SHEPHERD CENTER, INC.
RESEARCH PATIENT INFORMATION AND CONSENT FORM WITH AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

TITLE: Expanding Access to mTBI Treatment for Veterans and Service Members with Co-Occurring Substance Use – *Clinical Trial Participants*

SPONSOR: Department of Defense, Congressionally Directed Medical Research Programs

INVESTIGATOR: Russell K. Gore, MD, Principal Investigator

PROJECT NO.: 981

PARTICIPANT NAME: _____MR #: _____

This form is called an "Informed Consent Form." Its purpose is to give you information about a research study, about study procedures to be followed, alternatives to this treatment, any possible risks and benefits, and your rights as a research participant. Study personnel will go over this form with you. You should read this Informed Consent Form carefully and ask questions before you decide whether or not to agree (consent) to participate in this study. If this Informed Consent Form contains any words that you do not understand, please ask study personnel to explain it to you. You may take as much time as you wish to make up your mind about whether or not to participate. If you agree to participate, we ask that you sign this showing that you understand the purpose of the study and are volunteering to participate. You will be given a copy of this Informed Consent Form to keep.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

A. BACKGROUND INFORMATION

Traumatic brain injury (TBI) can cause significant problems related to thinking and memory, movement, sensation, and emotions. Many U.S. military service members and veterans report a history of experiencing one or more TBI's and may have ongoing symptoms after injury. Substance use can limit participation in TBI treatment programs for some of these individuals, and treatment for substance use disorders and TBI has historically been completed separately. There is a need for research that can describe what substance use looks like among service members and veterans seeking TBI treatment and for an improved understanding of problems (including substance use, pain, and mental health symptoms) which may influence the response to TBI treatment.

This study will enroll veterans and active-duty service members with TBI histories who are interested in and eligible for participation in treatment with the SHARE Military Initiative. This study will recruit both individuals who do and do not have substance use histories or ongoing substance use.

B. PURPOSE OF STUDY

The main goals of this study are to evaluate the combined treatment of TBI and substance use including completion of treatment and changes in symptoms. The study aims to identify factors that predict treatment outcomes and completion and evaluate improvements in symptoms six months after completing the program. Results from this study have the potential to improve understanding of treatment needs for veterans and service members with TBI histories and to inform future improvements in treatment.

C. PROCEDURES

Participants in this study will be recruited from the Shepherd Center based on their expressed interest in comprehensive treatment for TBI in the SHARE Military Initiative Program. To participate in this research study, you must be eligible for treatment in the SHARE program and be experiencing ongoing mild TBI symptoms.

Participation in the study involves completing a series of questionnaires at three time points. The questionnaires will ask about general functioning, TBI symptoms, mental health symptoms, and substance use (including use alcohol, and/or other drugs). Questionnaires will be completed online through REDCap, a secure, HIPAA-compliant web application, unless you prefer to complete forms on paper or technical difficulties prevent use of the computer application. You may complete these questionnaires in the SHARE clinic or from home. While you are completing questionnaires, you will have access (either in person or by phone) to a member of the research study staff, in case you have questions or concerns about completing the measures. To protect your privacy, this person will be someone who is not part of your clinical treatment team.

Examples of questionnaire items include:

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We will also ask you to allow research staff to access information in your medical records for the purpose of answering research questions.

Each assessment session is expected to take less than 30 minutes to complete. To minimize the length of assessment sessions, we will not ask you to repeat questionnaires that you have already completed for your treatment within the past two weeks. There are three total sessions over the course of the study. Below are the scheduled assessment session time points for this research study:

- **Enrollment** assessment to be completed during the initial evaluation period with SHARE providers

- Assessment session at the time of **discharge or graduation from SHARE program**

- Follow-up assessment session **6 months after discharge from treatment**

Example items from the questionnaires include:

- In the past 30 days, how many days have you consumed any alcohol?
- Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?

Early Withdrawal from the Study

You have the right to leave a study at any time without penalty. Please inform any study staff member in writing if you wish to withdraw from the study.

D. RISKS AND DISCOMFORTS

We do not anticipate significant risks or adverse events during this study. Any medical emergencies will be addressed per SHARE program protocols.

