WALTER REED NATIONAL MILITARY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

FORM Title: Traumatic Nightmares Treated by NightWare (To Arouse Not Awaken)
A Randomized Controlled Trial
Principal Investigator: J. Kent Werner, MD PhD

1. STUDY OVERVIEW:

You are being asked to participate in a research study. Consent is being sought to participate in this research study and participation is voluntary. If you choose to take part in this study, you will wear the Study Watch every night for the duration of your participation. This study is about the effectiveness of the NightWare digital system (NW System) in reducing the number and/or intensity of trauma related nightmares and improving sleep. You will receive either an "Active System" or a "Sham System" at random (50/50 chance). Neither you, nor the study staff will know which version of the system you will receive. You will receive a minimum of 10 phone texts/calls and a maximum of 15 phone texts/calls from study staff. These texts/calls will be used to determine how well you are doing using the NW System and to fill out questionnaires. This research study is not a clinical sleep study requiring in-hospital stays.

Engagement should take about 25 minutes altogether. You will have 2 visits done either in-person or virtual that will take about 1 hour and 30 minutes each. The first being the consent and enrollment for randomization, then another visit will be done in person or virtual every 30 days. After 30 days of randomized treatment, you will be unblinded and informed on if you received the active or sham system. If you receive the sham system, you will be converted to active treatment. If you received the active system, you will continue to receive active treatment. You will be followed for an additional 60 days following this with 2 more visits done in person or virtual. You may withdraw from this study at any time if you choose to do so. You may experience improved sleep quality and reduced nightmares by taking part in this study but this cannot be guaranteed. Worsening sleep quality is a potential risk of this device intervention due to the device awakening the individual or incorrectly diagnosing a nightmare. Other treatments include medication and Cognitive Behavioral Therapy.

2. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether to volunteer for a research study conducted by the Department of Defense. It is a study being funded by the Department of Defense and the NightWare company. This study is about the effectiveness of the NightWare digital system in reducing the number and/or intensity of trauma related nightmares. This initial information is to give you key information to help you decide whether to participate. We have included detailed information below.

Ask the research team questions. Taking part in this study is completely voluntary.

If you need additional assistance, we encourage you to visit the Military OneSource website at https://www.militaryonesource.mil or contact the Military Crisis Line at 1-800-273-8255

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

By doing this study, we hope to find out if the NightWare digital system (NW System) can reduce the number and/or intensity of trauma-related nightmares.

Your participation in this research will last about 90 days.

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

There may be no direct benefit to you from being in the study. You may be given the Active or Sham system that may or may not work in reducing the number and/or intensity of your nightmares. You must return the device after the study. If you wish to continue using the NW System after completing the study, the team will connect you with a provider for prescription for you to obtain your own device. The knowledge gained from this study may benefit others in the future. For a complete description of benefits, refer to the Detailed Consent Section.

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

Some of the possible risks or discomforts of your participation include:

An increase in the number of nightmares you experience. An increase in the intensity of the nightmares you experience. The onset of sleepwalking or acting out your dreams. Other, unforeseen, negative experiences. For a complete description of risks, refer to the Detailed Section of the Consent.
There is, as always, a risk of possible breach of confidentiality. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

You may want to partake in alternative treatments that are available. There are currently 2 commonly used alternative treatments for trauma-related nightmares. One involves medication and the other is a type of Cognitive Behavior Therapy. If you wish to try one of these treatments you would need to go to your primary care physician and get referred to the proper department. For a complete description of alternate treatments refer to the Detailed Section of the Consent.

6. 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. Data already collected prior to any withdrawal may continue to be reviewed by the investigator and the study team but not collect further information, except from public records, such as survival data.

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

The person in charge of the study is Dr. J. Kent Werner of the Walter Reed National Military Medical Center. This person is the Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study their contact information is:
Principal Investigator: J. Kent Werner, MD, PhD Phone Number: 301-295-4771

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

It's up to you. If you choose to be in the study, then you can sign the form. If you do not want to take part in this study, you should not sign the form.

