Participant Name:_____Date:_____

Title of Study: _TelemEdiciNe-bAsed CognItive TherapY (TENACITY): Pilot Intervention

Principal Investigator: Hurd, Paul, M.D Co-Investigator(s)Teresa Damush MD; Jason Sico MD.
VA Facility: Dallas VANTHCS_

Before agreeing to take part in this research study, it is important that you read and understand the proposed research explained below. It describes the procedures, benefits, risks and discomforts of the study. It also describes other treatments that are open to you and your right to withdraw from the study at any time. It is important for you to understand that no promises can be made about the results of the study. Please ask as many questions as you need to before you decide if you want to bein the study.

KEY INFORMATION

A. 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 VA Health Services Research & Development (HSR&D) about cognitive behavioral therapy for Veteran patients diagnosed with headache disorders, for example chronic migraine. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

Cognitive Behavioral Therapy is a psychological treatment that involves various problem-solving and coping skills to change thinking and behavioral patterns. Cognitive Behavioral Therapy focuses on challenging and changing unhelpful cognitive distortions and behaviors, improving emotional regulation, and the development of personal coping strategies that target solving current problems.

B. WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to evaluate the telehealth delivery of cognitive behavioral therapy for Veteran patients diagnosed with headache disorders, for example chronic migraine. Telehealth delivery is a generic term for remote delivery of healthcare by a range of options, including by videoconferencing, landline or mobile phones and the internet. Your participation in this research will last about 7 months.

C. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this study, we hope to provide relief of pain due to chronic migraines and provide easy access of Cognitive Behavioral Therapy to Veteran patients. For a complete description of benefits, refer to the Detailed Consent.

D. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

By participating in this study, you agree to take part in 6 telehealth sessions with a clinical psychologist over a 12-week period. You may also be interviewed at baseline, 3 months after you start the treatment program, and 6 months after you start the treatment program. For a complete description of risks and alternate treatment, refer to the Detailed Consent.

E. 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.

F. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study at the Dallas VAMC is Dr. Paul Hurd of the VANTHCS. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 214-857-0114.

DETAILED CONSENT

1. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to conduct an evaluation of the telehealth delivery of clinical Cognitive Behavioral Therapy (CBT) for chronic migraine, compared to outpatient clinic based, health psychology treatment. You can receive telehealth care ay home through your computer. Telehealth cognitive behavioral therapy is provided through video conferencing or video chat via virtual platforms such as VA Video Connect. We are interested in learning more about how

telehealth may improve access to such care by delivering the therapy directly to the patient in theirhome. We are also interested in the impact of the program on the patient's health.

You were selected as a possible participant because you experience chronic headaches 8 or more days a month and your physician thought you might qualify for the cognitive behavioral therapy that is offered through this study.

The study is being conducted by investigators, Dr. Teresa Damush, PhD, Research Scientist Richard L. Roudebush VA Medical Center and Research Professor Indiana University School of Medicine, and Dr. Jason Sico, MD, National Clinical Director, VA Medical Center Headache Center of Excellence and Associate Professor of Neurology, Yale University. Dr. Paul Hurd, M.D. is the doctor in charge of the study here at the Dallas VA Medical Center. If you have any questions about the study Dr Hurd can be reached at 214-857-0273. This study is funded by VA Health Services Research and Development.

2. HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2 years. Your individual participation in the project will take 7 months.

If you agree to participate, you will be one of 150 participants nationally taking part in this study. There are three VA Medical Centers enrolling participants from each site, Birmingham Healthcare System, Dallas VAMC, and Connecticut Healthcare System. Seventy-five participants will be randomized to Program A, which is the telehealth Cognitive Behavioral Therapy for migraine group (TENACITY) and 75 participants will be randomized to Program B, which is the outpatient clinic based, health psychology treatments for chronic migraine.

Randomization involves selecting participants for each program by chance, such as through the flip of a coin. Participants randomized to Program A will receive the telehealth CBT for migraine treatment and related patient self-management tools, while participants randomized to Program B will receive outpatient clinic-based health psychology treatments which may include CBT and patient self-management tools. Participants in both Program A and B will have access to education and self-management materials on chronic migraine management.

3. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you agree to be in the study, you will do the following things:

1. **Headache Diary:** You will be asked to complete a 30-day headache diary when you agree to participate in the study (baseline), again at approximately 2 months after start of treatment, and then approximately 5 months after start of treatment. In total, you will be expected to complete **90 days of headache diaries**. In order to continue to be enrolled in the study, you must complete the first question of the baseline headache dairy on at least 28 days. Headache diaries will be completed using the VA Annie app. The VA Annie app will send you daily automated text messages that contain the headache diary questions and willprompt you to respond. You will provide answers to the headache diary questions byreplying to the VA Annie App texts.
2. **My HealtheVet and the VA Annie App:** In order to be a part of this study, you must be enrolled in My HealtheVet and the VA Annie app. Research and My HealtheVet staff will assist you with this. Research staff will send secure messages through My HealtheVet throughout the study to remind you of upcoming tasks. We will not store these messages in your electronic health record, but you should be aware that any research related notes saved in your electronic health record could be viewed by any VA staff with appropriate access.
3. **Surveys:** You will be asked to complete study questionnaires over the phone or electronically (VA Qualtrics) at a time convenient for you. The questionnaires will be administered when you first agree to participate in the study (baseline), approximately 3 months after you start the treatment program, and approximately 6 months after you start the treatment program.
4. **Possible Interviews:** We are interested in how Veterans perceive the headache care they receive, and you may be asked to complete three interviews at a time convenient for you that will focus on this topic. We will interview participants at the beginning of the study (baseline). We will conduct a second set of interviews three months after you start the treatment program. We will conduct a third set of interviews approximately 6 months after you start the treatment program. The interviews will be completed via Microsoft TEAMS or phone. Microsoft TEAMS is a communications computer application that can be used for audio or video calls. For this study, we will only

be doing audio calls. Interviews will be audiotaped and are estimated to take no more than 1 hour. The questions will ask about your headaches, your ability to complete normal daily activities, medications, other forms of therapies that you may have tried for your headaches, symptoms, health-related quality of life, telehealth use, your experience with the CBT, and your overall experiences with VA healthcare and Community Care.

5. **Telehealth CBT Sessions:** You will be asked to participate in the Headache Center of Excellence CBT for Headache telehealth sessions delivered to your home as partof VA telehealth care services (Program A), or outpatient clinic based health psychology for chronic migraine (Program B). The CBT will include approximately 6 telehealth sessions with a clinical psychologist over a 12-week period. These sessions will be scheduled by the Headache Center and will be conducted using your VA's telehealth services. If you are assigned to Program B, you will be referred to the health psychology clinic and receive otheravailable headache treatments which may include CBT.

6. **Medical Chart Review:** A review of your medical records will take place byVA Research staff to collect information related to any hospitalizations (ED visits or Admissions) that occur during the study. Our staff will also look at your medical care during the study, including prescribed medications, blood pressure measurements, as well as any headache care or treatments you may receive during the 6 months of your participation inthe study.

If you are assigned to the Treatment As Usual group, you will continue with your currently established treatment plan for chronic migraine pain, or discuss other options with your doctors. Other options include pain medication or health psychology treatment.

During your participation in this research study, you will interact with some or all the following research study personnel: The Principal Investigators, Dr Paul Hurd and Dr. Teresa Damush, one or more of the research study Co-Investigators, and/or the research study coordinator/research assistant(s). Your involvement in the interviews will take place over the telephone at a time convenient to you.

During any portion of this research study, including phone interviews and completion of any of the interview questions, you are free to skip any questions that you would prefer not to answer.

Additionally, routine monitoring of the study data will occur to ensure privacy of each study participant's information meets all VA and Federal guidelines for the protection of research participants and their privacy.

Veteran Patient Study Timeline		
Timeline	Standard Care Group	TENACITY Group
Screening & Baseline	• SIS & Verbal Consent • Baseline Interview • Health Screening • Questionnaires • 30-day Headache Diary • Mailed $25 gift card following completion of questionnaires and/or interview	• SIS & Verbal Consent • Baseline Interview • Health Screening • Questionnaires • 30-day Headache Diary • Mailed $25 gift card following completion of questionnaires and/or interview
30-days post baseline	• Randomization • Schedule health psychology consult and/or 3-month f/u appointment with care providers. • Mailed $25 gift card following completion of questionnaires and/or interview	• Randomization • Technology Introduction (telehealth) • Mailed $25 gift card following completion of questionnaires and/or interview
1-week post randomization		• CBT
3-week post		• CBT
5-week post		• CBT

