## National Aeronautics and Space Administration (NASA) IRB

## HUMAN RESEARCH INFORMED CONSENT FORM

**Title:** Evaluation of Fatigue in Short-Haul Operations Across Multiple Airlines

A. **Purpose:** The purpose of the present study is to collect objective and subjective measures of sleep, sleepiness, reaction time, and workload that can be used to assess fatigue levels of short-haul pilots during normal operations.

B. **Investigators:**

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## 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?**
  - Complete a set of background questionnaires on demographics, sleep and sleepiness, reaction time, diet, and exercise.
  - Wear a wristwatch-like device (actiwatch) to monitor sleep/wake patterns and fill out a daily log (including sleep timing and quality, napping, caffeine use, meals, exercise) at the start and end of each day.
  - Complete a series of cognitive tests (e.g., reaction time) and subjective scales (e.g., sleepiness) pre-duty, during flight, post-flight, post-duty, and on days off duty.
  - Wear a small light sensor that allows us to determine your daily patterns of light exposure.
  - Collect data up to 3 days before (off duty), up to 7 days during (on duty) and up to 3 days after (off duty) two trips for a total data collection period of 8-26 days depending on the duration of your trips.

- **What are the possible risks/discomforts?**

- This study is classified as Minimal Risk.
- The risks associated with the protocol may differ from normal flying duties due to potential discomfort and inconvenience with wearing the actiwatch and the potential for distraction while completing cognitive tests.
- It is possible that you could experience slight discomfort and inconvenience from wearing an actiwatch, although no more than from wearing a wristwatch. An actiwatch is the size of a wristwatch and is designed to be worn for weeks at a time.
- Some crew could experience a degree of discomfort and inconvenience as the result of having to complete the reaction time tests throughout the day. It is also possible you could become distracted by the study tests and procedures during flight. You may also be inconvenienced by having to complete alertness, fatigue, workload, and sleep ratings. However, it is estimated that this information will take no longer than a total of 30 minutes per day to record, with each phase of collection no more than 7 minutes (e.g., pre-duty tasks, evening sleep log).
- Your name and other information that could identify you will only be used for study coordination (e.g., sending data collection devices to you). Your name and other identifying information will be stored in a separate location from the data collected as part of the study.
- Your study data will be collected using a participant identification code ("ID code"). All of the coded data will be collected and stored in password protected locations at your airline and at Washington State University. Although all possible measures will be taken to ensure confidentiality, there remains a remote risk of personal data becoming identifiable.
- As the study data will be maintained at your airline, it is possible that individual, coded participant data could be viewed or used by airline personnel for purposes unrelated to the study.

- **What are the benefits for me?**
  - There are no direct benefits to you. The results of this study may inform evidence-based practices for scheduling and fatigue mitigation strategies employed during short-haul operations.
  - If you decide not to participate in this study, you may be eligible to participate in other studies.

- **Is there any compensation for my time?**
  - All participants will be provided with NASA stickers, patches, mugs, or similar items as a token of appreciation for participation.
  - Further compensation will be provided to participants according to the established rate and procedures for similar studies at each airline (if any).

- **How will my information and/or identity be protected?**
  - **Data Identification.** You will be assigned an individual participant identification code ("ID code"). Identifiable 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.** Coded study data will be stored on devices provided by each airline and/or their research partner (Delta Airlines partners with Dr. Barger at Brigham and Women's Hospital; United Airlines partners with Dr. Lamp at Washington State University). Coded data from all airlines will be archived and aggregated at Washington State University for processing and analysis. Data access will be limited to personnel named on this protocol. NASA researchers will access study data either via computers provided by the airlines or their research partners or via encrypted VPN. The results of the research will not be presented in any form that identifies individuals. The data sheet linking names and codes will be stored on an encrypted hard drive following NASA IT security rules.

## Detailed Information

### D. Nature of Tests or Experiment:

**Briefing session:** The protocol requires that you attend a briefing session at which the study will be explained in depth and any questions will be answered by the Principal Investigator or by a designated member of the study staff.

