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CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: Use of the Frequen-ZZZ Sleep Pad to Increase Restorative Sleep: A Proof-of-Concept Study

Principal Investigator: Anne-Marie Chang, PhD, Biobehavioral Health, College of Health and Human Development (HHD)

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Telephone Numbers: 814-863-5226

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?
We are asking you to take part in this voluntary research study because you have shown that you are interested in being a participant and you have met the screening qualifications to be a participant.

What is the purpose of this research study?
The purpose of this research study is to test a new, investigational device that produces a magnetic field that may have some benefits for sleep amount or quality.

How long will the research study last?
The research study will last 8 weeks.

What will I need to do?
The study consists of four segments:
1) Baseline (to see how you sleep before we try the Sleep Pad; week 1),
2) Sleep Pad Use Part 1 (weeks 2-4),
3) Washout (a break from the Sleep Pad; week 5), and
4) Sleep Pad Use Part 2 (weeks 6-8)

You will have several (~12-15) in-person study appointments, either in your personal home, at our Penn State laboratory, or at the Penn State Clinical Research Center.

Your sleep will be monitored for 6 separate overnights using a method that is commonly used in outpatient sleep clinics. The monitoring method uses wires that are attached to the outside of your body to record your brain activity and other biosignals.

You will provide 3 fasted blood samples during the course of the study, collected by a qualified medical professional.

You will complete daily and weekly electronic surveys during the study.

Throughout the entire study, both day and night, you will wear a watch-like device to measure your physical activity and light exposure.

What are the main risks of taking part in the study?

- Devices that are used to monitor sleep pose little or no risk to you. The tape used to attach the sensors to your skin may cause minor skin irritation.
- You may have trouble sleeping with the equipment/sensors attached to your body.
- You may feel uncomfortable answering personal survey questions related to your health, wellbeing, and/or sleep.
- Blood draws can cause mild pain, swelling or bleeding, or bruising. Unlikely risks include infection, dizziness, or fainting. Fasting before blood samples may be uncomfortable.
- You may have trouble sleeping with the Sleep Pad device. You may feel warmer than usual when using the Sleep Pad properly. Although it is rare, improper use of the Sleep Pad can cause headaches for short periods of time, restlessness, nausea, and perspiration. You may awaken feeling temporarily more drowsy, dizzy, or disoriented, and these sensations can increase your risk of falling.

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no direct benefits to you from taking part in this research. Results of the study may benefit other people in the future by helping us learn more about whether & how a magnetic field can be used to improve sleep.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?
This small-scale 'pilot' research is being done to test whether a new, investigational device may have some benefits for sleep amount or quality. The device produces a magnetic field. It is not yet FDA approved.

Approximately 10 mid-life adults (men and women aged 40-65 years) will be in this study.

2. What will happen in this research study?

You have already completed the screening procedures and have qualified to participate. If you agree to participate, then after completing this form the rest of the study will last about 8 weeks. Participation will involve you being monitored passively throughout, will have about 15 hours of procedures that you will be actively engaged in, and will require 15-17 visits. Visits may occur in a private location of the PSU-UP campus or, if you reside within ~20min commute from PSU-UP campus, may occur in your personal residence.

The study consists of four segments:
1) Baseline (to see how you sleep before we try the Sleep Pad; week ~1),
2) Sleep Pad Use Part 1 (weeks ~2-4),
3) Washout (a break from the Sleep Pad; week ~5), and
4) Sleep Pad Use Part 2 (weeks ~6-8)

The intervention in this study is the Sleep Pad investigational device. You will not receive any drugs or biologics as a part of this research intervention.

During this Consent and Study Start visit:

This appointment takes about 2 hours to complete. During the first part of the appointment you will confirm your enrollment in the study. During the second part of the appointment data collection will begin with several surveys about your demographics, health, sleep, and to collect necessary information for your study payment. You will receive some study devices and you will be trained on their use. You will be outfitted with sleep monitoring devices that you will wear overnight; this is the first of 2 separate overnights (at least 1 night apart) using a monitoring method called Polysomnography, that is commonly used in outpatient sleep clinics.

