Participant Name:	Date:
Study Title: Group Cognitive Behavioral Therapy for Anger and Aggression in Veterans with PTSD – Veteran Version	
Principal Investigator: Elizabeth Van Voorhees, Ph.D.	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to compare two different types of group therapy for anger and aggression in combat veterans with Posttraumatic Stress Disorder (PTSD), to see if one is more effective than the other. In this study we will collect information about whether the group treatment you participate in is useful to you in your efforts to control your anger and reduce aggressive behavior. We also want to learn whether the group helps you to reduce the negative effects that anger and aggression has on your health, overall functioning, and quality of life. This study is being funded by the Research Rehabilitation Service in the Office of Research and Development, Department of Veterans Affairs.

You are being asked to participate in this research study because 1) you are a combat veteran; 2) you have told us that you have been diagnosed with PTSD or think you may have PTSD; and 3) you have told us that you have had some problems controlling your anger in the past 30 days. About 60 combat veterans (40 men and 20 women) will be screened for this study, and about 36 veterans will be enrolled in this study. Half of the veterans who are enrolled will be assigned to a group that focuses specifically on learning skills to manage anger and aggression. The other half will be assigned to a type of group therapy that has been found to help people reduce their PTSD symptoms, but that has not been tested in the treatment of anger and aggression symptoms.

Study visits will take place at the Durham Veterans Affairs Medical Center, the Raleigh Vet Center, Raleigh II Community-Based Outpatient Clinic (CBOC) or Hillandale II CBOC. Altogether, participation in this study requires 1 screening visit, 12 weekly group therapy visits (each with a set of self-report questionnaires to complete right before group begins), and 1 post-treatment assessment visit. We will also send you questionnaires through the mail for you to complete 3 months and 6 months after the therapy groups have finished.

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WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

If you choose to participate in this study, the group therapy you receive is likely to be similar to therapy you would receive if you were treated for anger or aggression in a VA clinic. However, it is different because if you were treated in a clinic, you and your doctor would decide together which treatment group would be best for you. But if you participate in this study, you will not get to choose which treatment group you will participate in. Instead, you will be assigned to one of two types of therapy based on which group begins the soonest after your screening visit.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study you will be asked to complete the steps described below.

1. **Complete interviews about psychological symptoms and a screening for traumatic brain injury.** At the first study visit, we will ask you about your health and about any medications you are taking. We will also ask you to participate in two interviews about your current psychological health. These interviews will include questions about your mood, including feelings of sadness or nervousness. They also include questions about traumatic events you may have experienced. Finally, you will be asked questions to determine if there is a possibility that you have experienced a traumatic brain injury (TBI). If this screening suggests that you may have a TBI, we will request permission to talk to your doctor about whether the head injury is likely to be mild, moderate, or severe. If you have a moderate or severe head injury you will not be eligible for participation in this study, and you will be compensated $70 for your participation in the screening visit. We will talk with you about potential TBI assessment or treatments that are available to you in the VA, and we will recommend that you follow up with your doctor to identify the most appropriate next steps for you.

2. **Complete questionnaires.** If you are determined to be eligible for the study, we will ask you to complete a packet of questionnaires. The questionnaires will include items about basic demographic information, such as your age, work status, and financial status. They will include questions about any life threatening or traumatic events you may have experienced, and questions about mood, sleep, anger and aggressive behavior. Finally, the questionnaires will also include items about family, work, and social functioning, your quality of life, and current psychological symptoms you may be experiencing.

   This first session will last approximately 4 hours. You will be paid $70 for completing this session.

3. **Complete weekly questionnaires, and participate in 12 weekly anger and aggression therapy groups.** If you decide to participate in the study and meet screening criteria based on the

information collected in the first visit, you will be invited to attend 12 sessions of therapy for anger and aggression in combat veterans with PTSD. You will be assigned to one of two types of therapy. One group will be using the therapy we are testing. The other group will be using a type of therapy that has been found to help people reduce their PTSD symptoms, but that has not been tested in the treatment of anger and aggression symptoms. The type of therapy you are assigned to will depend upon which group we start the soonest after your screening visit. Treatment groups will include 5 or 6 members, and each group will include only women or only men. You will be asked to come in 15 minutes before each session so that you can complete questionnaires about your mood and feelings of anger over the past week. You will be compensated $15 for each set of assessments you complete. You do not have to attend the group session to be compensated for completing the assessment forms. Each treatment group will last for 90 minutes. The treatment sessions are videotaped so that another staff member can watch them to determine that the treatment is being done correctly. It is likely that your face and/or voice will be captured on the videorecording. If you are not willing to be videorecorded, you will not be allowed to participate in the study.

