SUBJECT NAME		
TITLE OF STUDY	**Structured Treatment of Pain (STOP) Study**	
PRINCIPAL INVESTIGATOR	**Rhonda M. Williams, PhD**	

LAY TITLE: Structured Treatment of Pain (STOP) Study

Researchers:

Rhonda Williams, PhD	Principal Investigator	(206) 277-6290
Jeanne Hoffman, PhD	Co-Investigator	
Dawn Ehde, PhD	Co-Investigator	

STOP Study toll-free number: 1-800-329-8387; then dial 1-61845

24-hour emergency contact:

- In case of medical emergency, you are advised to call 911. If you feel like harming yourself or others, you are advised to go to the nearest Emergency Room or call the Veteran's Hotline at 1-800-273-8255.
- For any other psychiatric emergency, please call the VA operator at 206-762-1010 and press "0" for the operator. Both during and outside of business hours, there is an on-call provider. The operator will take your name and number, contact the on-call provider, and have the provider call you back. You are also welcome to come to the Psychiatric Emergency Room at the VA Puget Sound.

You are being invited to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." You will be given a copy of this form once it is signed.

If you have any questions regarding the study after you speak to us, you may contact the staff by phone.

1. Purpose of research study and how long it will last: People with a history of traumatic brain injury (TBI) often have physical pain, such as headaches or neck pain, as well as pain from other injuries. Effective treatments that teach people how to manage pain have been used in the general population. However, it is often hard for people to access these treatments because they are usually offered only in person.

The purpose of this study is to examine whether two treatments for coping with pain can be effectively delivered by telephone and if each of the treatments is effective for Veterans with a history of TBI. The treatments to be used in the study are called "self-management" approaches to pain management.

One of the self-management approaches emphasizes one set of factors that impact pain and how to manage them, and the other emphasizes another set of factors that impact pain and how to manage them. Both of these treatments are offered in the community and have been used to treat pain in persons with TBI.

Additionally, the researchers want to determine if each of these treatments can help reduce the negative consequences associated with pain such as changes in mood, daily activities, and enjoyment of life.

You are being asked to participate in this study because:

- You experienced a TBI after the beginning of Operation Enduring Freedom (OEF), and this TBI has been documented in your medical record.
- You have reported to the researchers that you experience moderate to severe chronic pain on a regular basis.
- You served in Operation Enduring Freedom, Iraqi Freedom, or New Dawn (OEF/OIF/OND).

2. Description of the study including procedures to be used:

How many people will participate? This study is a joint effort between the VA Puget Sound Health Care System ("VA Puget Sound") and the University of Washington. The sponsor of this study is the Department of Defense.

All of the participants in this study will be OEF/OIF/OND Veterans recruited from the VA Puget Sound. The study will enroll up to 250 subjects.

How long will I be in this study? The study involves one in-person testing session, several telephone interviews and assessments, and eight telephone-based treatment sessions (described below). The total time involved in the study is approximately 21 hours over a 7-month period. All study activities can be completed by telephone, except for the baseline cognitive testing which must be completed in person.

This study is time intensive, so you should enroll only if you think you can finish the study. A flowchart of study procedures is at the end of this consent form to help you decide if you can make the time commitment. If you move away from the Puget Sound area during the study, you can still continue to participate.

Research vs. Clinical Care

All of the activities included in the study are considered research and are not part of the normal treatment you would receive at the VA Puget Sound.

When you enroll in the study, a research enrollment note will be entered into your medical record stating that you have agreed to participate in the study. When you have completed the study, or if you leave the study for any reason, a note will be entered into your medical record stating that you have stopped participation in the study.

Other than the notes regarding your enrollment and completion of the study, *no notes regarding your study treatment will be entered into your medical chart.* All information that you share in your telephone-based treatment sessions will remain confidential unless you express risk of imminent harm to yourself or others, as noted in the mandatory reporting guidelines.

Overview of Study Activities

- Informed consent process
- Medical record review
- Assessments:
  - One in-person cognitive assessment (20-30 minutes)
  - One interview that can be done in person or by telephone (20-30 minutes)
  - Four "Pain Plus" assessments
  - One 5-minute treatment assessment
- Telephone-based treatment sessions

Informed Consent Process

This process will take place at the VA in Seattle or at the American Lake Campus. A research staff member will review the details of the study with you and answer any questions you may have to see if you are interested in participating.

