Subject Name:_____
First Name MI Last Name

Title of Study: Remotely-Delivered Benefits Counseling for Service-Connection Applicants

Principal Investigator: Marc Rosen, MD VA Central Connecticut Healthcare System (v.06.28.16)

SECTION I: THE PURPOSE OF THE STUDY AND HOW LONG IT WILL LAST

You are invited to participate in a research study designed to determine the usefulness of a new computerized program for Veterans. You have been invited because you are a Veteran applying for service-connection for a psychiatric condition. Your participation will last for 24 weeks.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form provides detailed information about the research study which a member of the research team will discuss with you. This discussion will go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study you will be asked if you wish to participate, and (if so) you will be asked to sign this form.

SECTION II: DESCRIPTION OF THE STUDY INCLUDING PROCEDURES TO BE USED

This study will help us learn if Veterans who are given access to a new computer program are more likely to engage in work and work-related activities as compared to Veterans who are given standard VA information. The study is funded by a grant from the VA Rehabilitation Division of Research and Development. We plan to enroll 190 Veterans in the study. Your participation will involve a 90-minute, face-to-face interview and up to three telephone interviews over a 24-week period. You will also be asked to log into a research website at home after the first visit.

If you decide to participate in this research study, this is what will happen:

1) You will meet in-person with a research assistant for an initial meeting lasting approximately 90 minutes. At this meeting, you will be asked about topics including your psychological symptoms, alcohol and drug use, views about the disability application process, and working. You will also be asked about your life situation including your legal status, sources of income, what services you have received from VA, and about any problems you may have related to physical, psychological or substance use conditions. Researchers will also collect information from your medical record, including information about your Compensation and Pension records and any VA treatments you have received.

2) At the end of the first meeting, you will be given a user ID and password and will be instructed to log onto a research website. There are two versions of the website. One version has a computer program and the other has other information about the VA. The version that you are assigned to will be determined by chance (like a flip of a coin, or rolling dice). If you do not log onto the study website within one week of completing the initial evaluation interview, a study therapist will call you and encourage you to log in. If you don't log in within one week of hearing from the therapist, your participation in the study will end.

   Within two days of logging onto the website, you will receive a call from a study therapist. The therapist will speak with you about what you thought about the information on the study website and will be available to answer questions about the website. You will have up to three calls with the study therapist lasting up to thirty minutes each. The first two calls with the therapist will

occur within the first month of your participation. All of these telephone calls will be audio-recorded.

3) Follow-up interviews with research staff will be conducted over the phone at approximately four, twelve, and twenty-four weeks after the initial meeting. These phone calls will take about 45 minutes each to complete. You will be asked questions similar to those asked in the initial face-to-face meeting.

   You will be asked to give the names and telephone numbers of up to three people who will know where you will be over the next six months. If you miss a research appointment and cannot be reached, the research staff will contact these people. Research staff will ask these three people where you are and will ask them to help the research staff contact you.

   If we continue to have trouble contacting you, we may also consult your VA medical record to check for upcoming scheduled appointments and other locations where you may be reached so that we may re-establish contact. Please initial below to indicate that you agree to have us consult your chart for this information in the event that we are unable to contact you for missed research appointments. If you would prefer us to not consult your medical record for this information, please leave this blank.

I agree to have research staff consult my VA medical record for upcoming scheduled appointments and other locations where I may be reached in the event that I am not able to be contacted. _____

Participant's Initials

All the study meetings are part of the research. The meetings are separate from the clinical care you may be receiving at the VA and will not impact your service connection in any way.

SECTION III: DESCRIPTION OF ANY PROCEDURES THAT MAY RESULT IN DISCOMFORT OR INCONVENIENCE

Completing the study questionnaires is not expected to be stressful but you may become bored frustrated, or upset in some way. You may skip questions that you find too uncomfortable to answer. Your decision to skip some questions will not affect your participation in the study. We will offer you breaks during the interviews, and you may request a break at any time.

The research team might end your participation in the study if your continued participation is thought to be harmful to you or cannot be managed by the study staff.

SECTION IV: EXPECTED RISKS OF STUDY

Before you decide to participate, there are some risks you should know about:

1. All data from the study will remain confidential and will not be shared with VA providers or those involved with your service connection evaluation. A note will be entered into your VA medical record indicating that you are participating in a research study, but no information about the answers you provide as part of this research will be in your medical record. This limited information will have no impact on your service-connection or the care you may receive from VA providers.

   The results of the assessments and telephone counseling sessions will not be placed in your

medical record or disclosed to anyone at the VA outside of the research study team. The results are used for research purposes only, with one exception. If the research staff discover that you might harm yourself or someone else, the staff member will give that information to VA clinicians who are not connected to the study. This will happen so that you can get an emergency evaluation and treatment. If there is an emergency, the VA clinicians will describe the emergency in your medical record. The notes by the VA clinician would then become available to someone who reviews your service-connection application. It is very unlikely that an emergency disclosure would prevent you from receiving service-connected disability benefits.

