Sample Consent Form.
The following consent form has been approved by the Institutional Review Board (IRB). Any amendments to this form are required to undergo IRB review.

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT FORM

Protocol Title:	National Sleep Study
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Summary

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to learn more about how aircraft noise in communities impacts sleep. You are being invited to take part in this research study because of the predicted nighttime aircraft noise levels in your community. This study has been approved by the University of Pennsylvania Institutional Review Board.

If you agree to join the study, study equipment will be mailed to your home. An instruction manual and videos on how to use the equipment will be provided. You will be asked to record sounds inside your bedroom using a small audio-recording device for 5 consecutive nights. You will also be asked to wear a small device that measures your heart rate and body movements for the 5 study nights. The device is small, battery operated, and has two electrodes that you will place on your chest. On each morning of the study, you will be asked to complete a brief questionnaire on your previous night's sleep. You will also be asked to complete an additional questionnaire about your sleep over the past month, your sleep habits, your noise sensitivity, noise inside your bedroom and any regular medications you use. During the study you can go to sleep and wake up at your normal times. When you have finished taking measurements, you will be asked to return the study equipment at no shipping cost to you. You will receive compensation for your participation.

You may not benefit personally from participating in this research study. There are minimal risks associated with measuring heart rate and body movements with the study device. There is a minimal risk of a loss of privacy when measuring sounds in your home at night. When study equipment is shipped to and from your residence, there is a risk the package, which contains your personal information, may be lost. The alternative to participating in this study is to not participate. Your participation is completely voluntary.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take your time and share the consent document with friends and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

The purpose of the study is to learn more about how aircraft noise in communities impacts sleep. We want to collect information on heart rate and body movement during the night to evaluate your sleep and to record indoor sounds during a 5 consecutive night, in-home, unattended sleep study.

Why was I asked to participate in the study?

You are being asked to join this study because of the predicted nighttime aircraft noise levels in your community and because of your expressed interest and availability.

How long will I be in the study?

The study will take place over one week, from Monday night to Saturday morning. We aim to recruit 400 people in total for the study over the course of 2 years.

Where will the study take place?

The study will take place in your home.

What will I be asked to do?

You will receive the equipment for the study in the mail. Written instructions and a link to a website which contains videos on how to operate the equipment will be provided in the package. You will need to review the instructions. If you have any questions, members of the study team will be available by phone and email to answer them. After completing the study, you will need to mail the equipment back to the study team using the packaging the equipment arrived in and the provided return shipping label.

Noise Measurements

- You will record audio inside your bedroom during the night using equipment that is provided to you by the study team.
- The equipment will consist of one sound recorder, one microphone, and a tripod. The equipment will need to be placed near the head of the bed on a nightstand or dresser and the recorder will need to be plugged into an available electrical outlet.
- Each night before going to bed you will start the sound recorder and each morning when you wake up you will need to stop the sound recorder.

Physiological Measurements

- Each night your heart rate and body movements will be measured using a small device that is attached with two electrodes to your chest.
- Each night you will apply the electrodes to your chest and press a button to start the measurements. Each morning you will need to press a button to stop the measurements and take off the device and electrodes. After you take off the device, you will need to plug the device into an electrical outlet to charge.

Questionnaires

- Each morning you will be asked to complete a brief questionnaire which contains questions on your previous night's sleep, noise during the night, and your degree of fatigue. The questionnaire should take you less than 5 minutes to complete.
- You will also be asked to complete an additional questionnaire about your sleep over the past month, your sleep habits, noise in your bedroom, how you are affected by noise, and the noise environment in your bedroom. This questionnaire can be completed at any point during your time in the study and will take approximately 15 minutes to complete.

What are the risks?

1.) Measuring heart activity (electrocardiogram-ECG) and body movements involves minimal risks. This measurement device is powered by batteries that pose no risk to you. The ECG-electrodes attached to your chest may cause some minor discomfort and/or skin irritation. If skin irritation occurs, there is a potential risk of changes in skin pigmentation where the ECG

electrodes were worn, which results in a darker or lighter skin color. These rare changes in skin pigmentation typically resolve over time. To decrease the likelihood of skin irritation, we ask you to change the position of the ECG electrodes from night to night. You will also be provided with a second set of ECG electrodes from a different manufacturer that you can use should your skin react to our standard ECG electrodes. Additionally, you will be given a cream that can be applied to the site where the ECG electrodes were worn to reduce skin irritation.