7-week post		• CBT
8-week post (2 month)	• 30-day headache diary assigned	• 30-day headache diary assigned
9-week post		• CBT
11-week post		• CBT
12-week post (3 month)	• Standard of care treatment appointment Questionnaires • 3-month interview • Mailed $25 gift card following • completion of questionnaires and/or interview	• Study 3-month Interview • Questionnaires • Mailed $25 gift card following completion of questionnaires and/or interview
20-week post (5 month)	• 30-day headache diary assigned	• 30-day headache diary assigned
24-week post (6 month)	• Standard of care treatment appointment 6-month • interview • Questionnaires • Mailed $25 gift card following completion of questionnaires and/or interview Thank you Letter	• Study 6-month Interview • Questionnaires • Mailed $25 gift card following completion of questionnaires and/or interview Thank You Letter

4. WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

If you agree to take part in this study, it is expected that you attend your telehealth therapy sessions every two weeks over a 12-week period. You will be expected to conduct three telephone interviews, at baseline, 3-months and 6-months. It is also expected that you complete a total of 90 days of headache diary, and answer the questionnaires involved in the study. You will complete your headache diary through the VA Annie App, and you will need to register for MyHealtheVet to be able to use the VA Annie App.

Keep your study telephone appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.

While participating in this research study, please inform the research staff if you plan on participating in another research project. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

5. WHAT ARE MY RISKS?

Any procedure has possible risks and discomforts. The procedures in this study are no different and may cause all, some, or none of the risks or side effects listed. If you agree to be a part of this study, the primary risk is loss of confidentiality. We will do our best to keep your information confidential. All research data will be stored behind the firewall-protected VA servers and in locked cabinets in private offices accessible only to the research study team. Only combined data will be presented in reports and publications, so no individual responses will be identifiable.

Additional risks for each portion of your involvement in this research study are explained below:

- Phone Interviews: You may experience discomfort or may not be comfortable answering specific questions during the phone interview. You are free to skip any questions you would prefer not to answer or withdraw from this portion of the study at any time without penalty.
- Health and functioning questions: You may experience discomfort or not be comfortable answering specific questions asked in the surveys. You are free to skip any questions you would prefer not to answer or withdraw from this portion of the study at any time without penalty.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

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.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating in this study. You also authorize disclosure of the voice recording to Dr. Teresa Damush, PhD, Research Scientist Richard L. Roudebush VA Medical Center and Research Professor Indiana University School of Medicine, and Dr. Jason Sico, MD, National Clinical Director, VA Medical Center Headache Center of Excellence and Associate Professor of Neurology, Yale University The said picture, video, and/or voice recording is intendedfor the following purposes: verify accuracy and veracity of data collected during telephone interviews conducted in this research study.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

6. WHAT ARE POSSIBLE BENEFITS OF THIS STUDY?

Participating in this study may not make your health better. However, the potential benefits of Cognitive Behavioral Therapy for Chronic Pain include:

- reduction in the number of headache days per month,
- reduction on the severity of chronic migraine headaches,
- increased skills for managing headache triggers and associated events.
- Participating in the TENACITY study may provide participants with more timely access to health psychology Cognitive-based Therapy treatment for patients with Chronic migraine headache.

The information we obtain from this study may aid in our understanding of how to best deliver cognitive behavioral therapy to increase access to Veterans with headache disorders across the national VA healthcare system.

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

There may be other options for treatment of your headaches, and you are invited to discuss these with your care provider. Cognitive behavioral therapy is available without participating in this study.

8. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Our standard operating procedures for data collection and data management have been designed to protect againstdata loss and maintain patient confidentiality. These procedures have been developed and used in many studies and we will adhere to these procedures for the proposed TENACITY project. Computer files will be password protected. Files containing names or other personal identifiers will have a separate password and will be accessible only to personnel who need to contact participants. Our study data will be maintained on VHA network servers which are secured and backed-up on a nightly basis. Access to these servers is controlled by network administrators. There is little risk to loss of privacy or confidentiality given these measures, and there has been no instance of a problem in this area in prior trials conducted by this investigative team.

Audio Recording

You may be selected to participate in up to three interviews. All interviews will be audio recorded, which will be used for research purposes. At any time, you may tell the researcher that you feel uncomfortable or do not wish to continue.

The Audio files will be stored on a password-protected, restricted-access server at theRichard L. Roudebush VA Medical Center, 1401 W. 10th Street, Indianapolis, Indiana 46202. All recording devices used for this study are encrypted for security and once the files are uploaded tothe server, the files are deleted from the device. Interviews that are recorded on Microsoft Teams will be downloaded to the password-protected, restricted-access server and deleted from the TEAMS application. Recordings are then transferred to a VA-contracted transcription service where the recordings are transcribed and wiped of any information that would identify you.

