National Aeronautics and Space Administration (NASA) IRB

HUMAN RESEARCH INFORMED CONSENT FORM

Title:
Sleep and Wake Countermeasures for Artemis: In-laboratory Study

A. Purpose:
The purpose of this study is to investigate whether certain experiences help you sleep when you aren't sleepy or help you stay awake when you are sleepy. If we find that exposure to different experiences help you fall asleep or help you stay awake, we may be able to use that information to help astronauts during spaceflight missions.

B. Investigators:

Erin E. Flynn-Evans, PhD MPH
NASA Ames Research Center
Human Systems Integration Division
Mail Stop 262-4, Code TH
Moffett Field CA 94035
Phone: (650) 279-3459
Email: erin.e.flynn-evans@nasa.gov

Co-Investigators:
Rachel Jansen PhD
NASA Ames Research Center
Human Systems Integration Division
Mail Stop 262-4, Code TH
Moffett Field CA 94035
Email: Rachel.a.jansen@nasa.gov

Cassie Hilditch, PhD
San Jose State University
NASA Ames Research Center
Human Systems Integration Division
Mail Stop 262-4, Code TH
Moffett Field CA 94035
Email: cassie.j.hilditch@nasa.gov

Key Information

C. **What is the key information needed to help me decide if I should participate in this study or not?**

- **What am I being asked to do?**
  - Participate in two, 24-hour laboratory visits one week apart.
  - Maintain a regular sleep schedule at home the week before each laboratory visit (as described in the at-home consent form)
  - Wear a wristwatch-like device (actiwatch) to monitor your sleep/wake patterns
  - Wear a sleep monitoring cap which measures brain electrical activity, eye movements, and muscle activity with adhesive electrodes on your forehead and face while you are in the lab.
  - Complete a series of cognitive tests (e.g., reaction time, math) and subjective scales (e.g., sleepiness, mood) frequently while you are in the lab.
  - Take naps scheduled by the study staff during your time in the lab while sometimes wearing headphones that may produce sound.
  - Complete tasks under very dim or very bright lighting conditions.
  - Stay awake for an extended duration of time and/or overnight while in the lab.

- **What are the possible risks/discomforts?**
  - This study is classified as Greater Than Minimal Risk.
  - It is possible that you could experience slight discomfort and inconvenience from wearing an actiwatch, although no more than from wearing a wristwatch. The actiwatch is designed to be worn for months at a time.
  - Measuring the brain electrical activity, eye movements, and muscle activity involves no risks. The adhesive on electrode pads and gel used in the cap may cause some minor discomfort or skin irritation.
  - You will likely feel sleepy on the day following your laboratory visits.
  - It is possible that sitting under bright light may cause slight and transitory discomfort, headaches, visual discomfort, or nausea.
  - Although all possible measures will be taken to ensure confidentiality, there remains a remote risk of personal data becoming identifiable.
  - People of child-bearing potential should be aware that disrupted sleep is a potential risk factor for adverse pregnancy outcomes.

- **What are the benefits for me?**
  - There are no direct benefits to participating in this study for you.

- **Is there any compensation for my time?**
  - You will receive $1500 for completing each laboratory visit.

- **How will my information and/or identity be protected?**
  - **Data Identification.** You will be assigned a study code. Identifiable and demographic information will be stored separately from coded data. No cognitive tests will contain identifiable information. Data collected on devices will only be identified by your ID code. No

identifying information will be collected in the test setting. Only aggregate summarized data will be shared for any subsequent analyses.

- **Data Storage.** All identifiable information will be stored in a locked file cabinet in the Fatigue Countermeasures Laboratory or in the Principal Investigator's office. Data stored in electronic format will be stored on a secure NASA network. Only researchers and study staff listed on the IRB will have access to the data on an as needs basis. No one outside of the study team will have access to the study records or raw data.

Detailed Information

D. Nature of Tests or Experiment:

In order to participate in the in-laboratory part of the study, you must adhere to all of the requirements described in the at-home study.

