in turns leads to poor cognition.

Previous studies of neuroplasticity were limited to examinations in animals, through invasive medical procedures in humans (such as putting sensors inside the brain), or through examination of brain tissue after death. Recently, methods using non-invasive measures using electroencephalography (EEG; the recording of the brain's electrical activity) have been developed to safely and comfortably assess neuroplasticity in the human brain. However, these measures have only recently been explored in people with schizophrenia and have not been explored in people with TBI to the best of our knowledge. We hope to gain a better understanding of how neuroplasticity is affected by these two disorders.

INVESTIGATOR DISCLOSURE

Sponsor: This study is funded by the Department of Veterans Affairs.

If any doctor listed on this consent form is your treating physician, he (or she) is also an investigator for this study. As an investigator, he (or she) is interested not only in your clinical welfare, but also in the results of this study. It is possible that occasionally these two goals may be in conflict. At any time during this study, you may ask for a second opinion from another doctor who is in no way associated with this study.

CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: New Applications of Neuroplasticity Biomarkers in Veterans with Traumatic Brain Injury or Schizophrenia

Principal Investigator: Jonathan K. Wynn, Ph.D. [redacted]

DURATION OF THE RESEARCH

Your participation in this study will take approximately 8 hours spread over two days.

STUDY PROCEDURES

All study activities are being conducted for research purposes. If you choose to participate, you will be asked to do the following:

Day 1 (3 hours)

- Complete interviews that assess psychiatric diagnoses, psychiatric symptoms, brain injuries, and community functioning. In some cases, we will need to review your medical records to corroborate any potential psychiatric or neurological diagnosis.

Due to the COVID19 Pandemic and to reduce the risk for spreading the virus, you are being offered to have your interviews conducted with an interviewer in a remote location. If you agree to having the interview be conducted remotely you will be placed in front of a camera attached to a VA computer in a private room located in Building 210. The interviewer will be in a remote location, either within Building 210 or at their private homes, and will conduct the interview using their camera using approved VA technologies, including but not limited to VA Video Connect, Zoom, Microsoft Teams, Google Meet, or Apple FaceTime. The video will NOT be recorded. If you do not want the interview to be conducted remotely you will still be able to participate in this study with an in-person interview following all VA-approved COVID safety protocols. Please check YES in the checkbox below if you are willing to have the interview conducted remotely and initial your response or check NO in the checkbox below if you want the interview to be conducted in-person and initial your response.

☐ YES, I agree to have my interview conducted remotely. Initials: _____

☐ NO, I prefer to have my interview conducted in-person. Initials: _____

Day 2 (5 hours)

- Complete assessments of your brain's electrical activity using electroencephalography (EEG). EEG is a non-invasive procedure. You will wear a cap that contains several small electrodes. The cap and electrodes simply sit on the surface of your head. A gel will be squirted under each of these electrodes. The gel can be easily washed out of

your hair when the recording session is completed. Additionally, you will have electrodes placed above your left eyebrow and below your left eye, to the out edge of your left and right eye, and on the tip of your nose. For the EEG you will complete two separate tasks:

- You will listen to a series of brief auditory tones while you watch a silent movie. We will ask you questions about the movie at the end of the recording. You do not need to pay attention to the tones. The tones will be delivered by small tubes attached to a small piece of foam inserted in the outer ear canal.
- You will view a series of simple visual stimuli (black and white checkerboards) that will quickly flash on a computer screen. You will also see a small dot at the center of the screen that will occasionally change color from red to green and back. You will press a mouse button whenever you see this small dot change color.

- Complete assessments of your cognition. You will be given standard computer and pen-and-paper tasks that assess your attention, memory, learning, and speed of processing. You will also view a series of videos of a person recounting a brief personal story. You will use a computer to continually rate how you think the person was feeling while telling the story. Finally, you will view a series of photos of faces on a computer depicting several different emotions. You will be asked to identify the emotion on each face.

