Department of Veterans Affairs | VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Studv: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs **VAMC:** North Florida/South Georgia Veterans Health System

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

3. Who can you call if you have questionsconcerns, or complaints about this research study?

Principal Investigator: Dr. J. Kay Waid-Ebbs @ 352-871-0282

or 352-376-1611 X105224

4. Who is paying for this research study?

The sponsor of this study is the Rehabilitation Research and Development Service of the Veterans Administration.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board **(IRB) office at (352) 273-9600** or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

a) **In general, what is the purpose of the research, how long will you be involved?** The purpose of this research study is to determine whether Goal Management Training (GMT) plus attention training is more effective than a control treatment on planning and organization skills for veterans diagnosed with mild traumatic brain injury. We anticipate your participation in this study to be a total of 9 months.

b) **What is involved with your participation, and what are the procedures to be followed in the research?** The research study will include a total of 1-23 sessions. The first session is a screening session where you will answer questionnaires and complete tests of your thinking skills both in-person and over the internet . Some of the tests will determine whether or not you meet the criteria to be included in the study. Typically, testing takes 3-4 hours. After the screening you will be told whether or not you meet the inclusion criteria to participate in the rest of the study. If you do not meet the criteria to continue with the study, you will again confirm that you are OK with the retention of the data collected (results of tests of thinking skills, attention, effort, word reading, planning and problem solving, depression, post-traumatic stress disorder, combat exposure, pain, alcohol use, concussions, symptoms, anxiety, sleep, fatigue, community participation, age, employment status, time from deployment and service). If the test results meet the inclusion criteria you will be scheduled for a test of grocery shopping skills at a local grocery store that will take approximately 1 hour. You will be assigned to either GMT plus attention training

or Brain Health Workshop plus movies. Training consists of 20 weekly 2-hour sessions. Sessions will include an interactive group or individual training conducted using telehealth through the Veterans' Health Administration. You will also be asked to do homework up to five hours a week if you are randomized to the GMT/attention training. Two follow-up testing sessions are approximately 3 hours long and occur once training is completed and repeated six-months after. Additionally, a friend or family member you identify will answer a questionnaire about your thinking skills at each of the three testing sessions.

☐ This study also has an option to engage in an Magnetic resonance imaging (MRI) before and after GMT or BHW if you are not a women with childbearing potential. An MRI is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. The scan will last no more than 90 minutes that includes a 15 minute task where you will select what direction an arrow is pointing and a 15 minute task where you will do nothing. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. Initial the boxes if you are interested in participating in an MRI for this study.

c) What are the likely risks or discomforts to you? The following facts are important in considering your participation in this research:
You may experience some anxiety when answering questions about depression and post-traumatic stress. Additionally, you may become frustrated and/or tired during testing of your thinking skills. Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally.

If you choose the option of participating in the MRI scan, refer to the following potential risks: 1) The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. 2)There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in closed spaces ("claustrophobia"). 3)The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. 4) If you are a woman of childbearing potential, there may be unknown risks to the fetus so you will not be able to participate in the MRI.

Subject Name: _____ Date _____

Title of Study: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs VAMC: North Florida/South Georgia Veterans Health System

d) What are the likely benefits to you or to others from the research? You may or may not benefit from participating in this research study. The possible benefits are that you will have a thorough assessment of your thinking skills. Your participation may improve future treatment of the thinking skills of individuals who have been affected by a traumatic brain injury.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you? As a Veteran, Individual Speech or Occupational Therapy is available to treat difficulties with your thinking skills.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Individual or group cognitive therapy for improving your thinking skills will be available to you, even if you do not wish to participate in this research study.

7. What will be done only because you are in this research study?

The research study will include a total of 1-23 sessions. The first session is a screening session where you will answer questionnaires and complete tests of your thinking skills in-person and over the internet. Typically, testing takes 3-4 hours. If the test results meet the inclusion criteria you will be randomly assigned (much like being selected by the toss of a coin) to one of two groups: #1 Goal Management Training plus attention training or #2 Brain Health Workshop plus movies. Additionally, a friend or family member you identify will answer questionnaires about your thinking skills. You will also be asked to participate in a test demonstrating your grocery shopping skills in a neighborhood grocery store.

#1Goal Management Training plus attention training consists of 20 session, 2-sessions/week that are 2-hours long. Goal Management Training will include interactive power point presentations to learn strategies to plan and organize. Sessions will include lecture, paper and pencil tasks and discussions about strategies. You may participate individually or in a group setting using telehealth.

You will be asked to monitor your behavior at home and use a Smartphone AP to record practicing strategies to plan and organize in the community. Attention training will be conducted during 10-individual telehealth sessions on the computer and for five hours each week at home.