You may stop attending the groups at any time. If you miss two group sessions in a row, you will be discontinued from the study. If you miss more than 3 group sessions during the entire 12-session group therapy cycle, you will be discontinued from the study.

4. **Complete a post-treatment assessment visit.** You will be asked to participate in a post-treatment assessment. During this session you will complete many of the same questionnaires you filled out during the screening session. This visit will take about 1 ½ hours to complete, and you will be compensated $80.

5. **Complete questionnaires 3 and 6 months later.** If you have attended at least two therapy sessions, the study coordinator will keep in touch with you for the next few months through phone calls and cards through the mail. At 3 months and 6 months after the therapy has ended, we will send you a packet of questionnaires through the mail. Each packet will include some of the questionnaires you completed during your initial and/or post-treatment visits, and a stamped envelope to use to return the packet to us. It will take you about 1 hour to complete each packet. If you'd rather complete the questionnaires in person, we will schedule you to come in to complete them. We will compensate you $35 for each packet that you complete and return to us.

While you're in the study, you may find that you'd like to refer another Veteran to participate. In order to encourage you to refer other Veterans to the study, we'll give you two referral coupons that are marked with an identification number that is unique to you. You can give these referral coupons to any Veteran you think might be interested in the study. If that Veteran comes in for a screening visit and brings us his/her coupon, we'll offer you a $5 payment for taking the time to make the referral. Please note that we won't be able to tell you whether or not a specific Veteran uses your

coupon. We ask that you not discuss with others whether you think/believe a Veteran you have referred may be participating in the study. You can choose not to distribute the coupons we give you, and you can refuse to even receive the coupons.

There are some optional portions of the study, too.

Option 1: Provide the name and contact information of someone close to you who will be asked to answer some questions about your anger. We will ask the person you identify to attend one session in person in which they will answer questions about you. They will be asked to complete similar questionnaires again after you have completed treatment, and again at 3 and 6 months after treatment. If you choose not to do this portion of the study, you can still participate in the rest of the study.

I give permission for Dr. Van Voorhees and/or her study staff to contact the family member or friend I identify about answering some questions about me.

YES ☐ NO ☐ Initials:_____Date:_____

Option 2: Provide permission to include your research data in the VISN 6 MIRECC Post-Deployment Mental Health Data Repository. *This section only applies to you if you previously participated in the Study on Post-Deployment Mental Health. If you did not participate in that study, please mark "N/A" below.* In the past you may have participated in a Study on Post-Deployment Mental Health (IRB # 0933) in which you were asked and agreed to contribute your research data to a Post-Deployment Mental Health Data Repository (IRB # 01706), and in which you were asked and agreed to be contacted for future research studies. If you participated in this prior study we would like to add the data we are collecting today to the Post-Deployment Mental Health Data Repository so that the information can be used for additional and future research studies, and so that the information we obtain today can be linked to your already collected data. The data collected that would be added to the repository includes: questionnaires, blood pressure, heart rate data, and information from clinical interviews. Combining the information you share from multiple VISN 6 MIRECC studies can help us better answer certain research questions. It may also help us better understand post-deployment mental health issues.

I give permission for the data collected from me during this study entitled, "-Group Cognitive Behavioral Therapy for Anger and Aggression in Veterans with PTSD" to be entered into the Post-Deployment Database within the Post-Deployment Mental Health Data Repository for use in future mental health research studies.

YES ☐ NO ☐ N/A ☐ Initials:_____Date:_____

Option 3: Provide permission to update your re-contact information in the Re-Contact Database (RCD) of the Post-Deployment Mental Health Data Repository. *This section only applies to you if you were previously included in the Re-Contact Database (RCD) of the Post-Deployment Mental Health Repository. If you were not previously included in this database, please mark "N/A" below.* In the past you may have participated in a study on Post-Deployment Mental Health (IRB # 00933) in which you were asked and agreed to be re-contacted for future studies such as this study entitled, "Group Cognitive Behavioral Therapy for Anger and Aggression in Veterans with PTSD ". If you did participate in the Study on Post-Deployment Mental Health we would like to update your contact information in the RCD of the Post-Deployment Mental Health Data Repository (IRB # 01706) so that this information remains current and so that you may be re-contacted for additional studies. The purpose of future studies is to learn more specific information about post-deployment mental health.

