UT Austin IRB Approved

Protocol Number:

Approved:

**Title of the Project**: Effects of Common Indoor Air Pollutants on Occupant Sleep Quality

**Principal Investigator**: Dr. Zoltan Nagy, PhD

**Graduate Research Assistant:** Hagen Fritz

**Consent to Participate in Research**

### Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

### Important Information about this Research Study

Things you should know:

* The purpose of the study is to better understand the relationship between indoor air quality and sleep quality
* In order to participate, you must be 18-35 years old and willing to consent to participation and living in a dormitory on the University of Texas at Austin’s campus
* If you choose to participate in this 8-12 week study (depending on the study start date), you will be asked to participate in the three components of the study:

1) pre-experiment questionnaire covering basics about your dormitory environment and sleep quality over the previous 30 days;

2) dormitory indoor environmental quality monitoring for the entire study period; and

3) personal sleep quality monitoring for the entire study period

* Possible risks or discomforts from this research include discomfort from answering queries about your sleep quality and access to personal information regarding your measured sleep quality
* The possible benefits of this study include personalized feedback about your sleep/activity patterns and specific aspects of your home/dorm environment. Societal benefits include potentially identifying behavioral, psychological, and environmental factors that influence human biology.
* Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

### What is the study about and why are we doing it?

You have been asked to take part in a research study that aims to better understand the relationship between your indoor environment – air quality in particular – and your sleep quality. This study will use emerging technologies to measure biological variables such as sleep quality and dormitory environmental characteristics, namely indoor pollutant concentrations, thermal comfort, and lighting levels.

### What will happen if you take part in this study?

If you agree to be in this study, you will be asked take part in an 8-12 week study period over the course of the semester (depending on the study start date).

The experiment begins with a visit by a researcher from the team. The researcher will distribute the environmental monitor and the activity band (similar to Fitbit), answer any questions about the research, obtain the signed informed consent document, and instruct in the use of study related equipment. The environmental monitor will measure carbon dioxide, particulate matter, and total volatile organic compound concentrations in addition to temperature, relative humidity, and lighting levels. The activity band measures multiple variables, but only the heart rate, sleep times, and sleep stages will be used in this study.

The researcher will also aid in the setup of the activity band including a detailed walk-through of how to set the band up and downloading/using the smartphone app.

After retrieving the equipment, you will be asked to do the following for the study period:

* Wear the activity band on your non-dominant wrist while you sleep. The activity band can be used for personal use if the participant desires, but it must be worn any time the participant expects to be sleeping. The activity band is water-resistant and can be worn while bathing or swimming to a depth of 30 feet.
* Setup the environmental monitoring device as instructed by the researchers, ideally on a bedside table. Locations to consider should be away from significant sunlight exposure, at a height of about 3 feet above ground, and away from any location that might present a hazard to the device. If the participant is unsure where to place the monitoring device, the researcher can be asked to help as long as consent to enter the participant’s dormitory has been explicitly given.
* Complete the online pre-experiment survey. The survey will be distributed via email to the account provided by the participant and should be completed as soon as possible.
* Complete short sleep questionnaires distributed to your phone on random days for a maximum of three days out of the week.

### What Happens if a device breaks or malfunctions?

Please take care when handling any of the devices. If equipment provided to should malfunction for any reason during the study, please notify the research team immediately so they can assist in repairing the device or providing you with a new one. If the device must be picked up, the student file a maintenance request for the device in question to be picked up. A repaired or new device will be delivered by the maintenance staff.

Upon completion of the study period, you will be required to return all study related equipment to our FAC location. Failure to return the equipment could result in your being responsible for the cost of each piece not returned.

### How long will you be in this study and how many people will be in the study?

Participation in this study will last 8-12 weeks (depending on the study start date). The anticipated number of participants is approximately 12 individuals.