At the beginning of the study, you will be assigned a subject code, unique to you. This will be the only identifier on the transcript and your research documents. Only research staff on this

study will have access to the coding system. Research records will be maintained by the investigatorin accordance with the VHA Records Control Schedule.

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing the Sponsor, VA Research Services and Development, the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

If you choose to take part in the study, certain government agencies (such as the FDA orVA) may look at your research records. Your name as a subject in this study is private and will not be included in any report prepared as a result of this study.

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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

Health Information Portability and Accountability Act (HIPAA)

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 or mental health treatment.

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 notbe able to continue to participate in the study. This will not affect your rights as a VHA patient totreatment or benefit outside of the study.

If you revoke this authorization, Dr. Hurd and his 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.

9. 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.

WILL I BE PAID FOR PARTICIPATING?

You will receive a payment for taking part in this study. You may receive up to $150 to compensate for your time and participation in the study as follows:

- $25 gift card for the initial interview/assessment
- $25 gift card for the initial headache diary
- $25 gift card for the interview/assessment at 3 months
- $25 gift card for the headache diary at 3 months
- $25 gift card for the interview/assessment at 6 months
- $25 gift card for the headache diary at 6 months

The gift cards will be mailed to you. The gift cards will be for a national merchant (Walmart, K-mart, etc.). The gift cards may not be substituted for cash or other items of value.

In order to receive payment, an Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.You are responsible for paying any state, federal, or Social Security taxes. If you have questionsregarding how this impacts your tax return, please contact a tax professional to assist you.

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

The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees in accordance with applicable federal regulations. This does not apply to (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.

The VA has the obligation to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare programnoted that payments by a clinical trial sponsor for injuries related to a trial are a form of liability insurance and must be reported to CMS. Therefore, if VA HSR&D pays for treatment of an illness or injury caused by this research, we will need to collect your name, date of birth, gender, SSN and your Medicare or Medicaid Health Insurance Number. VA HSR&D will use and share this information with Medicare or Medicaid for reviewing your status with them. If you are a Medicare or Medicaid beneficiary, the VA is required to report any injury payments to CMS. The information will not be used for any other purpose.

There are no plans to provide any other payments or other forms of compensation for a study related injury (for example, for lost wages or discomfort). You do not give up any legal rights by signing this consent form.

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: Opemipo Omotara at 214-857-1013
After hours: The DVARC answering service at 800-725-4436

Emergency and ongoing medical treatment will be provided as

needed.

11. DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is entirely voluntary. You cannot be forced to be in this study. You may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled and without affecting your future medical care.

If you do choose to leave the study, no further information about you will be collected for this study. However, all the information you gave us before you left the study may still be used.

12. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The study doctor can take me out of the study at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that Ido not meet the study requirements, or if the study is cancelled.

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

If you have any questions about this study or have any bad effects of your treatment, you should call the study doctor at 214-857-0273 or a member of the research team Schatze C. Parham at 214-857-3040 or Opemipo A. Omotara at 214-857-1013 . You should also contact the study doctor or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System approved research study, you may contact the Research Compliance Officer at 214-857-0341.

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 may call the Dallas VAMC Patient Representative at 214-857-0482 if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

If you have a medical emergency, you should immediately call 911 for assistance.

14. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If new findings develop that affect your safety or treatment outcomes, you will benotified. If safety concerns arise, the study will be halted until those concerns are addressed.

15. WHO COULD PROFIT FROM THE STUDY RESULTS?

There is no potential conflict of interest involved in this study.

16. DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED?

This study does not involve genetic testing.

17. FUTURE USE OF DATA AND RE-CONTACT

De-identified data may be used in the future without notice or re-consent. The data will be storedat the VA for a minimum of two years.

18. DOES THIS STUDY INVOLVE TISSUE BANKING?

This study does not involve tissue banking.

Participant Name:_____Date:_____

Title of Study: _TelemEdiciNe-bAsed CognItive TherapY (TENACITY): Pilot Intervention

Principal Investigator: Hurd, Paul, M.D Co-Investigator(s)Teresa Damush MD; Jason Sico MD.
VA Facility: Dallas VANTHCS_

19. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have read or have had read to you all of the above. The study has been explained to you bya member of the research team. 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.

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 have received a copy of this consent to keep for your records.

Your verbal consent to participate in the study will be entered in your medical records.

Do you give your verbal consent to participate in thisstudy as has been explained in this document?