If you were placed in group #2 "Brain Healthworkshop plus movies, you will not participate in GMT plus attention training. Group #2 consists of 20 session, 2-sessions/week that are 2-hours long using telehealth. Lectures and quizzes will be used to learn how the brain works. You will also select movies you are interested in, to view and answer 2-3 questions about the content.

Once training is completed for either group, you will participate in another 3 hour testing of your thinking skills and you will be asked to participate in a test regarding grocery shopping skills in your neighborhood grocery store. Testing of your thinking skills will be repeated again 6 months after training is completed.

☐ During the study, you have the option to participate in an MRI scan, unless you are a women of childbearing age. If you want to pursue this option, you will undergo an MRI scan at the University of Florida MRI facility before and after GMT or BHW. The scan provides an analysis of brain structure, focusing on those areas important for attention and takes approximately 1 hour to complete. While in the scanner you will complete two tasks, one for 15 minutes called the attention network task where you will click a button when a middle arrow points left or right on a video screen. The second task you will do nothing for 15 minutes. This MRI procedure is optional; if you decide to participate in this procedure, initial this box .

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information and that, after such 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.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. How long will you be in this research study?

We anticipate your participation in this study to be a total of 9 months.

9. How many people are expected to take part in this research study?

Subject Name: _____ Date _____

Title of Study: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs VAMC: North Florida/South Georgia Veterans Health System

Approximately 100 people will participate in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

Risks Associated with MRI: Magnetic resonance imaging (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur.

If you choose the option of participating in the MRI scan, refer to the following risks: 1) The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI. 2) There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in closed spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan. 3) The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk. 4) If you are a woman of childbearing potential, there may be unknown risks to the fetus so you will not be able to participate in the MRI.

Question 17 in this form discusses what information about you will be collected, used, protected, and shared.

Subject Name: _____ **Date** _____

Title of Studv: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs **VAMC:** North Florida/South Georgia Veterans Health System

Other possible risks to you may include: You may experience some anxiety when answering questions about depression and post-traumatic stress. Additionally, you may become frustrated and/or tired during testing of your thinking skills. We will call the Veterans Crisis Line (also called the National Suicide Prevention Lifeline 800.273.8255 press 1 for Veterans Crisis Line) if you have thoughts of harming yourself.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study ?

You may or may not benefit from participating in this research study. The possible benefits are that you will have a thorough assessment of your thinking skills.

11b. How could others possibly benefit from this study?

Your participation may improve future treatment of the thinking skills of individuals who have been affected by a traumatic brain injury.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is to do nothing. If you do not want to take part in this study tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- Missing more than two therapy sessions that can't be rescheduled.
- Treating other group members disrespectfully.
- If the Principal Investigator feels that continuation in group therapy is causing too much stress to you.

Subject Name: _____ Date _____

Title of Study: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs VAMC: North Florida/South Georgia Veterans Health System

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however 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 VA-provided medical care and services that are not part of this study.

15. Will you be paid for taking part in this study?

You will receive reimbursement of $25.00 per completed session for a potential of $575.00. If you are randomized to the GMT and attention training you will also be paid $25 for each 5 hours of attention training homework, for a potential total reimbursement of $825.00. If you choose to participate in MRI scanning, you will be reimbursed $50 per completed scan for a potential total of an additional $100.

Your compensation for participation in this research study will come from the VA Finance Office, who will issue payment to you by direct deposit to your bank account.

The US Treasury requires that all participants in this study receive their study related compensation as an electronic transfer of money directly to your bank account. You will need to complete a “Vendor Form for EFT Payments (Direct Deposit)”, and turn it into the VA Finance Office. This form will ask for your name, social security number, and banking information so that the study payment can be processed. Alternatively, you can mail the form directly to Finance Office.

You are responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, has to be reported to the Internal Revenue Service (IRS) because the payment system cannot distinguish payment from reimbursement for expenses.

Subject Name: _____ Date _____

Title of Studv: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs VAMC: North Florida/South Georgia Veterans Health System

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day and (352) 871-0282 after business hours. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Study data will be collected in an application called the University of Florida REDCap on the University of Florida database. Only staff are given access to the application. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this

Subject Name: _____ **Date** _____

Title of Studv: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs **VAMC:** North Florida/South Georgia Veterans Health System

research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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.

Subject Name: _____ **Date** _____

Title of Studv: Combining attention and metacognitive training to improve goal directed behavior in Veterans with TBI

Principal Investigator: Dr. Julia Kay Waid-Ebbs **VAMC:** North Florida/South Georgia Veterans Health System

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date