Each laboratory study will last 24 hours. During each visit, you will be randomly assigned to any of the following taking a nap, listening to noises while you sleep, sitting quietly, or working under special lights or room light. Your study could involve a combination of these situations or you may be asked to remain awake throughout your stay, with no special conditions.

You will arrive at the lab five hours after you wake up and you will leave the lab 24 hours later. The laboratory study involves sleep deprivation. When you leave the lab you will likely be very sleepy and it will not be safe for you to drive or complete any risky activities. You will not be allowed to drive to or from the lab. If possible, arrange for a friend or family member to drive you to and from the lab. If this is not possible, we will provide you with a car service (taxi, Uber, Lyft, etc.). We will escort you to the gate outside of NASA and wait with you until your ride arrives.

Once you arrive at the laboratory, you will stay in a private room for the entire lab visit. A study staff member will remain with you whenever you are awake and we will also monitor you via a camera while you are awake and asleep. This is for your safety. Nothing will be recorded. You will only leave the room if you need to go to the bathroom. There are no cameras in the bathroom. Wipes and paper towels will be provided to you.

The study room has a bed and desk, but there are no windows and it is sound-proofed. There are also no clocks and study staff will make no references to time. We will ask you to give us your phone and any other device that has the time on it. We will store these items in a secure location outside of your room until your study is over. This is because we do not want the time of day to influence the way you respond to the study tests and measures.

The lighting in the lab will range from very dim to very bright. The dim light is similar to a room lit by only a few candles. The bright light is similar to sitting in a sunlit room with the curtains open. You will not be allowed to change the lighting.

You may not feel sleepy at times when we ask you to try to sleep. Please remain in bed and try to sleep. You will not be allowed to get out of bed or turn on any lights during times that we ask you to try to

sleep. If you need to go to the bathroom during a time when we ask you to try to sleep, we will bring a small portable toilet to your room and we will turn off the cameras so you can go to the bathroom.

We will ask you to wear headphones during some sleep episodes. These headphones may produce sounds. You will need to keep the headphones on throughout the time that we ask you to try to sleep.

We will provide you with three meals based on your dietary restrictions and personal preferences.

During your stay in the lab, you will be required to perform the tests described below during the experiment. We will ask you to complete these tests multiple times. These tests include the following:

Reaction Time. We will ask you to complete a reaction test in which you react as fast as possible by hitting the iPod screen as soon as you see numbers appear.

Sleepiness scale. You will be asked to rate how you are feeling at different points throughout the study on simple scales.

Math, memory, and logic tasks. We may ask you to perform neuropsychological assessment tasks such as completing a series of simple mathematical calculations as fast as possible, memorizing a list of words or images and then recalling them later, or tasks that are similar to logic puzzles.

Emotion recognition. We may show you pictures of people and ask you to tell us whether you think the picture is expressing emotion. For example, you may be asked to indicate if you think the person in the picture is happy, angry, sad, or neutral.

Mood scales. You may be asked to rate how you are feeling at different points throughout the study on simple scales.

Dot test. In order to obtain a clear view of your brain activity, we will ask you to stare at a dot for several minutes.

In addition to testing, we will ask you to provide the following biomeasures:

Temperature readings. We will take your temperature frequently using an ear-based thermometer.

Vital signs. We will measure your blood pressure and heart rate throughout the study.

Saliva samples. We will ask you to spit into a test tube several times throughout the study. We will use these saliva samples to measure the amount of melatonin your body produces. Melatonin is a hormone that is associated with your internal clock (circadian rhythm).

Brain activity. We will measure your brain activity throughout your time in the study. To do this, we will have you wear a cap on your head and sensors on your face near your eyes, and on your chin. These sensors are commercially available and are approved for measuring brain activity.

At the end of each laboratory experiment, your personal devices (phone, watch) will be returned to you. At the end of your first laboratory experiment, you will be reminded to continue collecting data at-home in the same manner that you did before the first laboratory visit. You will continue to wear the actiwatch throughout the 3-week period for participation.

