DECEMBER 6, 2021

EFFICACY AND NEURAL MEDIATORS OF RESPONSE TO TRAUMA MANAGEMENT THERAPY FOR PTSD

NCT03449576

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: **Efficacy and neural mediators of response to Trauma Management Therapy for PTSD**

Principal Investigator: **Brooks King-Casas, Ph.D.** **VAMC:** **Salem**

PRINCIPLES CONCERNING RESEARCH:

You are being asked to take part in a research project. It is important that you read and understand these principles which apply to all individuals who agree to participate:

1. Taking part in the research is entirely voluntary.

2. You may not personally benefit from taking part in the research.

3. You may refuse to participate in this research study or withdraw from this study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If, during your participation in the research project, new information becomes available, your study therapist will discuss this new information with you and will help you make a decision about continuing in the research.

5. Participants in VA-approved research cannot be charged, nor their insurance be billed, for research-related interventions or procedures that are required by the protocol.

6. Participants cannot be charged, nor their insurance billed, for research-related injuries.

7. Some Veterans (or non-Veteran subjects) are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

Subject Name: _____ **Date** _____

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Principal Investigator: **Brooks King-Casas, Ph.D.** **VAMC:** **Salem**

DESCRIPTION OF RESEARCH BY INVESTIGATOR

PURPOSE: Your participation in this research study will help us learn more about how the brain responds to emotional and social information after a traumatic event has been experienced. Specifically, we are looking for people whose traumatic experience may have caused them prolonged difficulties that could lead or have led to a diagnosis of Post-Traumatic Stress Disorder (PTSD). Your participation in a course of treatment will help us understand how treatment changes brain responses to emotional and social information. In order to accomplish this, we plan to have approximately 88 veterans complete this study over the course of four years.

PROCEDURES: The research will be conducted at the following location(s): Salem Veterans Affairs Medical Center and Fralin Biomedical Research Institute at Virginia Tech Carilion.

You are being asked to participate because you have already chosen to receive treatment for PTSD in the Residential PTSD Program at the Salem VA Medical Center. As part of the intake process, you will be asked to complete clinical assessments that include interviews and questionnaires. These will take between two to five hours to complete, and may be split into multiple sessions depending on how you are feeling. The assessments will focus on the traumatic experience that has caused you prolonged difficulties. Some of the assessments will ask about difficulties you may be having now or may have had in the past. You will be asked to complete some or all of these assessments again after your course of treatment.

Failure to complete every component (interview, questionnaires, and/or scans/tasks) at every time point may be grounds for dismissal from the study. If you do not complete the pre-treatment study procedures, you may be excluded or withdrawn from the study. If you choose not to participate at the beginning of treatment, we will not be able to enroll you after you have begun treatment.

Your participation in this research will include a functional magnetic resonance imaging (fMRI) scan or behavioral task visit and assessment session before you begin treatment, a fMRI or behavioral task scanning visit after you finish treatment, and three follow-up phone calls at 1-week, 3 and 6 months after you complete treatment.

Today, after we talk about everything in this consent form and the researchers have answered all of your questions, we will begin the initial part of the study.

You may be asked to complete the consent process via telephone/VA Video Connect and FedEx or USPS or UPS mail if you are not able to complete it in person. Additionally, if you consent, we may ask you to complete the pretreatment interviews by telephone/VA Video Connect with authorized clinical study staff. You may choose not to complete these procedures remotely and still be eligible to participate in the study. Study staff will work with you to schedule your interviews close to your estimated admission date (i.e., within

approximately 1-2 months). If your admission date is significantly delayed after completing your interviews remotely, study staff may ask you to complete new interviews to ensure that the information you share with us is accurate and up to date when you arrive.

MRI scans: Your participation in this research will include fMRI scans during which you will be asked to complete behavioral tasks and look at pictures. For persons unable to complete a fMRI scan, the behavioral tasks may be completed outside the scanner. These fMRI visits will be completed at Fralin Biomedical Research Institute (FBRI) prior to treatment and upon treatment completion. Prior to your fMRI visit, we will ask you to review your answers to the fMRI screening form you completed when you were screened for this study. This is to make sure that fMRI scanning will be safe for you. We are not able to scan people who have metal in their bodies or who become very afraid in closed spaces. Should you not be eligible to participate in the fMRI portion of this study, you will have the opportunity to participate in the treatment, behavioral tasks, and assessment-only portion.