At this session you will be provided with an iPod with the NASA PVT+ and NASA-Task Load Index (TLX) applications installed and will be asked to complete questionnaires including a demographic questionnaire, self-perception questionnaires, a baseline exercise questionnaire, the Morningness/Eveningness Questionnaire (MEQ), the Epworth Sleepiness Scale (ESS), the Pittsburgh Sleep Quality Index (PSQI), the Insomnia Severity Index (ISI), and the NASA Task Load Index (TLX), as well as signing consent forms for the study, which will be reviewed and signed prior to completing any of the study procedures.

You will be provided with training for the reaction time test (the psychomotor vigilance task [PVT]), sleep log, and self-report scales, as well as with the Actiwatch, which you will be asked to wear throughout the study period. An Actiwatch is a device that looks like a wristwatch and records movement and light, from which investigators can determine the duration, quality, and timing of sleep objectively. You will also be provided with a small light and temperature sensor (~1 square inch) which you will wear clipped to your shirt throughout the study. The sensor will record light levels and ambient temperature. Lastly, you will also be asked to complete a daily sleep log to record the time you went to bed and woke up; you will also rate your sleep quality and how tired you felt when you woke up. A study staff member will check in (e.g., via phone call) regularly to remind you to complete the study tasks and to answer any additional questions.

**Timing of Data Collection**

You will collect data during two trips, one with circadian disruption and the other without circadian disruption (in any order). These trip types are defined as follows:

a. Trip *with* Circadian Disruption: A trip containing one of the following types of WOCL infringement:

   i. *Overnight FDPs*. An FDP in which the pilot is operating one or more flights through the WOCL (0200-0559h) relative to the pilot's home-base time or clock time.

   **OR**

   ii. *Circadian Switching*. At least one FDP that starts between 0000-0659h relative to home-base time, followed by at least one FDP that ends between 0000-0659h, or *vice versa*, within the same trip (e.g., an FDP that begins at 0500h and the next FDP ends at 0100h or *vice versa*).

   **AND**

b. Trip *without* Circadian Disruption: This trip must not contain any duties that are scheduled to begin or end between 0000h and 0659h) relative to home-base time.

You will collect data for each trip as described below:

**Phase 1: Pre-trip Data Collection. (1-3 days)** You will be asked to record data into the sleep log, complete the PVT and scales, and wear the Actiwatch and light sensor.

**Phase 2: Flight Data Collection. (2- 7 days)** You will be asked to collect data during each designated trip. You will continue to enter data into the sleep log and will complete the PVT and alertness and fatigue scales pre-duty as well as in flight, whilst continuously wearing the Actiwatch and light sensor. Upon landing, you will complete the PVT (if needed), alertness and fatigue scales, report any countermeasures used, complete the TLX workload scale, and will indicate any flight hassle factors (e.g., weather, congestion, air traffic controller issues). Post-duty you will report on any additional factors that affected your duty day (e.g., unplanned changes, long sits).

**Phase 3: Post-trip Data Collection. (1-3 days)** You will collect data for up to three days following each trip using the same procedures as during pre-trip data collection.

**Return of equipment.** You will be provided with either a return pre-paid box or instructions on where to return the equipment to a designated staff member. Your data will be downloaded, cleared, and a study ID reset on each device before sending to another participant. Data collected on iPod and actiwatch devices will only be identified by an ID code. No identifying information will be collected during the study period.

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

**Screening:** If you are eligible to participate in this study, the study staff member will coordinate a time to deliver the data collection devices to you. Study staff will review with you how to use study equipment prior to the study start and will be available for questions at any time during the study.

You will be one of up to 51 participants in this study at your airline.

**F. Duration and Location:**

Your participation will involve a minimum of 8 days and a maximum of 26 days depending on the duration of your trips and time off between trips.

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

This study is classified as Minimal Risk.