Medical Record Review

Research staff members will collect some information about you from your medical record, including the following:

- Level of service connection
- Number of TBI events
- Where you were located when the TBI-related events occurred (for example, in combat, in the USA)
- Cause of TBI(s)
- Severity of TBI(s)

This information will be linked to the data you provide while you participate in the study.

Assessments

There are several assessments required as part of your participation in this study: cognitive tests, a baseline assessment interview, four "Pain Plus" assessments, and one 5-minute assessment.

- **Cognitive Testing.** The first assessment is a short series of cognitive tests. These assessments will test your memory and how quickly you process information. These tests will take about 20 minutes to complete and need to be completed in person at either the VA in Seattle or at the American Lake Campus (whichever is more convenient for you). You can complete the cognitive tests immediately following the informed consent process, or schedule them for a time that is more convenient for you.

- **Baseline Assessment Interview.** A research staff member will interview you for 20-30 minutes. You will be asked a number of standard questions. The most straightforward of these questions will ask about your age, gender, race, ethnicity, education level, your service in the military, and your pain problem(s). When asking about your pain, you will be asked when it began, the location of your pain, how often you experience pain, and different treatments you have received for your pain problem(s). We will also ask if you have recently started, stopped, or changed any pain medications, and if you have plans to start, stop, or change any pain medications sometime in the near future. You will also be asked about personal habits and history, including alcohol and drug use, as well as any problems you may experience related to stressful military experiences. You will also be asked two questions about whether or not you ever experienced military sexual trauma.

  Some examples of the questions that will be asked during the evaluation include, *"How often do you have a drink containing alcohol?"* and *"How much have you been bothered by repeated disturbing memories, thoughts, or images of a stressful military experience?"* You are free not to answer any questions you do not wish to answer.

  These questions can be completed in person at either the VA in Seattle or at the American Lake Campus after you complete the Cognitive Testing or over the telephone at a later time.

- **Four "Pain Plus" Telephone Assessments.** Each of the four "Pain Plus" telephone assessments includes a set of **four telephone calls on different days, all within the same week.** The "Pain Plus" assessments include a total of 16 telephone calls over the 7-month study period.

  During ***each*** telephone call, research staff will ask you to rate your current, average, worst, and least pain intensity over the past 24 hours. Researchers will also ask you questions about the frequency and intensity of any headaches you may have had in the past 24 hours. Some examples of these questions that will be asked in each of the four assessment periods include, *"In the past 24 hours, on the average, how intense was your pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'?"*

  Researchers may ask you to answer these questions more than four times within an assessment period if you do not complete the four telephone calls within 1 week.

Within each "Pain Plus" assessment period, additional questions will be asked relating to how pain has interfered with your life, how you have been feeling recently, and thoughts or feelings you have had about your pain. These extra questions take up to 25 minutes to answer. Examples of these extra questions include, *"How much time over the last 2 weeks have you been bothered by feeling down, depressed, or hopeless?*" and *"How much has pain interfered with your enjoyment of life?"* You will also be asked questions about how logical the treatment seems to you, how successful you think it will be in reducing your pain, and how your relationship is with your clinician. We will also ask you about your satisfaction with treatment once the treatment is over. You are free not to answer any questions you do not wish to answer.

To make each of the "Pain Plus" 1-week telephone assessments more convenient to your schedule, you may choose to:

- Complete the extra set of questions all at once in any one of the four telephone interviews;
- Spread the extra set of questions across four telephone interviews so that each call is about 10 minutes long; or
- Complete the extra set of questions on a paper questionnaire and return it to staff by postal mail. Should you choose to finish the extra set of questions by mail, you will receive a postage-paid return envelope to return the questionnaire. Research staff will call you if we have not received the completed questionnaire after a certain period of time.

The entire time required for of the four telephone calls in a 1-week period is about 30-45 minutes.

Throughout your participation in the study, research staff will call you to complete four sets of "Pain Plus" telephone interviews. They will ask you about your progress within the study on the following schedule:

Pre-Treatment "Pain Plus" Assessment. The first series of four phone interviews must be completed before the first phone treatment session. These questions can be completed only via phone. This assessment may be repeated if you do not complete all of your pre-treatment telephone calls and get assigned to one of the two interventions within 14 days of completing your initial pre-treatment assessment period..