After we have determined that you are eligible to participate in the fMRI portion, you will be accompanied by a member of the research team to the Human Neuroimaging Laboratory at the Fralin Biomedical Research Institute at Virginia Tech Carilion for the first fMRI scanning session. It will take approximately 20 minutes to get there, and you will have the option to be transported in a Department of Veterans Affairs vehicle or arrange your own transportation. Forms with your personally identifiable information, including this Informed Consent document and the fMRI screening form, will be transported to the FBRI by a study staff member in a locked, secure bag, and will return to the Salem VA Medical Center with a study staff member at the end of the scanning session. All forms with personally identifiable information will be kept in a locked, secure location at the Salem VAMC and stored separately from data produced by your participation to protect your confidentiality.

Once you arrive at the Human Neuroimaging Laboratory, we will once again review your fMRI screening form to confirm your eligibility to participate, and you will undergo the fMRI procedure. At this time, we will give you a detailed description of what it will be like to be in the scanner and answer any questions you have.

The fMRI scanner uses a strong magnet and radio waves to obtain a pictures of the brain. To be scanned, you will enter a large room where a powerful magnet is located. During scanning, the machine will produce loud knocking noises similar to a washing machine out of balance. This is normal. Before you go into the scanner room, we will play a recording of the sounds that the scanner makes and show you examples of the images and/or stimuli you will be presented with while in the scanner so you know what to expect. Some of these stimuli may be combat-related. Then, you will be instructed to remove all jewelry and other metal-containing objects. Once in the room with the scanner, you will lie on a narrow table with a plastic-encased metal coil close to your head. Next, the technician will instruct the machine to slide you into a small tunnel approximately 3 feet long and 25 inches in diameter. Only the top of your body goes into the scanner, so your

legs will "stick out" from the scanner tunnel. We will ask you to lie very still for the entire duration of each task. Each task will last between 15 and 30 minutes and you may complete 1 to 3 tasks during your visit, depending on how you are feeling and the time available. You will be taken out of the scanner between the tasks for a break. Some of the tasks may be conducted in a separate visit if necessary.

While you lie in the scanner, a computer display will be positioned at one end of the scanner. You will be able to see this display through a mirror positioned above your head. You will be asked to do one to three tasks. In one task, you will see emotional images flash on the computer screen. You are not required to make any response but to remain still and look at each picture. In the other tasks, you will hold a button box in your hands so you can respond to the things you see on the screen. More specific instructions about what you will see and do during the fMRI will be given to you before the scan.

A senior member of the clinical research team will be available throughout your scanning sessions. If you become upset and are unable to continue the experiment, you will be removed from the scanner immediately. Clinical staff members will be available to talk with you and ensure your well-being.

Following the scanning session, we will ask you to fill out a few brief questionnaires related to the computer games you played. We will also give you a CD with images of your brain from your fMRI scan. When the visit is done, you will be transported back to the Salem VAMC.

Approximately 7 weeks later, after you have finished treatment in the Domicile of the Salem VA Medical Center, you will be asked to return to the Fralin Biomedical Research Institute at Virginia Tech Carilion for the second fMRI scanning visit. The second scanning visit will follow the same procedures as the first scanning visit.

Under certain conditions, you may be asked to complete the consent process and the subsequent pretreatment interviews, questionnaires and/or fMRI scans in-person during the week prior to your admission to the PTSD Program. You may choose not to complete these procedures prior to admission and still be eligible to participate in the study. If you decide to delay your admission date, you will be unenrolled from the study but may still participate at a later date. You may also be asked to complete the posttreatment study procedures during the week after you are discharged from the Residential PTSD Program.