E. Manner in Which Tests or Experiment Will Be Conducted:

Only individuals who successfully complete the at-home study procedures and are considered eligible based on that study will be invited to participate in the laboratory study. If the questionnaires, tests, or medical results that you provide during the at-home study indicate that you may have a sleep disorder, such as sleep apnea, a mental health disorder, like bipolar disorder, or another chronic condition that would interfere with data collection or put you at risk, you will not be eligible to participate in the laboratory study.

We will collect a urine sample and a breathlyzer when you arrive in the laboratory to confirm that you have not used any substances that are not allowed in the study. As a reminder from the at-home portion of the study, you must abstain from alcohol, caffeine, nicotine, marijuana and cannabis products throughout the at-home and in-lab portions of the study. If these tests show that you have consumed a banned substance, we will end your participation in the study and we will destroy the toxicology results so that they cannot be directly linked to your name and your participation in the study. The results of your toxicology results will not be shared with your primary physician or added to your medical record. The medical monitor may follow up with you for further guidance. We will test for amphetamines, barbiturates, benzodiazepines, cocaine, marijuana, MDMA (ecstasy), methadone, methamphetamines, opiates, oxycodones, caffeine, and nicotine.

The tests that we collect require fluency in English. If you are not fluent in English, you will not be able to participate in the study.

You will be one of 40 participants in this study.

F. Duration and Location:

Each laboratory visit will last for 24 hours. You will need to maintain a regular schedule for a minimum of one week prior to each laboratory visit as described in the at-home study protocol.

The study will be conducted in the Fatigue Countermeasures Laboratory at NASA Ames Research Center.

G. Foreseeable Inconvenience, Discomfort, and/or Risks:

This study is classified as Greater Than Minimal Risk. “Greater Than Minimal Risk” means that the probability and magnitude of harm or discomfort anticipated in the research is greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

It is possible that you could experience slight discomfort and inconvenience from wearing an actiwatch such as skin irritation or a rash, although no more than from wearing a wristwatch. An actiwatch is the size of a small watch and is designed to be worn for months at a time. If you experience any discomfort you may remove the watch and discontinue the study.

Measuring your brain electrical activity, eye movements, and muscle activity involves no risks. The adhesive on electrode pads or gel used in the cap may cause some minor discomfort or skin irritation. If you experience any discomfort you may remove the electrodes and discontinue the study.

You will likely feel sleepier on the day following the experimental night of sleep disruption. As a result, you should avoid engaging in activities that could be compromised by sleep loss, such as driving and operating heavy machinery. We will work with you to schedule your overnight laboratory visit on a night when you do not need to engage in tasks that require focus and attention the next day. You will need to have someone pick you up from the lab or we will provide you with transportation to get home. You will not be allowed to drive home after the laboratory visit.

It is possible that the lighting levels may cause you some slight and transitory discomfort, headaches, visual discomfort, or nausea. The light is significantly dimmer than the light that you are exposed to when you go outside during the day; however, the light may be irritating to you, particularly because the lighting will vary during your lab visit. If the light causes discomfort you may ask us to turn off the light and discontinue the study.

Although all possible measures will be taken to ensure your confidentiality, there remains a remote risk of your personal data becoming identifiable. This includes information provided in the screening questionnaires.

If you are a person of child-bearing potential, you should be aware that disrupted sleep is a potential risk factor for adverse pregnancy outcomes.

H. Benefits of Participation:

There are no direct benefits of participating in this study to you. The results of this study will inform whether certain experiences can help people fall asleep or stay awake.

