Title: Reducing Sedentary Behavior to Improve Sleep: An Ancillary Study to the RESET BP Clinical Trial (RESET-SLEEP)

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Title:	Reducing Sedentary Behavior to Improve Sleep (RESET SLEEP)
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Key Information Summary

You are being asked to take part in a research study on sleep while you participate in the RESET BP study. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you may have. You should take time to make your decision.

Here is a summary of the research study:

- The purpose of this study is to see whether participating in the RESET BP study leads to changes in your sleep and whether your sleep habits impact how well you follow the RESET BP intervention;
- The duration of the research study would be around 14 weeks because we will be measuring your sleep before and after the RESET BP intervention that lasts 12 weeks;
- Sleep measurements will include monitoring your sleep at home for 1 night using a variety of electrodes and wires attached to your body;
- This research study will not require any study visits that are in addition to the study visits for RESET BP, but we will visit you in your home on 1 evening at the beginning and end of the study to monitor your sleep.

Risks related to the study include those which are:

- Likely: boredom, stress, or frustration from completing study questionnaires; discomfort or sleep disruption from having the overnight sleep assessment;

- Less likely: breach of confidentiality from providing personal information; skin irritation from having the overnight sleep assessment.

There may be no direct benefit to you from participating in this study. However, you may find it helpful to learn more about your sleep habits. This study will also help doctors learn about whether changing how much you sit each day impacts your sleep, which could help in the treatment of future individuals with sleep complaints.

Study Overview

We are recruiting approximately 220 participants who have already agreed to participate in the RESET BP trial. In this study, you will be asked to complete additional assessments related to your sleep at the beginning and end of the study. You would continue to take part in the RESET BP study as well. The study team members will explain the study to you and answer any questions you might have. You should take your time to make your decision.

Purpose of Research Study

Poor sleep is common, and could lead to other bad health outcomes. Scientists think that reducing the amount of time you sit during the day could improve your sleep. The goal of this research study is to see whether the intervention in RESET BP leads to changes in sleep and whether your sleep habits impact how well you follow the intervention.

Basic Eligibility Criteria

Everyone who provided informed consent to participate in the RESET BP study will be invited to participate in this study. If we find that you have a severe sleep disorder during our sleep assessments at the beginning of the study, you will not be eligible to complete your participation in this study.

Research Procedures to be Performed

If you decide to take part in this study, you will undergo the following procedures:

Procedure Number	***When***	***Time to Complete***	***Purpose***	***Specific Activities***
1	Visit 1 or 2 for RESET BP, via phone call, or Zoom tele-conference call	Up to 1 hour (in addition to RESET BP procedures)	To explain study, obtain contact information, and obtain consent	• Explain study • Complete contact information release form • Discuss scheduling of home-based sleep assessment • Obtain consent (in person or online)
2A *(if in-person research restrictions are not in place)*	After completing 9 days of activity and sleep tracking during RESET BP	1 full night (8-10 hours)	Sign consent (if not already signed); To objectively assess your sleep patterns	• Staff arrive at your home 2-4 hours prior to bedtime • Sign consent (if not already signed) • Staff set you up for sleep recording by placing electrodes on face and scalp, elastic bands on chest, and oximeter on finger

				• You wear the sleep and activity monitors previously worn for 9 days • After staff leave for the night, you go to bed and get out of bed at normal times • Remove equipment on your own the next morning • Complete questionnaire • Staff pick up equipment the next morning
2B *(if in-person research is restricted or participants are not willing to complete full home-based assessment)*	After completing 9 days of activity and sleep tracking during RESET BP	1 full night (8-10 hours)	To objectively assess your sleep patterns	• Staff drop off the sleep assessment device at your home during the day of your assessment using a 'contact-less' method • You apply electrodes on face and scalp, elastic bands on chest, and oximeter on finger on your own • You go to bed and get out of bed at normal times • Remove wires on your own the next morning • Complete questionnaire • Staff pick up equipment the next morning using a 'contact-less' method
3	After 9 days of activity and sleep tracking at post-intervention during RESET BP	1 full night (8-10 hours)	To objectively assess your sleep patterns	• Same procedures as either 2A or 2B listed above

Procedure 1 (Description of study): The purpose of this initial visit is to explain the procedures of the study to you. This visit will take place at the Physical Activity and Weight Management Research Center immediately following your first or second study visit for RESET BP. If there is not enough time at these RESET BP visits or these visits are conducted remotely, we can discuss the study over the phone or with a Zoom teleconference call. It will take up to 1 hour in addition to however long it takes to complete activities related to RESET BP.