Treatment: You have chosen to come to the Salem Residential PTSD Program to receive PTSD treatment from the VA. If applicable, any treatment copays you may be required to pay will still apply to your treatment received through the residential unit. In collaboration with the unit, this study is examining Trauma Management Therapy (TMT), which consists of exposure-based individual treatment and skills-based groups, compared to Prolonged Exposure Therapy (PE) and skills-based groups. Both treatments are empirically-supported to be effective at treating PTSD. Both treatments are exposure-based and may utilize additional

trauma-related cues to enhance the patient's engagement with the trauma memory. For Veterans who have experienced relevant traumas (e.g., desert combat), the use of a virtual reality (VR) system may be utilized during TMT. The Bravemind VR system includes visual VR environments viewed through goggles, sounds administered through headphones, scents, and a vibrotactile (i.e., vibrating) platform.

Randomization: The treatment package administered will be randomized by cohort, so that every participating Veteran in a given cohort receives the same treatment. You will not know which treatment will be assigned until you meet with your individual therapist. Therapists on the unit are also research study staff and have access to research data. By agreeing to participate in this research study, you are agreeing to receive the treatment package identified by the study (either TMT or PE). If you do not wish to be randomized to and receive one of these treatments (either TMT or PE), you may not be eligible to participate in this study. However, this will in no way impact your status in the PTSD Program or your ability to receive the individual treatment of your choice while in the PTSD residential program.

Participation in other studies: Based on your eligibility and outcome of participation in this study, you may also be eligible to participate in the Neuroscience of Social Behavior study conducted at the Salem VAMC. If you're interested in learning more about the study, you will be asked to complete a Release of Information form for your contact information to be shared with the staff of the Neuroscience of Social Behavior study. This process enables you to be contacted directly by their study staff for more information about the study. Participation in the study is completely voluntary and optional. Not choosing to participate in the Neuroscience of Social Behavior study will in no way impact your participation in this study. You can choose to withdraw from participation at any point of time without any consequences. Please indicate below whether or not you're interested in being contacted for the Neuroscience of Social Behavior study:

_____ Yes, I agree to be contacted by the staff of the Neuroscience of Social Behavior study to learn more about participation
_____ No, I do not agree to be contacted by the staff of the Neuroscience of Social Behavior study

If you are interested in being involved in the above study, you will be asked for your consent by the other study team to share some of the deidentified data collected in the present study. The reason this will be asked of you is to reduce time spent on similar study procedures across studies. If you do consent to have your data shared with the other study, we will be notified by their team and we will transfer a copy of the relevant data. Data will not be shared with their study team without your written consent.

RISKS:

There are no known risks involved with fMRI scanning. The scanner we use has been approved for safety by the Food and Drug Administration (FDA). There is no evidence that it is harmful in any way. The magnetic

field will affect any metallic object. You should not participate if you have any type of metallic implant in your body, including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, IUDs or piercings that you cannot remove. If you have any of these, there is a risk that the magnetic field could cause them to move or heat up. There is a slight risk that dental fillings containing magnetic materials could heat up or shift during the fMRI scan.

You may experience some muscle discomfort from lying in the scanner. You may also become cold while lying in the scanner. If this happens, we can provide you with a sheet or blanket. Some people become nervous or claustrophobic in the scanner. If this happens to you, you may ask to be withdrawn and we will do so immediately. A small number of people experience a sense of dizziness in the magnet. This is due to the magnetic field, and if it disturbs you, you may ask to be withdrawn and we will do so immediately. When running, the fMRI machine produces loud noises. Ear protection will be provided in order to protect you from experiencing any discomfort or harm while lying in the scanner. Additionally, the images that you are asked to view during the scanning task could potentially cause you to have a strong emotional reaction or a "flashback." If you experience any difficulties, you can ask to be removed from the scanner and we will do so immediately. There is an intercom hooked up so that you can talk to the scanner technician and clinical research staff member in the control room between scanning sessions.

During the experiment you may experience strong emotions. Although feeling emotions such as sadness and anxiety may be unpleasant, it will be temporary. A member of the research team will be with you at all times. In the rare event that you should experience prolonged or intense feelings of anxiety, sadness, or distress from the study, please notify a member of the research team immediately. If needed, a senior member of the clinical research team or the principal investigator will be available to talk about these feelings with you.

