Title of Study: ___SUMMIT Phase 2__

Principal Investigator's Name: Manik Chhabra, MD

SUMMARY OF STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?
We are asking you to choose whether or not to volunteer for a research study being funded by the VA Health Services Research and Development Service (VA HSRD) in order to better understand ways to support tapering efforts on opioid pain medications. The study is called SUMMIT, which is the name of a mobile phone application being tested.

This initial material is to give you key information to help you decide whether to participate. We have included detailed information about this study. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?
By doing this study, we hope to learn whether a mobile phone application can be helpful in tapering down on opioid pain medications. Your participation in this research will last about 9 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
Your participation in this study will be helpful to see if there are ways for the VA to better support Veterans in helping reduce their need for opioid pain medications through mobile applications.

For a complete description of benefits, *refer to the Research Details section of this document.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
You may not want to participate if you would not like to have a mobile application software product downloaded on your phone or if you do not like to use a mobile application.

For a complete description of risks, refer to the *Research Details section of this document*.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

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WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Manik Chhabra, MD of the Corporal Michael J. Crescenz VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: Corporal Michael J. Crescenz VA Medical Center, Room# 1B248A, 3900 Woodland Ave, Philadelphia, PA 19104 or 215-823-4498

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is whether the SUMMIT mobile phone application and a motivational session can be helpful in tapering down on opioid pain medications when compared to the Manage My Pain application alone. With this research we hope to learn if there are ways for the VA to better support Veterans in helping reduce their need for opioid pain medications.

You are being invited to participate because you have been on opioids for a long period of time for treatment of pain and may be interested in reducing the amount of opioid pain medication you are on.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

Your individual participation in this this study will take 9 months This research study is expected to take approximately 18 months.

We plan to enroll 64 Veterans from CMCVAMC. This study is being done in collaboration with researchers at the West Haven VA in Connecticut.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

- If you decide to participate in this study, you will be randomly (like a flip of a coin) assigned to one of two groups:
    - SUMMIT mobile phone application, along with a motivational interview session
      or
    - Manage My Pain mobile phone application

  These programs will provide information on ways to manage your pain as well as help taper your medications.

- To access the application that you are randomly assigned to, you will need to either set up a link to a website or download a software application on your mobile device. The research team will help you with the setup process of either application on your phone.

- As part of participation in the study, you will be offered the opportunity to be referred to a clinical pharmacy specialist within the pain clinic. In that appointment, you will have a chance to discuss ways to safely reduce your medications.

- If you wish to reduce your opioid medication, your pain care provider(s) will discuss options for how to do this safely.

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- If you are randomly assigned to the group getting the SUMMIT mobile application, you may be asked to participate in a single session with a member of the research team discussing reasons you may be interested in tapering down on your opioid pain medications. These sessions will be audiotaped for review but will remain confidential.
- If you are assigned to either the group getting the SUMMIT mobile application or the Manage My Pain application, you may also be randomly asked to participate in a single session exit interview with a member of the research team discussing your experience with the study.

  The voice recording is intended for the following purposes: better understanding of your perspectives on the opioid tapering process. You can participate in this study even if you decide not to be audio taped.

  ☐ I AGREE to be audio taped.

  ☐ I do NOT agree to be audio taped, but still want to participate in this study.

- No matter which group you are assigned, you will be asked to complete different assessments on your pain, your function and daily activities, and on the medications you are taking. These assessments will occur every two weeks (up to 18 times over 9 months), in addition to quarterly surveys (up to 4 times over 9 months). You will be contacted by a study coordinator to help complete these surveys.

- During your participation in this study, we will be collecting data from your medical record.

- If you are found to have an opioid use disorder or substance use disorder during the study, you will be withdrawn from the study and referred for treatment. The study team will notify your Primary Care Physician.

PAYMENT

- As part of completion of the above surveys, you will be provided a $50 dollar payment for completion of the baseline questionnaire, a $5 payment for completion of the biweekly survey (up to 18 times over 9 months), a $25 payment for completion of the quarterly survey (up to 4 times over 9 months, for up to $240 in total for participating. If you are chosen and agree to participate in an exit interview you will be provided an additional $50 payment.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

- The program will provide assistance in helping taper your opioid pain medications. If at any point you become injured or develop symptoms that are concerning to you, you should seek care from your primary care physician, and you should inform them you are in a research study.

- The study will keep all research data as well as all survey data on a secure, password protected server and remove any identifying information when possible. However, there is always a chance of breach of data. However, this risk is minimal given the security standards in place.

- While no participant data from either mobile application is being used as part of the study, the use of a mobile application has the following possible risks to privacy depending on the study arm:

    - If you are selected for the SUMMIT application study arm – you will be given an anonymized login and password to use the application through a web browser on your personal device. The application will not be collecting any personal information, but may collect aggregated non-personal information, including the frequency of use of particular features embedded within the application.

      If you are selected for the Manage My Pain application study arm – the use of the application does not require the creation of a personal account that would require providing an email address or password. However, by using the application on your personal device, the application may collect aggregated non-personal information from all users, including pain records, age, geographic location and gender as noted in the end user license agreement (EULA). By agreeing to participate in the study, you are agreeing to have the Manage My Pain software product installed on to your personal device and by subsequent use of the software, you agree to comply with the terms of the general End User License Agreement ("EULA") where no specific agreement is in place between the study and the creator of the software. If you do not agree to the terms of this EULA, do not install or use the Licensed Software but uninstall it from your device. This EULA applies to any upgrades and supplements to the original Licensed Software provided and is referred to on your opening screen. For further information, the creator of the application, Managing Life, Inc can be contacted at contact@managinglife.com.

There is always a chance that any procedure can harm you. The procedures in this study are no different.

- Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

- You may need less opioid medication to manage your pain
- You may improve your overall functioning
- You may not benefit from participating in this research study. But we hope the information

and research we gather will be able to design programs for all Veterans.

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WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. You may discuss options to taper your opioids outside of a research study with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

During the course of this study, we will collect personal information such as your:

- your name,
- gender,
- age,
- race/ethnicity
- and your list of medical conditions.

All of this information will be stored on secure VA servers and any hard copies of surveys or interview transcripts will be kept in a locked file cabinet in a locked office at CMCVAMC. Your name and last four digits of your social security/medical record number will be used only as necessary within the CMCVAMC. Only people who must access this information for the purposes of this research study will be able to access this data.

Other collected private information may be disclosed to the research team to contact you such as your name, phone number, email, and home address.

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

- We will include information about your study participation in your medical record.

- The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. 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.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

You should contact the study physician and your primary care physician. You should also notify

the study team by phone.
If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: Dr. Chhabra at 215-823-4498, option 5

AFTER HOURS: Call 215-823-4498, option 3 -which will place you in contact to an after-hours nurse who can direct you to appropriate medical care.

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in the study is voluntary. Any refusal to participate in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled.

Similarly, you may withdraw from the study at any time, and your withdrawal would not impact the ongoing care or services to which you're otherwise entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation in this study can end if

- You do not follow study instructions or complete assessments
- You are found to have an opioid use disorder or substance use disorder during the study.
- You exhibit inappropriate behavior online or with a peer specialist

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM, Monday through Friday if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study coordinator 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. You also confirm that you have read this consent, or it has been read to you. A copy of this consent will be given to you or sent to you via postal mail.