During this visit, we will first provide a detailed description of the procedures involved in this study, and you will be able to ask any questions before we do anything related to the study. If you choose to participate in the study, you will sign this consent form. We will also have you sign a form that allows the RESET BP team to share your contact information with us. We need your contact information so we can get in touch with you to schedule your sleep assessment.

If you do not have enough time to talk about this study when you come in for these visits for RESET BP or you complete these visits remotely, we can talk to you about the study over the phone or during a Zoom teleconference call. You will still need to sign a form that allows the RESET BP team to share your contact information with us so that we can get in touch with you to describe the study. During the phone call or Zoom teleconference call, we will describe the study to you in detail and you will be able to ask any questions. If you choose to participate, you could provide informed consent by choosing the 'I consent to participate in the study' button at the end of an online consent document delivered by Qualtrics.

Procedure 2 (Sleep study assessment in your home): If in-person research is not restricted, procedure 2A will be completed. If in-person research is restricted or the participant is not comfortable with the procedures outlined in 2A, procedure 2B will be completed.

2A (Full sleep assessment): Research staff will come your home around 2-4 hours before your usual bedtime. If you have not already provided written informed consent, we will first meet with you to review the study and sign consent. Following this step (or if written informed consent has already been obtained), the staff will set you up for an overnight recording of your sleep. They will apply small metal discs (called electrodes) to your scalp, face, and legs. Two additional electrodes will be placed on your chest to measure your heart rhythm (called an electrocardiogram). We will also monitor your breathing during sleep with some elastic belts around your chest and abdomen, a small tube near your nose and mouth, and a clip on your finger to measure oxygen levels in your blood. You will also be given the activity and sleep monitors (previously worn during RESET BP) to wear overnight. One device will be worn on the wrist, while the other device will be worn on the upper thigh. Once you are all set up, research staff will give you final instructions on how to start the recording, how to end the recording, and how to remove the equipment. Staff will then leave for the night. You will be asked to follow your normal bedtime and waketime habits. When you wake up in the morning, you will remove all the electrodes and equipment. You will complete a brief questionnaire that asks whether any of your recording materials like electrodes or wires came loose overnight. The questionnaire will also ask about your sleep last night. Research staff will come to the home to pick up the equipment.

2B (Limited sleep assessment): Research staff will drop off the recording device equipment using 'contact-less' delivery. In the evening of your sleep assessment, you will need to apply electrodes to your scalp and face, two elastic belts to your chest, a small tube near your nose, a clip on your finger, and a headband using written instructions that the staff provide to you. These measures will help us assess your brain wave activity and your breathing during sleep. You will follow your normal bedtime and waketime habits. When you wake up in the morning, you will remove the electrodes and equipment. You will complete a brief questionnaire that asks whether any of your recording materials came loose overnight. The questionnaire will also ask about your sleep last night. Research staff will come to the home to pick up the equipment.

Between Procedures 2 and 3 (RESET BP intervention): Following procedures 1 and 2, you will be randomized to a RESET BP treatment group (immediate intervention, delayed control). You will follow the assigned treatment for 12 weeks. For the purpose of this ancillary study, it does not matter which RESET BP intervention group you are randomized.

Procedure 3 (Repeat of sleep study assessment in your home): After completing 12 weeks of the RESET BP intervention, you will be asked to repeat Procedure 2A or 2B. You will have another sleep study assessment in your home following the same procedures that were previously performed.

For all study-related procedures: You are responsible for returning the study equipment that is provided to you, and police may be contacted if the equipment is not returned after repeated contact from the research team.