I. Data/Identity Security and Protection:

- **Data Identification.** All participants will be assigned a study code. The data linking your identifiable data to this study code will be maintained by a single designated staff member. This data sheet will be maintained in a locked file cabinet at Ames Research Center. Identifiable and demographic information will be stored separately from coded data. No cognitive tests will contain identifiable information. Only aggregate summarized data will be shared for any subsequent analyses.
- **Data Storage.** All identifiable information obtained through background questionnaires will be stored in a locked file cabinet in the Fatigue Countermeasures Laboratory or in the Principal Investigator's office. Data stored in electronic format will be stored on a secure NASA network. Only researchers and study staff listed on the IRB will have access to the data on an as needs basis. No one outside of the study team will have access to the study records or raw data.
- **Data Encryption/Authentication Methods.** Data will only be stored on computers and storage devices subject to NASA IT security rules.
- **Data Privacy and Confidentiality.** Data collected on devices will only be identified by your ID code. No identifying information will be collected in the test setting. Demographic and pre-study questionnaires will be collected on paper and transferred to a locked file cabinet in the Fatigue Countermeasures Laboratory at NASA Ames Research Center.
- **Data Release.** De-identified data may be archived in the NASA Life Sciences Data Archive. These data will be sent via encrypted, secure transfer (e.g. NASA Box) and stored in accordance with the data security protocols outlined in this application. No identifiable information about you will be used or shared with individuals outside the research team at NASA Ames Research Center.
- **Biospecimens.** After removal of identifying information from biospecimens, they could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Positive toxicology results will be destroyed.

Your privacy and the confidentiality of data collected as a part of this research study will be protected from unauthorized disclosure according to applicable federal law.

A blank informed consent form will be made available on Regulations.gov. This website will not include any information that can identify you. You can search this website at any time.

Items with a strikethrough are not relevant to the current study protocol.

Your protected health information may be used or shared with others during the research. This may include:

- Existing medical records;
- ~~Video and photographic materials;~~
- New information created from study-related tests, procedures, visits, and/or questionnaires.

Your protected information may be used or shared by NASA offices of research oversight or quality assurance, medical monitors, and researchers for the reasons below:

- To conduct and oversee the present research;
- To make sure the research meets NASA requirements;
- To conduct monitoring activities (including situations where you or others may be at risk of harm or reporting of adverse events);
- To become part of your medical record, if necessary, for your medical care;
- To review the safety of the research.
- ~~To support "NASA Clinical Summit" activities where clinical experts evaluate relevant medical and research data to recommend clinical practice guidelines~~

Every effort will be made to maintain the confidentiality of your study records. There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- NASA and other government officials may need the information to make sure that the study is done in a safe and proper manner. These agencies may include the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and/or the Office for Human Research Protections (OHRP) or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- ~~The FDA may need to review the information if the study involves the use of an experimental drug or device.~~
- Safety monitors, medical personnel, or safety committees may review your research data, stored biospecimens, and/or medical records for the purposes of medical safety or for verification of research procedures.
- ~~A data and safety monitoring board (DSMB) may oversee the research, if applicable.~~
- The results may be used by the research team and possibly be presented/published at scientific conferences and/or in an article but would not include information that would identify you without your consent.

J. Remuneration:

You will receive $1500 for completing each laboratory visit for a total of $3000.

K. Participant Rights:

Participation in this study is voluntary. You may withdraw from the study at any time. If you decide to leave before the study is finished, please tell the investigator or study staff. Your refusal will be honored, except in cases when the responsible physician's opinion is that study termination could

have undesired consequences for your health and/or the health of other subjects. You will be told if there could be any harm to you if you decide to leave before the study is finished. If you tell the researchers your reasons for leaving the study, that information will be part of the study record.

Your withdrawal or refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you decide not to join the study, you may be eligible to participate in other studies.

Researchers may need to stop your participation in the study even if you want to continue participation. Some examples of this scenario include: (Check applicable boxes)

_X__ The researcher believes that it is not in your best interest to stay in the study

_X__ There is any problem with following study related instructions

_X__ There is any problem with following hospital, clinic, or laboratory policies and procedures

_X__ There is any serious complication during the study

_X__ There is inappropriate behavior

_X__ The study is suspended or canceled

_X__ Your information is or becomes unusable for any reason

_X__ Events beyond NASA's control occur, for example: fire, explosion, disease, weather, floods, terrorism, wars, insurrection, civil strife, riots, government action, or failure of utilities

_X__ Existing data reveal answers earlier than expected

L. Answers to Questions:

You may receive answers to any questions related to this study by making contact with the Principal Investigator, Dr. Erin Flynn-Evans at 650-279-3459. Should any problems related to the study occur during its course, please contact the Principal Investigator at that number. You may also call the medical monitor, Dr. Ralph Pelligra, MD, Ames's Chief Medical Officer.