2.) Please be aware that the sound recording equipment will record all sounds after you turn it on (when going to bed at night) and until you turn it off (after getting up in the morning). Anything you say or do will be recorded when the device is on. The sound recordings will be listened to by staff in order to identify aircraft noise events during the sleep period time. To minimize the risk of loss of confidentiality or privacy, sound recordings will be stored on a secure server with limited personnel access secured by passwords. The files will be named using study codes. If any identifiers are detected by the staff during analysis this information will be removed from the sound recordings.

3.) The study equipment will be shipped to and from the address you provide. There is the risk that the package can be lost or damaged during transit. Therefore there is a risk of loss of confidentiality and privacy as your physiological measurements, sound recordings, questionnaires, and copy of your consent form could become lost during shipment.

How will I benefit from the study?

There is no benefit to you. However, your participation could help us understand how noise in communities affects sleep, which can benefit you indirectly. In the future, this may help other people develop nighttime noise mitigation policies.

Will I receive the results of research testing?

The data recorded in this study are for research purposes only. They will not be used for diagnostic purposes. Therefore, no results will be returned to you.

What other choices do I have?

Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?

You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study.

When is the study over? Can I leave the study before it ends?

The study is expected to end after you have completed all 5 nights of sleep and noise measurements and all 5 morning questionnaires and all equipment has been mailed back to the study team. The study may be stopped without your consent for the following reasons:

- The Principal Investigator (PI) feels it is best for your safety and/or health - you will be informed of the reasons why.
- You have not followed the study instructions.
- The Principal Investigator (PI), the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so.

If you no longer wish to be in the research study, please contact the Principal Investigator (Mathias Basner) at 215-573-5866.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. Your name and private identifiable information will be entered into the Redcap database. Redcap is a secure web application designed to support data capture for research studies. All consent forms and any other documents that contain your name or other identifiable information will be stored in a locked cabinet in a research office located in Blockley Hall at the University of Pennsylvania. Confidentiality will be maintained by giving you a study code and all your study information will relate to this code number. All computer based files will be kept on a secure server with limited access privileges and passwords.

What may happen to my information collected on this study?

Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

As part of the study, the Principal Investigator and study team may disclose your information to those listed below:

<u>Individuals or organizations responsible for administering the study:</u>

- Federal Aviation Administration (the funding organization)

<u>Regulatory and safety oversight organizations</u>

- The Office of Human Research Protections

Prior to the conclusion of this project, you can cancel your permission to use and disclose your information at any time by contacting the Principal Investigator of this study. The Principal Investigator can be reached by phone or mail at the number and address listed above.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

If you join this study:

- You will not own the data given by you to the investigators for this research.
- Any funder of this research may study the data collected from you.
- You will not own any product or idea created by the researchers working on this study.

- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

Will I have to pay for anything?

There are no known costs to participating in this study.

Will I be paid for being in this study?

You will receive $30 for each night you complete the sleep and noise measurements, $2 for each completed morning questionnaire, and $10 for completing the 15-minute participant characteristics questionnaire, for a maximum total of $170 for the 5 consecutive nights/mornings. If you decide to withdraw from the study before the study is over, you will be fully compensated for your participation up to the point you chose to withdraw. We need the equipment and questionnaires to be returned in order to process your payment.

Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120-XXXX which has been approved for collection of voluntary responses only. Public reporting for this collection of information is estimated to be 8.25 minutes to complete the postal survey and 2 hours and 33 minutes of active participation across 5 study days to complete the field study. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Donald Scata, FAA-AEE-100, 800 Independence Ave. SW, Washington, DC 20591, or by email at SleepStudy@faa.gov.

Who can I call with questions, complaints or if I am concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

_____	_____	_____
Printed Name of Subject	Signature of Subject	Date