Informed Consent Form and
Authorization to Use and Disclose Protected Health Information

Sponsor / Study Title:	**Nightware, Inc. / "Traumatic Nightmares Treated by NightWare (To Arouse Not Awaken): A Randomized Controlled Trial"**
Protocol Number:	**NCT04040387 / NW101002**
Principal Investigator:	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by NightWare and conducted at a few military bases and VA locations. 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. Taking part in this study is completely voluntary.

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

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. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information.

Your participation in this research will last about 90 days (about 3 months.)

WHAT ARE 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 system that may work in reducing the number and/or intensity of your nightmares. The knowledge gained from this study may benefit others in the future. For a complete description of benefits, refer to the section "WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?" of this form.

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 section "WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?" of this form.

You may want to partake in alternative treatments that are available. There are currently 2 approved treatments for trauma-related nightmares. One involves medications 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 treatment/procedures, refer to the section "DO I HAVE TO TAKE PART IN THE STUDY?" of this consent form.

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.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, or CONCERNS?
The person in charge of this study is the Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, the contact information is listed on the first page of this form.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?
By doing this study, we hope to learn if the NightWare digital therapeutic 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. This study seeks to evaluate the effectiveness and safety of the NW system for the treatment of nightmares.

The investigators hypothesize that the Active System will significantly improve sleep quality in participants with post-traumatic stress disorder-related (PTSD) sleep disorders who are suffering from nightmares and poor sleep quality, and that the magnitude of improvement will be greater than that observed in the participants who receive a Sham System

HOW LONG WILL I BE IN THE STUDY?
About 50 people will take part in this study site. This is a multicenter study that will have a total of 240 people in this study.

This research study is expected to take approximately 3 years. Your individual participation in the project will take 90 days (about 3 months.)

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?
Visit 1 Enrollment and Randomization (Day 0)
You will be asked to sign this informed consent and combined Health Information Portability and Accountability Act (HIPAA) 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. If you are not a good candidate, the study team will explain other options available to you.

You can expect the following to occur at this visit:
- You will be asked questions and given handouts regarding your demographics, sleep behavior, drug use, suicidality, and medical history
- Collection of your vitals (heart rate, blood pressure, height and weight)
- Collection of all your current medications with you

If you are a good candidate for this study, you will be randomized, like a flip of coin, into the active system or 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 than the Sham system.

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.

If you are in the group that gets the Sham system, you will be getting a watch that will not actively treat you until you are switched to the Active Group at Day 30. That could make your condition get worse. Scales monitoring your sleep and suicidal ideation will be conducted throughout this study to monitor and determine your condition.

Both systems monitor your sleep at night and report to the study team.

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

The Active system will take about 3 days to calibrate. Every person has their own sleep pattern that is almost as unique as a fingerprint. The NW System adjusts to a person's usual sleep pattern by going through an observation-only calibration stage. Usual sleep information is gathered during the first 500 minutes of sleep after the person begins wearing the NW System.

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, however. 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 (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.

If a study device is lost or stolen, it will be replaced. You should contact the study site to notify them of the study device being lost or stolen. Nightware will replace the study device.

Start Up Phone Call (Day 1)

A member of the study team will call you and make sure that the NW system is working properly and to see if you have any questions. They will also administer some questionnaires regarding your sleep.

You will receive a minimum of 10 phone calls from study team. These calls will be used to determine how well you are doing using the NW System and to fill out questionnaires.

Help Calls (Days 2-6)
A member of the study team may call to check in you and your progress with the NW system. During these calls, the study team will address any issues arising with Wi-Fi connectivity, misunderstandings and the proper use of the devices, as well as any other issues that may arise. They will also administer some questionnaires about your sleep. These calls are only as needed and may not occur.

Checkup Phone Call 1 and 2 (Day 7 and Day 21 ± 2 days)
A member of the study team may call to check in you and your progress with the NW system. They will also administer some questionnaires about your sleep.

Visit 2 (Day 30 ±7 days)
This visit will be done in-person or remotely. The study team will administer questionnaires relating to your sleep behavior, drug use, suicidality, current medications, and medical history. They will collect your blood pressure, height and weight. They will also go over the NW system and any questions or concerns you may have. The team will also ask you questions related to which group you were placed in.

At this visit, everyone will be placed into the Active System. If you were in the Sham System, you now will receive the same system as the Active group. The NW system will need about 3 days to calibrate to your specific sleep habits.

If you were in the Active System group, there will be no change for you.

If you have OSA, they will collect your CPAP compliance report and upload it to REDCAP.

Visit 3 (Day 60 ±7 days)
You will complete questionnaires relating to sleep behavior, drug use, suicidality, and medical history. They will collect your current medications. They will also go over the NW system and any questions or concerns you may have.

If you have OSA, they will collect your CPAP compliance report and upload it to REDCAP.

Visit 4 (Day 90 ± 7 days)
You will complete questionnaires relating to sleep behavior, drug use, suicidality, and medical history. They will collect your current medications. They will also go over the NW system and any questions or concerns you may have.

Visit 4 will be your last visit for this study. You will return the device upon study completion and will receive a $100 compensation for completing that task. If you would like to continue to use the device after your participation, the study team will connect you with a provider that can prescribe you NightWare. If you have OSA, they will collect your CPAP compliance report and upload it to REDCAP.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?
If you take part in this research, you will be responsible for the following:

- 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 calls
- Giving answers to questionnaires either in-person or remotely.
- Completing study visits
- 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

If you need to, you can:

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

However, you should tell the study investigator or the study team about all the medicines you take and about any planned surgery you may have scheduled, as this can potentially affect the study.