Your decision will not affect your future care at Walter Reed National Military Medical Center. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

8. WHAT IS THE PURPOSE OF THIS STUDY?

By doing this study, we hope to learn if the NightWare digital system (NW System) can reduce the number and/or intensity of trauma-related nightmares. The NightWare system is an investigation device that consists of a smartphone, smartwatch, and an application. You will be given an Apple smartphone and smartwatch to use for the duration of the study. This study seeks to evaluate the effectiveness and safety of the NW system for the treatment of nightmares.

9. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY

About 50 people will take part in this study at Walter Reed National Military Medical Center. This is a multicentered study that will have a total of 240 people in this study.

10. HOW LONG WILL I BE IN THE STUDY?

Your participation will be about 90 days.

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

You will be asked to sign this informed consent document, sign the HIPAA privacy document, complete several questionnaires, and, if your scores on the questionnaires meet the requirements for inclusion into this study, you will be provided a NW System.

You will be trained in how to use this system, which should take about 20 minutes. You will be sent home with the NW System and an instruction sheet. You will wear the Study Watch every night for the duration of your involvement in this study. You will receive EITHER an "Active System" or a "Sham System" at random (50/50 chance of getting one system or the other).

The Active system and the Sham System appear identical. The Active System has a fully functional version of the NW Application installed. The Sham System has an inactive NW Application installed. Neither you, nor the study staff will know which version of the system you will receive.

You will receive a minimum of 10 phone texts/calls and a maximum of 15 phone texts/calls from study staff. You will be required to use your personal phone to receive text/calls. The phone you will be given to participate in this research will have text/call features deactivated. These texts/calls will be used to determine how well you are doing using the NW System and to fill out questionnaires. Engagement should take about 25 minutes added together.

You will have 2 visits done in person or virtual that will take about1 hour and 30 minutes each. The first being the consent and enrollment for randomization, then another visit will be done 30 days later. After 30 days of randomized treatment, you will be unblinded and informed on if you received the active or sham system. If you receive the sham system, you will be converted to active treatment. If you received the active system, you will continue to receive active treatment. You will be followed for an additional 60 days. You may withdraw from this study at any time.

Information about the Study Phone and Study Watch:

The devices provided to you have been pre-imaged by NightWare. They do NOT function as regular

smartphone /smartwatch watches. During the pre-imaging process any functions/ applications that are not needed to do this research study have been removed and the NightWare application has been pre-installed on both the phone and watch. Due to the limited functionality of these devices, we will refer to them as "study equipment, study phone, and/or study watch".

As part of its operation, the NightWare Application will collect heart rate and movement information from the sensors on the watch while the application is running (i.e., beginning when the Start button is pressed and ending when the Stop button is pressed). This information is used to distinguish your normal sleep patterns from those that may indicate a distressing dream. Some of this information (duration of use, number of interventions) is transmitted to NightWare, the sponsor of this study, for monitoring the use and performance of the software. This information is not sent in real time, and no information about your identity or location will be transmitted.

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

During this study you will answer questions and handouts regarding your demographics, sleep behavior, drug use, suicidality, and medical history. You will also have your vitals taken and your medical records and charts reviewed. You will have multiple phone calls/text regarding how you are doing in terms of using the system and your sleep behaviors and in order to assist in any questions or problems you are having with the study or system. Below is a chart indicating when these actions will take place. The kind of medical treatment you now get from your regular doctor will not change because you take part in this study. You will continue seeing your regular doctor. Your regular doctor will give you the same kind of treatment you would get anyway, whether you take part in the study.

If you need to, you can:

- Use other medicines prescribed by your regular doctor
- Have surgery you need

However, you should tell the study doctor about all the medicines you take and about any planned surgery you may have scheduled.

If you decide to take part in the study, you will complete several questionnaires (21 in total) with the study team to determine your eligibility. Based on your answers, you will be informed whether you qualify. If you do qualify, you will be randomized to either the Active System or Sham System.