During your exposure therapy, you will be using a VR machine to experience a fully immersive effect. The VR experience involves the use of scents that may help to reproduce your experience more accurately. There are no known risks to being exposed to the scents, however, if you decide you do not want to us them, you may inform your therapist and they will discontinue use of the scents.

REPRODUCTIVE INFORMATION: Due to the investigative nature of this study, there may be other risks that are currently unknown. Although there is no evidence of harmful effects of magnetic fields on the developing fetus, we feel that women who are pregnant should not participate in this study. Please inform study staff if you are pregnant.

BENEFITS: While there are no direct individual benefits to participating in this study, the results of this study may help us further identify the most effective ways to treat other people who are suffering from PTSD. Also, your participation may help the investigators better understand how the brain responds to specific emotions

and social interactions. This may eventually lead to a better understanding of the brains of people who have difficulty processing certain emotional and social information.

ALTERNATIVES: You may choose to not participate in this study. This choice will not affect your medical treatment or your participation in the residential PTSD program in any way. If at any time during any part of this study, you feel that performing the task is causing you anxiety or any other unpleasant sensation, please inform the study staff. The study will be immediately stopped. If you experience distress while in the fMRI scanner, please inform study staff, and you will be withdrawn from the scanner. You are free to end your participation in this study at any time without any penalty. It is important that you understand that your benefit status and/or medical treatment will not be affected in any way.

CONFIDENTIALITY: As with any research, there is always a chance that confidentiality of the collected information may be breached. However, study staff will store all data in a secure location. Paper records from the study will be kept in a locked cabinet in a locked, secure office. Electronic data will be stored on secured, password-protected servers. Further, protected health information will be immediately destroyed if you choose to withdraw from the study or if you are withdrawn from the study by research staff. Neuroimaging data, identified only by a code, will be stored on a hard drive equipped with FIPS 140-2 validated encryption located at the Fralin Biomedical Research Institute at Virginia Tech Carilion for the duration of the study. A Federal Information Processing Standard (FIPS) 140-2 encrypted hard drive will also be used to securely transport an original copy of the data from the Fralin Biomedical Research Institute at Virginia Tech Carilion to the Salem VA Medical Center at the completion of the data collection phase of the study. If the VA-owned hard drive becomes corrupted or non-functional, it will be returned to the VA Office of Information Technology for appropriate destruction.

As part of this research study, you will be asked to sign an Authorization for Use and Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research. This authorization will allow us we will access your past and present individually identifiable health information (IIHI) in the form of 1) information from your VA Health Records such as diagnoses, progress notes, medications, and lab or radiology findings; 2) specific information concerning alcohol and/or drug abuse; 3) demographic information such as name, age, and race; 4) diagnostic assessments and interviews conducted as part of the standard intake and treatment procedures in audio and/or written form (as detailed in the next paragraph); 5) questionnaire, survey, and/or Subject Diary information. Signing the authorization is completely voluntary—however, your authorization (permission) is necessary to participate in the study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign the authorization. We are committed to protecting your privacy and the confidentiality of information related to your health care, and this information will be used for the purpose of data analysis.

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To evaluate the reliability of the clinical assessment procedures used in this research, and to evaluate whether the treatment protocol is being carried out correctly, your clinical interviews and therapy sessions will be audio recorded. These recordings will be made via a recorder with removable SD cards such that no material is left on the recording device once the SD cards are removed. The recordings will be stored in a secure, locked room within the VA, on their protected server, and will only be accessible to appropriately trained study staff. We will not use your name or any identifying information on the tape. The recordings will not be disclosed outside of the VA.

The Salem VA Research & Development Committee and its subcommittees (i.e. Institutional Review Board {IRB} and Safety Committee {SRS} which are committees that oversee research and protect the safety of research subjects) will have access to the records. Federal agencies including, but not limited to the, FDA, Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), Office of Research & Development (ORD), Office of General Counsel (OGC), Government Accountability Office (GAO), and the VA Office of the Inspector General (OIG) may have access to the records. To receive monetary compensation for this study, your name, address and social security number will be disclosed to the VA Financial Service Center in Austin.