Mid-Treatment "Pain Plus" Assessment. The second set of four telephone interviews will occur about 5 weeks after you start treatment. Even if you have missed treatment sessions, we will still ask you to do the assessment about 5 weeks after you do the Pre-Treatment "Pain Plus" Assessment.

Post-Treatment "Pain Plus" Assessment. The third set of telephone interviews will occur at the end of your treatment if you complete treatment. If you don't complete the treatment, we will still conduct this assessment about 10-12 weeks after you complete the Pre-Treatment "Pain Plus" Assessment.

Follow-Up "Pain Plus" Assessment. The fourth set of interviews will occur about 6 months after you complete the Pre-Treatment "Pain Plus" Assessment, regardless of how many treatment sessions you complete.

In summary, you will complete 16 brief telephone assessments over the study (four per week at the beginning, middle, and end of treatment) and then again 6 months after you are assigned to one of the treatment interventions. The assessments will take approximately 3 hours total, over a 6-7 month period.

One 5-MinuteTreatment Assessment. You will be asked to complete one 5-minute assessment after your initial treatment phone call. A research staff member will call you following your first treatment session to ask you some questions about your relationship with the treatment clinician and your thoughts about the treatment.

Telephone-Based Treatment Sessions

You will receive one of two types of treatment offered in this study. Both treatment interventions involve eight 1-hour telephone calls with your assigned study clinician. Both interventions involve educating you about pain, discussing the impact of pain on your life, and discussing different ways to manage it in hopes of decreasing your pain and its impact on your life. These approaches are called "self-management" approaches to pain management. You will be encouraged to use what you learn in the telephone sessions outside of treatment to help you with your pain.

Every participant will receive eight 60-minute sessions conducted by telephone by one of the study's clinicians. Whenever possible, research staff will try to schedule the treatment sessions an average of once a week so that your total time in treatment is 8 weeks.

The research staff has the flexibility to call you more or less often, depending on which is more convenient for your schedule. You will need to complete all eight treatment sessions within a 12-week period.

The clinicians who will conduct the treatment sessions are clinical psychologists or master's-level therapists with special training in the treatment interventions. These clinicians are supervised by the study investigators, who are all licensed psychologists. The study clinician will have the following information: your name, contact information, and gender. Your assigned study clinician will not have access to any of your responses to the questions you answered during the assessments except for the following information: average pain intensity over the past week, date of diagnosis, and responses to questions about thoughts of suicide and/or self-harm.

Before the first treatment session, you will be randomly assigned (by chance, like flipping a coin) to one of two treatment interventions. Your study clinician will not disclose to you which of the two self-management pain treatment interventions you have been assigned to. Before the first treatment session, you will also be asked to complete the Pre-Treatment "Pain Plus" Assessment.

You will receive a reminder call or text message, whichever you prefer, prior to each of your scheduled sessions. You will receive treatment materials for Session 1 after the consent session. Research staff will also send you a workbook by standard mail or a CD containing the workbook, whichever you prefer. The workbook will include materials to refer to and discuss during the telephone treatment sessions. You will also receive additional materials to review between sessions. You may also receive audio recordings as part of the material that will be discussed during sessions.

You will schedule your treatment sessions with your assigned clinician at your mutual convenience. You can participate in these calls during the day or evening, including weekends, from wherever you choose. You will be encouraged to find a place that is private, quiet, and free of any interruptions.

Your treatment sessions are considered research activities that are separate from your VA clinical care. As such, the telephone appointments you have will not be scheduled as VA medical appointments nor documented into your medical record.

The research staff members who will conduct the assessments with you will not know which treatment intervention you have been assigned to nor will they have access to any information covered during the treatment sessions with your study clinician. Any questions about the treatment you are receiving should be directed towards your clinician.

You may not participate in the treatment sessions in person. All treatment will be by telephone only.

A clinician may call you about 2, 6, and 10 weeks after your last treatment session. The clinician will call you to ask how you are doing and answer any questions you may have. These telephone calls are called “booster sessions” and will take 5-15 minutes each.

Use of Telephone Headsets for Assessments and Treatment

Some telephones have the ability to be used with a headset. If your telephone accepts a headset input and you would like to use a headset over the course of the study, the research staff will offer you a headset. You may request a headset to be sent to you at any time during your participation in the study. The purpose of the telephone headset is to reduce physical discomfort that you may experience while speaking on the telephone to research staff and clinicians for extended periods of time. You may keep the headset after your participation in the study has ended.