We will study 2 groups of people. People in one group will have the Sham System. People in the other group will have the Active System. You have a 50/50 chance of getting the Active system or the Sham system. For this study, you and the study team will not know which group you are in. This way, nobody puts their own thoughts into if the active system is working differently for results then the Sham system. Scales monitoring your sleep and suicidal ideation will be conducted throughout this study to monitor and determine your condition.

After randomization, the study team will instruct you on how to use your watch and the NightWare Application.

You will receive phone calls from the study team periodically for a checkup and to complete assessments. This will be no more than one time per week after the first week of study activity.

You will have an in-person or virtual visit with the study team on Day 30 and an additional in person or virtual visit on Day 60 and 90. At these visits, you will complete several assessments and questionnaires.

At the end of the 30-day visit you will be converted to active treatment and be followed for an additional

60 days. You will have 4 in person or virtual visits with the study team. At the end, you will need to return both the Study Phone and Study Watch in order to avoid potential undue influence to participation. These devices have been pre-imaged to contain only what is needed for using the NightWare Application. No other applications are enabled on this device.

Study Activity	Pre-Tx	Visit 1	Cali-bration	Start Up Call	Help Calls	Check Up Call 1	Assessment Call	Check Up Call 2	Visit 2	Visit 3	Visit 4
Study Day	Before Day 0	Day 0	Days 0-3	Day 1	Days 2-6 (Optional)	Day 7 (+/-2)	Day 14 (+/- 2)	Day 21 (+/- 2)	Day 30 (+ 7)	Day 60 (+ 7)	Day 90 (+ 7)
Recruitment	X										
Phone Screen	X										
Inclusion/ Exclusion	X	X									
ICF and HIPAA		X									
Modified Dysken l		X[a]									
AUDIT		X[b]									
DAST-10		X[c]									
Demographics		X									
Medical History		X									
Collect CPAP Compliance Reporting[g]		X							X[g]	X[g]	X[g]
Blood Pressure, Height, and Weight		X[h]							X[h]		
Med Recon-ciliation		X							X	X	X
PSQI		X					X		X	X	X
PSQI-A		X							X		
ESS		X							X	X	X
ISI		X							X	X	X
PCL-5		X					X		X	X	X
CAPS-5		X[i]									
VR-12 (QOL)		X							X	X	X
TRNS		X							X	X	X
FOSQ-10		X							X		
PHQ-9		X					X		X	X	X
C-SSRS Lifetime		X									
Blinding Assessment Questionnaire									X		
NW Likert Scale		X							X	X	X
Daily Use Questionnaire (Days 1-90)			X	X	X	X	X	X	X	X	X
Calculate Cutoffs/ Eligible?		X									

Study Activity	Pre-Tx	Visit 1	Cali-bration	Start Up Call	Help Calls	Check Up Call 1	Assessment Call	Check Up Call 2	Visit 2	Visit 3	Visit 4
Study Day	Before Day 0	Day 0	Days 0-3	Day 1	Days 2-6 (Optional)	Day 7 (+/-2)	Day 14 (+/- 2)	Day 21 (+/- 2)	Day 30 (+ 7)	Day 60 (+ 7)	Day 90 (+ 7)
Dispense NW Devices		X									
Train Subject		X									
Activate Devices		X									
C-SSRS Since Last Contact									X	X	X
Payment of Subject(Bi-weekly)	See Reimbursement Section 20										
Start Up Call				X							
Help Calls Questionnaires (Optional)					X	X					
Check Up Call				X		X	X	X	X	X	X
Calibration			X								
Active/Sham Treatment			Post-Calib.[f]								
Sham Cross-over to Active Treatment									X		

a - Administered DURING informed consent process to ensure subjects are capable of consent. Subjects must get all responses correct to be enrolled into the study,
b - Exclude if score is equal to or greater than 8.
c - Exclude if score is greater than 2.
f - Only the Active System goes through calibration and on to Active Treatment.
g - Only perform this activity if the participant has OSA.
h - If the study visit is being conducted remotely, height and weight can be self-reported. Blood pressure monitors with instructions will also be provided for those participating remotely to record blood pressure.
i-. If participant has had a CAP-5 within 30 days from consent, that CAPS-5 will be accepted and no repeat will be required.