All of the information you provide us with is kept confidential. However, if we believe you are at great risk of harming yourself or someone else, we are required to act to prevent this. We may break confidentiality only in order to ensure your safety and the safety of others in this situation. We are also mandated reporters of ongoing child abuse and/or abuse of elderly or disabled persons.

RESEARCH-RELATED INJURIES: The VA will provide necessary medical treatment to a research subject injured by participation in a VA-approved research project in accordance with applicable federal regulations. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures.

Care for VA research subjects with research-related injuries must be provided in VA medical facilities, except in the following situations: (1) If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility Directors shall contract for the needed care; (2) If inpatient care must be provided to a non-Veteran research subject with a research-related injury, VA medical facility Directors may contract for such care; or (3) If a research subject needs treatment in a medical emergency for a research-related injury, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

Some Veterans (or non-Veteran subjects) are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

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The VA has not set aside compensation payable in the event of physical injury or illness resulting from participation in this research study.

In the case of a research related injury, you may speak with a member of the study staff: Nanda Sankarasubramanian at 540-526-2091 or Dr. Brooks King-Casas at 540-526-2009. A member of the study staff can be reached 24 hours a day at 832-573-3695.

You cannot be charged, nor can your insurance be billed, for research-related injuries.

VOLUNTARY PARTICIPATION STATEMENT: Your participation in this research is entirely voluntary. If you refuse to participate, there will be no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

FINANCIAL COMPENSATION: You will be compensated for your participation in this study which includes the transportation time between the Salem VAMC and the FBRI to complete the fMRI visits. You will be paid for each portion of the study (i.e., pre-treatment, post-treatment, 1-week, 3-month, and 6-months follow ups). If you withdraw from the study at any time, you are still entitled to the compensation that you have earned through the point at which you withdraw from the study.

You will be compensated at a set rate described in the table below. Payment is based on an estimated rate of $15/hour for the modal time required to complete each assessment session. These assessments will be completed prior to beginning treatment, after you have completed treatment, one week after leaving the unit over the phone, and at 3-month and 6-month follow-up sessions over the phone.. For each fMRI task, you will be compensated at a set rate described in the table below. Payment is based on an estimated rate of $30/hour if completed inside the scanner and $15/hour if completed outside the scanner. You will either be transported from the Salem VAMC to the FBRI to participate in the fMRI visits via a state vehicle or you may arrange your own transportation arrangement. A $10 compensation for travel to/from FBRI for the scanning sessions (i.e., a rate of $15/hr) has been incorporated into payment for the scanning visits. If you choose to end a scanning session early for any reason, you will still receive travel compensation. You may earn completion bonuses at each follow up phone call, for completing all procedures for those visits (i.e, posttreatment, 3- and 6-month follow ups up to a total of $40, as described in the table). If you participate in all portions of the study you will receive a participation bonus of $50 at the end of your participation. In total, you can expect to earn a minimum of $170 and a maximum of $700 for completing all portions of the study.

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Payment Schedule

Pretreatment Interviews	$60
Pretreatment questionnaires	$30
Pretreatment fMRI	$45/90 (depending on in/out of scanner)
MRI Task performance	$20-75 (depending on performance)
Posttreatment Interviews	$30
Posttreatment questionnaires	$30
Posttreatment fMRI	$45/90 (depending on in/out of scanner)
MRI Task performance	$20-75 (depending on performance)
1-week post questionnaires	$10
Pre + Post + 1week bonus	$20 (for completing all)
3-month Interviews	$30
3-month questionnaires	$30
3-month completion bonus	$10 (for completing both)
6-month Interviews	$30
6-month questionnaires	$30
6-month completion bonus	$10 (for completing both)
Final completion bonus	$50 (if completed all procedures)

Should you choose to end a procedure early without completing it, you will be paid $15/hour for time spent, up to the scheduled payment for that procedure. Likewise, if there are unusually long delays due to technical problems outside the control of the study staff during an fMRI visit to FBRI, you may, at the discretion of study staff, be paid $15/hour for the duration of the delay to compensate for your time.