Use of Electronic Correspondence

If you prefer, you can get reminders of your study appointments by telephone or text. You will also be free to contact study staff at any time if you have questions about your upcoming appointments.

3. Description of any procedures that may result in discomfort or inconvenience: You may experience mild physical discomfort as a result of spending a moderate amount of time on the telephone with research staff during the assessment periods and treatment. You will be offered a headset to use to reduce physical discomfort.

You may experience boredom and/or fatigue while completing the questionnaires, interviews, and cognitive tests. You may also experience mild anxiety, frustration, and/or stress while reporting on your psychiatric and/or physical symptoms and history.

Some of the questions you will be asked in the evaluation portion of the study may seem personal or embarrassing, or they may upset you. You may refuse to answer any of the questions. It might be uncomfortable to answer questions having to do with whether you have experienced traumatic events, felt depressed, experienced thoughts of suicide, or had the urge to harm others. You can refuse to answer any of the questions or may leave the study at any time without affecting your current or future care at the VA.

4. Potential risks of the study: All of the risks that we expect and know about in regards to this study are listed above. However, there may be other risks which we do not know about or may later be discovered during future studies. We will contact you as soon as possible should we find any new risks or discomforts during this research study that may pose a risk to you.

Breach of Confidentiality. Information that identifies you will be used in this study and shared with research staff. Although the research team will make every effort to protect your private health information and guard against any loss of privacy, accidental breaches in confidentiality do sometimes occur. Although extremely unlikely to occur, a breach in confidentiality and a resulting loss of privacy could have significant effects (such as monetary loss due to identity theft, some type of discrimination resulting in loss of health and/or life insurance coverage, or loss of job). Other risks that are possible: if certain protected health information reaches your current or future health insurance carrier, your employer, or others may include current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history, status in the community, or embarrassment.

The steps we take to protect your confidentiality to the best of our ability are further detailed in Section 7. The Principal Investigator and all researchers associated with this study will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists despite every reasonable effort. If you have any questions, please ask Dr. Rhonda Williams at 206-277-6290 or Dr. Jeanne Hoffman at (206) 221-6511.

Worsening or Discovery of Problems. As a result of participation in this study, you may learn information that could be upsetting to you.

If you are upset about the results learned during the course of the research study, or for any other reason related to the project, one of the co-investigators will talk with you and, if appropriate, may refer you to a counselor. Further, just like with any type of therapy, you may not feel like the type of therapy being offered in this study is helping you get much better.

It is even possible that your symptoms will get worse over time. Again, you are free to discontinue with the study at any time. If, at any point during the study you or research staff feels like your symptoms are getting worse, please call Dr. Rhonda Williams at 206-277-6290. She will work with you and your study clinician to figure out additional or alternative treatment options. This is to make sure that you are receiving the best possible care at all times.

What if I discover I am depressed or suicidal based on my responses to the surveys?
You will be asked questions about symptoms of depression as part of this study. Our study survey is not intended to diagnose depression. If you feel depressed and would like more information, we encourage you to follow up with your mental health provider. If you do not already have a provider, you may contact the Principal Investigator (Dr. Williams) or the Co-Investigators (Drs. Hoffman and Ehde) for referral information.

If you are having thoughts of harming yourself in some way, or indicate to us that you may be in some danger of hurting yourself, the study clinicians and/or investigators (who are clinical psychologists) will assist you in getting additional help. This may include talking with you and/or your mental health provider in order to further evaluate these risks. Additional steps that we might take to ensure you are safe might include referring you to an Emergency Room for further evaluation, reporting the incident to the Institutional Review Board, and having our research monitor review the adverse event documentation. You will be reminded that you can come to the Emergency Room at the VA at any time if you are concerned about depression or suicidal thoughts. Another alternative is to call the VA Suicide Prevention Hotline at 1-800-273-TALK (1-800-273-8255) if you are having thoughts of harming yourself.

5. Potential benefits of study: There may not be any direct benefit to you by participating in this study. However, if the treatment you receive is effective for you, you may experience a decrease in your daily pain or an improvement in how you manage your pain. As a result, pain may interfere less with your daily activities. The investigators expect the information gathered during the study will help them to better understand and formulate treatment for individuals with chronic pain and TBI in the future.

6. Other treatment available: There may be other treatments or procedures available to help you manage your pain if you choose not to participate in this study. The research staff recommends that you speak to your health care provider about the different options for pain management that may be available to you. If you would like any additional information on national resources for disability, pain, mental health, and other resources at any time, you may request assistance from study staff in obtaining up-to-date information.

