Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: Evidence-Based Multidimensional Pain Self-Management Planning: Personalized by and for Veterans via Web-Based Application (Phase 1: Focus Group)

Principal Investigator: [redacted] Facility: VA Maryland Health Care System

IRB Study Number: [HP-00086659]
Sponsor: VA Office of Research and Development

INTRODUCTION:

You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

CONCISE SUMMARY

This is a research study to evaluate the utility of a tablet-based application (App) in assisting patients and their providers in designing and using customized pain management plans. Participation is voluntary.

The purpose of this single visit study is to evaluate participants' perceptions of an early version of our computer App for pain management. We will ask for your participation in a focus group discussion about the App, during which general questions about your impressions of App features will be asked. At the end of the App focus group discussion, we will ask you to complete 6 short questionnaires regarding your experience of pain, sleep, your daily activities, mobile phone and App use, and pain management planning. In total, no more than two hours of your time will be needed to complete this study.

The risks are minimal and consist primarily of the minimal risk of information disclosure. All information collected for the study will be stored in secure VA computers but will not become part of your clinical record. Embarrassment or discomfort when responding to questionnaires is possible. This study will not have direct benefits to you, the participant, although our goal is to help

patients and their healthcare providers to design and use effective customized pain management plans. Participants will be provided with $25 compensation for completion of the focus group study.

If you are interested in learning more about this study, please continue reading below.

RESEARCH DETAILS

PURPOSE OF THE STUDY

Chronic pain is highly prevalent in Veterans and often resistant to medications so that non-medication management is required. For many patients, the most effective approach is comprehensive pain management including multiple therapies addressing: physical, mental, mind-body, sleep, safety, and environmental needs. For patients completing an intensive pain management program, these therapies are coordinated into comprehensive, multidimensional evidence-based plans for pain self-management (pain self-management plans) tailored to each patient. This approach, while effective, is not more widely available due to cost and health system factors. Our vision is a mobile web-based application (App) that provides immediate feedback to a Veteran seeking to develop their own pain self-management plan.

We are conducting an early stage study of a newly developed mobile App to assist patients and their healthcare providers in designing pain self-management plans. At this stage, we would like to invite your feedback about the App and to learn how Veterans respond to an App for pain self-management. As part of this process, we will ask for your participation in a focus group discussion about the App features as presently configured. Your input may help guide future modification of the App for general improvement.

As someone with chronic or persistent pain, you are being asked to participate. No placebo treatment is used in this study. All participants will have the opportunity to assess the App.

A total of 5 participants will be enrolled in this phase of the study which is taking place at Loch Raven VAMHCS.

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STUDY PROCEDURES:

In this early stage study, every participant will have the opportunity to provide their impressions about the pain self-management planning App. Each of the five focus group participants will first be asked to try using the computer tablet App to create a pain self-management plan.

The focus group will then include general questions on how you perceived the App in terms of ease-of-use and potential effectiveness in the home environment. Then, after conclusion of focus group questioning, we will ask you to complete 6 short questionnaires regarding your experience of pain, sleep, your daily activities, mobile phone and App use, and pain management planning. In total, no more than two hours of your time will be needed to complete this study.

This single visit study will take place at the Loch Raven VA.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to participate in the focus group by communicating your impressions about the App openly and respectfully.

POTENTIAL RISKS/DISCOMFORTS:

There are potential risks associated with this study, but the investigators have worked to minimize these risks. We anticipate no risks to health, well-being, or personal safety to you in this study. We will explain every aspect of the study to you and you may refuse to participate in any part of the study.

Tablet use: Proper use of the tablet computer is not associated with risk.

App exposure: The app is designed to encourage normal, safe activities. Risk is minimal.

Questionnaires: Completing questionnaires can make people feel tired or mildly frustrated. You will be able to take breaks or stop if needed. The results are confidential to the study. Loss of confidentiality will be minimized by storing data in a secure environment.

There may be risks in this study which are not yet known.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. Potential personal benefits include an introductory experience in developing a pain self-management plan and receipt of compensation for participation.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected.

COSTS TO PARTICIPANTS

You will not be charged for participation in this single-visit focus group. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

It will not cost you anything to take part in this study.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

If you complete the focus group session, you will receive a check for $25.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: [redacted]

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve the collection of confidential information. As with any scientific research study involving the collection of potentially sensitive medical information, participation in this study may involve a risk of breach of confidentiality. The investigator and research staff will have access to your information and data. Your data will be coded to protect your privacy. All study-related information will be stored in secure locations. Paper reports will be stored in locked cabinets in a locked room. Electronic data will be password protected.

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

Health Information Portability and Accountability Act (HIPAA)

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There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr.[redacted] and the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

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WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information from this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Because identifying information will be removed, we may not ask for your additional consent.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or if you need to report a medical injury related to the research, please contact the investigator Dr. [redacted]

- There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research. All study materials must be returned at the time of withdrawal. Written handouts may be retained by the participant, however, these materials should not be disseminated or posted to the internet by the participant at any time. A written withdrawal request is required if the participant decides to withdraw from the study. The request for study withdrawal should be sent to: [redacted]
    - If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include information that indicates that you are at risk of harm from continuing in the study, inappropriate use of study materials or technology,

behavior or conduct that places yourself or others at risk. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO).

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56582 or 56568

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

. Your signature indicates that the research team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Furthermore, by signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date