During Baseline week 1:

-You will not use the Sleep Pad device.
-You will complete electronic surveys about your sleep and related activities each morning and evening, taking about 1min each (~2min total daily).
- Sleep monitoring this week will require 4 separate in-person visits with study staff (including the visit you are attending now).
-Staff will ask you questions at study visits about your health, medications, and behaviors to confirm your ongoing well-being and qualification in the study

Sleep Monitoring Details: You will wear sensors on your body overnight and carry with you a small bag containing a box that connects to the sensors. This equipment cannot get wet, so you will schedule your bathing times to not overlap with wearing the sensors. Your brain activity and sleep patterns will be recorded by electroencephalograph (EEG), your heart will be recorded by electrocardiogram (EKG), and your muscle activity will be recorded by electromyogram (EMG, recording of jaw and eyes). To apply these sensors for recording, a research staff member will measure, mark, and clean several places on your head, face, and torso with special skin markers, skin cleanser, and alcohol. Then, the research staff member will put small metal electrodes (sensors) on top of the skin of your head, face, and torso. Researchers will stick the sensors on your head with special temporary glue that is designed for skin and will cover sensors to keep them in place. Researchers will stick the sensors on your face and torso with tape/stickers. All of the sensors are non-invasive. There will be 9 sensors on your head, 6 sensors on your face, and 2 on your torso. It takes approximately 1hr to apply all these sensors to your body. The sensors will be on while you are awake before bed and after you awaken the following

morning for a short time as well as when you are asleep, and will be recording information all the time until removed by study staff at a scheduled morning appointment. Removing sensors after awakening takes approximately 15min.

-Your physical activity and light exposure will be measured close to 24/7 by a watch-like device that you wear throughout the week.
-Your first blood sample occurs at the end of this study week. You will need to fast (i.e., no food and minimal water for ~8hrs immediately preceding the blood draw) before this appointment. Fasted appointments typically occur in the early morning, on a weekday (M-F). Blood sampling takes approximately 30min to collect a maximum of 40cc's (i.e., less than 3 tablespoons) of blood.
-You will complete electronic surveys related to your sleep and health near the end of this study week that take about 15min, usually at the same time as other study procedures (e.g. blood draw) take place.
-You will be randomly assigned to a sequence of Sleep Pad device use. This study is designed so that all participants get to experience 2 different settings of the Sleep Pad, but the order of that experience will differ by person. Researchers will not know, and cannot tell you, the order of your assigned Sleep Pad settings until the entire study has concluded for all participants. Researchers will contact you at that time using the information that you provide to share this information.

During Sleep Pad Use Part 1 (weeks 2-4):
-You will lay on top of the Sleep Pad device when sleeping each night. The Sleep Pad is placed beneath bed sheets and plugs into a bedside controller. You will receive instructions for using the Sleep Pad.
-You will complete electronic surveys about your sleep, related activities, and device use each morning and evening, taking about 1min each (~2min total daily).
-Your sleep will be monitored for 2 separate overnights (once near the end of week 3 and once near the end of week 4) using the method described above. This will require 4 separate in-person visits with study staff.
-Your physical activity and light exposure will be measured close to 24/7 by a watch-like device that you wear throughout the week.
-Your second blood sample occurs near the end of the 4th week, and takes approximately 30min to collect a maximum of 40cc's of blood.
-Staff will ask you questions at study visits about your health, medications, and behaviors to confirm your ongoing well-being and qualification in the study
-You will complete electronic surveys related to your sleep and health near the end of each study week that take about 15min, sometimes combined with other study procedures (e.g. blood draw).
-Study staff will retrieve the bedside controller device that is a part of your Sleep Pad system.

During Washout (week 5):
-The Sleep Pad device will not function during this time (i.e. without the bedside controller).
-You will complete electronic surveys about your sleep and related activities each morning and evening, taking about 1min each (~2min total daily).
-Your physical activity and light exposure will be measured close to 24/7 by a watch-like device that you wear throughout the week.
-You will complete electronic surveys related to your sleep and health near the end of this study week that take about 15min, usually at the same time as other study procedures (e.g. blood draw) take place.

During Sleep Pad Use Part 2 (weeks 6-8):
-Study staff will provide you with a bedside controller for your Sleep Pad system.

-Remaining study procedures are identical to those listed in study weeks 2-4 (i.e., the same as those listed for Sleep Pad Use Part 1), excepting the timing corresponds to weeks 6-8. Therefore, sleep monitoring will occur near the end of week 7 and again near the end of week 8, and the final blood sample (up to 40cc's) will be collected near the end of the 8th week.