Do I have to participate in this study?
No. Your choice about being in this study or not is entirely up to you. Participation is voluntary. Your medical care and any VA-related benefits will not be affected in any way whatsoever by your choice about study participation.

Participation is voluntary.
Your participation in this research study is voluntary. The authorization to use your protected health information is also voluntary. You may refuse to sign this Informed Consent Form and authorization. However, in order to participate in this study, you must sign the Informed Consent Form and authorization. The authorization is attached at the end of this document.

7. Use of research results / Confidentiality: The information obtained about you will be kept confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records. The purpose of this access is to review the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

- Research team members
- Department of Defense, the study sponsor
- Federal agencies including, but not limited to, the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accounting Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies Institutional Review Board, Oversight, and Compliance groups at the University of Washington (UW)
- Banking and Accounting Operations at the University of Washington may be provided with your full name and mailing address for payment and reporting purposes
- Research monitor

How will my confidentiality be protected?
The identifiers that will be used in this research study include your name, social security number, birth date, address, and contact information. These identifiers will be used to obtain personal information about you or your health from VA records, interviews, surveys, and tests.

All information obtained about you will be held in the strictest confidence by taking several precautions. The researchers will make sure that your identifying information (such as your name, address, and social security number) is kept separate (both electronically and in hard copy) from your personal information. “Personal information” would include your answers to the interview questions and information from your medical records.

We will create and use a study code to link your personal information and identifying information. This study code will be accessible only to the investigators and research staff listed within this consent. The “crosswalk” that will link your identifying information to your research data will be stored in a password-protected file on a secure server at the VA.

The master list linking names to code numbers will be kept separately from other research records at the VA Puget Sound (Seattle Division).

Part of your research records will be stored in paper form in a locked file cabinet at the VA Puget Sound (Seattle and American Lake Campus), and part will be stored electronically. The file cabinets and computers will be housed in rooms that are locked when unoccupied.

Data will not be stored on any laptops or computers outside of the VA. All electronic data will be stored in encrypted, password-protected files on the VA secure research server. Any data that needs to be transmitted will be done so electronically through a shared server. The UW investigators will have access to all data by logging into the VA secure server. There will be limited staff who have access to the identifiable information within the crosswalk.

We will ask you for your permission to include your data from this study in a larger data repository. If you agree, we will provide you with a separate consent form specifically for the repository.

Once this study is completed, the investigators will not use the code linking you to your data for any additional research. The code linking you to your data will be held in a secure database until the VA receives authorization to destroy it in accordance with federal records regulations. It may be several years before the code linking you to your data is actually destroyed. All coded data will be stored on secured computers or in file cabinets in locked offices. This coded data will be kept indefinitely.

If you are consented at the VA at the American Lake Campus, hard copies of your research records will be completely de-identified and photocopied; the originals will be sent by United Parcel Service to the VA in Seattle for data entry and long-term storage. The copy at American Lake will be stored in a locked file cabinet within a locked office until it is verified that the original was received in Seattle. After receipt, the copies at American Lake will be shredded and securely disposed.

All publications resulting from this study in the future will be based on unidentifiable data; your personal identity will be confidential. No identifying or personal information will be published. Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information that you provide.

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.

Certificate of Confidentiality & Mandatory Reporting

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

Exceptions: A Certificate of Confidentiality does not prevent researchers from disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information.

The Certificate cannot be used to resist a demand for information from personnel of the United States government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

Will I be able to see my research data?
During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your personal health information from Dr. Williams at 206-277-6290.

8. Special circumstances: Veterans are not required to pay for services received as a subject in a VA research project. However, the VA requires some Veterans to pay co-payments for medical care and services (such as normal hospital and prescription expenses, which are not part of the research study). You will still have to pay these co-payments as long as they are not related to this research study.

We will enter two notes into your medical record as part of your participation in this study; specifically, when you consent and enroll into the study and when you withdraw from or complete the study. All authorized users of the national VA medical records system can have access to your medical record and will potentially be aware of your participation in this study. This record will be kept forever.

You will be reimbursed a total of up to $130 for your participation by the University of Washington and Department of Defense. Details of payments are outlined in the attached flowchart for your convenience.