The most common risk with this study would be the potential for mild emotional discomfort when reporting on symptoms, similar to what you might experience when reporting on symptoms in a treatment session. You may opt not to answer individual questions on assessment measures without any penalty.

Please tell study staff if you believe you have experienced an adverse event during the study. Staff will be happy to answer any questions. You should report any discomfort and/or emergencies during the study to your study doctor at (404) 603-4980.

E. BENEFITS ASSOCIATED WITH THIS STUDY

This study is not designed to benefit you directly. This study is designed to learn more about predictors of outcomes in TBI treatment in order to inform improvements in treatment for TBI and for co-occurring TBI and substance use disorders. Thus, the study results may be used to help other veterans and service members in the future. You will not have any rights to new procedures or products developed as a result of this research.

F. NEW FINDINGS

All new information learned during this study which could affect your willingness to continue to participate in this study will be given to you as soon as such information becomes available. It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

G. ALTERNATIVE TREATMENT

You may choose not to participate in the study, and this choice will not affect the care that you would otherwise receive. Treatment decisions in the SHARE program and referral to any outside treatment will be based on the best clinical care for each individual patient and will not be affected by a person's study participation.

H. RIGHT TO WITHDRAW FROM STUDY

Your participation in this study is entirely voluntary. You have the right to withdraw from the study at any time and for any reason. There will be no penalty or loss of alternative medical treatment or benefits to which you may be otherwise entitled. If you withdraw from the study, you must contact the study investigators immediately. For your protection, you may be asked questions about your experience during the study. By signing this consent from, you do not waive any of your legal rights.

I. REASONS FOR REMOVAL FROM THIS STUDY WITHOUT YOUR CONSENT

The study staff and researchers have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- Or for any other reason.

J. COST OR PAYMENT TO YOU

There will be no charge for participation in the study. Participation will not change the way you pay for normal health care.

You will be paid for your time spent completing additional measures for this research study. Please note that active-duty military personnel must be participating while off-duty to be compensated.

The schedule for payments lines up with the schedule for assessment sessions and is as follows:

- **Enrollment** assessment completed during the initial evaluation period: **$20**

- Assessment session at the time of **discharge or graduation from SHARE program**: **$20**

- Follow-up assessment session **6 months after discharge from treatment**: **$50**

You will be paid for each assessment upon completion of that session. Payment will occur only for the assessment sessions attended and completed. If you miss an assessment session, you are still eligible to complete future scheduled assessment sessions up until the final scheduled assessment session.

You can earn a total possible amount of $90 over the course of this research study for your completion of questionnaires at assessment sessions.

K. RESEARCH-RELATED INJURY

If you get ill or injured from being in the study, Shepherd Center would help you to get medical treatment. Shepherd Center and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of a Shepherd Center or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this research study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact the study doctor at telephone number (404) 603-4980. You should also let any health care provider who treats you know that you are in a research study. Signing this Informed Consent Form will not cause you to give up any of your legal rights.

L. CONFIDENTIALITY

Care will be taken to protect the confidentiality of your medical information. Shepherd Center will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish study results or study results are made public. Any researcher who is also a member of your treatment team will only have access to data collected for the purpose of this study after it has been de-identified (i.e., after your name has been removed) to preserve the confidentiality of your responses.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Data Sharing

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a biomedical informatics system and data repository, created by the Department of Defense (DoD) and the National Institutes of Health (NIH) to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat, and prevent traumatic brain injuries. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by qualified researchers only. Before we send the data to FITBIR, we will remove information such as name, date of birth, and city of birth and replace that information with a code number. The NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help FITBIR and participating institutions avoid being forced to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Other researchers nationwide can then file an application to obtain access to your data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you or others. With respect to you, we do not plan to make voluntary disclosures except in response to severe threats to public health or safety. You may also decide now or later that you do not want to share your information using FITBIR. If so, contact the researchers who conducted this study, and they will tell FITBIR, which can stop sharing your research information. FITBIR cannot take back information that was shared before you changed your mind.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time" 21 CFR 50.25(c) For more information see Federal Register; January 4, 2011, Volume 76, Number 2, pages 256 – 270.

M. AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION

By signing this Informed Consent Form, you give permission to the study staff at Shepherd Center to gather, use and disclose (release) your protected health information ("PHI") to certain

individuals or entities in accordance with federal privacy rules. PHI is individually identifiable information that may be gathered, used or disclosed during the study including, but not limited to, medical records (e.g. doctors' notes, hospital charts), results of physical examinations, medical history, laboratory tests, and certain health information indicating or relating to a particular condition.

The individuals or entities who may receive your PHI from the study doctor or study staff include the Federal Government Office for Human Research Protections, the Food and Drug Administration (FDA), the Institutional Review Board, the Data Safety and Monitoring Board, representatives of the study sponsor, insurance companies for billing purposes, and other persons or agencies as required by law or allowed by federal regulations. Those individuals and entities who may receive your PHI may not be required by federal privacy rules (such as the Privacy Rule) to protect PHI and may share PHI with others without your permission, if permitted by laws governing them.

The gathering, use, and disclosure of PHI is routinely carried out during clinical studies. PHI may be gathered, used or disclosed during this study for a variety of reasons including, but not limited to, verification that you are eligible to participate in the study and monitoring your treatment and ensuring that the study is carried out as it should be.

By signing this Informed Consent Form, you are agreeing to the gathering, use and disclosure of your PHI as described above. If you do not agree to the use or disclosure of the PHI as described above, and therefore do not sign this Informed Consent Form, you will be ineligible to participate in the study. If you decide not to take part in this study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. Unless told otherwise, your consent to use or share your PHI does not expire.

You may withdraw your consent at any time and for any reason. If, after signing this Informed Consent Form, you do change your mind, we ask that you contact the study investigators (Dr. Gore and Dr. McCauley) in writing and let them know that you withdraw your consent. Their mailing address is 2020 Peachtree Rd NW, Atlanta, Georgia 30309. At that time, we will stop getting any more PHI about you; however, the PHI we stored before you withdrew your consent may still be used for reporting and research quality.

N. RIGHT TO ASK QUESTIONS

You may freely ask questions about this Informed Consent Form or the study, now or at any time during the study. If you have any questions about this study or have any study-related problems, you may call Dr. Russell Gore or Dr. Katherine McCauley at (404) 603-4980. If you have any questions about your rights as a research subject, you may call Deborah Backus, Ph.D., Chair, Shepherd Research Review Committee at (404) 350-7599.

O. ***Review Questions Instructions:*** Read and discuss the following statements with the person performing the consent discussion with you. As you consider each statement, tell the study staff member whether the statement is true (yes) or false (no). You do not have to circle a response. You will be given enough time to ask questions and review each statement that you do not

understand. Once you understand each statement, you may proceed to the next section of this form and sign this consent form.

Review Questions:

1. The main purpose of this study is to evaluate the combined treatment of TBI and substance use including completion of treatment and changes in symptoms. Yes or No?

2. I will be asked to report on my substance use, my mental health, and my overall functioning through questionnaires at each assessment session. Yes or No?

3. In agreeing to participate in this research study, I am allowing research staff to access information in my medical record for research purposes. Information that I provide for research will NOT be shared with my treatment team, unless there is a medical emergency (e.g., if I say that I intend to harm myself or another person). Yes or No?

4. Participation in the study does not influence my access to treatment or the recommendations for my clinical care. Yes or No?

5. I should tell study staff and my doctor if I have any unusual symptoms or change in the state of my health while participating in this study. Yes or No?

P. CONSENT STATEMENT

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form. My questions have been answered and I will receive a signed copy of this consent form to keep. I voluntarily consent to participate in this research study involving the procedures stated above, with an understanding of the known possible risks that might occur and with an understanding that not all such risks may be completely known. I am aware that I may not benefit directly from my participation in this study. I am also authorizing the use and disclosure of my personal health information. I cannot participate in this research study without this authorization. If I refuse to give my authorization, my medical care will not be affected.

By signing this consent form, I am not giving up any legal rights. I also understand that nothing in this consent form is intended to change any applicable federal, state or local laws regarding informed consent.

You will get a copy of this form after it is signed.

_____ _____

Date Signature of Participant

_____

Printed Name of Participant

Person Conducting the Informed Consent Form Discussion:

_____ _____

Date Signature

_____

Printed Name and Title