In order to compensate you for your participation and travel expenses, your name, address, social security number, date of birth, payment amount, and bank account number (for direct deposit, if applicable) will be disclosed to the Fiscal Service at the Salem VA Medical Center and Austin Financial Services Center. A deposit will be made directly into your bank account unless you are unable or do not wish to be reimbursed in this manner; in which case a reimbursement can be made via a check which can take 2-3 weeks to process. Due to limitations in the Financial Management System, payments made to participants through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount of reimbursement. Your SSN will be used for this purpose in reimbursement.

Your name, address, social security number, and amount of payment will be submitted to the Internal Revenue Service for tax reporting purposes for any financial compensation you receive per calendar year as a result of your participation in this research study.

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CONFLICT OF INTEREST: There are no conflicts of interest to be disclosed by the study doctor or research staff for this study.

TERMINATION OF SUBJECT'S PARTICIPATION: Your participation may be ended by the investigator without your consent if: 1) it is determined that it would be in your best interest to no longer participate in the study for your own mental and/or physical health and well-being; 2) you do not comply with the study protocol; 3) changes to your substance use habits and/or other changes in your mental or physical status prevent you from safely and comfortably continuing in the study; 4) you choose to request medically unnecessary changes to your medications (you will be expected to remain stable on your prescribed medications, unless changes are medically necessary) are grounds for dismissal from the study. Additionally, you cannot discontinue treatment at the Salem VAMC Residential PTSD Program and remain in this research study. Additionally, if you discontinue treatment at the Salem VAMC Residential PTSD Program you may be unenrolled from the study at the discretion of study staff

RESEARCH SUBJECT COSTS: You will not be asked to pay any costs related to this research.

CONSEQUENCES OF WITHDRAWAL FROM STUDY: You are free to end your participation in this study at any time without any penalty. Your benefit status and/or medical treatment will not be affected in any way. If at any time during scanning or study tasks, you feel that performing a task is causing you anxiety or any other unpleasant sensation, please inform the study staff, and the study will be immediately stopped.

NEW FINDINGS: Significant new findings developed during the course of this research study that may relate to your willingness to continue participation will be provided to you. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

RESEARCH SUBJECT'S RIGHTS:

- You have read, or have had read to you, all of the above information. A member or members of the research team have explained the study to you and have answered all your questions. The risks or discomforts and possible benefits and the alternatives of the study have been explained to you.
- The results of this study may be published but your identity and records will not be revealed unless required by law.
- In case there are any medical problems or if you have questions, concerns, and/or complaints about the research study, you can call Dr. Brooks King-Casas or a member of the study staff at 540-526-2032 during the day and Dr. Brooks King-Casas at 832-573-3695 after hours.

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- In the event of illness or injury that you believe to be related to the study, or if you have any questions about your rights as a research subject, complaints or concerns, you can contact the Chairperson of the Institutional Review Board (IRB) or designee at 540-982-2463, ext.1568 or the Research and Development Office at 540-982-2463, ext. 2029.

- If you wish to contact someone other than the research study staff, you may call the Research & Development office at 540-982-2463, ext. 2029 or contact the Research Compliance Officer at 540-982-2463, ext. 1226.

- If you wish to verify that this is an approved Salem VAMC research study or you are unable to reach the research study team during normal business hours, you may call the Research & Development office at 540-982-2463, ext. 2029.

- 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.

- No guarantees or assurances have been given to you since the results and the risks of an investigation are not always known beforehand. However, every reasonable precaution will be taken to protect your well-being. You have not released this institution from liability for negligence.

STATEMENT OF CONSENT: I have read this informed consent document and have been given the opportunity to ask questions. I understand that I will receive a signed copy of this informed consent document and the original signed document will be placed in my case history in the investigator files. I authorize the use of my identifiable information as described in this form.

I voluntarily consent to participate in this study. This research study and my rights as a research participant have been explained to me.

_____ _____

Signature of Subject Date

_____ _____

Signature of Person Obtaining Consent Date