Sham Systems will not go through a calibration phase, nor will they ever provide study interventions. Data is collected throughout and a stress threshold is initially calculated during the initial phase, though the subject isn't aware of this or shown it in any way. The stress threshold is continually calculated in both groups. The sham group never receives treatments regardless of stress threshold.

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

If you take part in this research, you will be responsible for answering questionnaires as fully and correctly as possible. Provide demographic and military-service information. Be willing to have your blood pressure, height, and weight taken. Connecting the Study Phone AND the Study Watch to your home WIFI. Wearing the study watch every night. Keeping the phone and watch charged.

Accepting study-related phone texts/calls. Giving answers to questionnaires either in-person, over the phone, or via text. There are four in-person or virtual study visits that will be required. The first is the initial intake/device delivery and will be done in-person or virtual. Your second, third, and fourth visit will be in-person or virtual with a member of the study team. The purpose of these visits are for additional questionnaires and checking in. While participating in this research study, do not take part in any other

research project without approval from the investigators. 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.

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

There is always a chance that any procedure can harm you. The procedures in this study are no different. The risk is believed to be low however, unexpected risks may exist. You may experience a previously unknown risk or side effect. It is important for you to tell us when you experience a side effect.

Known Potential Risks

Currently, there are no devices to date that are used to treat nightmares specifically. However, there are many variations of over-the-counter applications and wearable devices that vibrate to signal the wearer. The same risks known to over-the-counter wearable fitness devices apply to this device. The System is designed to interrupt during a nightmare, but not awaken the individual. The device may instead awaken, or incorrectly diagnose a nightmare and alarm (false positive). Therefore, worsening sleep quality is a potential risk of this device intervention.

Although it is a standard Apple watch with watchband, if you have allergies or skin sensitivities, you may experience a reaction when wearing the watch. Wearing the watch with the right fit allowing for proper circulation and comfort may prevent skin irritation.

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.

Questionnaires:

Some specific questions will be asked concerning your use of tobacco products, alcohol, and marijuana. We realize that such questions are potentially sensitive. For us to determine your eligibility for the study there are two questionnaires (the DAST-10 and AUDIT) that require responses. There is another questionnaire that is NOT required that goes into more detail regarding your use of these substances. You may choose not to answer this questionnaire, but we encourage you to do so, as information regarding potential results of using the NightWare System could be detected and be beneficial to others.

If you become upset at any time during the questionnaires, study personnel will do the following:

- Stay with participant until Dr. Werner, or a designated alternative medical staff arrive, if needed.
- If the participant is an outpatient, this will involve taking the participant to the Emergency Room for evaluation.
- All study personnel who work directly with research participants will be given the names and phone numbers of the participant's medical care team. After the participant has been assessed by the appropriate staff, the Principal Investigator will be alerted.

If you are a woman of childbearing potential, there may be some risks:

The safe use of the NightWare System in pregnant women and nursing mothers has not been established. Consequently, there may be risks to you (or to your embryo or fetus) if you are or may become pregnant that are unknown.

If, while participating in the study, you suspect you have become pregnant, please contact the study

physician immediately. Women are considered to be of childbearing potential unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are postmenopausal, that is, no menstrual period for more than 6 months.

We will tell you as soon as possible if we find out more information about the side effects from the NightWare System.

15. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. You may experience improved sleep quality and reduced nightmares by taking part in this study but this cannot be guaranteed.

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

Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. You may choose not to participate in this study. If this is your decision, there are currently 2 approved treatments. One involves medication and the other is a type of Cognitive Behavior Therapy. If you wish to try one of these treatments you would need to go to your primary care physician and get referred to the proper department. You may discuss these options with your doctor.

17. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

18. WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. The results of this study may be published or presented, but your identity and records will not be revealed unless required by Federal Law. Organizations that are required by law to provide oversight of research projects may review your records. This includes several federal agencies, the Walter Reed Department of Research Programs, WRNMMC Institutional Review Board, and the Henry M. Jackson Foundation Office of Regulatory Affairs and Research Compliance. The sponsor or sponsors of the research project will also be allowed to review your medical records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed. Your de-identified data may be used to develop, refine, or improve a marketable software application (NightWare). Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Data will be entered by the research team into HJF REDCap. The electronic files will have additional protection by being placed inside of a limited-access folder. Only IRB-Approved research staff will be permitted access to this folder.

Identifiers will be removed from the identifiable private information that is 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.

Your de-identified data may be provided to the FDA by the sponsor (NightWare) of the study so that the

FDA can determine if the NightWare application is effective and that it appears to be safe. When, or if, this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the site will include a summary of the results. You can search this website at any time.

We will include information about your study participation in your medical record. Data will be collected by the research staff at WRNMMC and will be stored for six years. After the sixth year, the data will be destroyed according to institutional policy.

19. WHAT ARE THE COST 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. All the study costs, including the study watch, study phone, and procedures related directly to the study, will be paid for by NightWare. If you usually pay co-payments for health insurance and medications, you will still pay these co-payments for medical care and medications that are not part of this study. There should be no additional medical costs to you for taking part in this study. However, frequent clinic visits may result in transportation costs and possible wages lost due to time missed from work.

20. WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

You will be compensated for completion of certain study activities. You will receive $50 for enrolling and completing study-related surveys at their baseline visit. At each two-week interval during the Study (Days 15, 30, 45,60,75 & 90) you will receive $25 for continuing to participate in the study. You will also receive an additional $25 every two weeks (Day 15, 30, 45,60,75 & 90) for wearing the device for ≥70% or 10 of the 15 nights in a two-week period. In addition, you will also receive $100 upon returning the NW System and completing study-related surveys and $15 upon returning the blood pressure cuff (virtual participants only). In total, you may receive between $200-$465 for participating in the Study, which averages up to $5/day depending on the study activities you complete. Compensation will be through a reloadable debit card (ClinCard).

Compensation Table

Study Day	Base Amount	Incentive Amount	Condition of incentive Amount
1	$50		
15	$25	$25	Study device use in 10 of 15 nights in a two-week period.
30	$25	$25	
45	$25	$25	
60	$25	$25	
75	$25	$25	
90	$25	$25	
Return of study device		$100	
Return of blood pressure cuff		$15	Virtual participants only
TOTAL	$200	$265	

In order to receive payment for your participation in this study, you may be asked to provide your social security number and home address on a W-9 form. If you receive $600 or more for taking part in a combination of research studies in one tax year, you will be sent a 1099 form for tax purposes. The form will be sent to the Henry M. Jackson Foundation accounts payable office.

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

You are participating in a research project approved by the Walter Reed National Military Medical Center Institutional Review Board and the Department of Research Programs, and conducted under the supervision of one or more DoD employees. Every reasonable safety measure will be used to protect your well-being.

If you are injured from this research study, treatment will be available, including first aid, emergency treatment, and follow-up care, as needed, by the Walter Reed National Military Medical Center. In the event you cannot reach Walter Reed, your health insurance will pay for necessary medical care for any injury or illness directly related to your participation in this research study. If you do receive this type of care, you must contact the Research Investigator immediately, as stated below.

In all cases, the injury must meet the following requirements:

1. It must result directly from the study procedures and/or the study devices/software.
2. All study procedures must have been done correctly.
3. You must have followed all directions from the study staff.

NightWare will voluntarily provide medical care or reimburse you for emergency medical care provided outside of the Military Healthcare System (MHS) if there is no Military Healthcare System within a reasonable distance (20 to 30-minute drive) from the participant which causes the participant to go to a non-MHS Facility for urgent/emergency care.