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. In addition to the risks described below, 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

There are no predicate devices used specifically to treat nightmares. 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.

If you have allergies or skin sensitivities you may experience a reaction when wearing the watch. Wearing the watch with the right fit with room for your skin to breathe 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, they can be stopped immediately and if the study team member feels you need additional care, they will work with you and the medical team to provide you with appropriate assistance.

Suicide is a risk in PTSD. You must tell your study investigator right away if you have any thoughts about hurting yourself.

If you are having suicidal thoughts or feel in crisis, call the study investigator at the telephone number listed on the first page of this form. You can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.

Reputational Risks (Active-Duty Military Personnel Only)

If you are an **active-duty** member of the military and you disclose use of illegal drugs, **the study team is required to report your drug use to your commanding officer**. This could impact your reputation, employability, and/or military career.

No other information about you or your research participation will be shared with your commanding officer.

Terms of Use (TOU)

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study investigator.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the study investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

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. However, uninterrupted sleep due to interrupting nightmares by arousing the participant without waking them, resulting in a more restful sleep, could be a benefit you experience. Improved sleep quality and duration can improve overall psychological effects of sleep deprivation and life satisfaction.

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 study investigator.

HOW WILL MY PRIVATE INFORMATION 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 Research & Development Committee, and the Institutional Review Board (IRB). 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 information may be used to develop, refine, or improve a marketable software application (NightWare).

All research data will be stored in electronic form on the study site's secure computer server behind the protection of a firewall. The electronic files will have additional protection by being placed inside of a limited-access folder. Only study team members will be permitted access to this folder. The Principal Investigator (PI) and the study team may provide de-identified and anonymous data to other Researchers who make such a request from the Repository Administrator, but no personally identifiable information will ever be given to any other Researcher. The study teams' activities are monitored by, and must abide by all Research regulations. Monitoring and approval are done by the study site's Institutional Review Board, Research Privacy Office, and Information Security Officer. Other relevant oversight committees that may be created or identified during the study team's existence will also be allowed to monitor and approve the activities.

Identifiers might 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.

Your de-identified information may be provided to the Food and Drug Administration (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.

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

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

Health Information Portability and Accountability Act (HIPAA)
There are rules to protect your private information. Federal and state laws and the federal medical 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 Privacy Rule.

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

The study team may also need to disclose the information to others as part of the study progress. Others may include the following:

- Sponsor-NightWare
- The Advarra Institutional Review Board
- Food and Drug Administration (FDA)
- Office of Human Research Protections (OHRP)
- The Office of Research Oversight (ORO)
- The Government Accountability Office (GAO).
- Greenphire-provider of ClinCards

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.

While this study is being conducted you will not have access to your research related health records.

This will not affect your healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

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 study site or you can ask a member of the study 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, the study investigator and his/her study team can continue to use information about you that was collected before receipt of the revocation. The study 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.

STATEMENT OF AUTHORIZATION

I have read this authorization form and its contents were explained. My questions have been answered. I voluntarily agree to allow study team to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

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 a part of this study. All the study costs, including the study watch, study phone, and procedures related directly to the study, will be provided by NightWare. If you decide to keep the watch upon completion of the study, there will be no cost for you.

If you usually pay co-payments for care and medications, you will still pay these co-payments for care and medications that are not part of this study.

WILL I BE PAID FOR MY PARTICIPATION?
«Compensation»

You will be paid for your participation in this study. Upon completion of the first visit after consent, you will be given $50 on a ClinCard, a reloadable debit card. At each two-week interval during the study (day 15, 30, 45, 60, 75, & 90), you will receive $25 for your continued participation. You will also receive an additional $25 every two weeks (Day 15, 30, 45, 60, 75, & 90) for wearing the device for more than or equal to 70% or 10 of the 15 nights in a two-week period.

Participants will also receive $100 upon returning the device and completing study-related surveys. In total, participants will receive between $200-$465 for participating in the Study, which averages up to $5/day. Study participants may also be reimbursed for any travel expenses if required. You will also receive $15 upon returning the blood pressure device if you participated in the study remotely.

The ClinCard will be used throughout the entire study. If you lose it, please let the study team know. They can replace and transfer any remaining money on the card.

Greenphire ClinCard Reimbursement Program:
Greenphire is a company working together with the study site to manage your compensation. You will be issued a Greenphire ClinCard, which works like a debit card. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 1 business day and can be used at your discretion. In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you from your study investigator, including your name, address and date of birth.

All information about you is stored in a secure fashion and is deleted from Greenphire's system once the study has been completed. Your information will not be shared with any third parties and will be kept completely confidential.

By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up payments. You agree that the information you provide is used by Greenphire to perform reimbursement payments to you.

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program. You may be required to provide your tax payer ID (Social Security #) if thresholds for IRS (Internal Revenue Service) reporting are met. This will only happen in the event that you receive a total of $600 in a year while participating in any research study at the study site.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
If you are injured as a result of taking part in this study, the study site will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for the study site under contract with an individual or non-study site institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call the study investigator at the phone number listed on the first page of this form.

By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

DO I HAVE TO TAKE PART IN THE STUDY?
Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits that you are otherwise entitled.

If you are an employee or relative of an employee of this study site, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical study site. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

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

RIGHT OF STUDY 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 without your consent 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.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00072219.

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 study.

WHO COULD PROFIT FROM THE STUDY RESULTS?
If a commercial product is developed as part of this research, you will not profit from them.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team 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.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in 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. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Investigator's Name	_____ Investigator's Signature	_____ Date