Staff will ask you questions at study visits about your health, medications, and behaviors to confirm your ongoing well-being and qualification in the study.

At the conclusion of the study you will return study devices (by pickup or mail).

At your discretion, researchers can arrange for you to receive reminders for the study activities above.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

-Outside of study visits you will be responsible for completing daily (morning and evening) and weekly electronic surveys, for which you will receive a survey link to your preferred location (phone text and/or email) and additional reminders according to your preference (phone call, text, and/or email).
-You will be responsible for setting up, maintaining, and using the investigational Sleep Pad device consistent with the instructions in your home.
-You will be responsible for wearing the activity monitor and removing it when it may become too wet or during activities when, in your opinion, it is unsafe to wear a watch.
-If you live more than ~20min from PSU-UP campus, you will need to travel to campus for study visits.
-Unless directed otherwise by your physician, during the study we ask you to **NOT**:

-engage in rotating or nocturnal shift employment
-initiate new, sleep-directed interventions (e.g. medication; behavioral) that are not a part of this study protocol
-use controlled substances (except according to a prescription by your physician, if applicable)
-use any nicotine

We will ask you about these behaviors at most study visits; you may be withdrawn from the study if any of them change.

3. What are the risks and possible discomforts from being in this research study?
There are no known discontinuation or 'rebound' effects of stopping use of the Sleep Pad, therefore, if you stop participating in the study early the risks to you are risks you would have with or without participation in the research.

- Devices that are used to monitor sleep pose little or no risk to you. The skin tape and special paste used to attach the sensors may cause some minor discomfort or skin irritation. The paste and measurement marks may be inconvenient to wash off/out of hair and may leave some trace of flakes.
- You may feel uncomfortable or have trouble sleeping with the equipment/sensors attached to your body. You may feel irritable or frustrated if you do not have the same quality or amount of sleep during the study as you normally have.
- You may feel uncomfortable answering personal survey questions related to your health, wellbeing, and/or sleep.
- You may feel bored or uncomfortable looking at a screen to complete the surveys regularly administered as a part of this research.

- You may feel somewhat isolated from close personal interaction, particularly with a significant other, during your participation in some study procedures because of the worn monitoring equipment.
- If you do not start new therapeutic interventions for issues pertaining to sleep for the duration of study participation, you may be delaying a potentially effective therapy alternative until your participation concludes.
- You may experience discomfort when fasting in advance of blood draws or while blood samples are being taken. Blood draws can cause mild pain, swelling or bleeding. There may be some bruising (blood under the surface of the skin), which can be minimized by pressing on the site after the needle is removed. There is also a small chance of infection, dizziness, or fainting. If dizziness or fainting occurs, the symptoms will be alleviated by closely monitoring you, and you may be asked to permit study staff to stay with you until they have checked your blood pressure and are confident that you are well enough for them to leave you.
- The Sleep Pad is not guaranteed to improve sleep, it is not guaranteed to prevent the worsening of sleep, and although it is not expected to worsen sleep that is also an unlikely possibility. If your sleep is successfully deepened by Sleep Pad system use, then you may experience temporary drowsiness, dizziness, or disorientation upon awakening from deeper sleep. You may be at higher fall risk resulting from these sensations. To help reduce this risk, you are encouraged to complete your Morning Survey prior to getting out of bed in the morning. You are also encouraged to take care if getting out of bed after awakening during the night.
- Although it is rare, improper use of the Sleep Pad has potential to lead to negative side effects, including headaches for short periods of time, restlessness, nausea, and perspiration. The Sleep Pad does not 'heat up' but may deliver a sensation of warmth that is uncomfortable. Study devices should only be used in accordance with instructions by the study participant and not by other individuals or members of their household. You may choose to inform a bed partner about the device's presence so that they do not use it. The Sleep Pad has not been evaluated under certain conditions, and so should not be used together with other powered equipment (i.e. heated blankets or similar). The Sleep Pad should not be used on a water bed.
- Please note that all research personnel are required to report suspected child abuse.

The particular intervention procedure being used in this study may involve risks to you that are currently unknown or unforeseeable. During the course of your participation you will be provided with any new information about study procedures that may affect your health, welfare, or your decision to continue participating in this research.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There will not be a benefit to you directly from participating in this study. However, we will provide you with health information that you can share with your physician if you choose to do so.

4b. What are the possible benefits to others?