I give permission for my contact information to be updated in the Re-Contact Database in the Post-Deployment Mental Health Data Repository (IRB # 01706) for the purpose of updating or confirming the accuracy of the already stored information so that I may continue to be contacted for future research studies.

YES ☐ NO ☐ N/A ☐ Initials:_____Date:_____

Option 4: Provide permission to store your contact information along with your interview results in a database called "Contact Database." This information will be used to determine if you may be eligible for future studies run in the Traumatic Stress and Health Research Laboratory and to contact you about participation. These future studies include studies related to smoking, posttraumatic stress disorder (PTSD), and trauma. Your choice to give permission to be recontacted or not to give permission to be recontacted will not affect your enrollment in the current study. If you do not wish for us to keep your information, we will not contact you in the future about other studies.

I give permission for my contact and interview information to be stored for the purpose of being contacted in the future about these other studies for which I might be qualified.

YES ☐ NO ☐ Initials:_____Date:_____

Option 5: Provide permission for the data we collect from you to be entered into a large database called "Trauma Database." The information you provide may become part of this larger database, which will be used for future research. Information collected from many study participants (500 or more) from different studies will then be examined to inform researchers about the topic they are trying to learn more about. Topics of research change over time and for that reason, the

development of a combined research database is particularly useful. Your identifying information will only be available to staff in the Traumatic Stress and Health Research Laboratory. Your choice to be included or not to be included will not affect your enrollment in the current study.

I give permission for the data collected from me during this study to be entered into the "Trauma Database" for use in future research.

YES ☐ NO ☐ Initials:_____Date:_____

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. You do not have to join this or any other research study. If you do join and later change your mind, you may quit at any time. If you withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate. If you choose not to take part in this study, your other choices may include:

- Getting no treatment
- Getting treatment without being in a study (i.e. psychotherapy for PTSD, or anger management therapy through the Mental Health Clinic)

We will ask you not to participate in another psychotherapy treatment for anger or aggression or for PTSD while you are still in this study. However, you can still participate in treatment for any other emotional problem while you are in this study. You can participate in treatment for PTSD before you participate in this study, and you can also participate in treatment for PTSD after you complete the post-treatment assessment for this study at the end of the 12 weekly group sessions (i.e. during the 6-month follow up phase). If you decide that you want to participate in another psychotherapy treatment for PTSD, anger or aggression, we will ask you to discontinue participation in this study before beginning the other treatment. However, if you decide to withdraw from the study to receive treatment for PTSD, you will still be eligible to be re-screened for the study after you finish the PTSD treatment.

Deciding not to participate in this study or pulling out of the study later on will not affect your medical care at this VA or any other VA. It will not affect the VA benefits that you get or you might be

able to get in the future. Your participation in this study is not a substitute for your regular medical care or check-ups.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

If you choose to participate in the research study, you will be screened for eligibility on the day you sign this consent form. If you are found to be eligible to participate, you will be assigned to the next available study group. The next group may start any time within the next two to 6 weeks, depending upon how long it takes to enroll six eligible group members. The group will meet weekly for 12 weeks. About one week after the group ends you will be asked to participate in a post-group assessment. At 3 months and 6 months after the group ends you will be sent materials to complete through the mail. If you decide to participate in the entire research study, you will be enrolled in the study for a total of between 9 and 12 months.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

There are a few possible discomforts if you take part in this study. Answering some of the questionnaires and participating in some of the treatment groups may be upsetting to you. It may bring back painful memories, sadness, or anger. You may talk to us if you have a hard time handling these feelings.

Unauthorized access of your personal information is very unlikely. It may be possible for people to get access to your information by breaking into our system. However, we use data security measures to limit the likelihood of this occurring. Personal information (i.e. your research data) collected from you may also be kept at VA Informatics and Computing Interface (VINCI), which is a secured website hosted by and under the control of the VA Health System. Your data will be encrypted while stored, and will only be available to Dr. Van Voorhees and her study staff.

There may be additional discomforts related to your participation in this study that we cannot predict. If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. People who are suffering from emotional problems related to war may be helped by you taking part in this study.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans 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.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

If you complete the screening visit, you will be compensated $70. If you complete part of the screening visit but are excluded because we learn that you may have a moderate to severe brain injury, you will be compensated for the entire study visit ($70). You will be compensated $15 for each of the 12 weekly sets of assessment measures you complete (up to a total of $180). If you complete the post-treatment assessment, you will be compensated $80. For each follow-up packet of questionnaires you complete, you will be compensated an additional $35. You may be compensated up to $10 for referring other Veterans to the research study. Added together, the maximum amount you could be compensated for participation in this study is $410.

Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

HOW WILL I BE COMPENSATED?

After the first assessment and screening visit you will be paid $70 by direct deposit or check. After the first six weekly study visits, you will receive a lump sum direct deposit or check that includes $15 payment for each of the assessments you completed (up to $90). Then, after you have completed the final six weekly study treatment visits, you will receive another lump sum direct deposit or check for each of the assessments you completed (up to $90). After the post-treatment assessment visit a direct deposit or check for $80 will be mailed to you. If we receive referral coupons with your identification code, a direct deposit will be made or a check will be mailed to you. Finally, you will receive a $35 direct deposit or check for each of the follow-up packet of questionnaires you complete and return. You can anticipate that it will take about 4 to 6 weeks for you to receive your payments after we request them.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Elizabeth Van Voorhees, the Principal Investigator, may take you out of the study without your consent for one or more of the following reasons: the study is cancelled; Dr. Van Voorhees decides that continuing your participation could be harmful to you; you do not follow instructions the instructions of Dr. Van Voorhees and/or the study staff; you are unable to complete the study requirements; you need treatment that is not allowed during participation the study; you are unwilling to be recorded during treatment sessions; you decide to participate in another form of psychotherapy for PTSD, anger or aggression before completing this study; we suspect that you are

drunk or high during group therapy sessions or cannot participate in sessions for other reasons; or other administrative reasons.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study. With your consent, we will let your physician know of any important discoveries made during this study that may affect you or your condition. For example, the study may show that you have suicidal thoughts, severe depression, or other health problems that could affect your health care.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

If you are interested in the scientific results of this research study, you may request to receive copies of papers that come from this study as they are published.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is being funded by a Career Development Award (1IK2RX001298-01A2) to the Principal Investigator, Dr. Elizabeth Van Voorhees. This grant is through the Rehabilitation Research and Development Service of the Office of Research and Development, Department of Veterans Affairs. Dr. Van Voorhees' salary and some of the salary of research staff are funded by this grant.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

To ensure confidentiality of data, all records will be identified by the participant's identification number, not by name. All raw hard copy data will be kept in a locked cabinet in a locked room at the Durham Veterans Affairs Medical Center. Videorecordings of the treatment sessions will be moved from the videocamera to be stored along with data files. If videorecordings are made at a location other than the Durham VA (for example, Hillandale II), a study staff member will transport the video camera in a locked briefcase to reduce the risk of violation of confidentiality. The recordings and data

files will be stored on secure, password-protected computers, to which only study personnel will have access.

There are VA rules (called records control requirements) about how long your research records are kept. Right now the rules say your research records cannot be destroyed. This may change in the future; at that time we will follow the new VA rules. Your medical records will be maintained according to this medical center's requirements.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). If you have been referred to this research study by a counselor or case manager in the North Carolina National Guard Integrated Behavioral Health System, we will notify your counselor or case manager about whether or not you are eligible to participate in the study. Also, we will notify them if you are withdrawn from the study for any reason or drop out of treatment.

ARE THERE ANY LIMITS TO THE PRIVACY AND CONFIDENTIALITY OF MY RESEARCH INFORMATION?

If you reveal current intent to harm yourself or someone else, we may be required to escort you, or have you escorted, to this hospital's emergency room to be seen by staff in the Psychiatric Emergency Clinic (PEC). If there is any "life or death" information that tells us that you or some other person is in extreme danger, we are required by federal and state regulations to report the concern. Only relevant information will be given to a doctor that is called on to treat you.

If during the course of the study you discuss or mention anything that gives us cause to suspect abuse or neglect of any child, elderly adult, or person with a disability, we are required by federal law to report the suspected abuse to your local Department of Social Services.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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

Participant Name:	**Date:**
Study Title:	
Principal Investigator: Elizabeth Van Voorhees, Ph.D.	**VAMC:** Durham

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Elizabeth Van Voorhees at 919-286-0411 x. 6435 during the day and Dr. Van Voorhees at 984-234-2667 after hours. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 7632.

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

_____

Participant's Signature **Date**

_____

Signature of Person Obtaining Consent **Date**