### What risks and discomforts might you experience from being in this study?

This procedure may involve risks that are currently unforeseeable. Possible risks associated with this study include discomfort from knowing that your sleep times and duration will be available to the researchers. The home environment monitor measures temperature, relative humidity, particulate matter of different sizes (airborne particles), carbon dioxide, and total volatile organic compounds (typically present in household cleaning products). To avoid biasing the experiment, participants will not have access to the air quality data during the experiment. However, the participants and UT University Housing and Dining will be notified if the concentration of pollutants exceeds the following unhealthy thresholds:

* Carbon Dioxide: 2000 parts-per-million
* Particulate Matter with a diameter or 2.5 micrometers: 35 micrograms per cubic meter
* Particulate Matter with a diameter of 10 micrometers: 150 micrograms per cubic meter
* Total Volatile Organic Compounds: 2000 parts-per-million of an equivalent carbon dioxide concentration

The thresholds for carbon dioxide and total volatile organic compounds are twice the concentration recommended by ASHRAE and the Occupational Health and Safety Association and for particulate matter, the thresholds are based on the 24-hour exposure limit defined by the EPA (<https://www.epa.gov/criteria-air-pollutants/naaqs-table>). Since pollutant concentrations will not be monitored by a researcher in real-time, participants may receive notice the thresholds outlined above were violated up to a week after the event has occurred.

Participants are cautioned against trying to “help” or manipulate the study by altering their habits as that would also bias the experiment. Please continue to conduct your day and actions as you normally would.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

### How could you benefit from this study?

We plan to provide you with some personalized feedback about your sleep/activity patterns and specific aspects of your dormitory environment after the study period. You may benefit from knowing about your sleep quality and ways to improve metrics associated with your sleep.

This study also has benefits for society as we will be testing novel methods for the collection of behavioral and environmental data in an effort to more accurately assess these variables in research. In addition, we hope to identify behavioral and environmental factors that potentially influence human biology.

### What will happen to the samples and/or data we collect from you?

All data being collected will be encoded numerically (not indexed by the student’s EID). As a result, these data will contain no personally identifying information when stored, catalogued, and/or processed. Data will only be identified using this numerical code and information tying a specific student to that code will be kept in a separate double-encrypted database that is only accessible by the PIs and study staff.

### How will we protect your information?

An index of identity information that links numerical codes used for participant data with student EIDs and/or emails will be stored in a separate, password-protected electronic file to which only senior research staff will have access. Consent forms will be kept in locked filing cabinets inside of the laboratory, which is itself locked when not in use.

All electronic records will be stored on a secure Amazon Web Services cloud-based computing system for protected data. The web-based portal will be designed and maintained to support data capture for research studies, providing secure log in and user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Data will be maintained indefinitely.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order.

We may share your data with other researchers for future research studies that may be similar to this study or may be very different. The data shared with other researchers will not include information that can directly identify you.

### What will happen to the information we collect about you after the study is over?

We will keep your research data to use for data analysis and future research. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

### How will we compensate you for being part of the study?

Students completing the experiment will not receive monetary compensation but will print outs of some of their data such as a sleep activity summary chart and analysis of their dormitory environmental quality. In addition, information will be provided on how to further improve their sleep quality and/or indoor environmental quality.

### Who can profit from study results?

Your data will not be used for commercial profit.

### Your Participation in this Study is Voluntary

Participation is totally up to you to decide to be in this research study – participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

### Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

### Contact Information for the Study Team

Prior, during, or after your participation you can contact the PI, Zoltan Nagy (nagy@utexas.edu) or the researcher Hagen Fritz (hagenfritz@utexas.edu OR 817-727-1934) for any questions or if you feel that you have been wronged/harmed by participation in the study.

### Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board

Phone: 512-232-1543

Email: irb@austin.utexas.edu

Please reference study number 2019-09-0120.

### Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered.*

(a)

\_\_\_\_\_\_\_ I **do** agree to wear an activity band and place a small monitoring device in my living space for the study period.

\_\_\_\_\_\_\_ I **do not** agree to wear an activity band and place a small monitoring device in my living space for the study period.

(b)

\_\_\_\_\_\_\_ I **do** agree to complete a pre-study survey about my activity and sleep habits in addition to completing short sleep quality surveys distributed to my phone, at most three days out of the week.

\_\_\_\_\_\_\_ I **do not** agree to complete a pre-study survey about my activity and sleep habits in addition to completing short sleep quality surveys distributed to my phone, at most three days out of the week.

(c)

\_\_\_\_\_\_\_ I **do** agree that my data can be used by the study investigators for research purposes.

\_\_\_\_\_\_\_ I **do not** agree that my data can be used by the study investigators for research purposes.

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Printed Subject Name

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Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

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Print Name of Person obtaining consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person obtaining consent Date