POSSIBLE RISKS OR DISCOMFORTS

This study involves the following risks, discomforts, and possible inconveniences:

- If taking a sedative or benzodiazepine, we will ask you to refrain from taking these medications 12 hours prior to your study visits. You may find that not taking these will impact your normal sleep, you may become more anxious, or you may experience a headache or slight tremors. You may choose to reschedule your visit for another day if you feel you cannot stop taking these medications, or you may withdrawal from the study.
- You may feel upset while responding to questions during interviews and questionnaires. You can choose not to answer any question that makes you uncomfortable.
- You may find the tasks boring and you may become tired or restless. You will be able to take as many breaks as you wish or reschedule testing for another day.
- You may find the EEG cap to be uncomfortable due to its snug fit to your head. Though rare, you may get a headache from wearing a cap that may be too tight. You will be asked during setup of the EEG how the cap feels or if it is too tight and we will use a larger cap.
- As in any research study, it is possible that personal information about you could become known to other people. The investigators will take precautions to prevent this from happening. Your name will not appear on any interviews, questionnaires, or tests that you complete during the study. Instead, all information tests in the lab will be coded with a unique, random identifier.
- If you elected to have your interview conducted remotely, there is a small risk that the video is not fully secure and your information divulged in the interview may be made public if somebody intercepts the video.

POTENTIAL BENEFITS

Although you will not benefit directly from being in this study, the scientific knowledge (or information that may result) may help doctors understand and develop new treatments for Veterans with schizophrenia or TBI

CONFIDENTIALITY – DATA PROTECTION DURING RESEARCH STUDY

Taking part in this study will involve collecting private information about you. We will protect the confidentiality of your research records in the following ways:

- Your research data in this study will be identified only by an assigned study number. All physical data collected will be coded where possible (for example, using a random subject number instead of your name), and original documents with sensitive information (such as your name) will be stored separately from coded data.
- Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project
- All physical data will be stored in locked drawers in locked offices. Electronic data with identifiers (such as your name or birth date) will be password protected, encrypted and stored on the secure VA network, and no data with identifiers collected at the VA will leave the VA lab space.

We will keep your name and all the information about you used in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

This study is funded by the Department of Veterans Affairs. The Department of Veterans Affairs will receive results of analyses, but no identifiable data or source documentation will leave the VA. The study results may also be used in reports of the study, scientific presentations, and/or publications, but your identity will not be disclosed.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is 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 information then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

SHARING OF INDIVIDUAL AND OVERALL RESEARCH RESULTS

This is a study which is not designed to give us any information about your health. Generally, tests done for research purposes are not meant to provide clinical information and therefore no results from this study will be shared with you.

Aggregate results: Results from this study will be published in research journals when the study is completed. You may visit the study site (http://greenlab.dgsom.ucla.edu) where results from this project and other VA project results are listed. It is anticipated that results from this study should be publicly available in three years' time.

DATA USE/SHARING WITH RESEARCHERS

We will not keep your research data to use for future research or other purposes. We will not share your research data with other investigators.

WITHDRAWAL FROM PARTICIPATION

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

If you want to stop being in the study, you should tell the investigators or study staff. You can do this by phone by calling Jonathan K. Wynn, Ph.D., [redacted]. You should

ask for a HIPAA revocation form, which you can sign in order to revoke any data collection. The study staff can provide this to you upon request.

PARTICIPANTS' RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

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

COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any treatments or procedures that are part of this research study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

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

PAYMENT OFFERED FOR PARTICIPATION

You will receive $15 cash for each hour of participation in the study procedures conducted in our VA offices. You will receive up to $13 to cover your travel costs, which is also applicable if you make more than one visit to our lab. We estimate that your participation will take a total of 8 hours over two days; you will be compensated up to $146 for your participation. You will be paid in cash at the end of each of your visits to the lab. If you choose to withdraw from the research before the end of the study, you will be compensated for all the procedures you have completed up to that point.

With few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A Form 1099 will be sent to you if your total payments for research participation are $600.00 or more in a calendar year.

PERSONS TO CONTACT ABOUT THIS STUDY

CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: New Applications of Neuroplasticity Biomarkers in Veterans with Traumatic Brain Injury or Schizophrenia

Principal Investigator: Jonathan K. Wynn, Ph.D. [redacted]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Greater Los Angeles Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Greater Los Angeles IRB at 1-310-268-4437 if you have questions, complaints or concerns about the study, or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment (if applicable) available to you. You have been given the chance to ask questions and obtain answers.

The California Bill of Rights of Human Subjects in Medical Experiments is provided.

California Bill of Rights of
RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: New Applications of Neuroplasticity Biomarkers in Veterans with Traumatic Brain Injury or Schizophrenia

Principal Investigator: Jonathan K. Wynn, Ph.D. [redacted]

SIGNATURES

By signing, you are agreeing to volunteer for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent. Your signature also confirms that The California Bill of Rights of Human Subjects in Medical Experiments has also been given to you. A copy of this signed consent will be retained in the investigator's research records.

I agree to participate in this research study as has been explained in this document.		
Participant's Name	Participant's Signature	Date