If you need emergency care:

Go to your nearest hospital or emergency room right away. Call 911 for help. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go. Call the study doctors as soon as you can. They will need to know that you are hurt or ill. Call Dr. J. Kent Werner at 301-295-4771.

If you need emergency care in a private hospital, have a friend or family member contact Tricare within 72 hours of their hospitalization. If there is a need to notify Tricare of hospitalization you should contact Tricare within 72 hours at 1-800-TRICARE.

If you do NOT need emergency care:

Go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, DURING THE DAY please contact Dr. J. Kent Werner at 301-295-4771. AFTER HOURS: Call Tricare at 1-800-TRICARE

Emergency and ongoing medical treatment will be provided as needed.

22. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen, you may show signs of suicidality, or we may find that the NightWare system could harm you.
- You are not utilizing the NightWare system properly or not coming for your study visits as scheduled.

- Your military mission requires termination of your participation
- You lose your right to receive medical care at a military hospital.
- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

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

The research team can be reached at the number: 612-250-6692 or 571-563-8662.

The Principal Investigator Dr. J. Kent Werner can be reached at: 301-295-4771 or John.k.werner.mil@health.mil

If you have questions about your rights as a study participant, or you want to make sure this is a valid MHS 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

WRNMMC IRB at 301-295-8239 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the WRNMMC Department of Research Programs at 301-295-8239.

WRNMMC Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: 301-295-8239

WRNMMC Department of Research Programs Phone: 301-295-8239

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the office of the IRB of Record at:

4650 Taylor Road, Bldg.17B, 3rd Fl.

Bethesda, MD 20889

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

During the study, we will tell you about any new information that may affect your health, welfare, or choice to stay in the research

25. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding.

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to

an appropriate doctor for further evaluation.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

26. WHO COULD PROFIT FROM THE STUDY RESULTS?

If a commercial product is developed as part of this research, you will not profit from them.

27. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Nightware, Inc. is the study sponsor and provides funds to the Henry M. Jackson Foundation to carry out all study related tasks.

28. LOCATION OF THE RESEARCH

Walter Reed National Military Medical Center, 4494 North Palmer Road, Bethesda, MD 20889 – Building 19, Neurology Clinic.

29. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no conflicts of interest by the study team. The sponsor of this research study has agreed to reimburse the Henry Jackson Foundation for some of the costs related to your participation in this study at WRNMMC.

TROOPS REFFERAL PROGRAM

You may be eligible for other CNRM-funded or CNRM-collaborative studies. If you would like to be referred to these research studies through a CNRM participant referral program (TROOPS), please visit https://troops.cnrm.nih.gov. Your participation in this program is voluntary. If you decide to take part, you will be asked to provide some information about yourself and your health, which will be used to determine your eligibility for CNRM-funded and collaborative studies. Please contact CNRMstudies@usuhs.edu with any questions that you may have about participating in this referral program.

In addition, you may provide consent for study staff to provide your name and contact information (email, phone number) to the TROOPS staff. Your information will be sent securely and will not be shared with anyone else. This is voluntary. Please indicate your choice below. With regard to sharing my contact information with TROOPS CNRM investigators and approved study staff:

____ YES, I authorize the sharing of my contact information with TROOPS staff
____ NO, I do not authorize sharing of my contact information with TROOPS staff.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study. I have not given up any of my legal rights as a research participant.

I agree to take part in the research described in this consent form.

In-Person Consent

_____

Printed Name of Participant

_____ _____ _____

Signature of Participant Date Time

Virtual Consent

I agree that by checking this box and entering my legal name, I am providing an electronic signature that is held to the same standard as a legally binding equivalent of a handwritten signature. (This box is not required to be checked if you are signing this informed consent document in person).

_____

Printed Name of Participant

_____ _____ _____

Participant's Personal Identifying Nonword Date Time

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

_____

Printed Name of Administering Individual

_____	_____	_____
Signature of Administering Individual	Date	Time