The results of this research may guide future research related to sleep or sleep related health issues. This research may give a better understanding of whether magnetic fields can improve sleep.

5. What other options are available instead of being in this research study?
You may choose not to be in this research study. Because it is investigational, the therapy offered in this research is only available to you if you take part in the research study.

6. How long will I take part in this research study?
If you agree to take part, it will take you about 8 weeks to complete this research study.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?
Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- A list that matches your name with your code number will be kept in a locked file in Dr. Chang's office.
- Your research records will be labeled with your code number and the date/time of collection, and will be kept in a safe area in Dr. Chang's research office.
- Your research samples will be labeled with a code number and the date/time of collection and will be stored in the locked research space of the PI (Dr. Chang), in the PSU Clinical Research Center, and/or in the PSU Biomarker Core Lab.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research. If required to share records, the data will be in deidentified form whenever possible.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- U.S. Food and Drug Administration
- The research study sponsor, Kunasan, Inc.
- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

For research records sent to the Sponsor (Kunasan, Inc.), your data will be identified with a code number, the date(s)/time(s) of data collection, and (if applicable) any hospitalization admission/discharge dates related to the study.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information and samples may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement, if applicable, to ensure it continues to be used under the terms of this consent and authorization.

7b. What will happen to my research information and/or samples after the study is completed?
We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information we will remove any information that shows your identity.
Your biological samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. Information produced by this research study is NOT diagnostic. This research is not expected to give results that have meaning for your health. If your identifiable information or samples do give results that have meaning for your health, the researchers may contact you to let you know what they have found.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?
The only expected costs related to participation are those of electricity supplied to study devices (charging, etc.), WiFi usage by study devices, data/WiFi usage for survey reminders, and travel/parking for study appointments to/from/at the PSU-UP campus (15-17 visits expected), for which study payment is expected to compensate.

For costs of tests and procedures that are only being done for the research study:
- You or your insurance provider will not have to pay for the study device (Sleep Pad) while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?
It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

<u>Penn State compensation for injury</u>
There are no plans for Penn State to provide financial compensation or free medical treatment for research-related injury.

<u>Sponsor's compensation for injury</u>
If you suffer an illness, injury, or adverse event arising from utilizing the SleepPad Investigational Device in this research study listed in this consent form, medical care will be provided. The Sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a SleepPad Investigational Device related injury, illness, or adverse event.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will receive payment in the amounts described below for your participation in this research study, for a total of up to $3,000. If you do not complete the study for any reason, you will be paid for the visits/activities you have completed. If you are an employee of Penn State at the time of your participation conclusion, you may elect to provide your PSU ID number to receive payment via your Penn State paycheck. Alternatively, you will need to provide your social security number and address to receive a check for payment and for tax reporting purposes. In that case, you will receive payment by check to the address that you designate on payment paperwork as compensation for your participation in this study.

If you complete the entire screening process through the first overnight sleep monitoring, you will receive $300. Each subsequently completed overnight sleep monitoring will accrue an additional $300 compensation.

You will also receive $50 for completion of each blood draw and will receive $100 * the number of study weeks that you complete (up to 8). No additional by-week compensation is awarded for extension of Washout to accommodate scheduling.

You will receive a $250 bonus for completing the entire study and returning equipment in working order. Taken together by-part, this amounts to the following compensation accrual across the course of the ~8wk study:

Baseline completion: $750
Part 1 completion: $950
Washout completion: $100
Part 2 completion and return of devices/equipment: $1200

Maximum study compensation is therefore up to $3,000. If you are not a US citizen, you may need to supply Penn State with additional information in order to receive payment.

It is possible that your research information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others, or otherwise used for commercial profit. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

10. Who is paying for this research study?

The sponsor, Kunasan, Inc., is paying Penn State for the research to be done.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include*:*

- Failure to comply with the study requirements or instructions given by a team member.
- Failure to actively participate in the procedures needed to carry out the research study.
- Equipment failure.

Also, the sponsor of the research may end the research study early. If your participation ends early, you may be asked to visit the researchers for a final visit.

12. If I have questions or concerns about this research study, whom should I call?
Please call the head of the research study (principal investigator), *Anne-Marie Chang, Ph.D.* at (814)-863-5226 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://www.research.psu.edu/irb/participants if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or questions about the research.
- You may also call this number if you cannot reach the research team or prefer to talk to someone else about any concerns related to the research.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law or policy. 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.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name