9. Withdrawal from the study: If you decide you no longer want to participate in the study before you finish the treatment sessions, you will be asked to complete the follow-up assessments. You do not have to answer any question that you do not want to, and if you prefer you may request not to be contacted for further assessments and withdraw from the study completely.

If you withdraw from the study for any reason, we will place a note in your medical record indicating that you are no longer participating.

You may be withdrawn from the study without your consent if the researchers feel you are not able to fulfill the study requirements. Sample reasons that you may be withdrawn from the study include:

- The researchers cannot reach you to coordinate appointments;
- You become incarcerated during the course of this study;
- The researchers feel that this study is not in your best interest.

What if I decide not to participate?
You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision not to participate or if you withdraw. You will not lose your VA or any other benefits if you decide to do so. If at any time you wish to drop out of the study, please call Dr. Rhonda Williams at 206-277-6290.

Can I withdraw my permission to use my personal health information?
You may withdraw permission to use your personal health information for research purposes at any time. To withdraw your permission, you can write to:

Dr. Rhonda Williams
VA Puget Sound Health Care System
1660 S. Columbian Way (RCS-117)
Seattle, WA 98108

Or, you can ask a member of the research team to give you a form to withdraw your authorization. If you withdraw your authorization, you may not be able to continue to participate in the study.

Use of personal health information if I withdraw my authorization.
If you send a letter to the Principal Investigator to withdraw this authorization, the use and disclosure of your protected health information will stop as of the date she receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. If your information has already been combined with other people's information in the study, it will continue to be used, but no further information about you will be collected after you withdraw the authorization.

Questions about revoking authorization.
If you have any questions concerning your withdrawal of authorization to use your protected health information, you may contact the Principal Investigator, Dr. Rhonda Williams, at (206) 277-6290.

10. Questions or concerns related to the study: The study researchers (listed below) *must* be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

During business hours (8:00 a.m. – 4:30 p.m.)	Call Dr. Rhonda Williams at (206) 277-6290.
After business hours (nights and weekends)	Call 206-762-1010 and ask the operator to page the on-call Psychiatrist.

In the event of a life-threatening emergency, call 911 or go to the Emergency Room.

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, whose job it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.

11. Research-related injury: Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

_____ _____
Subject Signature **Date**

_____
Print Name of Subject

_____ _____
Signature of Person Obtaining Consent **Date**

_____
Print Name of Person Obtaining Consent

STUDY TITLE: Structured Treatment of Pain (STOP) Study

Procedure	Number of Visits or Assessments	How Often / When	Time Required for Subjects	Compensation
Cognitive Testing Session	One in-person cognitive testing session at VA Seattle or American Lake	Once, following informed consent process	About 20 minutes	$20
Baseline Assessment	One interview assessment in person at the VA or by telephone	Once, following cognitive testing	About 20-30 minutes	$0
Pre-Treatment "Pain Plus" Assessment	4 telephone assessments conducted within a one-week period	After completion of cognitive testing; before treatment begins	About 30-45 minutes total	$20
Treatment	8 treatment sessions (conducted by telephone)	After completion of cognitive testing, baseline assessment, and Pre-treatment "Pain Plus" Assessment. Includes eight treatment sessions; once per week on average	About 60 minutes per treatment session. Treatment will last 8 weeks if one treatment session is conducted per week.	$0
Treatment Assessment	One assessment administered via phone	After first treatment session	About 3-5 minutes	$0
Mid-Treatment "Pain Plus" Assessment	4 telephone assessments within a one-week period with the option of completing some questions on own with paper and pencil	Approximately halfway through treatment or approximately 5 weeks after Pre-treatment "Pain Plus" Assessment (if treatment sessions missed)	About 30-45 minutes total	$20
Post-Treatment "Pain Plus" Assessment Period	4 telephone assessments within a one-week period with the option of completing some questions on own with paper and pencil	After completion of treatment or approximately 10 weeks after Pre-treatment "Pain Plus" Assessment (if treatment sessions missed)	About 30-45 minutes	$20
6-Month "Pain Plus" Assessment Period	4 telephone assessments within a one-week period with the option of completing some questions on own with paper and pencil	6 months after you are enrolled in one of the two treatment interventions	About 30-45 minutes	$20
Bonus Payment: All assessments completed	All 16 telephone assessments, cognitive tests, telephone interventions, and baseline assessment are completed	Over 6-month period (see timeline listed above)	Totaling approximately 20 hours over a 7-month period	$30