2. Potential effect of work on the benefits application process. Veterans compensated for physical or mental problems that developed during or were made worse by military service are not supposed to be penalized for coping well with these problems by working. However, the Veterans Benefits Administration reviews claims on a case-by-case basis, and it is unknown to what extent working will influence your disability determination process.

3. The three people whose names you give us to help us find you may find out that you are in a research study. Your participation in this study may be disclosed to these three individuals in the event that you cannot be reached directly for assessment visits.

4. Someone may learn that you have accessed the study web site. Although the study website will not contain personal health information, it is likely that the computer you use to access the website will keep a record of your having accessed the research site (i.e., in the history of browsed sites on the computer you use). Someone who discovers your computer linked to the study website may suspect that you have applied for service connection.

Confidentiality of Information:

Participation in research may involve a loss of privacy. You will be provided with a user ID and a temporary password. Keeping your user ID and password private will help ensure that questions you answer on the website will only be accessible to research staff.

Your research records will be kept as confidential as possible according to strict VA policies and procedures. All research data including questionnaires, enrollment records, and consent forms will be secured in locked files and maintained according to VA requirements. Your enrollment records and consent forms will be stored separately from the research data. Only approved members of the research team will have access to the questionnaires, which will be secured in a locked cabinet and will not be labeled with any information that can identify you. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, your social security number, initials, birth date, etc.). The master list linking your name to your code number will be stored separately from your research data.

Information with personal identifiers (e.g., Compensation and Pension examinations, records of treatments you received) will be stored on VA clinical servers behind a secure VA firewall and will not be stored with research data. Other forms that contain personal information such as consent forms will be collected by the research staff and will be stored in locked file cabinets.

Research data and audio-recordings will be uploaded to a secure VA server. All data will then be stored on the VA Connecticut's secure data storage servers and kept for as long as VA regulations require it to be stored.

Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government

Accountability Office (GAO), the Office for Human Research Protections (OHRP), Office of Research Oversight (ORO), and VA Connecticut Healthcare System Research Office.

The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for Veteran and non-Veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits to the VA, procedures, and laboratory tests will be included in this record. In addition to the research team and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

SECTION V: EXPECTED BENEFITS OF STUDY

Your ability to work may improve as a result of engaging in the study interventions. Your participation may lead to knowledge that may help others.

SECTION VI: ALTERNATIVE THERAPY OR DIAGNOSTIC TEST

The alternative is to not participate in this study. Participation in the study is voluntary and you can withdraw at any time without affecting your VA care or service connection in any way. During the course of the study, we will inform you if there are any new findings that develop that may affect your willingness to participate.

SECTION VII: USE OF RESEARCH RESULTS

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

During your study participation, if researchers discover that you are a danger to yourself or someone else, you will be recommended to meet with the principal investigator, a doctor who is covering for him, or emergency room staff for further evaluation. In these cases, a clinician could decide that voluntary (or involuntary) hospitalization is necessary in order to protect your safety or the safety of others.

SECTION VIII: SPECIAL CIRCUMSTANCES.

You will be paid for participating after each study assessment. You will be paid $60 for the initial interview session and $30 for each four, twelve, and twenty-four week follow-up telephone session for a total of up to $150. You will be reimbursed 57.5¢ per mile traveled from your residence to and from the assessment session.

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

There will be no charge for care received as part of your participation in this study. However, some Veterans are required to pay a co-payment for medical and other services received at a VA medical facility that are not part of the study. These co-pay requirements will continue to apply to medical care and services provided by VA that are not part of this study.

If you are injured as a direct result of your participation in this research study, VA will provide necessary medical treatment at no cost to you. Except in very limited circumstances, this medical treatment will be provided by a VA medical facility. There are no plans to provide compensation for injury, disability, or other losses after your participation in the study has ended. However, by agreeing to participate in this research study you are not waiving or giving up any legal rights to seek compensation. If you have any questions about your rights as a subject you may contact the Chairperson of the Human Studies Subcommittee (HSS) at 203-932-5711, extension 3350. If you have any complaints, concerns, or

pertinent questions regarding the conduct of this study (or if you have any questions about compensation for injury) you may contact the HSS Coordinator in the Research Office at 203-937-3830.

RESEARCH SUBJECTS' RIGHTS

I have read or have had read to me all of the above, and I voluntarily consent to participate in this study. The study has been explained to me and all of my questions have been answered. I have been told of the risks or discomforts and possible benefits of the study. I have been informed of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. I will receive a signed copy of this consent form.

The results of this study may be published, but my records will not be revealed unless required by law.

If I have any medical problems, a research-related injury, complaints, concerns, or questions about the research I have been told I can call Marc Rosen, MD, at 203-932-5711, extension 2112 (during normal working hours) and the Research Doctor on Call at the Psychiatry Emergency Room, 203-932-5711 extension 4471 after hours.

Signature of Subject	Date

Signature of Person Obtaining Consent	Name of Person Obtaining Consent (Print)	Date

Signature of Principal Investigator	Date

HSS Approval Stamp

APPROVED

JUL 18 2016

HUMAN STUDIES SUBCOMMITTEE