The risks associated with the protocol may differ from your normal duties due to potential discomfort and inconvenience with wearing the actiwatch and completing tests with the PVT+ App.

a. 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 wristwatch and is designed to be worn for weeks at a time. If you experience any discomfort, you may remove the watch and discontinue the study.

b. You will complete a five-minute reaction time test (the PVT) several times using an iPod. It is possible that you could experience a degree of discomfort and inconvenience as the result of having to complete the reaction time test several times each day. It is also possible that you could become distracted by the study tests. If you feel that your flight duties require your attention while you are completing a study test, then you should stop taking the study test and attend to your flight duties.

c. You may also be inconvenienced by having to complete a sleep log and fatigue ratings.

d. Although all possible measures will be taken to ensure confidentiality, there remains a remote risk of personal data becoming identifiable, which could lead to loss of confidentiality. While airline IT security provisions are in place, in the case of a breach of airline computer systems, coded individual study information could become accessible to unauthorized individuals.

e. As the study data will be maintained by airline personnel, your coded data can be viewed and used by airline personnel for analysis and reporting.

**H. Benefits of Participation:**

There are no direct benefits of participating in this study to you.

I. **Data/Identity Security and Protection:**

- **Data Identification.** To ensure that individual crew data (e.g., sleep log, reaction times) remains confidential, you will be allocated an individual participant identification code ("ID code"). All data recorded will be referenced to this ID code and not to your name. All data and information linking crew names and ID codes will be stored on an encrypted hard drive at NASA Ames Research Center.
- **Data Storage.** All data, except for identifiable information used to manage participant recruitment and study coordination (e.g., to contact you and send you the study equipment), will be referenced to this ID code and not your name. Coded study data will be stored on devices provided by each airline and/or their research partner (Delta Airlines partners with Dr. Barger at Brigham and Women's Hospital; United Airlines partners with Dr. Lamp at Washington State University). Coded data from all airlines will be archived and aggregated at Washington State University for processing and analysis. Data access will be limited to personnel named on this protocol. NASA researchers will access study data either via computers provided by the airlines or their research partners or via encrypted VPN. The results of the research will not be presented in any form that identifies individuals. The data sheet linking names and codes will be stored on an encrypted hard drive following NASA IT security rules. Consent forms will be stored on an encrypted hard drive at NASA Ames Research Center.
- **Data Encryption/Authentication Methods.** All of the data that you collect using the iPod app and actiwatch is associated with a study ID code. No identifiable information is stored on these devices. The iPod is only accessible by typing the passcode. The coded data on the airline equipment is not encrypted, but identifiable and coded data are stored in separate locations that are each password protected and only accessible to designated study staff, including airlines personnel. Your identifiable information is used to communicate study information with you and is only accessible to study staff who need this information to communicate with you during the study. The data that you collect using the iPod (e.g., questionnaires, PVT, TLX, alertness and fatigue scales) are stored in a separate location within the server and are used by study staff to analyze the data.
- **Data Privacy and Confidentiality.** Data collected on iPod and actiwatch devices will only be identified by your ID code. No identifying information will be collected during the study period.
- **Data Release.** The principal investigator is responsible for overall data security and will control who has data access, for how long and at what level. The data will not be coded in a manner that would allow it to be used to make employment measures or decisions

with respect to individuals at any airline. No identifiable information about you will be used or shared with individuals outside the research team listed on this protocol.

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.

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

- 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 review the safety of the research.

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.
- 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.
- 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:**

- All participants will be provided with NASA stickers, patches, mugs, or similar items as a token of appreciation for participation.
- Further compensation will be provided to participants according to the established rate and procedures for similar studies at each airline (if any).

**K. Participant Rights:**

Participation in this study is voluntary. You may withdraw from the study at any time without being penalized or disadvantaged in any way. If you decide to leave before the study is finished, please inform the study staff and return the data collection devices promptly. Any partial data that has been collected will be considered for analysis unless you request that your data be deleted.

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 contacting the Principal Investigator at NASA, Dr. Erin E. 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.

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.

Insurance or medical support provided normally to all air crew under current company policy provisions will apply for study participants.

## 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 that the Principal Investigator may request my withdrawal from the study if I am not conforming to the requirements of the study. 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 (contact information available at 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.

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|---|---|
| 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<br>(Street / City, State, Zip Code) |
| | Principal Investigator Phone Number |