Study Risks and Side Effects

Risks and side effects related to the study procedures are minimal. They include risks that are considered to be:

- Likely:

Type of Research Activity	Risk Associated
Answering study questionnaires	Boredom, stress, or frustration
Having sleep assessed via polysomnogram	Discomfort or disruption of sleep

- Less likely:

Type of Research Activity	Risk Associated
Providing personal information	Breach of confidentiality
Having sleep assessed via polysomnogram	Skin irritation where electrodes and tape are placed on scalp and face
Wearing the sleep and activity monitors	Skin irritation where monitors are worn

- Rare but serious: None identified

Benefits of Participating in the Study

You may not directly benefit from participating in this research. However, it may be helpful for you to learn more about your sleep habits by participating in the study. This study will also help doctors learn about whether changing how much you sit each day impacts your sleep, which could help in the treatment of future individuals with sleep complaints.

Costs of Participating in the Study

Being in this research study will not cost you anything. None of the procedures described above will be billed to you or your health insurance.

Study Compensation

You can earn up to $300 if you complete all parts of the study using the ‘full sleep assessment’ procedures. This payment is in addition to any compensation you may receive from the RESET BP study. If, for whatever reason, you complete the baseline portion of the study using the ‘full study assessment’ procedures but choose not to complete the post-intervention assessment, you will receive $100. If you complete the ‘limited sleep assessment’ procedures because of restrictions placed on in-person research, payment will be the same as completing the ‘full sleep assessment’ procedures.

If there are no in-person research restrictions but you decline to perform the ‘full sleep assessment’ procedures and choose the ‘limited sleep assessment’ procedures instead, you will be paid $150 if you complete all parts of the study. If you complete only the baseline portion of the study under these conditions, you will be paid $50.

No payment will be made for any assessments until the study equipment that we have provided to you has been returned.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

Additional Important Information Before You Join this Study

Voluntary Participation: Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh or the RESET BP study. Whether or not you provide your consent for participation will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If You Are Injured: If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC.

Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

Your Privacy: The risk of collecting your protected health information is a breach of confidentiality. This risk is minimal in this study as you will be identified only by a number, and this will only be available to the study investigators. The information collected will then only be linked to the de-identified number, and will not be associated with any other identifying information. The data will be used only for research purposes. No one except for study teams will have access to this data. All electronic data will be kept behind firewalls in accordance with institutional security policies. You will not be identified by name in any publication of research results. Your research results may be shared with other investigators but they will never be provided with information that would allow them to identify you. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project.

In addition to the investigators listed on this first page of this consent form and their research staff, the following may have access to identifiable information related to your participation in this research study:

- The University of Pittsburgh Office of Research Protections may review your identifiable research information for monitoring the appropriate conduct of this research study. In unusual circumstances, your identifiable information may be inspected by appropriate government agencies or may be released in response to an order from a court of law. If investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

- Authorized people sponsoring this research study may also have access to information because they need to make sure that the information collected is correct, accurate, and complete, and to determine the results of this research study.

Use of Data: All data will be de-identified prior to analysis. Once the research data are de-identified, this information may be used for future research or shared with other investigators conducting similar research. However, any data that are shared will have identifying information removed.

Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure of information to state or local authorities when required by laws.

Discontinuing Participation: After signing this form, you may end your participation at any time by contacting the investigator listed on the first page of this form. Your data provided prior to discontinuing will still be used by the study investigators, but you will no longer be asked to provide further data unless you agree to return for a final assessment.

It is possible that you may be removed from the research study by the researchers to protect your safety or if you are unable or unwilling to complete the research protocol. For example, if you become pregnant, you will no longer be eligible to participate in the study.

Website: A description of this clinical trial is available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Disclosure of Research Results: Individual research results from the sleep watch and the overnight home sleep assessment will be provided to participants if desired. Please keep in mind that these assessments are performed for research purposes and should not form the basis for medical and/or lifestyle decisions. Recommendations for follow-up with your health care provider will be clearly indicated. In addition, if we discover any information during the course of the study that indicates any severe, undiagnosed health issue, we will share this with you immediately. A summary of the results of the overall study will not be provided to participants.

Questions About the Study

If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

VOLUNTARY CONSENT

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature	Date

Participant's Printed Name

INVESTIGATOR'S CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date