The NASA Human Research Institutional Review Board is your advocate and you can speak with them confidentially about any concerns and questions relating to this study using the following contact information:

Office of Research Assurance: Research Integrity & Protection of Human Subjects

2101 NASA Parkway
Mail Code SA
Houston, Texas 77058
Visit: https://irb.nasa.gov/?p=irbContactInfo

M. Remedy in the Event of Injury:

In the event of injury or illness resulting from this study and calling for immediate action or attention, NASA will provide, or cause to be provided, the necessary emergency treatment. If you are eligible for and receive workers compensation benefits while participating in this study, you cannot sue your employer because the law makes workers compensation your only remedy against your employer. You may have other remedies against other persons or organizations, depending upon the circumstances of the injury. NASA will pay for any claims of injury or loss of life to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act.

Signature

TO THE SUBJECT: Please read this form CAREFULLY. Make sure all of your questions have been answered to your satisfaction. Do not sign this form until you have read and understand the informed consent. You will receive a signed copy of the Consent Form.

A. I, _____(Print Name of Test Subject HERE) agree to participate as a subject in this study and experiments described in this form.

B. I am aware of possible foreseeable consequences that may result from participation, and that such participation may otherwise cause me inconvenience or discomfort as described.

C. My consent has been freely given. I understand that study participation is voluntary and I may withdraw my consent, and thereby withdraw from the study, at any time. I understand (1) that the Principal Investigator may request my withdrawal from the study if I am not conforming to the requirements of the study; (2) that the NASA Medical monitor may request my withdrawal from the study if they feel that my health and well-being are threatened; and (3) that the NASA Facility Safety Manager may terminate the study in the event that unsafe conditions develop that cannot be immediately corrected. I understand that if I withdraw from the study, or am dismissed, I will be paid for the time served up to the point of my departure, but not thereafter.

D. I am not releasing NASA or any other person or organization from liability for any injury arising as a result of this study. I understand that I will receive emergency care if I am injured during the study, but payment for any follow-on care will depend on whether I have some form of applicable insurance, or whether I have made some other arrangements for such follow-on care. I may have other remedies against other persons or organizations, depending upon the circumstances of my injury.

E. I hereby agree that all records collected by NASA in the course of this experiment are available to the NASA Medical Officer, Principal Investigator and Co-Investigators and duly authorized research review committee. I grant NASA permission to reproduce and publish all records, notes or data collected from my participation provided that there will be no association by name with the collected data and that confidentiality is maintained unless specifically waived by me. All stated precautions will be taken to protect your anonymity, but there is a small risk that your confidentiality could be breached.

F. I understand that I have the right to contact the NASA Institutional Review Board by visiting https://irb.nasa.gov/?p=irbContactInfo if I have questions or I feel that my rights as a human research subject have been abused or violated.

G. I have had an opportunity to ask questions and I have received satisfactory answers to each question I have asked. I understand that the P.I. for the study is the person responsible for this activity and that any pertinent questions will be addressed to her during the course of this study. I have read the above agreement, the attached protocol and/or instructions prior to my signature and understand the contents.

Signature of Test Subject Date	Signature of Principal Investigator Date
Printed/Typed Name of Test Subject	Printed/Typed Name of Principal Investigator
Test Subject Phone Number	
	Principal Investigator Address (Street / City, State, Zip Code)
	Principal Investigator Phone Number

~~Test Subject Signature: Authorization for Video Recording~~

Test Subject Signature: Authorization for Release of Information to Non-NASA Source(s)